Quality Management Systems – Requirements for Aviation, Space, and Defense organization

质量管理体系－航空、航天和国防组织的要求

1. Scope

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

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

If there is a conflict between the requirements of this standard and applicable statutory or 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.

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.

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

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

1. 范围

本标准包括 ISO9001：2015 质量管理体系要求，并规定了额外的航空、航天和国防工业要求、定义和注释。

要强调的是本标准所规定的质量管理体系要求是对顾客和适用法律法规要求的补充（不是取代）。

如果本标准要求和适用法律法规之间有任何冲突，以后者优先.

本国际标准为有下列需求的组织规定了质量管理体系要求：

a）需要证实其有能力稳定地提供满足顾客和适用的法律法规要求的产品；

b）通过对体系的有效应用，包括体系持续改进的过程，以及保证符合顾客与适用的法律法规要求，旨在增强顾客满意。

本国际标准的所有要求是通用的，旨在适用于各种类型的、不同规模或者提供的不同产品和服务的组织。

注 1：在本国际标准中，术语“产品”或“服务”仅适用于预期提供给顾客或顾客所要求的产品的服务。

注 2：法律法规要求可称作法定要求

2. Normative references

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.

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

ISO 9001: 2015 Quality management system-Requirement

2 规范性引用文件

下列文件中的全部或部分内容在本标准中并在引用中不可或缺。凡是注日期的引用文件，仅该版本适用本标准。凡未标注日期的引用文件，其最新版本适用于本标准（包括任何修改）。

ISO 9000:2015，质量管理体系－基础与术语

ISO 9001:2015 质量管理体系-要求

3. Terms and definitions

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

3．术语与定义

本国际标准采用 ISO9000:2015 *和下列*中的术语与定义。

3.1 counterfeit parts

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

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

3.1 假冒零件

通过未授权的复制，模仿，替代或者改装零件的方式（如材料，零件或组件），故意误导这是一个原始或者授权厂家指定的真品。
注：假冒零件可能包括但不限于：假的标识或标签，等级，序列号，日期代码，文件，或者性能特性。

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 关键项目

对产品和服务的提供和使用有重要影响的项目(如功能，零件，软件，特性，过程)，包括安全，性能，形成，安装，功能，可生产性，使用寿命等，需要特定的措施以保证能充分地管理。关键项目举例如安全关键项目，破裂关键项目，任务关键项目，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.

3.4 关键特性

是一种属性或特征，其变化将对产品安装，形成，功能，性能 ，使用寿命或可制造性产生重大影响，因而需要采取特殊措施对其变化进行控制。

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

在没有引起人员伤害或财产损失的不可接受风险的情况下，产品能履行其设计或者预期用途的状况。

3.5 special requirements

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

NOTE Special requirements (3.5) and critical items (3.2), along with key characteristics(3.3), are interrelated. Special requirements are identified when determining and reviewing requirements related to the product (see 8.2.2 and 8.2.3). Special requirements can require the identification of critical items. Design output (see 8.3.5) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled.

3.5 特殊要求

由顾客识别或组织自己确定的要求，不能满足这些要求具有高风险性，因而要求它们包含在运行风险管理过程中。确定特殊要求的因素，包括产品或过程的复杂性，过去的经验，以及产品或过程的成熟度.特殊要求的例子包括顾客强制的行业极限能力，或者是组织自身确定的技术或过程的极限能力。

注：特殊要求（3.5）和关键项目（3.2）以及关键特性(3.3)是相互关联的。特殊要求是在确定和评审与产品有关的要求时识别的（见 8.2.2 和 8.2.3）。特殊要求可能要求识别关键项目。设计输出（见 8.3.5)可能包括识别要求采取特殊措施保证其得到充分管理的关键项目。一些关键项目由于需要对其变化进行控制，会被进一步分为关键特性。

4 Context of the organization

4 组织环境

4.1 Understanding the organization and its context

4.1 理解组织及其环境

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，并影响其质量管理体系实现预期结果能力的外部和内部问题。

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

组织应监视和评审这些外部及内部问题的信息。

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

注1：这些问题可以包括需要考虑的正面和负面因素或状况；

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：通过考虑国际、国家、地区或当地的法律、技术、竞争、市场、文化、社会和经济环境方面的问题有助于对外部环境的理解。

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

注3：通过考虑组织的价值、文化、知识和绩效相关的问题有助于对内部环境的理解。

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:

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

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

a) 与质量管理体系有关的相关方；

b) 这些相关方对质量管理体系的要求；

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

组织应对与这些相关方及其要求的相关信息进行监视和评审。

4.3 Determining the scope of the quality management system

4.3 确定质量管理体系的范围

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

组织应明确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:
a) the external and internal issues referred to in 4.1;
b) the requirements of relevant interested parties referred to in 4.2;
c) the products and services of the organization.

在确定范围时，组织应考虑：
a) 各种内部和外部问题，见4.1；
b) 相关方的要求，见4.2；
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.

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

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International

组织的质量管理体系范围应作为形成文件的信息加以保持。该范围应描述所覆盖的产品和服务类型。若组织认为本标准的某些要求不适

Standard that the organization determines is not applicable to the scope of its quality management system.

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.

用其质量管理体系的范围，应说明理由。

那些不适用于组织的质量管理体系要求，不能影响组织确保产品和服务符合性以及增强顾客满意的能力或责任，否则不能声称符合本标准。

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也应考虑顾客和适用法律法规对质量管理体系要求。

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

组织应确定质量管理体系所需的过程及其在整个组织中的应用，且应：

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

a) 确定这些过程所需的输入和预期的输出；

b) determine the sequence and interaction of these processes;

b) 确定这些过程的顺序和相互作用；

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

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

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

d) 确定这些过程所需的资源并确保其可用性；

e) assign the responsibilities and authorities for these processes;

e) 分配与这些过程相关的职责和权限；

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

f）应对按照6.1 的要求所确定的风险和机遇；

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

g）评价这些过程，实施所需的变更，以确保实现这些过程的预期结果；

h) improve the processes and the quality management system.

h）改进过程和质量管理体系。

NOTE Subclauses a) through h) are considered essential to the adoption of a process approach as described in clause 0.3.

注： 子条款a）到h）被认为是对章节0.3中描述的过程方法的采用必不可少的。

4.4.2 To the extent necessary, the organization shall:

4.4.2 在必要的程度上，组织应：

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

a) 保持形成文件的信息以支持过程运行；

b) retain documented information to have confidence that the

b）保留确认其过程按策划进行的形成文件的

processes are being carried out as planned.

