TECHNICAL SPECIFICATION

技术规范

ISO/TS 16949

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第三版

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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NOTE: In this table of contents, ISO 9001:2008 headings are normal type face, *IATF headings are in italics*.
备注：目录中，ISO 9001:2008部分使用的是正体字，*IATF的要求是斜体。*

Foreword
前言

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for whom a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

ISO（国际标准化组织）是一个全球范围内的国家标准组织的组织。国际标准的准备工作一般是通过ISO技术委员会进行的。每一个成员组织与ISO有联系的国际组织，政府机构或非政府机构，也参与到工作中。ISO与国际电工委员会（IEC）在电子技术的标准化方面有非常密切的合作。

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

国际标准的制定是根据在ISO/IEC条款第二部分中的规则制定的。

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote.

技术委员会的主要任务是准备国际标准。技术委员会所制定的国际标准的草案将传达到每一个成员组织以获得表决通过。国际标准的公布需要获得至少75%的成员的赞成。

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

在其他情况下，特别是在一些迫切需要此类文件的情况下，技术委员会将决定发布其他类型的标准化文件：

— An ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50% of the members of the parent committee casting a vote;

ISO PAS（ISO可发布规范），它表示在ISO工作小组中的技术专家所达成的一致协议，并在获得50%的成员通过时可以公布。

— An ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

ISO技术规范（ISO/TS），它表示在技术委员会中的成员所达成的协议，并在获得了委员会2/3多数通过是可以发布。

An ISO/PAS or ISO/TS is reviewed after three years with a view to deciding whether it should be confirmed for a further three years, revised to become an International Standard, or withdrawn. In the case of a confirmed ISO/PAS or ISO/TS, it is reviewed again after three years at which time it has to be either transposed into an International Standard or withdrawn.

ISO/TS16949技术规范每隔三年会重新审查，以决定是否能转换成为国际标准。在ISO/PAS或ISO/TS获得通过成为国际标准的情况下，再每三年进行审查，以决定它能否继续保留为国际标准或被取消。

ISO/TS 16949:2002 was prepared by the International Automotive Task Force (IATF) and Japan Automobile Manufacturers Association, Inc. (JAMA), with support from ISO/TC 176, *Quality management and quality assurance*.

ISO/TS 16949:2002是由国际汽车行动小组（IATF）和日本汽车制造协会（JAMA）编制，并得到ISO/TC176支持，*质量管理和质量保证*。

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.

第三版的ISO/TS16949取消及取代第二版（ISO/TS 16949:2002）并基于ISO9001:2008。

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

本技术规范内容是汽车行业特殊补充要求。其共同内容参阅ISO 9001:2008质量管理体系。

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.

本技术规范中所有含“Shall（必须）”的条文表示要求，标有“Note（注）”的段落是对理解和解释有关要求的指导纲要，在“Note（注）”中出现的“Should（应该、可以）”仅为指导作用。

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

当使用“Such as（如同）”一词时，表示给予的建议仅为指导作用。

Annex A forms a normative part of this Technical Specification.

附录A是本技术规范的标准部分。

Remarks for certification
认证的注解

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”).

本技术规范的认证，包含了顾客的所有特殊要求，并得到IATF的顾客成员的认可（当满足了依照IATF验证要求时）。

Details can be obtained at the addresses of the local oversight bodies of IATF cited below:
详细的资料可以在IATF以下的监督机构中查询：

Associazione Nazionale Fra Industrie Automobilistiche (ANFIA)
Web site: www.anfia.it e-mail: anfia@anfia.it

International Automotive Oversight Bureau (IAOB)
Web site: www.iaob.org e-mail: quality@iaob.org

IATF-France
Web site: www.iatf-france.com e-mail: iatf@iatf-France.com

Society of Motor Manufacturers and Traders Ltd. (SMMT Ltd.)
Web site: www.smmt.co.uk e-mail: quality@smmt.co.uk

Verband der Automobilindustrie Qualitätsmanagement Center (VDA-QMC)
Web site: www.vda-qmc.de e-mail: info@vda-qmc.de

All public information about IATF can be found at: www.iatfglobaloversight.org

0. Introductions

简介

0.1 General

总　则

ISO 9001:2008, Quality management systems - Requirements

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

质量管理体系的采用是组织战略性的决定，组织对质量管理体系的设计和实施会受到以下影响：

a) its organizational environment, change in that environment, and the risks associated with that environment;
组织的环境、环境的变化和与之相关的环境的风险；
b) its varying needs;
不同的需要
c) its particular objectives;
特殊的目的
d) the products it provides;
产品的提供
e) the processes it employs;
过程的员工
f) its size and organizational structure.
组织的规模和结构

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

本国际标准并不意图推行统一的质量管理体系结构和统一的文件。

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.

在本国际标准中所规定的质量管理体系要求是对产品要求的补充。标有“备注”字样的信息是为能更好的理解相应的标准要求和对标准要求做更详细的说明。

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

本国际标准可使用于内部及外部团体，包括认证机构，在评价组织符合客户能力、对于产品适用的法令和法规要求和组织自身的要求。

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

在此标准的发展中已考虑了 ISO 9000 及 ISO 9004 中所陈述的质量管理原则。

0.2 Process approach

过 程 导 向

ISO 9001:2008, Quality management systems — Requirements

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.

本标准鼓励采用过程方法来发展、实施和改进质量管理体系，以通过满足顾客要求提升顾客

满意度。

For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities 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.

为了组织有效地运行，它必须确定和管理大量的相互关联的活动。过程可以被理解为运用资源进行管理而使输入转化为输出的活动或一组活动。通常一个过程的输出将会直接是下一个过程的输入。

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".

在一个组织和管理层内过程体系的应用，结合这些过程的识别及其相互作用和这些程序期望的结果的管理，可以被看作是"过程方法"。

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.

过程方法的优点是对过程的系统中个别过程之间相互衔接、结合和相互作用进行不间断的控制。

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

过程方法在质量体系中应用时强调以下几点的重要性：

a) Understanding and meeting requirements,
   理解和符合要求；
b) The need to consider processes in terms of added value,
   在增加价值要求方面考虑过程；
c) Obtaining results of process performance and effectiveness, and
   获得过程业绩和有效性的结果；和
d) Continual improvement of processes based on objective measurement.
   基于客观测量结果对过程实施持续改进。

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.

图1中所示的以过程为基础的质量管理体系阐述了在条款4~8中表达的过程衔接方式。此模式以图标的形式阐明了顾客在决定输入的要求时起了非常重要的作用。组织必须根据顾客感觉的信息评价对顾客满意度进行监控以决定是否满足了顾客的要求。图1模型所示覆盖了本标准的所有要求，但是没有对其中的过程做详细的展示。

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.

备注：另外，众所周知的"计划—执行—检查—行动"（PDCA）的方法可以被运用于所有的过程。PDCA模式可以被简要的描述成：

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

计划：为满足顾客的要求和组织的方针，建立目标和过程；

Do: implement the processes.

执行：实现过程；

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

检查：按照方针、目标和对产品的要求对过程和产品进行监控和测量，并汇报结果；

Act: take actions to continually improve process performance.

行动：采取行动对于过程业绩进行持续地改进；

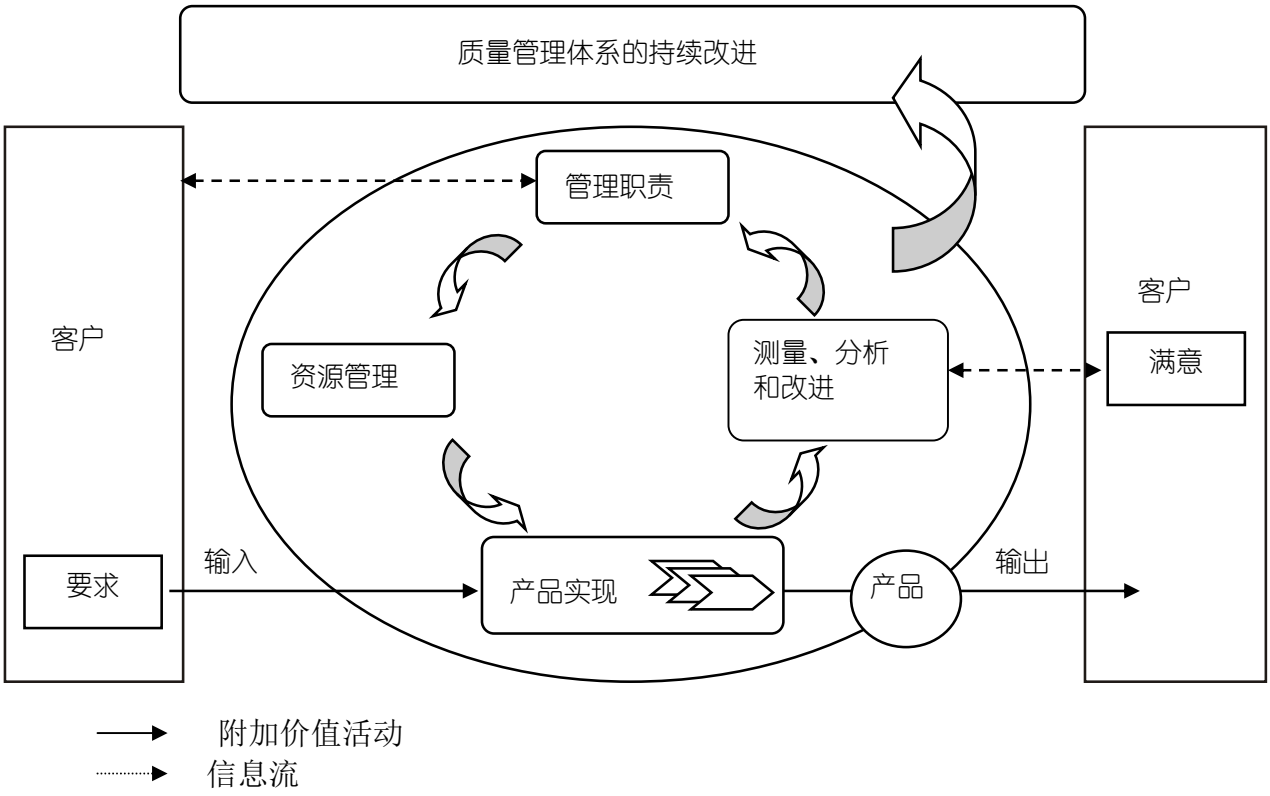

Figure 1 — Model of a process-based quality management system

图 1　过程基础质量管理体系模型

0.3 Relationships with ISO 9004

与 ISO 9004 的关系

ISO 9001:2008, Quality management systems — Requirements

ISO 9001 and ISO 9004 quality management system standards, which have been designed to complement each other, but can also be used independently.

ISO 9001和ISO 9004质量管理体系标准，它们可以相互补充，也可单独使用。

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.

