Quality management systems — Requirements for Aviation, Space, and Defense Organizations

质量管理体系 – 对于航空、航天以及国防组织的要求

RATIONALE

理论基础

This standard has been revised to incorporate the new clause structure and content of ISO 9001:2015. In addition, industry requirements, definitions, and notes have been revised in response to both ISO 9001 revisions and stakeholder needs.

本标准已经根据 ISO9001:2015 的新条款结构及内容进行了修订。此外，应 ISO9001 修订及相关利益方的需求，行业要求、定义及注释也做了相应修订。

FOREWORD

前言

To assure customer satisfaction, aviation, space, and defense organizations must provide, and continually improve, safe and reliable products and services that meet or exceed customer and applicable statutory and regulatory requirements. The globalization of the industry and the resulting diversity of regional and national requirements and expectations have complicated this objective. Organizations have the challenge of purchasing products and services from external providers throughout the world and at all levels of the supply chain. External providers have the challenge of delivering products and services to multiple customers having varying quality requirements and expectations.

为了确保客户满意，航空、航天和国防组织必须提供并持续改进安全及可靠的产品和服务，以满足并超越客户和适用的法律法规要求。该行业的全球化，各区域及各国要求和期望的多样性，使这个目标更为复杂。从世界及供应链的各级外部供方处采购产品和服务，对于组织来说是一项挑战。向具有不同质量要求和期望的各类客户交付产品和服务，对外部供方来说也是一项挑战。

Industry has established the International Aerospace Quality Group (IAQG., with representatives from aviation, space, and defense companies in the Americas, Asia/Pacific, and Europe, to implement initiatives that make significant improvements in quality and reductions in cost throughout the value stream. This standard has been prepared by the IAQG.

行业建立了国际航空质量组织（IAQG.，代表来自美国、亚太和欧洲的航空、航天及国防的公司，来推进质量方面的重大改进和整个价值流中成本降低。本标准由 IAQG 编制。

This document standardizes quality management system requirements to the greatest extent possible and can be used at all levels of the supply chain by organizations around the world. Its use should result in improved quality, cost, and delivery performance through the reduction or elimination of organization-unique requirements, effective implementation of the quality management system, and wider application of good practice. While primarily developed for the aviation, space, and defense industry, this standard can also be used in other industry sectors when a quality management system with additional requirements over an ISO 9001 system is needed.

本文尽最大可能使质量管理体系要求标准化，以适用于全世界组织的供应链上的各级公司。通过减少或者消除组织的特殊要求，质量管理体系的有效执行，以及良好实践的广泛应用，本标准的应用可以带来质量、成本和交付表现上的改进。尽管主要是为航空、航天和国防行业开发的，当需要超越 ISO9001 之上的要求的质量管理体系时，本标准也可应用于其他工业部门。

This standard includes ISO 9001:2015 1 quality management system requirements and specifies additional aviation, space, and defense industry requirements, definitions, and notes as shown in bold, italic text.

本标准包含了 IOS9001:2015 质量管理体系要求，并规定了航空、航天和国防行业的附加要求、定义和注释，该内容以粗斜体字表示。

INTENDED APPLICATION

预期应用

This standard is intended for use by organizations that design, develop, or provide aviation, space, and defense products and services; and by organizations providing post-delivery activities, including the provision of maintenance, spare parts,

本标准适用于设计、开发、或提供航空、航天和国防产品和服务，以及提供售后服务的组织，包括给自己的产品提供维修，备件，或材料的组织。

or materials for their own products and services.

NOTE: Organizations whose products are deliverable software, or contain deliverable software, should use the IAQG-developed 9115 standard (see Bibliography) when planning and evaluating the software design, development, or management activities of the organization. The 9115 standard provides guidance to the requirements of the 9100 standard when it is desired to add "software" to the 9100 quality management system scope.

注：产品是交付软件，或包含交付软件的组织在策划和评估组织的软件设计、开发或者管理活动时，应当使用 IAQG 开发的 9115 标准（见参考目录）。9115 标准在希望在 9100 质量管理体系范围内增加"软件"时提供了针对 9100 标准要求的指南。

Organizations whose primary business is providing maintenance or continuing airworthiness management services for civil or military aviation articles and products; and original equipment manufacturers with maintenance, repair, and overhaul operations that are operated autonomously, or that are substantially different from their production operations; should use the IAQG-developed 9110 standard (see Bibliography).

主要业务是给民用和军用航空项目和产品提供维修或者持续适航管理服务的组织;以及独立地进行维护，修理和大修操作，或者明显不同于他们自己的生产操作的原始设备厂家，应当采用 IAQG 开发的 9110 标准(见参考目录)。

Organizations that procure parts, materials, and assemblies and resells these products to a customer in the aviation, space, and defense industry should use the IAQG-developed 9120 standard (see Bibliography). This includes organizations that procure products and split them into smaller quantities, as well as those that coordinate a customer or regulatory controlled process on the product.

采购零件，材料和装配件，并销售这些产品给航空，航天和国防工业客户的组织，应当采用 IAQG 开发的 9120 标准（见参考目录）。包括采购产品并分组成小额数量，以及那些协助客户或者法规部门控制基于产品的过程的那些组织。

INTRODUCTION

简介

0.1 General

0.1 总则

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

采用质量管理体系是组织的一项战略决策，能够帮助其提高整体绩效，为推动可持续发展奠定良好基础。

The potential benefits to an organization of implementing a quality management system based on this International Standard are:

组织根据本标准实施质量管理体系具有如下潜在益处：

a. the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;

a. 持续提供满足顾客要求以及适用的法律法规要求的产品和服务的能力；

b. facilitating opportunities to enhance customer satisfaction;

b. 促成增强顾客满意的机会；

c. addressing risks and opportunities associated with its context and objectives;

c. 应对与组织环境和目标相关的风险和机遇；

d. the ability to demonstrate conformity to specified quality management system requirements.

d. 证实符合规定的质量管理体系要求的能力。

This International Standard can be used by internal and external parties.

内部和外部各方均可使用本标准。

It is not the intent of this International Standard to imply the need for:

实施本标准并不意味着需要：

− uniformity in the structure of different quality management systems;

− alignment of documentation to the clause structure of this International Standard;

− the use of the specific terminology of this International Standard within the organization.

— 统一不同质量管理体系的架构；

— 形成与本标准条款结构相一致的文件；

— 在组织内使用本标准的特定术语。

The quality management system requirements specified in this International Standard are complementary to requirements for products and services.

本标准规定的质量管理体系要求是对产品和服务要求的补充。

This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

本标准采用过程方法，该方法结合了 PDCA（策划、实施、检查、处置）循环与基于风险的思维。

The process approach enables an organization to plan its processes and their interactions.

过程方法使组织能够策划其过程及其相互作用。

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

PDCA 循环使组织能够确保其过程得到充分的资源和管理，确定改进机会并采取行动。

Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see Clause A.4).

基于风险的思维使组织能够确定可能导致其过程和质量管理体系偏离策划结果的各种因素，采取预防控制，最大限度地降低不利影响，并最大限度地利用出现的机遇（见附录 A.4）。

Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation, and re-organization.

在日益复杂的动态环境中持续满足要求，并针对未来需求和期望采取适当行动，这无疑是组织面临的一项挑战。为了实现这一目标，组织可能会发现，除了纠正和持续改进，还有必要采取各种形式的改进，如突破性变革、创新和重组。

In this International Standard, the following verbal forms are used:
− “shall” indicates a requirement;
− “should” indicates a recommendation;
− “may” indicates a permission;
− “can” indicates a possibility or a capability.
Information marked as “NOTE” is for guidance in understanding or clarifying the associated requirement.

在本标准中使用如下助动词：
“应”表示要求；
“宜”表示建议；
“可以”表示允许；
“能”表示可能或能够。
“注”的内容是理解和说明有关要求的指南。

0.2 Quality Management Principles

0.2 质量管理原则

This International Standard is based on the quality management principles described in ISO 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle, and examples of typical actions to improve the organization’s performance when applying the principle.

本标准是在 ISO9000 所述的质量管理原则基础上制定的。每项原则的介绍均包含其释义、该原则对组织的重要性的理论依据、应用该原则的主要益处示例以及应用该原则改进组织绩效的典型措施示例。

The quality management principles are:
- customer focus;
- leadership;
- engagement of people;
- process approach;
- improvement;
- evidence-based decision making;
- relationship management.

质量管理原则包括：
—以顾客为关注焦点；
—领导作用；
—全员积极参与；
—过程方法；
—改进；
—循证决策；
—关系管理。

0.3 Process Approach

0.3 过程方法

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. Specific requirements considered essential to the adoption of a process approach are included in 4.4.

本标准倡导在建立、实施质量管理体系以及提高其有效性时采用过程方法，通过满足顾客要求增强顾客满意。采用过程方法所需满足的具体要求见 4.4。

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

将相互关联的过程作为一个体系加以理解和管理,有助于组织有效和高效地实现其预期结果。这种方法使组织能够对体系过程之间相互关联和相互依赖的关系进行有效控制，以增强组织整体绩效。

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2. with an overall focus on risk-based thinking (see 0.3.3. aimed at taking advantage of opportunities and preventing undesirable results.

过程方法包括按照组织的质量方针和战略方向，对各过程及其相互作用，系统地进行规定和管理，从而实现预期结果。可通过采用 PDCA 循环（见 0.3.2.以及始终基于风险的思维（见 0.3.3.对过程和完整的体系进行管理，旨在有效利用机遇并防止发生非预期结果。

The application of the process approach in a quality management system enables:
a. understanding and consistency in meeting requirements;
b. the consideration of processes in terms of added value;
c. the achievement of effective process performance;
d. improvement of processes based on evaluation of data and information.

在质量管理体系中应用过程方法能够：
a．理解并持续满足要求；
b．从增值的角度考虑过程；
c．获得有效的过程绩效；
d．在评价数据和信息的基础上改进过程。

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring check points, which are necessary for control, are specific to each process, and will vary depending on the related risks.

过程的各要素及其相互作用如图 1 所示。每一过程均有特定的监视和测量检查点，以用于控制，这些检查点根据不同的风险有所不同。

Figure 1 – Schematic representation of the elements of a single process

图 1：过程要素示意图(略)

0.3.2 Plan-Do-Check-Act Cycle

0.3.2 策划-实施-检查-处置循环

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how clauses 4

PDCA 循环能够应用于所有过程以及完整的质量管理体系。图 2 表明了本标准第 4 章至第 10

to 10 can be grouped in relation to the PDCA cycle.

章如何组成 PDCA 循环。

The PDCA cycle can be briefly described as follows:

PDCA 循环可以简要描述如下：

− Plan: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address risks and opportunities;

—策划：根据顾客的要求和组织的方针，建立体系的目标及其过程，确定实现结果所需的资源，并识别和应对风险和机遇。

− Do: implement what was planned;

—实施：实施所做的策划；

− Check: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements, and planned activities, and report the results;

—检查：根据方针、目标、要求和经策划的活动，对过程以及形成的产品和服务进行监视和测量（适用时），并报告结果；

− Act: take actions to improve performance, as necessary.

—处置：必要时，采取措施提高绩效。

Figure 2 – Representation of the structure of this International Standard in the PDCA cycle

图 2：本标准的结构在 PDCA 循环中的展示（略）

NOTE: Numbers in brackets refer to the clauses in this International Standard.

注：括号中的数字表示本标准的相应章节。

0.3.3 Risk-Based Thinking

0.3.3 基于风险的思维

Risk-based thinking (see Clause A.4) is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of this International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analyzing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

基于风险的思维（见附录 A.4）是实现质量管理体系有效性的前提。本标准以前的版本已经隐含基于风险思维的概念，例如：采取预防措施消除潜在的不合格，对发生的不合格进行分析，并采取与不合格的影响相适应的措施,防止其再发生。

To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results, and preventing negative effects.

为了满足本标准的要求,组织需策划和实施应对风险和利用机遇的措施。应对风险和利用机遇可为提高质量管理体系有效性、实现改进结果以及防止不利影响奠定基础。

Opportunities can arise as a result of a situation favorable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste, or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

机遇的出现可能意味着某种有利于实现预期结果的局面，例如：有利于组织吸引顾客、开发新产品和服务、减少浪费或提高生产率的一系列情形。利用机遇所采取的措施也可能包括考虑相关风险。风险是不确定性的影响,不确定性可能有正面或负面的影响。风险的正面影响可能提供机遇，但并非所有的正面影响均可提供机遇。

0.4 Relationship with Other Management System Standards

0.4 与其他管理体系标准的关系

This International Standard applies the framework developed by ISO to improve alignment among its International Standards for management systems (see Clause A.1).

本标准采用 ISO 制定的管理体系标准框架，以提高与其他管理体系标准的兼容性（见附录 A.1）。

This International Standard enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its quality management system with the requirements of other management system standards.

本标准使组织能够使用过程方法，并结合 PDCA 循环和基于风险的思维，将其质量管理体系要求与其他管理体系标准要求进行协调或整合。

This International Standard relates to ISO 9000 and ISO 9004 as follows:

本标准与 ISO 9000 和 ISO 9004 存在如下关系：

− ISO 9000, “Quality management systems – Fundamentals and vocabulary”, provides essential background for the proper understanding and implementation of this International Standard;

ISO 9000《质量管理体系 基础和术语》为正确理解和实施本标准提供必要基础；

− ISO 9004, “Managing for the sustained success of an organization A quality management approach”, provides guidance for organizations that choose to progress beyond the requirements of this International Standard.