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;***

NOTE The above description of the quality management system can be complied into a single 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;

信息。

组织应建立和保持的文件化信息，包括：

-相应相关方的总体描述（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及其在组织中应用的描述；

-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；

注：上述质量管理体系的描述可以写入一个单一的文件化信息源，称为质量手册。

5 领导作用

5.1 领导作用和承诺

5.1.1 总则

最高管理者应证实其对质量管理体系的领导作用和承诺，通过：

a) 对质量管理体系的有效性承担责任；

b) 确保制定质量管理体系的质量方针和质量目标，并与组织环境和战略方向保持一致；

c) 确保质量管理体系要求融入组织的业务过程；

d) 促进过程方法和基于风险思维的应用；

e) 确保获得质量管理体系所需的资源；

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) 确保实现质量管理体系的预期结果；

h) 鼓励、指导和支持员工为质量管理体系的有效性做出贡献；

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 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.

5.2 Policy

5.2.1 Developing 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 supports its 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.

5.2.2 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.

i) 推动改进；

j) 支持其他管理者履行其相关领域的职责。

注：本标准使用的"业务"一词可大致理解为涉及组织存在目的的核心活动，无论是公营、私营、盈利或非盈利组织。

5.1.2 以顾客为关注焦点

最高管理者应证实其以顾客为关注焦点的领导作用和承诺，通过：

a) 确定、理解并持续满足顾客要求以及适用的法律法规要求；

b) 确定和应对能够影响产品和服务的符合性，以及增强顾客满意能力的风险和机遇；

c) 始终致力于增强顾客满意。

d) 产品和服务的符合性和准时交付绩效应得到测量，如果策划的结果不能或将不能实现时，应采取适当的措施。

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) 为制定质量目标提供框架；

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 沟通质量方针

质量方针应：

a) 作为文件化信息，可获得并保持；

b) 在组织内得到沟通、理解和应用；

c) 适当时，可为有关相关方获取。

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.

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 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.

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

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

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.

5.3 组织的岗位、职责和权限

最高管理者应确保整个组织内相关岗位的职责、权限得到分配、沟通和理解。

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) 将质量管理体系的绩效及其改进机会（见10.1）报告给最高管理者；

d) 确保在整个组织内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。

最高管理者必须在本组织的管理层中任命一名指定的人员作为管理者代表，其应具有监督上述要求的职责和权限。

管理者代表应具有在组织内自由地和不受限制地直达最高管理者解决质量管理问题。

注：管理者代表的职责可能包括与外部机构进行有关质量管理体系事务的联络。

6 策划

6.1 应对风险和机遇的措施

6.1.1 策划质量管理体系时，组织应考虑4.1所描述的问题和4.2所提及的要求，确定需要应对的风险和机遇，以便：

a) 确保质量管理体系能够实现其期望结果；

b) 增强有利影响；

c) 避免或减少不利影响；

d) 实现改进。

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 practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

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.

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

a) what will be done;

b) what resources will be required;

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。

应对风险和机遇的措施应与其对于产品和服务符合性的潜在影响相适应。

注1：应对风险可包括规避风险、为寻求机遇而承担风险、消除风险源、改变风险发生的可能性或后果、分担风险、或通过明智决策延缓风险。

注2：机遇可能会导致采用新实践、推出新产品、开辟新市场、赢得新客户、建立合作伙伴关系、利用新技术以及能够解决组织或其顾客需求的其它有利的可能性。

6.2 质量目标及其实现的策划

6.2.1 组织应针对质量管理体系所需的相关职能、层次和过程建立质量目标。

质量目标应：
a） 与质量方针保持一致；

b） 可测量；
c） 考虑到适用的要求；

d） 与提供合格产品和服务以及增强顾客满意相关；

e） 予以监视；

f） 得到沟通；
g） 适当时进行更新。

组织应保持有关质量目标的形成文件的信息。

6.2.2 策划如何实现质量目标时，组织应确定：

a） 采取的措施；

b） 所需的资源；

c) who will be responsible;

d) when it will be completed;

e) how the results will be evaluated.

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.

7 Support

7.1 Resources

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 constraints on, existing internal resources;

b) what needs to be obtained from external providers.

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.

7.1.3 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.

NOTE Infrastructure can include:
a) buildings and associated utilities;

b) equipment including hardware and software;

c) 由谁负责；

d) 何时完成；

e) 如何评价结果。

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，此种变更应经策划并系统地实施（见4.4）。
组织应考虑到：
a) 变更的目的及其潜在后果；

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 支持

7.1 资源

7.1.1 总则

组织应确定并提供为建立、实施、保持和持续改进质量管理体系所需的资源。

组织应考虑：

a) 现有内部资源的能力和局限；

b) 需要从外部供方获得的资源。

7.1.2 人员

组织应确定并提供有效实施质量管理体系并运行和控制其过程所需要的人员。

7.1.3 基础设施

组织应确定、提供和维护为实现产品和服务符合性及其过程运行所需的基础设施。

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) transportation resources;

d) information and communication technology.

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.

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, burnout prevention, emotionally protective);

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

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

7.1.5 Monitoring and measuring resources

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.

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.

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

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;

c）运输资源；

d）信息和通讯技术。

7.1.4 过程运行环境

组织应确定、提供和维护为实现产品和服务符合性及其过程运行所需的环境。

注：合适的过程运行的环境可以是人文因素和物理因素的组合，例如：
a) 社会因素（如无歧视，和谐稳定，无对抗）；

b) 心理因素（如舒缓心理压力、预防过度疲劳、保护个人情感）；
c) 物理因素（如温度、热度、湿度、照明、空气流通、卫生、噪音等）。

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 监视和测量资源

7.1.5.1 总则

当使用监视或测量验证产品和服务是否符合要求时，为确保结果的有效和可靠，组织应确定和提供所需的资源。

组织应确保所提供的资源：
a) 适用于指定类型的监视和测量活动；

b) 得到适当的维护，以确保持续适用其用途。

组织应保留作为监视和测量资源适合其用途的证据的形成文件的信息。

7.1.5.2 测量可追溯性

当有测量可追溯性要求时，或组织把测量结果有效性作为提供信任的重要部分时，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，应以形成文件的信息的方式保留校准或检定的依据。

b) identified in order to determine their status;

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

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

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.

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

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

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

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.

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

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.

