SLOVENSKI STANDARD
SIST EN 9100:2009

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Nadomešča:
SIST EN 9100:2004

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 9100:2009**

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

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EUROPEAN STANDARD

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

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

Qualitätsmanagementsysteme - Anforderungen an Organisationen der Luftfahrt, Raumfahrt und Verteidigung

This European Standard was approved by CEN on 3 July 2009.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

iTeh STANDARD PREVIEW

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN 9100:2009) 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 February 2010, and conflicting national standards shall be withdrawn at the latest by February 2010.

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 9100:2003.

This standard has been revised to incorporate the requirements of ISO 9001:2008. In addition, industry requirements, definitions and notes have been revised and additional requirements have been included in response to stakeholder needs.

Industry has established the International Aerospace Quality Group (IAQG), with representatives from 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, schedule and cost performance by the reduction or elimination of organization-unique requirements 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 where a quality management system with additional requirements over an ISO 9001 system is needed.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

0   INTRODUCTION

0.1   General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by

a)   its organizational environment, changes in that environment, and the risks associated with that environment,

b)   its varying needs,

c)   its particular objectives,

d)   the products it provides,

e)   the processes it employs,

f)   its size and organizational structure.

It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

0.2   Process approach

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.

For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach".

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a)   understanding and meeting requirements,

b)   the need to consider processes in terms of added value,

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c)   obtaining results of process performance and effectiveness, and

d)   continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in Clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE   In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

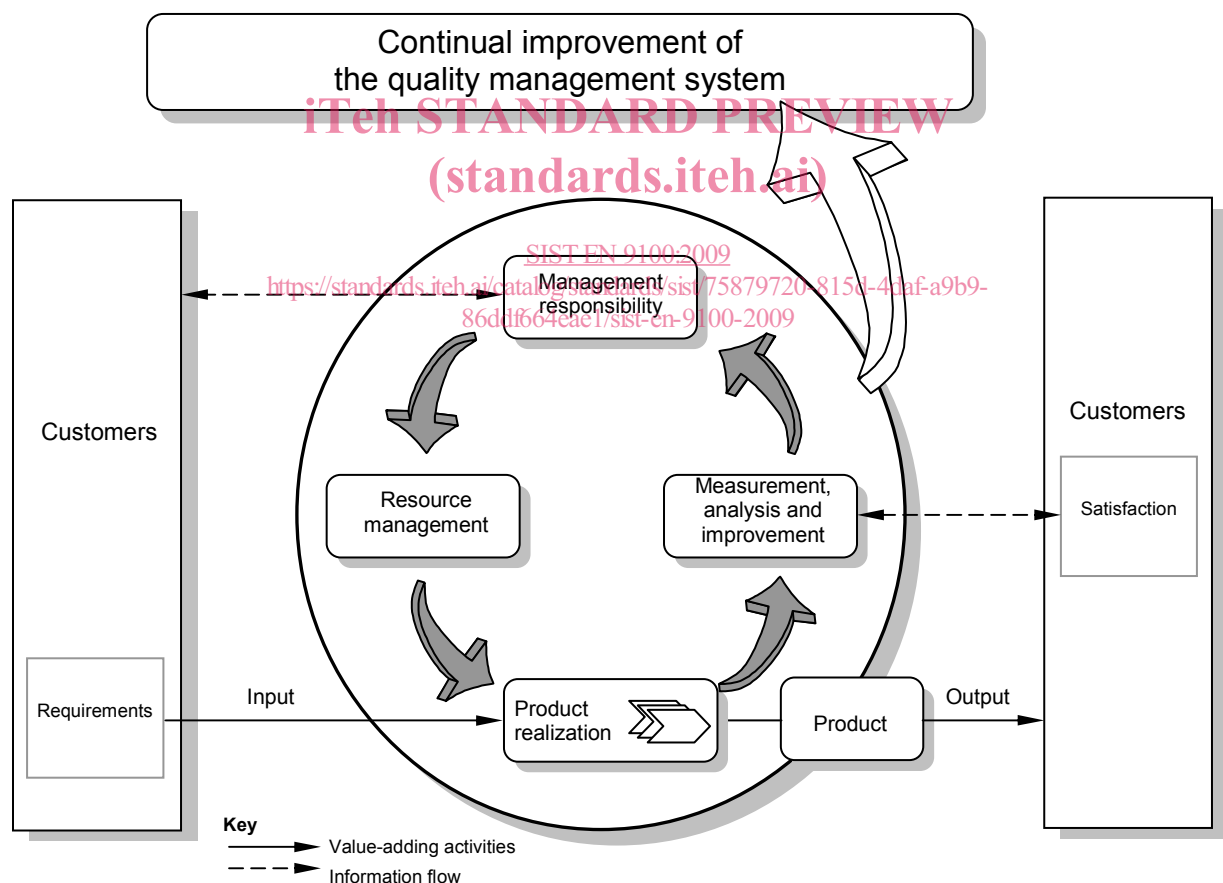Act: take actions to continually improve process performance.