ISO 9004 《追求组织的持续成功 质量管理方法》为组织超出本标准要求提供指南。

Annex B provides details of other International Standards on quality management and quality management systems that have been developed by ISO/TC 176.

附录 B 给出了 ISO/TC176 质量管理和质量保证技术委员会制定的其他质量管理和质量管理体系标准的详细信息。

This International Standard does not include requirements specific to other management systems, such as those for environmental management, occupational health and safety management, or financial management.

本标准不包括针对环境管理、职业健康和安全管理或财务管理等其他管理体系的特定要求。

Sector-specific quality management system standards based on the requirements of this International Standard have been developed for a number of sectors. Some of these standards specify additional quality management system requirements, while others are limited to providing guidance to the application of this International Standard within the particular sector.

在本标准的基础上，已经制定了若干行业特定要求的质量管理体系标准。其中的某些标准规定了质量管理体系的附加要求，而另一些标准则仅限于提供在特定行业应用本标准的指南。

A matrix showing the correlation between the clauses of this edition of this International Standard and the previous edition (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access web site at: www.iso.org/tc176/sc02/public.

本标准的章节内容与之前版本（ISO 9001—2008）章节内容之间的对应关系见 ISO/TC176/SC2（国际标准化组织/质量管理和质量保证/质量体系分委员会.的公开网站：www.iso.org/tc176/sc02/public 。

Quality management systems — Requirements

质量管理体系 – 要求

1 Scope

1 范围

This standard includes ISO 9001:2015 2 quality management system requirements and specifies additional aviation, space, and defense industry requirements, definitions, and notes.

本标准包括了ISO9001:2015 质量管理体系要求并规定了航空、航天和国防工业的附加要求、定义和注释。

It is emphasized that the requirements specified in this standard are complementary (not alternative) to customer and applicable statutory and regulatory requirements.

必须强调，本标准所规定的质量管理体系要求是对客户和适用法律法规要求的补充（不是替代）。

If there is a conflict between the requirements of this standard and customer or applicable statutory or regulatory requirements, the latter shall take precedence.

如果本标准的要求与客户、适用法律或法规之间有冲突,则以后者为准.

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

本标准为下列组织规定了质量管理体系要求：

a. needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and

a.需要证实其具有持续地提供满足顾客要求和适用法律法规要求的产品和服务的能力；

b. aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

b.通过体系的有效应用，包括体系改进的过程，以及保证符合顾客和适用的法律法规要求，旨在增强顾客满意。

All the requirements of this International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

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

NOTE 1 In this International Standard, the terms “product” or “service” only apply to products and services intended for, or required by, a customer.

注 1：在本标准中，术语“产品”或“服务”仅适用于预期提供给顾客或顾客所要求的产品和服务；

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

注 2：法律法规要求可称作法定要求。

2 Normative references

2 规范性引用文件

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

下列文件对于本文件的应用是必不可少的。凡是注日期的引用文件，仅注日期的版本适用于本文件。凡是不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

ISO 9000—2015 质量管理体系 基础和术语

ISO 9001:2015 Quality management systems – Requirements

ISO 9001:2015 质量管理体系 – 要求

3 Terms and definitions

3 术语与定义

For the purposes of this document, the terms and definitions given in ISO 9000:2015 ***and the following*** apply.

ISO 9000—2015 ***及下文***界定的术语和定义适用于本文件。

3.1
Counterfeit Part

An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer.

NOTE: Examples of a counterfeit part can include, but are not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.

3.2 Critical Items

Those items (e.g., functions, parts, software, characteristics, processes. having significant effect on the provision and use of the products and services; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

3.3 Key Characteristic

An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life, or producibility, that requires specific actions for the purpose of controlling variation.

3.4 Product Safety

The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

3.5 Special Requirements

Those requirements identified by the customer, or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used in the determination of special requirements include product or process complexity, past experience, and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

NOTE: Special requirements (3.5) and critical items (3.2), along with key characteristics (3.3), are interrelated.

Special requirements are identified when determining and reviewing requirements related to the product (see 8.2.2 and 8.2.3). Special requirements can require the identification of

3.1
仿冒件

未经授权的复制品、仿制品、代用品或者改造品（如原材料、零件和组件），让人误以为是原厂或者授权制造商的指定真品。

注：仿冒件的例子包含但不限于：标印、等级、系列号、日期代码、文件和性能特性方面的虚假标识。

3.2 关键项目

对产品的实现和使用有重要影响的项目(如功能，零件,软件,特性,过程.,包括安全，性能，成形，安装，功能,可制造性，使用寿命等；其要求特定的措施以确保其受到充分管理。关键项目的案例包括安全关键项目，断裂关键项目，任务关键项目,关键特性,等等。

3.3 关键特性

是一种属性或特性，其变化将对产品装配,成形，功能，性能 ,使用寿命或可制造性产生重大影响，因而要求特定的措施对其变化进行控制。

3.4 产品安全性

产品能够履行其设计或预期目的而不会对人员伤害或者财产损坏造成不可接受的风险的一种状态。

3.5 特殊要求

由顾客识别或组织自己确定的要求,这些要求有无法满足的高风险,因而要求它们包含在运营风险管理过程中.确定特殊要求的因素包括产品或过程的复杂性,过去的经验以及产品或过程的成熟性.特殊要求的例子包括顾客提出的已接近业界能力极限的性能要求,或是由组织按自身技术或过程能力极限确定的要求。

注：特殊要求（3.5）和关键项目（3.2），连同关键特性（3.3）一起是相互关联的。

特殊要求是在确定和评审与产品有关的要求时识别的（见 8.2.1 和 8.2.2）。特殊要求可能要求识别关键项目。设计输出（见 8.3.5）可能包

critical items. Design output (see 8.3.5) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled.

括识别要求特定的措施以确保其充分管理的关键项目。一些关键项目由于需要对其变化进行控制会被进行一步归类为关键特性。

4 Context of the organization

4 组织环境

4.1 Understanding the organization and its context

4.1 理解组织及环境

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

组织应确定与其宗旨和战略方向相关并影响其实现质量管理体系预期结果的能力的各种外部和内部因素。

The organization shall monitor and review information about these external and internal issues.

组织应对这些内部和外部因素的相关信息进行监视和评审。

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

注 1：这些因素可能包括需要考虑的正面和负面要素或条件。

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

注 2：考虑来自于国际、国内、地区和当地的各种法律法规、技术、竞争、市场、文化、社会和经济环境因素，有助于理解外部环境。

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

注 3：考虑与组织的价值观、文化、知识和绩效等有关的因素，有助于理解内部环境。

4.2 Understanding the needs and expectations of interested parties

4.2 理解相关方的需求和期望

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

由于相关方对组织持续提供符合顾客要求和适用法律法规要求的产品和服务的能力具有影响或潜在影响，因此，组织应确定：

a. the interested parties that are relevant to the quality management system;

a.质量管理体系有关的相关方；

b. the requirements of these interested parties that are relevant to the quality management system.

b.与质量管理体系有关的相关方的要求。

The organization shall monitor and review information about these interested parties and their relevant requirements.

组织应对这些相关方及其要求的相关信息进行监视和评审。

4.3 Determining the scope of the quality management system

4.3 确定质量管理体系的范围

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

组织应确定质量管理体系的边界和适用性，以确定其范围。

When determining this scope, the organization shall consider:

在确定范围时，组织应考虑：

a. the external and internal issues referred to in 4.1;

a.内部和外部因素，见 4.1；

b. the requirements of relevant interested parties referred to in 4.2;

b.有关相关方的要求，见 4.2；

c. the products and services of the organization.

c.组织的产品和服务。

The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

如果本标准的全部要求适用于组织确定的质量管理体系范围,组织应遵循本标准的全部要求。

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

组织的质量管理体系范围应作为形成文件的信息,可获得并得到保持。该范围应描述所覆盖的产品和服务类型，如果组织确定本标准的某些要求不适用于其质量管理体系范围，应说明理由。

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

除非组织所确定的不适用于其质量管理体系的标准要求不影响组织确保其产品和服务合格以及增强顾客满意的能力或责任，否则不能声称符合本标准要求。

4.4 Quality management system and its processes

4.4 质量管理体系及其过程

4.4.1 The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

4.4.1 组织应按照本标准的要求，建立、实施、保持和持续改进质量管理体系，包括所需过程及其相互作用。

The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.

组织的质量管理体系必须考虑并落实顾客和适用法律法规的质量管理体系要求.

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

组织应确定质量管理体系所需的过程及其在整个组织中的应用，且应：

a. determine the inputs required and the outputs expected from these processes;

a.确定这些过程所需的输入和期望的输出；

b. determine the sequence and interaction of these processes;

b.确定这些过程的顺序和相互作用；

c. determine and apply the criteria and methods (including monitoring, measurements and related performance indicators. needed to ensure the effective operation and control of these processes;

c.确定和应用所需的准则和方法（包括监视、测量和相关绩效指标.，以确保这些过程有效的运行和控制；

d. determine the resources needed for these processes and ensure their availability;

d.确定这些过程所需的资源并确保其可用性；

e. assign the responsibilities and authorities for these processes;

e.分派这些过程的职责和权限；

f. address the risks and opportunities as determined in accordance with the requirements of 6.1;

f.应对按照 6.1 的要求所确定的风险和机遇；

g. evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;

g.评价这些过程，实施所需的变更，以确保实现这些过程的预期结果；

h. improve the processes and the quality management system.

h.改进过程和质量管理体系。

4.4.2 To the extent necessary, the organization shall:

4.4.2 在必要的范围和程度上，组织应：

a. maintain documented information to support the operation of its processes;

a.保持形成文件的信息以支持过程运行；

b. retain documented information to have confidence that the processes are being carried out as planned.

b.保留确信其过程按策划进行的形成文件的信息。

The organization shall establish and maintain documented information that includes:

组织应建立和保持形成文件的信息以包含：

− a general description of relevant interested parties (see 4.2 a);

-相关方（见 4.2 a）的概述；

− the scope of the quality management system, including boundaries and applicability (see 4.3);

-质量管理体系的范围，包括边界和适用性（见 4.3）；

− a description of the processes needed for the quality management system and their application throughout the organization;

-质量管理体系所需过程的描述及其在整个组织中的应用；

− the sequence and interaction of these processes; assignment of the responsibilities and authorities for these processes.

-过程之间的相互关系；过程职责和权限的分配。

NOTE: The above description of the quality management system can be compiled into a single source of documented information and referred to as a quality manual.

注：上述质量管理体系的描述可以编制为一份单一的形成文件的信息，参考质量手册。

5 Leadership

5 领导作用

5.1 Leadership and commitment

5.1 领导作用和承诺

5.1.1 General

5.1.1 总则

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

最高管理者应证实其对质量管理体系的领导作用和承诺,通过：

a. taking accountability for the effectiveness of the quality management system;

a.对质量管理体系的有效性承担责任；

b. ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;

b.确保制定质量管理体系的质量方针和质量目标,并与组织环境和战略方向相一致；

c. ensuring the integration of the quality management system requirements into the organization's business processes;

c.确保质量管理体系要求融入组织的业务过程；

d. promoting the use of the process approach and risk-based thinking;

d.促进使用过程方法和基于风险的思维；

e. ensuring that the resources needed for the quality management system are available;

e.确保质量管理体系所需的资源是可用的；

f. communicating the importance of effective quality management and of conforming to the quality management system requirements;

f.沟通有效的质量管理和符合质量管理体系要求的重要性；

g. ensuring that the quality management system achieves its intended results;

g.确保质量管理体系实现其预期结果；

h. engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

h.促进、指导和支持人员为质量管理体系的有效性做出贡献；

i. promoting improvement;

i.推动改进；

j. supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

j.支持其他相关管理者在其职责范围内发挥领导作用。

NOTE Reference to “business” in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization’s existence, whether the organization is public, private, for profit or not for profit.

注：本标准使用的“业务”一词可广义地理解为涉及组织存在目的的核心活动，无论是公营、私营、营利或非营利组织。

5.1.2 Customer focus

5.1.2 以顾客为关注焦点

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

最高管理者应通过确保以下方面，证实其以顾客为关注焦点的领导作用和承诺：

a. customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

a.确定、理解并持续地满足顾客要求以及适用的法律法规要求；

b. the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

b.确定和应对能够影响产品和服务的符合性以及增强顾客满意能力的风险和机遇；

c. the focus on enhancing customer satisfaction is maintained.

c.始终致力于增强顾客满意。

d.. product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved.

d..产品符合性和及时交付表现被测量，如果策划的结果不能或将不能达到时，应当采取适当的措施。

5.2 Policy

5.2 方针

5.2.1 Establishing the quality policy

5.2.1 制定质量方针

Top management shall establish, implement and maintain a quality policy that:

最高管理者应制定、实施和保持质量方针,质量方针应：

a. is appropriate to the purpose and context of the organization and supports its strategic direction;

a.适应组织的宗旨和环境并支持其战略方向；

b. provides a framework for setting quality objectives;

b.为建立质量目标提供框架；

c. includes a commitment to satisfy applicable requirements;

c.包括满足适用要求的承诺；

d. includes a commitment to continual improvement of the quality management system.

d.包括持续改进质量管理体系的承诺。

5.2.2 Communicating the quality policy

5.2.2 沟通质量方针

The quality policy shall:

质量方针应：

a. be available and be maintained as documented information;

a.作为形成文件的信息，可获得并保持；

b. be communicated, understood and applied within the organization;

b.在组织内得到沟通、理解和应用；

c. be available to relevant interested parties, as appropriate.

c.适宜时，可为有关相关方所获取。

5.3 Organizational roles, responsibilities and authorities

5.3 组织的岗位、职责和权限

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

最高管理者应确保组织内相关岗位的职责、权限得到分派、沟通和理解。

Top management shall assign the responsibility and authority for:

最高管理者应分派职责和权限，以：

a. ensuring that the quality management system conforms to the requirements of this International Standard;

a.确保质量管理体系符合本标准的要求；

b. ensuring that the processes are delivering their intended outputs;

b.确保各过程获得其预期输出；

c. reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;

c.报告质量管理体系的绩效及其改进机会（见10.1），特别是向最高管理者报告；

d. ensuring the promotion of customer focus throughout the organization;

d.确保在整个组织推动以顾客为关注焦点；

e. ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

e.确保在策划和实施质量管理体系变更时保持其完整性。

Top management shall appoint a specific member of the organization's management, identified as the management representative, who shall have the responsibility and authority for oversight of the above requirements.

