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Quality management systems — Requirements

Systèmes de management de la qualité — Exigences

Warning

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前言

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

国际标准化组织（ISO）是由各国标准化团体（ISO 成员团体）组成的世界性的联合会。制定国际标准工作通常由 ISO 的技术委员会完成。各成员团体若对某技术委员会确定的项目感兴趣，均有权参加该委员会的工作。与 ISO 保持联系的各国际组织（官方的或非官方的）也可参加有关工作。ISO 与国际电工委员会（IEC）在电工技术标准化方面保持密切合作的关系。

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

国际标准是根据 ISO / IEC 导则第 3 部分的规则起草。

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

技术委员会主要负责国际标准的制定，技术委员会采用的草案版的国际标准将在 ISO 成员中传发旨在随后投票进行表决。一份国际标准的发布需要不少于 75%的成员机构投票赞成。

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

本文件中的某些内容有可能涉及一些专利权问题，对此应引起注意，ISO 不负责识别任何这样的专利权问题。

ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality Management and Quality Assurance*, Subcommittee SC 2, *Quality Systems*.

ISO9001 由 ISO / TC176 质量管理和质量保证技术委员会 SC2 质量体系分委员会制定。

This second/third/... edition cancels and replaces the first/second/... edition (), [clause(s) / subclause(s) / table(s) / figure(s) / annex(es)] of which [has / have] been technically revised.

本版取代第一 / 二版（包原版文件的括技术修订）。

The title of ISO 9001 has been revised in this edition and no longer includes the term “Quality assurance“. This reflects the fact that the quality management system requirements specified in this edition of ISO 9001, in addition to quality assurance of product, also aim to enhance customer satisfaction.

本标准的名称发生了变化，不再有“质量保证”一词。这反映了本标准规定的质量管理体系要求除了产品质量保证以外，还旨在增进顾客满意。

Annex A of this International Standard is for information only.

本标准附件 A 仅为通告用。

Notes to this Committee Draft:

本文提注：

1. The differences between ISO 9001:2000 and this draft are highlighted in yellow. Text with "~~strikethrough~~" indicates ISO 9001:2000 text proposed for deletion.

本文与 ISO9001：2000 的不同之处已用黄色突出显示，

2. The former Annex B "Correspondence between ISO 9001:2000 and ISO 9001:1994" has been deleted.

原附件 B“ISO 9001:2000 与 ISO 9001:1994 对照表”已被删除。

Introduction

0.1 General

0.1 总则

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization ‘s quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. lt is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

采用质量管理体系应该是组织的一项战略性决策。一个组织的质量管理体系的设计和实施受各种需求、具体的目标、所提供的产品、所采用的过程以及组织的规模和结构的影响。统一质量管理体系的结构或文件不是本标准的目的。

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked “NOTE“ is for guidance in understanding or clarifying the associated requirement.

本标准所规定的质量管理体系要求是对产品要求的补充。“注”中的内容是理解和说明有关要求的指南。

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

本标准能用于内部和外部（包括认证机构）评价组织满足顾客、产品适用的法律法规和组织自身要求的能力。

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

本标准的制定已经考虑了 GB/T 19000 和 GB/T 19004 中所阐明的质量管理原则。

0.2 Process approach

0.2 过程方法

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

本标准鼓励在制定、实施质量管理体系以及改进其有效性时采用过程方法，通过满足顾客要求，增进顾客满意。

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

为使组织有效运作，必须识别和管理众多相互关联的活动。通过利用资源和管理，将输入转化为输出的一项活动，可以视为一个过程。通常，一个过程的输出可直接形成下一过程的输入。

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the “process approach“.

组织内诸过程的系统的应用，连同这些过程的识别和相互作用及其管理，可称之为“过程方法”。

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

过程方法的优点是对诸过程的系统中单个过程之间的联系以及过程的组合和相互作用进行连续的控制。

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

a) understanding and meeting requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.

在质量管理体系中应用过程方法时强调以下方面的重要性：

a) 理解和满足要求；

b) 需要从增值的角度考虑过程；

c) 获得过程业绩和有效性的结果；

e) d) 基于客观的测量，持续改进过程。

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

图 1 所反映的以过程为基础的质量管理体系模式展示了 4－8 章中所提出的过程联系。这种展示反映了在规定输入要求时，顾客起着重要的作用。对顾客满意的监视要求对顾客有关组织是否已满足其要求的感受信息进行评价。该模式虽覆盖了本标准的所有要求，但却未详细地反映各过程。

NOTE In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

注：此外，称之为"PDCA"的方法可适用于所有过程。PDCA 模式可简述如下：

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

Do: implement the processes.