Figure 1 — Model of a process-based quality management system

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QUALITY MANAGEMENT SYSTEMS – REQUIREMENTS

1   SCOPE

1.1   General

This standard includes ISO 9001:2008 [1] *quality management system requirements and specifies additional aviation, space and defense industry requirements, definitions and notes as shown in bold, italic text.*

It is emphasized that the requirements specified in this standard are complementary (not alternative) to contractual and applicable statutory and regulatory requirements. Should there be a conflict between the requirements of this standard and applicable statutory or regulatory requirements, the latter shall take precedence.

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

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and

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.

NOTE 1   In this International Standard, the term "product" only applies to

      a)   product intended for, or required by, a customer,

      b)   any intended output resulting from the product realization processes.

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

1.2   Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

This standard is intended for use by organizations that design, develop and/or produce aviation, space and defense products; and by organizations providing post-delivery support, including the provision of maintenance, spare parts or materials for their own products.

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1   *With the permission of the International Organization for Standardization (ISO). The complete 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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Organizations whose primary business is providing maintenance, repair and overhaul services for aviation commercial and military products; and original equipment manufacturers with maintenance, repair and overhaul operations that operate autonomously, or that are substantially different from their manufacturing/production operations; should use the IAQG-developed 9110 standard (see Bibliography).

Organizations that procure parts, materials and assemblies and resell these products to a customer in the aviation, space and defense industries, including organizations that procure products and split them into smaller quantities for resale, should use the IAQG-developed 9120 standard (see Bibliography).

2 NORMATIVE REFERENCES

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.

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

ISO 9001:2008, *Quality management systems — Requirements*

3 TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in ISO 9000:2005 apply.

Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".

3.1 *Risk*

An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

3.2 *Special requirements*

Those requirements identified by the customer, or determined by the organization, which have high risks to being achieved, thus requiring their inclusion in the 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.

3.3 *Critical items*

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product; 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.

3.4   *Key characteristic*

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

NOTE   Special requirements and critical items are new terms and, along with key characteristics, are interrelated. Special requirements are identified when determining and reviewing requirements related to the product (see 7.2.1 and 7.2.2). Special requirements can require the identification of critical items. Design output (see 7.3.3) 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   QUALITY MANAGEMENT SYSTEM

4.1   General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness 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

a)   determine the processes needed for the quality management system and their application throughout the organization (see 1.2),

b)   determine the sequence and interaction of these processes,

c)   determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d)   ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e)   monitor, measure where applicable, and analyse these processes, and

f)   implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

NOTE 1   Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.

NOTE 2   An "outsourced process" is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3   Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,

b) the degree to which the control for the process is shared,

c) the capability of achieving the necessary control through the application of 7.4.

4.2 Documentation Requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures and records required by this International Standard, and

d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

The organization shall ensure that personnel have access to, and are aware of, relevant quality management system documentation and changes.

NOTE 1   Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2   The extent of the quality management system documentation can differ from one organization to another due to

   a)   the size of organization and type of activities,

   b)   the complexity of processes and their interactions, and

   c)   the competence of personnel.

NOTE 3   The documentation can be in any form or type of medium.

4.2.2 Quality Manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

4.2.3 Control of Documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,