最高管理者应任命一名组织的管理层的特定成员，作为管理者代表，其应有监督以上要求的职责和权限。

The management representative shall have the organizational freedom and unrestricted access to top management to resolve quality management issues.

管理者代表应能不受组织干预和直接接触最高管理层以解决有关质量问题。

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

注：管理者代表的职责可包括与质量管理体系有关事宜的外部联络。

6 Planning

6 策划

6.1 Actions to address risks and opportunities

6.1 应对风险和机遇的措施

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

6.1.1 在策划质量管理体系时，组织应考虑到4.1所描述的因素和4.2所提及的要求，并确定需要应对的风险和机遇，以：

a. give assurance that the quality management system can achieve

a.确保质量管理体系能够实现其预期结果；

its intended result(s.;

b. enhance desirable effects;

b.增强有利影响；

c. prevent, or reduce, undesired effects;

c.避免或减少不利影响；

d. achieve improvement.

d.实现改进。

6.1.2 The organization shall plan:

6.1.2 组织应策划：

a. actions to address these risks and opportunities;

a.应对这些风险和机遇的措施；

b. how to:
1. integrate and implement the actions into its quality management system processes (see 4.4);
2. evaluate the effectiveness of these actions.

b.如何：
1.在质量管理体系过程中整合并实施这些措施（见 4.4）；
2.评价这些措施的有效性。

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

应对风险和机遇的措施应与其对于产品和服务符合性的潜在影响相适应。

NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

注 1：应对风险可选择规避风险，为寻求机遇承担风险，消除风险源，改变风险的可能性或后果，分担风险，或通过信息充分的决策保留风险。

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

注 2：机遇可能导致采用新实践，推出新产品，开辟新市场，赢得新顾客，建立合作伙伴关系，利用新技术以及其他可取和可行的事物，以应对组织或其顾客需求。

6.2 Quality objectives and planning to achieve them

6.2 质量目标及其实现的策划

6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.

6.2.1 组织应在相关职能、层次和质量管理体系所需的过程建立质量目标。

The quality objectives shall:

质量目标应：

a. be consistent with the quality policy;

a.与质量方针保持一致；

b. be measurable;

b.可测量；

c. take into account applicable requirements;

c.考虑适用的要求；

d. be relevant to conformity of products and services and to enhancement of customer satisfaction;

d.与产品和服务合格以及增强顾客满意相关；

e. be monitored;

e.予以监视；

f. be communicated;

f.予以沟通；

g. be updated as appropriate.

g.适时更新。

The organization shall maintain documented information on the

组织应保持有关质量目标的形成文件的信息。

quality objectives.

6.2.2 When planning how to achieve its quality objectives, the organization shall determine:

6.2.2 策划如何实现质量目标时，组织应确定：

a. what will be done;

a.做什么；

b. what resources will be required;

b.需要什么资源；

c. who will be responsible;

c.由谁负责；

d. when it will be completed;

d.何时完成；

e. how the results will be evaluated.

e.如何评价结果。

6.3 Planning of changes

6.3 变更的策划

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).

当组织确定需要对质量管理体系进行变更时，变更应按所策划的方式实施（见 4.4）。

The organization shall consider:

组织应考虑：

a. the purpose of the changes and their potential consequences;

a.变更目的及其潜在后果；

b. the integrity of the quality management system;

b.质量管理体系的完整性；

c. the availability of resources;

c.资源的可获得性；

d. the allocation or reallocation of responsibilities and authorities.

d.职责和权限的分配或再分配。

7 Support

7 支持

7.1 Resources

7.1 资源

7.1.1 General

7.1.1 总则

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

组织应确定并提供为建立、实施、保持和持续改进质量管理体系所需的资源。

The organization shall consider:

组织应考虑：

a. the capabilities of, and constraints on, existing internal resources;

a. 现有内部资源的能力和局限性；

b. what needs to be obtained from external providers.

b. 需要从外部供方获得的资源。

7.1.2 People

7.1.2 人员

The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

组织应确定并配备所需的人员，以有效实施质量管理体系并运行和控制其过程。

7.1.3 Infrastructure

7.1.3 基础设施

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

组织应确定、提供并维护所需的基础设施，以运行过程并获得合格产品和服务。

NOTE Infrastructure can include:

注：基础设施可包括：

a. buildings and associated utilities;

a.建筑物和相关设施；

b. equipment, including hardware and software;

b.设备，包括硬件和软件；

c. transportation resources;

c.运输资源；

d. information and communication technology.

d.信息和通信技术。

7.1.4 Environment for the operation of processes

7.1.4 过程运行环境

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

组织应确定、提供并维护所需的环境，以运行过程并获得合格产品和服务。

NOTE A suitable environment can be a combination of human and physical factors, such as:

注：适当的过程运行环境可能是人为因素与物理因素的结合，例如：

a. social (e.g. non-discriminatory, calm, non-confrontational);

a.社会因素（如无歧视、和谐稳定、无对抗）；

b. psychological (e.g. stress-reducing, burnout prevention, emotionally protective);

b.心理因素（如缓解紧张情绪、预防职业倦怠、保证情绪稳定）；

c. physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

c.物理因素（如温度、热量、湿度、照明、空气流通、卫生、噪声等）。

These factors can differ substantially depending on the products and services provided.

由于所提供的产品和服务不同，这些因素可能存在显著差异。

7.1.5 Monitoring and measuring resources

7.1.5 监视和测量资源

7.1.5.1 General

7.1.5.1 总则

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

当利用监视或测量来验证产品和服务符合要求时，组织应确定并提供确保结果有效和可靠所需的资源。

The organization shall ensure that the resources provided:

组织应确保所提供的资源：

a. are suitable for the specific type of monitoring and measurement activities being undertaken;

a.适合所进行的监视和测量活动的类型；

b. are maintained to ensure their continuing fitness for their purpose.

b.得到维护，以确保持续适合其用途。

The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

组织应保留适当的形成文件的信息，作为监视和测量资源适合其用途的证据。

7.1.5.2 Measurement traceability

7.1.5.2 测量溯源

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

当要求测量溯源时，或组织认为测量溯源是信任测量结果有效的前提时，测量设备应：

a. calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

a.对照能溯源到国际或国家标准的测量标准，按照规定的时间间隔或在使用前进行校准和（或）检定（验证），当不存在上述标准时，应保留作为校准或检定（验证）依据的形成文件的信息；

b. identified in order to determine their status;

b.予以识别，以确定其状态；

c. safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

c.予以保护，防止可能使校准状态和随后的测量结果失效的调整、损坏或劣化。

The organization shall establish, implement, and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.

组织应建立、实施并保持一个过程以在要求校准和检定时召回监视和测量设备。

The organization shall maintain a register of the monitoring and measuring equipment. The register shall include the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.

组织应保持一份监视和测量设备的登记册，并规定其校准/检定的过程，包括设备型号、唯一性标识、所在位置、校验周期、校验方法和接收准则。

NOTE: Monitoring and measuring equipment can include, but are not limited to: test hardware, test software, automated test equipment (ATE), and plotters used to produce verification data. It also includes personally owned and customer supplied equipment used to provide evidence of product and service conformity.

注：监视和测量设备包括但不限于：试验硬件、试验软件、自动试验设备（ATE）和用于获取检验数据的绘图仪。也包括用于提供产品符合证据的个人拥有的和顾客提供的设备。

Calibration or verification of monitoring and measuring equipment shall be carried out under suitable environmental conditions (see 7.1.4).

监视和测量设备的检定和校准应在合适的环境条件下实施（见 7.1.4）。

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

当发现测量设备不符合预期用途时，组织应确定以往测量结果的有效性是否受到不利影响，必要时应采取适当的措施。

7.1.6 Organizational knowledge

7.1.6 组织的知识

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

组织应确定所需的知识，以运行过程并获得合格产品和服务。

This knowledge shall be maintained and be made available to the extent necessary.

这些知识应予以保持，并在必要范围内可得到。

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

为应对不断变化的需求和发展趋势，组织应审视现有的知识，确定如何获取更多必要的知识和知识更新。

NOTE 1 Organizational knowledge is knowledge specific to the

注 1：组织的知识是组织特有的知识，通常从其

organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.

经验中获得。是为实现组织目标所使用和共享的信息。

NOTE 2 Organizational knowledge can be based on:

注 2：组织的知识可以基于：

a. internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);

a.内部来源（如知识产权；从经历获得的知识；从失败和成功项目得到的经验教训；获取和分享未形成文件的知识和经验；过程、产品和服务的改进结果）；

b. external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

b.外部来源（如标准；学术交流；专业会议；从顾客或外部供方收集的知识）。

7.2 Competence

7.2 能力

The organization shall:

组织应：

a. determine the necessary competence of person(s. doing work under its control that affects the performance and effectiveness of the quality management system;

a.确定受其控制的工作人员所需具备的能力，这些人员从事的工作影响质量管理体系绩效和有效性；

b. ensure that these persons are competent on the basis of appropriate education, training, or experience;

b.基于适当的教育、培训或经历，确保这些人员是胜任的；

c. where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

c.适用时，采取措施获得所需的能力，并评价措施的有效性；

d. retain appropriate documented information as evidence of competence.

d.保留适当的形成文件的信息，作为人员能力的证据。

NOTE: Consideration should be given for the periodic review of the necessary competence.

注：对于人员能力的定期评审应当予以考虑。

NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

注：采取的适当措施可包括对在职人员进行培训、辅导或重新分配工作，或者招聘、分包给胜任的人员等。

7.3 Awareness

7.3 意识

The organization shall ensure that persons doing work under the organization's control are aware of:

组织应确保受其控制的工作人员知晓：

a. the quality policy;

a.质量方针；

b. relevant quality objectives;

b.相关的质量目标；

c. their contribution to the effectiveness of the quality management system, including the benefits of improved performance;

c.他们对质量管理体系有效性的贡献，包括改进绩效的益处；

d. the implications of not conforming with the quality management system requirements.

d.不符合质量管理体系要求的后果。

e. relevant quality management system documented information and changes thereto;

e.相关质量管理体系的形成文件的信息和随后的变更；

f. their contribution to product or service conformity;

f.他们对于产品或者服务符合性的贡献；

g. their contribution to product safety;

g.他们对于产品安全性的贡献；

h. the importance of ethical behavior.

h.道德行为的重要性。

7.4 Communication

7.4 沟通

The organization shall determine the internal and external communications relevant to the quality management system, including:

组织应确定与质量管理体系相关的内部和外部沟通，包括：

a. on what it will communicate;

a.沟通什么；

b. when to communicate;

b.何时沟通；

c. with whom to communicate;

c.与谁沟通；

d. how to communicate;

d.如何沟通；

e. who communicates.

e.谁负责沟通。

NOTE: Communication should include internal and external feedback relevant to the quality management system.

注：沟通应当包含有关质量管理体系的内部和外部反馈。

7.5 Documented information

7.5 形成文件的信息

7.5.1 General

7.5.1 总则

The organization's quality management system shall include:

组织的质量管理体系应包括：

a. documented information required by this International Standard;

a. 本标准要求的形成文件的信息；

b. documented information determined by the organization as being necessary for the effectiveness of the quality management system.

b. 组织确定的为确保质量管理体系有效性所需的形成文件的信息；

NOTE The extent of documented information for a quality management system can differ from one organization to another due to:

注：对于不同组织，质量管理体系形成文件的信息的多少与详略程度可以不同，取决于：

— the size of organization and its type of activities, processes, products and services;

—组织的规模，以及活动、过程、产品和服务的类型；

— the complexity of processes and their interactions;

—过程的复杂程度及其相互作用；

— the competence of persons.

—人员的能力。

7.5.2 Creating and updating

7.5.2 创建和更新

When creating and updating documented information, the organization shall ensure appropriate:

在创建和更新形成文件的信息时，组织应确保适当的：

a. identification and description (e.g. a title, date, author, or reference number.;

a.标识和说明（如：标题、日期、作者、索引编号等.；

b. format (e.g. language, software version, graphics. and media (e.g. paper, electronic.;

b. 格式（如：语言、软件版本、图示.和载体（如：纸质、电子格式.；

c. review and approval for suitability and adequacy.

c. 评审和批准，以确保适宜性和充分性。

7.5.3 Control of documented information

7.5.3 形成文件的信息的控制

7.5.3.1 Documented information required by the quality management system and by this International Standard shall be controlled to ensure:

7.5.3.1 应控制质量管理体系和本标准所要求的形成文件的信息，以确保：

a. it is available and suitable for use, where and when it is needed;

a.在需要的场合和时机，均可获得并适用；

b. it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

b.予以妥善保护（如：防止失密、不当使用或不完整）。

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

7.5.3.2 为控制形成文件的信息，适用时，组织应进行下列活动：

a. distribution, access, retrieval and use;

a.分发、访问、检索和使用；

b. storage and preservation, including preservation of legibility;

b.存储和防护，包括保持可读性；

c. control of changes (e.g. version control);

c.更改控制（如版本控制）；

d. retention and disposition.

d.保留和处置。

e. prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

e.如果为了任何目的需保留，应通过清除，进行适当的标识或者控制，以防止作废的形成文件的信息的非预期使用，

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.

