Quality Management System-Requirements

1 Scope

1.1 General

This standard includes ISO 9001:2000 quality management system requirements and specifies additional requirements for a quality management system for the aerospace industry. The additional aerospace requirements are shown in bold, italic text.

It is emphasized that the quality management system requirements specified in this standard are complementary (not alternative) to contractual and applicable law and regulatory requirements.

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

a). needs to demonstrate its ability to consistently product what meets customer and applicable regulatory requirements, and

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

NOTE: In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.

1.2 Application

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

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

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

2 Normative reference

The following normative document contains provisions which through reference in this text constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are

质量管理体系—要求

1 范围

1.1 总则

本标准包括 ISO9001：2000 质量管理体系要求并规定了对于航空航天工业的质量管理体系的一些补充要求，补充要求以粗斜体显示。

特别强调本标准规定的质量管理体系要求是对合同要求和适用的法律法规要求的补充，而非替代。

本标准为有下列要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) 通过体系的有效应用，包括体系的有效应用，包括体系持续改进的过程以及保证符合顾客与适用法律法规要求，旨在增强顾客满意。

注：本标准中，术语“产品”仅适用于预期提供给顾客或顾客所要求的产品。

1.2 应用

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

当本标准的任何要求因组织及其产品的特点而不适用时，可以考虑对其进行删减。

除非删减仅限于标准第 7 章中那些不影响组织提供满足顾客和适用法律法规要求的产品的能力或责任要求，否则不能声称符合本标准。

2 引用标准

本国际标准引用下列名称文件的内容以构成本国际标准的条款，如果所引用的标准指明日期版次的，其后之修订或改版均不适用与本国际标准。然而，依据本国际标准达成协议之各方仍应探求使用下列引用标准

encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standard.

最近版次的可能性。如果引用的标准未指明日期版次的，则应使用改标准的最新版本。ISO （国际标准组织）及 IEC （国际电工委员会）会员皆持有国际标准的最新有效版本。

ISO 9000:2000, Quality management system-Fundamentals and vocabulary.

ISO 9000：2000 质量管理体系-基础与词汇

3 Terms and definitions

3 术语和定义

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

ISO 9000：2000 中之术语与定义均适用与本国际标准

The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:

本标准表达供应链使用的以下术语经过了更改，以反映当前的使用情况：

supplier → organization → customer

供方→ 组织→ 顾客

The term “organization” replaces the term “supplier” used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term “supplier” now replaces the term “subcontractor”.

本标准中的术语“组织”用以取代 ISO9001:1994 中所使用的术语“供方”，指应用本国际标准的单位。术语“供方”用以取代术语“分承包方”。

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

本标准中所出现的术语“产品”，也可指“服务”。

Key characteristics:

关键特性：

The features of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability.

指材料、工艺或零件的这样一些特性，其变化对产品装配、性能、服役寿命或可制造性有重大影响。

4 Quality management system

4 质量管理体系

4.1 General requirements

4.1 总要求

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

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

The organization shall

组织应：

a) Identify the processes needed for the quality management system and their application throughout the organization (see 1.2)

a) 识别质量管理体系所需的过程及其在组织中的应用（见 1.2）；

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 criteria and methods needed to ensure that both the operation and control of these processes are effective

c) 确定为确保这些过程的有效运行和控制所需的准则和方法；

d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

d) 确保可以获得必要的资源和信息，以支持这些过程的运行和对这些过程的监视；

e) Monitor, measure and analyze these processes, and

e) 监视、测量和分析这些过程；

f) Implement actions necessary to achieve planned results and continual improvement of these processes.

f) 实施必要的措施，以实现对这些过程策划的结果和对这些过程的持续改进。

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

组织应按本标准的要求管理这些过程。

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

针对组织所选择的任何影响产品符合性要求的外包过程，组织应确保对其实施控制。对此类外包过程的控制应在质量管理体系中加以识别。

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

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

4.2 Documentation requirement

4.2 文件要求

4.2.1 General

4.2.1 总则

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,
b) a quality manual,
c) documented procedures required by this International Standard,
d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and
e) records required by this International Standard(see 4.2.4), and
f) quality system requirements imposed by the applicable regulatory authorities.

质量管理体系文件应包括：

a) 形成文件的质量方针和质量目标；
b) 质量手册；
c) 本标准所需要的形成文件的程序；
d) 组织为确保其过程的有效策划，运行和控制所需的文件；
e) 本标准所要求的记录（见 4.2.4），以及
f) 由相应的法规当局强制的质量管理体系。

The organization shall ensure that personnel have access to quality management system documentation and are aware of relevant procedures. Customer and/or regulatory authorities representatives shall have access to quality management system documentation.

组织应确保其人员可以接触质量管理体系文件并了解相关程序。顾客和／或法规机构代表应能够接触到质量管理体系文件。

NOTE 1: Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

注 1：本标准出现“形成文件的程序”之处，即要求建立该程序，形成文件，并加以实施和保持。

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

注 2：不同组织的质量管理体系文件的多少和详略程度取决于：

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

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

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

注 3： 文件可采用任何形式或类型的媒体

4.2.2 Quality manual

4.2.2 质量手册

The organization shall establish and maintain a quality manual that includes

组织应编制和保持质量手册，质量手册包括：

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

a) 质量管理体系的范围，包括任何删减的细节与合理性（见 1.2）

b) the documented procedures established for the quality management system, or reference to them, and

b) 为质量管理体系编制的形成文件的程序或对其引用；

— ***when referencing the documented procedures, the relationship between the requirements of this International Standard and the documented procedures shall be clearly shown.***

