INTERNATIONAL STANDARD

**ISO 22163**

First edition
2023-07

# Railway applications — Railway quality management system — ISO 9001:2015 and specific requirements for application in the railway sector

*Applications ferroviaires — Système de management de la qualité ferroviaire — Exigences de l'ISO 9001:2015 et exigences particulières concernant les applications dans le secteur ferroviaire*

Reference number
ISO 22163:2023(E)

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# Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 269, *Railway applications*.

This first edition of ISO 22163 cancels and replaces ISO/TS 22163:2017.

The main changes are as follows:

— the scope has been simplified;

— the terms and definitions in Clause 3 have been revised;

— the previous subclause 6.4 “Business planning” has been moved to 4.1.1;

— a new subclause 4.1.2 on “Social responsibility” has been added;

— subclause 7.2.1 “Competence — Supplemental” has been revised;

— the previous subclause 8.11 “Innovation management” has been moved to 8.1.1.1;

— “Project review management” has been separated from the previous subclause 8.1.3.7 “Project communications management” as a new subclause 8.1.3.11;

— the previous subclauses 8.1.4 “Configuration management” and 8.1.5 “Change management” have been combined in 8.1.4 “Configuration management and change control”;

— product safety requirements have been integrated in the quality requirements;

— reliability, availability, maintainability, safety and life cycle costing requirements have been clarified in 8.8;

— the notion of performance indicators versus key performance indicators has been added;

— the performance indicators have been revised;

— Annex A on “List of processes” has been added;

— Annex B on “Subordinate concept of requirements for products and services” has been added;

— Annex C on “Performance indicators” has been added.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

# Introduction

## 0.1 General

The aim of this document is to develop and continually improve a railway quality management system to ensure product quality including safety in the global railway sector, in order to satisfy customer needs.

This document adds the supplemental railway sector specific requirements to ISO 9001:2015.

The content inside the boxed text of this document is ISO 9001:2015 text.

Whenever the ISO 9001:2015 text in this document refers to "quality management system", this term is understood hereinafter as "railway quality management system", not limited to quality, so that it encompasses all railway quality processes of the organization. Therefore, in the supplemental railway sector specific requirements, the term "railway quality management system" is used outside the boxed text.

Whenever the ISO 9001:2015 text refers to "this International Standard", this applies to this document, including the text outside the boxes.

Whenever this document refers to clause numbers, it is to be understood that all the requirements under this clause including subclauses are to be considered.

Whenever this document refers to "safety", the term is to be understood as "safety of products and services", not to be confused with "occupational safety".

Whenever this document requires a process, this process can be either

— defined within a single process,

— combined with another process or other processes, or

— split in several processes

according to the railway quality management system defined by the organization.

**ISO 9001:2015, Quality management systems — Requirements**

**0.1 General**

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

The potential benefits to an organization of implementing a quality management system based on this International Standard are:

a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;

b) facilitating opportunities to enhance customer satisfaction;

c) addressing risks and opportunities associated with its context and objectives;

d) the ability to demonstrate conformity to specified quality management system requirements.

This International Standard can be used by internal and external parties.

It is not the intent of this International Standard to imply the need for:

— uniformity in the structure of different quality management systems;

— alignment of documentation to the clause structure of this International Standard;

— the use of the specific terminology of this International Standard within the organization.

The quality management system requirements specified in this International Standard are complementary to requirements for products and services.

This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

The process approach enables an organization to plan its processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise.

Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

In this International Standard, the following verbal forms are used:

— "shall" indicates a requirement;
— "should" indicates a recommendation;
— "may" indicates a permission;
— "can" indicates a possibility or a capability.

Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.

## 0.2 Quality management principles

**ISO 9001:2015, Quality management systems — Requirements**

**0.2 Quality management principles**

This International Standard is based on the quality management principles described in ISO 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of typical actions to improve the organization's performance when applying the principle.

The quality management principles are:

— customer focus;
— leadership;
— engagement of people;
— process approach;
— improvement;
— evidence-based decision making;
— relationship management.

## 0.3 Process approach

### 0.3.1 General

**ISO 9001:2015, Quality management systems — Requirements**

**0.3 Process approach**

**0.3.1 General**

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. Specific requirements considered essential to the adoption of a process approach are included in 4.4.

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results.

The application of the process approach in a quality management system enables:

a) understanding and consistency in meeting requirements;

b) the consideration of processes in terms of added value;

c) the achievement of effective process performance;

d) improvement of processes based on evaluation of data and information.