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

NOTE 2 Organizational knowledge can be based on:
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);

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

7.2 Competence

b）予以标识，以确定其校准状态；

c）予以保护，防止可能使校准状态和随后的测量结果失效的调整、损坏或退化。

组织必须对要求校准或检定的监视和测量设备的召回，建立、实施并保持一个过程。

组织必须保持一份监视和测量设备的清单。清单应包括设备型号、唯一性标识、位置、校准或检定方法、校准周期和接收准则。

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

监视和测量设备的校准或检定应在适宜环境条件下实施。

当发现测量设备不适合其预期用途时，组织应确定以往测量结果的有效性是否受到负面影响，必要时采取适当的措施。

7.1.6 组织的知识

组织应确定过程运行以及达到产品和服务符合性所必要的知识

这些知识应予以保持，并在需要范围内可获得。

为应对不断变化的需求和发展趋势，组织应考虑现有的知识，确定如何获得更多必需的知识，并进行更新。

注1：组织的知识是从经验中获得的特定知识，是实现组织目标所使用和共享信息。

注2：组织的知识可以基于：
a）内部来源（例如知识产权、从经历获得的知识、从失败和成功项目得到的经验教训；得到和分享未形成文件的知识和经验，过程、产品和服务的改进结果）；
b）外部来源（例如标准、学术交流、专业会议，从顾客或外部供方收集的知识）。

7.2 能力

The organization shall:

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

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

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.

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 not conforming with the quality management system requirements;

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

f) their contribution to product or service conformity;

g) their contribution to product safety;

h) the importance of ethical behavior.

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;

组织应：

a) 确定在组织控制下从事影响质量管理体系绩效和有效性工作的人员所必要的能力；

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，采取措施获得所需的能力，并评价措施的有效性；

d) 保留适当的形成文件的信息，作为人员能力的证据。

注： 应当考虑定期评审所需的能力。

注：适当的措施可包括对在职人员进行培训、辅导或重新分配工作，或者招聘或外包具备能力的人员等。

7.3 意识

组织应确保其控制范围内的相关工作人员知晓：

a) 质量方针；

b) 相关的质量目标；

c) 他们对质量管理体系有效性的贡献，包括改进质量绩效的益处；

d) 偏离质量管理体系要求的后果；

e) 相关质量管理体系文件化的信息及其更改；

f) 他们对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 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) 沟通的内容；

b) 沟通的时机；

c) 沟通的对象；

d) how to communicate;

e) who communicates.

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

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.

7.5.2 Creating and updating

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

a) identification and description (e.g. a title, 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.

7.5.3 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, improper use, or loss of integrity).

d) 沟通的方式；

e) 负责沟通的人员；

注： 沟通应包括质量管理体系相关的内部和外部反馈。

7.5 形成文件的信息

7.5.1 总则

组织的质量管理体系应包括：
a) 本标准所要求的形成文件的信息；

b) 组织确定的为确保质量管理体系有效运行所需的形成文件的信息。

注：不同组织的质量管理体系形成文件的信息的多少与详略程度可以不同，取决于：
- 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 编制和更新

在编制和更新形成文件的信息时，组织应确保下列内容得到适当安排：
a) 标识和说明（如：标题、日期、作者、索引编号等）；
b) 格式（如：语言、软件版本、图示）和媒介（如：纸质、电子格式）；
c) 评审和批准，以确保适宜性和充分性。

注：批准意味着针对相关类型文件的信息应能识别出组织所确定的授权人员和批准方法。

7.5.3 形成文件的信息的控制

7.5.3.1 组织应控制质量管理体系和本标准所要求的形成文件的信息，以确保：

a) 无论何时何处需要这些信息，均可获得并适用；

b) 予以妥善保护（如防止泄密、不当使用或不完整）。

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

a) distribution, access, retrieval and use;

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.

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 can 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;***

7.5.3.2 为控制形成文件的信息，适用时，组织应实施下列控制活动：

a） 分发、访问、检索和使用；

b） 存储和保护，包括保持可读性；

c） 变更的控制（比如版本控制）；

d） 保留和处置。

e） 当出于任何目的需要保留作废文件时，需要通过移除、或使用适当地标识或控制，防止这些作废的形成文件的信息非预期的使用。

应对组织所确定的策划和运行质量管理体系所需的来自外部的形成文件的信息进行适当标识和控制。

应对保存的作为符合性证据的形成文件的信息予以保护，防止非预期的篡改。

当形成文件的信息是电子化管理时，数据保护过程应规定（如防止丢失，非授权变更，无意识的修改，损坏，物理性破坏）。

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

8 运行

8.1 运行策划和控制

组织应通过采取下列措施，策划、实施和控制满足产品和服务要求所需的过程（见4.4），并实施第6章所确定的措施：

a） 确定产品和服务的要求；

注：确定产品和服务的要求应考虑下述方面：

-人员和产品的安全；

-可生产性和可检验性；

-可靠性、可用性和可维护性；
-产品中使用的零件和材料的适宜性；

-嵌入式软件的选择和开发；

- ***product obsolescence;***

- ***prevention, detection, and removal of foreign objects;***

- ***handling, packaging and preservation;***

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

b) establishing criteria for:

1) the processes;

2) the acceptance of products and services;

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 experiment;***

- ***verification;***

- ***failure mode, effect and criticality analysis.***

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

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

e) determining and keeping 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***;***

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

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

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

-产品的报废；

-预防、探测和移除外来物；

-处理、包装和防护；

-产品在寿命结束时的回收和最终处置。

b) 制定有关下列内容的准则：

1) 过程；
2) 产品和服务的接收；

注：根据产品特性并取决于特定条件，统计技术可以用于支持：
一设计验证（如：可靠性、可维修性、产品安全）；

一过程控制：

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

一验证，和

一失效模式、影响和危害性分析。

c) 确定实现产品和服务符合性要求*以及满足产品和服务准时交付*所需的资源；

d) 按照准则实施过程控制；

e) 在需要的范围和程度上，确定并保持形成文件的信息：

1) 证实过程已经按策划进行；

2) 证明产品和服务符合要求。

f) 确定管理关键项目所需的过程和控制，包括当关键特性已经识别时的生产过程控制；

g) 受影响的组织职能代表参与运行策划和控制；

h) 确定支持产品和服务的使用和维护的过程和资源；

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

i) 确定从外部供方处获取的产品和服务；

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

j) 建立所需的控制防止不合格的产品和服务交付给顾客。

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

注：一种实现运行策划和控制的方法可能贯穿用于完整过程阶段。

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, with resource and schedule constraints.

