SLOVENSKI STANDARD
SIST EN 9100:2018

01-julij-2018

Nadomešča:
SIST EN 9100:2009

Sistemi vodenja kakovosti - Zahteve za organizacije na področju zračnega prometa, vesoljskih poletov in obrambe

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

Qualitätsmanagementsysteme - Anforderungen an Organisationen der Luftfahrt, Raumfahrt und Verteidigung

Systèmes de management de la Qualité - Exigences des Organisations pour l'Aviation, l'Espace et la Défense

Ta slovenski standard je istoveten z: **EN 9100:2018**

ICS:

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
49.020	Letala in vesoljska vozila na splošno	Aircraft and space vehicles in general

SIST EN 9100:2018 **en,fr,de**

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Quality Management Systems - Requirements for Aviation, Space and Defence Organizations

Systèmes de Management de la Qualité - Exigences pour les Organismes de l'Aéronautique, l'Espace et la Défense

Qualitätsmanagementsysteme - Anforderungen an Organisationen der Luftfahrt, Raumfahrt und Verteidigung

This European Standard was approved by CEN on 27 February 2017.

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European foreword

This document (EN 9100:2018) has been prepared by the Aerospace and Defence Industries Association of Europe - Standardization (ASD-STAN).

After enquiries and votes carried out in accordance with the rules of this Association, this Standard has received the approval of the National Associations and the Official Services of the member countries of ASD, prior to its presentation to CEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2018, and conflicting national standards shall be withdrawn at the latest by November 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 9100:2009.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Rationale

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

Foreword

To assure customer satisfaction, aviation, space and defence 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 defence 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 document 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 defence industry, this document can also be used in other industry sectors when a quality management system with additional requirements over an EN ISO 9001 system is needed.

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

1 *With the permission of the International Organization for Standardization (ISO). The complete EN ISO 9001 standard can be obtained from any ISO member or from the ISO Central Secretariat: BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, SWITZERLAND, or visit www.iso.org. Copyright remains with ISO.*

Intended application

This document is intended for use by organizations that design, develop, or provide aviation, space and defence 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 EN 9115 standard (see Bibliography) when planning and evaluating the software design, development, or management activities of the organization. The EN 9115 standard provides guidance to the requirements of the EN 9100 standard when it is desired to add "software" to the EN 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 EN 9110 standard (see Bibliography).

Organizations that procure parts, materials and assemblies and resells these products to a customer in the aviation, space and defence industry should use the IAQG-developed EN 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.

0 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 EN 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.

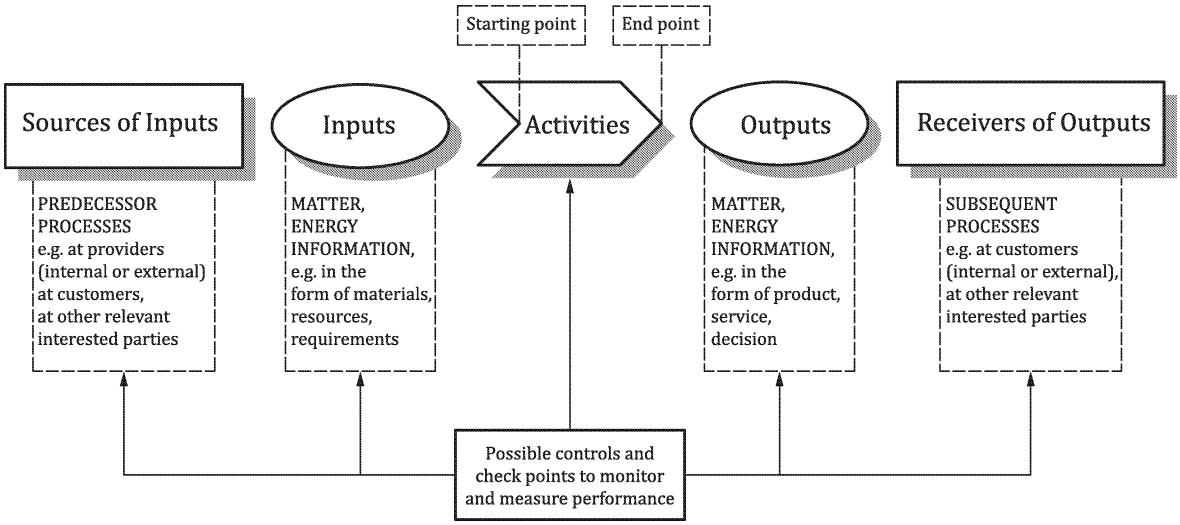


Figure 1 — Schematic representation of the elements of a single process

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.

