AEROSPACE STANDARD

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Superseding AS9120A

Technically equivalent writings published in all IAQG sectors.

(R) Quality Management Systems – Requirements for Aviation, Space, and Defense Distributors

RATIONALE

This standard has been revised to incorporate the new clause structure and content of ISO 9001:2015. In addition, industry requirements, definitions, and notes have been revised in response to both ISO 9001 revisions and stakeholder needs.

FOREWORD

To assure customer satisfaction, aviation, space, and defense organizations must provide, and continually improve, safe and reliable products and services that meet or exceed customer and applicable statutory and regulatory requirements. The globalization of the industry and the resulting diversity of regional and national requirements and expectations have complicated this objective. Organizations have the challenge of purchasing products and services from external providers throughout the world and at all levels of the supply chain. External providers have the challenge of delivering products and services to multiple customers having varying quality requirements and expectations.

Industry has established the International Aerospace Quality Group (IAQG), with representatives from aviation, space, and defense companies in the Americas, Asia/Pacific, and Europe, to implement initiatives that make significant improvements in quality and reductions in cost throughout the value stream. This standard has been prepared by the IAQG.

This document standardizes quality management system requirements to the greatest extent possible and can be used at all levels of the supply chain by organizations around the world. Its use should result in improved quality, cost, and delivery performance through the reduction or elimination of organization-unique requirements, effective implementation of the quality management system, and wider application of good practice. While primarily developed for the aviation, space, and defense industry, this standard can also be used in other industry sectors when a quality management system with additional requirements over an ISO 9001 system is needed.

This standard includes ISO 9001:2015[1] quality management system requirements and specifies additional aviation, space, and defense industry requirements, definitions, and notes as shown in bold, italic text.

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[1] *With the permission of the International Organization for Standardization (ISO). The complete ISO 9001 standard can be obtained from any ISO member or from the ISO Central Secretariat: 1, ch. de la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, SWITZERLAND, or visit www.iso.org. Copyright remains with ISO.*

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INTENDED APPLICATION

This standard is intended for use by organizations that procure parts, materials, and assemblies and resell these products to a customer in the aviation, space, and defense industries. This includes organizations that procure products and split them into smaller quantities, including those that coordinate a customer or regulatory controlled process on the product. This standard is not intended for organizations that maintain or repair products, or for organizations that perform work that affect or could affect product characteristics or conformity.

Organizations that design, develop, or provide aviation, space, and defense products and services should use the IAQG-developed 9100 standard (see Bibliography). This includes organizations providing post-delivery activities, including the provision of maintenance, spare parts, or materials for their own products and services.

Organizations whose primary business is providing maintenance or continuing airworthiness management services for civil or military aviation articles and products; and original equipment manufacturers with maintenance, repair, and overhaul operations that are operated autonomously, or that are substantially different from their production operations; should use the IAQG-developed 9110 standard (see Bibliography).

INTRODUCTION

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 (see clause A.4).

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

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

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.