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

Act: take actions to continually improve process performance.

P—策划：根据顾客的要求和组织的方针，为提供结果建立必要的目标和过程；

D—做：实施过程；

C—检查：根据方针、目标和产品要求，对过程和产品进行监视和测量，并报告结果；

A—处置：采取措施，以持续改进过程业绩。

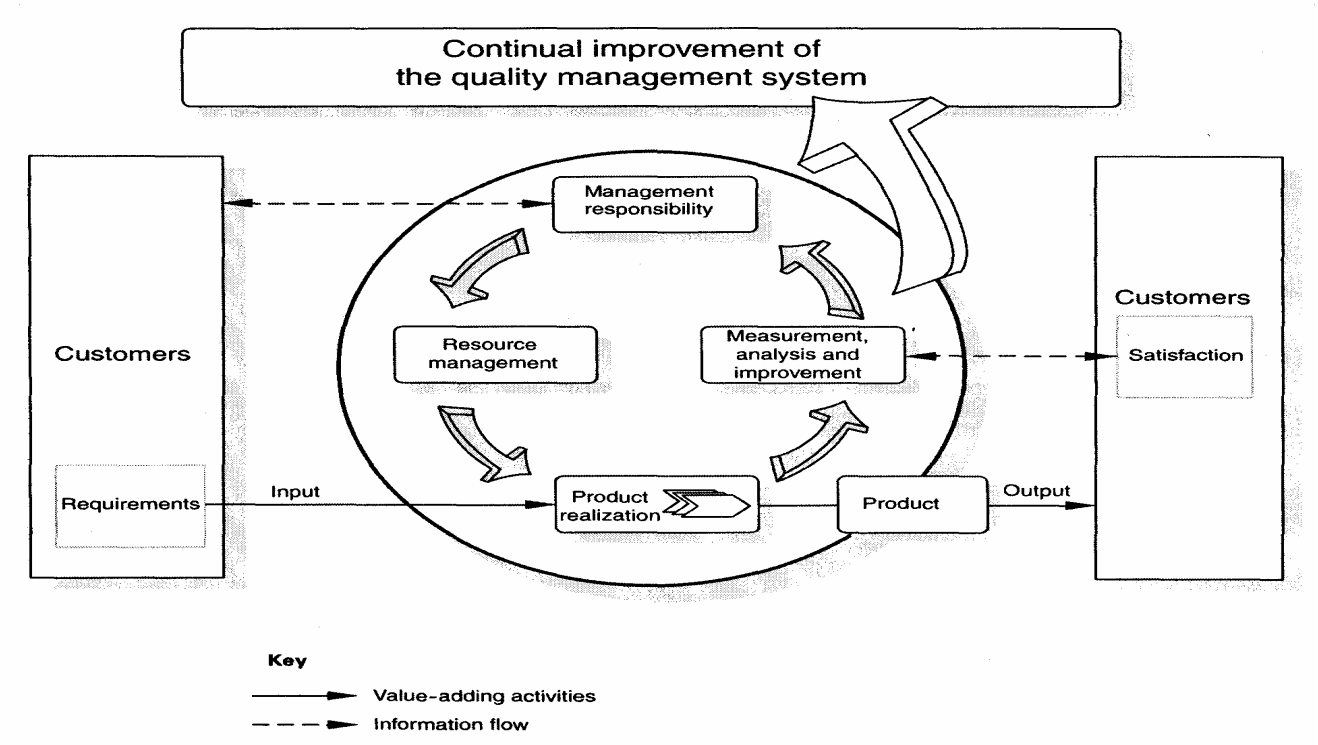

Figure 1 — Model of a process-based quality management system

0.3 Relationship with ISO 9004

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organizations overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

0.3 与 GB/T 19004 的关系

ISO 9001 和 ISO 9004 已制定为一对协调一致的质量管理体系标准，这两项标准相互补充，但也可单独使用。虽然两项标准具有不同的适用范围，但具有相似的结构，以有助于他们作为协调一致的一对标准的应用。