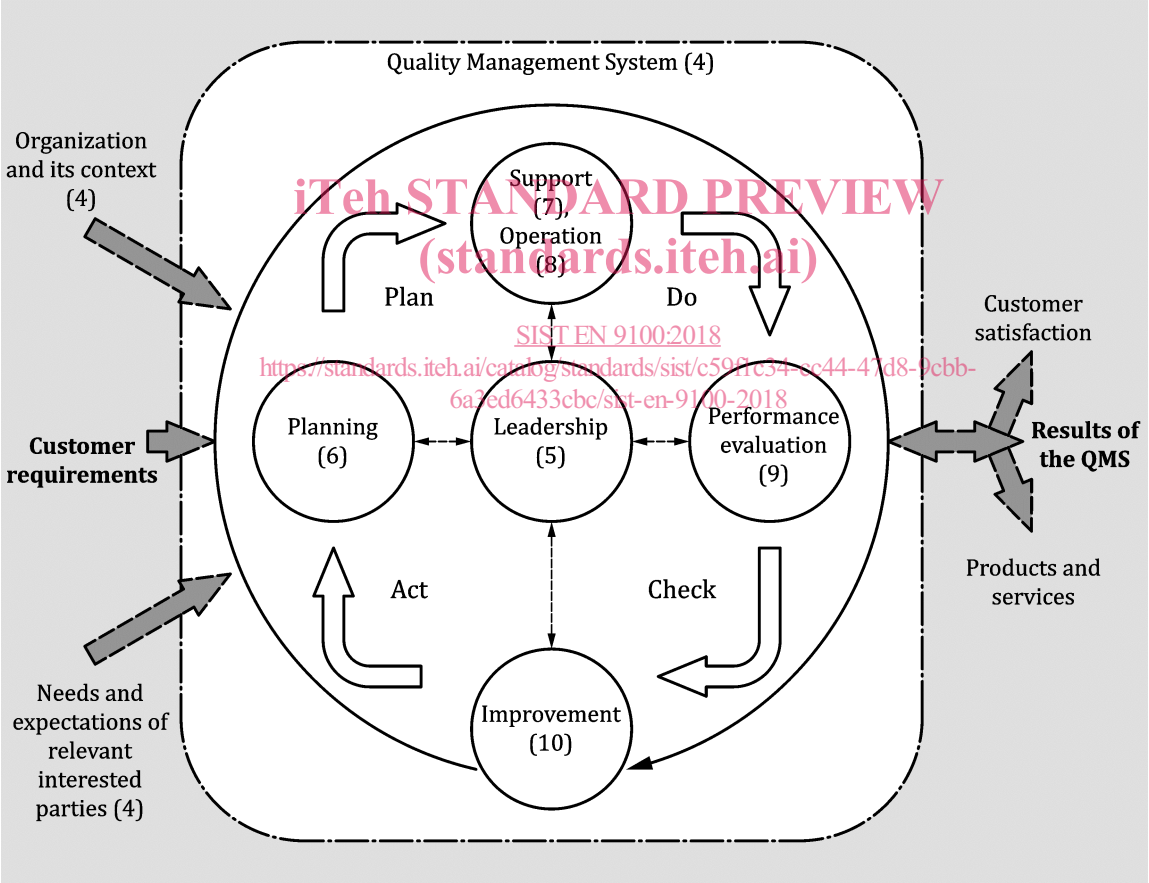
The PDCA cycle can be briefly described as follows:

— 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, 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

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 EN ISO 9000 and EN ISO 9004 as follows:

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

— EN 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 (EN ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access web site at: www.iso.org/tc176/sc02/public.

1 Scope

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

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

If there is a conflict between the requirements of this document 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 are referred to in the text in such a way that some or all of their content constitutes requirements 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.

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

EN ISO 9001:2015, Quality management systems — Requirements

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 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.

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2 *With the permission of the International Organization for Standardization (ISO). The complete EN ISO 9001 standard can be obtained from any ISO member or from the ISO Central Secretariat: BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, SWITZERLAND, or visit www.iso.org. Copyright remains with ISO.*

Note 1 to entry: ***Examples of a counterfeit part can include, but are not limited to, the false identification of marking or labelling, grade, serial number, date code, documentation, or performance characteristics.***

3.2
Critical items
Those items (e. g., functions, parts, software, characteristics, processes) having significant effect on the provision and use of the products and services; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

3.3
Key characteristic
An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life, or producibility, that requires specific actions for the purpose of controlling variation.

3.4
Product safety
The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

3.5
Special requirements

Those requirements identified by the customer, or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

Note 1 to entry: ***Special requirements (3.5) and critical items (3.2), along with key characteristics (3.3), are interrelated. Special requirements are identified when determining and reviewing requirements related to the product (see 8.2.2 and 8.2.3). Special requirements can require the identification of critical items. Design output (see 8.3.5) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled.***

4 Context of the organization

4.1 Understanding the organization and its context

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 result(s) of its quality management system.

The organization shall monitor and review information about these external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional, or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

a) the interested parties that are relevant to the quality management system;

b) the requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.

4.3 Determining the scope of the quality management system

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization shall consider:

a) the external and internal issues referred to in 4.1;

b) the requirements of relevant interested parties referred to in 4.2;

c) the products and services of the organization.

The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

4.4 Quality management system and its processes

4.4.1 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.

The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.

The organization shall determine the processes needed for the quality management system and their application throughout the organization and shall:

a) determine the inputs required and the outputs expected from these processes;

b) determine the sequence and interaction of these processes;

c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

d) determine the resources needed for these processes and ensure their availability;

e) assign the responsibilities and authorities for these processes;

f) address the risks and opportunities as determined in accordance with the requirements of 6.1;

g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;

h) improve the processes and the quality management system.

4.4.2 To the extent necessary, the organization shall:

a) maintain documented information to support the operation of its processes;

b) retain documented information to have confidence that the processes are being carried out as planned.

The organization shall establish and maintain documented information that includes:

— ***a general description of relevant interested parties (see 4.2 a);***

— ***the scope of the quality management system, including boundaries and applicability (see 4.3);***

— ***a description of the processes needed for the quality management system and their application throughout the organization;***

— ***the sequence and interaction of these processes;***

— ***assignment of the responsibilities and authorities for these processes.***

NOTE The above description of the quality management system can be compiled into a single source of documented information and referred to as a quality manual.