适用时，根据组织、顾客要求，以及产品和服务，组织应以一种结构化和受控的方式策划和管理产品和服务的提供，包括在可接受的风险内、在资源和时间限制的状况下，安排活动按照策划的顺序执行以满足要求。

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

注：这种活动通常称为项目策划，项目管理或专案管理。

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

运行策划的输出应与组织的运行相适应。

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

注：作为策划的输出，规定质量管理体系过程以及用于一个具体产品、服务、项目或合同的资源的形成文件的信息，可称为质量计划。

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

组织应对策划的变更进行控制并评审非预期变更的结果，必要时采取措施减轻任何负面影响。

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

组织应确保外包过程得到控制（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.

组织必须建立、实施和保持一个过程，以策划和控制工作的临时性或永久性转移，并保证工作持续地符合要求。应确保工作转移过程的影响和风险是受控的。

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

注：对于从组织到外部供方，或从一个外部供方转移到另一个外部供方的工作转移控制，见 8.4。对于从组织的一处设施转移到另一处，或从外部供方转移到组织的工作转移控制，见 8.5.

8.1.1 Operation risk management

8.1.1 运行风险管理

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

组织应策划、实施和控制一个过程，以管理实现适用要求的运行风险，适用时包括组织，产品和服务的要求：

a) assignment of responsibilities for operational risk management;

a) 运行风险管理的职责分配；

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

b) 风险评估准则的确定（如：可能性、后果，风险接受水平）；

consequences, risk acceptance);

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

c） 在运行的整个过程，识别、评估和沟通风险；

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

d） 当风险超过定义的风险接受准则时，应确定、实施和管理措施消除风险；

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

e） 当消除风险措施实施后，风险应保持在可接受水平。

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 operation of products and services (clause 8).

注 1：条款 6.1 阐明了策划组织质量管理体系时的风险和机遇，条款 8.1.1 的范围限于产品和服务运行有关的风险（见 8 章节）。

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

注 2：在航空，航天和国防领域，风险通常从发生的可能性和后果的严重度进行表述。

8.1.2 Configuration management

8.1.2 技术状态管理

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

组织应策划、实施和控制一个适用于组织、产品和服务的技术状态管理过程，以确保在产品生命周期内识别和控制物理和功能特性。该过程应：

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

a）控制产品标识和要求的可追溯性，包括实施变更的标识；

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

b）确保形成文件的信息(如要求、设计、验证、确认和接收等文件)与产品和服务的实际特性一致；

8.1.3 Product safety

8.1.3 产品安全

The organization shall plan, implement and control the processes needed to assure product safety during the entire product life cycle, as appropriate to the organization and the product.

组织应策划、实施和控制必要的过程，确保在适用于组织和产品的整个产品生命周期内产品安全。

NOTE Examples of these processes include:

注： 这些过程的示例包括：

- assessment of hazards and management of associated risks (see 8.1.1);

- 危害性评估和相关风险管理（见 8.1.1）；

- management of safety critical items;

-安全关键项目的管理；

- analysis and reporting of occurred events affecting safety;

-分析和报告发生的影响安全的事件；

- communication of these events and training of persons.

-沟通安全事件并进行人员培训。

8.1.4 Prevention of counterfeit product

8.1.4 预防假冒件

The organization shall plan, implement and control a process,

组织必须策划、实施和控制适用于产品的过程，防止假冒或可疑假冒件的使用

appropriate to the product, for the prevention of counterfeit or suspect counterfeit product use and their inclusion in product(s) delivered to the customer.

和包含在交付给客户的产品中。

NOTE Counterfeit part prevention processes should consider:

注： 假冒件预防过程应当考虑：

-training of appropriate persons in the awareness and prevention of counterfeit part;

-培训适用人员假冒件的意识和防范；

- application of a parts obsolescence monitoring program;

-使用零件报废监控程序；

-control for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources.

-控制从外部原始或授权厂家、授权分销商、或其他批准方获得的产品；

- requirements for assuring traceability of parts and components to their original or authorized manufacturers;

-要求保证零部件可追溯到其原始或授权厂家；

- verification and test methodologies to detect counterfeit parts;

-规定发现假冒件的验证和测试方法；

-monitoring of counterfeit parts reporting from external sources;

-监控来自外部假冒件的报告；

-quarantine and reporting of suspect or detected counterfeit parts.

-隔离和报告可疑的或发现的假冒件。

8.2 Requirements for products and services

8.2 产品和服务的要求

8.2.1 Customer communication

8.2.1 顾客沟通

Communication with customers shall include:

与顾客沟通的内容应包括：

a) providing information relating to products and services;

a) 提供有关产品和服务的信息；

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

b) 处理问询、合同或订单，包括变更；

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

c) 获得有关产品和服务的顾客反馈，包括顾客抱怨；

d) handling or controlling customer property;

d) 处理或控制顾客财产；

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

e) 当关系重大时，制定有关应急措施的特定要求。

8.2.2 Determining the requirements related to products and services

8.2.2 与产品和服务有关要求的确定

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要求时，组织应确保：

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

a) 所确定的产品和服务的要求包括：

1) any applicable statutory and regulatory requirements;
2) those considered necessary by the organization;

1) 任何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) 组织能够满足所提供产品和服务的要求。

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

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

8.2.3 Review of requirements related to products and services

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:

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 specified or 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.

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

If upon review the organization determines that some customer requirements cannot be met or can only partially be met, the organization shall negotiate a mutually acceptable requirement with the customer.

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

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

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

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.

8.2.4 Changes to requirements for products and services

The organization shall ensure that relevant documented information

c）产品和服务的特殊要求得到确定；

d）运行风险（如新的技术,提供的能力和产能,短的交付期）已经识别。

8.2.3 与产品和服务有关要求的评审

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

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；

e） 适用产品和服务的法律法规要求；

f） 与先前表述存在不一致的合同或订单的要求；

评审应有组织的相关职能参与。

如果依据组织的评审确定某些顾客的要求不能满足或者只能部分满足，组织应与顾客商讨相互可接受的要求。

组织应确保与以前表述不一致的合同或订单的要求已得到解。

若顾客提供的要求没有形成文件，组织在接受顾客要求前应对顾客要求进行确认。

注：在某些情况下，例如网络行销，对每一份订单进行正式评审是不现实的。取代的做法可以对有关产品信息，例如产品目录、或者广告材料等进行评审。

8.2.3.2 适用时，组织应保留下列形成文件的信息：
a）评审结果；

b）任何产品和服务的新要求。

8.2.4 产品和服务要求的更改

is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

若产品和服务的要求发生变更，组织应确保相关形成文件的信息得到修改，并确保相关人员知晓已变更的要求。

8.3 Design and development of products and services

8.3 产品和服务的设计和开发

8.3.1 General

The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.1 总则

组织应建立、实施和保持设计和开发过程，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;

e) the internal and external resource needs for the design and development of products and services;

