AEROSPACE STANDARD **航空航天标准**	**9100**	
	Issued 15 March 2016 发布时间：2016-3-15 **Superseding January 2009** 替代版本：2009-01 **Technically equivalent writings published in all IAQG sectors.** 技术评价稿发布给 IAQG 的所有成员	

(R) Quality Management Systems – Requirements for Aviation, Space, and Defense Organizations

（R）质量管理体系——航空、航天和国防组织的要求

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RATIONALE

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.

依据

本标准的此次修订纳入了ISO 9001:2015 新的条款结构和内容。此外，行业要求、定义和注也根据 ISO 9001 标准的修订内容和利益相关方的需求进行了修订。

FOREWORD

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.

前言

为确保顾客满意，航空、航天和国防组织必须提供并持续改进满足或超越顾客和适用的法律法规要求的安全和可靠的产品和服务。行业的全球化及其带来的地区和国家要求与期望的多样性，使该目标更为复杂。组织面临着从全世界范围内在供应链各个层级的外部供方采购产品和服务的挑战。外部供方面临着将产品和服务交付给有多样质量要求和期望的众多顾客的挑战。

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.

为显著改进质量并降低贯穿价值流的成本，美洲、亚太和欧洲的航空、航天和国防的企业代表建立了行业的“国际航空航天质量组织”（IAQG），本标准由“国际航空航天质量组织”（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

本标准尽可能地在最大程度上使质量管理体系的要求标准化，可供全世界各组织用于供应链的各个层级。通过减少或消除组织独特的要求、有效实施质量管理体系并更广泛地应用好的实践，本标准的应用能改进质量、成本和交付绩效。本标准虽然主要是为航空、航天和国防工业开发的，但也可用于那些质量管理体系需要在 ISO9001 体系基础上有附加要求的其他行业。

an ISO 9001 system is needed.

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

本标准包括了 ISO 9001:2015 质量管理体系的要求，并以斜粗体表示其所规定的附加的航空、航天和国防的行业要求、定义和注。

INTENDED APPLICATION

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, or materials for their own products and services.

预期应用

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的组织，以及提供交付后活动（包括为自己的产品和服务提供维修、备件或材料）的组织。

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：产品是交付软件或者是包括交付软件的组织，在策划和评估其软件设计、开发或者管理活动时，宜使用 IAQG 编制的 9115 标准（见参考文献）。9115 标准为意在 9100 质量管理体系范围中加入"软件"的组织提供了指南。

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 operated autonomously, or that are substantially different from their production operations; should use the IAQG-developed 9110 standard (see Bibliography).

主营业务是为民用或者军用航空零部件和产品提供维修或者持续适航管理服务的组织，以及维修，修理以及翻修独立运行或与生产运行有实质区别的的原始设备制造商，宜使用 IAQG 编制的 9110 标准（见参考文献）。

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、材料和组件，再将这些产品转售给航空、航天和国防行业的顾客的组织宜使用 IAQG 编制的 9120 标准（见参考文献）。这也包括采购产品，再将产品分成较小批量转售的组织，以及协调涉及产品的过程受顾客或当局控制的组织。

INTRODUCTION

0.1 General

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.

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

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

b. Facilitating opportunities to enhance customer satisfaction;

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

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

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

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

– 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.

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

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

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

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that

引言

0.1 总则

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。

组织根据本标准实施质量管理体系具有如下潜在益处：

a）稳定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）促成增强顾客满意的机会；

c）应对与其环境和目标相关的风险和机遇；

d）证实符合规定的质量管理体系要求的能力。

内部和外部各方均可使用本标准。

实施本标准并不意味着需要：

——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。

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。

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。

过程方法能使组织策划其过程及其相互作用。

PDCA 循环使得组织确保对其过程得到充分的资源和管理，确定改进机会并采取行动。

opportunities for improvement are determined and acted on.

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).

基于风险的思维使得组织能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，采取预防措施，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，比如突破性变革、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”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

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.

0.2 质量管理原则

本标准是在 ISO 9000 所描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概述、该原则对组织的重要性的依据、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

0.3.1 General

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.

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.

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.

The application of the process approach in a quality management system enables:

a. understanding and consistency in meeting requirements;

b.the consideration of processes interms of added value;

c. the achievement of effective process performance;

d.improvement of processes based on evaluation of data and information.

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.

0.3.2 Plan-Do-Check-Act Cycle

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

0.3 过程方法

0.3.1 总则

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。

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，以提高组织整体绩效。

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，进行系统的规定和管理，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)对过程和整个体系进行管理，旨在有效利用机遇并防止发生不良结果。

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。

单一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，这些检查点根据相关的风险有所不同。

0.3.2 策划-实施-检查-处置循环

PDCA 循环能够应用于所有过程以及整个质量管理体系。图 2 表明了本标准第 4 章至第 10 章是

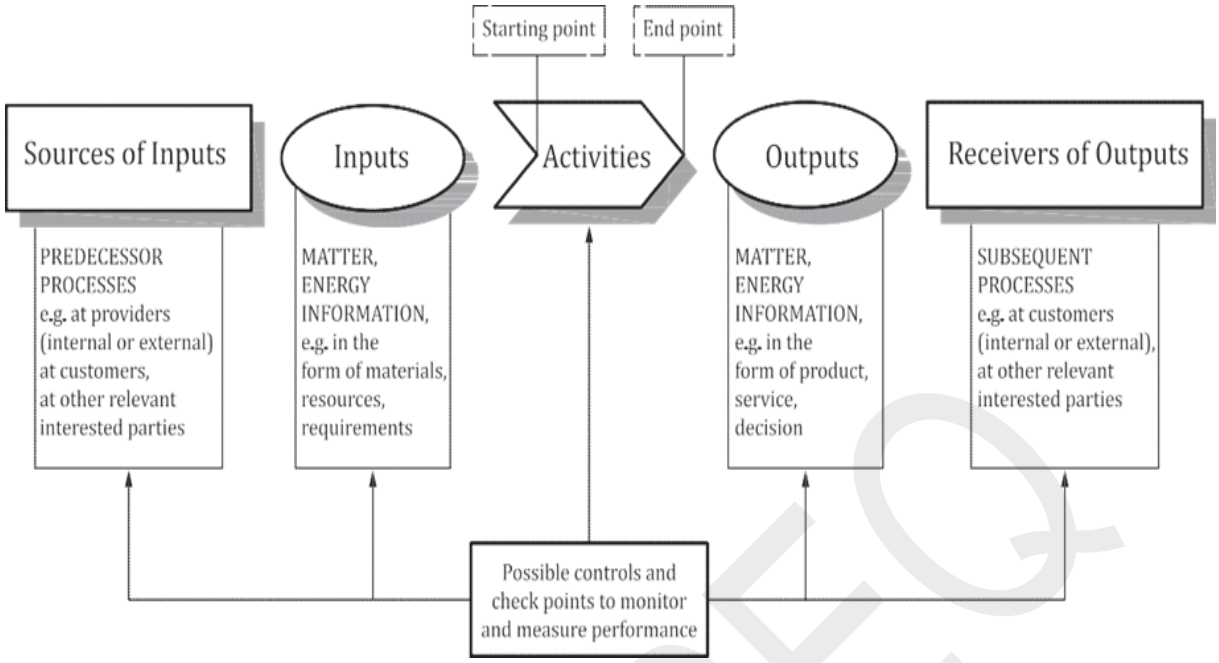


FIGURE 1 - SCHEMATIC REPRESENTATION OF THE ELEMENTS OF A SINGLE PROCESS

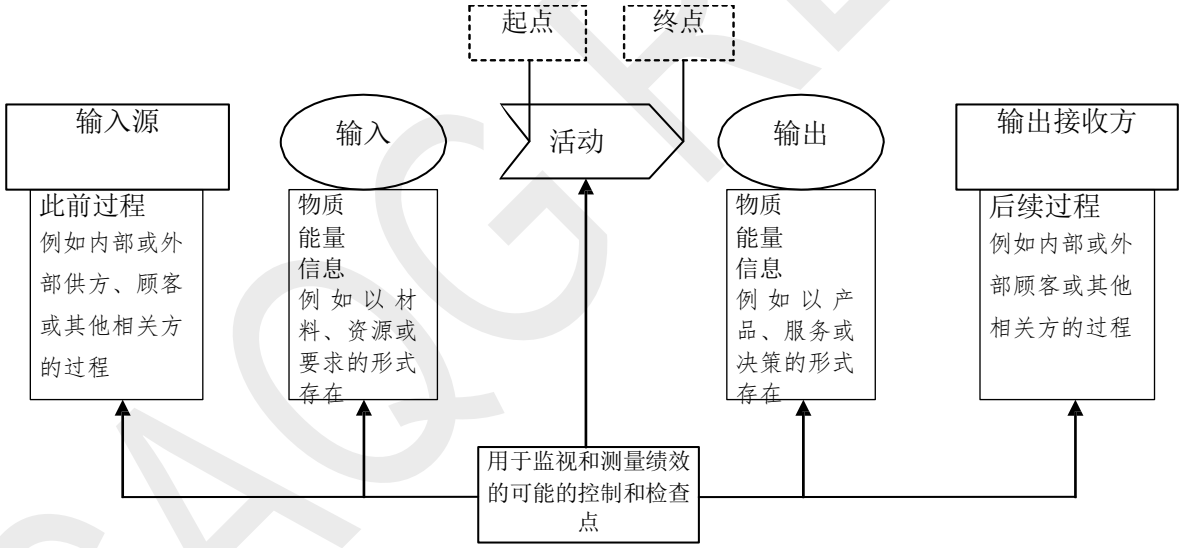


图 1： 单一过程要素示意图

how clauses 4 to 10 can be grouped in relation to the PDCA cycle.

如何构成 PDCA 循环的。

The PDCA cycle can be briefly described as follows:

– 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;

– Do: implement what was planned;

– Check: monitor and (where applicable) measure processes and the resulting products and services against

PDCA 循环可以简要描述如下：

——策划(Plan)：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；

——实施(Do)：执行所做的策划；

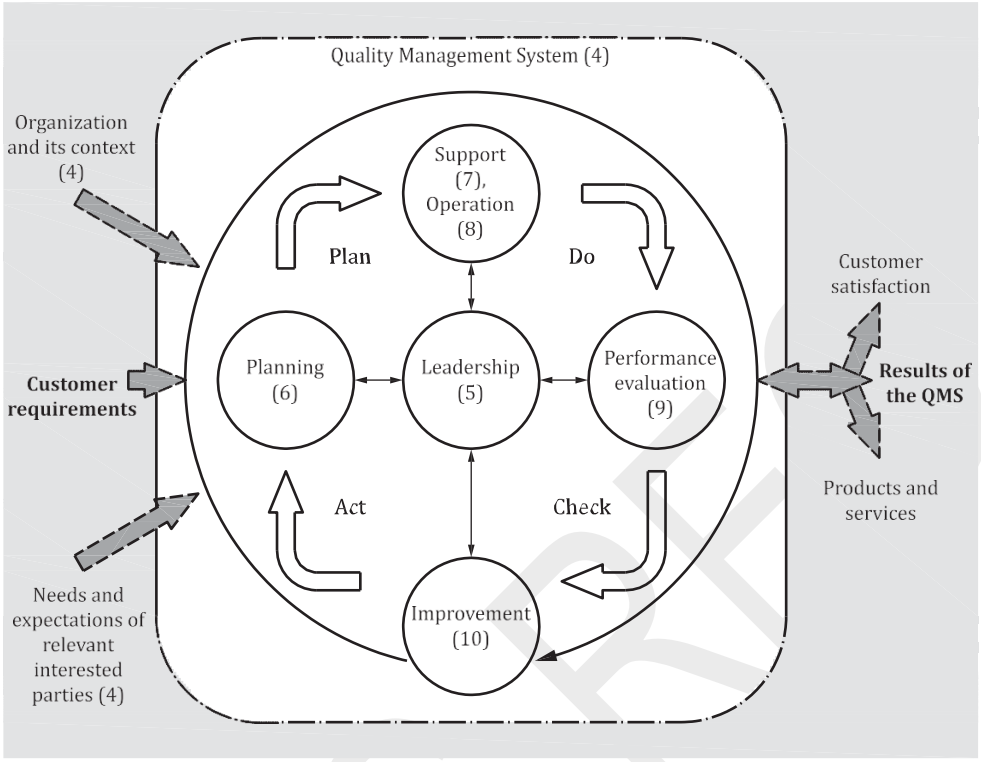
——检查(Check)：根据方针、目标、要求和所策划的活动，对过程以及形成的产品和服务进

policies, objectives, requirements, and planned activities, and report the results;

行监视和测量(适用时),并报告结果;

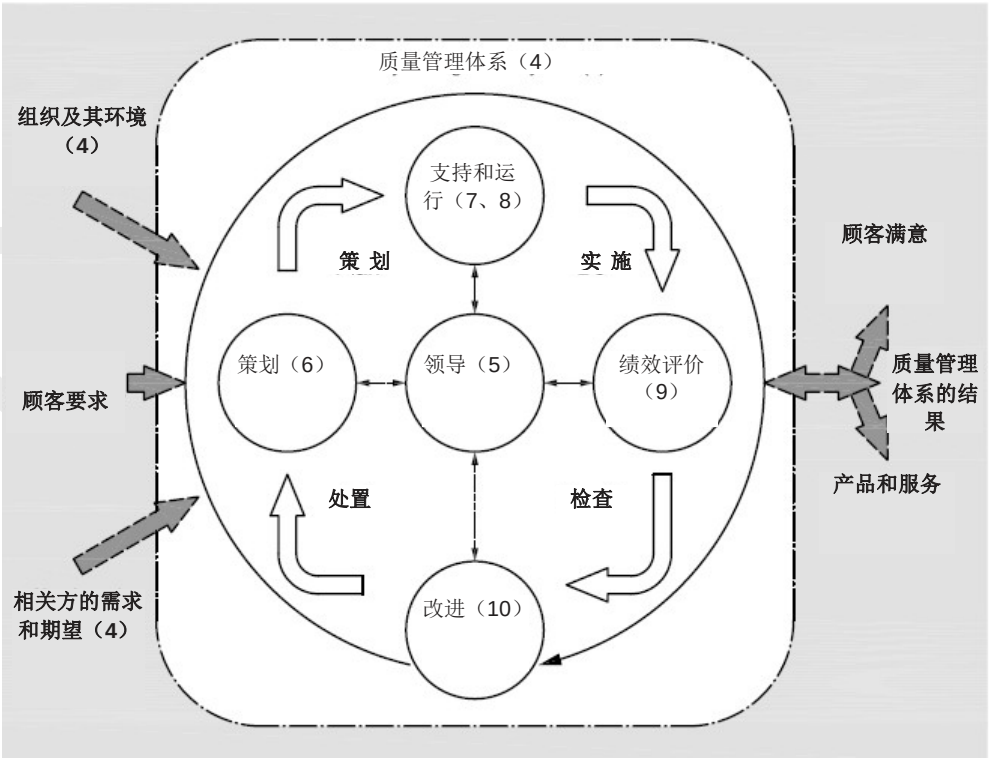
– Act: take actions to improve performance, as necessary.