— ***当采用引用方式时，应清晰地说明这些程序文件与本国际标准的要求之间的对应关系。***

c) a description of the interaction between the processes of the quality management system.

c) 质量管理体系过程之间的相互作用的表述

4.2.3 Control of documents

4.2.3 文件控制

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

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

A documented procedure shall be established to define the controls needed

应编制形成文件的程序，以规定以下方面所需的控制：

a) to approve documents for adequacy prior to issue,

a) 文件发布前得到批准，确保文件是充分和适宜的；

b) to review and update as necessary and re-approve document

b) 必要时对文件进行评审与更新，并再次批准；

c) to ensure that changes and the current revision status of documents are identified,

c) 确保文件的更改和现行修订状态得到识别；

d) to ensure that relevant versions of applicable documents are available at points of use,

d) 确保在适用处可获得适用文件的有关版本；

e) to ensure that documents remain legible and readily identifiable,

e) 确保文件保持清晰，易于识别；

f) to ensure that documents of external origin are identified and their distribution controlled, and

f) 确保外来文件得到识别，并控制其分发；

g) to prevent the unintended use of obsolete document, and to apply suitable identification to them if they are retain for any purpose,

g) 防止作废文件的非预期使用，若因任何原因而保留作废文件时，对这些文件进行适当的标识。

The organization shall coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

组织应按照合同或法规要求，与顾客和／或法规授权的管理部门协调文件的更改。

4.2.4 Control of records

4.2.4 记录控制

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

应建立并保持记录，以提供符合要求和质量管理体系有效运行的证据。记录应保持清晰、易于识别和检索。应编制形成文件的程序，以规定记录的标识、保护、检索、保存期限和处置所需的控制。

The documented procedure shall define the method for controlling records that are created by and/or retained by supplier.

形成文件的程序应规定由供应商产生和／或保持的记录的控制方法。

Records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

按照合同或法规要求，记录应能供顾客和法规机构评审。

NOTE See AS/EN 9130 for guidance

注：指南见 AS／EN 9130

4.3 Configuration Management
The organization shall establish, document and maintain a configuration management process appropriate to the product.

4.3 技术状态管理（构型管理）
组织应建立适合于产品的技术状态管理过程,形成文件并加以保持.

NOTE Guidance on configuration management is given in ISO 10007.

注: 技术状态管理的指南在 ISO10007 中.

5 Management responsibility

5 管理职责

5.1 Management commitment

5.1 管理承诺

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

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

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

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

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

5.2 以顾客为关注焦点
最高管理者应以增强顾客满意为目的,确保顾客的要求得到确定并予以满足(见 7.2.1 和 8.2.1).

5.3 Quality policy
Top management shall ensure that the quality policy

5.3 质量方针
最高管理者确保质量方针

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

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

5.4 Planning

5.4 策划

5.4.1 Quality objectives

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

5.4.1 **质量目标**

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

5.4.2 Quality management system planning

Top management shall ensure that

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

5.4.2 **质量管理体系策划**

最高管理者应确保：

a） 对质量管理体系进行策划，以满足质量目标以及4.1 的要求。

b） 在对质量管理体系的变更进行策划和实施时，保持质量管理体系的完整性。

5.5 Responsibility, authority

5.5 职责、权限与沟通

5.5.1 Responsibility and authority

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

5.5.1 职责和权限

最高管理者应确保组织内的职责，权限得到规定和沟通。

5.5.2 Management representative

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

a) ensuring that processes needed for the quality management system are established implemented and maintained,
b) reporting to top management on the performance of the quality management and any need for improvement, and
c) ensuring the promoting of awareness of customer requirement throughout the organization.
d) The organizational freedom to resolve matters pertaining to quality.

5.5.2 管理者代表

最高管理者应指定一名管理者，无论该成员在其他方面的职责如何，应具有以下方面的职责和权限：

a) 确保质量管理体系所需的过程得到建立，实施和保持；
b) 向最高管理者报告质量管理体系的业绩和任何改进度需求；
c) 确保在整个组织内提高满足顾客要求的意识。
d) ***保证能自由地解决质量有关的事务。***

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

注：管理者代表的职责可包括与质量管理体系有关事宜的外部联络。

5.3.3 Internal communication

Top management shall ensure that appropriate Communication processes are established within the

5.3.3 **内部沟通**

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

organization and that communication take place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

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

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

5.6.2 Review input

The input to management review shall include information on

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

5.6.3 Review output

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

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

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

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

6.2 Human resources

6.2.1 General

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

5.6 管理评审

5.6.1 总则

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

应保持管理评审的记录(见 4.2.4).

5.6.2 评审输入

管理评审的输入应包括以下方面的信息:

a) 审核结果;
b) 顾客反馈;
c) 过程的业绩和产品的符合性;
d) 预防和纠正措施的状况;
e) 以往管理评审的跟踪措施;
f) 可能影响质量管理体系的变更;
g) 改进的建议.

5.6.3 评审输出

管理评审的输出应包括与以下方面有关的任何决定和措施:

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

6 资源管理

6.1 资源提供

组织应确定并提供以下方面所需的资源:

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

6.2 人力资源

6.2.1 总则

基于适当的教育，培训，技能和经验，从事影响产品质量工作的人员应是能够胜任的。

6.2.2 Competence, awareness and training

The organization shall

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

6.3 Infrastructure

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

a) building, workplace and associated utilities,
b) process equipment (both hardware and software), and
c) supporting services (such as transport or communication).

6.4 Work environment

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

NOTE Factors that affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.