ISO 9001规定了质量管理体系的要求，它可用于组织内部或用于认证或为达到合同要求。它关注质量管理体系的有效性以满足顾客的要求。

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.

在本标准发布时，ISO9004处于修订过程中。修订后的ISO9004将为组织在复杂的、要求更高的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不拟用于认证、法律法规和合同的目的。

NOTE: The knowledge and use of the eight quality management principles referred to in ISO 9000:2005 and ISO 9004:2000 should be demonstrated and cascaded through the organization by top management.

备注：八项质量管理原则的知识及应用依据ISO 9000:2005及ISO 9004:2000可由最高管理阶层展现及分布于整个组织。

0.4 Compatibility with other management systems
与其它管理体系的兼容性

ISO 9001:2008, Quality management systems — Requirements

During the development of this International Standard, due consideration was given to the provisions of ISO14001:2004 to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO9001:2008 and ISO14001:2004.

为方便使用者，本标准在修订过程中适当考虑了ISO14001:2004的内容，以增强两个标准的相容性。附录A表明了ISO9001:2008与ISO14001:2004之间的对应关系。

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.

本标准不包括其它管理体系的要求，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，本标准使组织能将他们自己的质量管理体系与相关管理体系的要求并列或相结合。为建立符合国际本标准要求的质量管理体系，组织有可能改变现有的管理体系。

0.5 Goal of this Technical Specification
ISO/TS 16949技术规范的目的

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.

技术规范其目的是发展质量管理系统，在供应链中提供持续改善、强调预防不良、减低变差与浪费。

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

本技术规范是包含了所需的顾客特殊要求、规定了那些赞同此基本的质量管理体系的要求的文件。

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.

本技术规范是为了避免多重认证，并为汽车的零部件的生产和服务的组织提供了质量管理体系的共同方法。

Quality management systems-Particular requirements for the application of ISO 9001:2008 for automotive production and relevant service part organizations
质量管理体系-汽车行业生产件与相关服务的组织实施ISO 9001:2008的特定要求

1 Scope
范 围

1.1General
概 述

ISO 9001:2008, Quality management systems - Requirements

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

本国际标准为有以下要求的组织规定其对质量管理体系的要求：

a) Needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
证明其有能力稳定地提供符合顾客和适用法律、法规要求的产品；和

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 statutory and regulatory requirements.
通过体系有效的运作以提升顾客满意为目标，包括对体系持续改进，以及确保满足顾客和相应法规要求。

NOTE1: In this International Standard, the term “product” applies only to
备注1：在本国际标准中，“产品”是指适用于

a) Product intended for, or required by, a customer.
预期的或顾客要求的产品；

b) any intended output resulting from the product realization processes
产品实现过程所产生的任何预期输出。

NOTE2: Statutory and regulatory requirements can be expressed as legal requirements.
备注2：法律法规的要求能被作为明确的要求。

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.

本技术规范结合ISO9001:2008，定义质量管理系统要求对汽车相关产品的设计和开发、生产、以及适用时，包含安装及服务的要求。

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

本技术规范适用于生产顾客指定的生产件和/或服务件产品的组织。

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

设计中心、公司总部及销售中心等支持功能，无论位于认证地点或远距地点，构成认证地点的一部分，但不能单独取得技术规范证书。

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

技术规范也可应用到整个汽车零件的供应链。

1.2 Application
应用

ISO 9001:2008, Quality management systems — Requirements

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

本标准的所有要求是通用的，可用于所有组织，不论该组织的类型、规模和所提供的产品。

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.

当由于组织和它所提供的产品的性质而不能应用此标准中的某些要求时，这种情况可被视为“排除”。

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 statutory and regulatory requirements.

“排除”仅限于条款 7 中的规定要求，并且这些“排除”不影响组织提供满足顾客和适用的法律、法规要求产品的能力和职责，否则无法宣称符合本国际标准。

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

唯一可获得技术规范排除的是与7.3相关条文，当该组织不负责产品设计与开发。

Permitted exclusions do not include manufacturing process design.

允许排除不包含过程设计。

2 Normative references
基本参考

ISO 9001:2008, Quality management systems — Requirements

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.

以下参考文件对本标准的应用是必不可少的。对于参考日期，仅仅是版本的引用。凡是不注日期的引用文件，其最新版本适用于本标准（包括任何修订）。

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

ISO 9000:2005，*质量管理体系-基本原则和词汇*

3 Terms and definitions
3术语与定义

ISO 9001:2008, Quality management systems — Requirements

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

为了本文件的意图，运用在ISO 9000中规定的术语和定义。

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

在本国际标准的全文中，“产品”一词等同于“服务”。

3.1 Terms and definitions for the automotive industry
汽 车 工 业 的 术 语 和 定 义

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

ISO 9001:2005及以下的名词和定义都可应用在本技术规范上。

3.1.1 Control plan
控制计划

Documented description of the systems and processes required for controlling product (see annex A)

书面描述对控制零组件及过程和系统的要求（参见附录A）。

3.1.2 Design responsible organization
有设计责任的组织

Organization with authority to establish a new, or change an existing, product specification.
被授权建立新产品规格或更改现有产品规格的组织。

NOTE: This responsibility includes testing and verification of design performance within the customer's specified application.
备注：此项职责包括按顾客指定的方法进行设计性能的测试和验证。

3.1.3 Error proofing
错误防止

Product and manufacturing process design and development to prevent manufacture of nonconforming products.
采用产品和过程的设计和开发以预防产出不合格品。

3.1.4 Laboratory
实验室

Facility for inspection, test or calibration that may include, but is not limited to, chemical, metallurgical, dimensional, physical, electrical or reliability testing
用以作为检验、测试或校准的设施。测试设备可能有化学、冶金、容积、物理、电气可靠度测试或测试验证。

3.1.5 Laboratory scope
实验室范围

Controlled document containing
受控文件包括以下：
— Specific tests, evaluations and calibrations that a laboratory is qualified to perform,
实验室有能力执行的测试、评价、及校准的项目。
— List of the equipment which it uses to perform the above, and
用于执行以上作业的设备清单。
— List of methods and standards to which it performs the above
用于执行以上作业的方法和标准的清单。

3.1.6 Manufacturing
制造

Process of making or fabricating
制作或生产以下的过程
— Production materials,

生产材料

— Production or service parts,
生产件或服务件

— Assemblies, or
组装品、或

— Heat-treating, welding, painting, plating or other finishing services
热处理、焊接、涂装、电泳或其它表面处理的服务。

3.1.7 Predictive maintenance
预测性保养

Activities based on process data aimed at the avoidance of maintenance problems by prediction of likely failure modes
依据避免保养问题为目标的过程数据，预估可能失败的模式施行的活动。

3.1.8 Preventive maintenance
预防性保养

Planned action to eliminate causes of equipment failure and unscheduled interruptions to production, as an output of the manufacturing process design
消除生产设备失败和非计划中断的策划行动，为制造过程设计的输出。

3.1.9 Premium freight
超额运费

Extra costs or charges incurred additional to contracted delivery.
协议运输外增加的运输费用。

NOTE: This can be caused by method, quantity, unscheduled or late deliveries, etc.
备注：这可能会因为方法、数量、非计划或交付延迟而导致。

3.1.10 remote location
远距地点

Location that supports sites and at which non-production processes occur.
支持地点和非生产过程的地点

3.1.11 site
场所

Location at which value-added manufacturing processes occur.
具附加价值生产过程发生的地点。

3.1.12 special characteristic
特殊特性

Product characteristic or manufacturing process parameter, which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product
有变异存在时，可能对会影响到安全性、不符合法规、配合性、功能、绩效或后续的产品加工的产品特性或是过程参数。

4. Quality management systems
质 量 管 理 体 系

4.1 General requirements
总 要 求

ISO 9001:2008, Quality management systems — Requirements

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.

组织必须依照本标准的要求建立、文件化、实施、维护和持续地改进质量管理体系。

The organization shall:

组织必须：

a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2),
确定质量管理体系所需的过程和在整个组织中的运用（参见1.2）

b) Determine the sequence and interaction of these processes,
决定这些过程的顺序和相互作用；

c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
决定所需的标准和方法以确保这些过程是有效的运作和控制；

d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
确保必要的资源和信息的适用性，以支持这些过程的运作和监控；

e) Monitor, measure where applicable and analyses these processes, and
测量、适当时监控和分析这些过程；和

f) Implement actions necessary to achieve planned results and continual improvement of these processes.
实施为达到计划的结果所必须的措施和对这些过程进行持续改进。

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

组织必须按照本标准的要求管理这些过程。

Where an organization chooses to outsource any process that affects product conformity to 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.

当组织选择将某些会影响产品符合性要求的过程外包，那么组织必须确保对这些过程的控制。对这些外包过程控制的类型和程度应定义在质量管理体系中。

NOTE 1: 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.

备注1：以述质量管理体系所需的过程包括管理活动、资源提供、产品实现和测量、分析与改进。

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.

备注2：“外包过程”为了质量管理体系需要，由组织识别，外部执行的过程。

NOTE 3: Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customers, statutory and regulatory requirements. The type

and extent of control to be applied to the outsourced process can be influenced by factors such as:

备注 3：组织对外包过程的控制，并不免除其满足所有顾客要求和法律法规责任。对外包过程控制类型和程度受如下因素的影响：

a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,
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) the degree to which the control for the process is shared,
对外包过程控制的分担程度；
c) the capability of achieving the necessary control through the application of 7.4.
通过应用7.4实现所需的控制能力。

4.1.1 General requirements - Supplemental
总要求—补充

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

确保外协过程的控制，不容许组织推卸其符合客户要求的责任。

NOTE: See also 7.4.1 and 7.4.1.3.

备注：参见7.4.1和7.4.1.3。

4.2 Documentation requirements
文 件 要 求
4.2.1 General
总 则

ISO 9001:2008, Quality management systems — Requirements

The quality management system documentation shall include

质量管理体系文件必须包括：

a) Documented statements of a quality policy and quality objectives,
以文件化形式阐明的质量方针和质量目标；
b) A quality manual,
质量手册；
c) Documented procedures and records required by this International Standard,
本国际标准所需的文件化的程序和记录；
d) Documents, including records determined by the organization to be necessary to ensure the effective planning, operation and control of its processes
组织为确保对过程有效的策划、运行和控制所必需的文件，包括记录。

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.