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

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

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

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

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

8.3.2 设计和开发策划

在确定设计和开发的各个阶段及其控制时，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) 所要求的过程阶段，包括适用的设计和开发评审；

c) 所要求的设计和开发验证和确认活动；

d) 设计和开发过程涉及的职责与权限；

e) 产品和服务的设计和开发所需的内部和外部资源；

f) 设计和开发过程参与人员之间接口的控制需求；

g) 设计和开发过程中顾客和用户参与的需求；

h) 后续产品和服务提供的要求；

i) 顾客和其他相关方期望的设计和开发过程的控制水平；

j) 证实已经满足设计和开发要求所需的形成文件的信息。

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

适用时，组织必须将设计和开发工作量分解为若干项不同的活动，对每项活动，确定任务、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 the product and service (reference output of 8.1 a).

设计和开发策划应考虑产品和服务的提供、验证、测试和维修的能力（见 8.1a 的输出）。

8.3.3 Design and development inputs

The organization shall determine the requirements essential for the

8.3.3 设计和开发输入

组织应确定特定类型产品和服务的设计和开

specific types of products and services to be designed and developed. The organization shall consider:

a) functional and performance requirements ***(see 8.1 a)***;

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

c) statutory and regulatory requirements;

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

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

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

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

Conflicting design and development inputs shall be resolved.

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

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.

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.

Participants in design and development reviews shall include representatives of functions concerned with the design and

发所必需的要求。组织应考虑：

a) 功能和性能的要求（见8.1a）；

b) 来源于以前类似设计和开发活动的信息；

c) 法律法规要求；

d) 组织承诺实施的标准或行业规范；

e) 由产品和服务特性引发的潜在失效后果。

f) 适用时，性能衰退的潜在后果（如材料、过程、部件、设备和产品）。

设计和开发输入应完整、清楚，满足设计和开发的目的。

设计和开发输入的冲突应予解决。

组织应保留有关设计和开发输入的形成文件的信息。

注：组织也可考虑其它信息如标杆水准，外部供方反馈，内部产生数据和服务中数据作为设计和开发的输入。

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的措施；

f) 保留这些活动的形成文件的信息。

g) 批准转入下一阶段。

设计和开发评审的参加者应包括与评审的设计和开发阶段有关的职能代表。

development stage(s) being reviewed.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

注：设计和开发的评审、验证和确认具有不同的目的。根据组织的产品和服务的具体情况，可以单独或以任意组合进行。

8.3.4.1 When tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed and documented to ensure and prove the following:

8.3.4.1 当验证和确认必须进行试验时，必须对这些试验进行策划、控制、评审并形成文件，以确保证实下列要求：

a) test plans or specifications identify the test item being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria;

a. 试验计划或规范确定了要进行试验的项目和需要使用的资源；规定了试验目的和条件、要记录的参数以及相关接收准则；

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

b. 试验程序描述了使用的测试方法、如何进行试验，和如何记录结果；

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

c. 提交试验的产品的技术状态正确；

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

d. 遵守了试验计划和试验程序的要求；

e) the acceptance criteria are met.

e. 满足接收准则。

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

试验中使用的监视和测量设备应按条款 7.1.5 控制.

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

在设计和开发完成时，组织应确保报告、计算、试验结果等能证明在所有规定的运行条件下，产品或服务的设计满足规范要求。

8.3.5 Design and development outputs

8.3.5 设计和开发输出

The organization shall ensure that design and development outputs:

组织应确保设计和开发输出：

a) meet the input requirements;

a) 满足输入的要求；

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

b) 对于产品和服务提供的后续过程是充分的；

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

c) 包含或引用监视和测量的要求，适当时，包括接收准则；

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

d) 规定对于实现预期用途、保证安全和正确提供（使用）所必须的产品和服务特性。

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

e) 适用时，规定任何关键项目包括任何关键特性，以及对这些项目要采取的特殊措施。

f) are approved prior to release.

f) 放行前得到批准。

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

组织应确定对产品进行标识、制造、验证、使

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.

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

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.

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

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.

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

8.4 Control of externally provided processes, products and services

8.4.1 General

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

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

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

The organization shall identify and manage the risks

用和维修所需要的数据。

注： 数据可包括：

-确定产品的技术状态和设计特性的图纸，零件清单和规范；

-提供和维护产品和服务符合性需要的材料、过程、制造和装配，处理，包装和防护的数据。

-运行和维护产品的技术数据和修理方案。

组织应保留有关设计和开发输出的形成文件的信息。

8.3.6 设计和开发变更

组织应识别、评审和控制在产品和服务设计和开发期间以及后续所做的变更，以避免不利影响，确保符合要求。

组织应执行规定了要求的过程，在更改实施前，通知顾客影响到顾客要求的任何更改。

组织应保留下列形成文件的信息：
a) 设计和开发变更；
b) 评审的结果；

c) 变更的授权；

d) 预防负面影响所采取的措施。

设计和开发更改应按技术状态管理过程要求进行控制。

8.4 外部提供过程、产品和服务的控制

8.4.1 总则

组织应确保外部提供的过程、产品和服务符合要求。

组织必须对所有从外部提供的过程、产品和服务的符合性负责，包括顾客指定的外部供方。

当要求时，组织应确保使用顾客指定或批准的外部供方，包括过程外包方（如特殊过程）；

组织应识别和管理与外部提供的过程、产品和

associated to the external provision of processes, products and services, as well as the selection and use of external providers.

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

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.

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.

NOTE During external provider selection and evaluation, 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.

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 type, process family);

c) periodically review external provider performance including 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 process for controlling documented information created by and/or retained by external providers.

服务、以及在选择和使用外部供方时面临的相关风险。

组织应要求外部供方对他们的直接和次级供方进行适当的控制，以确保满足要求。

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过程或部分过程。

组织应基于外部供方提供所要求的过程、或产品和服务的能力，确定并使用外部供方的评价、选择、绩效监控以及再评价的准则。组织应保留这些活动及由评价引发的任何必要的措施的形成文件的信息。

注：在选择和评价外部供方时，可使用来自客观和可靠外部供方提供的质量数据作为组织自己的评估（例如：信息来自认可的质量管理体系或过程认证机构、政府机构或顾客批准的外部供方）。使用这种数据只能是组织对外部供方控制过程的一个组成部分，组织仍然有验证外部提供的过程、产品和服务满足规定要求的责任。

8.4.1.1 组织应：

a）确定决定批准状态、批准状态变更、以及依据其批准状态控制使用外部供方条件的过程、职责和权限。

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

c）周期性地评估外部供方的业绩，包括产品和服务的符合性和准时交付能力；

d）当外部供方不能满足要求时，确定采取必要的措施；

e）确定过程控制由外部供方生成和/或

保留的形成文件的信息。

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.