7 Product realization

7.1 Planning of product realization

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

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

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

6.2.2 **能力、意识和培训**

组织应

a) 确定从事影响产品质量工作的人员所必要的能力;
b) 提供培训或采取其它措施以满足这些需求;
c) 评价所采取措施的有效性;
d) 确保员工认识到所从事活动的相关性和重要性,以及如何为实现质量目标做出贡献;
e) 保持教育、培训、技能和经验的适当记录(见4.2.4)。

6.3 基础设施

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

a) 建筑物，工作场地和相关的设施；
b) 过程设备（硬件和软件）；
c) 支持性服务（如运输和通讯）。

6.4 工作环境

组织应确定并管理为达到产品符合要求所需的工作环境。

注：可能影响产品符合性的因素包括温度、湿度、照明、清洁度以及静电防护等等

7 产品实现

7.1 产品实现的策划

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

在对产品实现进行策划时，组织应确定以下方面的适当内容：

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

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

策划的输出形式应适合于组织的运作方式。

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

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

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

注 2：组织也可将 7.3 的要求应用于产品实现过程的开发。

7.2 Customer-related processes

7.2 与顾客有关的过程

7.2.1 Determination of requirements related to the product

7.2.1 与产品有关的要求的确定

The organization shall determine

组织应确定：

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

a) 顾客规定的要求，包括对交付及交付后活动的要求；

b) requirements not stated by the customer but necessary for specified or intended use, where known,

b) 顾客虽然没有明示，但规定的用途或已知的预期用途所必需的要求；

c) statutory and regulatory requirements related to the product, and

c) 与产品有关的法律法规要求；

d) any additional requirements determined by the organization.

d) 组织确定的任何附加要求。

7.2.2 Review of requirements related to the product

7.2.2 与产品有关的要求的评审

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

组织应评审与产品有关的要求。评审应在组织向顾客做出提供产品承诺之前进行（如：提交标书、接受合同或订单及接受合同或订单的修改），并应确保：

a) product requirements are defined,

a) 产品要求得到规定；

b) contract or order requirements differing from those previously expressed are resolved, and

b) 与以前标书不一致的合同或订单的要求予以解决；

c) the organization has the ability to meet the defined requirements, ***and***

c) 组织有能力满足规定的要求，***和***

d) risks (e.g., new technology, short delivery time scale) have been evaluated.

d) 风险（如新技术、短的交付期限）已被评估。

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

评审结果及评审所引起的措施的记录应予以保持（见 4.2.4）。

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

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。

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

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

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

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

7.2.3 Customer communication

7.2.3 顾客沟通

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

a) product information,
b) enquiry, contracts or order handling, including amendment, and
c) customer feedback, including customer complaints.

组织应对一下有关方面确定并实施与顾客沟通的有效安排：

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

7.3 Design and development

7.3 设计和开发

7.3.1 Design and development planning

7.3.1 设计和开发策划

The organization shall plan and control design and development of the product.
During the design and development planning, the organization shall determine

a) the design and development stages,

— in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control,

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

组织应对产品的设计和开发进行策划和控制。在进行设计和开发时，组织应确定：

a) 设计和开发各个阶段；

— 关于机构、任务顺序、强制步骤、重大阶段和技术状态控制方法

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

Where appropriate, due to complexity, the organization shall give consideration to the following activities:

— structuring the design effort into the significant element;

— ***for each element, analyzing the tasks and the necessary resources for its design and development. This analysis shall consider an identified responsible person, design content, input data, planning constraints, and performance conditions. The input data specific to each element shall be reviewed to ensure consistency with requirements.***

适当时，基于产品的复杂程度，组织应考虑以下活动：

— 将设计努力构建于重要元素之内；

— 对每个元素，分析其设计开发的任务和必需的资源。分析应考虑一个确定的责任人、设计内容、输入数据、策划限制和性能条件。每个元素特定的输入数据应被评审，以确保与产品要求一致。

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

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

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

随设计和开发的进展，在适当时，策划的输出应予更新。

The different design and development tasks to be carried out shall be defined according to specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirement.

按照顾客和／或法规要求，依据产品特点的安全或功能目标，确定要进行的不同的设计开发任务。

7.3.2 Design and development inputs

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

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

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

7.3.3 Design and development outputs

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

Design and development outputs shall
a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and for service provision,
c) contain or reference product acceptance criteria, and
d) specify the characteristics of the product that are essential for its safe and proper use, ***and***
e) ***identify key characteristics, when applicable, in accordance with design or contract requirements.***

All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained shall be defined by the organization;
for example:
--drawing, part lists, specifications;
--a listing of those drawing, part lists and specifications necessary to define the configuration and the design features of the product;
-- information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product.

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)
a) to evaluate the ability of the results of design and development to meet requirements, and
b) identify any problems and propose necessary actions, ***and***
c) ***to authorize progression to the next stage.***

7.3.2 设计和开发输入

应确定与产品要求有关的输入,并保持记录(见 4.2.4)。这些输入应包括：

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

应对这些输入进行评审,以确保输入是充分和适宜的。要求应完整、清楚，并且不能自相矛盾。

7.3.3 设计和开发输出

设计和开发输出应以能够针对和开发的输入进行验证的方式提出，并应在发放前得到批准。

设计和开发输出应：
a) 满足设计和开发输入的要求；
b) 给出采购、生产和服务提供的适当信息；
c) 包含或引用产品接收标准；
d) 规定对产品的安全和正常使用所必需的产品特性，***和***
e) ***按照设计或合同要求，适用时识别关键特性。***