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring check points, which are necessary for control, are specific to each process and will vary depending on the related risks.

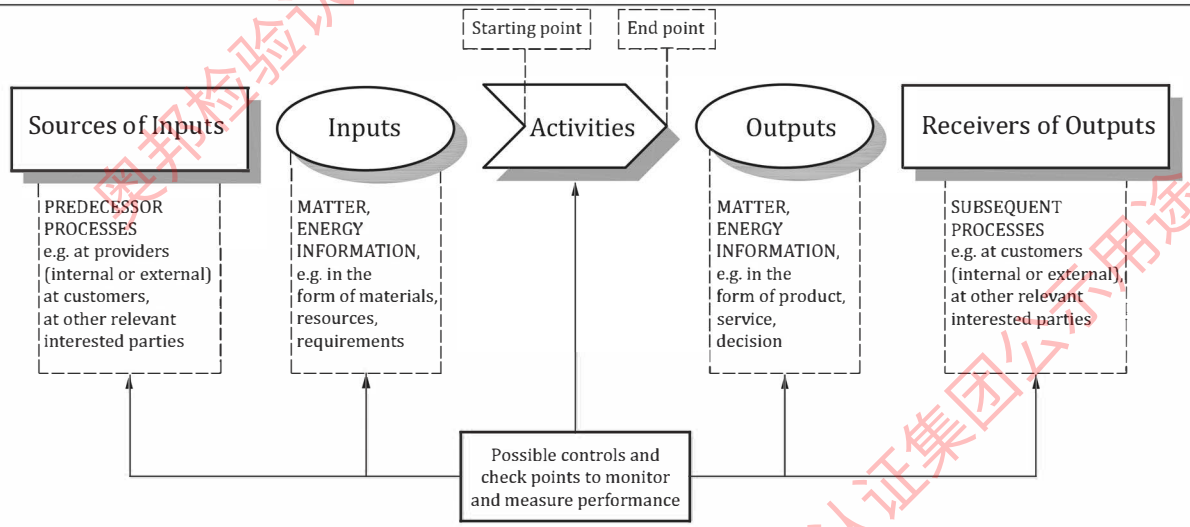


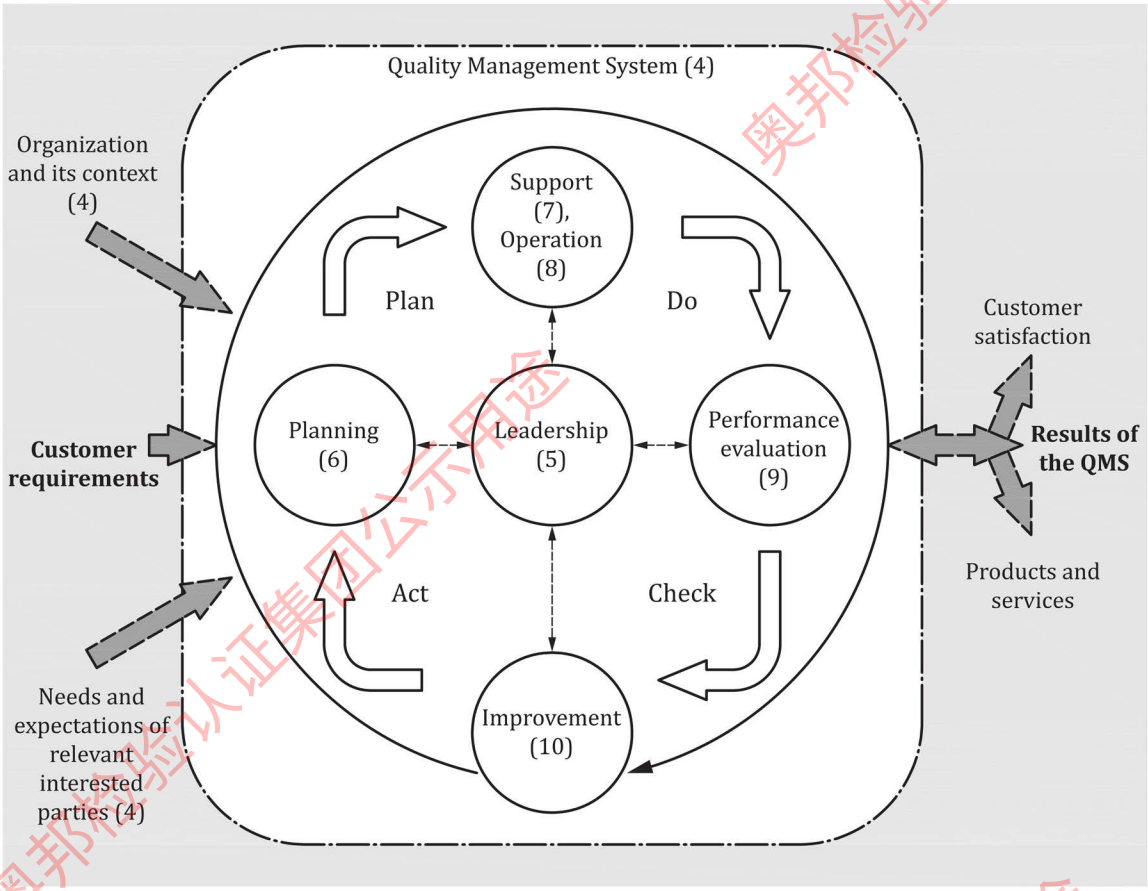

**Figure 1 — Schematic representation of the elements of a single process**

### 0.3.2 Plan-Do-Check-Act cycle

**ISO 9001:2015, Quality management systems — Requirements**

**0.3.2 Plan-Do-Check-Act cycle**

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle.




NOTE Numbers in brackets refer to the clauses in this International Standard.

**Figure 2 — Representation of the structure of this International Standard in the PDCA cycle**

The PDCA cycle can be briefly described as follows:

— **Plan**: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address risks and opportunities;

— **Do**: implement what was planned;

— **Check**: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;

— **Act**: take actions to improve performance, as necessary.

### 0.3.3 Risk-based thinking

**ISO 9001:2015, Quality management systems — Requirements**

**0.3.3 Risk-based thinking**

Risk-based thinking is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of this International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analysing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.

Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

## 0.4 Relationship with other management system standards

**ISO 9001:2015, Quality management systems — Requirements**

**0.4 Relationship with other management system standards**

This International Standard applies the framework developed by ISO to improve alignment among its International Standards for management systems.

This International Standard enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its quality management system with the requirements of other management system standards.

This International Standard relates to ISO 9000 and ISO 9004 as follows:

— ISO 9000 *Quality management systems — Fundamentals and vocabulary* provides essential background for the proper understanding and implementation of this International Standard;

— ISO 9004 *Managing for the sustained success of an organization — A quality management approach* provides guidance for organizations that choose to progress beyond the requirements of this International Standard.

