

## Quality management system – Requirement 质量管理体系 – 要求



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# ISO 9001:2008

## Introduction

引言

### 0.1 General

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

- a) its organizational environment, changes in that environment, and the risks associated with that environment,
- b) its varying needs,
- c) its particular objectives,
- d) the products it provides,
- e) the processes it employs,
- f) its size and organizational structure.

采用质量管理体系应当是组织的一项战略性决策。一个组织质量管理体系的设计和实施受下列因素的影响：

- a) 组织的业务环境、该环境的变化或与该环境有关的风险，
- b) 组织的不同需求，
- c) 组织的特定目标，
- d) 所提供的产品，
- e) 所采用的过程，
- f) 组织的规模和组织结构。

It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

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”是帮助理解、澄清有关要求的参考性信息。

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各方（包括认证机构）评定组织满足顾客要求、适用的产品的法律法规要求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ISO 9000和ISO 9004中所阐明的质量管理原则。

### 0.2 Process approach

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.

本标准鼓励在建立、实施质量管理体系以及改进其有效性时采用过程方法，旨在通过满足顾客要求，增强顾客满意。

For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities 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.

为使组织有效运行，需确定和管理众多相互关联的活动。通过使用资源和实施管理，将输入转化为输出的一项或一组活动，可以视为一个过程。通常，一个过程的输出可直接形成下一个过程的输入。

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

为了产生期望的结果，组织内诸过程组成的应用，连同这些过程的识别和相互作用，以及对这些过程的管理，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.

过程方法的一个优点就是实现了对过程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，该方法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) 获得过程绩效和有效性的结果；
- 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。该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关于组织是否已满足其要求的感受的信息进行评价。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.

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.

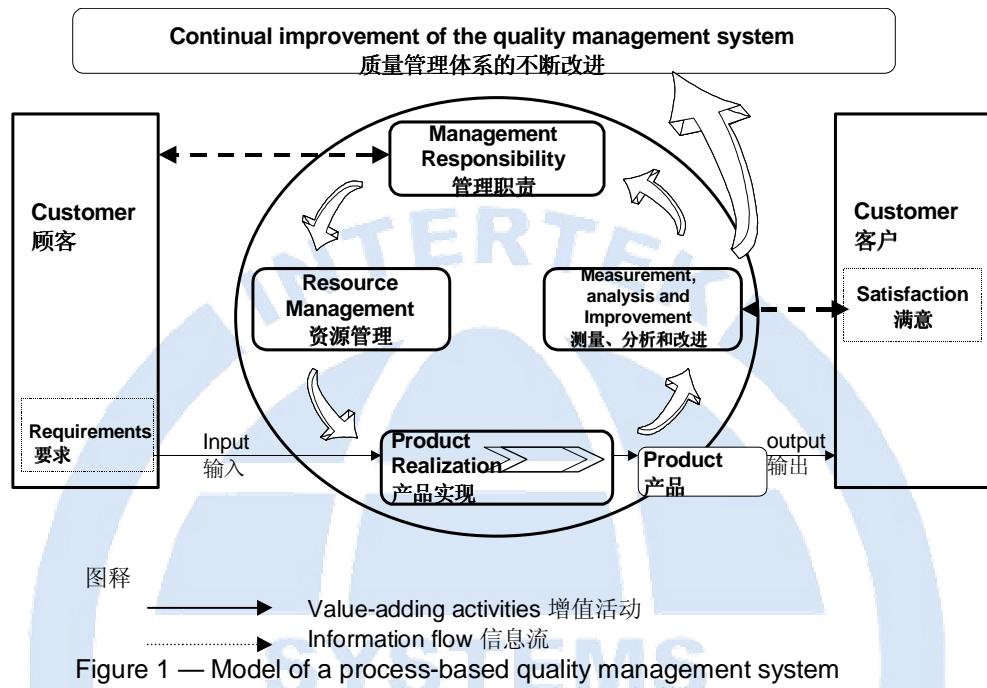
Act: take actions to continually improve process performance.

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：

P—策划：根据顾客的要求和组织的方针，建立实现结果所必需的目标和过程；

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，以持续改进过程绩效。



### 0.3 Relationship with ISO 9004

#### 与 ISO 9004 的关系

ISO 9001 and ISO 9004 are quality management system standards which have been designed to complement each other, but can also be used independently.

ISO 9001 和 ISO 9004 都是质量管理体系标准，这两项标准相互补充，但也可单独使用。

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 9001 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。ISO 9001 所关注的是质量管理体系在满足顾客要求方面的有效性。

At the time of publication of this International Standard, ISO 9004 is under revision. The revised edition of ISO 9004 will provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.