备注1：在本国际标准中凡出现“文件化的程序”的术语时，这表示程序需建立、文件化、实施和维护。单个文件可包括一个或多个程序要求。一个文件化的程序可被包含在多个文件中。

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

备注2：一个组织的质量管理体系文件的详略程度可以不同于另一组织，这取决于：

a) The size of organization and type of activities,
组织的规模和活动的类型；
b) The complexity of processes and their interactions, and
过程的复杂程度及它们之间的相互作用；
c) The competence of personnel.
人员的能力。

NOTE 3: The documentation can be in any form or type of medium.
备注3：文件可以是任何媒体的格式或形式。

4.2.2 Quality manual
质 量 手 册

ISO 9001:2008, Quality management systems — Requirements

The organization shall establish and maintain a quality manual that includes
组织必须建立和维护质量手册，它包括：

a) The scope of the quality management system, including details of and justification for any exclusions (see 1.2),
质量管理体系的范围，包括任何排除的条款的细节和理由（见1.2）；
b) The documented procedures established for the quality management system, or reference to them, and
为质量管理体系而建立的文件化的程序或对其的引用；
c) A description of the interaction between the processes of the quality management system.
质量管理体系的过程之间相互作用关系的描述。

4.2.3 Control of documents
文件控制

ISO 9001:2008, Quality management system — Requirements

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.
质量管理体系所要求的文件必须受控。质量记录是一种特殊类型的文件，并且必须根据4.2.4条款的要求将其受控。

A documented procedure shall be established to define the controls needed
必须建立文件化的程序以定义所需要的控制，

a) To approve documents for adequacy prior to issue,
在发放之前批准其适用性；
b) To review and update as necessary and re-approve documents,
根据需要评审及更新并重新批准文件；
c) To ensure that changes and the current revision status of documents are identified,
确保文件的更改和文件现行版本状态已被鉴别；
d) To ensure that relevant versions of applicable documents are available at points of use,
确保在使用场所都有相应文件的有效版本；
e) To ensure that documents remain legible and readily identifiable,
确保文件保持清晰和易于识别；
f) To ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and

确保组织所确定的策划和运行质量管理体系所需的外部文件已得到识别，并且在受控状态下发布；

g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.
避免误用任何作废的文件，如果因任何目的而保留作废的文件，这些文件应被适当地识别。

4.2.3.1 Engineering specifications
工程规范

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.

组织必须有一个过程以确保所有顾客的工程标准/规格及变更，能依据顾客要求的日程及时的评审、分发和执行。及时评审必须越快越好，并且不宜超过两个工作周。

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

组织必须记录每项生产中实施变更的日期并加以保存，变更的实施必须包括所有相关文件的更新。

NOTE: 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.

备注：此种规格/规范的变更如果属于设计记录的规范，或会影响到生产件批准过程的资料如控制计划、FMEA等，则须更新生产件批准过程的记录。

4.2.4 Control of records
记录控制

ISO 9001:2008, Quality management system — Requirements

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

为提供符合要求及质量管理体系有效性运行的证据而建立的记录，应得到控制。

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

组织应建立文件化的程序以确定记录的标示、储存、保护、检索、保留和处理所需的控制。

Records shall remain legible, readily identifiable and retrievable.

记录应保持清晰、易于识别和检索。

NOTE 1 “Disposition” above includes disposal.

备注1：上面提到的“处理”包含处置。

NOTE 2 “Records” also include customer-specified records.

备注2：“记录”也包含顾客指定的记录。

4.2.4.1 Records retention
记 录 保 存

The control of records shall satisfy regulatory and customer requirements.

记录的控制必须满足法规和客户要求。

5 Management responsibility
管 理 职 责

5.1 Management commitment
管 理 层 的 承 诺

ISO 9001:2008, Quality management systems — Requirements

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

高层管理者必须通过以下几点来证明其在质量管理体系的发展和改进，和对体系有效性的持续改进所提供的承诺：

a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
在组织沟通满足顾客和法令、法规要求的重要性；

b) Establishing the quality policy,
建立质量方针；

c) Ensuring that quality objectives are established,
确保已建立质量目标；

d) Conducting management reviews, and
实施管理评审；

e) Ensuring the availability of resources.
确保资源的适用性。

5.1.1 Process efficiency
过程效率

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

高层管理者必须评审产品实现过程及支持过程，以确保其有效性和效率。

5.2 Customer focus
顾客焦点

ISO 9001:2008, Quality management systems — Requirements

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

高层管理者必须确保顾客的要求已被决定且符合提升顾客满意为目标（参见7.2.1和8.2.1）。

5.3 Quality policy
质量方针

ISO 9001:2008, Quality management systems — Requirements

Top management shall ensure that the quality policy

高层管理者必须确保质量方针：

a) is appropriate to the purpose of the organization,
适合于组织的目的；

b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
包含符合要求和对质量管理体系有效性持续地改进的承诺；

c) provides a framework for establishing and reviewing quality objectives,
为建立和评审质量目标提供基准；
d) is communicated and understood within the organization, and
在组织中被沟通和理解，和；
e) is reviewed for continuing suitability.
评审持续的适应性。

5.4 Planning
策 划

5.4.1 Quality objectives
质 量 目 标

ISO 9001:2008, Quality management systems — Requirements

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.

高层管理者必须确保在组织的相关职能和层级建立质量目标，包括为达到产品要求的那些需求（参见7.1.a）。质量目标必须是可以度量的，并与质量方针一致。

5.4.1.1 Quality objectives — Supplemental
质 量 目 标—补充

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

高层管理者必须定义质量目标并加以测量，质量目标必须包含在经营计划中，并将质量方针加以展开。

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

备注：质量目标应界定顾客期望并且可在制订期限内达成。

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

ISO 9001:2008, Quality management systems — Requirements

Top management shall ensure that
高层管理者必须确保：

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
为符合在4.1 条款中规定的要求和质量目标而执行质量管理体系的策划；
b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
在对质量管理体系的更改进行策划和执行时，维护质量管理体系的完整性。

5.5 Responsibility, authority and communication
职 责、权 限 与 沟 通

5.5.1 Responsibility and authority
职 责 与 权 限

ISO 9001:2008, Quality management systems — Requirements

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

高层管理者必须确保组织中职责、权限和相互关系已被确定与沟通。

5.5.1.1 Responsibility for quality

质 量 职 责

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

当产品或过程无法符合要求时，此信息必须立即通知负责与授权进行纠正措施的管理层。

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

产品质量的负责人员必须有权停止生产以纠正质量问题。

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

对于生产过程，所有的作业班次都必须明确质量控制的责任人员或委派代表以确保产品质量。

5.5.2 Management representative

管 理 者 代 表

ISO 9001:2008, Quality management systems — Requirements

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

高层管理者必须在管理层中指定一名为管理者代表，不论其在其它方面的职责，必须包括以下的职责和权限：

a) Ensuring that processes needed for the quality management system are established, implemented and maintained,
确保质量管理体系所需的过程已建立、实施和维护；

b) Reporting to top management on the performance of the quality management system and any need for improvement, and
向高层管理者报告质量管理体系的业绩，及任何改进的要求；

c) Ensuring the promotion of awareness of customer requirements throughout the organization.
确保在整个组织内对顾客要求的意识的促进。

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

备注：管理者代表的职责还可包括就质量管理体系的有关事宜与外部各方的联络工作。

5.5.2.1 Customer representative

顾客代表

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

最高管理管理者必须指派人员代表顾客提出质量要求。这包括对特殊特性的选择、质量目标的制订、相关的培训、纠正与预防措施、产品设计和开发等。

5.5.3 Internal communication

内部沟通

ISO 9001:2008, Quality management systems — Requirements

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.

高层管理者必须确保在组织内部建立适当的沟通过程，并对质量管理体系的有效性进行沟通。

5.6 Management review
管理评审

5.6.1 General
总则

ISO 9001:2008, Quality management systems — Requirements

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.

高层管理者必须按照计划的时间间隔对组织的质量管理体系进行评审，以确保其持续的适宜性、充分性和有效性。管理评审必须包括评定是否有改进的机会和对质量管理体系是否有修改的要求，包括质量方针和质量目标。

Records from management reviews shall be maintained (see 4.2.4).

管理评审的记录必须被维护（参见4.2.4）。

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

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

管理评审必须包括质量管理系统的所有要求与其绩效趋势，以将其作为持续改善过程的必要部分。

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).

管理评审的部分内容必须对质量目标进行监控，并对不良的质量成本进行定期报告和评估（见8.4.1及8.5.1） 。

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

上述各项结果必须留下记录，以作为达成以下各项的证据（应视为最低要求）：

— The quality objectives specified in the business plan, and
经营计划中制订的质量目标；和

— Customer satisfaction with product supplied.
顾客对所供应产品的满意度。

5.6.2 Review input
评审的输入

ISO 9001:2008, Quality management systems — Requirements

The input to management review shall include information on

管理评审的输入必须包括以下信息：

a) Results of audits,
审核结果；

b) Customer feedback;
顾客反馈;
c) Process performance and product conformity,
过程业绩和产品符合性;
d) Status of preventive and corrective actions,
预防和纠正措施的状况;
e) Follow-up actions from previous management reviews,
上一次管理评审的后续措施;
f) Changes that could affect the quality management system, and
可能影响到质量管理体系的更改;
g) Recommendations for improvement.
改进的建议。

5.6.2.1 Review input - Supplemental
评审输入—补充

Input to management review shall include an analysis of actual and potential field-failures and their impact on quality, safety or the environment.
管理评审输入必须包含实际和潜在使用现场失效的分析与其对质量、安全和环境的冲击。

5.6.3 Review output
评审的输出

ISO 9001:2008, Quality management systems — Requirements

The output from the management review shall include any decisions and actions related to
管理评审的输出必须包括与以下方面有关的任何决策和措施:
a) Improvement of the effectiveness of the quality management system and its processes,
对质量管理体系及其过程有效性的改进;
b) Improvement of product related to customer requirements, and
与顾客要求有关的产品的改进;
c) Resource needs.
资源要求。

6. Resource management
资源管理

6.1 Provision of resources
资源的提供

ISO 9001:2008, Quality management systems — Requirements

The organization shall determine and provide the resources needed
组织必须决定和提供所需的资源:
a) To implement and maintain the quality management system and continually improve its effectiveness, and
实施和维护质量管理体系，和持续地改进其有效性;
b) To enhance customer satisfaction by meeting customer requirements.
通过符合顾客的要求，提高顾客满意度。

6.2 Human resources
人力资源

6.2.1 General
总则

ISO 9001:2008, Quality management systems — Requirements

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

从事对产品要求有影响的工作的人员必须在适当的教育、培训、技能和经验的基础上具备能力。

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

备注：在质量管理体系中承担任何工作的人员都有可能直接或间接地影响产品要求的符合性。

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

ISO 9001:2008, Quality management systems - Requirements

The organization shall
组织必须：

a) Determine the necessary competence for personnel performing work affecting conformity to product requirements,
决定从事对产品要求符合性工作的人员所需具备的能力；

b) where applicable, provide training or take other actions to achieve the necessary competence,
适当时，提供培训或采取其它措施以获取所需的能力；

c) Evaluate the effectiveness of the actions taken,
评价所采取的措施的有效性；

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
确保这些人员都能意识到他们所从事的活动的关联性和重要性，和他们对达成质量目标的所做的贡献；和

e) Maintain appropriate records of education, training, skills and experience (see 4.2.4).
维护教育、培训、技能和经验的记录（参见4.2.4）。

6.2.2.1 Product design skills
产品设计技能

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

组织必须确保负责产品设计人员具备资格以达成设计要求，并且拥有操作必须的应用工具及技术的技能。

Applicable tools and techniques shall be identified by the organization.

