



Secretariat of ISO/TC 176/SC 2

Date: 3 June

2013

**To the Members of  
ISO/TC 176/SC 2 -  
Quality Management and  
Quality Assurance/  
Quality Systems**

**ISO/CD 9001**

**目录**

**1 Scope 范围**

**2 Normative references 规范性引用文件**

**3 Terms and definitions 术语和定义**

**4 Context of the organization 组织的背景**

**4.1 Understanding the organization and its context 理解组织及其背景**

**4.2 Understanding the needs and expectations of interested parties 理解相关方的需求和期望**

**4.3 Determining the scope of the quality management system 质量管理体系范围的确定**

**4.4 Quality management system 质量管理体系**

**5 Leadership 领导作用**

**5.1 Leadership and commitment 领导作用和承诺**

**5.2 Quality policy 质量方针**

**5.3 Organizational roles, responsibilities and authorities 组织的作用、职责和权限**

**6 Planning 策划**

**6.1 Actions to address risks and opportunities 风险和机遇的应对措施**

**6.2 Quality objectives and planning to achieve them 质量目标及其实施的策划**

**6.3 Planning of changes 变更的策划**

**7 Support 支持**

**7.1 Resources 资源**

**7.2 Competence 能力**

**7.3 Awareness 意识**

**7.4 Communication 沟通**

**7.5 Documented information 形成文件的信息**

**8 Operation 运行**

**8.1 Operational planning and control 运行的策划和控制**

**8.2 Determination of market needs and interactions with customers 市场需求的确定和顾客沟通**

**8.3 Operational planning process 运行策划过程**

8.4 Control of external provision of goods and services 外部供应产品和服务的控制  
8.5 Development of goods and services 产品和服务开发  
8.6 Production of goods and provision of services 产品生产和服务提供  
8.7 Release of goods and services 产品和服务放行  
8.8 Nonconforming goods and services 不合格产品和服务  
9 *Performance evaluation* 绩效评价  
9.1 *Monitoring, measurement, analysis and evaluation* 监视、测量、分析和评价  
9.2 *Internal Audit* 内部审核  
9.3 *Management review* 管理评审  
10 **Continual** improvement 持续改进  
10.1 *Nonconformity and corrective action* 不符合和纠正措施  
10.2 *Improvement* 改进附录  
A Annex A Quality management principles (**Informative**) 质量管理原则文献

## 1. Scope 范围

This International Standard specifies requirements for a quality management system where an organization 本标准对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 goods and services that meet customer and applicable statutory and regulatory requirements, and 需要证实其具有稳定地提供满足顾客要求和适用法律法规要求的产品和服务的能力；

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

注 1：In this International Standard, the term “product” only applies to 在本标准一中，术语“产品”仅适用于：

a) goods and services intended for, or required by, a customer, and 预期提供给顾客或顾客所要求的商品和服务；

b) any intended output resulting from the operational processes 运行过程所产生的任何预期输出。

注 2：Statutory and regulatory requirements can be expressed as legal requirements 法律法规要求可称为法定要求。

## 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构成本标准的条款。凡是注日期的引用文件，只有引用的版本适用。凡是不注日期的引用文件，其最新版本（包括任何修订）适用于本标准。

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

GB/T19000-2015 质量管理体系 基础和术语

### 3 Term 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 GB/T19000 中所确立的术语和定义。

## 4 Context of the organization 组织的背景环境

### 4.1 Understanding the organization and its context 理解组织及其背景环境

*The organization shall determine external and internal issues, that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended outcome(s) of its quality management system* 组织应确定外部和内部那些与组织的宗旨、战略方向有关、影响质量管理体系实现预期结果的能力的事务。

The organization shall update such determinations when needed 需要时，组织应更新这些信息。

When determining relevant external and internal issues, the organization shall consider those arising from:在确定这些相关的内部和外部事宜时，组织应考虑以下方面：

- a) changes and trends which can have an impact on the objectives of the organization 可能对组织的目标造成影响的变更和趋势；
- b) relationships with, and perceptions and values of relevant interested parties 与相关方的关系，以及相关方的理念、价值观；
- c) governance issues, strategic priorities, internal policies and commitments; and 组织管理、战略优先、内部政策和承诺；
- d) resource availability and priorities and technological change 资源的获得和优先供给、技术变更。

注 1: Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, cultural, social, economic and natural environment, whether international, national, regional or local. 外部的环境，可以考虑法律、技术、竞争、文化、社会、经济和自然环境方面，不管是国际、国家、地区或本地。

注 2: When understanding the internal context the organization could consider those related to perceptions, values and culture of the organization. 内部环境，可以组织的理念、价值观和文化。

### 4.2 Understanding the needs and expectations of interested parties 理解相关方的需求和期望

*The organization shall determine* 组织应确定：

- a) *the interested parties that are relevant to the quality management system, and* 与质量管理体系有关的相关方
- b) *the requirements of these interested parties* 相关方的要求

The organization shall update such determinations in order to understand and anticipate needs or expectations affecting customer requirements and customer satisfaction 组织应更新以上确定的结果，以便于理解和满足影响顾客要求和顾客满意度的需求和期望。

The organization shall consider the following relevant interested parties 组织应考虑以下相关方：

- a) direct customers 直接顾客

- b) end users 最终使用者
- c) suppliers, distributors, retailers or others involved in the supply chain 供应链中的供方、分销商、零售商及其他
- d) regulators; and 立法机构
- e) any other relevant interested parties 其他

注：Note Addressing current and anticipated future needs can lead to the identification of improvement and innovation opportunities 应对当前的和预期的未来需求可导致改进和变革机会的识别。

### **4.3 Determining the scope of the quality management system 确定质量管理体系的范围**

*The organization shall determine the boundaries and applicability of the quality management system to establish its scope* 组织应界定质量管理体系的边界和应用，以确定其范围。

*When determining this scope, the organization shall consider* 在确定质量管理体系范围时，组织应考虑：

- a) *the external and internal issues referred to in 4.1, and* 标准 4.1 条款中提到的内部和外部事宜
- b) *the requirements referred to in 4.2* 标准 4.2 条款的要求

The scope shall be stated in terms of goods and services, the main processes to deliver them and the sites of the organization included 质量管理体系的范围应描述为组织所包含的产品、服务、主要过程和地点。