GB/T19001 规定了质量管理体系要求，可供组织内部使用，也可用于认证或合同目的。在满足顾客要求方面，GB/T 19001 所关注的是质量管理体系的有效性。

与 GB/T19001 相比，GB/T 19004 对质量管理体系更宽范围的目标提供了指南。除了有效性，该标准还特别关注持续改进一个组织的总体业绩与效率。对于最高管理者希望通过追求业绩持续改进而超越 GB/T19001 要求的那些组织，GB/T19004 推荐了指南。然而，用于认证或合同不是 GB/T19004 的目的

0.4 Compatibility with other management systems

During the development of this International Standard, due consideration has been taken of the provisions of ISO 14001:2004 to enhance the compatibility of the two standards for the benefit of the user community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

0.4 与其他管理体系的相容性

为便于两个标准的应用方使用，本标准在编写过程中考虑了 ISO14001:2004 的规定，以增强两标准的相容性。

本标准不包括针对其他管理体系的特定要求，例如环境管理、职业卫生与安全管理、财务管理或风险管理有关的特定要求。然而本标准使组织能够将自身的质量管理体系与相关的管理体系要求结合或一体化。组织为了建立符合本标准要求的质量管理体系，可能会改变现行的管理体系。

Quality management systems — Requirements

质量管理体系——要求

1 Scope

1. 范围

1.1 General

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

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and 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 statutory and regulatory requirements.

NOTE 1 In this International Standard, the term "product" applies ~~only~~ to the product intended for, or required by, a customer. This also includes purchased product and product resulting from intermediate stages of the realization process.

NOTE 2 Statutory and regulatory requirements may be expressed as legal requirements

1.1 总则

本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，旨在增进顾客满意。

注 1：在本标准中，术语"产品"适用于预期提供给顾客或顾客所要求的产品，也包括直接购买的产品和由产品实现的中间过程产生的产品。

注 2： 法规和相关要求可能是法定要求。

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 nature 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 organizations ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

1.2 应用

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

当本标准的任何要求因组织及其产品的特点不适用时，可以考虑对其进行删减。
除非删减仅限于本标准第 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的要求,否则不能声称符合本标准。

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 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 Standards.

ISO 9000:~~2000~~ 2005 *Quality management systems — Fundamentals and vocabulary.*

2 引用标准

下列标准所包含的条文，通过在本标准中引用而构成为本标准的条文。本标准出版时，所示版本均为有效。所有标准都会被修订，使用本标准的各方应探讨使用下列标准最新版本的可能性。

ISO 9000:2005 质量管理体系 基础和术语

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.

本标准采用 ISO 9000 中的术语和定义

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

~~supplier → organization → customer~~

~~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".~~

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”。

4 Quality management system

4.1General requirements

4 质量管理体系

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

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

b) determine the sequence and interaction of these processes,

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

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

e) monitor, measure and analyse these processes, and

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

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

组织应：

a) 确定质量管理体系所需的过程及其在组织中的应用（见 1.2）；

b) 确定这些过程的顺序和相互作用；

c) 确定为确保这些过程的有效运作和控制所需的准则和方法；

d) 确保可以获得必要的资源和信息，以支持这些过程的运作和监视；

e) 监视、测量和分析这些过程；

f) 实施必要的措施，以实现对这些过程所策划的结果和对这些过程的持续改进。

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~~ to requirements, the organization shall ensure control over such processes. The controls to be applied to these outsourced processes shall be defined within the quality management system.

NOTE 1 Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

NOTE 2 The requirements of Clause 7.4 of this international standard may also apply to outsourced processes.

针对组织所选择的任何影响产品符合要求的外包过程，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。

注 1：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。

注 2：本标准 7.4 条款的要求也可应用于外包过程。

4.2 Documentation requirements

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 and records required by this International Standard, and

d) documents, including records, ~~needed~~ determined by the organization to be necessary to ensure the effective planning, operation and control of its processes~~, and~~

~~e) records required by this International Standard (see 4.2.4).~~

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）本标准所要求的形成文件的程序和记录；

d) 组织为确保其过程有效策划、运作和控制所确定的必要的文件，包括记录；

NOTE 1 Where the term “documented procedure“ appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may include the

requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

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

a) the size of organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

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

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。某一个文件可以包括一个或多个程序。一个形成文件的程序的要求也可以采用一个或多个文件来实现。

注 2：不同组织的质量管理体系文件的多少与详略程度取决于：

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。

注 3：文件可采用任何形式或类型的媒体。

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

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

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

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

4.2.2 质量手册

组织应编制和保持质量手册，质量手册包括：

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) 为质量管理体系编制的形成文件的程序或对其引用；

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

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

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

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

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

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

f) to ensure that documents of external origin necessary for the planning and operation of the quality management system are identified and their distribution controlled, and