——处置(Act):必要时,采取措施提高绩效。



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

FIGURE 2 - REPRESENTATION OF THE STRUCTURE OF THIS INTERNATIONAL STANDARD IN THE PDCA CYCLE



注：括号中的数字表示本标准的相应章节。

图 2： 本标准的基本结构适用 PDCA 循环示意图

0.3.3 Risk-based Thinking

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.

0.3.3 基于风险的思维

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基础。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机遇的措施。应对风险和机遇为提高质量管理体系有效性、获得改进结果以及防止不利影响奠定了基础。

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.

某些有利于实现预期结果的情况可能导致机遇的出现，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相关风险。风险是不确定性的影响，不确定性可能有正面的影响，也可能有负面的影响。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

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

0.4 与其他管理体系标准的关系

本标准采用ISO制订的管理体系标准框架，以提高与其他管理体系标准的协调一致性（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:

– ISO 9000, "*Quality management systems – Fundamentals and vocabulary*", provides essential background for the proper understanding and implementation

本标准与ISO 9000和ISO 9004存在如下关系：

——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；

of this International Standard;

– 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》为选择超出本标准要求的组织提供指南。

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制订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，而另外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/TC 176/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 quality management system requirements and specifies additional aviation, space, and defense industry requirements, definitions, and notes.

本标准包括ISO 9001:2015质量管理体系要求，并规定了附加的航空、航天和国防的行业要求、定义和注。

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

要强调的是，本标准规定的要求是对顾客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

如果本标准的要求与顾客或适用法律法规要求之间有冲突，应以后者优先。

regulatory requirements, the latter shall take precedence.

This International Standard specifies requirements for a quality management system when an organization:
a. needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
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.

本标准为下列组织规定了质量管理体系要求：

a）需要证实其具有稳定提供满足顾客要求及适用法律法规要求的产品和服务的能力；

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：本标准中的术语“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：法律法规要求可称为法定要求。

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 9000:2015 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***.***

ISO9000:2015界定的*以及下列*术语与定义适用于本文件。

3.1 Counterfeit Part

3.1 假冒件

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.

有意冒充特定的原始或授权制造商真件的未经授权的复制、仿制、替代或改装件（如材料、零件、部件）。

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.

注：假冒件的例子包括但不限于虚假的标记或标签、等级、序列号、日期代码、文件或性能特性。

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.

3.2 关键项
对产品和服务的提供和使用，包括安全性、性能、形状、配合、功能、可生产性、使用寿命等有显著影响的，要求专门措施来确保它们被充分控制的那些项（如功能、零件、软件、特性、过程等）。关键项的例子包括安全性关键项、断裂关键项、任务关键项、关键特性等。

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.

3.3 关键特性
其波动对产品配合、形状、功能、性能、使用寿命或可生产性有显著影响的属性或特性，要求专门措施来控制其波动。

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.

3.4 产品安全
产品能实现其设计或预期的目的，而对人身伤害或财产损失的风险不会达到不可接受程度的状态。

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.

3.5 特殊要求
那些由顾客识别或组织确定的要求，满足这些要求具有高风险，因而将它们包括在风险管理过程中。确定特殊要求时所考虑的因素包括产品或者过程的复杂性、过去的经验以及产品或过程的成熟度。特殊要求的例子包括顾客坚持的处于行业能力极限的性能要求，或组织确定的处于其技术或过程能力极限的要求。

NOTE:Specialrequirements(3.5)andcriticalitems(3.2),alon

注：特殊要求（3.5）和关键项（3.2）连同关键特性，

gwithkey 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 critical items. Design output (see 8.3.5) can include dentification 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.

都是互相关联的。特殊要求在确定和评审与产品有关的要求时进行识别（见8.2.2和8.2.3），特殊要求可能要求识别关键项。设计输出（见8.3.5）可包括要求专门措施的关键项的识别，以确保其得到充分控制。有些关键项由于其波动需要受控，将进一步分为若干关键特性。

4. CONTEXT OF THE ORGANIZATION

4 组织环境

4.1 Understanding the Organization and its Context

4.1 理解组织及其环境

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.

组织应对这些外部和内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、社会和经济环境的因素，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:

由于相关方对组织稳定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）与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.

组织应监视和评审这些相关方的信息及其相关要求。

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 in4.1;

a）4.1中提及的各种外部和内部因素；

b.the requirements of relevant interested parties referred to in4.2;

b）4.2中提及的相关方的要求；

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，组织应实施本标准的全部要求。

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成文信息，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.

只有所确定的不适用的要求不影响组织确保其产品和服务合格的能力或责任，对增强顾客满意也不会产生影响，方可声称符合本标准的要求。

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同样应满足顾客和适用的法律法规的质量管理体系的要求。

The organization shall determine the processes needed for

组织应确定质量管理体系所需的过程及其在

the quality management system and their application throughout the organization, and shall:

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），以确保这些过程的有效运行和控制；

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获得；

e. assign the responsibilities and authorities for these processes;

e）分配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）按照6.1的要求应对风险和机遇；

g. evaluate these processes and implement any changes needed to ensuret hat 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:

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

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

4.4.2 在必要的范围和程度上，组织应：

a）保持成文信息以支持过程运行；

b）保留成文信息以确信其过程按策划进行。

The organization shall establish and maintain documented information that includes:

- ***a general description of relevant interested parties (see 4.2 a);***
- ***the scope of the quality management system, including boundaries and applicability (see 4.3);***
- ***a description of the processes needed for the quality management system and their application throughout the organization;***
- ***the sequence and interaction of these processes;***
- ***assignment of the responsibilities and authorities for these processes.***

组织应建立并保持成文信息，包括：

——有关的相关方综述（见4.2a）；

——质量管理体系的范围，包括边界和适用性（见4.3）；

——质量管理体系所需的过程的描述和其在整个组织中的应用；

——这些过程的顺序和相互作用；

—这些过程的职责和权限的分配。

NOTE: The above description of the quality management system can be compiled into a single

注：质量管理体系的上述描述可以汇编成一份单一的成文信息，称之为质量手册。

source of documented information and referred to as a quality manual.

5. LEADERSHIP

5.1 Leadership and Commitment

5.1.1 General

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

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

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;

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

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

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

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

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

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

i. promoting improvement;

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

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.

5.1.2 Customer Focus

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

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

b. the risks and opportunities that can affect conformity of

5 领导作用

5.1 领导作用和承诺

5.1.1 总则

最高管理者应通过以下方面，证实其对质量管理体系的领导作用和承诺：

a）对质量管理体系的有效性负责；

b）确保制订质量管理体系的质量方针和质量目标，并与组织环境相适应，与战略方向相一致；

c）确保质量管理体系要求融入组织的业务过程；

d）促进使用过程方法和基于风险的思维；

e）确保质量管理体系所需的资源是可获得的；

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）确保质量管理体系实现其预期结果；

h）促使人员积极参与，指导和支持他们为质量管理体系的有效性做出贡献；

i）推动改进；

j）支持其他相关管理者在其职责范围内发挥领导作用。

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,无论是公有、私有、营利或非营利组织。

5.1.2 以顾客为关注焦点

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）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）确定和应对风险和机遇，这些风险和机遇

products and services and the ability to enhance customer satisfaction are determined and addressed;
c. the focus on enhancing customer satisfaction is maintained;
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.

可能影响产品和服务合格以及增强顾客满意能力；
c）始终致力于增强顾客满意；
d）测量产品和服务的符合性和按时交付绩效，当策划的结果不能或将不能实现时，采取适当的措施。

5.2 Policy
5.2.1 Establishing the Quality Policy
Top management shall establish, implement, and maintain a quality policy that:
a.is appropriate to the purpose and context of the organization and supportsits strategic direction;
b.provides a framework for setting quality objectives;
c.includes a commitment to satisfy applicable requirements;
d.includes a commitment to continual improvement of the quality management system.

5.2 方针
5.2.1 制定质量方针
最高管理者应制定、实施和保持质量方针，质量方针应：
a）适应组织的宗旨和环境并支持其战略方向；
b）为建立质量目标提供框架；
c）包括满足适用要求的承诺；
d）包括持续改进质量管理体系的承诺。

5.2.2 Communicating the Quality Policy The quality policy shall:
a. be available and maintained as documented information;
b. be communicated,understood,and applied within the organization;
c. be available to relevant interested parties, as appropriate.

5.2.2 沟通质量方针
质量方针应：
a）可获取并保持为成文信息；
b）在组织内得到沟通、理解和应用；
c）适宜时，可为有关相关方所获取。

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

5.3 组织内的角色、职责和权限
最高管理者应确保组织内相关角色的职责、权限得到分配、沟通和理解。

Top management shall assign the responsibility and authority for:
a.ensuring that the quality management system conforms to the requirements of this International Standard;
b.ensuring that the processes are delivering their intended outputs;
c.reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;
d. ensuring the promotion of customer focus throughout the organization;
e. ensuring that the integrity of the quality management system is maintained when changes to the quality

最高管理者应分配职责和权限，以：
a）确保质量管理体系符合本标准的要求；
b）确保各过程获得其预期输出；
c）报告质量管理体系的绩效以及改进机会（见10.1），特别是向最高管理者报告；
d）确保在整个组织推动以顾客为关注焦点；
e）确保在策划和实施质量管理体系变更时保持其完整性。

management system are planned and implemented.

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.

最高管理者应在本组织管理层中指定一名特定的成员作为管理者代表，管理者代表应具有对以上要求进行监督的职责和权限。

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

为解决质量管理问题，管理者代表应在组织内可自由地和不受限制地接触最高管理者。

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

注：管理者代表的职责包括与外部各方联络质量管理体系有关事宜。

6. PLANNING

6.1 Actions to Address Risks and Opportunities

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:

a. give assurance that the quality management system can achieve its intended result(s);

b. enhance desirable effects;

c. prevent, or reduce, undesired effects;

d. achieve improvement.

6.1.2 The organization shall plan:

a. actions to address these risks and opportunities;

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.

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

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.

NOTE 2: Opportunities can lead to the adoption of new

6 策划

6.1 应对风险和机遇的措施

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

a）确保质量管理体系能够实现其预期结果；

b）增强有利影响；

c）预防或减少不利影响；

d）实现改进。

6.1.2组织应策划：

a）应对这些风险和机遇的措施；

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。

应对措施应与风险和机遇对产品和服务符合性的潜在影响相适应。

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，或通过慎重决策保留风险。

注2:机遇可能导致采取新实践，推出新产品，开辟新

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.

的市场，赢的新客户，建立合作伙伴关系，利用新技术和其他可行之处，以应对组织或其顾客的需求。

6.2 Quality Objectives and Planning to Achieve Them

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

The quality objectives shall:

a. be consistent with the quality policy;
b. be measurable;
c. take into account applicable requirements;
d. be relevant to conformity of products and services and to enhancement of customer satisfaction;
e. be monitored;
f. be communicated;
g. be updated,as appropriate.

The organization shall maintain documented information on the quality objectives.

6.2 质量目标及其实现的策划

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。

质量目标应：

a）与质量方针保持一致；
b）可测量；
c）考虑适用的要求；
d）与产品和服务合格以及增强顾客满意相关；
e）予以监视；
f）予以沟通；
g）适时更新。

组织应保持有关质量目标的成文信息。

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

a. what will be done;
b. what resources will be required;
c. who will be responsible;
d. when it will be completed;
e. how the results will be evaluated.

6.2.2策划如何实现质量目标时，组织应确定：

a）要做什么；
b）需要什么资源；
c）由谁负责；
d）何时完成；
e）如何评价结果。

6.3 Planning of Changes

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).

The organization shall consider:

a. the purpose of the changes and their potential consequences;
b. the integrity of the quality management system;
c. the availability of resources;
d. the allocation or reallocation of responsibilities and authorities.