When stating the scope, the organization shall document and justify any decision not to apply a requirement of this International Standard and to exclude it from the scope of the quality management system. Any such exclusion shall be limited to clause 7.1. 4 and 8 and shall not affect the organization's ability or responsibility to assure conformity of goods and services and customer satisfaction, nor can an exclusion be justified on the basis of a decision to arrange for an external provider to perform a function or process of the organization.描述质量管理体系的范围时，对不适用的标准条款，应将质量管理体系的删减及其理由形成文件。删减应仅限于标准第 7.1、4 和 8 章节，且不影响组织确保产品和服务满足要求和顾客满意的能力和 responsibility。过程外包不是正当的删减理由。

注：An external provider can be a supplier or a sister organization (such as a headquarters or alternate site location) that is outside of the organization's quality management system.外部供应商可以是组织质量管理体系之外的供方或兄弟组织。

*The scope shall be available as documented information* 质量管理体系范围应形成文件。

## **4.4 Quality management system 质量管理体系**

### **4.4.1 General 总则**

*The organization shall establish, implement, maintain and ~~continually~~ improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.*组织应按本标准的要求建立质量管理体系、过程及其相互作用，加以实施和保持，并持续改进。

### **4.4.2 Process approach 过程方法**

The organization shall apply a process approach to its quality management system. The

organization shall:组织应将过程方法应用于质量管理体系。组织应:

- a) determine the processes needed for the quality management system and their application throughout the organization;确定质量管理体系所需的过程及其在整个组织中的应用;
- b) determine the inputs required and the outputs expected from each process;确定每个过程所需的输入和期望的输出;
- c) determine the sequence and interaction of these processes;确定这些过程的顺序和相互作用;
- d) determine the risks to conformity of goods and services and customer satisfaction if unintended outputs are delivered or process interaction is ineffective;确定产生非预期的输出或过程失效对产品、服务和顾客满意带来的风险;
- e) determine criteria, methods, measurements, and related performance indicators needed to ensure that both the operation and control of these processes are effective 确定所需的准则、方法、测量及相关的绩效指标,以确保这些过程的有效运行和控制;
- f) determine the resources and ensure their availability 确定和提供资源;
- g) assign responsibilities and authorities for processes 规定职责和权限;
- h) implement actions necessary to achieve planned results 实施所需的措施以实现策划的结果;
- i) monitor, analyse and change, if needed, these processes ensuring that they continue to deliver the intended outputs; and 监测、分析这些过程,必要时变更,以确保过程持续产生期望的结果;
- j) ensure ~~continual~~ improvement of these processes.确保持续改进这些过程。

## 5 Leadership 领导作用

### 5.1 Leadership and commitment 领导作用与承诺

#### 5.1.1 Leadership and commitment with respect to the quality management system 针对质量管理体系的领导作用与承诺

*Top management shall demonstrate leadership and commitment with respect to the quality management system by* 最高管理者应通过以下方面证实其对质量管理体系的领导作用与承诺:

- a) *ensuring that quality policies and quality objectives are established for the quality management system and are compatible with the strategic direction of the organization;*确保质量方针和质量目标得到建立,并与组织的战略方向保持一致;
- b) ensuring the quality policy is understood and followed within the organization;确保质量方针在组织内得到理解和实施;
- c) *ensuring the integration of the quality management system requirements into the organization's business processes;*确保质量管理体系要求纳入组织的业务运作;
- d) promoting awareness of the process approach;提高过程方法的意识;
- e) *ensuring that the resources needed for the quality management system are available;*确保质量管理体系所需资源的获得;
- f) *communicating the importance of effective quality management and of conforming to the quality management system requirements and the requirements of goods and services;*传达有效的质量管理以及满足质量管理体系、产品和服务要求的重要性;
- g) *ensuring that the quality management system achieves its intended ~~outcomes~~ outputs;*确保质量管理体系实现预期的输出;
- h) *engaging, directing and supporting persons to contribute to the effectiveness of the quality*

*management system* 吸纳、指导和支持员工参与对质量管理体系的有效性作出贡献;  
i) *promoting ~~continual~~ improvement and innovation*; and 增强持续改进和创新;  
j) *supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility*.支持其他的管理者在其负责的领域证实其领导作用。

### 5.1.2 Leadership and commitment with respect to the needs and expectations of customers 针对顾客需求和期望的领导作用与承诺

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that 最高管理者应通过以下方面,证实其针对以顾客为关注焦点的领导作用和承诺:

- a) the risks which can affect conformity of goods and services and customer satisfaction are identified and addressed;可能影响产品和服务符合性、顾客满意的风险得到识别和应对;
- b) customer requirements are determined and met;顾客要求得到确定和满足;
- c) the focus on consistently providing goods and services that meet customer and applicable statutory and regulatory requirements is maintained;保持以稳定提供满足顾客和相关法规要求的产品和服务为焦点;
- d) the focus on enhancing customer satisfaction is maintained;保持以增强顾客满意为焦点;

注: Reference to “business” in this International Standard should be interpreted broadly to mean those activities that are core to the purposes of the organization’s existence.本标准中的“业务”可以广泛地理解为对组织存在的目的很重要的活动。

### 5.2 Quality policy 质量方针

Top management shall establish a quality policy that:最高管理者应制定质量方针,方针应:

- a) *is appropriate to the purpose of the organization*;与组织的宗旨相适应;
- b) *provides a framework for setting quality objectives*;提供制定质量目标的框架;
- c) *includes a commitment to satisfy applicable requirements, and* 包括对满足适用要求的承诺;
- d) *includes a commitment to ~~continual~~ improvement of the quality management system*.包括对持续改进质量管理体系的承诺。

The quality policy shall:质量方针应:

- a) *be available as documented information*;形成文件;
- b) *be communicated within the organization*;在组织内得到沟通;
- c) *be available to interested parties, as appropriate; and* 适用时,可为相关方所获取;
- d) *be reviewed for continuing suitability*.在持续适宜性方面得到评审。

注: Quality Management Principles can be used as the basis for the quality policy.质量管理原则可作为质量方针的基础。

### 5.3 Organizational roles, responsibilities and authorities 组织的作用、职责和权限

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned and communicated within the organization.最高管理者应确保组织内相关的职责、权限得到规定和沟通。

*Top management shall be accountable for the effectiveness of the quality management system and shall assign the responsibility and authority for:*最高管理者应对质量管理体系的有效性负责，并规定职责和权限以便：