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

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。

应编制形成文件的程序，以规定以下方面所需的控制：

a) 文件发布前得到批准，以确保文件是充分与适宜的；
b) 必要时对文件进行评审与更新，并再次批准；
c) 确保文件的更改和现行修订状态得到识别；
d) 确保在使用处可获得适用文件的有关版本；
e) 确保文件保持清晰、易于识别；
f) 确保质量管理体系策划和运行所必需的外来文件得到识别，并控制其分发；
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。

4.2.4 Control of records

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

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

Records shall be remain legible, readily identifiable and retrievable.

4.2.4 记录控制

建立记录以提供符合要求和质量管理体系有效运行的证据。应编制形成文件的程序，以规定记录的标识、贮存、保护、修改（修补／恢复）、保持和 disposition（处置）所需的控制。

记录应保持清晰、易于识别和 retrievable 获取（查询）。

5 Management responsibility

5.1 Management commitment

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

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.

5 管理职责

5.1 管理承诺

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) 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) 确保质量目标的制定；

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

最高管理者应以增进顾客满意为目的，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

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.

5.3 质量方针

最高管理者应确保质量方针：

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

5.4.1 Quality objectives

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

5.4 策划

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 7.1 a））。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 and communication

5.5.1 Responsibility and authority

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

5.5 职责、权限和沟通

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 the organization's 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 system and any need for improvement, and

c) ensuring the promotion of awareness of customer requirements throughout the organization.

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

5.5.2 管理者代表

最高管理者应指定一名组织的管理者，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的需求；

c) 确保在整个组织内提高满足顾客要求的意识。

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。

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.5.3 内部沟通

最高管理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。

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 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。评审应包括评价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 Review input

The input to management review shall include information on

a) results of audits,

b) customer 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.

5.6.2 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 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 product related to customer requirements, and

c) resource needs.

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 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 资源管理

6.1 资源的提供

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，增进顾客满意。

6.2 Human resources

6.2.1 General

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

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，所从事的工作会对产品符合要求产生影响的人员应是能够胜任的。

6.2.2 Competence, training and awareness

The organization shall

a) determine the necessary competence for personnel performing work affecting ~~product quality~~ conformity to product requirements,

b) where applicable, provide training or take other actions to ~~satisfy these needs~~ achieve the necessary competence,

c) ~~ensure the effectiveness of the actions taken,~~ ensure that the necessary competence has been achieved,

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, skills and experience (see 4.2.4).

6.2.2 能力、培训和意识

组织应：

a) 确定从事影响产品符合性工作的人员所必要的能力；

b) 适用时，提供培训或采取其他措施以达到这些要求；

c) 评价（该人员）是否达到了这些必要能力要求；

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作出贡献；

e) 保持教育、培训、技能和经验的适当记录（见 4.2.4）。

6.3 Infrastructure

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

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport, ~~or~~ communication or information systems).

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、工作场所和相关的设施；

b) 过程设备（硬件和软件）；

c) 支持性服务（如运输、通讯或信息系统）。

6.4 Work environment

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

Note: The term work environment relates to conditions necessary to achieve conformity to product requirements such as clean rooms, anti-static precautions and hygiene controls.

6.4 工作环境

组织应确定和管理为达到产品符合要求所需的工作环境。

注：条款工作环境指为符合产品要求所应达到的必要条件，如清洁的厂房，静电防护和卫生控制等。

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 the 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, measurement, 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).

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

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.

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

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、测量，检验和试验活动，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。

策划的输出形式应适于组织的运作方式。

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）

和资源作出规定的文件可称之为质量计划。

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

7.2.1 Determination of requirements related to the product

The organization shall determine

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

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

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

d) any additional requirements as needed ~~determined~~ by the organization.

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

7.2 与顾客有关的过程

7.2.1 与产品有关的要求的确定

组织应确定：

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) 产品适用的法律法规要求；

d) 其它组织必要的附加要求。

注 交付后的活动可以包括担保规定内的活动及约定的义务（职责），如维修服务、对用后产品的回收等额外服务。

7.2.2 Review of requirements related to the product

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

a) product requirements are defined,

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

c) the organization has the ability to meet the defined requirements.

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

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

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

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.