组织应规定产品识别、制造、检验、使用和维护所要求的所有相关数据资料；例如：

— ***图纸、零件目录、技术条件；***
— ***定义产品技术状态和设计特征所必需的那些图纸、零件目录和技术条件的目录；***
— ***确保产品符合性所必需的材料、工艺、制造和装配形式的信息。***

7.3.4 设计和开发评审

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

a) 评价设计和开发的结果满足要求的能力；
b) 识别任何问题并提出必要的措施，***和***
c) ***以批准进入下一阶段。***

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

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

7.3.5 Design and development verification

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

NOTE Design and/or development verification may include activities such as:

- ***performing alternative calculations,***
- ***comparing the new design with a similar proven design, if available,***
- ***undertaking tests and demonstrations, and***
- ***reviewing the design stage documents before release.***

7.3.5 设计和开发验证

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

注：设计和／或开发验证包括以下活动：

- ***变换方法进行计算***
- ***如可能，将新设计与已证实的类似设计进行比较，***
- ***执行试验和演示证明，***
- ***评审发放前的设计阶段文件。***

7.3.6 Design and development validation

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

NOTE

- ***Design and/or development validation follows successful design and/or development verification.***
- ***Validation is normally performed under defined operating conditions.***
- ***Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion.***
- ***Multiple validations may be performed if there are different intended uses.***

7.3.6 设计和开发确认

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

注：

- ***设计和／或开发确认在成功的设计和／或开发验证之后进行；***
- ***确认通常在规定的使用运行条件下进行；***
- ***确认通常在最终产品上进行，但也可能需要在产品完成之前的较早阶段进行***
- ***如果有不同的预期用途，可能需要进行多次确认***

7.3.6.1 Documentation of design and/or development verification and validation

At the completion of design and/or development, the organization shall ensure that reports, calculations, tests results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.

7.3.6.1 设计和／或开发验证和确认文件

在设计和／或开发的完成阶段，组织应确保报告、计算、试验结果等证实产品定义满足所有已确定使用条件下的技术要求。

7.3.6.2 Design and/or development verification and validation testing

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

a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria;
b) test procedures describe the method of operation, the performance of the test, and the recording of the results;
c) the correct configuration standard of the product is submitted for the test;
d) the requirements of the test plan and the test procedures are observed;
e) the acceptance criteria are met.

7.3.7 Control of design and development changes

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

The organization's change control process shall provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement.

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

7.4 Purchasing

7.4.1 Purchasing process

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

The organization shall be responsible for the quality of all products purchased from suppliers, including customer-designated sources.

The organization shall evaluate and select supplier based on their ability to supply in accordance with the organization's requirements. Criteria for selection,

7.3.6.2 设计和／或开发验证和确认试验

在试验对于验证和确认是必要的情况，这些试验必需被策划、控制、评审和形成文件，以确保和证实：

a) 试验计划或技术条件明了要测试的产品和要使用的资源，定义了试验目的和条件，要记录的参数，和有关的接受版别准则：
b) 试验程序描述了操作方法，试验性能和结果的记录；
c) 产品的正确技术状态被提交试验；
d) 试验计划和试验程序的要求得到遵守；
e) 接受判别准则得到满足。

7.3.7 设计和开发更改的控制

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

当合同或法规有要求时，组织的更改控制过程应规定顾客和／法规机构对更改的批准。

更改的评审结果及任何必要措施的记录应予保持（见4.2.4）。

7.4 采购

7.4.1 采购过程

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

组织对所有从供应商处采购的产品质量负责，包括顾客制定的供应源。

组织应根据供方按组织的要求提供产品的能力评价和选择供方。应制定选择、评价和重新评价的准则。评

Evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see4.2.4).

价结果及评价所引起的任何必要措施的记录应予保持（见 4.2.4）。

The organization shall:
a) maintain a register of approved suppliers that includes the scope of the approval;
b) periodically review supplier performance; records of these reviews shall be used as a basis for establishing the level of controls to be implemented;
c) define the necessary actions to take when dealing with suppliers that do not meet requirements;
d) ensure where required that both the organization and all suppliers use customer-approved special process sources;
e) ensure that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of the sources.

组织应
a) 保持一份批准的供应商的登记表，里面包括批准的范围；
b) 定期评审供应商的表现；这些评审记录应作为建立控制水平的基础；
c) 规定处理不满足要求的供应商时采取的措施；
d) 确保在有需要时，组织和所有供应商都必须试用顾客批准的特殊过程资源；
e) 确保具有批准供应商质量体系责任的部门有权否决供应源的使用。

7.4.2 Purchasing information
Purchasing information shall describe the product to be purchased, including where appropriate
a) requirements for approval of product, procedures, processes and equipment,
b) requirements for qualification of personnel, and
c) quality management system requirements,
d) the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data,
e) requirements for design, test, examination, inspection and related instructions for acceptance by the organization,
f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing,
g) requirements relative to
- supplier notification to organization of nonconforming product and
- arrangements for organization approval of supplier nonconforming material,
h) requirements for the supplier to notify the organization of changes in product and/or process definition and, where required, obtain organization, approval,
i) right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records, and
j) requirements for the supplier to flow down to sub tier suppliers the applicable requirements in the purchasing documents, including key characteristics where requires.