- a) *ensuring that the quality management system conforms to the requirements of this International Standard and*确保质量管理体系符合本标准的要求；
- b) *ensuring that the processes interact and are delivering their intended outputs;*确保过程相互作用并产生期望的结果；
- c) *reporting on the performance of the quality management system to top management and any need for improvement, and*向最高管理者报告质量管理体系的绩效和任何改进的需求；
- d) *ensuring the promotion of awareness of customer requirements throughout the organization.*确保在整个组织内提高满足顾客要求的意识。

## 6 Planning 策划

### 6.1 *Actions to address risks and opportunities* 风险和机遇的应对措施

*When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to* 策划质量管理体系时，组织应考虑 4.1 和 4.2 的要求，确定需应对的风险和机遇，以便：

- a) *assure the quality management system can achieve its intended outcome(s);*确保质量管理体系实现期望的结果；
- b) *assure that the organization can consistently achieve conformity of goods and services and customer satisfaction;*确保组织能稳定地实现产品、服务符合要求和顾客满意；
- c) *prevent, or reduce, undesired effects, and* 预防或减少非预期的影响；
- d) *achieve ~~continual~~ improvement.*实现持续改进。

*The organization shall plan:*组织应策划：

- a) *actions to address these risks and opportunities, and* 风险和机遇的应对措施；
- b) *how to* 如何
  - 1) *integrate and implement the actions into its quality management system processes (see 4.4), and* 在质量管理体系过程中纳入和应用这些措施（见 4.4）
  - 2) *evaluate the effectiveness of these actions.*评价这些措施的有效性

Any actions taken to address risks and opportunities shall be proportionate to the potential effects on conformity of goods and services and customer satisfaction.采取的任何风险和机遇的应对措施都应与其对产品、服务的符合性和顾客满意的潜在影响相适应。

注：Options to address risks can include for example risk avoidance, risk mitigation or risk acceptance 可选的风险应对措施包括风险规避、风险降低、风险接受等。

### 6.2 *Quality objectives and planning to achieve them* 质量目标及其实施的策划

*The organization shall establish quality objectives at relevant functions, levels and processes.*

*The quality objectives shall:*组织应在相关职能、层次、过程上建立质量目标。质量目标应：

- a) *be consistent with the quality policy;*与质量方针保持一致
- b) *be relevant to conformity of goods and services and customer satisfaction;*与产品、服务的

符合性和顾客满意相关

- c) *be measurable* (~~if practicable~~); 可测量 (可行时)
- d) *take into account applicable requirements*, 考虑适用的要求
- e) *be monitored*, 得到监测
- f) *be communicated, and* 得到沟通
- g) *be updated as appropriate*. 适当时进行更新

*The organization shall retain documented information on the quality objectives.* 组织应将质量目标形成文件。

*When planning how to achieve its quality objectives, the organization shall determine:* 在策划目标的实现时, 组织应确定:

- a) *what will be done*; 做什么;
- b) *what resources will be required* (see 7.1) 所需的资源 (见 7.1);
- c) *who will be responsible*; 责任人;
- d) *when it will be completed, and* 完成的时间表;
- e) *how the results will be evaluated*. 结果如何评价。

### 6.3 Planning of changes 变更的策划

The organization shall determine the needs and opportunities for change to maintain and improve the performance of the quality management system. 组织应确定变更的需求和机会, 以保持和改进质量管理体系绩效。

The organization shall undertake change in a planned and systematic manner, identifying risks and opportunities and reviewing the potential consequences of change. 组织应有计划、系统地进行变更, 识别风险和机遇, 并评价变更的潜在后果。

注: Specific requirements on control of changes are included in clause 8. 变更控制的特定要求在第 8 条规定。

## 7 Support 支持

### 7.1 Resources 资源

#### 7.1.1 General 总则

*The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and ~~continual~~ improvement of the quality management system.* 组织应确定、提供为建立、实施、保持和改进质量管理体系所需的资源。

The organization shall consider 组织应考虑:

- a) what are existing internal resources, capabilities and limitations, and 现有的资源、能力、局限
- b) which goods and services are to be sourced externally. 外包的产品和服务

#### 7.1.2 Infrastructure 基础设施

The organization shall determine, provide and maintain the infrastructure necessary for its

operations and to assure conformity of goods and services and customer satisfaction.组织应确定、提供和维护其运行和确保产品、服务符合性和顾客满意所需的基础设施。

注：Note Infrastructure can include:基础设施可包括：

- a) buildings and associated utilities;建筑物和相关的设施
- b) equipment including hardware and software, and 设备（包括硬件和软件）
- c) transportation, communication and information systems.运输、通讯和信息系统

### **7.1.3 Process environment 过程环境**

The organization shall determine, provide and maintain the process environment necessary for its operations and to assure conformity of goods and services and customer satisfaction.组织应确定、提供和维护其运行和确保产品、服务符合性和顾客满意所需的过程环境。

注：Process environment can include physical, social, psychological and environmental factors (such as temperature, recognition schemes, ergonomics and atmospheric composition).过程环境可包括物理的、社会的、心理的和环境的因素（例如：温度、承认方式、人因工效、大气成分）。

### **7.1.4 Monitoring and measuring devices 监视和测量设备**

The organization shall determine, provide and maintain the monitoring and measuring devices needed to verify conformity to product requirements and shall ensure that the devices are fit for purpose.组织应确定、提供和维护用于验证产品符合性所需的监视和测量设备，并确保监视和测量设备满足使用要求。

The organization shall retain appropriate documented information as evidence of fitness for purpose of monitoring and measuring devices.组织应保持适当的文件信息，以提供监视和测量设备满足使用要求的证据。

注 1：Monitoring and measurement devices can include measuring equipment and assessment methods such as surveys.监视和测量设备可包括测量设备和评价方法（例如：调查问卷）。

注 2：Monitoring and measurement devices can be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards.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对监视和测量设备进行校准和（或）检定。

### **7.1.5 Knowledge 知识**

The organization shall determine the knowledge necessary for the operation of the quality management system and its processes and to assure conformity of goods and services and customer satisfaction. This knowledge shall be maintained, protected and made available as necessary.组织应确定质量管理体系运行、过程、确保产品和服务符合性及顾客满意所需的知识。这些知识应得到保持、保护、需要时便于获取。

Where addressing changing needs and trends the organization shall take into account its current knowledge base and determine how to acquire or access the necessary additional knowledge.(See also 6.3)在应对变化的需求和趋势时，组织应考虑现有的知识基础，确定如何获取必需的更多知识。（见 6.3）