与 ISO 9001 相比，ISO 9004 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绩效与效率。对于最高管理者希望超越 ISO 9001 要求，追求绩效持续改进的那些组织，推荐 ISO 9004 作为指南。然而，用于认证或合同不是 ISO 9004 的目的。

## **0.4 Compatibility with other management systems**

### **与其他管理体系的相容性**

During the development of this International Standard, due consideration was given to the provisions of ISO 14001:2004 to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO 9001:2008 and ISO 14001:2004.

为了使用者的便利，本标准在制定过程中适当考虑了 ISO 14001:2004 标准的内容，以增强两个标准的相容性。附录 A 表明了 ISO 9001:2008 与 ISO 14001:2004 之间的对应关系。

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.

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、职业健康与安全管理、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**

范围

#### **1.1 General**

总则

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

本标准为有下列需求的组织规定了质量管理体系要求：

- 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.
- 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，旨在增强顾客满意。

NOTE 1 In this International Standard, the term “product” only applies to

- a) product intended for, or required by, a customer,
- b) any intended output resulting from the product realization processes.

注 1：在本标准中，术语“产品”仅适用于

- a) 预期提供给顾客或顾客所要求的产品，  
b) 产品实现过程所产生的任何预期输出。

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

注 2：法律法规要求可称作法定要求。

#### **1.2 Application**

应用

All requirements of this International Standard are generic and are intended to be applicable to all

organizations, regardless of type, size and product provided.

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。

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.

当本标准的任何要求由于组织及其产品的特点不适用时，可以考虑对其进行删减。

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 statutory and regulatory requirements.

如果进行了删减，而且这些删减仅限于本标准第 7 章的要求，同时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，方可声称符合本标准。

## **2 Normative references**

## 规范性引用文件

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

下列文件中的条款通过本标准的引用而成为本标准的条款。凡是注日期的引用文件，其随后所有的修改单（不包括勘误的内容）或修订版均不适用于本标准，然而，鼓励根据本标准达成协议的各方研究是否可使用这些文件的最新版本。凡是不注日期的引用文件，其最新版本适用于本标准。

ISO 9000:2005, Quality management systems — Fundamentals and vocabulary  
ISO9000:2005 质量管理体系 基础和术语

## 3 Terms and definitions

### 术语和定义

For the purposes of this document, the terms and definitions given in ISO 9000 apply.  
本标准采用 ISO 9000 中所确立的术语和定义。

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

### 质量管理体系

#### 4.1 General requirements

##### 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) 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 where applicable, and analyse these processes, and
- f) implement actions necessary to achieve planned results and continual improvement of these processes.

组织应：

- a) 确定质量管理体系所需的过程及其在整个组织中的应用（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(适用时)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。

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 to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

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。对此类外包过程控制的类型和程度应在质量管理体系中加以规定。

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

注 1：上述质量管理体系所需的过程包括与管理活动、资源提供、产品实现和测量、分析和改进有关的过程。

NOTE 2 An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

注 2：外包过程是经组织识别为质量管理体系所需的，但选择由组织的外部方实施的过程。

NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

- a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,
- b) the degree to which the control for the process is shared,
- c) the capability of achieving the necessary control through the application of 7.4.

注 3：确保对外包过程的控制并不免除组织满足顾客和法律法规要求的责任。对外包过程控制的类型和程度可受下列因素影响：

- a) 外包过程对组织提供满足要求的产品的能力的潜在影响；
- b) 对外包过程控制的分担程度；
- c) 通过应用 7.4 条款实现所需控制的能力。

## 4.2 Documentation requirements

文件要求

### 4.2.1 General

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, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

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) 组织确定的为确保其过程有效策划、运作和控制所需的文件，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 address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

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。一个文件可包括一个或多个程序的要求。一个形成文件的程序的要求可以被包含在多个文件中。

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.

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。

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**

质量手册

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.

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理由（见 1.2）；
- b) 为质量管理体系建立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**

文件控制

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. 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,
  - 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 determined by the organization to be 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.
- a) 文件发布前得到批准，以确保文件是充分与适宜的；为文件的充分性与适宜性，在文件发布前进行批准。
  - 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有关版本的适用文件;
- e) 确保文件保持清晰、易于识别;
- f) 确保组织所确定的策划和运行质量管理体系所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

##### 记录的控制

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

为符合要求和质量管理体系有效运行提供证据而建立的记录，应予以控制。

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

组织应编制形成文件的程序，以规定记录的标识、贮存、保护、检索、保存和处置所需的控制。

Records shall remain legible, readily identifiable and retrievable.

记录应保持清晰、易于识别和检索。



## **5 Management responsibility**

### 管理职责

#### **5.1 Management commitment**

##### 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

- 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.

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**

##### 以顾客为关注焦点

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).

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**

##### 质量方针

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.

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**

##### 策划

#### **5.4.1 Quality objectives**

##### 质量目标

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.