7.4.2 采购信息
采购信息应表述拟采购的产品， 适当时包括
a) 产品、程序、过程和设备的批准要求；
b) 人员资格的要求；
c) 质量管理体系的要求
d) 技术规范、图纸、过程要求、检验指导书和其它相关技术资料的名称或其它明确的标识，以及适用版次，
e) 设计、试验、考核、检验的要求和与组织接受有关的说明指导，
f) 用于设计批准、检查、研究或审核目的的试验样品要求（如生产方法、数量、储存条件），
g) 和下述有关的要求
- 供应商向组织通报不合格的产品，
- 组织批准供应商不合格材料的安排，
h) 供应商想组织通报产品和/或过程定义的更改，有要求时，并按要求获得组织的批准，
i) 组织、组织的顾客和法规机构有权进入采购订单所涉及的所有设施场所和查看所有相应记录，
j) 要求供应商向下层供应商传递采购文件中的适用要求，包括要求的关键特性。

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

在与供货沟通前，组织应确保所规定的采购要求是否分与适宜的。

7.4.3 Verification of purchased product

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

Verification activities may include

a) obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control),
b) inspection and audit at supplier's premises,
c) review of the required documentation,
d) inspection of products upon receipt, and
e) delegation of verification to the supplier, or supplier certification.

Purchased product shall not be used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure.

Where the organization utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. The organization shall periodically validate test reports for raw material.

Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.

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

Where specified in the contract, the customer or the customer's representative shall be afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conform to specified requirements.

Verification by the customer shall not be used by the organization as evidence of effective control of quality by the supplier and shall not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

7.5 Production and service provision

7.5.1 Control of production and service provision

Planning shall consider, as applicable,

7.4.4 采购产品的验证

组织应确定并实施检验或其它必要的活动，以确保采购的产品满足规定的采购要求。

验证活动可能包括

a) 从供应商处获得产品质量的客观证据（例如随行文件、合格证、试验报告、统计记录、过程控制）。
b) 在供应商的场所进行检验和审核
c) 要求文档的评审
d) 产品接受时的检验，和
e) 委托给供应商验证，或供应商取得认证

在被验证符合规定要求之前，采购产品不得适用或加工，除非它是在明确的追回程序控制之下放行的。

对组织利用实验报告验证采购产品的情况，这些报告中的数据对照相应的技术规范应是可以接受的，组织应定期确认原材料的试验报告。

对组织委托供应商验证的情况，委托验证的要求应予以规定，并保持一份委托人员登记表。

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

根据合同的规定，顾客或顾客的代表应有权到供应商的场所或组织的场所确认分包产品符合规定的要求。

顾客的验证不可以被组织用作供应商有效质量控制的证据，顾客的验证既不能免除组织提供合格产品的责任，也不能排除其后的顾客拒收。

7.5 生产和服务提供

7.5.1 生产和服务提供的控制

适用时，策划应考虑

- the establishment of process controls and development of control plans where key characteristics have been identified,
- the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization,
- the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and
- special processes (see 7.5.2).

- 建立过程控制，并在关键特性已经识别之处开发控制计划，

- 对产品实现的稍后阶段不能对符合性进行充分验证的情况，确定过程中的验证点，

- 工装的设计、制造和使用，以便可以实施可变的测量，尤其是对关键特性的测量，

- 特殊过程（见 7.5.2）

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

组织应策划并在受控条件下进行生产和服务提供。适用时，受控条件应包括：

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

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

g) accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product),
h) evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized,
i) provision for the prevention, detection, and removal of foreign objects,
j) monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality, and
k) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations).

g) 制造期间所有产品的可说明性（如零件数量、分开生产、不合格产品等等），

h) 所有制造和检验操作都已按策划或按另外的文件 或批准完成的证据，

i) 对外来异物的防护、探测和去除的规定，

j) 按照对产品质量的影响程度，对公用事业的供应（诸如水、压缩空气、电、化学产品）进行监控

k) 工人技艺的标准，应以最清晰实用的方式对其进行规定（如书面标准、代表性样件或图解说明）。

7.5.1.1 Production documentation

Production operations shall be carried out in accordance with approved data. This data shall contain as necessary

7.5.1.1 生产文件化

生产操作必须按批准的资料执行。这些资料包括

a) drawing, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveller, router, work order, process cards); and inspection documents (see 8.2.4.1), and

a) 图纸、零件目录、包括检验操作在内的工艺流程图、生产文件（例如制造计划、流程卡、路线卡片、工作指令、工艺卡等）；和检验

b) a list of specific or non-specific tools and Numerical Control (N.C.) machine programs required and any specific instructions associated with their use.