6.3 变更的策划

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）。

组织应考虑：

a）变更目的及其潜在后果；
b）质量管理体系的完整性；
c）资源的可获得性；
d）职责和权限的分配或再分配。

7. SUPPORT

7.1 Resources

7 支持

7.1 资源

7.1.1 General
the organization shall determine and provide the resources needed for the establishment, implementation, maintenance, and continual improvement of the quality management system.
The organization shall consider:
a. the capabilities of,and constraintson,existing internal resources;
b. what needs to be obtained from external providers.

7.1.1 总则
组织应确定并提供所需的资源，以建立、实施、保持和持续改进质量管理体系。

组织应考虑：
a）现有内部资源的能力和局限性；
b）需要从外部供方获得的资源。

7.1.2 People
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.

7.1.2 人员
组织应确定并配备所需要的人员，以有效实施质量管理体系并运行和控制其过程。

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

7.1.3 基础设施
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:
a. buildings and associated utilities;
b. equipment,including hardware and software;
c. transportation resources;
d. information and communication technology.

注：基础设施可包括：
a）建筑物和相关设施；
b）设备，包括硬件和软件；
c）运输资源；
d）信息和通讯技术。

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

7.1.4 过程运行环境
组织应确定、提供并维护所需要的环境，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:
a. social(e.g.,non-discriminatory,calm,non-confrontational);
b. psychological(e.g.,stress-reducing,burn out prevention,emotionally protective);
c. physical (e.g., temperature, heat, humidity, light, airflow, hygiene, noise).

注：适宜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）社会因素（如非歧视、安定、非对抗）；
b）心理因素（如减压、预防过度疲劳、保证情绪稳定）；
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 监测和测量资源

7.1.5.1 General
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.

7.1.5.1总则
当利用监视或测量来验证产品和服务符合要求时，组织应确定并提供所需的资源，以确保结果有效和可靠。

The organization shall ensure that the resources provided:
a. are suitable for the specific type of monitoring and measurement activities being undertaken;
b. are maintained to ensure their continuing fitness for their purpose.

组织应确保所提供的资源：
a）适合所开展的监视和测量活动的特定类型；
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.

组织应保留适当的成文信息,作为监视和测量资源适合其用途的证据。

7.1.5.2 Measurement Traceability
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:
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;
b. identified inorder to determine their status;
c. safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results.

7.1.5.2 测量溯源
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基础时，测量设备应：
a）对照能溯源到国际或国家标准的测量标准，按照规定的时间间隔或在使用前进行校准和（或）检定，当不存在上述标准时，应保留作为校准或验证依据的成文信息；
b）予以标识，以确定其状态；
c）予以保护，防止由于调整、损坏或衰减所导致的校准状态和随后的测量结果的失效。

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、实施和保持一个用于召回需要校准或检定(验证)的监视和测量设备的过程。

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.

组织应保持监视和测量设备的清单。该清单应包括设备型号、唯一性标识、位置和校准或检定（验证）方法、频率与接收准则。

NOTE: Monitoring and measuring equipment can include,but are not limited to: test hardware, test

注：监视和测量设备包括但不限于试验硬件、试验软件、自动化的测试设备（ATE）和用于生成验证数据的绘

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.

图仪，也包括个人所有的和顾客提供的用于提供产品和服务合格证据的设备。

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

监视和测量设备的校准或检定（验证）应在适宜的环境条件下（见7.1.4）进行。

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

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

7.1.6 组织的知识

组织应确定必要的知识，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，并能在所需的范围内可得到。

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，确定如何获取或接触更多必要的知识和知识更新。

NOTE 1: Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization’s objectives.

注1：组织的知识是组织特有的知识，通常从其经验中获得。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，从失败和成功项目吸取的经验教训，获取和分享未成文的知识和经验，过程、产品和服务的改进结果)；

b. externalsources(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

The organization shall:

a. determine the necessary competence of person(s) doing

7.2 能力

组织应：

a）确定在其控制下工作的人员所具备的能

work under its control that affects the performance and effectiveness of the quality management system;
b. ensure that these persons are competent on the basis of appropriate education, training, or experience;
c. where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
d. retain appropriate documented information as evidence of competence.

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）基于适当的教育、培训或经验，确保这些人员是胜任的；
c）适用时，采取措施以获得所需的能力，并评价措施的有效性；
d）保留适当的成文信息，作为人员能力的证据。

NOTE: Consideration should be given for the periodic review of the necessary competence.
NOTE: Applicable actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

注：考虑对必要能力进行定期评审。
注:适用措施可包括对在职人员进行培训、辅导或重新分配工作,或者聘用、外包胜任的人员。

7.3 Awareness
The organization shall ensure that persons doing work under the organization's control are aware of:
a. the quality policy;
b. relevant quality objectives;
c. their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
d. the implications of notconforming with the quality management system requirements***;***
e. relevant quality management system documented information and changes there to;
f. their contribution to product or service conformity;
g. their contribution to product safety;
h. the importance of ethical behavior.

7.3 意识
组织应确保在其控制下工作的人员知晓：
a）质量方针；
b）相关质量目标；
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）不符合质量管理体系要求的后果；
e）有关质量管理体系的成文信息及其更改；
f）他们对于产品或服务符合性的贡献；
g）他们对产品安全的贡献；
h）道德行为的重要性。

7.4 Communication
The organization shall determine the internal and external communications relevant to the quality management system, including:
a. on what it will communicate;
b. when to communicate;
c. with whom to communicate;
d. how to communicate;
e. who communicates.

7.4 沟通
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）沟通什么；
b）何时沟通；
c）与谁沟通；
d）如何沟通；
e）谁来沟通。

NOTE: Communication should include internal and
注：沟通宜包含关于质量管理体系的内部和外部的反

external feedback relevant to the quality management system.

馈。

7.5 Documented Information

7.5.1 General

The organization's quality management system shall include:

a. documented information required by this International Standard;

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

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

- the size of organization and its type of activities, processes, products, and services;
- the complexity of processes and their interactions;
- the competence of persons.

7.5 成文信息

7.5.1 总则

组织的质量管理体系应包括：

a）本标准要求的成文信息；

b）组织确定的为确保质量管理体系有效性所需的成文信息。

注：对于不同组织，质量管理体系成文信息的多少与详略程度可以不同，取决于：

——组织的规模，以及活动、过程、产品和服务的类型；

——过程及其相互作用的复杂程度；

——人员的能力。

7.5.2 Creating and Updating

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

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

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

c. review and approval for suitability and adequacy.

NOTE: Approval implies authorized persons and approval methods are identified for the relevant types of documented information, as determined by the organization.

7.5.2 创建和更新

在创建和更新成文信息时，组织应确保适当的：

a）标识和说明（如标题、日期、作者、索引编号等）；

b）形式（如语言、软件版本、图表）和载体（如纸质的、电子的）；

c）评审和批准，以保持适宜性和充分性。

注：批准意味着对组织确定的相关类型的成文信息规定了授权人员和批准方法。

7.5.3 Control of Documented Information

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

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

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

7.5.3 成文信息的控制

7.5.3.1 应控制质量管理体系和本标准所要求的成文信息，以确保：

a）在需要的场合和时机,均可获得并适用；

b）予以妥善保护(如防止泄密、不当使用或缺失)。

7.5.3.2 For the control of documented information, the

7.5.3.2 为控制成文信息，适用时，组织应进行

organization shall address the following activities, as applicable:

a. distribution,access,retrieval,anduse;

b. storage and preservation,including preservation of legibility;

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

d. retention and disposition***;***

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.

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.

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

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

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.

下列活动：

a）分发、访问、检索和使用；

b）存储和防护，包括保持可读性；

c)更改控制(如版本控制)；

d）保留和处置；

e）通过清除作废成文信息防止其非预期使用；如果出于某种目的而保留作废成文信息，应采用适当的标识或者控制以防止其非预期使用。

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成文信息,组织应进行适当识别,并予以控制。

对所保留的、作为符合性证据的成文信息应予以保护,防止非预期的更改。

电子化管理成文信息时，应规定数据保护过程（如防止丢失、未授权更改、非预期修改、损坏或物理损毁）。

注：成文信息的“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

8.1 Operational Planning and Control

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:

a.determining the requirements for the products and services;

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

- ***personal and product safety;***
- ***producibility and inspectability;***
- ***reliability, availability, and maintainability;***
- ***suitability of parts and materials used in the product;***
- ***selection and development of embedded software;***
- ***product obsolescence;***

8 运行

8.1 运行的策划和控制

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）确定产品和服务的要求；

注:产品和服务的要求的确定宜包括以下几个方面的考虑：

——人员与产品安全；

——可生产性和可检验性；

——可靠性、可用性和维修性；

——产品中使用的零件与材料的适宜性；

——嵌入式软件的选择与开发；

——产品过时；

- ***prevention, detection, and removal of foreign objects;***
- ***handling, packaging, and preservation;***
- ***recycling or final disposal of the product at the end of its life.***

——多余物的预防、探测和排除；

——搬运、包装和防护；

——寿命终止时，产品的回收或最终处置。

b. establishing criteria for:

1. the processes;
2. the acceptance of products and services;

b）建立下列内容的准则：

1）过程；

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:

- ***design verification (e.g., reliability, maintainability, product safety);***
- ***process control;***
  - ***selection and verification of key characteristics;***
  - ***process capability measurements;***
  - ***statistical process control;***
  - ***design of experiments;***
- ***verification;***
- ***failure mode, effects, and criticality analysis.***

注:根据产品的性质并依据特定要求，可使用统计技术以支持：

——设计验证（如可靠性、维修性、产品安全）；

——过程控制；

- ***关键特性的选择和验证；***
- ***过程能力的测量；***
- ***统计过程控制；***
- ***实验设计；***

——验证；

——失效模式，影响和后果分析。

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） 确定所需的资源以使产品和服务符合要求***并按时交付***;

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 to the extent necessary:

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

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

e）在必要的范围和程度上,确定并保持、保留成文信息：

1)确信过程已经按策划进行；

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）确定管理关键项所需的过程和控制，包括关键特性已被识别时的生产过程控制；

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

g）受影响的组织职能代表积极参与运行的策划和控制；

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

h）确定过程和资源，以支持产品和服务的使用和维护；

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）建立防止不合格的产品和服务交付给顾客所需的控制。

NOTE: One method to achieve operational planning and

注：使用整合的阶段化过程是实现运行策划和控制的

control can be through using integrated phased processes.

一种方法。

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.

当适合于组织、顾客要求及产品和服务时，组织应以结构化和受控的方式，包括按照计划的顺序完成预定的事项，来策划和管理产品和服务的提供，以在可接受的风险水平上、在限定的资源与进度条件下满足要求。

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

注:此活动通常被称为项目策划、项目管理或项目集管理。

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。

NOTE: As an out put 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:作为此策划的一项输出，对应用于特定的产品、服务、项目或合同的质量管理体系过程和资源作出规定的成文信息可被称为质量计划。

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 transfer impacts and risks are managed.

组织应建立、实施和保持一个过程，用于策划和控制暂时或永久性工作转移，以确保工作持续符合要求。该过程应确保工作转移的影响和风险得到管理。

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:关于从组织到外部供方，或从一个外部供方到另一个外部供方的工作转移的控制，见8.4。关于从组织内部的一处设施到另一处设施，或从外部供方到组织的工作转移的控制，见8.5。

8.1.1 Operational Risk Management

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:

a. assignment of responsibilities for operational risk management;

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

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

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

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

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).

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.

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:

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

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.

8.1.3 Product Safety

8.1.1 运行风险管理

组织应策划、实施和控制一个过程，用于管理运行风险，以满足适用要求。当适合于组织及产品和服务时，该过程包括：

a）分配运行风险管理的职责；

b）规定风险评估准则（如可能性、影响、风险可接受度）；

c）在整个运行过程中的风险识别、评估和沟通；

d）当超出规定的风险接受准则时，确定、实施并管理风险的措施；

e）风险措施实施后的剩余风险的可接受度。

注1：尽管6.1条阐述了组织策划质量管理体系的风险和机会，本条款（8.1.1）的范围仅限于产品和服务提供所需的运行过程的相关风险。

注2：在航空，航天和国防工业，风险通常从发生的可能性和后果的严重性的角度表示。

8.1.2 技术状态管理

组织应策划、实施和控制一个适合于组织及其产品和服务的过程来进行技术状态管理，以确保整个产品生命周期中的物理和功能特性的标识和控制。该过程应：

a）根据要求控制产品标识和可追溯性，包括已识别更改的实施；

b）确保成文信息（如要求、设计、验证、确认和接收文件）与产品和服务的实际特性一致。

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.