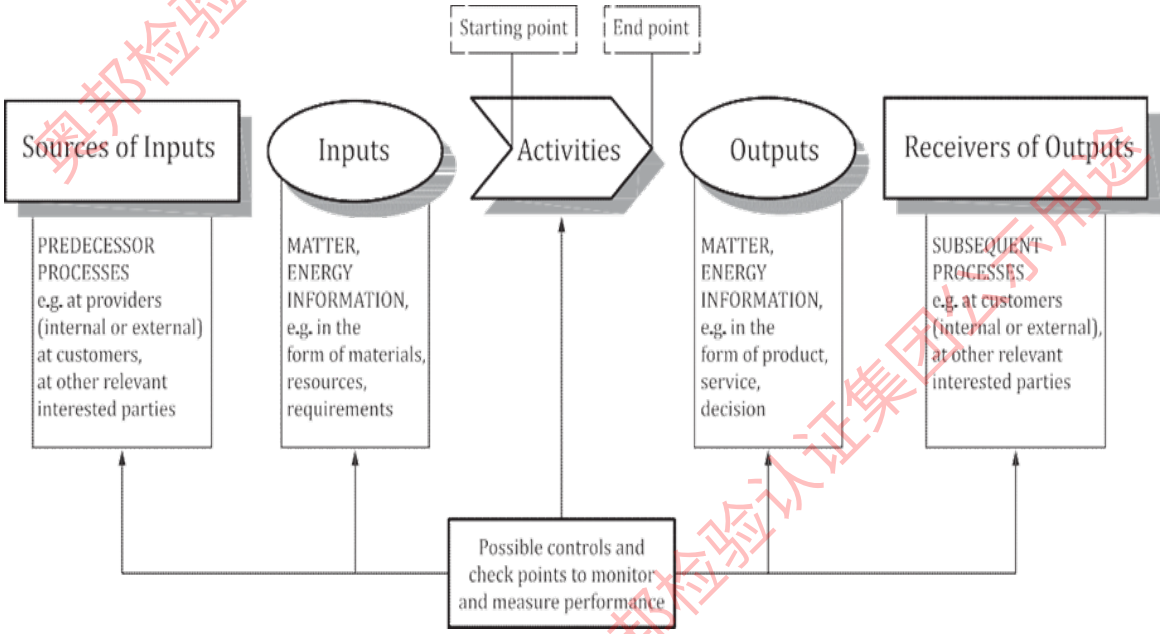


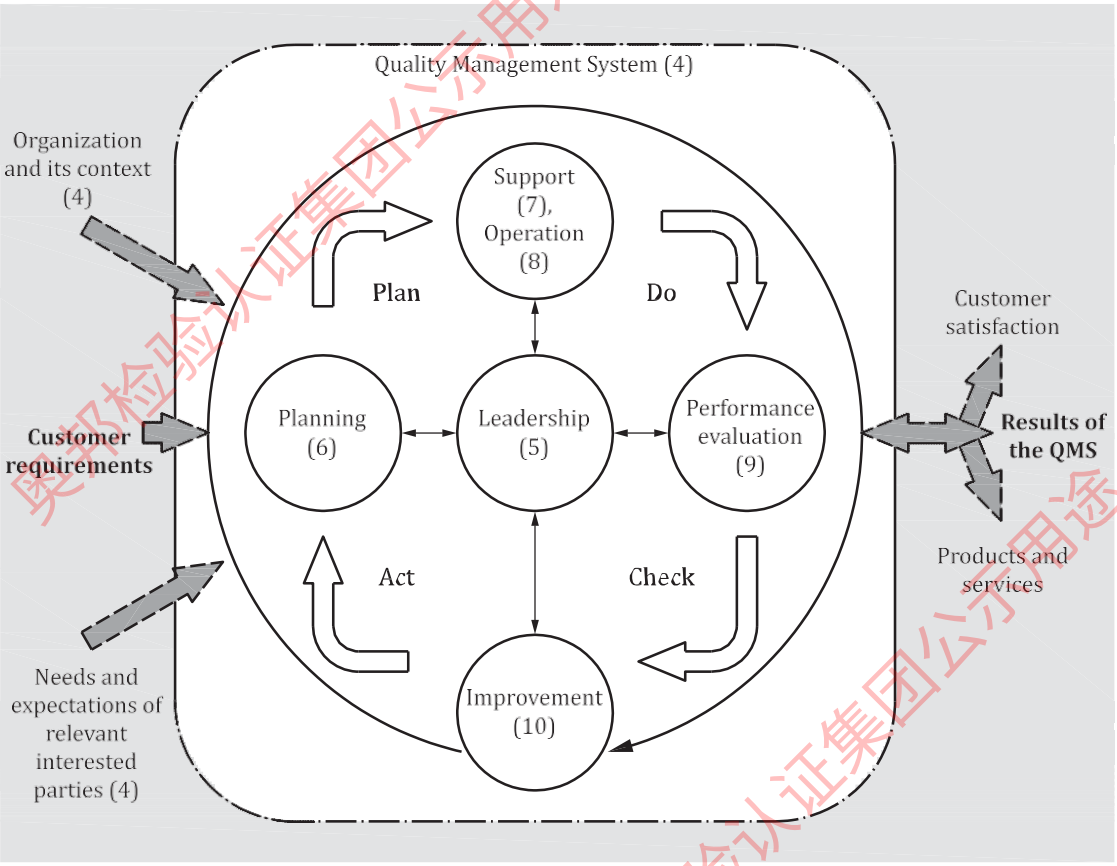
Figure 1 – Schematic representation of the elements of a single process

0.3.2 Plan-Do-Check-Act Cycle

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.

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.



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

0.3.3 Risk-Based Thinking

Risk-based thinking (see clause A.4) 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, analyzing 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 favorable 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

This International Standard applies the framework developed by ISO to improve alignment among its International Standards for management systems (see clause A.1).

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.

Annex B provides details of other International Standards on quality management and quality management systems that have been developed by ISO/TC 176.