应用工具及技术必须由组织进行识别。

6.2.2.2 Training
培 训

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

组织必须建立及维持书面程序，以对所有从事影响质量活动的人员识别培训需求以及达成其

能力。对从事特定指派工作，特别是满足顾客指定的要求的人员必须确定其资格。

NOTE1: This applies to all employees having an effect on quality at all levels of the organization.
备注1: 本项条款适用于组织内所有阶层的所有会影响质量的员工。
NOTE2: An example of the customer specific requirements is the application of digitized mathematically based data.
备注2: 顾客指定要求的例子是数字化的数学基础资料。

6.2.2.3 Training on the job
在职培训

The organization shall provide on-the-job training for personnel in any new or modified job affecting product quality, 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.

对于从事任何新的或修改的与质量有关的工作的员工，包括合同工和代理人员，组织必须提供在职培训。对质量有影响的人员，必须被告知有关不符合质量要求对顾客造成的后果。

6.2.2.4 Employee motivation and empowerment
员工激励和授权

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.

组织必须有一个激励员工去实现质量目标、并进行持续改进及建立促进革新的环境的过程。该过程必须包含整个组织对于质量及技术认知的提高。

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).

组织必须建立一个测量过程，用以衡量组织的人员认知他们活动的关联性和重要性以及他们如何对于质量目标的达成有所贡献（见6.2.2 d）。

6.3 Infrastructure
基础设施

ISO 9001:2008, Quality management systems — Requirements

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

组织必须决定、提供和维护所需的基础设施，以达成符合产品要求。适用时，基础设施包括：

a) Buildings, workspace and associated utilities,
办公楼、工作区和相关的公用设施；
b) Process equipment (both hardware and software), and
过程设备（包括硬件和软件）；
c) Supporting services (such as transport, communication or information systems).
支持性服务（例如：运输、通讯或信息系统）。

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

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.

组织必须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。工厂布局必须将物料流动和搬运程度减到最小以促进物料的同步流动，并且将工厂空间的使用附加价值提升到最大。必须展开并评价现有操作和过程效果的方法。

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

备注：这些要求应注重于精益生产原则，和其与质量管理系统有效性的联系。

6.3.2 Contingency plans
应急计划

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.

组织必须准备应急计划一旦发生紧急状况时仍满足顾客的要求，如：公共设施中断、劳工短缺、主要设备故障和市场退货等。

6.4 Work environment
工作环境

ISO 9001:2008, Quality management systems — Requirements

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

组织必须决定和管理所需要的工作环境，以达成符合产品要求。

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).

备注：术语“工作环境”是指工作时所处的工作条件，包括物理的、环境和其它因素（如噪音、温度、湿度、照明或天气）。

6.4.1 Personnel safety to achieve product quality
达成产品质量的人员安全

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.

组织必须制定产品安全和降低对员工造成危害的潜在风险之方法，特别是在设计与开发过程和在制造过程中应用。

6.4.2 Cleanliness of premises
作业场所的清洁

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

组织必须维持作业场所的整齐与清洁，以符合产品和制造过程的要求。

7 Product realizations
产品实现

7.1 Planning of product realization

产品实现策划

ISO 9001:2008, Quality management systems — Requirements

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).

组织必须策划和发展为产品实现所需的过程。产品实现过程的策划必须与质量管理体系的其它过程要求一致（参见4.1）。

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

在产品实现进行策划过程中，适当时，组织必须决定：

a) Quality objectives and requirements for the product;
质量目标和产品的要求；

b) The need to establish processes and documents, and to provide resources specific to the product;
针对产品建立过程、文件和提供资源的要求；

c) Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
明确的产品所要求的验证、确认、监视、测量、检验和试验活动及产品的接受标准；

d) Records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).
提供过程实现和最终产品符合要求的证据所需的记录（参见4.2.4）。

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

策划的输出必须是适合组织运作的方法的格式。

NOTE1: 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.

备注1：应用在特定产品、项目或合同的质量管理体系过程（包括产品实现的过程）的文件和资源可以被认为是质量计划。

NOTE2: The organization may also apply the requirements given in 7.3 to the development of product realization processes.

备注2：组织可将在条款7.3中规定的要求运用于产品实现过程的发展。

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.

备注：有些顾客将项目管理或者先期产品质量策划当作达成产品实现的方法。先期产品质量策划包括了缺陷预防以及持续改进的概念。与缺陷发现相反，并且以多方论证的方法为基础。

7.1.1 Planning of product realization - Supplemental

产品实现策划—补充

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

顾客要求和技术规范参考资料必须包含在产品实现策划作为质量策划的一部分。

7.1.2 Acceptance criteria

接 收 标 准

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

组织必须制订接收准则，需要时由顾客批准。

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

计数值抽样计划的接收准则必须是零缺点（见8.2.3.1）。

7.1.3 Confidentiality
保 密 性

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

组织必须确保顾客合同的产品、进行开发的项目和有关的产品信息的保密性。

7.1.4 Change control
变更控制

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.

组织必须有一过程以控制及反应对影响产品实现的变更。任何变更的结果，包含来自于供方的变更，必须被评估、验证和确认以确保符合顾客要求。变更必须确认后才能实施。对于具有专利权的设计，变更对外形、装配、性能（包含功能及/或耐久性）的影响，必须与顾客共同评审，以便适当评价变更的影响程度。

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

必须满足当顾客有附加的验证/鉴定要求，例如引进新产品说明要求。

NOTE1: Any product realization change affecting customer requirements requires notification to, and agreement from, the customer.

备注1：任何影响顾客要求之产品实现变更，必须通知顾客，并且得到顾客的同意。

NOTE2: The above requirement applies to product and manufacturing process changes.

备注2：本项要求适用产品和过程变更。

7.2 Customer-related processes
顾客相关过程

7.2.1 Determination of requirements related to the product
产品有关要求的决定

ISO 9001:2008, Quality management systems — Requirements

The organization shall determine

组织必须决定：

a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities,
顾客规定的要求，包括交付要求和对交付后活动的要求；

b) Requirements not stated by the customer but necessary for specified or intended use, where known,
非顾客规定的要求，但是已知且规定或预期的用途所必要的；

c) Statutory and regulatory requirements applicable to the product, and
适用的产品有关的法令和法规的要求；
d) Any additional requirements considered necessary by the organization.
任何由组织考虑必要的附加要求。
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.
备注：交付后活动包括诸如保证条款规定的措施、合同义务（例如，维护服务）、附加服务（例如，回收或最终处置）等。

NOTE1: Post-delivery activities include any after-sales product service provided as part of the customer contract or purchase order.
注1：交货后活动包含因应顾客合同或采购订单的任何售后服务。
NOTE2: 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).
注2：此要求包含识别出的回收、环境冲击和特性，作为组织拥有产品及过程知识的成果。（参见7.3.2.3）
NOTE3: Compliance to item c) includes all applicable government, safety and environmental regulations, applied to acquisition, storage, handling, recycling, elimination or disposal of materials.
注3：c)项的符合性必须包含所有适用的政府、安全及环保法规对物料的购买、储存、搬运、再回收、报废或处理。

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

The organization shall demonstrate conformity to customer requirements for designation, documentation and control of special characteristics.
组织必须展示符合顾客指定的要求、文件化和控制特殊特性。

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

ISO 9001:2008, Quality management systems — Requirements

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
组织必须评审与产品有关的要求。这种评审必须在组织决定或承诺对顾客供货之前进行（如：提交标书、接受合同或订单、接受修改的合同或订单），并确保：
a) Product requirements are defined,
产品要求已确定；
b) Contract or order requirements differing from those previously expressed are resolved, and
任何与先前说明不一致的合同或订单的要求已得到解决；
c) The organization has the ability to meet the defined requirements.
组织有能力符合规定的要求；
Records of the results of the review and actions arising from the review shall be maintained (see

4.2.4).

评审的结果和评审的后续措施的记录必须维护（参见4.2.4）。

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

当顾客的要求没有以书面的形式表达时，组织必须在接受之前确认顾客的要求。

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.

当产品的要求更改时，组织必须确保相应的文件已被修改，并且相关的人员已意识到被更改的要求。

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 advertising material.

备注：在某些情况下如网络销售，对每一订单进行正式的评审是不切实际的，此时可用对产品信息的评审替代，例如：目录、广告材料等。

7.2.2.1 Review of requirements related to the product — Supplemental

产品有关要求的评审—补充

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

免除7.2.2正式评审（见备注）规定的要求须取得顾客授权。

7.2.2.2 Organization manufacturing feasibility

组织的制造可行性

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

组织在合同评审时，必须对所策划的产品进行研究、确认制造的可行性，并且文件化、包含风险分析。

7.2.3 Customer communication

顾客沟通

ISO 9001:2008, Quality management systems — Requirements

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

组织必须对以下方面决定和实施与顾客沟通的有效的安排：

a) Product information,
产品信息；

b) Enquiries, contracts or order handling, including amendments, and
询价、处理中的合同或订单，包括其修改；

c) Customer feedback, including customer complaints.
顾客反馈，包括顾客投诉。

7.2.3.1 Customer communication — Supplemental

顾客沟通－补充

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).

组织必须具备以顾客指定的语言和格式的沟通能力，以沟通必要的信息、资料（例如：计算

机辅助设计资料、电子资料交换）。

7.3 Design and development
设计与开发

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

备注：7.3的要求包含产品及过程的设计与开发，着重于缺点预防而非察觉。

7.3.1 Design and development planning
设计与开发策划

ISO 9001:2008, Quality management systems - Requirements

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

组织必须策划和控制产品的设计和开发。

During the design and development planning, the organization shall determine

在设计和开发策划过程中，组织必须决定：

a) The design and development stages,
设计和开发过程的阶段；

b) The review, verification and validation that are appropriate to each design and development stage, and
在每个设计和开发阶段适当的评审、验证和确认活动；

c) The responsibilities and authorities for design and development.
设计和开发活动的职责和权限。

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

对于参与设计和开发过程的不同的群体，企业必须管理他们之间的接口关系，确保他们之间有效的沟通清楚的职责指派。

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

策划的输出必须随设计和开发的进展在适当时予以更新。

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.