当适合于组织和产品时，组织应策划，实施和控制所需的过程以保证整个产品生命周期内的产品安全。

NOTE: Examples of these processes include:
- ***assessment of hazards and management of associated risks (see 8.1.1);***
- ***management of safety critical items;***
- ***analysis and reporting of occurred events affecting safety;***
- ***communication of these events and training of persons.***

注：这些过程的例子包括：
- *——危害评估及相关风险的管理（见8.1.1）；*
- *——安全关键项的管理；*
- *——已发生的影响安全事件的分析和报告；*
- *——这些事件的沟通和人员培训。*

8.1.4 Prevention of Counterfeit Parts
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.

8.1.4 假冒件预防
当适合于组织和产品时，组织应策划、实施和控制一个过程，以防止假冒或疑似假冒件的使用及包含在产品中交付给顾客。

NOTE: Counterfeit part prevention processes should consider:
- ***training of appropriate persons in the awareness and prevention of counterfeit parts;***
- ***application of a parts obsolescence monitoring program;***
- ***controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources;***
- ***requirements for assuring traceability of parts and components to their original or authorized manufacturers;***
- ***verification and test methodologies to detect counterfeit parts;***
- ***monitoring of counterfeit parts reporting from external sources;***
- ***quarantine and reporting of suspect or detected counterfeit parts.***

注：假冒件预防过程宜考虑：
- *——对适当的人员进行假冒件的意识和预防培训；*
- *——过时零件监控方案的应用；*
- *——对于从原始或授权制造商、授权分销商或其他批准来源获得外部提供的产品的控制；*
- *——确保零件和部件可以追溯到其原始或授权制造商的要求；*
- *——发现假冒件的验证和试验的方法；*
- *——监视源于外部的假冒件报告；*
- *——疑似或已发现的假冒件的隔离和报告。*

8.2 Requirements for Products and Services
8.2.1Customer Communication
Communication with customers shall include:
a. providing information relating to products and services;

8.2 产品和服务的要求
8.2.1 顾客沟通
与顾客沟通的内容应包括；
a）提供有关产品和服务的信息；

b. handling enquiries, contracts, or orders,including changes;
c. obtaining customer feedback relating to products and services, including customer complaints;
d. handling or controlling customer property;
e. establishing specific requirements for contingency actions,whenrelevant.

b）处理问询、合同或订单，包括更改；
c）获取有关产品和服务的顾客反馈，包括顾客投诉；
d）处置或控制顾客财产；
e）关系重大时，制定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:
1.any applicable statutory and regulatory requirements;
2.those considered necessary by the organization;

a）产品和服务的要求得到规定，包括：
1）适用的法律法规要求；
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）提供的产品和服务能够满足所声明的要求；

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

c）产品和服务的特殊要求已确定；

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

d）运行风险（如新技术、提供的能力和产能、短交付期限）已识别。

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 the customer, to include:

8.2.3.1 组织应确保有能力向顾客提供满足要求的产品和服务。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;
b.requirements not stated by the customer,but necessary for the specifiedor intended use, when known;
c.requirements specified by the organization;
d.statutory and regulatory requirements applicable to the products and services;
e.contract or order requirements differing from those previously expressed.

a）顾客规定的要求，包括对交付及交付后活动的要求；
b）顾客虽然没有明示，但规定的用途或已知的预期用途所必需的要求；
c）组织规定的要求；
d）适用于产品和服务的法律法规要求；
e）与以前表述不一致的合同或订单要求。

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

评审应与组织相应的职能相协调。

If upon review the organization determines that some

若经评审组织确定不能或只能部分满足一些

customer requirements cannot be met or can only partially be met, the organization shall negotiate a mutually acceptable requirement with the customer.

顾客要求，组织应与顾客协商双方都能接受的要求。

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

组织应确保与以前规定不一致的合同或订单要求已得到解决。

The customer requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

若顾客没有提供成文的要求，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:
a. on the results of the review;
b.on any new requirements for the products and services.

8.2.3.2 适用时，组织应保留与下列方面有关的成文信息：
a）评审结果；
b）产品和服务的新要求。

8.2.4 Changes to Requirements for Products and Services
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.

8.2.4 产品和服务要求的更改

若产品和服务要求发生更改，组织应确保相关的成文信息得到修改，并确保相关人员知道已更改的要求。

8.3 Design and Development of Products and Services
8.3.1 General
The organization shall establish, implement, and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3 产品和服务的设计和开发
8.3.1 总则

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
In determining the stages and controls for design and development, the organization shall consider:
a. the nature, duration, and complexity of the design and development activities;
b. the required process stages, including applicable design and development reviews;
c. the required design and development verification and validation activities;
d. the responsibilities and authorities involved in the design and development process;

8.3.2 设计和开发策划

在确定设计和开发各个阶段和控制时，组织应考虑：
a）设计和开发活动的性质、持续时间和复杂程度；
b）所需的过程阶段，包括适用的设计和开发评审；
c）所需的设计和开发验证及确认活动；
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 development of products and services;

e）产品和服务的设计和开发所需的内部和外部资源；

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所期望的对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成文信息。

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，并对每项活动规定任务、必需的资源、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（见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，确定必需的要求。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和行业规范；

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

e）由产品和服务性质所导致的潜在的失效后果；

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

f）适用时，潜在的过时（如材料、过程、部件、设备、产品）后果。

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

针对设计和开发的目的，输入应是充分和适宜的，且应完整、清楚。

Conflicting design and development inputs shall be resolved.

相互矛盾的设计和开发输入应得到解决。

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成文信息。

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：组织还可考虑将其他信息，如标杆、外部供方反馈、内部产生的数据和在役数据作为设计和开发过程的输入。

8.3.4 Design and Development Controls

The organization shall apply controls to the design and development process to ensure that:

a. the results to be achieved are defined;

b. reviews are conducted to evaluate the ability of the results of design and development to meet requirements;

c. verification activities are conducted to ensure that the design and development outputs meet the input requirements;

d. validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;

e. any necessary actions are taken on problems determined during the reviews,or verification and validation activities;

f. documented information of these activities is retained;

g. progression to the next stage is authorized.

8.3.4 设计和开发控制

组织应对设计和开发过程进行控制，以确保：

a）规定拟获得的结果；

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）实施验证活动，以确保设计和开发输出满足输入的要求；

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）针对评审、验证和确认过程中确定的问题采取必要措施；

f）保留这些活动的成文信息；

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与者应包括与被评审的设计和开发阶段有关的职能代表。

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，可单独或以任意组合的方式进行。

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:

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;

b. test procedures describe the test methods to be used, how to perform the test, and how to record of the results;

8.3.4.1 当验证和确认必须试验时，应对这些试验进行策划、控制、评审并形成文件，以确保并证实：

a）试验计划或规范明确了被试验的试验项及使用的资源、规定了试验的目标和条件、需记录的参数以及相关的接收准则；

b）试验程序说明了使用的试验方法、如何实施试验及如何记录结果；

c. the correct configuration of the test item is submitted for the test;

c）提交试验的试验项的技术状态正确；

d. the requirements of the test plan and the test procedures are observed;

d）遵守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.

用于试验的监视和测量装置应按7.1.5条款规定予以控制。

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.

在完成设计和开发时，组织应确保报告、计算、试验结果等能证实产品或服务的设计在所有规定的运行条件下满足规范要求。

8.3.5 Design and Development Outputs

The organization shall ensure that design and development outputs:

a. meet the input requirements;

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

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

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

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

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

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

NOTE: Data can include:

- ***the drawings, part lists, and specifications necessary to define the configuration and the design features of the product;***
- ***the material, process, manufacturing, assembly, handling, packaging, and preservation data needed to provide and maintain a conforming product or service;***
- ***the technical data and repair schemes for operating and maintaining the product.***

8.3.5 设计和开发输出

组织应确保设计和开发输出：

a）满足输入的要求；

b）满足后续产品和服务提供过程的需要；

c）包括或引用监视和测量的要求，适当时，包括接收准则；

d）规定产品和服务特性，这些特性对于预期目的、安全和正常提供是必需的；

e）适用时，确定每个关键项，包括每个关键特性以及为这些关键项采取的专门措施；

f）发放前经授权人员批准。

组织应规定产品标识、制造、验证、使用和维护所需的数据。

注：数据可包括：

——规定产品技术状态和设计特性必需的图样、零件清单和规范；

——提供和维护合格产品和服务所需的材料、过程、制造、装配、搬运、包装和防护的数据；

——产品运行和维护所需的技术数据和修理方案。

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

组织应保留有关设计和开发输出的成文信息。

8.3.6 Design and Development Changes

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.

8.3.6 设计和开发更改

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，并明确准则，将影响顾客要求的更改在实施前通知顾客。

The organization shall retain documented information on:

a. design and development changes;

b. the results of reviews;

c. the authorization of the changes;

d. the actions taken to prevent adverse impacts.

组织应保留下列方面的成文信息：

a）设计和开发更改；

b）评审的结果；

c）更改的授权；

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.

组织应对所有外部供方包括来自顾客规定的来源提供的过程、产品和服务的符合性负责。

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，组织应确保使用顾客指定或批准的外部供方，包括工艺源（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.

组织应识别和管理外部提供的过程、产品和服务，以及选择和使用外部供方的相关风险。

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其直接和次级外部供方采取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:
a.products and services from external providers are intended for incorporation into the organization's own products and services;
b. products and services are provided directly to the customer(s) by external providers on behalf of the organization;
c. a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

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）外部供方的产品和服务将构成组织自身的产品和服务的一部分；

b）外部供方代表组织直接将产品和服务提供给顾客；

c）组织决定由外部供方提供的过程或部分过程。

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，确定并实施外部供方的评价、选择、绩效监视以及再评价的准则。对于这些活动和由评价引发的任何必要的措施，组织应保留成文信息。

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：在选择与评价外部供方时，组织能使用来自客观、可靠的外部来源的质量数据（如来自经认可的质量管理体系或过程认证机构的信息、政府机构或顾客对外部供方的批准）进行评价。这些数据的使用仅是组织外部供方控制过程的一部分，验证外部提供的过程、产品和服务满足规定的要求仍是组织的责任。

8.4.1.1 The organization shall:
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;
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

8.4.1.1 组织应：
a）对批准状态决定、批准状态更改和根据批准状态控制使用外部供方的条件规定过程、职责和权限；

b）保持其外部供方名录，名录包括批准状态（如批准、有条件批准、取消批准）和批准范围（如产品类型、过程类别）；

type, process family);
c. periodically review external provider performance including process, product and service conformity, and on-time delivery performance;
d. define the necessary actions to take when dealing with external providers that do not meet requirements;
e. define the requirements for controlling documented information created by and/or retained by external providers.

c）定期评审外部供方的绩效，包括过程、产品和服务的符合性和准时交付绩效；

d）当外部供方不能满足要求时规定采取必要的措施；

e）规定由外部供方产生和/或保持的成文信息的控制要求。

8.4.2 Type and Extent of Control
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.

8.4.2 控制类型和程度
组织应确保外部提供的过程、产品和服务不会对组织稳定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:
a. ensure that externally provided processes remain within the control of its quality management system;
b. define both the controls that it intends to apply to an external 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.

组织应：
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）规定对外部供方的控制及其输出结果的控制；
c）考虑：
1）外部提供的过程、产品和服务对组织稳定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）定期评审外部供方绩效的结果（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。

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.

应根据组织识别的风险对外部提供的过程、产品和服务进行验证活动。这些验证活动应包括检验或适用时，当存在不合格（包括假冒件）的高风险时，定期试验。

NOTE 1: Customer verification activities performed at any level of the supply chain does not absolve the

注1：顾客在供应链的任何层级进行的验证活动不能免除组织提供可接受的过程、产品和服务并符合所有要求

organization of its responsibility to provide acceptable processes, products, and services and to comply with all requirements.

的责任。

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.***

注2：验证活动包括：

——对来自外部供方的过程、产品和服务符合性的客观证据（如随货文件，合格证明，试验文件，统计文件，过程控制文件，生产过程验证结果及其后续更改的评估）的评审；

——在外部供方的现场进行检验和审核；

——对要求的文件的评审；

——对生产件批准程序数据的评审；

——接收时的产品检验或服务验证；

——对委托外部供方进行产品验证的评审。

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 not meet requirements.

当外部提供的产品在完成全部验证之前发放用于生产，应予以标识和记录，以便在随后发现产品不符合要求时可召回与更换。

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.

当组织委托外部供方进行验证活动时，应规定委托的范围和要求，并保持委托名录。组织应定期监视委托外部供方进行的验证活动。

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.

当使用外部供方的试验报告验证外部提供的产品时，组织应实施评价试验报告数据的过程，来确认该产品符合要求。当顾客或组织已将原材料视为显著的运行风险时（如关键项），组织应实施一个过程以确认试验报告准确性。

8.4.3 Information for External Providers

The organization shall ensure the adequacy of requirements

8.4.3 提供给外部供方的信息

组织应确保在与外部供方沟通之前所确定的

prior to their communication to the external provider.

The organization shall communicate to external providers its requirements for:

a. The processes,products,and services to be provided ***including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);***

b. the approval of:

1. products and services;
2. methods,processes,and equipment;
3. the release of products and services;

c. competence, including any required qualification of persons;

d. the external providers' interactions with the organization;

e. control and monitoring of the external providers'performance to be applied by the organization;

f. verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises;

g. design and development control;

h. special requirements, critical items, or key characteristics;

i. test, inspection, and verification (including production process verification);

j. the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;

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,***

要求是充分和适宜的。

组织应与外部供方沟通以下要求：

a）需提供的过程、产品和服务，***包括识别的相关技术数据（如规范、图样、过程要求、作业指导书）；***

b）对下列内容的批准：

1）产品和服务；
2）方法、过程和设备；
3）产品和服务的放行；

c）能力,包括所要求的人员资格；

d）外部供方与组织的互动；

e）组织使用的对外部供方绩效的控制和监视；

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）设计和开发控制；

h）特殊要求、关键项或关键特性；

i）试验、检验和验证（包括生产过程验证）；

j）组织使用的产品接收统计技术和相关的接收指导书；

k）对以下方面的需要：

——实施质量管理体系；

——使用顾客指定或批准的外部供方，包括工艺源（如特殊过程）；

——将不合格的过程、产品或服务向组织通知，并获得处置的批准；

——防止使用假冒件（见8.1.4）；

——将过程、产品或者服务的更改通知组织，包括他们的外部供方或制造地点的更改，并获得组织的批准；

——向外部供方传递适用的要求，包括顾客要求；

——为设计批准、检验/验证、调查或审核提

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

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.