7.2.2 与产品有关的要求的评审

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

a) 产品要求得到规定；

b) 与以前表述不一致的合同或订单的要求已予解决；

c) 组织有能力满足规定的要求。

评审结果及评审所引起的措施的记录应予保持（见 4.2.4）。

若顾客提供的要求没有形成文件，组织在接收顾客要求前应对顾客要求进行确认。

若产品要求发生变更，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。

注：在某些情况中，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、产品广告内容等进行评审。

7.2.3 Customer communication

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

a) product information,

b) enquiries, contracts or order handling, including amendments, and

c) customer feedback, including customer complaints.

7.2.3 顾客沟通

组织应对以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，包括对其的修改；

c) 顾客反馈，包括顾客抱怨。

7.3 Design and development

7.3.1 Design and development planning

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

During the design and development planning, the organization shall determine

a) the design and development stages,

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.

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

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

Note Design and development review, verification and validation have distinct purposes. They may be conducted and recorded separately or in any combination as suitable for the product and the organization.

7.3 设计和开发

7.3.1 设计和开发策划

组织应对产品的设计和开发进行策划和控制。

在进行设计和开发策划时，组织应确定：

a) 设计和开发阶段；

b) 适于每个设计和开发阶段的评审、验证和确认活动；

c) 设计和开发的职责和权限。

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

随设计和开发的进展，在适当时，策划的输出应予以更新。

注：设计和开发的评审、验证和确认是具有明确的目的性的。用于不同的组织和产品时可以单独或者结合进行实施和记录。

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.

7.3.2 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。

应对输入进行评审，以确保其充分性与适宜性。要求应完整、清楚，并且不能自相矛盾。

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables suitable for 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.

NOTE Production and service provision includes preservation of the product.

7.3.3 设计和开发输出

设计和开发的输出应以适于对设计和开发的输入进行验证的方式提出，并应在放行前得到批准。

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准则；

d) 规定对产品的安全和正常使用所必需的产品特性。

注：生产和服务提供包括产品的保存

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) to identify any problems and propose necessary actions.

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

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。

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。评审结果及任何必要措施的记录应予保持（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 outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (4.2.4).

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措施的记录应予保持（见 4.2.4）。

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. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (4.2.4).

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保持（见 4.2.4）。

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.

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

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。在适当时，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。

更改评审结果及任何必要措施的记录应予保持（见 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 evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained. (see 4.2.4)

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的产品实现或最终产品的影响。

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）。

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.

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

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。

在与供方沟通前，组织应确保规定的采购要求是充分与适宜的。

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.

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.

7.4.3 采购产品的验证

组织应确定并实施检验或其他必要的活动，以确保采购的产品满足规定的采购要求。

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作出规定。

7.5 Production and service provision

7.5.1 Control of production and service provision

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

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.

7.5 生产和服务提供

7.5.1 生产和服务提供的控制

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) 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) 获得和使用监视和测量装置；

e) 实施监视和测量；

f) 放行、交付和交付后活动的实施。

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.

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,

b) approval of equipment and qualification of personnel,

c) use of specific methods and procedures,

d) requirements for records (see 4.2.4) and

e) revalidation.

NOTE 1 For many service organizations, the service provided does not readily allow the verification before the delivery of the service. These types of processes should be considered and identified during the planning stage (see 7.1)

NOTE 2. Processes such as welding, sterilization, training, heat treatment, call center service, or emergency response may need validation

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。

确认应证实这些过程实现所策划的结果的能力。

组织应规定确认这些过程的安排，适用时包括：

a) 为过程的评审和批准所规定的准则；

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；

d) 记录的要求（见 4.2.4）；

e) 再确认。

注 1：对许多服务组织而言，其服务在交付前并不能够被验证，这类过程应在策划过程中予以考虑和识别（见 7.1）

注 2：诸如定位焊接、杀菌、培训、热处理（加工）、中央呼叫服务或紧急响应等过程可能需要确认。

7.5.3 Identification and traceability

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

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

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

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

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。

组织应在整个产品实现过程中针对监视和测量要求识别产品的状态。

在有可追溯性要求的场合，组织应控制产品的唯一性标识（见 4.2.4），并保持记录。

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 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~~ the organization shall report this to the customer and maintain records (see 4.2.4).

NOTE Customer property can include intellectual property and personal data.