备注：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。

7.3.1.1 Multidisciplinary approach
多方论证

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

组织必须采用多方论证方式进行产品实现的准备工作，包括：

－development/finalization and monitoring of special characteristics,
特殊特性的开发、最终确定及监督；

－development and review of FMEAs, including actions to reduce potential risks, and
潜在失效模式及后果分析（FMEAs）的开发和评审，包括采取降低风险的措施；和

－development and review of control plans.
控制计划的开发和评审。

NOTE: A multidisciplinary approach typically includes the organization's design, manufacturing, engineering, quality, production and other appropriate personnel.
备注：典型的多方论证包括组织的设计、制造、工程、质量、生产和其它适当人员。

7.3.2 Design and development inputs
设计与开发输入

ISO 9001:2008, Quality management systems — Requirements

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include
与产品要求有关的输入必须决定和维护其记录（参见4.2.4），输入必须包括：

a) Functional and performance requirements,
功能和性能要求；

b) Applicable statutory and regulatory requirements,
适用的法令和法规的要求；

c) Where applicable, information derived from previous similar designs, and
适用时，从以往类似设计中得到的信息；

d) Other requirements essential for design and development.
设计和开发的其它必要的要求。

The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.
输入都必须评审其适当性，所有要求都必须是完整、明确并且不相互矛盾。

NOTE: Special characteristics (see 7.2.1.1) are included in this requirement.
备注：特殊特性（见7.2.1.1）包含在本要求内。

7.3.2.1 Product design input
产品设计输入

The organization shall identify, document and review the product design inputs requirements, including the following:
组织必须对产品设计输入的要求进行识别、形成文件并进行评审，包括：

－customer requirements (contract review) such as special characteristics (see 7.3.2.3), identification, tractability and packaging;
顾客要求（合同评审）如特殊特性（见7.3.2.3）、标示、追溯和包装；

－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;
信息的利用：组织必须建立对从以往设计项目、竞争对手分析、供方的反馈、内部输入、使用现场资料与其它相关来源获取的信息进行利用的程序，以便于目前或未来有相似性的项目；

－targets for product quality, life, reliability, durability, maintainability, timing and cost.
产品的质量、寿命、可靠性、耐久性、可维护性、工时和成本目标。

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

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

requirements, including

组织必须对制造过程设计输入的要求进行识别、形成文件并进行评审，包括：

－product design output data,

产品设计输出资料；

－targets for productivity, process capability and cost,

生产力、过程能力和成本的目标；

－customers requirements, if any, and

顾客要求（若有的话）；和

－experience from previous developments.

以往的开发经验。

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.

备注：相对问题大小与可能产生的风险，在制造过程设计过程中使用适当程度的错误防止方法。

7.3.2.3 Special characteristics

特殊特性

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

组织必须识别特殊特性（见7.3.3d），并且

－include all special characteristics in the control plan,

所有的特殊特性都应包括在控制计划中；

－comply with customer-specified definitions and symbols, and

符合顾客指定的定义和代号；和

－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.

过程控制文件，包含图纸、FMEAs、控制计划及作业指导书，必须使用顾客的特殊特性符号或组织的同等符号或说明来加以标识，以表明对特殊特性有影响的那些过程步骤。

NOTE: Special characteristics can include product characteristics and process parameters.

备注：特殊特性包括产品特性和过程参数。

7.3.3 Design and development outputs

设计与开发输出

ISO 9001:2008, Quality management systems — Requirements

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

设计和开发过程的输出必须以适当的格式对设计和开发的输入要求进行验证，并必须在发放前予以批准。

Design and development outputs shall

设计和开发输出必须：

a) meet the input requirements for design and development,

符合设计和开发输入的要求；

b) provide appropriate information for purchasing, production and service provision,
为采购、生产和服务要求提供合适的信息；
c) contain or reference product acceptance criteria, and
包含或引用产品接受准则；
d) specify the characteristics of the product that are essential for its safe and proper use.
确定与产品安全和正常使用必要的产品特性。

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

备注：产品和服务提供的信息可能包括产品防护的细节。

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

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

产品设计输出的表达方式能对产品设计输入的要求验证及确认。产品设计输出必须包含：

— Design FMEA, reliability results,
设计FMEA，可靠性结果；
— Product special characteristics and specifications,
产品特殊特性和规格；
— Product error proofing, as appropriate,
适用时，产品的错误防止；
— Product definition including drawings or mathematically based data,
产品定义，包含图纸或数学基础资料；
— Product design reviews results, and
产品设计评审的结果；
— Diagnostic guidelines where applicable.
适用时，诊断指导书。

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

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

制造过程设计输出的表达方式能对制造过程设计输入的要求验证及确认，制造过程设计输出必须包含：

－specifications and drawings,
规格和图纸；
－manufacturing process flow chart/layout,
制造过程流程图/配置图；
－manufacturing process FMEAs,
制造过程FMEAs；
－control plan (see 7.5.1.1),
控制计划（见7.5.1）；
－work instructions,
作业指导书；

－process approval acceptance criteria,
过程批准的接收准则；
－data for quality, reliability, maintainability and measurability,
质量、可靠度、维修度及可测量性的资料；
－results of error-proofing activities, as appropriate, and
适用时，错误防止活动的结果；
－methods of rapid detection and feedback of product/manufacturing process nonconformities.
产品/制造过程不合格的快速追查和反馈方法。

7.3.4 Design and development review
设计与开发评审

ISO 9001:2008, Quality management systems — Requirements

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)
在适当阶段，必须根据计划的安排对设计和开发进行系统的评审（参见7.3.1）：
a) to evaluate the ability of the results of design and development to meet requirements, and
评价设计和开发结果符合要求的能力；
b) to identify any problems and propose necessary actions.
识别所有问题和提出必要的措施。
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).
评审的参加者必须包括与被评审的设计和/或开发阶段有关的职能部门的代表。必须维护评审和任何必要的措施的结果的记录（参见4.2.4）

NOTE: These reviews are normally coordinated with the design phases and include manufacturing process design and development.
备注：这些评审通常是与各设计阶段协调并且应该包含在制造过程的设计与开发之内。

7.3.4.1 Monitoring
监督

Measurements at specified stages of design and development shall be defined, analyses and reported with summary results as an input to management review.
必须实施对设计与开发各阶段的评审、分析并向管理评审报告结果。

NOTE: These measurements include quality risks, costs, lead-times, critical paths and others, as appropriate.
备注：适用时，评审包含如质量风险、成本、前置时间、重要途径等等。

7.3.5 Design and development verification
设计与开发的验证

ISO 9001:2008, Quality management systems — Requirements

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).
必须执行验证以确保设计和开发输出符合设计和开发输入的要求（参见7.3.1），必须维护验

证和任何必要的措施的结果的记录（参见4.2.4）。

7.3.6 Design and development validation
设计与开发的确认

ISO 9001:2008, Quality management systems — Requirements

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).

必须按照计划的安排（参见7.3.1）进行设计和开发确认，以确保最终的产品能满足规定的应用或已知预期的使用的要求。可行时，确认必须在产品交付或实施之前完成。必须维护确认和任何必要的措施的结果的记录（参见4.2.4）。

NOTE 1: The validation process normally includes an analysis of field reports for similar products.
备注1：确认的过程应包含类似产品使用现场的分析报告。

NOTE 2: The requirements of 7.3.5 and 7.3.6 above apply to both product and manufacturing processes.
备注2：以上条文7.3.5和7.3.6 适用于产品和制造过程。

7.3.6.1 Design and development validation — Supplemental
设计与开发确认—补充

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

设计确认的执行必须配合顾客项目计划的日程要求。

7.3.6.2 Prototype programmed
原形样品计划

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.

当顾客要求时，组织必须制订原形样品计划和控制计划，组织必须尽可能使用与正式生产中相同的供方、模具和制造过程。

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

必须监督所有的性能试验活动，以及时完成并符合要求。

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

当这些服务被外包时，组织必须对供方的服务负责并提供技术指导。

7.3.6.3 Product approval process
7.3.6.3 产品批准过程

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

组织必须遵守顾客认可的产品和制造过程批准过程。

NOTE: Product approval should be subsequent to the verification of the manufacturing process.
备注：产品批准必须在制造过程验证以后。

This product and manufacturing process approval procedure shall also be applied to suppliers.
本产品和过程批准过程必须同样应用于供方。

7.3.7 Control of design and development changes
设计与开发变更控制

ISO 9001:2008, Quality management systems - Requirements

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

设计和开发的更改必须予以识别，并且保持相关的记录。更改必须被适当的评审、验证和确认，并在实施之前得到批准。对设计和开发更改的评审必须包括更改对组成部份和已交付的产品所造成的影响的评价。必须维护更改的评审和任何必要的措施的结果的记录（参见4.2.4）。

NOTE: Design and development changes include all changes during the product programme life (see 7.1.4).
备注：设计与开发变更应包含在产品计划寿命期间内的所有变更（参见7.1.4）。

7.4 Purchasing
采购

7.4.1 Purchasing process
采购过程

ISO 9001:2008, Quality management systems — Requirements

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.

组织必须确保所采购的产品符合规定的采购要求。对供方和采购的产品实行控制的方式和程度必须取决于采购的产品对其往后产品的实现或最终产品的影响。

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)

组织必须根据供方提供组织要求的产品的能力来评价和选择。必须建立选择、评价和重新评价的标准。必须维护评价和任何因评价产生的必要措施的结果的记录（参见4.2.4）。

NOTE 1: Purchased products above include all products and services that affect customer requirements such as subassembly, sequencing, sorting, and rework and calibration services.
备注1: 上述的采购产品包括所有对顾客要求有影响的产品和服务，如：部件组装、排序、分类、返工和校准服务。

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.

备注2：如供方牵涉到有合并、收购或加盟事宜，组织应验证供方的质量管理体系之持续性和有效性。

7.4.1.1 Regulatory conformity
符 合 法 规

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

用于产品生产的所有采购的产品或材料均必须满足适用的法规要求。

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

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 in achieving this goal.

组织必须以供方符合本技术规范为目标来开发供方的质量管理体系，符合ISO9001:2008是达成本目标的第一步。

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

备注：供方开发的先后顺序应取决于供方的质量实绩以及所提供产品的重要性。

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.

除非顾客另有指定，组织的供方必须取得第三方认证机构ISO9001:2008的注册。

7.4.1.3 Customer-approved sources
顾客批准的供方

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

当合同有规定时（例如顾客的工程图纸、规范），组织必须从顾客指定的供方中采购产品、材料和服务。

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.

采用顾客指定的供方，包括工具/量具的供方，不能免除组织对供方确保产品质量的责任。

7.4.2 Purchasing information
采购信息

ISO 9001:2008, Quality management systems — Requirements

Purchasing information shall describe the product to be purchased, including where appropriate
采购信息必须描述所采购的产品，包括适当的：

a) Requirements for approval of product, procedures, processes and equipment,
产品、程序、过程、和设备批准的要求；

b) Requirements for qualification of personnel, and
人员资格的要求；和

c) Quality management system requirements.
质量管理体系的要求。

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

组织必须在与供方进行沟通之前确保所规定的采购要求的适当性。

7.4.3 Verification of purchased product
采购产品的验证

ISO 9001:2008, Quality management systems — Requirements

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

组织必须建立和实施为确保采购的产品能符合规定采购要求所必须的检验或其它活动。

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.