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

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;

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

- ***criteria for acceptance and rejection;***
- ***where in the sequence verification operations are to be performed;***
- ***measurement results to be retained (at a minimum an indication of acceptance or rejection);***

供试验样品；

——保留成文信息，包括保留期限和处置要求。

l）组织及其顾客和管理当局有权接接触供应链任何层级的适用设施区域和适用的成文信息；

m）确保人员知晓：

——他们对产品或服务符合性的贡献；

——他们对产品安全的贡献；

——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）可获得成文信息，以规定以下内容：

1）拟生产的产品、提供的服务或进行的活动的特性；

2）拟获得的结果。

注1：定义产品和服务特性的成文信息能包括数字化产品定义数据、图样、零件清单、材料和工艺规范。

注2 ：用于实施活动和实现结果的成文信息能包括过程流程图、控制计划、生产文件（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）可获得和使用适宜的监视和测量资源；

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）确保用于产品接收的监视和测量活动的成文信息包括：

——接收和拒收准则；

——在工序的何处实施验证工作；

——需要保留的测量结果（至少表明接收或拒收）；

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

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).

——所需的专用监视测量设备以及有关其使用的指导书。

2）当组织采用抽样作为产品接收的方法时，确保其抽样计划在公认的统计原理基础上应是合理的，并适于使用（即抽样计划与产品的重要性和过程能力相匹配）。

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

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

d）为过程的运行使用适宜的基础设施，并保持适宜的环境；

注：适宜的基础设施能包括产品专用工装（如型架、夹具和模具）和软件程序。

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

e）配备胜任的人员,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;

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

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；

注：这些过程可以称之为特殊过程（见8.5.1.2）。

g. the implementation of actions to prevent human error;

g）采取措施防止人为错误；

h. the implementation of release,delivery,and post-delivery activities;

h）实施放行、交付和交付后的活动；

i. the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);

i）建立技艺评定准则（如书面标准、代表性样件、图示）；

j. the accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);

j）在制造中所有产品的可核查性（如零件数量，分作业指令，不合格品）；

k.the control and monitoring of identified critical items,including key characteristics, in accordance with established processes;

k）按照建立的过程,控制和监视已识别的关键项，包括关键特性；

l. the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);

l）确定计量型数据的测量方法（如工装、在线检测和检验设备）；

m. the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;

m）在后续阶段不能对符合性进行充分验证时，识别过程中的检验/验证点；

n. the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;

n）可获得所有生产和检验/验证操作已按策划，或按文件和授权完成的证据；

o. the provision for the prevention, detection, and removal of foreign objects;

o）关于预防、探测和排除多余物的规定；

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）按照对产品要求符合性的影响程度监视和控制设施和供应（如水、压缩空气、电和化学品）（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）当产品在未完成全部要求的监视和测量活动之前发放用于生产，应予以标识和记录，以便在随后发现产品不符合要求时可召回与更换。

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.

设备、工装和用于生产过程自动化、控制、监视或测量的软件程序，在用于生产前应进行确认并予以维护。

Storage requirements shall be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

对贮存的生产设备或工装应规定贮存要求，包括定期的防护/状态检查。

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:

对于产生的输出不能由后续的监视或测量加以验证的过程，组织应建立对这些过程的安排，适用时包括：

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

a）规定过程评审和批准的准则；

b. determination of conditions to maintain the approval;

b）确定保持批准的条件；

c. approval of acilities and equipment;

c）设施和设备的批准；

d. qualification of persons;

d）人员的资格；

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

e）使用特定方法和程序实施和监控过程；

f. requirements for documented information to be retained.

f）保留成文信息的要求。

8.5.1.3 Production Process Verification

8.5.1.3生产过程验证

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

组织应实施生产过程验证活动，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, capacitystudies, capability studies, and control plans.

注：这些活动包括风险评估，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部件。当发生使原来验证结果无效的更改时，应进行重新验证过程(如工程更改、制造过程更改、工装更改)。

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

注：本活动可以称之为首件检验(FAI)。

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

组织应保留生产过程验证结果的成文信息。

8.5.2 Identification and Traceability

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

8.5.2 标识和可追溯性

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.

组织应保持产品和服务技术状态的标识，以便识别实际的技术状态和要求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.

当使用接收授权媒介时（如印章、电子签名、口令等），组织应对媒介建立控制。

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

当有可追溯要求时，组织应控制输出的唯一性标识，并应保留所需的成文信息以实现可追溯。

NOTE: Traceability requirements can include:

- ***the identification to be maintained throughout the product life;***
- ***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);***

注：可追溯性要求包括：

——在产品的全寿命中保持标识；

——追溯从同一批原材料或同一个制造批次制造的所有产品的最终去向（如交付、报废）的能力；

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

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

——对于组件，追溯其单元件到组件然后到更高级的组件的能力；

——对于产品，可追溯其生产（制造、装配、检验/验证）的连续记录。

8.5.3 Property Belonging to Customers or External Providers

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.

8.5.3 顾客或外部供方的财产

组织应爱护在组织控制下或组织使用的顾客或外部供方的财产。

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、保护和防护。

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，并保留所发生情况的成文信息。

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、场所、知识产权和个人资料。

8.5.4 Preservation

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

8.5.4 防护

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:

输出的防护按产品的规范和适用的法律法规要求进行，适用时还包括下列措施：

a. cleaning;

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

c. special handling and storage for sensitive products;

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

e. shelf life control and stock rotation;

a）清洁；

b）预防，探测和排除多余物；

c）对敏感产品的特殊处置和储存；

d）包括安全警示和警告的标记和标签；

e）贮存期的控制和存货周转；

f. special handling and storage for hazardous materials.

f）对危险材料的特殊处置和储存。

8.5.5 Post-delivery Activities

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

8.5.5 交付后活动

组织应满足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:

a. statutory and regulatory requirements;

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

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

d. customerrequirements;

e. customer feed back***;***

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

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

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

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

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）法律法规要求；

b）与产品和服务相关的潜在不良的后果；

c）产品和服务的性质、使用和预期寿命；

d）顾客要求；

e）顾客反馈；

f）收集和分析使用中数据（如性能、可靠性、经验教训）；

g）控制、更新和提供与产品使用、维修、修理和翻修有关的技术文件；

h）组织外部执行工作所要求的控制(如异地工作)；

i）产品/顾客支持（如询问、培训、质保、维修、替换零件、资源和过时）。

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，包括调查和报告。

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：交付后活动可包括保证条款所规定的措施、合同义务（如维修服务）、附加服务（如回收或最终处置）。

8.5.6 Control of Changes

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

8.5.6 更改控制

组织应对生产或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.

应识别批准生产或服务提供更改的授权人员。

NOTE: Production or service provision changes can

注：产品或服务提供的更改包括影响过程、生产设备、

include the changes affecting processes, production equipment, tools, or software programs.

工装或软件程序的更改。

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.

组织应保留成文信息，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

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

8.6 产品和服务的放行

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:

a. evidence of conformity with the acceptance criteria;

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

组织应保留有关产品和服务放行的成文信息。成文信息应包括：

a）符合接收准则的证据；

b）可追溯到授权放行人员的信息。

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.

当需要证明产品合格时，组织应确保保留的成文信息能够证明产品和服务满足规定的要求。

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的成文信息随产品和服务一起交付。

8.7 Control of Nonconforming Outputs

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 不合格输出的控制

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"不合格输出"包括在内部产生的、从外部供方接收的、或由顾客确定的不合格的产品或服务。

The organization shall take appropriate action based on the

组织应根据不合格的性质及其对产品和服务

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.

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:

- ***defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;***
- ***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;***
- ***defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).***

组织的不合格控制过程应保持成文信息，成文信息包括：

——规定不合格输出的评审和处置的职责和权限，以及批准作这些决定的人员的过程；

——采取必要的措施遏制不合格对其它过程、产品或者服务的影响；

——及时将影响已交付产品和服务的不合格报告顾客和相关方；

——对于交付后发现的不合格产品和服务，制定与其影响相适应的纠正措施（见 10.2）。

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

注：需要通知不合格产品和服务的相关方可包括外部供方、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:

a. correction;

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

c. informing the customer;

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

组织应通过下列一种或几种途径处置不合格输出：

a）纠正；

b）隔离、限制、退货或暂停对产品和服务的提供；

c）告知顾客；

d）通过相关授权，适用时通过顾客获得让步接收的授权。

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

- ***after approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;***
- ***after authorization by the customer, if the nonconformity results in a departure from the contract requirements.***

按原样使用或返修接收不合格品的处置应只有符合以下条件才能执行：

——经组织负责设计的授权代表或由设计组织授权的人员批准；

——如果不合格导致偏离合同要求，由顾客授权。

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

对处置为报废的产品，应进行明显地和永久地标记，或进行有效的控制，直到使之物理上不可能被使用。

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

假冒或疑似假冒件应得到控制以防止其再进入供应链。

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:
a.describes the nonconformity;
b.describes the actions taken;
c.describes any concessions obtained;
d.identifies the authority deciding the action inrespect of the nonconformity.

8.7.2 组织应保留下列成文信息：

a）描述不合格；
b）描述所采取的措施；
c）描述获得的让步；
d）标识处置不合格的授权。

9. PERFORMANCE EVALUATION

9.1 Monitoring, Measurement, Analysis, and Evaluation

9.1.1 General

The organization shall determine:
a.what needs to be monitored and measured;
b.the methods for monitoring,measurement,analysis,and evaluation needed to ensure valid results;
c.when the monitoring and measuring shall be performed;
d.when the results from monitoring and measurement shall be analyzed and evaluated.

9 绩效评价

9.1 监测，测量，分析和评价

9.1.1 总则

组织应确定：

a）需要监视和测量什么；
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）何时实施监视和测量；
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.

组织应保留适当的成文信息,以作为结果的证据。

9.1.2 Customer Satisfaction

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.

9.1.2 顾客满意

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、监视和评审该信息的方法。

NOTE: Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered

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

products and services, meetings with customers, market-share analysis, compliments, warranty claims, and dealer reports.

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.

监视并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、准时交付绩效、顾客抱怨和纠正措施要求。组织应针对这些评价识别的问题制定与实施顾客满意改进计划并评估其结果的有效性。

9.1.3 Analysis and Evaluation

The organization shall analyze and evaluate appropriate data and information arising from monitoring and measurement.

9.1.3 分析和评价

组织应分析和评价通过监视和测量获得的适当的数据和信息。

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

注：适当的数据可包括外部来源（如政府/行业警示、公告）报告的产品和服务问题的信息。

The results of analysis shall be used to evaluate:

a. Conformity of products and services;

b. The degree of customer satisfaction;

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

d. if planning has been implemented effectively;

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

f. the performance of external providers;

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

NOTE: Methods to analyze data can include statistical techniques.

应利用分析结果评价：

a）产品和服务的符合性；

b）顾客满意程度；

c）质量管理体系的绩效和有效性；

d）策划是否得到有效实施；

e）应对风险和机遇所采取措施的有效性；

f）外部供方的绩效；

g）质量管理体系改进的需求。

注：数据分析方法可包括统计技术。

9.2 Internal Audit

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

9.2 内部审核

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:

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

NOTE: The organization's own requirements should

a）是否符合：

1）组织自身的质量管理体系要求；

注：组织自身的要求宜包括顾客和适用的法律法规的

include customer and applicable statutory and regulatory quality management system requirements.

2. the requirements of this International Standard;

b. is effectively implemented and maintained.

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

质量管理体系要求。

2）本标准的要求；

b）是否得到有效的实施和保持。

注：实施内部审核时，可通过评价绩效指标来确定质量管理体系是否得到有效地实施与保持。

9.2.2 The organization shall:

a.plan,establish,implement,and maintain an audit program(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;

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

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

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

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

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

9.2.2 组织应：

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）规定每次审核的审核准则和范围；

c）选择审核员并实施审核，以确保审核过程客观公正；

d）确保将审核结果报告给相关管理者；

e）及时采取适当的纠正和纠正措施；

f）保留成文信息，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ISO 19011。

9.3 Management Review

9.3.1 General

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.

9.3 管理评审

9.3.1 总则

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

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

a. the status of actions from previous management reviews;

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

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

1.customer satisfaction and feedback from relevant

9.3.2 管理评审输入

策划和实施管理评审时应考虑下列内容：

a）以往管理评审所采取措施的情况；

b）与质量管理体系相关的内外部因素的变化；

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）顾客满意和有关相关方的反馈；

interested parties;
2.the extent to which quality objectives have been met;
3.process performance and conformity of products and services;
4. nonconformities and corrective actions;
5. Monitoring and measurement results;
6. audit results;
7. the performance of external providers***;***
8. on-time delivery performance;
d. the adequacy of resources;
e. the effectiveness of actions taken to address risks and opportunities(see6.1);
f. opportunities for improvement.

2）质量目标的实现程度；
3）过程绩效以及产品和服务合格情况；
4）不合格及纠正措施；
5）监视和测量结果；
6）审核结果；
7）外部供方的绩效；
8）按时交付绩效。
d）资源的充分性；
e）应对风险和机遇所采取措施的有效性(见6.1)；
f）改进的机会。

9.3.3 Management Review Outputs
The outputs of the management review shall include decisions and actions related to:
a. opportunities for improvement;
b. any need for changes to the quality management system;
c. resource needs***;***
d. risks identified.

9.3.3 管理评审输出
管理评审的输出应包括与下列事项相关的决定和措施：
a）改进的机会；
b）质量管理体系所需的变更；
c）资源需求；
d）识别的风险。

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

组织应保留成文信息，作为管理评审结果的证据。

10. IMPROVEMENT
10.1 General
The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These shall include:
a. improving products and services to meet requirements as well as to address future needs and expectations;
b. correcting,preventing,orreducing undesired deffects;
c. improving the performance and effectiveness of the quality management system.