This International Standard does not include requirements specific to other management systems, such as those for environmental management, occupational health and safety management, or financial management.

Sector-specific quality management system standards based on the requirements of this International Standard have been developed for a number of sectors. Some of these standards specify additional quality management system requirements, while others are limited to providing guidance to the application of this International Standard within the particular sector.

A matrix showing the correlation between the clauses of this edition of this International Standard and the previous edition (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access website at: https://www.iso.org/tc176/sc02/public.

# Railway applications — Railway quality management system — ISO 9001:2015 and specific requirements for application in the railway sector

## 1 Scope

**ISO 9001:2015, Quality management systems — Requirements**

**1 Scope**

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

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and

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

All the requirements of this International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

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

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

### 1.1 Scope — Supplemental

This document specifies the requirements for a railway quality management system (RQMS)

— applicable throughout the whole supply chain of the railway sector related to industrial products and services,

— providing continual improvement, emphasizing defect prevention and defect reduction in the supply chain, and

— enhancing and sustaining product quality, including its safety aspects.

## 2 Normative references

**ISO 9001:2015, Quality management systems — Requirements**

**2 Normative references**

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

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

## 3 Terms, definitions and abbreviated terms

**ISO 9001:2015, Quality management systems — Requirements**

**3 Terms and definitions**

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

# 国标标准

ISO22163

第 1 版
2023-7-25

# 铁路应用-铁路质量管理体系-

# ISO9001:2015 及铁路行业应用的特定要求


ISO 22163：2023 en

# 目录

# 前言

ISO（国际标准化组织）是一个由国家标准机构（ISO 成员机构）组成的全球联合会。制定国际标准的工作通常是通过 ISO 技术委员会进行的。对已成立的技术委员会感兴趣的每个成员机构都有权派代表参加该委员会。政府和非政府组织与 ISO 联络，也参与这项工作。国际标准化组织与国际电工委员会（IEC）就所有的电工标准化问题进行了密切的合作。