对于组织确定的、策划和运行质量管理体系所必需的、来自外部的形成文件的信息，组织应进行适当识别，并予以控制。

Documented information retained as evidence of conformity shall be protected from unintended alterations.

对所保留的作为符合性证据的形成文件的信息应予以保护，防止非预期的更改。

When documented information is managed electronically, data protection processes shall be defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).

当形成文件的信息以电子化管理时，数据保护过程应定义（例如：保护以防丢失，非授权的更改，非预期变更，讹误，物理损坏）。

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

注：对形成文件的信息的“访问”可能意味着仅允许查阅，或者意味着允许查阅并授权修改。

8 Operation

8 运行

8.1 Operational planning and control

8.1 运行的策划和控制

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

为满足产品和服务提供的要求，并实施第 6 章所确定的措施，组织应通过以下措施对所需的过程（见 4.4）进行策划、实施和控制：

a. determining the requirements for the products and services;

a.确定产品和服务的要求；

NOTE: Determination of requirements for the products and services should include consideration of:

注：产品和服务的要求的确定应当考虑：

- personal and product safety;

- 人身和产品的安全；

- producibility and inspectability;

- 可制造性和可检验性；

- reliability, availability, and maintainability;

- 可靠性、可利用性和可维护性；

- suitability of parts and materials used in the product;

- 用于产品的零部件和材料的适用性；

- selection and development of embedded software;

- 嵌入式软件的选择和开发；

- product obsolescence;

- 产品的淘汰性；

- prevention, detection, and removal of foreign objects;

- 多余物的预防、侦测和移除；

- handling, packaging, and preservation;

- 处置、包装和防护；

- recycling or final disposal of the product at the end of its life.

-产品在寿命结束时的回收和最终处理

b. establishing criteria for:

b.建立下列内容的准则：

1. the processes;

1.过程；

2. the acceptance of products and services;

2.产品和服务的接收。

NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support:

注：根据产品的属性和基于特殊要去，可以使用统计技术已支持：

- ***design verification (e.g., reliability, maintainability, product safety);***

-设计验证（例如：可靠性、可维护性和产品安全性）；

- process control;

-过程控制；

□□

- ***selection and verification of key characteristics;***
- ***process capability measurements;***
- ***statistical process control;***
- ***design of experiments***

关键特性的选择和验证；
过程能力测量；
统计过程控制；
试验设计

- verification;

-验证；

- failure mode, effects, and criticality analysis.

-失效模式、影响和危害度分析。

c. determining the resources needed to achieve conformity to the product and service requirements ***and to meet on-time delivery of products and services***;

c.确定符合产品和服务要求所需的资源***及满足产品和服务的准时交付***;

d. implementing control of the processes in accordance with the criteria;

d.按照准则实施过程控制；

e. determining, maintaining and retaining documented information

e.在必要的范围和程度上，确定并保持、保留形

to the extent necessary:

成文件的信息：

1. to have confidence that the processes have been carried out as planned;

1.确信过程已经按策划进行；

2. to demonstrate the conformity of products and services to their requirements.

2.证实产品和服务符合要求。

f. determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;

f. 确定管理关键项目必须的过程和控制，包括关键特性被识别时的生产过程控制。

g. engaging representatives of affected organization functions for operational planning and control;

g.确保受影响的组织职能代表参与运营的策划和控制；

h. determining the process and resources to support the use and maintenance of the products and services;

h.确定支持产品和服务使用和维护的过程和资源；

i. determining the products and services to be obtained from external providers;

i.确定从外部供方获得的产品和服务；

j. establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

j.建立防止不合格产品和服务交付给客户所需的控制。

NOTE: One method to achieve operational planning and control can be through using integrated phased processes.

注：达成运营策划和控制的一个途径可以是使用综合分阶段过程。

As appropriate to the organization, customer requirements, and products and services, the organization shall plan and manage product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints.

当适用组织、客户要求和产品和服务时，组织应以一种结构化和受控的方式策划和管理产品和服务的提供，这种方式包括在有限的资源和时间内，按策划的顺序实施计划事件，并以可接受的风险满足要求。

NOTE: This activity is generally referred to as project planning, project management, or program management.

注：这个活动通常称之为项目策划，项目管理或者计划管理。

The output of this planning shall be suitable for the organization's operations.

策划的输出应适合组织的运行需要。

NOTE: As an output of this planning, documented information specifying the processes of the quality management system and the resources to be applied to a specific product, service, project, or contract can be referred to as a quality plan.

注：作为策划的输出，对应用于特定产品、服务、项目或合同的质量管理体系的过程和资源作出规定的形成文件的信息可称之为质量计划。

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

组织应控制策划的变更，评审非预期变更的后果，必要时，采取措施减轻不利影响。

The organization shall ensure that outsourced processes are controlled (see 8.4).

组织应确保外包过程受控（见 8.4）。

The organization shall establish, implement, and maintain a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements. The process shall ensure that work

组织应建立、实施和维持一个过程以策划和控制临时或者永久的工作转移，以确保工作对于要求的持续符合性。该过程应确保工作转移的影响和风险得到管理。

transfer impacts and risks are managed.

NOTE: For the control of work transfer from the organization to an external provider, or from an external provider to another external provider, see 8.4. For the control of work transfer from one organization facility to another, or from an external provider to the organization, see 8.5.

注：对于控制从组织到外部供方，或者从一个外部供方到另一个外部供方的工作转移，参见 8.4。对于控制从组织的一处设施到另一处，或者从外部供方到组织的工作转移，参见 8.5。

8.1.1 Operational Risk Management

8.1.1 运行风险管理

The organization shall plan, implement, and control a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to the organization and the products and services:

组织应建立、实施和保持一个过程，用于管理运行风险以实现适用的要求，包括适合于对组织及产品和服务的要求。

a. assignment of responsibilities for operational risk management;

a．运行风险管理的职责分配；

b. definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);

b．风险准则的确定（如：可能性、后果,风险接受程度）；

c. identification, assessment, and communication of risks throughout operations;

c．在整个运行中风险的识别、评估和沟通；

d. identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;

d．对于超过确定的风险接受准则时，减轻风险措施的识别、实施和管理，和

e. acceptance of risks remaining after implementation of mitigating actions.

e．减轻风险措施实施后,剩余风险可接受。

NOTE 1: While clause 6.1 addresses the risks and opportunities when planning for the quality management system of the organization, the scope of this clause (8.1.1) is limited to the risks associated to the operational processes needed for the provision of products and services (clause 8).

注 1：当组织质量管理体系策划期间，条款 6.1 已落实风险和机遇时，本条款（8.1）仅限于产品和服务提供所需的运行过程（条款 8）有关的风险。

NOTE 2: Within the aviation, space, and defense industry, risk is generally expressed in terms of the likelihood of occurrence and the severity of the consequences.

注 2：在航空、航天和国防工业中，风险通常以发生频度和后果严重度来表述。

8.1.2 Configuration Management
The organization shall plan, implement, and control a process for configuration management as appropriate to the organization and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process shall:

8.1.2 技术状态管理
组织应策划、实施和控制适合于组织及其产品和服务的技术状态管理过程，以确保在整个产品生命周期内物理和功能属性的识别和控制。该过程应：

a. control product identity and traceability to requirements, including the implementation of identified changes;

a.控制对于要求的产品识别和追溯，包括别识别的更改的执行。

b. ensure that the documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.

b.确保形成文件的信息（例如：要求、设计、验证、确认和接受文件）与产品和服务的实际属性一致。

8.1.3 Product Safety	***8.1.3 产品安全***
The organization shall plan, implement, and control the processes needed to assure product safety during the entire product life cycle, as appropriate to the organization and the product.	***组织应策划、实施和控制在整个产品生命周期所需，且适用于组织和产品的，用于确保产品安全的过程。***
NOTE: Examples of these processes include:	***注：这些过程的示例包括：***
- assessment of hazards and management of associated risks (see 8.1.1);	***-危害评估和相关风险的管理（见 8.1.1）；***
- management of safety critical items;	***-安全关键项目的管理；***
- analysis and reporting of occurred events affecting safety;	***-影响安全的已发生事项的分析和报告；***
- communication of these events and training of persons.	***-这些事件的沟通及人员的培训。***
8.1.4 Prevention of Counterfeit Parts	***8.1.4 仿冒件预防***
The organization shall plan, implement, and control processes, appropriate to the organization and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.	***组织应策划、实施和控制适合于组之和产品的过程，以防止仿冒件和可疑仿冒件的使用和混入交付给客户的产品中。***
NOTE: Counterfeit part prevention processes should consider:	***注：仿冒件预防过程宜考虑：***
− training of appropriate persons in the awareness and prevention of counterfeit parts;	***-相关人员在意识和仿冒件预防方面的培训；***
− application of a parts obsolescence monitoring program;	***-零件淘汰监控计划的应用；***
− controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources;	***-从原厂或者授权制造商、授权分销商，或其他批准来源获取外部提供产品的控制；***
− requirements for assuring traceability of parts and components to their original or authorized manufacturers;	***-确保零部件追溯到原厂或授权制造商的要求；***
− verification and test methodologies to detect counterfeit parts;	***-侦测仿冒件的验证和实验方法；***
− monitoring of counterfeit parts reporting from external sources;	***-监控来自外部的仿冒件报告；***
− quarantine and reporting of suspect or detected counterfeit parts.	***-可疑和侦测到的仿冒件的隔离和汇报。***
8.2 Requirements for products and services	**8.2 产品和服务的要求**
8.2.1 Customer communication	8.2.1 顾客沟通
Communication with customers shall include:	与顾客沟通的内容应包括：
a. providing information relating to products and services;	a.提供有关产品和服务的信息；

b. handling enquiries, contracts or orders, including changes;

b.处理问询、合同或订单，包括变更；

c. obtaining customer feedback relating to products and services, including customer complaints;

c.获取有关产品和服务的顾客反馈，包括顾客投诉；

d. handling or controlling customer property;

d.处置或控制顾客财产；

e. establishing specific requirements for contingency actions, when relevant.

e.关系重大时，制定有关应急措施的特定要求。

8.2.2 Determining the requirements for products and services

8.2.2 产品和服务要求的确定

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

在确定向顾客提供的产品和服务的要求时，组织应确保：

a. the requirements for the products and services are defined, including:

a.产品和服务的要求得到规定，包括：

1. any applicable statutory and regulatory requirements;

1.适用的法律法规要求；

2. those considered necessary by the organization;

2.组织认为的必要要求。

b. the organization can meet the claims for the products and services it offers.

b.对其所提供的产品和服务，能够满足组织声称的要求。

c. special requirements of the products and services are determined;

c.产品的特殊要求已得到确定，

d. operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified.

d.运行风险已被识别（如：新技术、供应能力，短交付期限）。

8.2.3 Review of the requirements for products and services

8.2.3 产品和服务要求的评审

8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:

8.2.3.1 组织应确保有能力满足向顾客提供的产品和服务的要求。在承诺向顾客提供产品和服务之前，组织应对如下各项要求进行评审：

a. requirements specified by the customer, including the requirements for delivery and post-delivery activities;

a.顾客明确的要求，包括对交付及交付后活动的要求；

b. requirements not stated by the customer, but necessary for the specified or intended use, when known;

b.顾客虽然没有明示，但规定的用途或已知的预期用途所必需的要求；

c. requirements specified by the organization;

c.组织规定的要求；

d. statutory and regulatory requirements applicable to the products and services;

d.适用于产品和服务的法律法规要求；

e. contract or order requirements differing from those previously expressed.

e.与先前表述存在差异的合同或订单要求。

This review shall be coordinated with applicable functions of the organization.