10 改进
10.1 总则
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。

这应包括：
a）改进产品和服务以满足要求并应对未来的需求和期望；
b）纠正、预防或减少不利影响；
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
10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall:

10.2 不合格和纠正措施
10.2.1 当出现不合格时，包括来自投诉的不合格，组织应：

a. react to the nonconformity and,as applicable:
1. take action to control and correct it;
2. deal with the consequences;
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:
1. reviewing and analyzing the nonconformity;
2. determining the causes of the nonconformity, ***including，as applicable， those related to human factors;***
3. determining if similar nonconformities exist,or could potentially occur;
c. implement any action needed;
d. review the effectiveness of any corrective action taken;
e. update risks and opportunities determined during planning,ifnecessary;
f. make changes to the quality management system, if necessary;
g. flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;
h. take specific actions when timely and effective corrective actions are not achieved.

a）对不合格做出应对，并在适用时：
1）采取措施以控制和纠正不合格；
2）处置后果。
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)评审和分析不合格；
2）确定不合格的原因，***适用时，包括与人为因素相关的原因；***
3）确定是否存在或可能发生类似的不合格。
c）实施所需的措施；
d）评审所采取的纠正措施的有效性；
e)需要时，更新策划期间确定的风险和机遇；
f）需要时，变更质量管理体系；
g）当确定不合格由外部供方负责时，向其传递纠正措施要求；
h）当未及时、有效地实现纠正措施时，采取专门措施。

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

纠正措施应与不合格所产生的影响相适应。

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

组织应保持规定不合格和纠正措施管理过程的成文信息。

10.2.2 The organization shall retain documented information as evidence of:
a.the nature of the nonconformities and any subsequent actions taken;
b. the results of any corrective action.

10.2.2 组织应保留成文信息，作为下列事项的证据：
a）不合格的性质以及随后所采取的措施；
b）纠正措施的结果。

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

10.3 持续改进
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

组织应考虑分析和评价的结果以及管理评审的输出，以确定是否存在需求或机遇，这些需求或机遇应作为持续改进的一部分加以应对。

addressed as part of continual improvement.

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

组织应监视改进活动的实施并评价其结果的有效性。

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

注：持续改进机会的例子包括经验教训、问题解决和最佳实践对标。

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

附录 A （资料性附录）新结构、术语和概念说明

A.1 Structure and Terminology

A.1 结构和术语

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.

为了更好地与其他管理体系标准保持一致，与此前的版本(ISO 9001：2008)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。

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.

本标准未要求在组织质量管理体系的成文信息中应用本标准的结构和术语。

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.

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例。若涉及组织运行的过程以及出于其他目的而保持信息，则质量管理体系成文信息的结构和内容通常在更大程度上取决于使用者的需要。

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 A.1 shows the major differences in terminology between this edition of this International Standard and the previous edition.

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“成文信息”；或者使用“供应商”、“伙伴”或“卖方”，而不是“外部供方”)。本标准与此前版本之间的主要术语差异如表 A.1所示。

TABLE A.1 – MAJOR DIFFERENCES IN TERMINOLOGY BETWEEN ISO 9001:2008 AND ISO 9001:2015

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used (See clause A.5 for clarification of applicability.)
Management representative	Not used (Similar responsibilities and authorities are assigned, but no requirement for a single management representative.) ***NOTE: The 9100 standard has retained the term management representative***
Documentation, quality manual, documented procedures, records	Documented information
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider

表 A.1——ISO 9001：2008 和 ISO 9001：2015 之间的主要术语差异

ISO 9001：2008	ISO 9001：2015
产品	产品和服务
删减	未使用（见 A.5 对适用性的说明）
管理者代表	未使用（赋予类似的职责和权限，但不要 求委任一名管理者代表） ***注：9100 标准保留了管理者代表的术语***
文件、质量手册、程序文件、记录	成文信息
工作环境	过程运行环境
监视和测量设备	监视和测量资源
采购产品	外部提供的产品和服务
供方	外部供方

A.2 Products and Services

ISO 9001:2008 used the term “product” to include all output categories. This edition of this International Standard uses

A.2 产品和服务

ISO 9001：2008使用的术语“产品”包括所有的输出类别。本标准则使用“产品和服务”。

“products and services”. “Products and services” include all output categories (hardware, services, software, and processed materials).

“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)。

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.

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。

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.

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实其有能力稳定地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

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

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.

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)，并有助于确定成文信息的范围和程度。

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、成文信息和组织职责方面的要求比ISO 9001：2008 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，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，包括是否保留成文信息，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、航天和国防行业中，风险是以对过程、产品、服务、顾客或者最终用户造成的潜在不良影响的严重性和可能性的组合的形式描述。

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、航天和国防行业过程、产品和服务的复杂性，以及潜在失效后果的严重性，8.1.1要求用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:

- ***understanding risk impacts on operational processes;***
- ***making decisions on operational processes and actions to manage (e.g., prevent, mitigate, control) potential undesired effects.***

支撑运行风险管理过程的具体要求贯穿于第8章，目的是加强关注以下方面：

- *理解风险对于运行过程的影响；*
- *对运行过程作出决策并且采取措施管理（如预防、缓解、控制）潜在不良影响。*

A.5 Applicability

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.

A.5 适用性

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

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.

A.6 成文信息

作为与其他管理体系标准相一致的共同内容，本标准有“成文信息”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，“成文信息”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 ISO 9001：2008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，在本标准中表述的要求为“保持成文信息”。

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

在 ISO 9001：2008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“保留成文信息”。组织有责任确定需要保留的成文信息及其存储时间和所用载体。

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”成文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“成文信息”(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成文信息。

A.7 Organizational Knowledge

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.

A.7 组织的知识

本标准在7.1.6中要求组织确定并管理其拥有的知识，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:

a. safeguarding the organization from loss of knowledge,e.g.,
   - through staff turnover;
   - failure to capture and share information;

b.encouraging the organization to acquire knowledge,e.g.,
   - learning from experience;
   - mentoring;
   - benchmarking.

引入组织的知识的要求的目的是：

a）避免组织损失其知识，如：
——由于员工更替；
——未能获取和共享信息。

b）鼓励组织获取知识，如：
——总结经验；
——专家指导；
——标杆比对。

A.8 Control of Externally Provided Processes, Products, and Services

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

a. purchasing from a supplier;

b.an arrangement with an associate company;

A.8 外部提供过程、产品和服务的控制

在 8.4 中提出了所有形式的外部提供过程、产品和服务，如是否通过：

a）从供方采购；

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。

ANNEX B – OTHER INTERNATIONAL STANDARDS ON QUALITY MANAGEMENT AND QUALITY MANAGEMENT SYSTEMS DEVELOPED BY ISO/TC 176
(Informative)

附录 B（资料性附录）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

The International Standards described in this annex have been developed by ISO/TC 176 to provide supporting information for organizations that apply this International Standard, and to provide guidance for organizations that choose to progress beyond its requirements. Guidance or requirements contained in the documents listed in this annex do not add to, or modify, the requirements of this International Standard.

本附录描述的标准由ISO/TC176质量管理和质量保证技术委员会制定，旨在为应用本标准的组织提供支持信息，并为组织选择追求超越本标准要求的目标提供指南。本附录所列文件中包含的指南或要求并不增加或修改本标准的要求。

Table B.1 shows the relationship between these standards and the relevant clauses of this International Standard.

本标准条款与其他相关标准之间的关系如表 B.1 所示。

This annex does not include reference to the sector-specific quality management system standards developed by ISO/TC 176.

本附录不包括参考 ISO/TC176制定的行业特定要求的质量管理体系标准。

This International Standard is one of the three core standards developed by ISO/TC 176.

本标准系ISO/TC176所制定的三个核心标准之一。

– ISO 9000, *“Quality management systems – Fundamentals and vocabulary”*, provides an essential background for the proper understanding and implementation of this International Standard. The quality management principles are described in detail in ISO 9000 and have been taken into consideration during the development of this

——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的基础。在制定本标准过程中考虑到了 ISO 9000详细描述的质量管理原则。这些原则本身不作为要求，但构成本标准所规定要求的基础。ISO 9000 还定义了应用于本标准的术语、定义和概念。

International Standard. These principles are not requirements in themselves, but they form the foundation of the requirements specified by this International Standard. ISO 9000 also defines the terms, definitions, and concepts used in this International Standard.

TABLE B.1 – RELATIONSHIP BETWEEN OTHER INTERNATIONAL STANDARDS ON QUALITY MANAGEMENT AND QUALITY MANAGEMENT SYSTEMS AND THE CLAUSES OF THIS INTERNATIONAL STANDARD

Other International Standards	Clause in this International Standard						
	4	5	6	7	8	9	10
ISO 9000	All	All	All	All	All	All	All
ISO 9004	All	All	All	All	All	All	All
ISO 10001					8.2.2, 8.5.1	9.1.2	
ISO 10002					8.2.1,	9.1.2	10.2.1
ISO 10003						9.1.2	
ISO 10004						9.1.2, 9.1.3	
ISO 10005		5.3	6.1, 6.2	All	All	9.1	10.2
ISO 10006	All	All	All	All	All	All	All
ISO 10007					8.5.2		
ISO 10008	All	All	All	All	All	All	All
ISO 10012				7.1.5			
ISO/TR 10013				7.5			
ISO 10014	All	All	All	All	All	All	All
ISO 10015				7.2			
ISO/TR 10017			6.1	7.1.5		9.1	
ISO 10018	All	All	All	All	All	All	All
ISO 10019					8.4		
ISO 19011						9.2	

NOTE: "All" indicates that all the sub-clauses in the specific clause of this International Standard are related to the other International Standards.

CAQG RFQ

表 B.1——本国际标准章节与其他质量管理和质量管理体系国际标准之间的关系

其他国际标准	本国际标准章节						
	4	5	6	7	8	9	10
ISO 9000	全部内容	全部内容	全部内容	全部内容	全部内容	全部内容	全部内容
ISO 9004	全部内容	全部内容	全部内容	全部内容	全部内容	全部内容	全部内容
ISO 10001					8.2.2，8.5.1	9.1.2	
ISO 10002					8.2.1	9.1.2	10.2.1
ISO 10003						9.1.2	
ISO 10004						9.1.2，9.1.3	
ISO 10005		5.3	6.1，6.2	全部内容	全部内容	9.1	10.2
ISO 10006	全部内容	全部内容	全部内容	全部内容	全部内容	全部内容	全部内容
ISO 10007					8.5.2		
ISO 10008	全部内容	全部内容	全部内容	全部内容	全部内容	全部内容	全部内容
ISO 10012				7.1.5			
ISO/TR 10013				7.5			
ISO 10014	全部内容	全部内容	全部内容	全部内容	全部内容	全部内容	全部内容
ISO 10015				7.2			
ISO/TR 10017			6.1	7.1.5		9.1	
ISO 10018	全部内容	全部内容	全部内容	全部内容	全部内容	全部内容	全部内容
ISO 10019					8.4		
ISO 19011						9.2	
注：“全部内容”表示本标准该章节的全部内容与其他的相应标准相关。							

- ISO 9001 (this International Standard) specifies requirements aimed primarily at giving confidence in the products and services provided by an organization and thereby enhancing customer satisfaction. Its proper implementation can also be expected to bring other

——ISO 9001（本标准）规定的要求旨在为组织的产品和服务提供信任，从而增强顾客满意。正确实施本标准也能为组织带来其他预期利益，如：改进内部沟通，更好地理解和控制组织的过程。

organizational benefits, such as improved internal communication, better understanding, and control of the organization's processes.

- 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, to address a broader range of topics that can lead to improvement of the organization's overall performance. ISO 9004 includes guidance on a self-assessment methodology for an organization to be able to evaluate the level of maturity of its quality management system. The International Standards outlined below can provide assistance to organizations when they are establishing or seeking to improve their quality management systems, their processes, or their activities.

——ISO 9004 《追求组织的持续成功——质量管理方法》，为组织选择超出本标准的要求提供指南，关注能够改进组织整体绩效的更加广泛的议题。ISO 9004包括自我评价方法指南，以便组织能够对其质量管理体系的成熟度进行评价。

在组织实施或寻求改进其质量管理体系、过程或相关活动的过程中，以下简要介绍的标准可以为其提供帮助。

- ISO 10001, *"Quality management – Customer satisfaction – Guidelines for codes of conduct for organizations",* provides guidance to an organization in determining that its customer satisfaction provisions meet customer needs and expectations. Its use can enhance customer confidence in an organization and improve customer understanding of what to expect from an organization, thereby reducing the likelihood of misunderstandings and complaints.

——ISO 10001《质量管理——顾客满意——组织行为规范指南》，为组织确定其在满足顾客需求和期望方面的满意程度提供指南。实施该标准可以增强顾客对组织的信心，使组织对顾客的预期更加准确，从而降低误解和投诉的可能性。

- ISO 10002, *"Quality management – Customer satisfaction – Guidelines for complaints handling in organizations"*, provides guidance on the process of handling complaints by recognizing and addressing the needs and expectations of complainants and resolving any complaints received. ISO 10002 provides an open, effective, and easy-to-use complaints process, including training of people. It also provides guidance for small businesses.