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 web site at: www.iso.org/tc176/sc02/public.

QUALITY MANAGEMENT SYSTEMS – REQUIREMENTS

1. SCOPE

This standard includes ISO 9001:2015[2] quality management system requirements and specifies additional aviation, space, and defense industry requirements, definitions, and notes.

It is emphasized that the requirements specified in this standard are complementary (not alternative) to customer and applicable statutory and regulatory requirements.

If there is a conflict between the requirements of this standard and customer or applicable statutory or regulatory requirements, the latter shall take precedence.

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.

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.

9100:2016 Quality Management Systems – Requirements for Aviation, Space, and Defense Organizations

ISO 9000:2015 *Quality management systems – Fundamentals and vocabulary*

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 ***and the following*** apply.

Within this standard, the term manufacturer is intentionally used to clearly delineate the relationship between the product creator and the organization. The terms external provider and original manufacturer can be synonymous.

external provider (manufacturer / provider) → ***organization*** → ***customer***

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AEROSPACE STANDARD

AS 9120B： 2016

质量管理体系 — 航空、航天和国防经销商的要求

Quality Management Systems - Requirements for Aviation，Space，and Defense Distributors

国际

航空

质量组织

第三版

2016 年 11 月 01 日

目　录

引言

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)稳定地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会；

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结构；

----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，确定改进机会并采取行动。

基于风险的思维使得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，如变革突变、创新和重组。

在本标准中使用如下助动词：

----“应”(shall)表示要求；

----“应当”(should)表示建议；

----“可”(may)表示允许；

----“能”(can)表示可能性或能够。

“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

本标准是在ISO9000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其概述、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

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。

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)实现有效的过程绩效；

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。

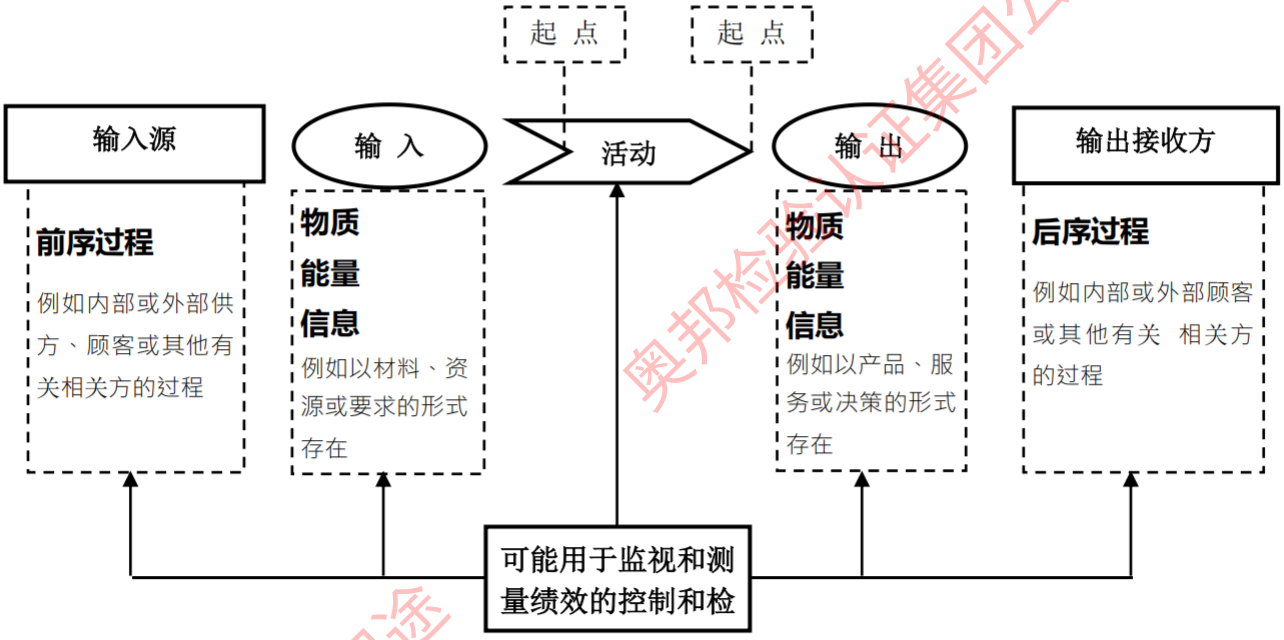
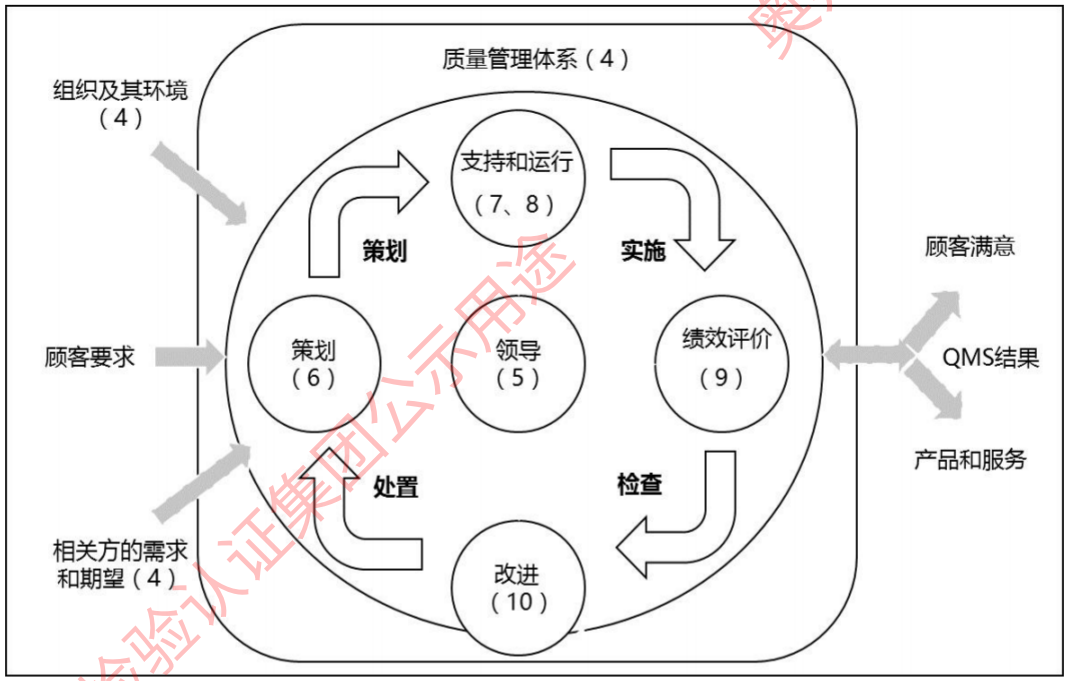