7.5.4 顾客财产

组织应爱护由组织管理或使用的顾客财产。组织应识别、验证、保护和维护供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，组织应报告顾客，并保持记录（见 4.2.4）。

注：顾客财产可包括知识产权和私人资料。

7.5.5 Preservation of product

The organization shall preserve the ~~conformity of~~ product during internal processing and delivery

to the intended destination in order to maintain conformity to requirements. ~~Where appropriate, This~~ As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.5.5 产品防护

在内部处理和交付到预定的地点期间，组织应对产品进行防护，以保证产品符合要求。适用时，这种防护应包括标识、搬运、包装、贮存和保护。防护也应用于产品的组成部分。

7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements ~~(see 7.2.1)~~.

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);

b) be adjusted or re-adjusted as necessary;

c) ~~be identified~~ have identification to enable ~~the~~ their calibration status to be determined;

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

7.6 监视和测量装置的控制

a) 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提供证据。

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式实施。

当有必要确保结果有效的场合时，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或检定。当不存在上述标准时，应记录校准或检定的依据；

b) 必要时进行调整或再调整；

c) 得以识别，以确定其校准状态；

d) 防止可能使测量结果失效的调整；

e) 在搬运、维护和贮存期间防止损坏或失效；

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 be maintained (see 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.

NOTE 1 See ISO 10012 for ~~ISO 10012-2 for guidance~~ further information.

NOTE 2 Monitoring and measurement devices, include measuring equipment (whether used for monitoring or measurement) and devices other than measuring equipment that are used for monitoring conformity to requirements.

NOTE 3 Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

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）。

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，并在必要时予以重新确认。

注 1：详见 ISO 10012。

注 2：监视和测量装置包括测量设备（无论其是否用于监视还是测量）和不同于测量设备而是用于对要求是否得到符合的监视的装置。

注 3：对计算机软件是否满足预期的应用要求的能力确认，应包括对其保持可用状态的验证和配置管理。

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.

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有效性。

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，。

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the ~~measurements~~ indicators 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 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指示性指标，组织应监视顾客关于组织是否满足其要求的感受的相关信息，并确定获取和利用这种信息的方法。

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.

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

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

~~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.~~

Records of the audit and its results shall be maintained (see 4.2.4).

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).

NOTE See ISO 19011 ~~ISO 10011-1, ISO 10011-2 and ISO 10011-3~~ for guidance.

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) 得到有效实施与保持。

应建立文件化的程序，以规定策划和实施审核、建立记录和报告审核结果的相关职责和要求。

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，组织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。审核员不应审核自己的工作。

应保持记录审核及审核结果的记录。

负责受审区域的管理者应确保及时采取措施，以消除所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）。

注：作为指南，参见 ISO19011。

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate~~, to ensure conformity of the product~~.

NOTE When determining suitable methods, the organization should consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

8.2.3 过程的监视和测量

组织应采用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。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。

注：在确定适宜的方法时，组织应考虑每个对产品符合性和质量管理体系有效性产生影响的过程适用的监测类型和范围

8.2.4 Monitoring and measurement of product

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

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

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

NOTE Evidence of conformity with acceptance criteria can be a record or as otherwise specified in the planned arrangements.

8.2.4 产品的监视和测量

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。应保持符合接收准则的证据。

记录应指明有权放行产品的人员（见 4.2.4）。

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（见 7.1）已圆满完成之前，不能放行产品和交付服务。

注：符合接收准则的证据可以是记录或其它已计划安排的特定的方法（形式）。

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. A documented procedure shall be established to define ~~T~~the controls and related responsibilities and authorities for dealing with nonconforming product. ~~shall be defined in a documented procedure.~~

Where practicable, 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.

d) when nonconforming product is detected after delivery or use has started, by taking action appropriate to the effects, or potential effects, of the nonconformity

~~Records of the nature of nonconformities 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.

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

~~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。应制定形成文件的程序，以规定不合格品控制以及不合格品处置的有关职责和权限。

适用时，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。

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

应对纠正后的产品再次进行验证，以证实符合要求。

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）。

8.4 Analysis of data

The organization shall determine, collect and analyse 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.

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) suppliers.

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。

数据分析应提供有关以下方面的信息：

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

8.5.1 Continual improvement

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

8.5 改进

8.5.1 持续改进

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

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

A documented procedure shall be established to define requirements for

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,

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

f) reviewing the effectiveness of the corrective action taken.

8.5.2 纠正措施

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。

应编制形成文件的程序，以规定以下方面的要求：

a) 评审不合格（包括顾客抱怨）；

b) 确定不合格的原因；

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) 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。

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 the effectiveness of the preventive action taken.