b) 要求的特殊或非特殊工装及数控机加程序的目录和任何与其使用相关的特别说明。

7.5.1.2 Control of production process changes

7.5.1.2 生产工艺更改的控制

Persons authorized to approve changes to production processes shall be identified.	***必须确定被授予权批准生产工艺更改的人。***
The organization shall identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.	***组织应按照合同或法规要求识别出需要客户和/或法规机构批准的更改，并获得他们对更改的接受。***
Changes affecting processes, production equipment, tools and programs shall be documented. Procedures shall be available to control their implementation.	***影响工艺过程、生产设备、工装和程序的更改应形成文件。应有程序来控制更改的实施。***
The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product quality.	***应对生产工艺更改的结果进行评估，以确认希望的效果已经达到而对产品质量无不利影响。***
7.5.1.3 Control of production equipment tools and Numerical Control (N.C) machine programs	***7.5.1.3 生产设备、工装和数控机加程序的控制***
Production equipment, tools and programs shall be validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use shall include verification of the first article produced to the design data/specification.	***生产设备、工装和数控机加程序应在使用前得到确认，并按照程序文件进行定期维护和检查。在生产使用前的确认应包括按设计资料/技术规范生产的首要产品的验证。***
NOTE See AS/EN9102 for guidance	***注： 指南见 AS/EN 9102***
Storage requirements, including periodic preservation/condition checks, shall be established for production equipment or tooling in storage.	***对于储藏中的生产设备或工装，组织应建立储藏要求，包括定期防护/状况检查等。***
7.5.1.4 Control of work transferred, on a temporary basis, outside the organization's facilities	***7.5.1.4 对临时将工作转移到组织设施之外的控制***
When planning to temporarily transfer work to a location outside the organization's facilities, the organization shall define the process to control and validate the quality of the work.	***在计划将工作临时转移到组织设备之外的地点的情况，组织应规定控制和确认工作质量的过程。***
7.5.1.5 Control of service operations	***7.5.1.5 服务运行的控制***
Where servicing is a specified requirement, service operation processes shall provide for	***当服务是一项规定要求时，服役运行过程应规定***
a) a method of collecting and analyzing in-service data,	***a) 收集和分析服役数据的方法。***
b) actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements,	***b) 对交付后识别的问题采取的措施，包括调查、报告活动，以及与合同和/或法规要求一致的服务通告的措施，***
c) the control and updating of technical documentation.	***c) 技术文件的控制和更新，***
d) the approval, control, and use of repair schemes, and	***d) 修理方案的批准、控制和使用，和***
e) the controls required for off-site work (e.g., organization's work undertaken at the customer's facilities).	***e) 外场工作所要求的控制（如组织在顾客的设施处进行的工作）***

7.5.2 *Validation of processes for production and service provision*

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

NOTE 1 These processes are frequently referred to as special processes.

Validation shall demonstrate the ability of these processes to achieve planned results.
The organization shall establish arrangements for these processes including, as applicable
a) defined criteria for review and approval of the processes,
- qualification and approval of special processes prior to use,
b) approval of equipment and qualification of personnel,
c) use of specific methods and procedures,
- control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto,
d) requirements for records (see 4.2.4), and
e) revalidation.

7.5.3 *Identification and traceability*

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

The organization shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

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

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

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

According to the level of traceability required by contract, regulatory, or other established requirement, the organization's system shall provide for:
a) identification to be maintained throughout the product life;

7.5.2 *生产和服务提供过程的确认*

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

注 1： 这些过程经常被称作特殊过程（特种工艺）

确认应证实这些过程实现所策划的结果的能力。
组织应对这些过程的做出安排，适用时包括：

a) 为过程的评审和批准所规定的准则；

- 在使用前鉴定和批准特殊过程

b) 设备的认可和人员资格的鉴定；
c) 使用特定的方法和程序
- 按照形成文件的工艺规范及其更改，控制特殊过程的重大步骤和参数

d) 记录的要求（见 4.2.4）
e) 再确认

7.5.3 *标识和可追溯性*

适当时，组织应在产品实现的全过程中使用适宜的方法识别产品。

组织应维持对产品技术状态的识别，以便于识别实际技术状态与要求技术状态之间的任何差异。

组织应针对监视和测量要求识别产品的状态。

当使用接受权限介质（例如印章，电子签名、口令等时，组织必须对介质建立控制并形成文件）

在有可追溯性要求的场合，组织应控制并记录产品的唯一性标识（见 4.2.4）

按照合同、法规或其它确立的规定所要求的追溯水平，组织的体系应对以下方面做出规定：

a) 在产品整个寿命期内维持标识；

b) all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch;
c) for an assembly, the identity of its components and those of the next higher assembly to be traced;
d) for a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.

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

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see4.2.4).

NOTE: Customer property can include intellectual property.

7.5.5 Preservation of product

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identifications， handling, handing, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.
Preservation of product shall also include, where applicable in accordance with product specifications and/or applicable regulations, provisions for:
a) Cleaning;
b) prevention, detection and removal of foreign objects;
c) special handing for sensitive products;
d) marking and labelling including safety warnings;
e) shelf life control and stock rotation;
f) special handling for hazardous materials.

The organization shall ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.

7.6 Control of monitoring and measuring devices
The organization shall determine the monitoring and measurement to be undertaken a measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).
b) The organization shall maintain a register of these