图 1：单一过程要素示意图

0.3.2 PDCA循环

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 基于风险的思想

基于风险的思维(见附录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当措施，防止其再次发生。

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。利用机遇所采取的实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，也可能有负面的影响。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

本标准采用ISO制定的管理体系标准框架，以提高与其他管理体系标准的协调一至性(见附录A.1)。

本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维，将其质量管理体系与其他管理体系标准要求进行协调或整合。

本标准与ISO9000和ISO9004的存在如下关系：

----ISO9000《质量管理体系 基础和术语》为正确理解和实施本标准提供必要的基础；

----ISO9004《追求组织的持续成功 质量管理方法》为组织选择超越本标准要求的质量管理方法提供指南。

附录B提供了ISO/TC176制定的其它质量管理和质量管理体系标准的详细信息。

本标准不包括针对环境管理、职业健康和安全管理或财务管理等其他管理体系的特定要求。

在本标准的基础上，已经制定了若干行业特定要求的质量管理体系标准。其中的某些标准规定了质量管理体系的附加要求，而另一些标准则仅限于提供在特定行业应用本标准的指南。

本标准的章节号与之前版本(ISO9001:2008)章节内容之间的对应关系见ISO/TC176/SC2(国际标准化组织/质量管理和质量保证/质量体系分委员会)的公开网站：www.iso.org/tc176/sc02/public。

质量管理体系-航空、航天和防务分销商的要求

1. 范围

本标准包括 ISO 9001:2015[2]“质量管理体系要求”，同时规定了附加的航空、航天和国防工业要求、定义和注释。

需强调的是本标准内规定的要求是顾客和相应法令和监管要求的补充（而不是替代）。

如果本标准要求与顾客或相应法令和监管要求之间存在冲突，应以后者为准。

本国际标准为有下列需求的组织规定了质量管理体系要求：

a）需要证实其有能力持续地提供满足顾客和相应法定和监管要求的产品或服务；和

b) 通过体系的有效应用，包括体系改进过程以及保证符合顾客与相应法定和监管要求，旨在增强顾客满意。

本国际标准的所有要求都是通用要求，同时将适用于所有组织，不管其类型，规模和它提供的产品和服务。

注1：在本国际标准中，术语“产品”或“服务”仅适用于预期提供给顾客或顾客所要求的产品和服务。

注2：法定和监管要求可称作法律要求。

2. 规范性引用文件

以下全部或部分文件被本文件规范性引用，同时作为其应用不可或缺的一部分。凡是注明日期的引用文件，仅引用的版本适用于本标准。凡是不注明日期的引用文件，引用文件（包括任何修改单）的最新版本适用。