用于制定本文件的程序和用于进一步维护本文件的程序在 ISO/IEC 指令中有所描述。

在 ISO/IEC 指令第 1 部分中有所描述。特别是，不同类型的 ISO 文件需要不同的批准标准。

本文件是按照 ISO/IEC 指令第 2 部分的编辑规则起草的（见 www.iso.org/directives）。

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关于标准的自愿性质的解释，与符合性评估有关的 ISO 特定术语和表达方式的含义，以及关于 ISO 遵守世界贸易组织（WTO）原则的信息，请参见 www.iso.org/iso/foreword.html。

本文件由 ISO/TC 269 铁路应用技术委员会编写。

这个 ISO 22163 的第一版取消并取代了 ISO/TS 22163:2017。

主要变化如下。

- 范围已经简化。
- 术语和定义已被修订。
- 6.4 "经营规划 "已移至第 4 条 "组织的环境"。
- 增加了新的子条款 4.1.2 "社会责任"。
- 7.2.1 "能力--补充 "已被修订。
- 8.11. "创新管理 "已移至 8.1. "运营计划和控制"。
- " 项目评审管理 "已从 8.1.3.9 "项目风险和机遇管理 "中分出来，成为 8.1.3.11 新的子条款。
- 8.1.4 "配置管理 "和 8.1.5 "变更控制 "已合并为 8.1.4"配置管理和变更控制"。
- 产品安全要求已被整合到质量要求中。
- 澄清了 RAMS/LCC 要求（8.8）。
- 增加了绩效指标（PI）与 KPI 的概念。
- 绩效指标已被修订。
- 增加了新的资料性附件 A "过程清单"。
- 增加了新的资料性附件 B "产品和服务要求的从属概念"。
- 增加了新的资料性附件 C "绩效指标"。

关于本文件的任何反馈或问题应直接向用户的国家标准机构提出。

这些机构的完整清单可在 www.iso.org/members.html 上找到。

## 简介

### 0.1 总则

本文件的目的是开发和不断改进铁路质量管理体系，以确保全球铁路部门的产品质量，包括安全，以满足客户的需求。

本文件对 ISO 9001:2015 补充了铁路部门的具体要求。

本文件方框内的内容是 ISO 9001:2015 的文本。

本文件中的 ISO 9001:2015 文本凡提到 "质量管理体系 "时，该术语在下文中被理解为 "铁路质量管理体系 "，不限于质量，它涵盖了组织的所有铁路质量过程。因此，在补充的铁路部门具体要求中，"铁路质量管理体系 "这一术语被用于框内文本之外。

凡是 ISO 9001:2015 文本中提到的 "本国际标准"，都适用于本文件，包括方框外的文本。

当本文件提到条款编号时，应理解为该条款下的所有要求，包括子条款。

当本文件提到 "安全 "时，该术语应理解为 "产品和服务的安全"，不能与 "职业安全 "混淆。

当本文件要求一个过程时，这个过程可以是：

- 在一个单一的过程中定义。
- 与另一过程或其他过程相结合，或
- 分成几个过程。

根据组织定义的铁路质量管理体系。

ISO9001:2015，质量管理体系—要求

0.1 总则

采用质量管理体系是组织的一项战略决策，能够帮助其提高整体绩效，为推动可持续发展奠定良好基础。

组织根据本标准实施质量管理体系的潜在益处是：

a） 稳定提供满足顾客要求以及适用的法律法规要求的产品和服务的能力；

b） 促成增强顾客满意的机遇；

c） 应对与组织环境和目标相关的风险和机遇；

d） 证实符合规定的质量管理体系要求的能力。

本标准可用于内部和外部各方。

实施本标准并非需要：

——统一不同质量管理体系的架构；

——形成与本标准条款结构相一致的文件；

——在组织内使用本标准的特定术语。

本标准规定的质量管理体系要求是对产品和服务要求的补充。

本标准采用过程方法，该方法结合了“策划-实施-检查-处置”（PDCA）循环和基于风险的思维。

过程方法使组织能够策划过程及其相互作用。

PDCA 循环使组织能够确保其过程得到充分的资源和管理，确定改进机遇并采取行动。

基于风险的思维使组织能够确定可能导致其过程和质量管理体系偏离策划结果的各种因素，采取预防控制，最大限度地降低不利影响，并最大限度地利用出现的机遇（见 A.4）。

在日益复杂的动态环境中持续满足要求，并针对未来需求和期望采取适当行动，这无疑是组织面临的一项挑战。为了实现这一目标，组织可能会发现，除了纠正和持续改进，还有必要采取各种形式的改进，如变破性变革、创新和重组。