## **7.2 Competence 能力**

*The organization shall:*组织应：

- a) *determine the necessary competence of person(s) doing work under its control that affects its quality performance, and* 确定在组织控制下从事影响质量绩效工作的人员所必要的的能力；
- b) *ensure that these persons are competent on the basis of appropriate education, training, or experience;*基于适当的教育、培训和经验，确保这些人员是胜任的；
- c) *where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken, and* 适用时，采取措施以获取必要的的能力，并评价这些措施的有效性；
- d) *retain appropriate documented information as evidence of competence* 保持形成文件的信息，以提供能力的证据。

注：Applicable actions may include, for example: the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.适当的措施可包括，例如提供培训、辅导、重新分配任务、招聘胜任的人员等。

## **7.3 Awareness 意识**

*Persons doing work under the organization's control shall be aware of* 在组织控制下工作的人员应意识到：

- a) *the quality policy;*质量方针
- b) *relevant quality objectives* 相关的质量目标
- c) *their contribution to the effectiveness of the quality management system, including the benefits of improved quality performance, and* 他们对质量管理体系有效性的贡献，包括改进质量绩效的益处
- d) *the implications of not conforming with the quality management system requirements.*偏离质量管理体系要求的后果

## **7.4 Communication 沟通**

*The organization shall determine the need for internal and external communications relevant to the quality management system including:*组织应确定与质量管理体系相关的内部和外部沟通的需求，包括：

- a) *on what it will communicate;*沟通的内容
- b) *when to communicate, and* 沟通的时机
- c) *with whom to communicate.*沟通的对象

## **7.5 Documented information 形成文件的信息**

### **7.5.1 General 总则**

*The organization's quality management system shall include* 组织的质量管理体系应包括:

- a) *documented information required by this International Standard*; 本标准所要求的文件信息
- b) *documented information determined by the organization as being necessary for the effectiveness of the quality management system*; 组织确定的为确保质量管理体系有效运行所需的形成文件的信息

注: *The extent of documented information for a quality management system can differ from one organization to another due to* 不同组织的质量管理体系文件的多少与详略程度可以不同, 取决于:

- a) *the size of organization and its type of activities, processes, products goods and services*; 组织的规模、活动类型、过程、产品和服务;
- b) *the complexity of processes and their interactions, and* 过程及其相互作用的复杂程度;
- c) *the competence of persons* 人员的能力。

### **7.5.2 Creating and updating 编制和更新**

*When creating and updating documented information the organization shall ensure appropriate* 在编制和更新文件时, 组织应确保适当的:

- a) *identification and description (e.g. a title, date, author, or reference number)*; 标识和说明 (例如: 标题、日期、作者、索引编号等)
- b) *format (e.g. language, software version, graphics) and media (e.g. paper, electronic)*; 格式 (例如: 语言、软件版本、图示) 和媒介 (例如: 纸质、电子格式)
- c) *review and approval for suitability and adequacy*. 评审和批准以确保适宜性和充分性

### **7.5.3 Control of documented Information 文件控制**

*Documented information required by the quality management system and by this International Standard shall be controlled to ensure:* 质量管理体系和本标准所要求的形成文件的信息应进行控制, 以确保:

- a) *it is available and suitable for use, where and when it is needed, and* 需要文件的场所能获得适用的文件
- b) *it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity)*. 文件得到充分保护, 如防止泄密、误用、缺损。

For the control of documented information, the organization shall address the following activities, as applicable 适用时, 组织应以下文件控制活动:

- a) *distribution, access, retrieval and use*, 分发、访问、回收、使用;
- b) *storage and preservation, including preservation of legibility*; 存放、保护, 包括保持清晰;
- c) *control of changes (e.g. version control), and* 更改的控制 (如: 版本控制);
- d) *retention and disposition*. 保留和处置。

*Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and controlled* 组织所确定的策划和运行质量管理体系所需的外来文件应确保得到识别和控制。

注: *Access implies a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information, etc.* “访问”指仅得到查阅文件

的许可，或授权查阅和修改文件。

## 8 Operation 运行

### 8.1 Operational planning and control 运行策划和控制

*The organization shall plan, implement and control the processes needed to meet requirements and to implement the actions determined in 6.1, by 组织应策划、实施和控制满足要求和标准 6.1 条确定的措施所需的过程，包括：*

- a) *establishing criteria for the processes 建立过程准则；*
- b) *implementing control of the processes in accordance with the criteria, and 按准则要求实施过程控制；*
- c) *keeping documented information to the extent necessary to have confidence that the processes have been carried out as planned.保持充分的文件信息，以确信过程按策划的要求实施。*

*The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.组织应控制计划的变更，评价非预期的变更的后果，必要时采取措施减轻任何不良影响。*

*The organization shall ensure that ~~outsourced processes are~~ the operation of a function or process of the organization by an external provider is controlled (see 8.4).组织应确保由外部供方实施的职能或过程得到控制（见 8.4）。*

注：Operation of a function or process of the organization by an external provider is often referred to as outsourcing..组织的某项职能或过程由外部供方实施通常称作为外包。

### 8.2 Determination of market needs and interactions with customers 市场需求的确定和顾客沟通

#### 8.2.1 General 总则

*The organization shall implement a process for interacting with customers to determine their requirements relating to goods and services.组织应实施与顾客沟通所需的过程，以确定顾客对产品和服务的要求。*

注 1：A “customer” means an existing or potential customer “顾客”指当前的或潜在的顾客；

注 2：The organization can interact with other relevant interested parties to determine additional requirements for goods and services (see 4.2).组织可与其他相关方沟通以确定对产品和服务的附加要求（见 4.2）。

#### 8.2.2 Determination of requirements related to the goods and services 与产品和服务有关要求的确定

*The organization shall determine as applicable 适用时，组织应确定：*

- a) *requirements specified by the customer including the requirements for delivery and post-delivery activities;顾客规定的要求，包括对交付及交付后活动的要求；*
- b) *requirements not stated by the customer but necessary for specified or intended use, where known,顾客虽然没有明示，但规定的用途或已知的预期用途所必需的要求；*

- c) statutory and regulatory requirements applicable to the goods and services, and 适用于产品和服务的法律法规要求;
- d) any additional requirements considered necessary by the organization 组织认为必要的任何附加要求。

注: Additional requirements can include those arising from relevant interested parties 附加要求可包含由有关的相关方提出的要求。

### **8.2.3 Review of requirements related to the goods and services 与产品和服务有关的要求评审**

The organization shall review the requirements related to the goods and services. This review shall be conducted prior to the organization's commitment to supply goods and services to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that 应在组织向顾客作出提供产品的承诺(如: 提交标书、接受合同或订单及接受合同或订单的更改)之前进行, 并确保:

- a) goods and services requirements are defined and agreed,产品和服务要求已得到规定并达成一致;
- b) contract or order requirements differing from those previously expressed are resolved, and 与以前表述不一致的合同或订单的要求已予解决;
- c) the organization is able to meet the defined requirements 组织有能力满足规定的要求。

Documented information describing the results of the review shall be maintained.评审结果的信息应形成文件。

Where the customer does not provide documented statement of their requirements, the customer requirements shall be confirmed by the organization before acceptance.若顾客没有提供形成文件的要求, 组织在接受顾客要求前应对顾客要求进行确认。

Where requirements for goods and services are changed, the organization shall ensure that relevant documented information is amended and that relevant personnel are made aware of the changed requirements 若产品和服务要求发生变更, 组织应确保相关文件信息得到修改, 并确保相关人员知道已变更的要求。

注: In some situations a formal review is impractical for each order. Instead the review can cover other relevant information available to the customer.在某些情况下, 对每一个订单进行正式的评审可能是不实际的, 作为替代方法, 可对提供给顾客的有关的产品信息进行评审。

### **8.2.4 Customer communication 顾客沟通**

The organization shall determine and implement planned arrangements for communicating with customers in relation to:组织应对以下有关方面确定并实施与顾客沟通的安排:

- a) goods and services information;产品和服务信息;
- b) enquiries, contracts or order handling, including amendments;问询、合同或订单的处理, 包括对其修改;
- c) customer feedback, including customer complaints (see 9.1);顾客反馈, 包括顾客抱怨(见

9.1) ;

d) the handling of customer property, if applicable, and 适用时，对顾客财产的处理；

e) the specific requirements for contingency actions, where relevant.相关时，应急措施的特定要求。

### 8.3 Operational planning process 运行策划过程

In preparing for the realization of goods and services, the organization shall implement a process to determine the following, as appropriate 为产品和服务实现作准备，组织应实施过程以确定以下内容，适用时包括：

a) requirements for the goods and services taking into consideration relevant quality objectives; 产品和服务的要求，并考虑相关的质量目标；

b) actions to identify and address risks related to achieving conformity of goods and services to requirements; 识别和应对与实现产品和服务满足要求所涉及的风险相关的措施；

c) the resources that will be required arising from the requirements for the goods and services 针对产品和服务确定资源的需求；

d) the criteria for the acceptance of goods and services 产品和服务的接收准则

e) required verification, validation, monitoring, measurement, inspection and test activities specific to the goods and services 产品和服务所要求的验证、确认、监视、检验和试验活动；

f) how the performance data will be established and communicated; and 绩效数据的形成和沟通；

g) requirements for traceability, preservation, goods and services delivery and post delivery activities 可追溯性、产品防护、产品和服务交付及交付后活动的要求。

The output of this planning process shall be in a form suitable for the organization's operations. 策划的输出形式应便于组织的运作。

注 1: Documented information specifying the processes of the quality management system (including the realization of goods and services processes) and the resources to be applied to a specific good and service, project or contract can be referred to as a quality plan. 对应用于特定产品、项目或合同的质量管理体系的过程（包括产品和服务实现过程）和资源作出规定的文件可称之为质量计划。

注 2: The organization can also apply the requirements given in 8.5 to the development of processes for the realization of goods and services. 组织也可将 8.5 的要求应用于产品和服务实现过程的开发。

### 8.4 Control of external provision of goods and services 供应的产品和服务的控制

#### 8.4.1 General 总则

The organization shall ensure that externally provided goods and services conform to specified requirements 组织应确保外部提供的产品和服务满足规定的要求。

注: Where the organization has arranged for an external provider to perform a function or process of the organization it is assumed this will result in the provision of goods, services or both goods and services. 当组织安排由外部供方实施其职能和过程时，这就意味由外部提供产品和（或）服务。

#### 8.4.2 Type and extent of control of external provision 外部供应的控制类型和程度

The type and extent of control applied to the external providers and the externally-provided processes, goods and services shall be dependent upon 对外部供方及其供应的过程、产品和服务的控制类型和程度取决于：

- a) the risks identified and the potential impacts, 识别的风险及其潜在影响
- b) the degree to which the control of an externally provided process is shared between the organization and the provider, and 组织与外部供方对外部供应过程控制的分担程度
- c) the capability of potential controls 潜在的控制能力

The organization shall establish and apply criteria for the evaluation, selection, and re- evaluation of external providers based on their ability to provide goods and services in accordance with the organization's requirements. 组织应根据外部供方按组织的要求提供产品的能力，建立和实施对外部供方的评价、选择和重新评价的准则。

Documented information describing the results of evaluations shall be maintained. 评价结果的信息应形成文件。

#### **8.4.3 Documented information for external providers 提供外部供方的文件信息**

Documented information shall be provided to the external provider describing, where appropriate: 适用时，提供给外部供方的形成文件信息应阐述：

- a) the goods and services to be provided or the process to be performed, 供应的产品和服务，以及实施的过程；
- b) the requirements for approval or release of goods and services, procedures, processes or equipment, 产品、服务、程序、过程 and 设备的放行或批准要求；
- c) the requirements for competence of personnel, including necessary qualification, 人员能力的要求，包含必要的资格；
- d) the quality management system requirements, 质量管理体系的要求；
- e) the control and monitoring of the external provider's performance to be applied by the organization; 组织对外部供方业绩的控制和监视；
- f) any verification activities that the organization, or its customer, intends to perform at the external provider's premises, and 组织或其顾客拟在供方现场实施的验证活动；
- g) the requirements for handling of external provider's property provided to the organization 将产品从外部供方到组织现场的搬运要求；

The organization shall ensure the adequacy of specified requirements prior to their communication to the external provider 在与外部供方沟通前，组织应确保所规定的要求是充分与适宜的。

The organization shall monitor the performance of external providers. Documented information describing ~~on~~ the results of monitoring shall be maintained. 组织应对外部供方的业绩进行监视。应将监视结果的信息形成文件。

## 8.5 Development of goods and services 产品和服务的开发

### 8.5.1 Development processes 开发过程

The organization shall plan and implement processes for the development of goods and services consistent with the process approach. 组织应采用过程方法策划和实施产品和服务开发过程。

In determining the stages and controls for the development processes, the organization shall take account of: 在确定产品和服务开发的阶段和控制时, 组织应考虑:

- a) the nature, duration and complexity of the development activities 开发活动的特性、周期、复杂性;
- b) customer, statutory and regulatory requirements specifying particular process stages or controls, 顾客和法律法规对特定过程阶段或控制的要求;
- c) requirements specified by the organization as essential for the specific type of goods and services being developed 组织确定的特定类型的产品和服务的关键要求;
- d) standards or codes of practice that the organization has committed to implement, 组织承诺遵守的标准或行业准则;
- e) the determined risks and opportunities associated with the development activities with respect to 针对以下开发活动所确定的相关风险和机遇:
  - 1) the nature of the goods and services to be developed and potential consequences of failure 开发的产品和服务的特性, 以及失败的潜在后果
  - 2) the level of control expected of the development process by customers and other relevant interested parties, and 顾客和其他相关方对开发过程期望的控制程度
  - 3) the potential impact on the organization's ability to consistently meet customer requirements and enhance customer satisfaction. 对组织稳定的满足顾客要求和增强顾客满意的能力的潜在影响
- f) internal and external resource needs for the development of goods and services 产品和服务开发所需的内部和外部资源
- g) the need for clarity with respect to the responsibilities and authorities of the individuals and parties involved in the development process 开发过程中的人员和各个小组的职责和权限
- h) the need for the management of the interfaces between individuals and parties involved in the development task or opportunity, 参加开发活动的人员和各个小组的接口管理的需求
- i) the need for involvement of customer groups and user groups in the development process and their interface with management of the development process, 对顾客和使用者参与开发活动的需求及接口管理
- j) the necessary documented information on the application of development processes, the outputs and their suitability, and 开发过程、输出及其适用性所需的形成文件的信息
- k) the activities needed to transfer from development to production or service provision 将开发转化为产品和服务提供所需的活动

### 8.5.2 Development controls 开发控制

The controls applied to the development process shall ensure that 对开发过程的控制应确保:

- a) the result to be achieved by the development activities is clearly defined 开发活动要完成的结果得到明确规定
- b) inputs are defined to a level sufficient for the development activities being undertaken and do

- not give rise to ambiguity, conflict or lack of clarity,开发输入应充分规定,避免模棱两可、冲突、不清楚;
- c) outputs are in a form suitable for subsequent use for production of goods and provision of services and related monitoring and measurement,开发输出的形式应便于后续产品生产和服务提供,以及相关监视和测量;
- d) problems and issues arising during the development process are resolved or otherwise managed before committing to further development work or setting priorities for that work,在进入下一步工作前,开发过程中提出的问题得到解决或管理,或者将其优先处理;
- e) the planned development processes have been followed, the outputs are consistent with the inputs and the objective of the development activity has been met,策划的开发过程得到实施,开发的输出满足输入的要求,实现了开发活动的目标;
- f) goods produced or services provided as a consequence of the development undertaken are fit for purpose, and 按开发的结果生产的产品和提供的服务满足使用要求;
- g) appropriate change control and configuration management is maintained throughout the development of goods and services and any subsequent modifications to goods and services 在整个产品和服务开发过程及后续任何对产品的更改中,保持适当的更改控制和配置管理。

### 8.5.3 Development transfer 开发的转化

The organization shall ensure that transfer from development to production or service provision only takes place when actions outstanding or arising from development have been completed or are otherwise managed such that there is no adverse impact on the organization's ability to consistently meet customer requirements, statutory or regulatory requirements, or to enhance customer satisfaction 组织不应将开发转化为产品生产和服务提供,除非开发活动中未完成的或提出措施都已经完毕或者得到管理,不会对组织稳定地满足顾客、法律和法规要求及增强顾客满意的能力造成不良影响。

### 8.6 Production of goods and provision of services 产品生产和服务提供

#### 8.6.1 Control of production of goods and provision of services 产品生产和服务提供的控制

The organization shall implement production of goods and provision of services under controlled conditions. Controlled conditions shall include, as applicable:组织应在受控条件下进行产品生产和服务提供。适用时,受控条件应包括:

- a) the availability of documented information that describes the characteristics of the goods and services;获得表述产品和服务特性的文件信息
- b) the implementation of controls 控制的实施
- c) the availability of documented information that describes the activities to be performed and the results achieved, as necessary;必要时,获得表述活动的实施及其结果的文件信息;
- d) the use of suitable equipment;使用适宜的设备;
- e) the availability, implementation and use of monitoring and measuring devices;获得、实施和使用监测和测量设备
- f) the competence of personnel or their qualification 人员的能力或资格
- g) the validation and approval, and periodic revalidation, of any process for production of goods and provision of services where the resulting output cannot be verified by subsequent

monitoring or measurement.当过程的输出不能由后续的监测和测量加以验证时，对任何这样的产品生产和服务提供过程进行确认、批准和再次确认；

h) the implementation of goods and services release, delivery and post-delivery activities; an 产品和服务的放行、交付和交付后活动的实施

i) prevention of nonconformity due to human error, such as unintentional mistakes and intentional rule violations 人为错误（如失误、违章）导致的不符合的预防

注：Validation demonstrates the ability of these processes to achieve planned results through 通过以下确认活动证实这些过程实现所策划的结果的能力：

a) definition of criteria for review and approval of the processes 过程评审和批准的准则的确定

b) approval of equipment and qualification of personnel 设备的认可和人员资格的鉴定

c) use of specific methods and procedures; and 特定的方法和程序的使用

d) definition of requirements for documented information 文件信息的需求的确定

### 8.6.2 Identification and traceability 标识和可追溯性

Where appropriate, the organization shall identify process outputs by suitable means 适当时，组织应使用适宜的方法识别过程输出。

The organization shall identify the status of process outputs with respect to monitoring and measurement requirements throughout realization of goods and services.组织应在产品实现的全过程中，针对监视和测量要求识别过程输出的状态。

Where traceability is a requirement, the organization shall control the unique identification of the process outputs, and maintain it as documented information 在有可追溯性要求的场合，组织应控制产品的唯一性标识，并保持形成文件的信息。

注：Process outputs are the results of any activities which are ready for delivery to the customer (external or internal) or become the inputs to the next process. They can include products, services, intermediate parts, components, etc 过程输出是任何活动的结果，它将交付给顾客（外部的或内部的）或作为下一个过程的输入。过程输出包括产品、服务、中间件、部件等。

### 8.6.3 Property belonging to customers or external providers 顾客或外部供方的财产

The organization shall exercise care with property belonging to the customer or external providers while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard the customer or external provider's property provided for use or incorporation into the goods and services.