b) 能追溯由同批原材料或同一加工批制造的所有的产品以及同批次的所有产品，以及通批所有产品的去向（交付、报废）；

c) 对于装配件，向下可追溯到其各个组成零件，上可追溯到下个较高级别的装配件；
d) 对一个所给产品，要能找出其连续的生产记录（制造、装配、检验记录）。

注：在某些行业，技术状态管理是保持标识和可追溯性的一种方法。

7.5.4 顾客财产

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

注：顾客财产可包括知识产权。

7.5.5 产品防护

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

依据产品技术条件和、或适用的法规要求，产品的防护还应包括以下方面的规定：

a) 清洁；
b) 防止、查明和去除外来异物；

c) 敏感产品的特殊处理；
d) 作标记和挂牌，包括安全警告；
e) 货架寿命控制和库存轮换；
f) 有害物质的特殊处理；

组织应确保合同、订单要求的产品随行文件在交付时齐全，并妥善保护以防丢失或损坏。

7.6 监视和测量装置的控制

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

b) 所有从同一批原材料制造出来或来自同一制造批

monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.	***次的产品，组织应维护一份这些监视和测量装置的登记表,并规定校准所采用的过程,这包括设备型号、唯一标识、所在位置、监察频率、监察方法和接受准则等细节。***
NOTE 1 Monitoring and measuring devices include, but are not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.	***注：监视和测量装置包括但不限于：试验硬件、试验软件、自动试验设备（ATE）、用来生成检验数据的绘图仪等。另外还包括用于提供产品符合性证据的个人拥有设备和顾客提供设备。***
The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in manner that is consistent with the monitoring and measurement requirements.	组织应建立过程，以确保监视和测量活动可行并以与监视和测量的要求相一致的方法实施。
The organization shall ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.	***组织应确保环境条件适宜所进行的校准、检验、测量和试验活动。***
Where necessary to ensure valid results, measuring equipment shall	为确保结果有效，必要时，测量设备应：
a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standard; where no such standards exist, the basis used for calibration of verification shall be recorded;	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或检定。当不存在上述标准时，应记录校准或检定的依据；
b) can adjusted or re-adjusted as necessary;	b) 进行调整或必要时再调整；
c) be identified to enable the calibration status to be determined;	c) 得到识别，以确定其校准状态；
d) be safeguarded from adjustments that would invalidate the measurement result;	d) 防止可能使测量结果失效的调整；
e) be protected from damage and deterioration during handling, maintenance and storage;	e) 在搬运、维护和贮存期间防止损坏或失效；
f) be recalled to a defined method when requiring calibration.	***f) 在要求校准时，按规定的方法被召回。***
In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall maintained (see 4.2.4)	此外，当发现设备不符合要求时，组织应对以往测量结果的有效性进行评价和记录。组织应对该设备和任何受影响的产品采取适当的措施。校准和验证结果的记录应予保持（见 4.2.4）。
When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.	当计算机软件用于规定要求的监视和测量时，应确认其满足预期用途的能力。确认应在初次使用前进行，必要时再确认。
NOTE: See ISO 10012 and ISO 10012-2 for guidance.	注：作为指南，参见 ISO10012 和 ISO10012-2。

8 measurement, analysis and improvement

8.1 General

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

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

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

NOTE
According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support:
- design verification (e.g., reliability, maintainability, safety);
- process control:
- selection and inspection of key characteristics;
- process capability measurement;
- statistical process control;
- design of experiment;
- inspection-matching sampling rate to the criticality of the product and to the process capability;
- failure mode and effect analysis;

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

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

8.2.2 Internal audit

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

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

An audit programmer shall planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audits criteria, scope, frequency and methods

8 测量、分析和改进

8.1 总则

组织应策划并实施以下方面所需的监视、测量、分析和改进过程：

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

这应包括对统计技术在内的适用方法及其应用程度的确定。

注：
按照产品的性质并依据规定的要求，可以用统计技术来支持下述活动

-设计验证（如可靠性、可维护性、安全性等）；

-过程控制：
-关键特性的选定和检验
-过程能力测量
-统计过程控制
-实验设计
-检验-按照产品的关键程度和过程能力选择抽样率；

破坏模式和影响分析

8.2 监视和测量

8.2.1 顾客满意

作为对质量管理体系业绩的一种测量，组织应对顾客有关组织是否已满足其要求的感受的信息进行监视，并确定获取和利用这种信息的方法。

8.2.2 内部审核

组织应按策划的时间间隔进行内部审核，以确定质量管理体系是否：

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

考虑拟审核的过程和区域的状况和重要性以及以往审核的结果，应对审核方案进行策划。应规定审核的准则、范围、频次和方法。审核员的选择和审核的实施应确保审核过程的客观性和公正性。审核员不应审核

shall be defines. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

自己的工作。

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

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

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

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

Detailed tools and techniques shall be developed such as check sheets, processes flowcharts, or any similar method to support audit of the quality management system requirements. The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall organization performance.

应开发具体的工具和技术方法，例如检查表、过程流程图或任何支持质量管理体系审核的类似方法。所选择工具的可接受性按照内部审核过程的有效性和整个组织业绩进行测量。

Internal audits shall also meet contract and/or regulatory requirements.

内部审核还应满足合同和／或法规性要求。

NOTE: See ISO 10011-1, ISO 10011-2 and ISO10011-3 for guidance.

注：作为指南，参见 ISO 10011-1, ISO 10011-2 and ISO10011-3。

8.2.3 Monitoring and measurement of processes

8.2.3 过程的监视和测量

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes.

组织应采取适宜的方法对质量管理体系过程进行监视，并在适用时进行测量。

These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of product.

这些方法应证实过程实现所策划的结果的能力。当未能达到所策划的结果时，应采取适当的纠正和纠正措施，以确保产品的符合性。

In the event of process nonconformity, the organization shall

当发生过程不符合的情况时，组织应

a) take appropriate action to correct the nonconformity process,

a) 采取相应措施来纠正不符合的过程

b) evaluate whether the process nonconformity has resulted in product nonconformity, and

b) 评估过程的不符合是否已经导致了产品的不合格，及

c) identify and control the nonconforming product in accordance with clause 8.3

c) 按照 8.3 的要求识别和控制不合格产品。

8.2.4 Monitoring and measurement of product

8.2.4 产品的监视和测量

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

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

When key characteristics have been identified, they shall be monitored and controlled.

当关键特性已被识别时，应对其进行监视和测量。

When the organization uses sampling inspection as a means of product acceptance, the plan shall be statistically valid and appropriate for use. The plan shall preclude the acceptance of lots whose samples have known nonconformities. When required, the plan shall be submitted for customer approval.

当组织使用臭氧检查作为产品接受的方法时，臭氧计划应是统计有效并适宜使用。臭氧计划应阻止接收其样本有已知不合格的生产批次。在要求时，抽样计划应提交客户批准。

Product shall not be used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities.

产品在被检查合格或由其它方式验证为符合规定要求之前不得使用，除非产品是在确切的追回程序控制之下放行的。直到完成所有必要的测量和监视活动。

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).