评审应在组织适用的职能之间进行协调。

If upon review the organization determines that some customer requirements cannot be met or can only partially be met, the organization shall negotiate a mutually acceptable requirement with the customer.	***如果评审后组织确定某些客户要求不能满足或者仅能部分的满足，组织应和客户协商一个互相都能接受的要求。***
The organization shall ensure that contract or order requirements differing from those previously defined are resolved.	若与先前合同或订单的要求存在差异，组织应确保有关事项已得到解决。
The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.	若顾客没有提供形成文件的要求，组织在接受顾客要求前应对顾客要求进行确认。
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.	注：在某些情况下，如网上销售，对每一个订单进行正式的评审可能是不实际的，作为替代方法，可评审有关的产品信息，如产品目录。
8.2.3.2 The organization shall retain documented information, as applicable:	8.2.3.2 适用时，组织应保留与下列方面有关的形成文件的信息：
a. on the results of the review;	a.评审结果；
b. on any new requirements for the products and services.	b.产品和服务的新要求。
8.2.4 Changes to requirements for products and services	8.2.4 产品和服务要求的更改
The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.	若产品和服务要求发生更改，组织应确保相关的形成文件的信息得到修改，并确保相关人员知道已更改的要求。
8.3 Design and development of products and services	8.3 产品和服务的设计和开发
8.3.1 General	8.3.1 总则
The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.	组织应建立、实施和保持适当的设计和开发过程，以确保后续的产品和服务的提供。
8.3.2 Design and development planning	8.3.2 设计和开发策划
In determining the stages and controls for design and development, the organization shall consider:	在确定设计和开发的各个阶段和控制时，组织应考虑：
a. the nature, duration and complexity of the design and development activities;	a.设计和开发活动的性质、持续时间和复杂程度；
b. the required process stages, including applicable design and development reviews;	b.所需的过程阶段，包括适用的设计和开发评审；
c. the required design and development verification and validation activities;	c.所需的设计和开发验证和确认活动；
d. the responsibilities and authorities involved in the design and development process;	d.设计和开发过程涉及的职责和权限；
e. the internal and external resource needs for the design and	e.产品和服务的设计和开发所需的内部和外部

development of products and services;

资源：

f. the need to control interfaces between persons involved in the design and development process;

f.设计和开发过程参与人员之间接口的控制需求；

g. the need for involvement of customers and users in the design and development process;

g.顾客和使用者参与设计和开发过程的需求；

h. the requirements for subsequent provision of products and services;

h.对后续产品和服务提供的要求；

i. the level of control expected for the design and development process by customers and other relevant interested parties;

i.顾客和其他有关相关方期望的设计和开发过程的控制水平；

j. the documented information needed to demonstrate that design and development requirements have been met.

j.证实已经满足设计和开发要求所需的形成文件的信息。

When appropriate, the organization shall divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, and inputs and outputs.

适当时，组织应将设计和开发工作划分为不同的活动，对每项活动，确定任务、必要的资源、职责、设计内容、输入和输出。

Design and development planning shall consider the ability to provide, verify, test and maintain products and services (reference output of 8.1 a).

设计和开发策划应考虑提供、验证、试验和维护产品和服务的能力（参考 8.1a 输出）。

8.3.3 Design and development inputs

8.3.3 设计和开发输入

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

组织应针对所设计和开发的具体类型的产品和服务，确定基本的要求。组织应考虑：

a. functional and performance requirements;

a.功能和性能要求；

b. information derived from previous similar design and development activities;

b.来源于以前类似设计和开发活动的信息；

c. statutory and regulatory requirements;

c.法律法规要求；

d. standards or codes of practice that the organization has committed to implement;

d.组织承诺实施的标准或行业规范；

e. potential consequences of failure due to the nature of the products and services.

e.由产品和服务性质所决定的、失效的潜在后果。

f. when applicable, the potential consequences of obsolescence (e.g., materials, processes, components, equipment, products).

f.适用时，淘汰的潜在后果（例如：材料、过程、部件、设备、产品）。

Inputs shall be adequate for design and development purposes, complete and unambiguous.

设计和开发输入应满足设计和开发的目的，且应完整、清楚。

Conflicting design and development inputs shall be resolved.

应解决相互冲突的设计和开发输入。

The organization shall retain documented information on design and development inputs.

组织应保留有关设计和开发输入的形成文件的信息。

NOTE: The organization can also consider as design and development inputs other information such as benchmarking, external provider feedback, internally generated data, and in-service data.	***注：组织也可以将其他的信息考虑作为设计和开发的输入，诸如标杆、外部供方反馈、内部生成的数据、和服务数据。***
8.3.4 Design and development controls	8.3.4 设计和开发控制
The organization shall apply controls to the design and development process to ensure that:	组织应对设计和开发过程进行控制，以确保：
a. the results to be achieved are defined;	a.规定拟获得的结果；
b. reviews are conducted to evaluate the ability of the results of design and development to meet requirements;	b.实施评审活动，以评价设计和开发的结果满足要求的能力；
c. verification activities are conducted to ensure that the design and development outputs meet the input requirements;	c.实施验证活动，以确保设计和开发输出满足输入的要求；
d. validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;	d.实施确认活动，以确保形成的产品和服务能够满足规定的使用要求或预期用途要求；
e. any necessary actions are taken on problems determined during the reviews, or verification and validation activities;	e.针对评审、验证和确认过程中确定的问题采取必要措施；
f. documented information of these activities is retained；	f.保留这些活动的形成文件的信息；
g. progression to the next stage is authorized.	***g.批准转入下一阶段。***
Participants in design and development reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed.	***设计和开发评审的参加者应包括与所评审的设计和开发阶段有关的职能的代表。***
NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.	注：设计和开发的评审、验证和确认具有不同目的。根据组织的产品和服务的具体情况，可以单独或以任意组合进行。
8.3.4.1 When tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove the following:	***8.3.4.1 当验证和确认必须进行试验时，应对这些试验进行策划、控制、评审和形成文件，以确保和证实：***
a. test plans or specifications identify the test item being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria;	***a.试验计划或规范识别了要进行试验的产品和使用的资源；确定了试验目的和条件、要记录的参数以及相关接收准则；***
b. test procedures describe the test methods to be used, how to perform the test, and how to record the results;	***b.试验程序描述了操作的方法、试验的实施以及结果的记录；***
c. the correct configuration of the test item is submitted for the test;	***c.提交试验的产品的样品技术状态正确；***
d. the requirements of the test plan and the test procedures are observed;	***d. 遵守了试验计划和试验程序的要求；***

e. the acceptance criteria are met.

e．满足接收准则。

Monitoring and measuring devices used for testing shall be controlled as defined in clause 7.1.5.

用于实验的监视和测量装置应按条款 7.1.5 进行控制。

At the completion of design and development, the organization shall ensure that reports, calculations, test results, etc., are able to demonstrate that the design for the product or service meets the specification requirements for all identified operational conditions.

在设计和/或开发完成时，组织必须确保报告、计算、试验结果等能够证实在所规定的运行条件下，产品或服务的设计符合规范的要求。

8.3.5 Design and development outputs

8.3.5 设计和开发输出

The organization shall ensure that design and development outputs:

组织应确保设计和开发输出：

a. meet the input requirements;

a.满足输入的要求；

b. are adequate for the subsequent processes for the provision of products and services;

b.对于后续的产品和服务的提供过程是充分的；

c. include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

c.包括或引用监视和测量的要求，适当时，包括接收准则；

d. specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision;

d.规定对于预期目的、安全和正确提供的产品和服务的基本特性；

e. specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items;

e.适用时，规定所有关键项目，包括所有关键特性，以及对这些项目要采取的特殊措施；

f. are approved by authorized person(s) prior to release.

f.发行前得到授权人员的批准。

The organization shall define the data required to allow the product to be identified, manufactured, verified, used, and maintained.

组织应确定对产品进行标识、制造、验证、使用和维护所要求的数据。

NOTE: Data can include:

注：数据可以包括：

- the drawings, part lists, and specifications necessary to define the configuration and the design features of the product;

-定义产品技术状态和设计特性所必要的图纸，零件清单和规范；

- the material, process, manufacturing, assembly, handling, packaging, and preservation data needed to provide and maintain a conforming product or service;

-保证产品符合性所需的材料、过程、制造和装配数据；

- the technical data and repair schemes for operating and maintaining the product.

-运行和维护产品的技术数据和维修方案。

The organization shall retain documented information on design and development outputs.

组织应保留设计和开发输出的形成文件的信息。

8.3.6 Design and development changes

8.3.6 设计和开发更改

The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

组织应对产品和服务设计和开发期间以及后续所做的更改进行适当的识别、评审和控制，以确保这些更改对满足要求不会产生不利影响。

The organization shall implement a process with criteria for notifying its customer, prior to implementation, about changes that affect customer requirements.

组织应实施一个过程，其含有对于影响客户要求的更改，在执行之前，通知其客户的准则。

The organization shall retain documented information on:

组织应保留下列形成文件的信息：

a. design and development changes;

a.设计和开发更改；

b. the results of reviews;

b.评审的结果；

c. the authorization of the changes;

c.更改的授权；

d. the actions taken to prevent adverse impacts.

d.为防止不利影响而采取的措施。

Design and development changes shall be controlled in accordance with the configuration management process requirements.

设计和开发的更改应按技术状态管理过程的要求进行控制。

8.4 Control of externally provided processes, products and services

8.4 外部提供的过程、产品和服务的控制

8.4.1 General

8.4.1 总则

The organization shall ensure that externally provided processes, products and services conform to requirements.

组织应确保外部提供的过程、产品和服务符合要求。

The organization shall be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.

组织应对所有从外部提供的过程、产品和服务的符合性负责，包括从顾客指定的来源。

The organization shall ensure, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.

当要求时，组织应确保使用客户指定或批准的外部供方，包括过程来源（例如：特殊过程）。

The organization shall identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.

组织应识别和管理与外部提供的过程、产品和服务，以及和外部供方的选择和使用有关的风险，。

The organization shall require that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.

组织应要求外部供方对他们直接或者次级的外部供方实施适当的控制，以确保满足要求。

The organization shall determine the controls to be applied to externally provided processes, products and services when:

在下列情况下，组织应确定对外部提供的过程、产品和服务实施的控制：

a. products and services from external providers are intended for incorporation into the organization's own products and services;

a. 外部供方的过程、产品和服务将构成组织自身的产品和服务的一部分；

b. products and services are provided directly to the customer(s. by external providers on behalf of the organization;

b. 外部供方代表组织直接将产品和服务提供给顾客；

c. a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

c. 组织决定由外部供方提供的过程或过程的一部分。

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

组织应基于外部供方按照要求提供过程、产品或服务的能力，确定外部供方的评价、选择、绩效监视以及再评价的准则，并加以实施。对于这些活动和由评价引发的任何必要的措施，组织应保留形成文件的信息。

NOTE: During external provider evaluation and selection, the organization can use quality data from objective and reliable external sources, as evaluated by the organization (e.g., information from accredited quality management system or process certification bodies, external provider approvals from government authorities or customers). Use of such data would be only one element of an organization's external provider control process and the organization remains responsible for verifying that externally provided processes, products, and services meet specified requirements.

注：在外部供方评价和选择时，组织可使用来自客观和可靠的外部来源的供应商质量数据作为组织的评估，（例如：来自授信的质量管理体系或过程认证机构的信息,政府当局或客户对外部供方的批准）。使用这种数据只是组织对外部供方控制过程的一个组成部分，组织仍然负有验证外部提供的过程、产品和服务满足规定要求的责任。

8.4.1.1 The organization shall:

8.4.1.1 组织应：

a. define the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;

a. 对于批准状态决定、批准状态更改以及根据其批准状态对外部供方的受控使用的条件确定过程、职责和权限。

b. maintain a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);

b.保持一份外部供方名录，包括批准状态（如：批准，有条件批准，不批准）和批准范围（如：产品类型、过程类别）；

c. periodically review external provider performance including process, product and service conformity, and on-time delivery performance;

c.定期评审外部供方的业绩，包括过程、产品和服务符合性，和准时交付业绩；

d. define the necessary actions to take when dealing with external providers that do not meet requirements;

d. 当外部供方不能满足要求时，规定采取必要的措施；

e. define the requirements for controlling documented information created by and/or retained by external providers.

e. 明确由供方生成和/或保持的形成文件的信息的控制要求。

8.4.2 Type and extent of control

8.4.2 控制类型和程度

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

组织应确保外部提供的过程、产品和服务不会对组织持续地向顾客交付合格产品和服务的能力产生不利影响。

The organization shall:

组织应：

a. ensure that externally provided processes remain within the control of its quality management system;

a.确保外部提供的过程保持在其质量管理体系的控制之中；

b. define both the controls that it intends to apply to an external

b.规定对外部供方的控制及其输出结果的控制；

provider and those it intends to apply to the resulting output;

c. take into consideration:

1. the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;

2. the effectiveness of the controls applied by the external provider;

3. the results of the periodic review of external provider performance (see 8.4.1.1 c);

d. determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

Verification activities of externally provided processes, products, and services shall be performed according to the risks identified by the organization. These shall include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.

NOTE 1: Customer verification activities performed at any level of the supply chain does not absolve the organization of its responsibility to provide acceptable processes, products, and services and to comply with all requirements.

NOTE 2: Verification activities can include:

- review of objective evidence of the conformity of the processes, products, and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter);

- inspection and audit at the external provider's premises;

- review of the required documentation;

- review of production part approval process data;

- inspection of products or verification of services upon receipt;

- review of delegations of product verification to the external provider.

When externally provided product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does

c.考虑：

1.外部提供的过程、产品和服务对组织持续地满足顾客要求和适用的法律法规要求的能力的潜在影响；

2.由外部供方实施控制的有效性；

3.定期评审外部供方业绩的结果（见8.4.1.1 c）

d.确定必要的验证或其他活动，以确保外部提供的过程、产品和服务满足要求。

外部提供的过程、产品和服务的验证活动应根据组织识别的风险执行。当有不合格含仿冒件的高风险时，适用时，应包括检验或定期试验。

注 1 顾客对供应链的任何层次所做的验证活动不能免除组织提供可接受的过程、产品，和服务及符合所有要求的职责。

注 2 验证活动可以包含：

-从外部供方处获得过程、产品、和服务符合性的客观证据（例如：随产品文件，合格证明，试验文件，统计文件，过程控制文件，生产过程验证的结果和之后生产过程更改的评估）；

-在外部供方的检验和审核；

-对要求的文件的评审；

-生产件批准过程数据的评审；

-接收时对产品的检验或者对服务的验证；

-对外部供方生产验证代表的评审。

在等待所有要求的验证活动完成期间，外部提供的产品如被发放用于生产，应对其进行标识和记录以便如果其随后的验证结果发现产品不满足要求时能召回和更换。

not meet requirements.