——ISO 10002《质量管理——顾客满意——组织处理投诉指南》，通过确认和理解投诉方的需求和期望，并解决所接到的投诉，为组织提供有关投诉处理过程的指南。该标准提供了一个开放、有效的和易于应用的投诉过程，包括人员培训。并且也为小企业提供指南。

- ISO 10003, *"Quality management – Customer satisfaction – Guidelines for dispute resolution external to organizations"*, provides guidance for effective and efficient external dispute resolution for product-related complaints. Dispute resolution gives an avenue of redress when organizations do not remedy a complaint internally. Most complaints can be resolved successfully within the organization, without adversarial procedures.

——ISO 10003《质量管理——顾客满意——组织外部争议解决指南》，为组织有效和高效地解决有关产品投诉的外部争议提供指南。当投诉不能在组织内部解决时，争议解决是一种补偿途径。大多数投诉无需更多的冲突过程，可以在组织内部成功解决。

- ISO 10004, "*Quality management – Customer satisfaction – Guidelines for monitoring and measuring",* provides guidelines for actions to enhance customer satisfaction and to determine opportunities for improvement of

——ISO 10004《质量管理——顾客满意——监视和测量指南》，为组织采取增强顾客满意的措施，并识别顾客所关注的产品、过程和属性的改进机会提供指南。这些措施能够增强顾客忠诚，

products, processes, and attributes that are valued by customers. Such actions can strengthen customer loyalty and help retain customers.

避免顾客流失。

- ISO 10005, *"Quality management systems – Guidelines for quality plans"*, provides guidance on establishing and using quality plans as a means of relating requirements of the process, product, project, or contract, to work methods and practices that support product realization. Benefits of establishing a quality plan are increased confidence that requirements will be met, that processes are in control and the motivation that this can give to those involved.

——ISO 10005《质量管理体系 质量计划指南》，为组织制定和实施质量计划，作为满足相关过程、产品、项目或合同要求的手段，形成支持产品实现的工作方法和实践提供指南。制定质量计划的益处在于能使相关人员增加可以满足质量要求并有效控制相应过程的信心，推动其积极参与。

- ISO 10006, *"Quality management systems – Guidelines for quality management in projects"*, is applicable to projects from the small to large, from simple to complex, from an individual project to being part of a portfolio of projects. ISO 10006 is to be used by personnel managing projects and who need to ensure that their organization is applying the practices contained in the ISO quality management system standards.

——ISO 10006《质量管理体系 项目质量管理指南》，可适用于从小到大、从简单到复杂、从单独的项目到项目组合中组成部分的各种项目。既可供项目管理人员使用，也可供需要确保其组织应用 ISO 质量管理体系相关标准所含实践的人员使用。

- ISO 10007, *"Quality management systems – Guidelines for configuration management"*, is to assist organizations applying configuration management for the technical and administrative direction over the life cycle of a product. Configuration management can be used to meet the product identification and traceability requirements specified in this International Standard.

——ISO 10007《质量管理体系 技术状态管理指南》，帮助组织在整个寿命周期内对产品的技术和管理状态应用技术状态管理。技术状态管理可用于满足本标准规定的产品标识和可追溯要求。

- ISO 10008, *"Quality management – Customer satisfaction – Guidelines for business-to-consumer electronic commerce transactions"*, gives guidance on how organizations can implement an effective and efficient business-to-consumer electronic commerce transaction (B2C ECT) system, and thereby provide a basis for consumers to have increased confidence in B2C ECTs, enhance the ability of organizations to satisfy consumers and help reduce complaints and disputes.

——ISO 10008《质量管理——顾客满意——组织对个人电子商务交易指南》，指导组织如何有效和高效地实施组织对个人电子商务交易系统，从而为增加顾客对电子商务交易的信心奠定基础，提高组织满足顾客要求的能力，以减少投诉和争议。

- ISO 10012, *"Measurement management systems – Requirements for measurement processes and measuring equipment"*, provides guidance for the management of measurement processes and metrological confirmation of measuring equipment used to support and demonstrate compliance with metrological requirements. ISO 10012 provides quality management criteria for a measurement management system to ensure metrological requirements are

——ISO 10012《测量管理体系——测量过程和测量设备的要求》，为测量过程管理以及支持和证明符合计量要求的测量设备的计量确认提供指南。该标准规定测量管理体系的质量管理准则，以确保满足计量要求。

met.

- ISO/TR 10013, *"Guidelines for quality management system documentation"*, provides guidelines for the development and maintenance of the documentation necessary for a quality management system. ISO/TR 10013 can be used to document management systems other than those of the ISO quality management system standards (e.g., environmental management systems and safety management systems).

——ISO/TR 10013《质量管理体系文件指南》，为编制和保持质量管理体系所需的文件提供指南。该标准还能用于质量管理体系相关标准以外的管理体系，如：环境管理体系和安全管理体系。

- ISO 10014, *"Quality management – Guidelines for realizing financial and economic benefits"*, is addressed to top management. It provides guidelines for realizing financial and economic benefits through the application of quality management principles. It facilitates application of management principles and selection of methods and tools that enable the sustainable success of an organization.

——ISO 10014《质量管理——实现财务和经济效益的指南》，专门为最高管理者制定。为通过应用质量管理原则实现财务和经济效益提供指南。有利于促进组织应用管理原则以及选择持续成功的方法和工具。

- ISO 10015, *"Quality management – Guidelines for training"*, provides guidelines to assist organizations in addressing issues related to training. ISO 10015 can be applied whenever guidance is required to interpret references to "education" and "training" within the ISO quality management system standards. Any reference to "training" includes all types of education and training.

——ISO 10015《质量管理——培训指南》，为组织解决培训相关问题提供帮助和指南。该标准可作为质量管理体系相关标准涉及"教育"与"培训"事宜时所需的指南。所描述的"培训"包括所有类型的教育和培训。

- ISO/TR 10017, *"Guidance on statistical techniques for ISO 9001:2000"*, explains statistical techniques which follow from the variability that can be observed in the behavior and results of processes, even under conditions of apparent stability. Statistical techniques allow better use of available data to assist in decision making, and thereby help to continually improve the quality of products and processes to achieve customer satisfaction.

——ISO/TR 10017《ISO 9001：2000 的统计技术指南》，即使在明显稳定条件下也可观察到过程状态和结果的变量来解释的统计技术。采用统计技术可以更好地利用获得的数据进行决策，从而有助于持续改进产品和过程质量，实现顾客满意。

- ISO 10018, "*Quality management – Guidelines on people involvement and competence"*, provides guidelines which influence people involvement and competence. A quality management system depends on the involvement of competent people and the way that they are introduced and integrated into the organization. It is critical to determine, develop, and evaluate the knowledge, skills, behavior, and work environment required.

——ISO 10018《质量管理——人员参与和能力指南》，提供影响人员参与和能力方面的指南。质量管理体系取决于胜任人员的积极主动参与，以及这些人员的组织管理方式。对所需知识、技能、行为、工作环境的确定、开发和评价至关重要。

- ISO 10019, *"Guidelines for the selection of quality management system consultants and use of their services"*, provides guidance for the selection of quality management system consultants and the use of their services. It gives guidance on the process for evaluating the competence of a

——ISO 10019《质量管理体系咨询师的选择及其服务使用的指南》，指导如何选择质量管理体系咨询师以及使用其服务。对质量管理体系咨询师的能力评价过程提供指南，帮助组织获得满足其需求和期望的咨询服务。

quality management system consultant and provides confidence that the organization's needs and expectations for the consultant's services will be met.

- ISO 19011, *"Guidelines for auditing management systems"*, provides guidance on the management of an audit program, on the planning and conducting of an audit of a management system, as well as on the competence and evaluation of an auditor and an audit team. ISO 19011 is intended to apply to auditors, organizations implementing management systems, and organizations needing to conduct audits of management systems.

——ISO 19011《管理体系审核指南》，就审核方案管理、管理体系审核的策划和实施以及审核员和审核组能力评价提供指南。适用于审核员、实施管理体系的组织以及实施管理体系审核的组织。

ANNEX C – OTHER STANDARDS ON QUALITY MANAGEMENT AND QUALITY MANAGEMENT SYSTEMS DEVELOPED BY THE INTERNATIONAL AEROSPACE QUALITY GROUP *(Informative)*

附录 C　IAQG 编制的质量管理和质量管理体系的其他标准

The International Aerospace Quality Group (IAQG) standards described in this annex have been developed by the IAQG to provide supporting information for organizations that apply the IAQG 9100 standard, and to provide guidance for organizations that choose to progress beyond its requirements. Guidance or requirements contained in the documents listed in this annex do not add to, or modify, the requirements of the 9100 standard.

本附录描述的国际航空航天质量组织（IAQG）标准由IAQG制定，为使用IAQG 9100标准的组织提供支持信息，并为选择超越该标准要求的组织提供指导。本附录中列出的文件包含的指南或者要求不增加或者修改9100标准的要求。

Table C.1 shows the relationship between these standards and the relevant clauses of the 9100 standard.

表C.1列出了这些标准和9100标准相应条款之间的关系。

The 9100 standard is one of the three quality management system standards developed by the IAQG.

9100标准是由IAQG制定的三个质量管理体系标准之一。

— IAQG 9100, "Quality Management Systems – Requirements for Aviation, Space and Defense Organizations": 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

——IAQG 9100《质量管理体系——航空、航天和国防组织的要求》：本标准尽可能地在最大程度上使质量管理体系的要求标准化，可供全世界各组织用于供应链的各个层级。通过减少或消除组织独特的要求、有效实施质量管理体系并更广泛地应用好的实践，本标准的应用宜能改进质量、成本和交付绩效。本标准虽然主要是为航空、航天和国防工业开发的，但也可用于那些质量管理体系需要在ISO 9001体系基础上有附加要求的其他行业。

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.

TABLE B.1 – RELATIONSHIP BETWEEN OTHER INTERNATIONAL STANDARDS ON QUALITY MANAGEMENT AND QUALITY MANAGEMENT SYSTEMS AND THE CLAUSES OF THIS INTERNATIONAL STANDARD

Other International Standards	Clause in this International Standard						
	4	**5**	**6**	**7**	**8**	**9**	**10**
ISO 9000	All	All	All	All	All	All	All
ISO 9004	All	All	All	All	All	All	All
ISO 10001					8.2.2, 8.5.1	9.1.2	
ISO 10002					8.2.1,	9.1.2	10.2.1
ISO 10003						9.1.2	
ISO 10004						9.1.2, 9.1.3	
ISO 10005		5.3	6.1, 6.2	All	All	9.1	10.2
ISO 10006	All	All	All	All	All	All	All
ISO 10007					8.5.2		
ISO 10008	All	All	All	All	All	All	All
ISO 10012				7.1.5			
ISO/TR 10013				7.5			
ISO 10014	All	All	All	All	All	All	All
ISO 10015				7.2			
ISO/TR 10017			6.1	7.1.5		9.1	
ISO 10018	All	All	All	All	All	All	All
ISO 10019					8.4		
ISO 19011						9.2	

NOTE: "All" indicates that all the sub-clauses in the specific clause of this International Standard are related to the other International Standards.

CAQG RFQ

表C.1——其他IAQG质量管理标准和质量管理体系标准和IAQG 9100章节之间的关系

其它IAQG标准	IAQG 9100标准中的条款						
	4	5	6	7	8	9	10
IAQG 9101	4.4					9.2	
IAQG 9102					8.4.2.1 8.5.1.3		
IAQG 9103					8.1，8.3.5 8.4.3，8.5.1		
IAQG 9107					8.6		
IAQG 9114					8.6		
IAQG 9115	全部内容	全部内容	全部内容	全部内容	全部内容	全部内容	全部内容
IAQG 9116					8.3.6,8.4.3 8.5.6		
IAQG 9131					8.7		10.2
IAQG 9132					8.5.2		
IAQG 9133					8.4.2,8.6		
IAQG 9134					8.4.1		
IAQG 9162					8.5.1,8.6		
注：“全部内容”是指所有的子条款都在IAQG9100标准的特殊条款中，与其他IAQG的标准是相关的。							

— IAQG 9110, “Quality Management Systems – Requirements for Aviation Maintenance Organizations”: 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, schedule, and cost performance by the reduction or elimination of organization-unique requirements and wider application of good practice. While primarily developed for the civil and military aviation industry organizations providing maintenance services, 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.

——IAQG 9110《质量管理体系——航空维修组织要求》：本标准尽可能地在最大程度上使质量管理体系的要求标准化，可供全世界各组织用于供应链的各个层级。通过减少或消除组织独特的要求、有效实施质量管理体系并更广泛地应用好的实践，本标准的应用宜能改进质量、成本和交付绩效。本标准虽然主要是为提供维修服务的民用和军用航空行业组织开发的，但也可用于那些质量管理体系需要在ISO 9001体系基础上有附加要求的其他行业。

— IAQG 9120, “Quality Management Systems – Requirements for Aviation, Space and Defense Distributors”: This standard is for use by organizations that procure parts, materials, and assemblies and resells these products to a customer in the aviation, space, and defense industries. This includes organizations that

——IAQG 9120《质量管理体系——航空、航天和国防组织分销商要求》：本标准供采购零件、材料和组件，再将这些产品转售给航空、航天和国防行业的顾客的组织使用。这也包括采购产品，再将产品分成较小批量转售的组织，以及协调涉及产品的过程受顾客或当局控制的组织。本标准

procure products and split them into smaller quantities including those that coordinate a customer or regulatory controlled process on the product. This standard is not intended for organizations that maintain or repair products, or for organizations that perform work that affect or could affect product characteristics or conformity.

不用于维修或修理产品，或实施的工作影响或可能影响产品特性或符合性的组织。

The IAQG standards outlined below can provide assistance to organizations when they are establishing or seeking to improve their quality management systems, their processes or their activities.