在本标准中使用如下助动词：

——“应”表示要求；

——“宜”表示建议；

——“可”表示允许；

——“能”表示可能或能够。

“注”的内容是理解和说明有关要求的指南。

## 0.2 质量管理原则

ISO9001:2015，质量管理体系—要求

0.2 质量管理原则

本标准是在 GB/T 19000 所阐述的质量管理原则基础上制定的。每项原则的介绍均包含概述、该原则对组织的重要性的依据，应用该原则的主要益处示例以及应用该原则提高组织绩效的典型措施示例。

质量管理原则是：

——以顾客为关注焦点；

——领导作用；

——全员积极参与；

——过程方法；

——改进；

——循证决策；

——关系管理

## 0.3 过程方法

### 0.3.1 总则

ISO9001:2015，质量管理体系—要求

0.3.1 总则

本标准倡导在建立、实施质量管理体系以及提高其有效性时采用过程方法，通过满足顾客要求增强顾客满意。采用过程方法所需考虑的具体要求见 4.4。

将相互关联的过程作为一个体系加以理解和管理，有助于组织有效和高效地实现其预期结果。

这种方法使组织能够对其体系的过程之间相互关联和相互依赖的关系进行有效控制，以提高组织整体绩效。

过程方法包括按照组织的质量方针和战略方向，对各过程及其相互作用进行系统的规定和管理，从而实现预期结果。可通过采用 PDCA 循环（见 0.3.2）以及始终基于风险的思维（见 0.3.3）对过程和整个体系进行管理，旨在有效利用机遇并防止发生不良结果。