应保持符合接受准则的证据。记录应指明有权放行产品的人员（见 4.2.4）。

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

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

8.2.4.1 Inspection documentation

8.2.4.1 检验文件化

Measurement requirements for product or service acceptance shall be documented. This documentation may be part of the production documentation, but shall include

产品和服务接收的测量要求应形成文件，该文件可以是生产文件的一部分，但必须包括下列内容

a) criteria for acceptance and/or rejection,
b) where in the sequence measurement and testing operations are performed,
c) a record of the measurement results, and
d) type of measurement instruments required and any specific instruments associated with their use.

a) 接收和／或拒收的准则，
b) 一次在何处进行测量和试验操作；
c) 测量结果的记录，和
d) 所要求测量仪器的型号及与其使用相关的任何特殊说明。

Test records shall show actual test results data when required by specification or acceptance test plan.

在技术条件或接收试验计划要求时，试验记录应显示实际的试验结果数据。

Where required to demonstrate product qualification the organization shall ensure that records provide evidence that the product meets the defined requirements.

在要求证实产品资格时，组织应确保记录能提供产品满足规定要求的证据。

8.2.4.2 First article inspection

8.2.4 首件检验

The organization's system shall provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result.

对于一种新零件的首次生产运行的代表件，或是使以前的首件检验结果无效的任何随后更改，组织的体系应建立一个检验、验证并编制文件的过程。

NOTE See AS/EN 9102 for guidance.

注：指南见 AS/EN 9102

8.3 Control of nonconforming product

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

NOTE The term 'non-conforming product' includes nonconforming product returned from a customer.

The organization's documented procedure shall define the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions.

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

a) by taking action to eliminate the detected nonconformity,
b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer,
c) by taking action to preclude its original intended use or application.

The organization shall not use dispositions of use-as-is or repaired, unless specifically authorized by the customer, if
- the product is produced to customer design, or
- the nonconformity results in a departure from the contract requirements.

Unless otherwise restricted in the contract, organization-designed product which is controlled via a customer specification may be dispositioned by the organization as use-as-is or repaired, provided the nonconformity does not result in a departure from customer-specified requirements.

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

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

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

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

8.3 不合格品控制

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

注：术语“不合格产品”包括客户退回的不合格品。

组织的程序文件应对不合格品评审和处置的职权以及批准人员做出决定的过程进行规定。

组织应通过下列一种或几种途径，处置不合格品：

a) 采取措施，消除已发现的不合格；
b) 经有关授权人员批准，适用时经顾客批准，让步使用、放行或接收不合格品；
c) 采取措施，防止其原预期的使用或应用。

在产品是按顾客的设计进行生产，或不合格特性违背了合同要求的情况下，除非由客户特别批准，组织不能采取“原样照用”或“返修”的处置方式。

对于在顾客技术条件控制下由组织设计的产品，如果不合格性没有违背顾客规定的要求，组织可以采取“原样照用”或“返修”的处置方式，除非合同另有限制。

处置为报废的产品必须作醒目和永久的标记或处于绝对控制之中，直到被实际致使不可用。

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

在不合格品得到纠正之后应对其再次进行验证，以证实符合要求。

当在交付或开始使用后发现产品不合格时，组织应采取与不合格的影响或潜在影响的程度相适应的措施。

In addition to any contract or regulatory authority reporting requirements, the organization's system shall provide for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification shall include a clear description of the nonconformity, which includes as necessary parts affected, customers and/or organization part numbers, quantity, and date(s) delivered.

除合同或法规当局的报告要求之外，组织的环境还应规定对已交付的可能会影响可靠性或安全的不合格产品进行及时报告的要求。通知应包括对不合格特性的清晰描述，其中必须包括受到影响的零件、顾客和／或组织的零件号、数量及交付日期等。

NOTE Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and regulatory authorities.

注：需要通告不合格产品的各方可能包括供应商、内部组织、顾客、分销商和管理当局。

8.4 Analysis of data

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

8.4 **数据分析**

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

The analysis of data shall provide information relating to
a) customer satisfaction (see 8.2.1),
b) conformity to product requirements (see 7.2.1),
c) characteristics and trends of processes and products including opportunities for preventive action, and
d) supplier.

数据分析应提供以下有关方面的信息：
a) 顾客满意（见 8.2.1）；
b) 与产品要求的符合性（见 7.2.1）；
c) 过程和产品的特性及趋势，包括采取预防措施的机会；
d) 供方。

8.5 Improvement

8.5 改进

8.5.1 Continual improvement

8.5.1 持续改进

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

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

8.5.2 Corrective action

8.5.2 纠正措施

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

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

The documented procedure shall be established to define requirements for

应编制形成文件的程序，以规定以下方面的要求：

a) reviewing nonconformities (including customer complaints),
b) determining the causes of nonconformities,
c) evaluating the need for action to ensure that nonconformities do not recur,
d) determining and implementing action needed,

a) 评审不合格（包括顾客抱怨）；
b) 确定不合格原因；
c) 评价确保不合格不再发生的措施的需求；
d) 确定和实施所需的措施；

e) records of the results of action taken (see 4.2.4),

f) reviewing of corrective action taken, and

g) flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and

h) specific actions where timely and/or effective corrective actions are not achieved.

8.5.3 Preventive action

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

A documented procedure shall be established to define requirements for

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

e) 记录所采取措施的结果（见 4.2.4）；

f) 评审所采取的纠正措施；

g) 当确定供应商对根本原因负有责任时，纠正措施要求向下传递到供应商处，和

h) 在没有达到及时和／或有效的纠正措施时，应采取的特别措施。

8.5.4 预防措施

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

应编制形成文件的程序，以规定以下方面的要求：

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