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 ***(see 8.4.2.1)***.

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

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

NOTE 2 Verification activities can include:
-review of objective evidence of the conformity of the processes, products and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter);

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

- review of the required documentation;

- review of production part approval process implementation;

- inspection of products or verification of services upon

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负面影响。

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和适用的法律法规要求的能力的潜在影响；

2) 外部供方自身控制的有效性。

3) 定期评审外部供方绩效的结果（见 8.4.1.1c）；

d) 确定必要的验证或其他活动，以确保外部提供的过程、产品和服务满足要求。

外部提供的过程、产品和服务的验证活动应按识别的风险进行，当存在不合格品或假冒件的高风险情况下，适用时应包括检验或定期测试。

注 1 顾客对任何层次的供应链所做的验证活动不能免除组织提供可接受的过程、产品和服务、以及符合所有要求的责任。

注 2 验证活动可以包括：
- 评审从外部供方处获得的过程、产品和服务的符合性客观证据（如随附产品文件、合格证明、测试文件、统计文件、过程控制文件、生产过程验证的结果、以及后续生产过程变更的评估）；

- 在外部供方处的检验和审核；

- 对要求文件的评审；

-评审生产件批准过程的执行情况；

- 按收货单进行产品检验或服务验证；

receipt;

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

When externally provided products are 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.

When the organization delegates verification activities to the external provider, the scope and requirements for delegation shall be defined and a register of delegations maintained. The organization shall periodically monitor the external provider's delegated verification activities.

When external provider test reports are utilized to verify externally provided products, the organization shall have a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or organization have identified raw material as a significant operational risk (e.g. critical items), the organization shall implemented a process to validate the accuracy of test reports.

8.4.3 Information for external providers

The organization shall ensure the adequacy of requirements 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 requirement, critical items, including key***

– 评审委托给外部供方的产品验证结果。

在等待所有要求的验证活动完成前，当外部提供的产品被放行用于生产，必须对其进行标识和记录，做到如果后续验证过程中发现产品不符合要求，能够对其进行召回和更换。

当组织委托供应商进行验证活动时，应规定委托的范围和要求，并保持一份委托人员的清单。组织应定期监控委托给外部供方的验证活动。

当使用外部供方的测试报告来验证外部提供的产品时，组织应建立过程评估测试报告中的数据以确认产品满足要求。当顾客或组织识别原材料作为一个很重要的运行风险时（如关键项目），组织应实施过程验证测试报告的准确性。

8.4.3 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要求是充分的。

组织应与外部供方沟通以下要求：

a） 所提供的过程、产品和服务，*包括相关技术数据的标识（如规范，图纸，过程要求，和作业指导书）；*

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质；

d） 外部供方与组织的接口；

e） 组织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，关键项目，包括关键特性；

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 products (see 8.1.4);

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

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

-provide test specimens (e.g., production method, number, storage conditions) for design approval, inspection/ verification, investigation or auditing;

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

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

m) ensuring persons are aware of
- their contribution to product and 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;

i) *试验、检验和验证（包括生产过程的验证）；*

j) *使用的产品验收的统计技术和组织相关验收指导书的统计技术；*

k) *需要*
-执行的质量管理体系；

-使用顾客指定或批准的外部供方，包括过程外包供方（如特殊过程）；

-向组织通报不合格的过程、产品或服务并获得组织处理批准；

-预防假冒件的使用（见 ***8.1.4****）；*

-通知组织过程、产品或服务的更改，包括外部供方的更改或生产场所的更改，并获得组织批准；

-向外部供方传递组织适用的要求，包括顾客要求；

-提供试验件用于设计批准、检验/验证、调查或审核（例如生产方法，序列号，储存条件）；

-需要保留的文件化信息，包括保存期限和处置要求。

i) *在供应链的任何层次，组织及其顾客和法规机构有权访问任何适用的场所,及适用的文件化信息。*

m) *确保人员意识到*
-他们对产品和服务符合性的贡献；
-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) 可获得形成文件的信息，以规定以下内容：

1）所生产的产品、提供的服务或进行的活动的特性；

2) the results to be achieved;

NOTE 1 Documented information that defines characteristics of products and services can include 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);***

   - ***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).

d) the use of suitable infrastructure and environment for the operation of processes;
NOTE Suitable equipment can include product specific tools (e.g., jigs, fixtures, molds) and software programs.

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

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).

g) the implementation of actions to prevent human error;

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

2）拟获得的结果。

注 1：确定产品和服务特性的文件化的信息可包括图纸、零件清单、材料和工艺规范。

注 2：执行活动和拟获得结果的文件化信息可包括过程流程图、控制计划，生产文件（如：生产计划、路线图、流程卡、工作指令和工艺卡）和验证文件。

b）获得并使用适宜的监测和测量资源；

c）在适当的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）确保产品验收的监视和测量活动的文件化信息包括：

-接收和拒收准则；

-按顺序进行验证操作；

-保留测量的结果（至少表明接收或拒收）；

-要求的任何特定的监视和测量设备及其相关的使用说明；

2）当使用抽样检验作为产品验收的方法时，抽样计划应基于认可的统计原理，并适于使用（抽样计划应与产品的重要性和过程能力相匹配）。

d）为过程的运行提供适宜的基础设施和环境；
注：适宜的设备包括产品专用工装（如型架、夹具、模具）和软件程序。

e）配备具备能力的人员，包括所要求的资格；

f）若输出结果不能由后续的监测或测量加以验证，应对生产和服务提供过程实现策划结果的能力进行确认和定期再确认；
注：这些过程也被称为特殊过程（见 8.5.1.2）。