组织应爱护在组织控制下或组织使用的顾客、外部供方财产。组织应识别、验证、保护和维护供其使用或构成产品和服务一部分的顾客、外部供方财产。

If any property of the customer or external provider is lost, damaged or otherwise found to be

unsuitable for use, the organization shall report this to the customer or external provider and maintain documented information.如果顾客、外部供方财产发生丢失、损坏或发现不适用的情况，组织应向顾客、外部供方报告，并保持文件信息。

注：Property belonging to customer or external providers can include intellectual property and confidential or personal data.顾客、外部供方财产可包括知识产权、秘密的或私人的信息。

#### **8.6.4 Preservation of goods and services 产品防护**

The organization shall ensure preservation of goods and services, including any process outputs, during processing and delivery to the intended destination in order to maintain conformity to requirements. Preservation shall also apply to process outputs that constitutes parts of the goods or any physical process output that is needed for the provision of the service 在处理过程中和交付到预定地点期间，组织应确保对产品和服务（包括任何过程的输出）提供防护，以保持符合要求。防护也应适用于产品的组成部分、服务提供所需的任何有形的过程输出。

注：Preservation can include identification, handling, packaging, storage and protection.防护可包括标识、搬运、包装、贮存和保护。

#### **8.6.5 Post delivery activities 交付后的活动**

Where applicable, the organization shall determine and meet requirements for post delivery activities associated with the nature and intended lifetime of the goods and services.适用时，组织应确定和满足与产品特性、生命周期相适应的交付后活动要求。

The extent of post delivery activities that are required shall take account of 产品交付后的活动应考虑：

- a) the risks associated with the goods and services,产品和服务相关的风险
- b) customer feedback, and 顾客反馈
- c) statutory and regulatory requirements 法律和法规要求

注：Post-delivery activities can include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal 交付后活动可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。

#### **8.6.6 Control of changes 变更控制**

The organization shall undertake change in a planned and systematic manner, taking account of the review of the potential consequences of changes (see 6.3) and taking action as necessary, to ensure the integrity of goods and services are maintained.组织应有计划地和系统地进行变更，考虑对变更的潜在后果进行评价，采取必要的措施，以确保产品和服务完整性。

Documented information describing the results of the review of changes, the personnel authorizing the change and any necessary actions shall be maintained.应将变更的评价结果、变更的批准和必要的措施的信息形成文件。

### **8.7 Release of goods and services 产品和服务的放行**

The organization shall implement the planned activities at appropriate stages to verify that goods and services requirements have been met (see 8.3). Evidence of conformity with the acceptance criteria shall be maintained. 组织应按策划的安排，在适当的阶段验证产品和服务是否满足要求。符合接收准则的证据应予以保持。

The release of goods and services to the customer shall not proceed until the planned arrangements for verification of conformity have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer. Documented information shall indicate the person(s) authorizing release of goods and services for delivery to 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，否则在策划的符合性验证已圆满完成之前，不应向顾客放行产品和交付服务。应在形成文件信息中指明有权放行产品以交付给顾客的人员。

### **8.8 Nonconforming goods and services 不合格产品和服务**

The organization shall ensure that goods and services which do not conform to requirements are identified and controlled to prevent their unintended use or delivery that will have a negative impact on the customer 组织应确保对不符合要求的产品和服务得到识别和控制，以防止其非预期的使用和交付对顾客造成不良影响。

The organization shall take actions (including corrections if needed) appropriate to the nature of the nonconformity and its effects. This applies also to nonconforming goods and services detected after delivery of the goods or during the provision of the service. 组织应采取与不合格品的性质及其影响相适应的措施，必要时进行纠正。这也适用于在产品交付后和服务提供过程中发现的不合格的处置。

When the nonconforming goods and services have been delivered to the customer, the organization shall also take appropriate correction to assure that customer satisfaction is achieved 当不合格产品和服务已交付给顾客，组织也应采取适当的纠正以确保实现顾客满意。

Appropriate corrective actions shall be implemented (see 10.1 应实施适当的纠正措施（见 10.1））。

注：The appropriate actions can include 适当的措施可包括：

- a) segregation, containment, returning and suspension of provision of goods and services; 隔离、制止、召回和停止供应产品和提供服务；
- b) informing the customer as appropriate; and 适当时，通知顾客；
- c) obtaining authorization for repair, regrade, use as is, release, continuation or re-provision of the service, acceptance under concession 经授权进行返修、降级、继续使用、放行、延长服务时间或重新提供服务、让步接收。

When the nonconforming goods and services are corrected it shall be subject to re-verification to demonstrate conformity to the requirements. 在不合格品得到纠正之后应对其再次进行验证，

以证实符合要求。

Documented information describing the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained 不合格品的性质以及随后所采取的任何措施的信息应形成文件，包括所批准的让步。

## 9 Performance evaluation 绩效评价

### 9.1 Monitoring, measurement, analysis and evaluation 监视、测量、分析和评价

#### 9.1.1 General 总则

*The organization shall ~~determine~~ take into consideration the determined risks and opportunities and shall:* 组织应考虑已确定的风险和机遇，应：

a) *determine what needs to be monitored and measured in order to:* 确定监视和测量的对象，以便：

- demonstrate conformity of goods and services to requirements, 证实产品和服务的符合性
- evaluate the performance of processes (see 4.4) 评价过程绩效（见 4.4）
- ensure conformity and effectiveness of the quality management system, and 确保质量管理体系的符合性和有效性
- evaluate customer satisfaction; and 评价顾客满意度

b) *evaluate the performance of external provider(s) (see 8.4)* 评价外部供方的业绩（见 8.4）；

c) *determine the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results* 确定监视、测量（适用时）、分析和评价的方法，以确保结果可行；

d) *determine when the monitoring and measuring shall be performed* 确定监测和测量的时机；

e) *determine when the results from monitoring and measurement shall be analysed and evaluated;* and 确定对监测和测量结果进行分析和评价的时机；

f) *determine what performance indicators of the quality management system are needed.* 确定所需的质量管理体系绩效指标。

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与监视和测量的要求相一致的方式实施。

*The organization shall retain appropriate documented information as evidence of the results* 组织应保持适当的文件信息，以提供“结果”的证据。

*The organization shall evaluate the ~~quality~~ performance and the effectiveness of the quality management system* 组织应评价质量绩效和质量管理体系的有效性。