When the organization delegates verification activities to the external provider, the scope and requirements for delegation shall be defined and a register of delegations shall be maintained. The organization shall periodically monitor the external provider's delegated verification activities.	***在组织授权外部供方进行验证活动时，应规定授权的范围和要求并保持授权人员登记表。组织应定期监控外部供方的授权验证活动。***
When external provider test reports are utilized to verify externally provided products, the organization shall implement a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), the organization shall implement a process to validate the accuracy of test reports.	***当使用外部供方试验报告来验证外部提供的产品时，组织应实施评估试验报告中的数据以确认产品满足要求的过程。当客户或者组织识别原材料存在重大运行风险（例如：关键项目），组织应实施确认试验报告准确性的过程。***
8.4.3 Information for external providers	8.4.3 提供给外部供方的信息
The organization shall ensure the adequacy of requirements prior to their communication to the external provider.	组织应确保在与外部供方沟通之前所确定的要求是充分的。
The organization shall communicate to external providers its requirements for:	组织应与外部供方沟通以下要求：
a. the processes, products and services to be provided ***including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions)***;	a.拟提供的过程、产品和服务，***包含相关技术数据的标识（例如：规范、图纸、过程要求、作业指导书）***;
b. the approval of:	b.对下列内容的批准：
1. products and services;	1.产品和服务；
2. methods, processes and equipment;	2.方法、过程和设备；
3. the release of products and services;	3.产品和服务的放行；
c. competence, including any required qualification of persons;	c.能力，包括所要求的人员资格；
d. the external providers' interactions with the organization;	d.外部供方与组织的互动；
e. control and monitoring of the external providers' performance to be applied by the organization;	e.被组织所用的外部供方绩效的控制和监视；
f. verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.	f.组织或其顾客拟在外部供方现场实施的验证或确认活动。
g. design and development control;	***g.设计和开发控制；***
h. special requirements, critical items, or key characteristics;	***h.特殊要求、关键项目，或关键特性；***
i. test, inspection, and verification (including production process verification);	***i.试验、检验、和验证（包含生产过程确认）；***
j. the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;	***j. 用于产品接收的统计技术的使用，和组织接收的有关指导书;***

k. the need to:

- implement a quality management system;

- use customer-designated or approved external providers, including process sources (e.g., special processes);

- notify the organization of nonconforming processes, products, or services and obtain approval for their disposition; prevent the use of counterfeit parts (see 8.1.4);

- notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization's approval;

- flow down to external providers applicable requirements including customer requirements;

- provide test specimens for design approval, inspection/ verification, investigation, or auditing;

- retain documented information, including retention periods and disposition requirements;

l. the right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;

m. ensuring that persons are aware of:

- their contribution to product or service conformity;

- their contribution to product safety;

- the importance of ethical behavior.

8.5 Production and service provision

8.5.1 Control of production and service provision

The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

a. the availability of documented information that defines:

1. the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

2. the results to be achieved;

NOTE 1: Documented information that defines characteristics of products and services can include digital product definition

k．所需要的：

-实施质量管理体系；

-使用客户指定或者批准的外部供方，包括过程来源（例如：特殊过程）；

-向组织通报不合格过程、产品或服务以及或得处置的批准；预防仿冒件的使用（见 8.1.4）；

-向组织通报过程、产品、或服务的更改，包含其外部供方的更改，或生产地点的更改，并获得组织的批准；

-向外部供方传递适用要求，包括顾客要求；

-提供用于设计批准、检验/验证、调查或审核的试验样件的要求；

-保持形成文件的信息，包含保存期限和处置要求；

i.在供应链的任何层次，组织及其顾客,和法规授权的管理部门有接触使用的设施区域和适用的形成文件的信息的权利。

m.确保人员意识到：

-对于产品和服务符合性的贡献；

-对于产品安全性的贡献；

-道德行为的重要性。

8.5 生产和服务提供

8.5.1 生产和服务提供的控制

组织应在受控条件下进行生产和服务提供。适用时，受控条件应包括：

a.可获得形成文件的信息，以规定以下内容：

1.所生产的产品、提供的服务或进行的活动的特性；

2.拟获得的结果。

注 1：定义产品和服务的形成文件的信息可以包含数字产品定义数据、图纸、零件清册、材料、

data, drawings, parts lists, materials, and process specifications.

和过程规范。

NOTE 2: Documented information for activities to be performed and results to be achieved can include process flow charts, control plans, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards), and verification documents.

注 2：执行的活动和达成的结果的形成文件的信息可以包含工艺流程图、控制计划、生产文件（例如：制造计划，周转卡、路线卡、工作指令和过程卡），和验证文件。

b. the availability and use of suitable monitoring and measuring resources;

b.可获得和使用适宜的监视和测量资源；

c. the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

c.在适当阶段实施监视和测量活动，以验证是否符合过程或输出的控制准则以及产品和服务的接收准则；

1. ensuring that documented information for monitoring and measurement activity for product acceptance includes:

1.对用于产品接收的监视和测量活动，确保形成文件的信息包含：

- criteria for acceptance and rejection;

-接收和拒收的准则；

- where in the sequence verification operations are to be performed;

-按顺序在何处执行验证操作；

- measurement results to be retained (at a minimum an indication of acceptance or rejection);

-保持测量结果（至少表明接收还是拒收）；

- any specific monitoring and measurement equipment required and instructions associated with their use;

-要求的任何专用监视和测量设备及与其使用有关的指导书。

2. ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).

2.当抽样作为产品接收的方法时，确保抽样计划在公认统计原理基础上应是合理的，并是适于使用（亦即，抽样计划与产品的重要度和过程能力相匹配）。

d. the use of suitable infrastructure and environment for the operation of processes;

d.为过程的运行提供适宜的基础设施和环境；

NOTE: Suitable infrastructure can include product specific tools (e.g., jigs, fixtures, molds) and software programs.

注：适宜的设备可以包含产品专用工装（例如：夹具、工装、模具）和软件程序。

e. the appointment of competent persons, including any required qualification;

e.配备具备能力的人员，包括所要求的资格；

f. the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

f.若输出结果不能由后续的监视或测量加以验证，应对生产和服务提供过程实现策划结果的能力进行确认，并定期再确认；

NOTE: These processes can be referred to as special processes (see 8.5.1.2).

注：这些过程通常被称为特殊过程（见 8.5.1.2）。

g. the implementation of actions to prevent human error;

g. 采取措施防范人为错误；

h. the implementation of release, delivery and post-delivery activities.	h．实施放行、交付和交付后活动。
i. the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);	***i．建立工艺准则（例如：文字标准、代表样件或图示）；***
j. the accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);	***j．在生产中所有的产品的可说明性（例如：零件数量、分单作业、不合格品）；***
k. the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;	***k.根据建立的过程，控制和监视识别的关键项目，包括关键特性；***
l. the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);	***l.测量变量方法的确定（例如：工具、在线探测、检验设备）；***
m. the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;	***m.当符合性的充分验证不能在后续阶段执行时，过程检验/验证点的识别；***
n. the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;	***n.所有生产和检验/验证操作已经按策划完成的证据的可用性，或另有形成文件且授权的。***
o. the provision for the prevention, detection, and removal of foreign objects;	***o．预防、检测和移除多余物的规定;***
p. the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 7.1.3);	***p．根据影响产品要求符合性的程度，对公用事业和供给（如水、压缩空气、电及化学产品）进行监视和控制(见 7.1.3)；***
q. the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.	***q．当产品在等待所有要求的监视和测量活动完成期间被发放用于生产时，应对其进行识别和记录，以便在随后发现产品不符合要求时，对其进行召回和更换。***
8.5.1.1 Control of Equipment, Tools, and Software Programs	***8.5.1.1 设备、工装和软件程序的控制***
Equipment, tools, and software programs used to automate, control, monitor, or measure production processes shall be validated prior to final release for production and shall be maintained.	***生产设备、工装和用于生产过程自动化和控制、监视或测量的软件程序在最终放行用于生产前应进行确认，并维护。***
Storage requirements shall be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.	***对储存的生产设备或工装必须确定储存要求，包括任何必要的定期进行防护和状况检查。***
8.5.1.2 Validation and Control of Special Processes	***8.5.1.2 特殊过程的确认和控制***
For processes where the resulting output cannot be verified by subsequent monitoring or measurement, the organization shall establish arrangements for these processes including, as applicable:	***对于导致输出不能由后续的监视或测量加以验证的过程，组织应规定确认这些过程的安排，适用时包括：***

a. definition of criteria for the review and approval of the processes;

a.为过程的评审和批准所规定的准则；

b. determination of conditions to maintain the approval;

b.维持批准的条件的确定；

c. approval of facilities and equipment;

c. 设施和设备的认可和

d. qualification of persons;

d.人员资格的鉴定；

e. use of specific methods and procedures for implementation and monitoring the processes;

e.为实施和监视过程使用特定的方法和程序；

f. requirements for documented information to be retained.

d.形成文件的信息得以保留的要求。

8.5.1.3 Production Process Verification

8.5.1.3 生产过程的验证

The organization shall implement production process verification activities to ensure the production process is able to produce products that meet requirements.

组织应实施生产验证活动以确保生产过程能够生产满足要求的产品

NOTE: These activities can include risk assessments, capacity studies, capability studies, and control plans.

注：这些活动可以包含风险评估，产能研究，能力研究，和控制计划。

The organization shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements. This activity shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes).

组织应使用从首批生产的新零件或组件中确定的有代表性的项目来验证生产过程、生产文件和工装能够生产满足要求的零件和组件。当发生使原来验证结果无效的更改时，应再次验证过程（如工程更改,生产过程更改,工具更改）。

NOTE: This activity can be referred to as First Article Inspection (FAI).

注：此项活动通常被称为首件检验。

The organization shall retain documented information on the results of production process verification.

组织应保留关于生产过程验证结果的形成文件的信息。

8.5.2 Identification and traceability

8.5.2 标识和可追溯性

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

需要时，组织应采用适当的方法识别输出，以确保产品和服务合格。

The organization shall maintain the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

组织应维持产品和服务的技术状态的标识，以便识别产品实际的技术状态和约定的技术状态之间的任何区别。

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

组织应在生产和服务提供的整个过程中按照监视和测量要求识别输出状态。

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish controls for the media.

当使用接收授权媒体时（例如，印章、电子签名、口令），组织应对媒体建立的控制。

The organization shall control the unique identification of the outputs

当有可追溯要求时，组织应控制输出的唯一性标

when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

识，且应保留所需的形成文件的信息以实现可追溯。

NOTE: Traceability requirements can include:

注：可追溯性要求可以包括：

- the identification to be maintained throughout the product life;

-整个产品寿命期内维持标识；

- the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap);

-能追溯由同批原材料生产的所有产品，或同一生产批产品的最终去向（如交付、报废）；

- for an assembly, the ability to trace its components to the assembly and then to the next higher assembly;

-对于组件，能追溯其装配的部件及上一级的组件；

- for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.

-对给定的产品，能追溯其生产（加工、装配、检验/验证）的连续的记录。

8.5.3 Property belonging to customers or external providers

8.5.3 顾客或外部供方的财产

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

组织在控制或使用顾客或外部供方的财产期间，应对其进行妥善管理。

The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

对组织使用的或构成产品和服务一部分的顾客和外部供方财产，组织应予以识别、验证、防护和保护。

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

若顾客或外部供方的财产发生丢失、损坏或发现不适用情况，组织应向顾客或外部供方报告，并保留相关形成文件的信息。

NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

注：顾客或外部供方的财产可能包括材料、零部件、工具和设备，顾客的场所，知识产权和个人信息。

8.5.4 Preservation

8.5.4 防护

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

组织应在生产和服务提供期间对输出进行必要防护，以确保符合要求。

NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

注：防护可包括标识、处置、污染控制、包装、储存、传输或运输以及保护。

Preservation of outputs shall also include, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:

适用时，按产品规范和适用的法律法规，产品的防护还应包括下列规定：

a. cleaning;

a. 清洁；

b. prevention, detection, and removal of foreign objects;

b. 预防、检测并移除多余物；

c. special handling and storage for sensitive products;

c. 对敏感的产品的特殊处理和储存；

d. marking and labeling, including safety warnings and cautions;

d. 包括安全警示和警告的标记和标贴；

e. shelf life control and stock rotation;

e. 贮存期控制和存货周转；

f. special handling and storage for hazardous materials.

f. 对危险物料的特殊处理和储存。

8.5.5 Post-delivery activities

8.5.5 交付后的活动

The organization shall meet requirements for post-delivery activities associated with the products and services.

组织应满足与产品和服务相关的交付后活动的要求。

In determining the extent of post-delivery activities that are required, the organization shall consider:

在确定所要求的交付后活动的覆盖范围和程度时，组织应考虑：

a. statutory and regulatory requirements;

a.法律法规要求；

b. the potential undesired consequences associated with its products and services;

b.与产品和服务相关的潜在不期望的后果；

c. the nature, use and intended lifetime of its products and services;

c.产品和服务的性质、用途和预期寿命；

d. customer requirements;

d.顾客要求；

e. customer feedback.

e.顾客反馈。

f. collection and analysis of in-service data (e.g., performance, reliability, lessons learned);

f.服役中数据的收集和分析(例如：性能、可靠性、经验教训)；

g. control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;

g.控制、升级和提供关于产品使用、维护、维修和大修的技术文件；

h. controls required for work undertaken external to the organization (e.g., off-site work);

h.对于组织之外进行工作所要求的控制（例如：外场作业）；

i. product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).

i.生产/客户支持（例如：询问、培训、质保、维护、备件、资源和淘汰）。

When problems are detected after delivery, the organization shall take appropriate action including investigation and reporting.