g）采取措施防止人为错误；

h）实施放行、交付和交付后活动。

i) the establishment of criteria for workmanship(e. g. written standards, representative samples, illustrations);	*i）工艺准则的建立（如文字标准、代表性样品，图示）；*
j) accountability for all product during production (e.g., parts quantities, split orders, nonconforming product);	*j）在生产过程中对所有产品负有责任（如零件数量、分作业指令、不合格品）；*
k) control and monitoring of identified critical items, including key characteristics, in accordance with established processes;	*k）按建立的过程，控制和监视已识别的关键项目，包括关键特性；*
l) determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);	*l）确定方法来测量可变数据（如工具，在线探测，检验设备）；*
m) identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages;	*m）在后续阶段不能进行足够符合性验证时，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）所有生产和检验/验证操作已按计划或者其他形成文件并经批准的要求完成的有效证据；*
o) provision for the prevention, detection and removal of foreign objects;	*o）提供预防、检测和去除外来物；*
p) 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）对会影响符合产品要求的公用设施和供给物（如水、压缩空气、电及化学产品）进行监视和控制，*
q) the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to recall and replacement if it is a later found that the product does not meet requirement.	*q）在等待所有要求的测量和监视活动完成前，产品被放行到后道工序，应对其进行标识和记录，做到如果后来发现产品不符合要求，能够对其进行召回和更换。*
8.5.1.1 Control of production equipment, tools and software programs	*8.5.1.1 生产设备、工装和软件程序的控制*
Equipment, tools and software programs used to automate, control, monitor or measure production processes shall be validated prior to final release for production and shall be maintained.	*生产设备、工装和用于自动操作、控制、监视或测量生产过程的软件程序在最终放行生产前应进行确认，并进行维护。*
Storage requirements shall be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.	*对储存中的生产设备或工装必须确定储存要求，包括任何必要的定期防护或状况检查。*
8.5.1.2 Validation and control of special processes	*8.5.1.2 特殊过程的验证和控制*
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:	*当过程输出不能由后续的监视或测量加以验证，组织应对这些过程作出安排，适用时包括：*
a) definition of criteria for the review and approval of the processes;	*a） 规定过程的评审和批准准则；*

b) determination of conditions to maintain the approval;

c) approval of facilities and equipment;

d) qualification of persons;

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

f) requirements for documented information to be retained.

b） 确定保持批准的条件；

c） 设施和设备的批准；

d） 人员资质；

e） 对过程的实施和监控使用特定的方法和程序；

f） 要求保留的文件化信息。

8.5.1.3 Production process verification

The organization shall implement production process verification activities to ensure the production process is capable of producing products that consistently meet requirements.

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

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 capable of producing 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).

NOTE This activity can be referred to as first article inspection.

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

8.5.1.3 生产过程验证

组织应执行生产过程验证活动以保证生产过程有能力生产持续满足要求的产品。

注：这些活动包括风险评估，产能研究，能力研究和控制计划。

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、生产文件和工装有能力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，应对过程重新进行验证（如工程更改，生产过程更改，工装更改）。

注：此项活动通常被称为首件检验。

组织应保留生产过程验证结果的文件化信息。

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.

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.

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

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

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.

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，以确保产品和服务符合要求。

组织应保持产品和服务技术状态的标识，以识别产品实际技术状态和所要求技术状态之间的任何差异。

组织应在产品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。

当使用接收授权媒介时（如印章、电子签名、密码），组织应对媒介建立适当的控制。

若要求可追溯，组织应控制输出的唯一性标识，且应保留实现追溯性所需的形成文件的信息。

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);

- 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.

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.

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

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.

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

8.5.4 Preservation

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

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

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

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;

注：追溯要求包括：
-在整个产品寿命期内保持标识；

-所有生产的产品能追溯到同一批原材料，或来自相同制造批次，以及最终去向（如交付、报废）；

-对于组件，能追溯其组合的单元件以及后面更高一级的组件；

-对于产品，能追溯其生产的连续记录（制造、装配、检验/验证）。

8.5.3 顾客或外部供方的财产

组织在控制或使用顾客或外部供方的财产期间，应对其进行妥善管理。

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、保护和维护。

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

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

8.5.4 防护

组织应在生产和服务提供过程中对输出进行必要防护，以确保符合要求。

注：防护可包括标识、处置、污染控制、包装、储存、传送或运输以及保护。

在适用处，按产品规范和适用的法律法规要求，产品的防护还应包括下列规定：

a. 清洁；

b. 预防、检测并去除外来物；

c. 对敏感产品的特殊处理和储存；

d. 标记和挂签，包括安全警示和告诫；

e. 贮存期控制和库存周转；

f) special handling and storage for hazardous materials.

8.5.5 Post-delivery activities

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

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) customer requirements;

e) customer feedback;

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).

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

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.

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.

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

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

f. 对危险材料的特殊处理和储存。

8.5.5 交付后的活动

组织应满足与产品和服务相关的交付后活动的要求。

在确定交付后的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的非预期后果；

c) 其产品和服务的特性、用途和预期寿命；

d) 顾客要求；

e) 顾客反馈；

f）对使用中数据的收集和分析（如性能、可靠性、经验教训）；

g）控制、更新和提供有关产品使用、维护、修理和大修的技术文件；

h）在组织外部现场工作的控制要求（如外场工作）；

i）产品/客户支援（如询问、培训、保修、维修、更换零件、资源、报废）。

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。

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

8.5.6 变更控制

组织应对生产和服务提供的变更进行必要的评审和控制，以确保稳定地符合要求。

应识别批准生产或服务提供变更的授权人员。

注：生产或服务提供的变更可包括影响过程、生产设备、工具或软件程序的变更。

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.

组织应保留有关变更评审结果、授权变更的人员以及根据评审所采取的必要措施的形成文件的信息。

8.6 Release of products and services

8.6 产品和服务的放行

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

组织应在适当阶段实施策划的安排，以验证产品和服务已符合要求。

When product is released for subsequent production use pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is later found that the product does not meet requirements.

在等待所有要求的测量和监视活动完成前，产品被放行到后续生产使用时，应对其进行标识和记录，做到如果后来发现产品不符合要求，能够对其进行召回和更换。

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

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

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

组织应保留有关产品和服务放行的形成文件的信息。形成文件的信息应包括：

a) evidence of conformity with the acceptance criteria;

a) 符合接收准则的证据；

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

b) 授权放行人员的可追溯信息。

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

当要求证明产品合格时，组织应确保保留的文件化信息能够提供产品和服务满足规定要求的证据。

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

组织应保证所有要求的形成文件的信息随同产品和服务一起交付。

8.7 Control of nonconforming outputs

8.7 不合格输出的控制

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

8.7.1 组织应确保对不符合要求的输出进行识别和控制，以防止其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"包括内部产生，收到的外部供方或顾客识别的不合格产品或服务。

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

组织应根据不符合的性质及其对产品和服务符合性的影响采取适当的措施，这也适用于产品交付之后发现的不合格产品和服务，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 nonconformance control process shall be maintained as documented information including the provisions for:

组织不合格控制过程应保持下列文件化信息，包括：

-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).