9100:2016 质量管理体系—航空、航天和国防组织的要求

ISO 9000:2015 质量管理体系—基础和术语

ISO 9001:2015 质量管理体系—要求

3. 术语和定义

ISO 9001:2015内定义的术语和定义以及以下术语和定义适用于本文件。

在本标准之内，术语“制造商”将用于明确地阐明产品创造者和组织之间的关系。术语“外部供方和原始制造商”可以是同义词。

外部供方 → 组织 → 顾客

（制造商/供方）

3.1 物品Article

由设计组织列出的且适宜安装在产品内或安装在产品上的材料、零件、部件、组件或设施，或包含在由监管机构批准的设计数据[资料]之内的材料、零件、部件、组件或设施。

3.2 授权放行证书Authorized Release Certificate

一种文件，其证明某一产品可放行以备使用（例如，放行或重新恢复服务），同时可证实已实施的活动以及已达到的结果满足已确立的组织、监管机构和顾客的要求。

3.3 合格证书（通常也成为一份“符合性证书”）Certificate of Conformity (commonly referred to as a ‘Certificate of Conformance’)

能证明产品合格以及能证明符合已确立的过程、设计和规范要求的记录信息。

3.4 伪造零件Counterfeit Part

一种未授权的复制、模仿、替换或改良的零件（例如，材料，零件，部件），其被故意地误传作为某一原始或授权制造商的一种规定的真正零件。

注：某一伪造零件的示例可以包括，但不局限于假造的标识或标记或标签、等级、序列号、日期编码、文件或性能特性。

3.5 分销商Distributor

实施产品的采购、储存、分解或销售，但不会影响产品合格的组织。在本标准的环境内，术语“组织”是指一个分销商。

3.6 产品安全性Product Safety

保持产品状态，以使得它能够实现其设计目的或预期目的，而不会导致不可接受的人员伤害或财产损坏的风险。

3.7 分解Splitting

在物理上或按批量划分产品，其不会影响产品特性或符合性。

3.8 可疑未批准零件Suspected Unapproved Part

一种零件，存在客观可信的证据表明其可能一种未批准或伪造零件。

注：这包括：由某一供方交付给某一最终用途的物品，而该供方没有从已批准的生产组织获得直接交付授权；不符合已批准设计/数据的新物品；不是由某一已批准来源制造或维护的物品；已经故意误传的物品，包括伪造零件；以及带不完整或不适当文件的物品。

3.9 试验报告 Test Report

一种记录信息，其显示了由制造商或某一认证试验机构所提供的客观证据来表明产品符合特定的设计要求、产品或性能特性。

3.10 未批准零件Unapproved Part

未按照已批准或可接受数据和相应法定、监管和顾客要求来生产或维护的一种零件。

4. 组织环境

4.1 理解组织及其环境

组织应确定其目的和战略方向相关的外部和内部问题，以及影响其达到其质量管理体系预期结果的能力的外部和内部问题。

组织应监测和评审这些外部和内部问题相关的信息。

注1：问题可能包括待考虑的积极和消极的因素或条件。

注2：通过考虑法律、技术、竞争、市场、文化、社会和经济环境，不管是国际的，国家的，地区的或局部的环境提出的问题，都可帮助理解外部环境。

注3：通过考虑组织的价值、文化、知识和绩效相关的问题，可以帮助理解内部环境。

4.2 理解相关方的需求和期望

由于相关方对组织持续提供满足顾客和相应法定和监管要求的产品和服务的能力存在影响或潜在影响，组织应确定：

a）相关方是指与质量管理体系相关的各方；

b）这些相关方要求是指与质量管理体系相关的要求。

组织应监测和评审这些相关方及其相关要求相关的信息。

4.3 确定质量管理体系的范围

组织应确定质量管理体系的边界和适用性，从而确立其范围。

当确定该范围时，组织应考虑：

a）4.1节提及的外部和内部问题；

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**。