当交付后发现问题时，组织应采取适当的措施，包括调查和汇报；

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

注：交付后活动可能包括保证条款所规定的相关活动，诸如合同规定的维护服务，以及回收或最终报废处置等附加服务等。

8.5.6 Control of changes

8.5.6 更改控制

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

组织应对生产和服务提供的更改进行必要的评审和控制，以确保持续地符合要求。

Persons authorized to approve production or service provision changes shall be identified.

应识别授权批准生产或服务提供的更改的人员。

NOTE: Production or service provision changes can include the changes affecting processes, production equipment, tools, or software programs.

注：生产或服务提供的更改可以包含影响过程、生产设备、工具或软件程序的更改。

The organization shall retain documented information describing the results of the review of changes, the person(s. authorizing the change, and any necessary actions arising from the review.

组织应保留形成文件的信息，包括有关更改评审结果、授权进行更改的人员以及根据评审所采取的必要措施。

8.6 Release of products and services

8.6 产品和服务的放行

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

组织应在适当阶段实施策划的安排，以验证产品和服务的要求已得到满足。

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

除非得到有关授权人员的批准，适用时得到顾客的批准，否则在策划的安排已圆满完成之前，不应向顾客放行产品和交付服务。

The organization shall retain documented information on the release of products and services. The documented information shall include:

组织应保留有关产品和服务放行的形成文件的信息。形成文件的信息应包括：

a. evidence of conformity with the acceptance criteria;

a.符合接收准则的证据；

b. traceability to the person(s. authorizing the release.

b.授权放行人员的可追溯信息。

When required to demonstrate product qualification, the organization shall ensure that retained documented information provides evidence that the products and services meet the defined requirements.

在需要证明产品检验合格时，组织应确保保留形成文件的信息能提供产品和服务满足规定要求的证据。

The organization shall ensure that all documented information required to accompany the products and services are present at delivery.

组织应确保所有要求随产品和服务的形成文件的信息在交付时一同提供。

8.7 Control of nonconforming outputs

8.7 不合格输出的控制

8.7.1 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

8.7.1 组织应确保对不符合要求的输出进行识别和控制，以防止非预期的使用或交付。

NOTE: The term "nonconforming outputs" includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.

注：术语"不合格品"包括内部产生的，从外部供方接受的，或由客户识别的不合格品和服务。

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

组织应根据不合格的性质及其对产品和服务符合性的影响采取适当措施。这也适用于在产品交付之后，以及在服务提供期间或之后发现的不合格产品和服务。

The organization's nonconformity control process shall be maintained as documented information including the provisions for:

组织的不合格控制过程应以形成文件的信息维持，包含能提供：

− defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;

-规定不合格输出和过程的评审及处置的职责和权限，以及批准作出这些决定的人员的过程。

- taking actions necessary to contain the effect of the nonconformity on other processes, products, or services; timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;

-采取必要的措施，遏制不合格品对其它过程、产品或服务的影响；及时报告已交付给客户和相关方的产品和服务的不合格。

- defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).

-规定交付后发现的不合格产品和服务的，适合于其影响（见 10.2）的纠正措施。

NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.

注：相关方要求的不合格产品和服务的通知可以包含：外部供方、内部组织、顾客、分销商和管理当局。

The organization shall deal with nonconforming outputs in one or more of the following ways:

组织应通过下列一种或几种途径处置不合格输出：

a. correction;

a.纠正；

b. segregation, containment, return or suspension of provision of products and services;

b.隔离、限制、退货或暂停对产品和服务的提供；

c. informing the customer;

c.告知顾客；

d. obtaining authorization for acceptance under concession ***by a relevant authority and, when applicable, by the customer..***

d.获得***有关当局和，适用时，客户对于***让步接收的授权。

Dispositions of use-as-is or repair for the acceptance of nonconforming products shall only be implemented:

对不合格品接收进行原样使用或返修的处置仅在以下情况下可以实施：

− after approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;

-只有经过负责设计的组织的授权代表，或者受设计组织委托的人员批准后；

− after authorization by the customer, if the nonconformity results in a departure from the contract requirements.

如果不合格导致偏离合同要求，经过顾客授权；

Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

处置为报废的产品，必须做出明显和永久性的标记，或进行有效地控制，直至在物理上不可能被使用。

Counterfeit, or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.

仿冒，或者被怀疑为仿冒件应进行控制以防止在进入供应链。

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

对不合格输出进行纠正之后应验证其是否符合要求。

8.7.2 The organization shall retain documented information that:

8.7.2 组织应保留下列形成文件的信息，以：

a. describes the nonconformity;

a.描述不合格；

b. describes the actions taken;

b.描述所采取的措施；

c. describes any concessions obtained;

c.描述获得的让步；

d. identifies the authority deciding the action in respect of the nonconformity.

d.识别处置不合格的授权。

9 Performance evaluation

9 绩效评价

9.1 Monitoring, measurement, analysis and evaluation

9.1 监视、测量、分析和评价

9.1.1 General

9.1.1 总则

The organization shall determine:

组织应确定：

a. what needs to be monitored and measured;

a.需要监视和测量什么；

b. the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;

b.需要用什么方法进行监视、测量、分析和评价，以确保结果有效；

c. when the monitoring and measuring shall be performed;

c.何时实施监视和测量；

d. when the results from monitoring and measurement shall be analysed and evaluated.

d.何时对监视和测量的结果进行分析和评价。

The organization shall evaluate the performance and the effectiveness of the quality management system.

组织应评价质量管理体系的绩效和有效性。

The organization shall retain appropriate documented information as evidence of the results.

组织应保留适当的形成文件的信息，以作为结果的证据。

9.1.2 Customer satisfaction

9.1.2 顾客满意

The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.

组织应监视顾客对其需求和期望已得到满足的程度的感受。组织应确定获取、监视和评审这些信息的方法。

NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

注：监视顾客感受的例子可包括顾客调查、顾客对交付产品或服务的反馈、顾客座谈、市场占有率分析、顾客赞扬、担保索赔和经销商报告。

Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. The organization shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

监视和用于评价顾客满意的信息应包括，但不限于：产品和服务符合性，准时交付表现，顾客抱怨和纠正措施要求。组织应开发和实施顾客满意度改进计划来解决识别出的不足，并评价结果的有效性。

9.1.3 Analysis and evaluation

9.1.3 分析与评价

The organization shall analyse and evaluate appropriate data and

组织应分析和评价通过监视和测量获得的适当

information arising from monitoring and measurement.

的数据和信息。

NOTE: Appropriate data can include information on product and service problems reported by external sources (e.g., government/industry alerts, advisories).

注：适当的数据可以包含外部来源报告的关于产品和服务问题的信息（例如：政府/行业警告，警报）。

The results of analysis shall be used to evaluate:

应利用分析结果评价：

a. conformity of products and services;

a.产品和服务的符合性；

b. the degree of customer satisfaction;

b.顾客满意程度；

c. the performance and effectiveness of the quality management system;

c.质量管理体系的绩效和有效性；

d. if planning has been implemented effectively;

d.策划是否得到有效实施；

e. the effectiveness of actions taken to address risks and opportunities;

e.针对风险和机遇所采取措施的有效性；

f. the performance of external providers;

f.外部供方的绩效；

g. the need for improvements to the quality management system.

g.质量管理体系改进的需求。

NOTE Methods to analyse data can include statistical techniques.

注：数据分析方法可包括统计技术。

9.2 Internal audit

9.2 内部审核

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

9.2.1 组织应按照策划的时间间隔进行内部审核，以提供有关质量管理体系的下列信息：

a. conforms to:

a.是否符合：

1. the organization's own requirements for its quality management system;

1.组织自身的质量管理体系要求；

2. the requirements of this International Standard;

2.本标准的要求；

b. is effectively implemented and maintained.

b.是否得到有效的实施和保持。

NOTE: When conducting internal audits, performance indicators can be evaluated to determine whether the quality management system is effectively implemented and maintained.

注：当执行内审时，绩效指标可以用于评估确定质量管理体系是否有效实施和保持。

9.2.2 The organization shall:

9.2.2 组织应：

a. plan, establish, implement and maintain an audit programme(s. including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

a. 依据有关过程的重要性、对组织产生影响的变化和以往的审核结果，策划、制定、实施和保持审核方案，审核方案包括频次、方法、职责、策划要求和报告；

b. define the audit criteria and scope for each audit;

b.规定每次审核的审核准则和范围；

c. select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

c.选择审核员并实施审核，以确保审核过程客观公正；

d. ensure that the results of the audits are reported to relevant management;

d.确保将审核结果报告给相关管理者；

e. take appropriate correction and corrective actions without undue delay;

e.及时采取适当的纠正和纠正措施；

f. retain documented information as evidence of the implementation of the audit programme and the audit results.

f.保留形成文件的信息，作为实施审核方案以及审核结果的证据。

NOTE See ISO 19011 for guidance.

注：相关指南参见 GB/T 19011。

9.3 Management review

9.3 管理评审

9.3.1 General

9.3.1 总则

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

最高管理者应按照策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，并与组织的战略方向一致。

9.3.2 Management review inputs

9.3.2 管理评审输入

The management review shall be planned and carried out taking into consideration:

策划和实施管理评审时应考虑下列内容：

a. the status of actions from previous management reviews;

a.以往管理评审所采取措施的情况；

b. changes in external and internal issues that are relevant to the quality management system;

b.与质量管理体系相关的内外部因素的变化；

c. information on the performance and effectiveness of the quality management system, including trends in:

c.下列有关质量管理体系绩效和有效性的信息，包括其趋势：

1. customer satisfaction and feedback from relevant interested parties;

1.顾客满意和相关方的反馈；

2. the extent to which quality objectives have been met;

2.质量目标的实现程度；

3. process performance and conformity of products and services;

3.过程绩效以及产品和服务的符合性；

4. nonconformities and corrective actions;

4.不合格以及纠正措施；

5. monitoring and measurement results;

5.监视和测量结果；

6. audit results;

6.审核结果；

7. the performance of external providers;

7.外部供方的绩效；

8. on-time delivery performance;

8.准时交付绩效。

d. the adequacy of resources;

d.资源的充分性；

e. the effectiveness of actions taken to address risks and

e.应对风险和机遇所采取措施的有效性（见

opportunities (see 6.1.;

6.1.；

f. opportunities for improvement.

f.改进的机会。

9.3.3 Management review outputs

9.3.3 管理评审输出

The outputs of the management review shall include decisions and actions related to:

管理评审的输出应包括与下列事项相关的决定和措施：

a. opportunities for improvement;

a.改进的机会；

b. any need for changes to the quality management system;

b.质量管理体系所需的变更；

c. resource needs.

c.资源需求。

d. risks identified.

d.风险识别。

The organization shall retain documented information as evidence of the results of management reviews.

组织应保留形成文件的信息，作为管理评审结果的证据。

10 Improvement

10 改进

10.1 General

10.1 总则

The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

组织应确定和选择改进机会，并采取必要措施，以满足顾客要求和增强顾客满意。

These shall include:

这应包括：

a. improving products and services to meet requirements as well as to address future needs and expectations;

a.改进产品和服务以满足要求并关注未来的需求和期望；

b. correcting, preventing or reducing undesired effects;

b.纠正、预防或减少不利影响；

c. improving the performance and effectiveness of the quality management system.

c.改进质量管理体系的绩效和有效性。

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

注：改进的例子可包括纠正、纠正措施、持续改进、突破性变革、创新和重组。

10.2 Nonconformity and corrective action

10.2 不合格和纠正措施

10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall:

10.2.1 若出现不合格，包括来自于投诉的不合格，组织应：

a. react to the nonconformity and, as applicable:

a.对不合格做出应对，并在适用时：

1. take action to control and correct it;

1.采取措施以控制和纠正不合格；

2. deal with the consequences;

2.处置所产生的后果。

b. evaluate the need for action to eliminate the cause(s. of the nonconformity, in order that it does not recur or occur elsewhere, by:

b.通过下列活动，评价是否需要采取措施，以消除产生不合格的原因，避免其再次发生或者在其他场合发生：

1. reviewing and analysing the nonconformity;

1.评审和分析不合格；

2. determining the causes of the nonconformity;

2.确定不合格的原因；

3. determining if similar nonconformities exist, or could potentially occur;

3.确定是否存在或可能发生类似的不合格。

c. implement any action needed;

c.实施所需的措施；

d. review the effectiveness of any corrective action taken;

d.评审所采取的纠正措施的有效性；

e. update risks and opportunities determined during planning, if necessary;

e.需要时，更新策划期间确定的风险和机遇；

f. make changes to the quality management system, if necessary.

f.需要时，变更质量管理体系。

g. flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;

g.当确定的不符合的责任者是外部供方时，向供应商传递纠正措施要求；

h. take specific actions when timely and effective corrective actions are not achieved.

h.当不能及时和/或有效地实现纠正措施时采取专门的措施。

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

纠正措施应与所产生的不合格的影响相适应。

The organization shall maintain documented information that defines the nonconformity and corrective action management processes.

组织应保持文件化的信息以规定不合格和纠正措施管理过程。

10.2.2 The organization shall retain documented information as evidence of:

10.2.2 组织应保留形成文件的信息，作为下列事项的证据：

a. the nature of the nonconformities and any subsequent actions taken;

a.不合格的性质以及随后所采取的措施；

b. the results of any corrective action.

b.纠正措施的结果。

10.3 Continual improvement

10.3 持续改进

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

组织应持续改进质量管理体系的适宜性、充分性和有效性。

The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

组织应考虑分析、评价结果以及管理评审的输出，确定是否存在应关注的持续改进的需求和机遇。

The organization shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.