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

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***.

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.

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

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

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

8.7.2 The organization shall retain documented information that:

a) describes the nonconformity;

-规定对不合格输出的评审和处置的职责和权限，以及批准人员作出决定的过程；

-采取必要的措施，围堵不合格对其它过程、产品或服务的影响；

-给顾客或相关利益方及时报告影响到已交付的产品和服务的不符合情况；

-不合格产品和服务在交付后发现时，应确定适合其影响的纠正措施（见 10.2）；

注：要求通知不合格产品和服务的相关利益方可能包括外部供方、内部组织、顾客、分销商和法规机构。

组织应通过下列一种或多种方式处置不合格输出：

a） 纠正；

b） 对提供的产品和服务进行隔离、限制、退货或暂停；

c） 告知顾客；

d） *通过相关法规机构*获得让步接收的授权，*适用时，由顾客批准*。

原样使用或返修接收不合格品应满足下列要求：

-经过负责设计组织的授权代表或者设计组织委托的授权人员的批准；

-如果不合格导致偏离合同要求，应经过顾客授权批准。

处置为报废的产品，必须做出明显的和永久性的标记，或进行积极控制，破坏产品本身直至不可能被使用。

假冒件或者是怀疑的假冒件应控制防止再次进入供应链。

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 组织应保留下列形成文件的信息：

a） 有关不合格的描述；

b) describes the actions taken;

c) describes any concessions obtained;

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

b) 所采取措施的描述；

c) 获得让步的描述；

d) 处置不合格的授权标识。

9 Performance evaluation

9 绩效评价

9.1 Monitoring, measurement, analysis and evaluation

9.1 监视、测量、分析和评价

9.1.1 General

9.1.1 总则

The organization shall determine:

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 analysed and evaluated.

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

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

组织应确定：

a) 需要监视和测量的对象；

b) 确保有效结果所需的监视、测量、分析和评价方法；

c) 实施监视和测量的时机；

d) 分析和评价监视和测量结果的时机。

组织应评价质量管理体系的绩效和有效性。

组织应保留适当的形成文件的信息，作为结果的证据。

9.1.2 Customer satisfaction

9.1.2 顾客满意

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

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

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.

组织应监视顾客对其需求和期望获得满足的程度的感受。组织应确定这些信息的获取、监视和评审方法。

注：监视顾客感受的例子可包括顾客调查、顾客对交付的产品或服务的反馈、拜访顾客、市场份额分析、顾客赞扬、担保索赔和经销商报告。

监视和用于评价顾客满意的信息应包括，但不限于：产品和服务的符合性，准时交付绩效，顾客抱怨和纠正措施要求。

组织应开发和实施顾客满意度持续改进计划来应对通过评价识别出的不足，并评估结果的有效性。

9.1.3 Analysis and evaluation

9.1.3 分析与评价

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

组织应分析和评价通过监视和测量获得的适宜数据和信息。

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

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.

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;

a) conforms to:
1) the organization's own requirements for its quality management system;
NOTE The organization's own requirements can 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.

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

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

c) select auditors and conduct audits to ensure objectivity and the

注：适宜数据包括来源于外部报告的关于产品和服务问题的信息（如政府或行业通报，公告）。

分析结果应用于评价下列内容：
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 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是否：

a) 符合：
1) 组织自身的质量管理体系要求；
注：组织自身要求包括顾客和适用法规机构对质量管理体系的要求。

2) 本标准的要求。

b) 得到有效的实施和保持。

注：进行内部审核时，绩效指标可用来评价并确定质量管理体系是否有效实施和维护。

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、实施和保持一个或多个审核方案，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；

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 programme and the audit results.

NOTE See ISO 19011 for guidance.

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.

9.3.2 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 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 (see 6.1);

c) 选择审核员并实施审核，以确保审核过程的客观性和公正性；

d) 确保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) 保留作为实施审核方案以及审核结果的证据的形成文件的信息。

注：相关指南参见 ISO 19011。

9.3 管理评审

9.3.1 总则

最高管理者应按策划的时间间隔对组织的质量管理体系进行评审，以确保其持续的保持适宜性、充分性和有效性，并与组织的战略方向一致。

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实施情况；

b) 与质量管理体系相关的内外部问题的变化；

c) 有关质量管理体系绩效和有效性的信息，包括下列趋势性信息：

1) 顾客满意和相关利益方的反馈；

2) 质量目标的实现程度；

3) 过程绩效以及产品和服务的符合性；

4) 不合格以及纠正措施；

5) 监视和测量结果

6) 审核结果；

7) 外部供方的绩效。

8) 准时交付业绩；

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) opportunities for improvement.

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.

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

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 or reducing undesired effects;

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

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

10.2 Nonconformity and corrective action

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

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***

f）改进的机会。

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。

组织应保留作为管理评审结果证据的形成文件的信息。

10 改进

10.1 总则

组织应确定和选择改进的机会，采取必要的措施，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关注未来的需求和期望；

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。

注：改进的例子可包括纠正、纠正措施、持续改进、突破性的改变、创新和重组。

10.2 不合格和纠正措施

10.2.1 若发生不合格，包括由投诉所引起的不合格，组织应：

a）适用时，对不合格做出应对：
1） 采取措施予以控制和纠正；

2）处置产生的后果。

b）通过下列活动，评价需要采取的措施，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；

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, if necessary;

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;

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

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

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.

10.3 Continual Improvement

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

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

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

NOTE Continual improvement opportunities can result from lessons learned, problem resolutions and the benchmarking of best practices.

2) 确定不合格的原因，*适用时，包括与人为因素有关的原因*；

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，对质量管理体系进行变更。

g) 当确定外部供方对不合格负责时，向外部供方传递纠正措施的要求；

h) 当不能及时和有效地实现纠正措施时，需采取特别措施。

纠正措施应与所产生的不合格的影响相适应。

组织应保持规定不合格和纠正措施管理过程的文件化信息。

10.2.2 组织应保留形成文件的信息，作为下列事项的证据：

a) 不合格的性质及随后所采取的措施；

b) 纠正措施的结果。

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。

组织应考虑管理评审的分析和评价的结果，以及管理评审的输出，确定是否存在持续改进的需求或机会。

组织应监视改进活动的实施情况，并评价结果的有效性。

注：持续改进机会来自经验教训、问题解决和最佳实践的标杆学习。