当组织或组织的顾客预期在供方处进行验证时，组织必须在采购信息中规定预期的验证安排和产品放行的方法。

7.4.3.1 Incoming product quality
进料产品的质量

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:

组织必须有一个过程以确保采购产品的质量（见7.4.3），利用下列一项或多项的方法：

－receipt of, and evaluation of, statistical data by the organization;
组织获取并评价统计数据；

－receiving inspection and/or testing such as sampling based on performance;
进料检验及/或测试，如依据交货实绩的抽样方法；

－second- or third-party assessments or audits of supplier sites, when coupled with records of acceptable delivered product quality;
在供方处执行的第二方或第三方评价或审核，且记录显示可接受的质量绩效；

－part evaluation by a designated laboratory;
委托由合格的实验室实施的零组件评价；

－another method agreed with the customer.
其它顾客同意的方法。

7.4.3.2 Supplier monitoring
供方的监督

Supplier performance shall be monitored through the following indicators:

供方的绩效必须通过下列指标来监督：

－delivered product quality;
交付的产品质量；

－customer disruptions including field returns;
顾客退货数、包含使用现场退回品；

－delivery schedule performance (including incidents of premium freight);
交付计划的绩效（包含超额运费）；

－special status customer notifications related to quality or delivery issues.
与质量或交货问题相关的顾客特殊状况报告。

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

组织必须促使供方监督其制造过程绩效。

7.5 Production and service provision

生产和服务提供

7.5.1 Control of production and service provision

生产和服务提供控制

ISO 9001:2008, Quality management systems - Requirements

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

组织必须在受控的条件下策划和展开生产和服务提供，适当时，受控条件包括：

a) The availability of information that describes the characteristics of the product,
描述产品特性的信息的适用性；

b) The availability of work instructions, as necessary,
必要时，作业指导书的适用性；

c) The use of suitable equipment,
使用适当的设备；

d) The availability and use of monitoring and measuring equipment,
监控和测量设备的适用性和使用；

e) The implementation of monitoring and measurement, and
监控和测量的实施；

f) The implementation of product release, delivery and post-delivery activities.
产品发放、交付和交付后的活动的实施。

7.5.1.1 Control plan

控制计划

The organization shall

组织必须：

- 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
  对所供应产品的系统、子系统、组件和/或物料等各层次上开发适当的控制计划（见附录A），包括生产散装材料和零部件的过程；和
- have a control plan for pre-launch and production that takes into account the design FMEA and manufacturing process FMEA outputs.
  有对于设计FMEA和制造过程FMEA输出考虑试生产和正式生产的控制计划。

The control plan shall

控制计划必须：

- list the controls used for the manufacturing process control,
  列出制造过程控制的控制项目；
- include methods for monitoring of control exercised over special characteristics (see 7.3.2.3) defined by both the customer and the organization,
  包含由顾客和组织双方制订的、可执行的特殊特性控制与监督方法（见7.3.2.3）；
- include the customer-required information, if any, and

包含顾客要求的信息，如果有；和

－initiate the specified reaction plan (see 8.2.3.1) when the process becomes unstable or not statistically capable.

当制造过程变得不稳定或统计能力不足时所采用指定的反应计划（见8.2.3.1）。

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).

当有任何变更影响到产品、制造过程、测量、运输、供应来源或FMEA（见7.1.4）时，必须评审和更新控制计划。

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

备注：控制计划评审和更新后可能需要顾客批准。

7.5.1.2 Work instructions

作业指导书

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

组织必须为所有负责操作影响产品质量的过程的员工准备书面的作业指导书，这些作业指导书在工作场所必须容易取得。

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

该指导书须取材自质量计划、控制计划和产品实现过程等资料。

7.5.1.3 Verification of job set-ups

作业设定的验证

Job set-ups shall be verified whenever performed, such as an initial run of a job, material changeover or job change.

任何时候完成作业设定后必须加以验证，如作业开始、材料变更、作业变更。

Work instructions shall be available for set-up personnel. The organization shall use statistical methods of verification where applicable.

作业指导书必须提供给予执行设定人员。适用时，组织必须使用统计的方法进行验证。

NOTE: Last-off-part comparisons are recommended.

备注：建议采用末件比较的方法。

7.5.1.4 Preventive and predictive maintenance

预防和预测性维护

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:

组织必须识别关键的过程设备，并且提供适当的资源以维护这些机器/设备，同时制订一套有效的、规划的全面预防保养制度。该制度至少必须包括：

— planned maintenance activities;

有计划的保养活动；

— Packaging and preservation of equipment, tooling and gauging;

为设备、工具和量具提供包装及保护；

— Availability of replacement parts for key manufacturing equipment;
重要制造过程设备替换零件的维持；
— Documenting, evaluating and improving maintenance objectives.
文件化、评价和改进预防保养目标。

The organization shall utilize predictive maintenance methods to continually improve the effectiveness and the efficiency of production equipment.
组织必须发挥预防性的保养方法以持续改进生产设备的效率及有效性。

7.5.1.5 Management of production tooling
生产工具的管理

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:
组织必须提供进行工具和量具设计、制造和验证作业的资源。组织必须制订和实施管理生产工具的系统，其包括：

— Maintenance and repair facilities and personnel;
保养和维修的设施和人员；
— Storage and recovery;
储存和防护；
— Set-up;
设置；
— Tool-change programmers for perishable tools;
易损工具的更换计划；
— Tool design modification documentation, including engineering change level;
包括在工程更改层级内的工具设计和变更文件；
— Tool modification and revision to documentation;
工具修改和文件编修；
— Tool identification, defining the status, such as production, repair or disposal.
确定工具的状态，如：生产用、修护用或处置中。

The organization shall implement a system to monitor these activities if any work is outsourced.
当任何的工具作业委外时，组织必须实施监督这些作业的系统。

NOTE: This requirement also applies to the availability of tools for vehicle service parts.
备注：此项要求同时也适用于交通和服务用工具。

7.5.1.6 Production scheduling
生 产 排 程

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 driven.
必须策划生产排程以达成顾客要求，如容许访问重要过程阶段，并且是订单导向的生产信息，如通过信息系统支持的准时化生产（JIT）。

7.5.1.7 Feedback of information from service
服务信息的反馈

A process for communication of information on service concerns to manufacturing, engineering

and design activities shall be established and maintained.
必须制定和维持一套沟通程序。将服务有关的信息，通报给制造、工程及设计部门。

NOTE: The intent of the addition of “service concerns” to these subclasses is to ensure that the organization is aware of nonconformities that occur external to its organization.
备注：增加“服务有关信息”的要求是要确保组织内部能了解发生在组织外部的不符合事项。

7.5.1.8 Service agreement with customer
与 顾 客 的 服 务 协 议

When there is a service agreement with the customer, the organization shall verify the effectiveness of
当与顾客达成服务协议时，组织必须验证以下项目的有效性：
— Any organization service centers,
组织的任何一个服务中心；
— Any special-purpose tools or measurement equipment, and
任何特殊用途工具或量测设备；和
— The training of service personnel.
服务人员的培训。

7.5.2 Validation of processes for production and service provision
生产和服务提供的确认

ISO 9001:2008, Quality management systems — Requirements

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.
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，使问题在产品使用后或服务交付后才显现时，组织应对任何这样的过程实施确认。

Validation shall demonstrate the ability of these processes to achieve planned results.
确认必须展现这些过程达到既定策划结果的能力。

The organization shall establish arrangements for these processes including, as applicable
组织必须建立对这些过程确认的安排，适当时，包括：

a) Defined criteria for review and approval of the processes,
为过程评审和批准所明订的标准；
b) Approval of equipment and qualification of personnel,
设备和人员的资格的批准；
c) Use of specific methods and procedures,
规定方法和程序的使用；
d) Requirements for records (see 4.2.4), and
记录的要求（参见4.2.4）；
e) Revalidation.
再次确认。

7.5.2.1 Validation of processes for production and service provision — Supplemental
生产和服务提供的确认—补充

The requirements of 7.5.2 shall apply to all processes for production and service provision.
条文7.5.2必须应用到所有生产和服务提供的过程。

7.5.3 Identification and traceability
标 识 和 追 溯

ISO 9001:2008, Quality management systems — Requirements

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

适当时，组织必须在整个产品实现的过程中以适当的方法标识产品。

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

组织应在产品实现的全过程中，针对监视和测量要求识别产品的状态。

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

当有追溯性要求时，组织必须控制和记录产品的唯一识别（参见4.2.4）。

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

备注：在某些产业部门，通过技术状态管理的方法标识和追溯性被维护。

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 achieve the designated purpose.

备注：产品在正常生产过程中的位置并不构成检验与测试状况的适当标示，除非先天明显易见者，如在自动生产传递过程的物料。除了自动生产传递过程之外，如果测试状况能被清楚的标识，记载与达成设定的目的时，在自动化生产传递过程之外允许采分区法来标识。

7.5.3.1 Identification and traceability — Supplemental
标示和追溯—补充

The words “Where appropriate” in 7.5.3 shall not apply.

在7.5.3中的“适当时”不适用。

7.5.4 Customer property
顾 客 财 产

ISO 9001:2008, Quality management systems — Requirements

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, the organization shall be report to this to the customer and maintained records (see 4.2.4).

当顾客的财产处于组织控制下或正在被组织使用时，组织必须对顾客的财产进行管理，组织必须对那些提供给组织使用或组成产品的顾客的财产进行鉴别、验证、保护和防护。如果任何顾客的财产有遗失、损坏或被发现不适用的情况，组织必须向顾客报告并且维护记录（参见4.2.4）。

NOTE: Customer property can include intellectual property and personal date.

注：顾客财产可包括知识产权和个人信息。

NOTE: Customer-owned returnable packaging is included in this clause.

备注：此项要求也包括那些属于顾客所拥有可回收包装材料。

7.5.4.1 Customer-owned production tooling
顾客所拥有的生产工具

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.

顾客所拥有的工具、制造、测试、检验的工具和设备必须赋予永久性标记以便使所有权能一目了然。

7.5.5 Preservation of product
产 品 防 护

ISO 9001:2008, Quality management systems — Requirements

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

组织必须按照定单的要求在内部的过程中和向预定的目的地交付的过程中对产品进行保护。适当时保护必须包括识别、搬运、包装、储存和保存。保护必须同样适用于产品的组成部份。

7.5.5.1 Storage and inventory
储 存 和 库 存 量

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

为发现产品变质，必须在计划的适当周期评价在库产品的状况。

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.

