AEROSPACE STANDARD

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Technically equivalent writings published in all IAQG sectors.	

(R) Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations

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 design, develop, or provide aviation, space, and defense products and services; and by organizations providing post-delivery activities, including the provision of maintenance, spare parts, or materials for their own products and services.

NOTE: Organizations whose products are deliverable software, or contain deliverable software, should use the IAQG-developed 9115 standard (see Bibliography) when planning and evaluating the software design, development, or management activities of the organization. The 9115 standard provides guidance to the requirements of the 9100 standard when it is desired to add "software" to the 9100 quality management system scope.

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).

Organizations that procure parts, materials, and assemblies and resells these products to a customer in the aviation, space, and defense industry should use the IAQG-developed 9120 standard (see Bibliography). This includes organizations that procure products and split them into smaller quantities, as well as those that coordinate a customer or regulatory controlled process on the product.

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.

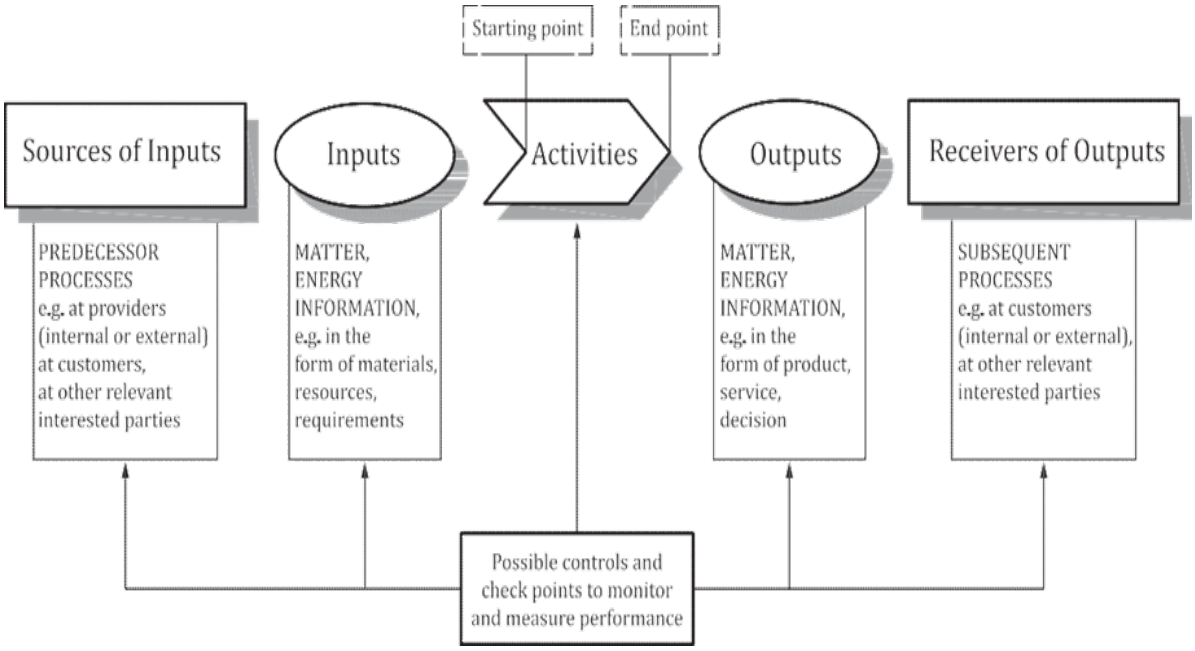


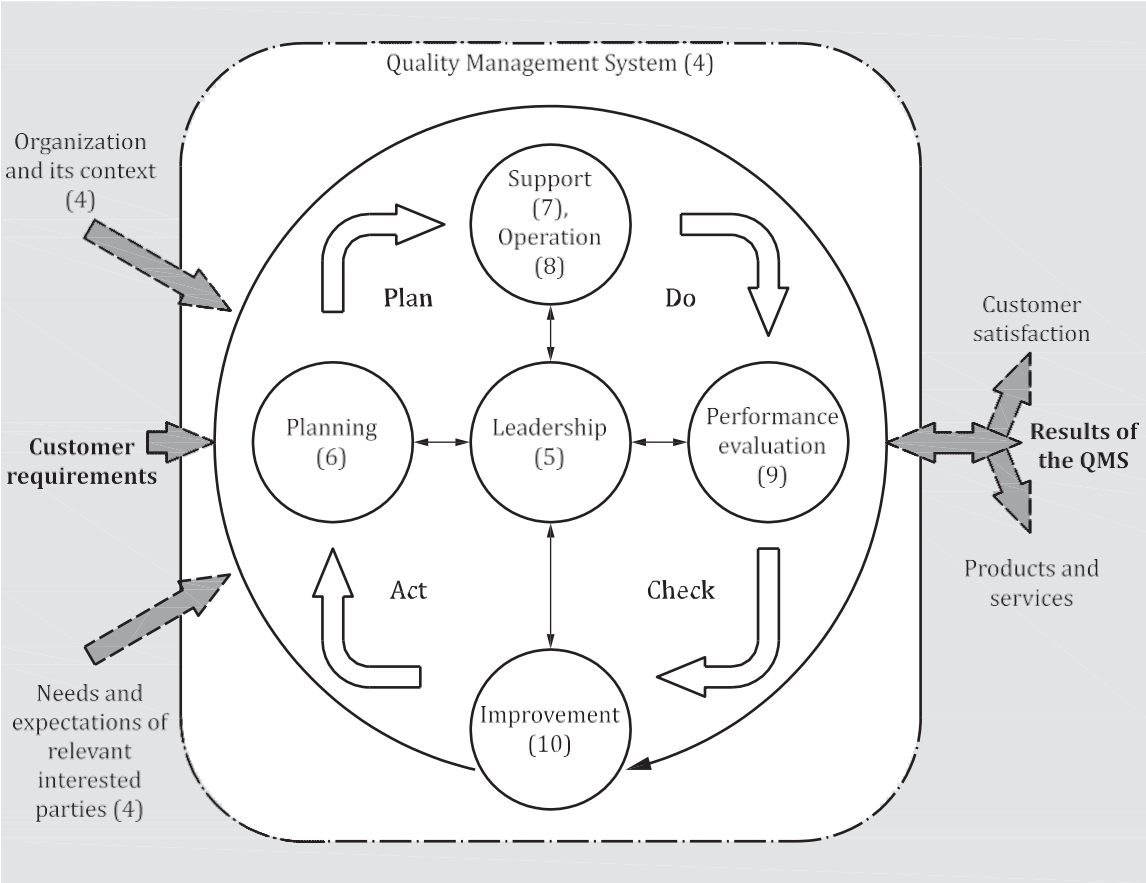
Figure 1 – Schematic representation of the elements of a single process

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.

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.

3.1 Counterfeit Part

An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer.

NOTE: Examples of a counterfeit part can include, but are not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.

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