组织应当监视改进活动的实施并评价结果的有效性。

NOTE: Examples of continual improvement opportunities can include lessons learned, problem resolutions, and the benchmarking of best practices.

注：持续改进机会可以包含经验教训、问题的解决和最佳实践的标杆。

ANNEX A – CLARIFICATION OF NEW STRUCTURE, TERMINOLOGY AND CONCEPTS (INFORMATIVE)

附录A - 新结构、术语和概念说明（资料性附录）

A.1 STRUCTURE AND TERMINOLOGY

The clause structure (i.e., clause sequence) and some of the terminology of this edition of this International Standard, in comparison with the previous edition (ISO 9001:2008), have been changed to improve alignment with other management systems standards.

There is no requirement in this International Standard for its structure and terminology to be applied to the documented information of an organization's quality management system.

The structure of clauses is intended to provide a coherent presentation of requirements, rather than a model for documenting an organization's policies, objectives, and processes. The structure and content of documented information related to a quality management system can often be more relevant to its users if it relates to both the processes operated by the organization and information maintained for other purposes.

There is no requirement for the terms used by an organization to be replaced by the terms used in this International Standard to specify quality management system requirements. Organizations can choose to use terms which suit their operations (e.g., using "records", "documentation", or "protocols" rather than "documented information"; or "supplier", "partner", or "vendor" rather than "external provider"). Table A1 shows the major differences in terminology between this edition of this International Standard and the previous edition.

A.1 结构和术语

为了更好地与其他管理体系标准保持一致，与此前的版本（ISO9001:2008）相比，本版标准的章节结构（即章节顺序）和某些术语发生了变更。

本标准未要求在组织质量管理体系的形成文件的信息中应用本标准的结构和术语。

本标准的结构旨在对相关要求进行连贯表述，而不是作为组织的方针、目标和过程的文件结构范本。若涉及组织运行的过程以及出于其他目的而保持信息，则质量管理体系形成文件的信息的结构和内容通常在更大程度上取决于用户的需要。

无需在规定质量管理体系要求时以本标准中使用的术语代替组织使用的术语。组织可以选择使用适合其运行的术语，（例如：可使用“记录”、“文件”或“协议”，而不是“形成文件的信息”；或者使用“供应商”、“伙伴”或“卖方”，而不是“外部供方”）。本版标准与此前版本之间的主要术语差异如表 A.1 所示。

A.2 PRODUCTS AND SERVICES

ISO 9001:2008 used the term "product" to include all output categories. This edition of this International Standard uses "products and services". "Products and services" include all output categories (hardware, services, software, and processed materials).

The specific inclusion of "services" is intended to highlight the differences between products and services in the application of some requirements. The characteristic of services is that at least part of the output is realized at the interface with the customer. This means, for example, that conformity to requirements cannot necessarily be confirmed before service delivery.

In most cases, products and services are used together. Most outputs that organizations provide to customers, or are supplied to them by external providers, include both products and services. For example, a tangible or intangible product can have some associated service or a service can have some associated tangible or intangible product.

A.2 产品和服务

ISO9001:2008 使用的术语“产品”包括所有的输出类别。本版标准则使用“产品和服务”。“产品和服务”包括所有的输出类别（硬件、服务、软件和流程性材料）。

特别包含“服务”,旨在强调在某些要求的应用方面，产品和服务之间存在的差异。服务的特性表明至少有一部分输出，是在与顾客的接触面上实现的。这意味着在提供服务之前不一定能够确认其是否符合要求。

在大多数情况下，“产品和服务”一起使用。由组织向顾客提供的或外部供方提供的大多数输出包括产品和服务两方面。例如：有形或无形产品可能涉及相关的服务，而服务也可能涉及相关的有形或无形产品。

A.3 UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

A.3 理解相关方的需求和期望

Sub-clause 4.2 specifies requirements for the organization to determine the interested parties that are relevant to the quality management system and the requirements of those interested parties. However, 4.2 does not imply extension of quality management system requirements beyond the scope of this International Standard. As stated in the scope, this International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.

4.2 规定的要求包括了组织确定与质量管理体系有关的相关方，并确定来自这些相关方的要求。然而，4.2 并不意味着因质量管理体系要求的扩展而超出了本标准的范围。正如范围中所述，本标准适用于需要证明其有能力持续提供满足顾客要求以及相关法律法规要求的产品和服务，并致力于增强顾客满意的组织。

There is no requirement in this International Standard for the organization to consider interested parties where it has decided that those parties are not relevant to its quality management system. It is for the organization to decide if a particular requirement of a relevant interested party is relevant to its quality management system.

本标准未要求组织考虑其确定的与质量管理体系无关的相关方。有关相关方的某个特定要求是否与其质量管理体系相关，需要由组织自行判断。

A.4 RISK-BASED THINKING

A.4 基于风险的思维

The concept of risk-based thinking has been implicit in previous editions of this International Standard (e.g., through requirements for planning, review, and improvement). This International Standard specifies requirements for the organization to understand its context (see 4.1) and determine risks as a basis for planning (see 6.1). This represents the application of risk-based thinking to planning and implementing quality management system processes (see 4.4), and will assist in determining the extent of documented information.

本标准以前的版本中已经隐含基于风险的思维的概念，如：有关策划、评审和改进的要求。本标准要求组织理解其组织环境（见 4.1），并以确定风险作为策划的基础（见 6.1）。这意味着将基于风险的思维应用于策划和实施质量管理体系过程（见 4.4），并有助于确定形成文件的信息的范围和程度。

One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this International Standard does not have a separate clause or sub-clause on preventive action. The concept of preventive action is expressed through the use of risk-based thinking in formulating quality management system requirements.

质量管理体系的主要用途之一是作为预防工具。因此，本标准并未就“预防措施”设置单独条款或子条款，预防措施的概念是通过在质量管理体系要求中融入基于风险的思维来表达的。

The risk-based thinking applied in this International Standard has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements. There is greater flexibility than in ISO 9001:2008 in the requirements for processes, documented information, and organizational responsibilities.

由于在本标准中使用基于风险的思维，因而一定程度上减少了规定性要求，并以基于绩效的要求替代。在过程、形成文件的信息和组织职责方面的要求比 ISO9001:2008 具有更大的灵活性。

Although 6.1 specifies that the organization shall plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Organizations can decide whether or not to develop a more extensive risk management methodology than is required by this International Standard (e.g., through the application of other guidance or standards).

虽然 6.1 规定组织应策划应对风险的措施，但并未要求运用正式的风险管理方法或将风险管理过程形成文件。组织可以决定是否采用超出本标准要求的更多风险管理方法，如：通过应用其他指南或标准。

Not all the processes of a quality management system represent the same level of risk in terms of the organization’s ability to meet its objectives, and the effects of uncertainty are not the same for all organizations. Under the requirements of 6.1, the organization is responsible for its application of risk-based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks.

在组织实现其预期目标的能力方面，并非质量管理体系的全部过程表现出相同的风险等级，并且不确定性影响对于各组织不尽相同。根据 6.1 的要求，组织有责任应用基于风险的思维，并采取应对风险的措施，包括是否保留形成文件的信息，以作为其确定风险的证据。

Within aviation, space, and defense, risk is expressed as a combination of severity and likelihood of having a potential negative impact to processes, products, services, customer, or end users.

在航空、航天，和国防领域，风险被表述为对过程、产品、服务、客户或最终用户有潜在负面影响的严重度和频度的结合。

Due to the complexity of aviation, space, and defense processes, products, and services, and the severity of the potential consequences of failures, a formal process to manage operational risks is required in clause 8.1.1.

由于航空、航天和国防过程、产品、和服务的复杂性，及潜在失效后果的严重性，在条款 8.1.1 要求建立正式的过程来管理运行风险。

The operational risk management process is supported by specific requirements throughout clause 8, with the goal of developing an enhanced focus on:

运行风险管理过程由整个条款 8 的特定要求支撑，其目的为重点关注：

- understanding risk impacts on operational processes;

- 理解运行过程的风险影响；

- making decisions on operational processes and actions to manage (e.g., prevent, mitigate, control) potential undesired effects.□/□

- 针对运行过程和管理（例如：预防、减缓、控制）潜在不期望的影响的行动做出决策。

□□

A.5 APPLICABILITY

A.5 适用性

This International Standard does not refer to “exclusions” in relation to the applicability of its requirements to the organization’s quality management system. However, an organization can review the applicability of requirements due to the size or complexity of the organization, the management model it adopts, the range of the organization’s activities, and the nature of the risks and opportunities it encounters.

本标准在其要求对组织质量管理体系的适用性方面不使用“删减”一词。然而，组织可根据其规模和复杂程度、所采用的管理模式、活动领域以及所面临风险和机遇的性质，对相关要求的适用性进行评审。

The requirements for applicability are addressed in 4.3, which defines conditions under which an organization can decide that a requirement cannot be applied to any of the processes within the scope of its quality management system. The organization can only decide that a requirement is not applicable if its decision will not result in failure to achieve conformity of products and services.

在 4.3 中有关适用性方面的要求，规定了在什么条件下，组织能确定某项要求不适用于其质量管理体系范围内的过程。只有不实施某项要求不会对提供合格的产品和服务造成不利影响，组织才能决定该要求不适用。

A.6 DOCUMENTED INFORMATION

A.6 形成文件的信息

As part of the alignment with other management system standards, a common clause on “documented information” has been adopted without significant change or addition (see 7.5). Where appropriate, text elsewhere in this International Standard has been aligned with its requirements. Consequently, “documented information” is used for all document requirements.

作为与其他管理体系标准相一致的共同内容，本标准有“形成文件的信息”的条款，内容未做显著变更或增加（见 7.5）。本标准的文本尽可能与其要求相适应。因此，“形成文件的信息”适用于所有的文件要求。

Where ISO 9001:2008 used specific terminology such as document” or “documented procedures”, “quality manual” or “quality plan”, this edition of this International Standard defines requirements to “maintain documented information”.

在 ISO9001:2008 中使用的特定术语如“文件”、“形成文件的程序”、“质量手册”或“质量计划”等，在本版标准中表述的要求为“保持形成文件的信息”。

Where ISO 9001:2008 used the term “records” to denote documents needed to provide evidence of conformity with requirements, this is now expressed as a requirement to “retain documented information”. The organization is responsible for determining what documented information needs to be retained, the

在 ISO9001:2008 中使用“记录”这一术语表示提供符合要求的证据所需要的文件，现在表述的要求为“保留形成文件的信息”。组织有责任确定需要保留的形成文件的信息及其存储时间和所用载体。

period of time for which it is to be retained, and the media to be used for its retention.

A requirement to “maintain” documented information does not exclude the possibility that the organization might also need to “retain” that same documented information for a particular purpose (e.g., to retain previous versions of it).

“保持”形成文件的信息的要求并不排除基于特殊目的，组织也可能需要“保留”同一形成文件的信息，如：保留其先前版本。

Where this International Standard refers to “information” rather than “documented information” (e.g., in 4.1: “The organization shall monitor and review the information about these external and internal issues”), there is no requirement that this information is to be documented. In such situations, the organization can decide whether or not it is necessary or appropriate to maintain documented information.

若本标准使用“信息”一词，而不是“形成文件的信息”（如在 4.1 中“组织应对这些内部和外部因素的相关信息进行监视和评审”），则并未要求将这些信息形成文件。在这种情况下，组织可以决定是否有必要或适合保持形成文件的信息。

A.7 ORGANIZATIONAL KNOWLEDGE

A.7 组织的知识

In 7.1.6, this International Standard addresses the need to determine and manage the knowledge maintained by the organization, to ensure the operation of its processes and that it can achieve conformity of products and services.

本标准在 7.1.6 中要求组织确定并管理其持有的知识，以确保其过程的运行，并能够提供合格的产品和服务。

Requirements regarding organizational knowledge were introduced for the purpose of:

引入组织的知识的要求的目的是：

a. safeguarding the organization from loss of knowledge, e.g.,

a.避免组织丧失其知识，如：

− through staff turnover;

-由于员工更替；

− failure to capture and share information;

-未能获取和共享信息。

b. encouraging the organization to acquire knowledge, e.g.,

b.鼓励组织获取知识，如：

− learning from experience;

-总结经验；

− mentoring;

-专家指导；

− benchmarking.

-标杆比对。

A.8 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS, AND SERVICES

A.8 外部提供过程、产品和服务的控制

All forms of externally provided processes, products, and services are addressed in 8.4, e.g., whether through:

在 8.4 中提出了所有形式的外部提供产品和服务，如是否通过：

a. purchasing from a supplier;

a.从供方采购；

b. an arrangement with an associate company;

b.关联公司的安排；

c. outsourcing processes to an external provider.

c.将过程分包给外部供方。

Outsourcing always has the essential characteristic of a service, since it will have at least one activity necessarily performed at the interface between the provider and the organization.

外包总是具有服务的基本特征，因为这至少要在供方与组织之间的接触面上实施一项活动。

The controls required for external provision can vary widely depending on the nature of the processes, products, and services. The organization can apply risk-based thinking to determine the type and extent of controls appropriate to particular external providers and externally provided processes, products, and services.

由于过程、产品和服务的性质，外部提供所需的控制可能存在很大差异。对外部供方以及外部提供的过程、产品和服务，组织可以应用基于风险的思维来确定适当的控制类型和控制程度。