8.5.3 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程度相适应。

应编制形成文件的程序，以规定以下方面的要求：

b) 确定潜在不合格及其原因；

c) 评价防止不合格发生的措施的需求；

d) 确定并实施所需的措施；

e) 记录所采取措施的结果（见 4.2.4）；

f) 评审所采取的预防措施的有效性。

Annex A
(Informative)

Correspondence between ISO 9001:2000 and ISO 14001:2004

Table A.1 — Correspondence between ISO 9001:2000 and ISO 14001:2004

ISO 9001:2000		ISO 14001:2004	
Introduction General Process approach Relationship with ISO 9004 Compatibility with other management systems	0.1 0.2 0.3 0.4		Introduction
Scope General Application	1 1.1 1.2	1	Scope
Normative reference	2	2	Normative references
Terms and definitions	3	3	Definitions
Quality management system (title only)	4	4	Environmental management system requirements (title only)
General requirements	4.1	4.1	General requirements
Documentation requirements (title only)	4.2		
General	4.2.1	4.4.4	Documentation
Quality manual	4.2.2		
Control of documents	4.2.3	4.4.5	Control of documents
Control of records	4.2.4	4.5.4	Control of records
Management responsibility (title only)	5		
Management commitment	5.1	4.2 4.4.1	Environmental policy Resources, roles, responsibility and authority
Customer focus	5.2	4.3.1 4.3.2 4.6	Environmental aspects Legal and other requirements Management review
Quality policy	5.3	4.2	Environmental policy
Planning (title only)	5.4	4.3	Planning
Quality objectives	5.4.1	4.3.3	Objectives, targets and programme(s)
Quality management system planning	5.4.2	4.3.3	Objectives, targets and programme(s)

Table A.1 - Correspondence between ISO 9001:2000 and ISO 14001:2004 (continued)

Responsibility, authority and communication (title only)	5.5		
Responsibility and authority	5.5.1	4.4.1	Resources, roles, responsibility and authority
Management representative	5.5.2	4.4.1	Resources, roles, responsibility and authority
Internal communication	5.5.3	4.4.3	Communication
Management review	5.6	4.6	Management review
General	5.6.1	4.6	Management review
Review input	5.6.2	4.6	Management review
Review output	5.6.3	4.6	Management review
Resource management (title only)	6		
Provision of resources	6.1	4.4.1	Resources, roles, responsibility and authority
Human resources (title only)	6.2		
General	6.2.1	4.4.2	Competence, training and awareness
Competence, awareness and training	6.2.2	4.4.2	Competence, training and awareness
Infrastructure	6.3	4.4.1	Resources, roles, responsibility and authority
Work environment	6.4		
Product realization (title only)	7	4.4	Implementation and operation
Planning of product realization	7.1	4.4.6	Operational control
Customer-related processes (title only)	7.2		
Determination of requirements related to the product	7.2.1	4.3.1 4.3.2 4.4.6	Environmental aspects Legal and other requirements Operational control
Review of requirements related to the product	7.2.2	4.3.1 4.4.6	Environmental aspects Operational control
Customer communication	7.2.3	4.4.3	Communication
Design and development (title only)	7.3		
Design and development planning	7.3.1	4.4.6	Operational control
Design and development inputs	7.3.2	4.4.6	Operational control
Design and development outputs	7.3.3	4.4.6	Operational control
Design and development review	7.3.4	4.4.6	Operational control
Design and development verification	7.3.5	4.4.6	Operational control
Design and development validation	7.3.6	4.4.6	Operational control
Control of design and development changes	7.3.7	4.4.6	Operational control

Table A.1 – Correspondence between ISO 9001:2000 and ISO 14001:2004 (continued)