当组织正在建立或寻求改进质量管理体系、过程或活动时，下列IAQG标准可对组织提供帮助。

— IAQG 9101, "Quality Management Systems Audit Requirements for Aviation, Space, and Defense Organizations": This standard defines requirements for the preparation and execution of the audit process. In addition, it defines the content and composition for the audit reporting of conformity and process effectiveness to the 9100-series standards, the organization's QMS, and customer and statutory/regulatory requirements.

——IAQG 9101《航空、航天和国防组织质量管理体系审核要求》：本标准规定了审核过程的准备和实施的要求。此外，也规定了对9100系列标准、组织的质量管理体系、顾客以及法律法规要求的符合性和过程有效性的审核报告的内容和结构。

— IAQG 9102, "Aerospace First Article Inspection Requirement": This document standardizes FAI process requirements to the greatest extent possible and can be used at all levels of the supply chain by organizations around the world to provide a consistent process and documentation requirements for verification of aviation, space, and defense product. Its use should result in improved quality, schedule, and cost performance by the reduction or elimination of organization-unique requirements and wider application of good practices. While primarily developed for the aviation, space, and defense industry, this standard can also be used in other industry sectors where a standardized FAI process is needed.

——IAQG 9102《航空航天首件检验要求》：本标准在最大可能程度上，规范了首件检验过程要求，可在全世界组织的各层次供方使用，为航空、航天和国防产品的验证提供一致的过程和文件要求。通过减少或消除组织的特有要求和最佳实践的广泛应用，以起到改进质量、进度和成本绩效的用途。虽然本标准主要为航空、航天和国防行业制定，但是当需要规范化的首件检验过程时，本标准也可用于其他行业。

— IAQG 9103, "Variation Management of Key Characteristics": This document standardizes requirements for "key characteristic" identification, control, documentation, and approval for the industry. The establishment of common requirements, for use at all levels of the supply chain by organizations, should result in improved quality and safety, and decreased costs, due to the elimination or reduction of organization-unique requirements and the resultant

——IAQG 9103《关键特性变更管理》：本文件标准化了行业关键特性识别、控制、文件化和批准的要求。组织建立供应链中所有层级的通用要求，可以提高质量、安全，降低由于消除或者减少组织特殊需求和这些多重期望中内在的相应变更带来的成本。

variation inherent in these multiple expectations.

— ***IAQG 9107, "Direct Delivery Authorization Guidance for Aerospace Companies": This document provides guidance to a production organization and a design organization on how to comply with the direct delivery authorization, including appropriate arrangement requirements.***

——IAQG 9107《航空航天公司直接交付授权指南》：本文件对生产组织和设计组织关于如何符合直接交付授权提供指导，包括分工安排要求。

— ***IAQG 9114, "Direct Ship Guidance for Aerospace Companies": This document standardizes requirements for the direct shipment of articles from a supplier of an approved manufacturer to a customer of an approved manufacturer and was originally produced as a cooperative effort between the Federal Aviation Administration (FAA) and the IAQG. The establishment of common expectations, for use at all levels of the supply-chain by organizations, should result in improved quality and safety, and decreased costs, due to the elimination or reduction of organization-unique requirements and the resultant variation inherent in these multiple expectations.***

——IAQG 9114《航空航天公司直接运输指导》：本标准作为FAA与IAQG共同努力的成果，规范了从经批准的制造商的供应商向经批准的制造商的顾客直接发运器材的要求。在组织供应链所有层次中建立共同期望，去除或减少了组织特有要求及由此导致的不同期望，将能来带质量和安全的改进以及成本的降低。

— ***IAQG 9115, "Quality Management Systems – Requirements for Aviation, Space and Defense Organizations – Deliverable Software": This document supplements the IAQG 9100 standard requirements for deliverable software and contains quality management system requirements for organizations that design, develop, and/or produce deliverable software and services for the aviation, space, and defense industry. This includes, as required, support software that is used in the development and maintenance of deliverable software and services. The deliverable software may be stand- alone, embedded, mobile application, or loadable into a target computer.***

——IAQG 9115《质量管理体系——航空、航天和国防组织要求——可交付的软件》：本文作就可交付软件对IAQG9100的要求进行了补充，并且包含了航空、航天和国防行业内设计、开发和/或生产可交付软件的组织的质量管理体系要求。当要求时，还包括用于开发和维护可交付软件和服务的支持软件。可交付软件可能是单独的、嵌入的、移动应用的或可加载至目标计算机的。"

— ***IAQG 9116, "Aerospace Series – Notice of Change (NOC) Requirements": This document was created to provide for the uniform submittal of change notifications and/or approval when contractually invoked at any level or as guidance within the aviation, space, and defense industries. This standard can be invoked as a stand-alone requirement or used in conjunction with AS/EN/JISQ 9100-series standards (i.e., 9100, 9110, 9120).***

——IAQG 9116《航空航天系列——变更通知（NOC）要求》：在航空、航天和国防行业内，当任何层级的合同要求或作为指南时，本文件规范了变更通知和/或批准的提交。本标准可被视为单独的要求或者与AS/EN/JISQ 9100系列标准（即9100, 9110, 9120）同时使用。

— ***IAQG 9131, "Quality Management Systems – Aerospace – Nonconformance Documentation": This document standardizes requirements for***

——IAQG 9131《质量管理体系——航空航天——不合格文件》：本文件标准了不合格数据定义和行业文件的要求。在组织供应链所有层次中建

nonconformance data definition and documentation for the industry. The establishment of common requirements, for use at all levels of the supply- chain by organizations, should result in improved quality and safety, and decreased costs, due to the elimination or reduction of organization-unique requirements and the resultant variation inherent in these multiple expectations.

立共同期望，去除或减少了组织特有要求及由此导致的不同期望，将能来带质量和安全的改进以及成本的降低。

— IAQG 9132, "Data Matrix Quality Requirements for Parts Marking": This document standardizes data matrix quality requirements for parts marking for the industry. The establishment of common requirements, for use at all levels of the supply-chain by organizations, should result in improved quality and safety, and decreased costs, due to the elimination or reduction of organization-unique requirements and the resultant variation inherent in these multiple expectations.

——IAQG 9132《零件标记的数据矩阵的质量要求》：本文件定义了航空、航天和国防行业中使用"数据矩阵符号"标记金属零件的统一的质量和技术要求。ISO/IEC 16022明确了通用要求（例如：数据字符、错误改正原则、译码算法）。除了ISO/IEC 16022明确的，用这样的符号标志零件是由于本标准的要求，以确保符号的电子阅读。

— IAQG 9133, "Qualification Procedure for Aerospace Standard Products": This standard defines a system for the qualification of standard products for aviation, space, and defense applications. It defines the principles that shall be adhered to carry out product qualification; applied in conjunction with the rules and procedures of the Certification Authority (CA). The system enables the CA to confirm compliance is achieved and maintained, in accordance with the requirements of its product definition and associated controlling technical specifications by an Original Component Manufacturer (OCM) of standard products.

——IAQG 9133《航空航天标准件鉴定程序》：本标准为航空、航天和国防应用规定标准件鉴定的体系。规定了执行产品鉴定应遵守的原则，与鉴定机构（CA）的规则和程序一起应用。该体系能使CA按照其产品定义的要求以及标准件原始部件制造商（OCM）的相关控制技术规范确认符合性的实现和保持。

— IAQG 9134, "Supply Chain Risk Management Guideline": The guideline focuses on Quality as a key risk assessment factor taking into account elements from all aspects of the business having a direct link to global quality management. While traditional "small q" Quality is a key element to be assessed, from a company business point of view, other elements play an important part in minimizing risk. This guideline defines such risk factors for consideration.

——IAQG 9134《供应链风险管理指南》：本指南将质量作为关键风险评估因素来考虑，商业中的所有方面对全球质量管理有直接的关联的元素。尽管传统"小Q"质量是要评估的关键元素，从一个公司商业的角度来看，其他的元素在减少风险中起到了重要作用。本指南定义了要考虑的这些风险因素。

— IAQG 9162, "Aerospace Operator Self-Verification Programs": This standard is focused on standardizing, to the extent possible, operator self- verification practices in the aviation, space, and defense industry. Establishing common requirements practices should result in improved quality and safety, decreased costs,

——IAQG 9162《航空航天操作者自我验证大纲》：本标准最大可能关注航空工业中标准运营商自我验证的实践。建立通用的航空实践将导致质量和安全提升，降低成本，消除或减少组织特殊要求。

and elimination or reduction of organization-unique requirements.

ANNEX D – BIBLIOGRAPHY

[1] ISO 9004, “Managing for the sustained success of an organization – A quality management approach”

[2] ISO 10001, “Quality management – Customer satisfaction – Guidelines for codes of conduct for organizations”

[3] ISO 10002, “Quality management – Customer satisfaction – Guidelines for complaints handling in organizations”

[4] ISO 10003, “Quality management – Customer satisfaction – Guidelines for dispute resolution external to organizations”

[5] ISO 10004, “Quality management – Customer satisfaction – Guidelines for monitoring and measuring”

[6] ISO 10005, “Quality management systems – Guidelines for quality plans”

[7] ISO 10006, “Quality management systems – Guidelines for quality management in projects”

[8] ISO 10007, “Quality management systems – Guidelines for configuration management”

[9] ISO 10008, “Quality management – Customer satisfaction – Guidelines for business-to-consumer electronic commerce transactions”

[10] ISO 10012, “Measurement management systems – Requirements for measurement processes and measuring equipment”

[11] ISO/TR 10013, “Guidelines for quality management system documentation”

[12] ISO 10014, “Quality management – Guidelines for realizing financial and economic benefits”

[13] ISO 10015, “Quality management – Guidelines for training”

[14] ISO/TR 10017, Guidance on statistical techniques for ISO 9001:2000

[15] ISO 10018, “Quality management – Guidelines on people involvement and competence”

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附录 D　参考文献

［1］ GB/T 19004 追求组织的持续成功 质量管理方法

［2］ GB/T 19010 质量管理 顾客满意 组织行为规范指南

［3］ GB/T 19012 质量管理 顾客满意 组织处理投诉指南

［4］ GB/T 19013 质量管理 顾客满意 组织外部争议解决指南

［5］ GB/Z 27907 质量管理 顾客满意 监视和测量指南

［6］ GB/T 19015 质量管理体系 质量计划指南

［7］ GB/T 19016 质量管理体系 项目质量管理指南

［8］ GB/T 19017 质量管理体系 技术状态管理指南

［9］ ISO 10008 Quality management-Customer satisfaction-Guidelines for business-to-consumer electronic commerce transactions

［10］ GB/T 19022 测量管理体系 测量过程和测量设备的要求

［11］ GB/T 19023 质量管理体系文件指南

［12］GB/T 19024 质量管理 实现财务和经济效益的指南

［13］ GB/T 19025 质量管理 培训指南

［14］ GB/Z 19027 GB/T19001-2000的统计技术指南

［15］ ISO 10018 Quality management-Guidelines on people involvement and competence

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ANNEX E – AVIATION, SPACE, AND DEFENSE BIBLIOGRAPHY

附录 E 航空、航天和国防参考文献

IAQG* 9101 Quality Management Systems Audit Requirements for Aviation, Space, and Defense Organizations

IAQG 9101 航空、航天和国防组织质量管理体系审核要求*

IAQG* 9102 Aerospace First Article Inspection Requirement

IAQG 9102 航空航天首件检验要求*

IAQG* 9103 Variation Management of Key Characteristics

IAQG 9103 关键特性变更管理*

IAQG* 9107 Direct Delivery Authorization Guidance for Aerospace Companies

IAQG 9107 航空航天公司直接交付授权指南*

IAQG* 9110 Quality Management Systems – Requirements for Aviation Maintenance Organizations

IAQG 9110 质量管理体系——航空维修组织要求*

IAQG* 9114 Direct Ship Guidance for Aerospace Companies

IAQG 9114 航空航天公司直接运输指导*

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IAQG* 9120 Quality Management Systems – Requirements for Aviation, Space and Defense Distributors

IAQG 9120 质量管理体系——航空、航天和国防组织分销商要求*

IAQG* 9131 Quality Management Systems – Aerospace –

IAQG 9131 质量管理体系——航空航天*

Nonconformance Documentation	*——不合格文件*
IAQG* 9132 Data Matrix Quality Requirements for Parts Marking	*IAQG* 9132 零件标记的数据矩阵的质量要求*
IAQG* 9133 Qualification Procedure for Aerospace Standard Products	*IAQG* 9133 航空航天标准件鉴定程序*
IAQG* 9134 Supply Chain Risk Management Guideline	*IAQG* 9134 供应链风险管理指南*
IAQG* 9162 Aerospace Operator Self-Verification Programs	*IAQG* 9162 航空航天操作者自我验证大纲*
ISO 9001 Quality management systems – Requirements	*ISO 9001 质量管理体系——要求*
www.iaqg.org IAQG Standards Support Material	*www.iaqg.org IAQG 标准支持材料*
IAQG Supply Chain Management Handbook	*IAQG 供应链管理手册*

**** Refers to the internationally harmonized standards published world-wide under the authority of the International Aerospace Quality Group (IAQG), coordinated by each of the IAQG sectors: the Americas Aerospace Quality Group (AAQG), Asia-Pacific Aerospace Quality Group (APAQG), and the European Aerospace Quality Group (EAQG).***

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The IAQG Standards Register lists the current standards published within each IAQG sector; see http://www.sae.org/iaqg/publications/standardsregister.pdf.

IAQG 标准登记表列出了目前主要的标准，发布在每个 IAQG 的部门；见 http://www.sae.org/iaqg/publications/standardsregister.pdf。

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