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** 质量管理体系策划

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.

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** 职责、权限和沟通

##### **5.5.1 Responsibility and authority** 职责和权限

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

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** 管理者代表

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.

最高管理者应指定一名本组织的管理者，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。

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。

##### **5.5.3 Internal communication** 内部沟通

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.

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

### 管理评审

#### 5.6.1 General

##### 总则

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.

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。

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

应保持管理评审的记录（见4.2.4）。

#### 5.6.2 Review input

##### 评审输入

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.

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

##### 评审输出

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.

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**

### 资源管理

#### **6.1 Provision of resources**

##### 资源的提供

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.

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 Human resources**

##### 人力资源

###### **6.2.1 General**

###### 总则

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

基于适当的教育、培训、技能和经验，从事影响产品与要求的符合性工作的人员应是能够胜任的。

NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

注：在质量管理体系中承担任何任务的人员都可能直接或间接地影响产品与要求的符合性。

###### **6.2.2 Competence, training and awareness**

###### 能力、培训和意识

The organization shall

- a) determine the necessary competence for personnel performing work affecting conformity to product requirements,
- b) where applicable, provide training or take other actions to achieve the necessary competence,
- 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, skills and experience (see 4.2.4).

组织应：

- a) 确定从事影响产品要求的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获得所需的能力；
- c) 评价所采取措施的有效性；
- d) 确保组织的人员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**

##### 基础设施

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, communication or information systems).

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

### 工作环境

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

组织应确定和管理为达到产品符合要求所需的工作环境。

**NOTE** The term “work environment” relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).

注：术语“工作环境”是指工作时所处的条件，包括物理的、环境的和其他因素（如噪音、温度、湿度、照明或天气）。

## 7 Product realization

### 产品实现

#### 7.1 Planning of product realization

##### 产品实现的策划

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).

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）。

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 and documents, and to 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).

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（见 4.2.4）。

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）和资源作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**

### **与顾客有关的过程**

#### **7.2.1 Determination of requirements related to the product**

##### **与产品有关的要求的确定**

The organization shall determine

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- b) requirements not stated by the customer but necessary for specified or intended use, where known,
- c) statutory and regulatory requirements applicable to the product, and
- d) any additional requirements considered necessary by the organization.

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) 适用于产品的法律法规要求；
- d) 组织认为必要的任何附加要求。

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

注：交付后活动包括诸如担保条件下的措施、合同规定的维护服务、附加服务（回收或最终处置）等。

#### **7.2.2 Review of requirements related to the product**

##### **与产品有关的要求的评审**

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.

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。

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

评审结果及评审所引起的措施的记录应予保持（见 4.2.4）。

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

若顾客提供的要求没有形成文件，组织在接收顾客要求前应对顾客要求进行确认。

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.

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。

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.

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、产品广告内容等进行评审。

### 7.2.3 Customer communication

#### 顾客沟通

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.

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

### 设计和开发

#### 7.3.1 Design and development planning

#### 设计和开发策划

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

组织应对产品的设计和开发进行策划和控制。

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.

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。

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实施管理，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.  
根据设计和开发的进展，在适当时候，策划的输出应予以更新。

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

注：设计和开发评审、验证和确认具有不同的目的。根据产品和组织的具体情况，可以单独或任意组合的形式进行并记录。

### **7.3.2 Design and development inputs**

#### **设计和开发输入**

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.

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。

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

应对设计和开发输入进行评审，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**

#### **设计和开发输出**

The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

设计和开发输出的方式应适合于针对设计和开发的输入进行验证，并应在放行前得到批准。

Design and development outputs shall

- a) meet the input requirements for design and development,
- b) provide appropriate information for purchasing, production and 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.

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。

NOTE Information for production and service provision can include details for the preservation of product.

注：生产和服务提供的信息可能包括产品防护的细节。

### **7.3.4 Design and development review**

#### **设计和开发评审**

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.

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。

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 (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。评审结果及任何必要措施的记录应予保持（见 4.2.4）。

### **7.3.5 Design and development verification**

#### **设计和开发验证**

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 (see 4.2.4).

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**

#### **设计和开发确认**

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 (see 4.2.4).

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**

#### **设计和开发更改的控制**

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). 应识别设计和开发的更改，并保持记录。在适当，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**

### **采购**

#### **7.4.1 Purchasing process**

##### **采购过程**

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.

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。

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.

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。

Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

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**

##### **采购信息**

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.

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。

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

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**

##### **采购产品的验证**

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

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。

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.

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**

##### **生产和服务提供**

#### **7.5.1 Control of production and service provision**

##### **生产和服务提供的控制**

The organization shall plan and carry out production and service provision under controlled conditions.