ISO 9001:2000		ISO 14001:2004	
Purchasing (title only)	7.4		
Purchasing process	7.4.1	4.4.6	Operational control
Purchasing information	7.4.2	4.4.6	Operational control
Verification of purchased product	7.4.3	4.4.6	Operational control
Production and service provision (title only)	7.5		
Control of production and service provision	7.5.1	4.4.6	Operational control
Validation of processes for production and service provision	7.5.2	4.4.6	Operational control
Identification and traceability	7.5.3		
Customer property	7.5.4		
Preservation of product	7.5.5	4.4.6	Operational control
Control of monitoring and measuring devices	7.6	4.5.1	Monitoring and measurement
Measurement, analysis and improvement (title only)	8	4.5	Checking
General	8.1	4.5.1	Monitoring and measurement
Monitoring and measurement (title only)	8.2		
Customer satisfaction	8.2.1		
Internal audit	8.2.2	4.5.5	Internal audit
Monitoring and measurement of processes	8.2.3	4.5.1 4.5.2	Monitoring and measurement Evaluation of compliance
Monitoring and measurement of product	8.2.4	4.5.1 4.5.2	Monitoring and measurement Evaluation of compliance
Control of nonconforming product	8.3	4.4.7 4.5.3	Emergency preparedness and response Nonconformity, corrective action and preventive action
Analysis of data	8.4	4.5.1	Monitoring and measurement
Improvement (title only)	8.5		
Continual improvement	8.5.1	4.2 4.3.4 4.6	Environmental policy Objectives, targets and programme(s) Management review
Corrective action	8.5.2	4.5.3	Nonconformity, corrective action and preventive action
Preventive action	8.5.3	4.5.3	Nonconformity, corrective action and preventive action

Table A.2 - Correspondence between ISO 14001:2004 and ISO 9001:2000

ISO 14001:2004		ISO 9001:2000	
Introduction	—	0 0.1 0.2 0.3 0.4	Introduction General Process approach Relationship with ISO 9004 Compatibility with other management systems
Scope	1	1 1.1 1.2	Scope General Application
Normative references	2	2	Normative reference
Terms and definitions	3	3	Terms and definitions
Environmental management system requirements (title only)	4	4	Quality management system (title only)
General requirements	4.1	4.1 5.5 5.5.1	General requirements Responsibility, authority and communication Responsibility and authority
Environmental policy	4.2	5.1 5.3 8.5.1	Management commitment Quality policy Continual improvement
Planning (title only)	4.3	5.4	Planning (title only)
Environmental aspects	4.3.1	5.2 7.2.1 7.2.2	Customer focus Determination of requirements related to the product Review of requirements related to the product
Legal and other requirements	4.3.2	5.2 7.2.1	Customer focus Determination of requirements related to the product
Objectives, targets and programme(s)	4.3.3	5.4.1 5.4.2 8.5.1	Quality objectives Quality management system planning Continual improvement
Implementation and operation (title only)	4.4	7	Product realization (title only)
Resources, roles, responsibility and authority	4.4.1	5.1 5.5.1 5.5.2 6.1 6.3	Management commitment Responsibility and authority Management representative Provision of resources Infrastructure
Competence, training and awareness	4.4.2	6.2.1 6.2.2	(Human resources) General Competence, awareness and training
Communication	4.4.3	5.5.3 7.2.3	Internal communication Customer communication
Documentation	4.4.4	4.2.1	(Documentation requirements) General

Table A.2 - Correspondence between ISO 14001:2004 and ISO 9001:2000 (continued)

ISO 14001:2004		ISO 9001:2000	
Control of documents	4.4.5	4.2.3	Control of documents
Operational control	4.4.6	7.1 7.2 7.2.1 7.2.2 7.3.1 7.3.2 7.3.3 7.3.4 7.3.5 7.3.6 7.3.7 7.4.1 7.4.2 7.4.3 7.5 7.5.1 7.5.2 7.5.5	Planning of product realization Customer-related processes Determination of requirements related to the product Review of requirements related to the product Design and development planning Design and development inputs Design and development outputs Design and development review Design and development verification Design and development validation Control of design and development changes Purchasing process Purchasing information Verification of purchased product Production and service provision Control of production and service provision Validation of processes for production and service provision Preservation of product
Emergency preparedness and response	4.4.7	8.3	Control of nonconforming product
Checking (title only)	4.5	8	Measurement, analysis and improvement (title only)
Monitoring and measurement	4.5.1	7.6 8.1 8.2.3 8.2.4 8.4	Control of monitoring and measuring devices (Measurement, analysis and improvement) General Monitoring and measurement of processes Monitoring and measurement of product Analysis of data
Evaluation of compliance	4.5.2	8.2.3 8.2.4	Monitoring and measurement of processes Monitoring and measurement of product
Nonconformity, corrective action and preventive action	4.5.3	8.3 8.4 8.5.2 8.5.3	Control of nonconforming product Analysis of data Corrective action Preventive action
Control of records	4.5.4	4.2.4	Control of records
Internal audit	4.5.5	8.2.2	Internal audit
Management review	4.6	5.1 5.6 5.6.1 5.6.2 5.6.3 8.5.1	Management commitment Management review (title only) General Review input Review output Continual improvement

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