组织必须使用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）”。废旧产品必须以处置不合格品的类似方法进行控制。

7.6 Control of monitoring and measuring equipment
监 督 和 测 量 设 备 控 制

ISO 9001:2008, Quality management systems - Requirements

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.

组织必须决定所采取的监控和测量方法，及为产品与规定要求相符合提供证据所需要的监控和测量设备。

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.

组织必须建立过程以确保监控和测量有被执行，且是与监控和测量要求相一致的方式被执行。

Where necessary to ensure valid results, measuring equipment shall

为确保结果的有效，测量设备必须：

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);
在规定的时间间隔或使用前与追溯至国际或国家测量标准相应的测量标准进行校准和/或验证。当不存在上述标准时，用于校准或验证的基础必须被记录（参见4.2.4）；

b) Be adjusted or re-adjusted as necessary;
在必要时进行调整或重新调整；

c) Have identified in order to determine its calibration status;
具有标识，以确定其校准状态；

d) Be safeguarded from adjustments that would invalidate the measurement result;
被防护避免因调整不当而使测量结果失效；

e) Be protected from damage and deterioration during handling, maintenance and storage.
被保护避免在搬运、维护和储存时的损坏和变质。

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.

此外，当发现设备与要求不一致时，组织必须评定和记录以前测量的结果的有效性。组织必须对设备和任何受影响的产品采取适当的措施。

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

必须维护校准和验证结果的记录（参见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.

当用于监控和测量规定要求时，必须确认计算机软件满足预期应用的能力。此项活动必须在首次使用前执行并在必要时重新确认。

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.

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

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

备注：追溯到其仪器校正记录的系列编号也可满足本要求。

7.6.1 Measurement system analysis
测 量 系 统 分 析

Statistical studies shall be conducted to analyses 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.

实施适当的统计性研究以分析各种测量及测试设备系统测量结果的变差。此项要求必须适用于控制计划里所列的量测系统。所采用的分析方法和接收标准必须符合顾客的测量系统分析参考手册的规定。

7.6.2 Calibration/verification records
校准/验证记录

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

所有量具、测量和试验设备，包含员工自备的和顾客所有的量具的校准活动记录，必须包括：

－equipment identification, including the measurement standard against which the equipment is calibrated,
设备的识别，包含与校准仪器对照的量测标准；

－revisions following engineering changes,
按工程变更进行的修订；

－any out-of-specification readings as received for calibration/verification,
校准/验证时获得的任何超出规范的读数；

－an assessment of the impact of out-of-specification condition,
超出规范的读数状况影响的评估；

－statements of conformity to specification after calibration/verification, and
校准/验证后有关符合规范的结论；

－notification to the customer if suspect product or material has been shipped.
如有可疑的产品或材料被发运应通知顾客。

7.6.3 Laboratory requirements
实 验 室 要 求

7.6.3.1 Internal laboratory
内 部 实 验 室

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

组织的内部实验室设施必须制订其进行所要求的检验、测试或校准服务的能力范围，在质量管理体系文件中必须包含实验室范围。实验室必须符合下列技术要求，包含：

— adequacy of the laboratory procedures,
实验室程序的适当性；
— competency of the laboratory personnel,
实验室人员的资格；
— testing of the product,
产品的测试；
— capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN, etc.); And
正确地操作这些测试试验之能力，可追溯到相关过程标准（如ASTM，EN等）；
— review of the related records.
记录的评审。

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

备注：ISO/IEC17025认证可能用于展现供方内部实验室对此要求的符合性，但不是强制性的。

7.6.3.2 External laboratory

外 部 实 验 室

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

组织用于外部/商业性质/独立性的检验、测试或校准服务的实验室设备必须被明订，进行所要求的检验、测试或校正作业的能力范围，并且

－there shall be evidence that the external laboratory is acceptable to the customer, or
必须有证据证明外部实验室可被顾客接受；或

－the laboratory shall be accredited to ISO/IEC 17025 or national equivalent.
实验室必须得到ISO/IEC17025或相等国家级之认可。

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

备注1：上述证据可能的证明，例如顾客验证，或是顾客认可的，满足ISO/IEC17025或相等国家级内容的实验室的第二方认证。

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.

备注2：当具备资格的实验室缺乏某种设备时，校准服务可能由设备制造商执行。在该例子，组织应确保条文7.6.3.1之要求已被满足。

8 Measurement, analysis and improvement

测量、分析和改进

8.1 General

总 则

ISO 9001:2008, Quality management systems — Requirements

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

组织必须策划和实施为实现以下目的所需进行的监控、测量、分析和改进的过程：

a) to demonstrate conformity to product requirements,
展现产品要求的符合性；

b) to ensure conformity of the quality management system, and
确保质量管理体系的符合性；

c) to continually improve the effectiveness of the quality management system.
持续改进质量管理体系的有效性。

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

这必须包括决定应用的方法（包括统计技术）和使用的程度。

8.1.1 Identification of statistical tools

确 定 统 计 工 具

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

必须在先期产品质量策划中对各项过程决定适当的统计工具并规定在控制计划中。

8.1.2 Knowledge of basic statistical concepts
基 本 统 计 概 念 知 识

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

组织内的全体人员必须了解并能运用各种统计基础概念，如变差、过程控制（稳定性）、过程能力及过度调整。

8.2 Monitoring and measurement
监 督 和 量 测

8.2.1 Customer satisfaction
顾 客 满 意 度

ISO 9001:2008, Quality management systems — Requirements

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.

作为衡量质量管理体系业绩的方法之一，组织必须对顾客感觉组织是否满足顾客要求的信息进行监控。获取和使用这一信息的方法必须被决定。

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.

备注：监视顾客感受可以包括从诸如顾客满意度调查、来自顾客的关于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获得输入。

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

备注：顾客满意应该考虑内部和外部顾客。

8.2.1.1 Customer satisfaction — Supplemental
顾客满意度—补充

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:

顾客对组织的满意度必须通过实现过程绩效的持续评价来监督。绩效指针必须依据客观资料并包含，但不局限于：

－delivered part quality performance,
交付产品的质量绩效；

－customer disruptions including field returns,
顾客退回包含使用现场退回；

－delivery schedule performance (including incidents of premium freight), and
交付准时的绩效（包含超额运费的事件）；

－customer notifications related to quality or delivery issues.
与质量或交货问题相关的顾客状况报告。

The organization shall monitor the performance of manufacturing processes to demonstrate

compliance with customer requirements for product quality and efficiency of the process.

组织必须监督制造过程绩效以证明符合顾客对产品质量和过程效率的要求。

8.2.2 Internal audit

内 部 审 核

ISO 9001:2008, Quality management systems — Requirements

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

组织必须按照计划的时间间隔进行内部审核，以决定质量管理体系是否：

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

与计划的安排、与本国际标准的要求和组织所建立的质量管理体系的要求相符合；和

b) Is effectively implemented and maintained.

有效地实施和维护。

An audit programmer 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. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

审核计划的安排必须考虑被审核的过程和区域的实际状态和重要性以及以前的审核结果。必须规定审核标准、范围、频率和方法。审核员的选择和审核工作必须确保审核过程的客观性和公正性。审核员不应该审核他们自己的工作。

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

必须建立文件化的程序，以定义审核的策划、实施、形成记录以及报告结果的职责和要求。

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

必须维护审核记录和结果（参见4.2.4）。

The management responsible for the area being audited shall ensure that any necessary correction and correction actions are taken without undue delay to eliminate detected nonconformities and their causes.

被审核区域的管理层必须确保及时地采取必要的纠正和纠正措施以消除发现的不合格和其原因。

Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

后续追查活动必须包括对已采取的措施的验证和验证结果的报告（参见8.5.2）。

NOTE: See ISO 10011 for guidance.

备注：参见ISO19011导则

8.2.2.1 Quality management system audit

质 量 管 理 体 系 审 核

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

组织必须审核质量管理体系以验证与本技术规范和任何附加的质量管理体系要求的符合性。

8.2.2.2 Manufacturing process audit

制 造 过 程 审 核

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

组织必须对制造过程进行审核，以确定有效性。

8.2.2.3 Product audit
产 品 审 核

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

组织必须以规定的频率在生产的适当阶段对其产品及其交货情况进行审核以验证与所有规定的要求，如产品尺寸、功能、包装、标签等的符合性。

8.2.2.4 Internal audit plans
内部审核计划

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

内部审核规划必须涵盖所有与质量管理有关的过程、活动和班次，并且根据年度审核计划制订时程。

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

当发生内/外部不合格或顾客抱怨时，审核频率必须适当地提高。

NOTE: Specific checklist should be used for each audit.

备注：每次审核应采用特定的查检表。

8.2.2.5 Internal auditor qualification
内 部 审 核 员 资 格

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

组织必须有合格的内部审核员来审核本技术规范（见6.2.2.2）。

8.2.3 Monitoring and measurement of processes
过 程 的 监 督 和 测 量

ISO 9001:2008, Quality management systems — Requirements

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.

组织必须运用适当的方法监控和在适当时测量质量管理体系过程。这些方法必须能展现过程达成计划的结果的能力。当计划的结果没有达成，适当时，必须采取纠正和纠正措施。

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.

备注：在确定适宜的方法时，建议组织根据每个过程对产品要求符合性和质量管理体系有效性的影响，考虑监视和测量的类型与程度。

8.2.3.1 Monitoring and measurement of manufacturing processes

制 造 过 程 的 监 督 和 测 量

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.

组织必须在所有新的制造程（包含安装或排序）实施过程研究以确认过程能力，并提供附加输出给过程控制。过程研究结果必须把规格加以文件化，适用时包括生产、测量和测试及保养的指导书。该文件必须包含过程能力、可靠度、可维修性和可用性，及接收标准的目标。

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

组织必须维持顾客的零件批准过程时所指定的过程能力或要求。组织必须确保控制计划和过程流程图被执行，并包括严守下列的规定：

－measurement techniques,
测量技术；

－sampling plans,
抽样方案；

－acceptance criteria, and
接收标准；和

－reaction plans when acceptance criteria are not met.
当不满足接收标准时的反应计划

Significant process events, such as tool change or machine repair, shall be recorded.
重要过程事件，如：工具更换和工具维修都必须记录于控制图上。

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.

组织必须根据控制计划对已在控制计划中呈现为不稳定或能力不足的特性提出适当的反应计划。反应计划应包括适当地遏止过程不良品及100 %的检验。为确保过程变得稳定和有能力，组织必须完成明确进度和责任要求的纠正措施计划。当顾客要求时，该计划将由顾客评审和批准。

The organization shall maintain records of effective dates of process changes.
组织必须保持过程变更生效日期的记录。

8.2.4 Monitoring and measurement of product
产 品 的 监 督 和 测 量

ISO 9001:2008, Quality management systems — Requirements

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.