组织应策划并在受控条件下进行生产和服务提供。

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 equipment,
- e) the implementation of monitoring and measurement, and
- f) the implementation of product release, delivery and post-delivery activities.

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设备；
- e) 实施监视和测量；
- f) 产品放行、交付和交付后活动的实施。

### **7.5.2 Validation of processes for production and service provision 生产和服务提供的过程确认**

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

当生产和服务提供的过程输出不能由后续的监视或测量加以验证，致使问题在产品投入使用后或服务已交付后才显现时，组织应对任何这样的过程实施确认。

Validation shall demonstrate the ability of these processes to achieve planned results.  
确认应证实这些过程实现所策划的结果的能力。

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.

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。

### **7.5.3 Identification and traceability 标识和可追溯性**

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

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。

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

组织应在产品实现的全过程中，针对监视和测量要求识别产品的状态。

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

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

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

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**

##### **顾客财产**

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

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）。

**NOTE Customer property can include intellectual property and personal data.**

注：顾客财产可包括知识产权和个人信息。

#### **7.5.5 Preservation of product**

##### **产品防护**

The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection.

Preservation shall also apply to the constituent parts of a product.

组织应在内部处理和交付到预定的地点期间对产品提供防护，以保持与要求的符合性。适用时，这种防护应包括标识、搬运、包装、贮存和保护。防护也应适用于产品的组成部分。

#### **7.6 Control of monitoring and measuring equipment**

##### **监视和测量设备的控制**

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

组织应确定需实施的监视和测量以及所需的监视和测量设备，为产品符合确定的要求提供证据。

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.

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。

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified, or both, 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) have identification in order to determine its calibration status;

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

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

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和（或）验证。

当不存在上述标准时，应记录校准或检定的依据；（见 4.2.4）

b) 必要时进行调整或再调整；

c) 能够识别，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.

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。

Records of the results of calibration and verification shall be maintained (see 4.2.4).  
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，并在必要时予以重新确认。

NOTE 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.

注：确认计算机软件满足预期用途能力的典型方法包括验证和保持其适用性的配置管理（技术状态管理）。

## 8 Measurement, analysis and improvement

### 测量、分析和改进

#### 8.1 General

##### 总则

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

- a) to demonstrate conformity to product requirements,
  - b) to ensure conformity of the quality management system, and
  - c) to continually improve the effectiveness of the quality management system.
- 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) 证实与产品要求的符合性；
  - 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。

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

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

##### 监视和测量

###### 8.2.1 Customer satisfaction

###### 顾客满意

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

作为对质量管理体系业绩的一种测量，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。

NOTE Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.

注：监视顾客感受可以包括从诸如顾客满意调查、来自顾客的关于交付产品质量方面数据、用户意见调查、业务损失分析、顾客赞扬、担保索赔、经销商报告之类的来源获得输入。

### 8.2.2 Internal audit

#### 内部审核

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.

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。

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. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

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。

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

应编制形成文件的程序，以规定审核的策划、实施以及形成记录和报告结果的职责和要求。

Records of the audits and their results shall be maintained (see 4.2.4).

应保持审核及其结果的记录（见 4.2.4）

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

负责受审区域的管理者应确保及时采取必要的纠正和纠正措施，以消除所发现的不合格及其原因。

Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

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）。

NOTE See ISO 19011 for guidance.

注：作为指南，参见 ISO 19011。

### 8.2.3 Monitoring and measurement of processes

#### 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. 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.  
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。

NOTE When determining suitable methods, it is advisable that the organization 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.  
注：当确定适宜的方法时，建议组织就这些过程对产品要求的符合性和质量管理体系有效性的影响，考虑监视和测量的类型与程度。

#### **8.2.4 Monitoring and measurement of product**

##### **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 the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

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。

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

记录应指明有权放行产品以交付给顾客的人员（见 4.2.4）。

The release of product and delivery of service 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.

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，不应向顾客放行产品和交付服务。

#### **8.3 Control of nonconforming product**

##### **不合格品控制**

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 the controls and related responsibilities and authorities for dealing with nonconforming product.

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。应编制形成文件的程序，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。

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

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，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。

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

应对纠正后的产品再次进行验证，以证实符合要求。

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

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

### 数据分析

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.

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 8.2.4),
- c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and
- d) suppliers (see 7.4).

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 8.2.4）；
- c) 过程和产品的特性及趋势，包括采取预防措施的机会（见 8.2.3 和 8.2.4）；
- d) 供方（见 7.4）。

## 8.5 Improvement

### 改进

#### 8.5.1 Continual improvement

##### 持续改进

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.

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

##### 纠正措施

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.

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。

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.

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的有效性。

### 8.5.3 Preventive action

#### 预防措施

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.

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。

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.

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) 确定并实施所需的措施；
- 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的有效性。