#### 9.1.2 Customer satisfaction 顾客满意

The organization shall monitor data relating to customer perceptions of the degree to which requirements have been met 组织应监视顾客对其要求满足程度的数据。

As appropriate, the organization shall obtain data relating to 适用时，组织应获取以下方面的数据：

a) customer feedback , and 顾客反馈

b) customer views and perceptions of the organization, its processes and its goods and services  
顾客对组织及其产品和服务的意见和感受。

The methods for obtaining and using this data shall be determined.应确定获取和利用这些数据的方法。

The organization shall evaluate the data obtained to determine opportunities to enhance customer satisfaction.组织应评价获取的数据，以确定增强顾客满意的机会。

### 9.1.3 Analysis and evaluation of data 数据分析与评价

The organization shall analyse and evaluate appropriate data arising from monitoring, measurement (see 9.1.1 and 9.1.2) and other relevant sources. This shall include determination of applicable methods.组织应分析、评价来自监视和测量（见 9.1.1 和 9.1.2）以及其他相关来源的适当数据。这应包括适用方法的确定。

The results of analysis and evaluation shall be used:数据分析和评价的结果应用于：

a) to determine the suitability, adequacy and effectiveness of the quality management system  
确定质量管理体系的适宜性、充分性、有效性

b) to assure that the goods and services can consistently meet customer requirements 确保产品和服务能持续满足顾客要求

c) to ensure that the operation and control of processes is effective, and 确保过程的有效运行和控制

d) to identify improvements within the quality management system 识别质量管理体系的改进机会

The results of analysis and evaluation shall be used as an input to the management review.数据分析和评价的结果应作为管理评审的输入。

### 9.2 Internal Audit 内部审核

*The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system;*组织应按照计划的时间间隔进行内部审核，以确定质量管理是否：

a) *conforms to* 符合

1) *the organization's own requirements for its quality management system; and* 组织对质量管理体系的要求

2) *the requirements of this International Standard;*本标准的要求

b) *is effectively implemented and maintained* 得到有效的实施和保持

*The organization shall:*组织应：

a) *plan, establish, implement and maintain an audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting. The audit programme(s) shall*

*take into consideration the quality objectives, the importance of the processes concerned, the related risks, and the results of previous audits;*策划、建立、实施和保持一个或多个审核方案, 包括审核的频次、方法、职责、策划审核的要求和报告审核结果。审核方案应考虑质量目标、相关过程的重要性、关联风险和以往审核的结果。

b) *define the audit criteria and scope for each audit;*确定每次审核的准则和范围

c) *select auditors and conduct audits to ensure objectivity and the impartiality of the audit process* 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

d) *ensure that the results of the audits are reported to relevant management* for evaluation, 确保审核结果提交给管理者以供评审

e) *take appropriate action without undue delay; and* 及时采取适当的措施

f) *retain documented information as evidence of the implementation of the audit programme and the audit results.*保持形成文件的信息, 以提供审核方案实施和审核结果的证据。

注: See ISO 19011 for guidance 作为指南, 参见 ISO19011。

### 9.3 Management review 管理评审

*Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness.*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。

Management review shall be planned and carried out, taking into account the changing business environment and in alignment with the strategic direction of the organization.管理评审策划和实施时, 应考虑变化的商业环境, 并与组织的战略方向保持一致。

*The management review shall include consideration of:*管理评审应考虑以下方面:

a) *the status of actions from previous management reviews;*以往管理评审的跟踪措施

b) *changes in external and internal issues that are relevant to the quality management system;*与质量管理体系有关的外部或内部的变更

c) *information on the performance of the quality management system, including trends and indicators for* 质量管理体系绩效的信息, 包括以下方面的趋势和指标:

1) *nonconformities and corrective actions;*不符合与纠正措施

2) *monitoring and measurement results;*监视和测量结果

3) *audit results* 审核结果

4) *customer feedback;*顾客反馈

5) *supplier and external provider issues; and* 外部供方

6) *process performance and product conformity;*过程绩效和产品的符合性

d) *opportunities for ~~continual~~ improvement* 持续改进的机会

*The outputs of the management review shall include decisions related to:*管理评审的输出应包括以下相关的决定:

a) ~~*continual*~~ *improvement opportunities, and* 持续改进的机会

b) *any need for changes to the quality management system* 对质量管理体系变更的需求

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

reviews including actions taken 组织应保持形成文件的信息，以提供管理评审的结果及采取措施的证据。

## **10-Continual improvement 改进**

### **10.1 Nonconformity and corrective action 不符合与纠正措施**

*When a nonconformity occurs, the organization shall:* 发生不符合时，组织应：

a) *react to the nonconformity, and as applicable* 作出响应，适当时：

- 1) *take action to control and correct it; and* 采取措施控制和纠正不符合
- 2) *deal with the consequences;* 处理不符合造成的后果

b) *evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere, by* 评价消除不符合原因的措施的需求，通过采取以下措施防止不符合再次发生或在其他区域发生：

- 1) *reviewing the nonconformity;* 评审不符合
- 2) *determining the causes of the nonconformity, and* 确定不符合的原因
- 3) *determining if similar nonconformities exist, or could potentially occur;* 确定类似不符合是否存在，或可能潜在发生

c) *implement any action needed;* 实施所需的措施

d) *review the effectiveness of any corrective action taken; and* 评审所采取纠正措施的有效性

e) *make changes to the quality management system, if necessary.* 对质量管理体系进行必要的修

*Corrective actions shall be appropriate to the effects of the nonconformities encountered* 改纠正措施应与所遇到的不符合的影响程度相适应。

*The organization shall retain documented information as evidence of* 组织应将以下信息形成文件：

- a) *the nature of the nonconformities and any subsequent actions taken; and* 不符合的性质及随后采取的措施
- b) *the results of any corrective action* 纠正措施的结果

### **10.2 Improvement 改进**

*The organization shall ~~continually~~ improve the suitability, adequacy and effectiveness of the quality management system.* 组织应持续改进质量管理体系的适宜性、充分性和有效性。

The organization shall improve the quality management system, processes and goods and services, as appropriate, through responding to: 适当时，组织应通过以下方面改进其质量管理体系、过程、产品和服务：

- a) *results of analysis of data;* 数据分析的结果；
- b) *changes in the context of the organization;* 组织的变更；
- c) *changes in identified risk (see 6.1); and* 识别的风险的变更（见 6.1）；
- d) *new opportunities* 新的机遇；

The organization shall evaluate, prioritise and determine the improvement to be implemented 组织应评价、确定优先次序及决定需实施的改进。