组织必须监控和测量产品的特性以验证产品的要求已被满足。这必须按照计划的安排在产品实现的适当阶段执行（参见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。

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

记录应指明有权放行产品以交付给顾客的人员（参见4.2.4）。

The release of product and delivery of service to the customer 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.

除非得到有关授权人员的批准，适当时得到顾客的批准，否则在策划的安排（见7.1）已圆满完成前，不应向顾客放行产品和交付服务。

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

备注：当选择产品参数以监督指定的内部和外部要求之符合性时，组织应决定产品特性类别、导向：

— The types of measurement,
测量类型；
— Suitable measurement means, and
适当的测量方法；和
— The capability and skills required.
所需的能力和技能。

8.2.4.1 Layout inspection and functional testing
全 尺 寸 检 验 与 功 能 测 试

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.

必须按照控制计划中规定并根据适用的顾客工程物料和性能标准对所有产品进行全尺寸检验与功能测试。其结果必须可供顾客评审。

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

备注：全尺寸检查是将显示在设计记录的所有零件尺寸完整的测量。

8.2.4.2 Appearance items
外 观 项 目

For organizations manufacturing parts designated by the customer as “appearance items”, the organization shall provide:

组织制造的零部件被顾客认定为“外观项目”时，组织必须提供：

－appropriate resources including lighting for evaluation,
适当的资源包含评价用的照明；
－masters for color, grain, gloss, metallic brilliance, texture, distinctness of image (DOI), as appropriate, maintenance and control of appearance masters and evaluation equipment, and
有适当的颜色、纹理、光泽、金属亮度、结构和形象明晰（DOI）的标准样品，对外观比对标准样品和判定设备的保养和控制；以及
－verification that personnel making appearance evaluations are competent and qualified to do so.
从事外观判定作业人员的验证资格。

8.3 Control of nonconforming product
不 合 格 品 控 制

ISO 9001:2008, Quality management systems — Requirements

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.

组织必须确保不符合要求的产品已被识别和控制，以防止被误用或交付。必须建立文件化的程序，以定义不合格品控制以及不合格品处置的有关职责和权限。

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

适当时，组织必须通过以下一种或多种方法来处理不合格品：

a) By taking action to eliminate the detected nonconformity;
采取措施消除发现的不合格；

b) By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
在相关授权和在适当时得到顾客的许可下授权使用、发放或接受不合格品；

c) By taking action to preclude its original intended use or application.
采取措施以防止它被用于原先的使用或运用；

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.
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。

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

产品的不合格在被纠正后必须进行再次验证以展现与要求相符合。

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

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（参见4.2.4）。

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

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

没有识别状态或可疑的产品必须被隔离为不合格品（见7.5.3）。

8.3.2 Control of reworked product
返工产品的控制

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

包含重新检验要求的返工作业指导书必须被相关人员容易取得与使用。

8.3.3 Customer information
顾客信息

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

当不合格品被交付后应立即通知顾客。

8.3.4 Customer waiver
顾客放弃

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

只要产品或过程与目前批准的产品或过程不同时，在进一步作业前组织必须取得顾客特许或偏差许可。

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.

组织必须维持一份授权变更的有效期限或数量的记录，当授权期限届满时，组织必须确保产品回复原有的或替代的规格或要求。

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

此要求同样也必须适用于所采购的产品。组织必须在交付给顾客前同意供方的任何要求。

8.4 Analysis of data
资料分析

ISO 9001:2008, Quality management systems — Requirements

The organization shall determine, collect and analyses 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.

组织必须决定、收集和分析适当的资料以展现质量管理体系的适宜性和有效性，并评价对质量管理体系的有效性的哪些方面可进行持续改进。这必须包括从监控和测量和从其它相关的渠道所得到的资料。

The analysis of data shall provide information relating to

资料的分析必须提供以下相关的信息：

a) Customer satisfaction (see 8.2.1),
顾客满意（参见8.2.1）；
b) Conformity to product requirements (see 8.2.4),
与产品要求的符合性（参见8.2.4）；
c) Characteristics and trends of processes and products including opportunities for preventive action(see8.2.3and8.2.4), and
过程和产品的特性和趋势，包括采取预防措施的机会（参见8.2.3和8.2.4）；
d) Suppliers.
供方。

8.4.1 Analysis and use of data
资料的分析和应用

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

质量和作业绩效的趋势必须与目标的进展相比较，并转化成据以行动以支持下列的信息：

－development of priorities for prompt solutions to customer-related problems;
开发与顾客相关问题的解决方案优先级；

－determination of key customer-related trends and correlation for status review, decision-making and longer term planning;

确定关键的与顾客相关的主要趋势和相互关系，以协助检查现况并做成决策和长期策划；

－an information system for the timely reporting of product information arising from usage.

通过使用、建立及时报告产品信息的信息系统。

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

备注：资料应与竞争对手和/或适当的基准来比较。

8.5 Improvement

改进

8.5.1Continual improvement

持续改进

ISO 9001:2008, Quality management systems — Requirements

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.

组织必须通过使用质量方针、质量目标、审核结果、资料分析、纠正和预防措施和管理评审对质量管理体系的有效性进行持续地改进。

8.5.1.1 Continual improvement of the organization

组织的持续改进

The organization shall define a process for continual improvement (see examples in annex B of ISO 9004:2000).

组织必须定义持续改进的过程（参见ISO 9004:2005的附录B）。

8.5.1.2 Manufacturing process improvement

制造过程的改进

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

必须将持续改进的焦点集中于产品特性和过程参数的控制和降低变差。

NOTE 1: Controlled characteristics are documented in the control plan.

备注1：特殊特性应列入控制计划。

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

备注2：当制造过程具备能力和稳定或产品特性可预测、满足顾客要求时实施持续改进。

8.5.2 Corrective action

8.5.2 纠正措施

ISO 9001:2008, Quality management systems — Requirements

The organization shall take action to eliminate the causes 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

组织必须采取措施以消除不合格的原因防止其再次发生。纠正措施必须适合于所遇到的不合格的影响。必须建立文件化的程序明确以下的要求：

a) Reviewing nonconformities (including customer complaints),
评价不合格（包括顾客抱怨）；
b) Determining the causes of nonconformities,
决定不合格的原因；
c) Evaluating the need for action to ensure that nonconformities do not recur,
评价是否需采取措施以确保不合格不会再发生；
d) Determining and implementing action needed,
决定和实施所需的措施；
e) Records of the results of action taken (see 4.2.4), and
记录所采取的措施的结果（参见4.2.4）；和
f) Reviewing the effectiveness of the corrective action taken.
评价所采取的纠正措施的效果。

8.5.2.1 Problem solving
问题的解决

The organization shall have a defined process for problem solving leading to root cause identification and elimination.
组织必须制订解决问题的过程以识别和消除问题的真正原因。

If a customer-prescribed problem-solving format exists, the organization shall use the prescribed format.
如果顾客有规定的解决问题的格式，组织必须以规定的格式处理。

8.5.2.2 Error-proofing
错误防止

The organization shall use error-proofing methods in their corrective action process.
组织必须在纠正措施的过程中使用防错的方法。

8.5.2.3 Corrective action impact
纠正措施的影响

The organization shall apply to other similar processes and products the corrective action, and controls implemented, to eliminate the cause of nonconformity.
组织必须在其它类似过程和产品上应用已经采行的纠正措施与控制来消除不合格的原因。

8.5.2.4 Rejected product test/analysis
退回产品的测试/分析

The organization shall analyses parts rejected by the customer's manufacturing plants, engineering facilities and dealerships.
织织必须对顾客的制造工厂、工程单位及经销商处退回的零部件进行分析。

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.
组织必须尽可能缩短本过程的周期时间。这些分析的资料必须予保存，且当顾客要求时可提供。为防止再发，组织必须实施分析，并提出纠正措施。

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

备注：和退回产品分析相关的周期时间应与真正因决定纠正行动和监控实施的有效性相一致。

8.5.3 Preventive action
预 防 措 施

ISO 9001:2008, Quality management systems — Requirements

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. A documented procedure shall be established to define requirements for

组织必须决定措施以消除不合格的潜在原因防止不合格发生。采取的预防措施必须适合于潜在问题的影响。必须建立文件化的程序明确以下的要求：

a) Determining potential nonconformities and their causes,
决定潜在的不合格和它们的原因；
b) Evaluating the need for action to prevent occurrence of nonconformities,
评价是否需采取措施以防止不合格的发生；
c) Determining and implementing action needed,
决定和实施所需的措施；
d) Records of results of action taken (see 4.2.4), and
记录所采取的措施的结果（参见4.4.2）；
e) Reviewing the effectiveness of the preventive action taken.
评价所采取预防措施的效果。

Annex A
附录A
(Normative)
Control plan
控制计划

A.1 Phases of the control plan
控制计划的阶段

The control plan shall cover three distinct phases as appropriate.

控制计划必须涵盖三个所适用的不同阶段

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.

样件：样件制造过程中所发生的尺寸测量、材料和性能试验的描述。如果顾客有要求，组织必须有样件制造控制计划。

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.

试生产：在样件制造后、批量生产前所发生的尺寸测量、材料和性能试验的描述。在产品实现的过程中，试生产被定义为样件制造后的可能要求的生产阶段。

c) Production: documentation of product/process characteristics, process controls, tests and measurement systems that occur during mass production.

量产：批量生产中所发生的产品/过程特性、过程控制、试验和测量系统的文件。

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.

每个零件必须有控制计划，但在很多案例中，一个控制计划系列可以覆盖采用同一过程生产的许多相似的零件。

A.2 Elements of the control plan
控制计划的要素

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

组织必须开发必须至少包括以下内容的控制计划：

a) General data

通用的信息

Control plan number,

控制计划编号

Issue date, and revision date, if any,

发行及修订日期，如需要

Customer information (see customer requirements),

客户信息（依据客户要求）

Organization’s name/site designation,

组织名称/工序名称

Part number(s),

零件编号

Part name/description,

零件名称/描述

Engineering change level,

工程变更水平
Phase covered (prototype, pre-launch, production),
阶段的涵盖（样件、试生产、量产）
Key contact,
主要联系人
Part/process step number,
零件/过程步骤编号
Process name / operation description.
过程名称/操作描述

b) Product control

产品控制

Product-related special characteristics,
产品特殊特性的描述
Other characteristics for control (number, product or process),
其他特性的控制
Specification/tolerance.
规范/公差

c) Process control

过程控制

Process parameters,
过程参数
Process-related special characteristics,
过程的特殊特性
Machines, jigs, fixtures, tools for manufacturing.
制造过程的设备、夹具、模具、工具

d) Methods

方法

Evaluation measurement technique,
评价测量技术
Error proofing,
防错
Sample size and frequency,
样本容量和频率
Control method.
控制方法

e) Reaction plan and corrective actions

反应计划与纠正措施

Reaction plan (include or reference),
反应计划（包含和涉及）
Corrective action.
纠正措施

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