在质量管理体系中应用过程方法能够：

a） 理解并持续满足要求；

b） 从增值的角度考虑过程；

c） 获得有效的过程绩效；

d） 在评价数据和信息的基础上改进过程。

单一过程的各要素及其相互作用如图 1 所示。每一过程均有特定的监视和和测量检查点以用于控制，这些检查点根据相关的风险有所不同。

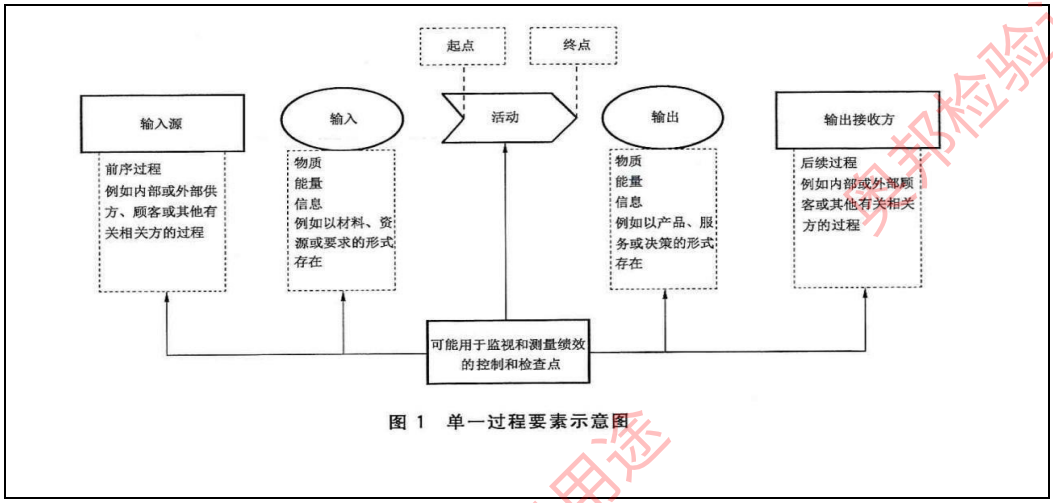


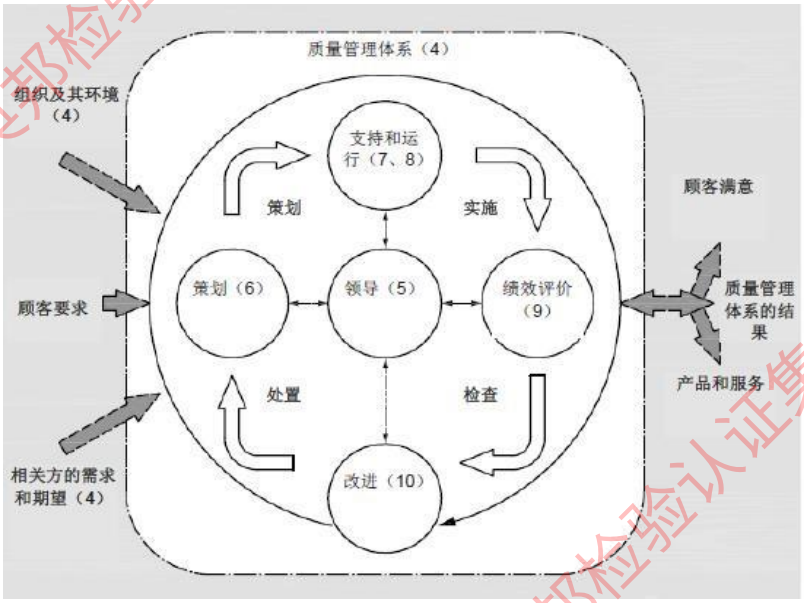

图 1　单一过程要素示意图

### 0.3.2 PDCA 循环

ISO9001:2015，质量管理体系—要求

0.3.2 PDCA 循环

PDCA 循环能够应用于所有过程以及整个质量管理体系。图 2 表明了本标准第 4 章至第 10 章是如何构成 PDCA 循环的。




注：括号中的数字表示本标准的相应章节

图 2：本标准的结构在 PDCA 循环中的展示

PDCA 循环可以简要描述如下：

——策划（Plan）：根据顾客的要求和组织的方针，建立体系的目标及其过程,确定实现结果所需的资源，并识别和应对风险和机遇；

——实施（Do）：执行所做的策划；

——检查（Check）：根据方针、目标、要求和所策划的活动，对过程以及形成的产品和服务进行监视和测量（适用时），并报告结果；

——处置（Act）：必要时，采取措施提高绩效。

**0.3.3** 基于风险的思维

ISO9001:2015，质量管理体系—要求

0.3.3 基于风险的思维

基于风险的思维（见 A.4）是实现质量管理体系有效性的基础。本标准以前的版本已经隐含基于风险思维的概念，例如：采取预防措施消除潜在的不合格，对发生的不合格进行分析，并采取与不合格的影响相适应的措施，防止其再发生。

为了满足本标准的要求,组织需策划和实施应对风险和机遇的措施。应对风险和机遇，为提高质量管理体系有效性、获得改进结果以及防止不利影响奠定基础。

某些有利于实现预期结果的情况可能导致机遇的出现，例如：有利于组织吸引顾客、开发新产品和服务、减少浪费或提高生产率的一系列情形。利用机遇所采取的措施也可能包括考虑相关风险。风险是不确定性的影响,不确定性可能有正面的影响，也可能是负面的影响。风险的正面影响可能提供机遇，但并非所有的正面影响均可提供机遇。

**0.4** 与其他管理体系标准的关系

ISO 9001:2015，质量管理体系-要求

0.4 与其他管理体系标准的关系本国际标准采用了 ISO 制定的框架，以改善其管理体系国际标准之间的一致性（见 A.1 条款）。本国际标准使组织能够使用过程方法，并结合 PDCA 循环和基于风险的思考，使其质量管理体系与其他管理体系标准的要求相一致或整合。本国际标准与 ISO 9000 和 ISO 9004 的关系如下。

- ISO 9000 质量管理体系—基础和词汇为正确理解和实施质量管理体系提供了基本背景。
- ISO 9004 为组织的持续成功而管理 – 质量管理方法为选择超越本国际标准要求的组织提供指导。

附件 B 提供了由 ISO/TC 176 制定的关于质量管理和质量管理系统的其他国际标准的详情。本国际标准不包括对其他管理系统的具体要求，例如环境管理、职业健康和安全管理或财务管理等方面的要求。

基于本国际标准的要求，特定行业的质量管理体系标准已经为许多国家制定。

其中一些标准规定了额外的质量管理体系要求，而其他标准则仅限于为本国际标准在特定部门的应用提供指导。

本版国际标准的条款与上一版(ISO 9001:2008)的条款之间的相互关系矩阵可以在 ISO/TC 176/SC 2 的开放网站上找到显示本国际标准的条款与上一版本（ISO 9001:2008）之间的相关性的矩阵。

http://www.iso.org/tc176/sc02/public。

如需获取全文，请联系奥邦检验认证集团客户服务部门：

1）通过邮件提出申请。请发送到邮箱：**17312273399@163.com**

2）也可通过客服电话咨询 **025-85307007**。