SLOVENSKI STANDARD
SIST EN 9120:2010

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Nadomešča:
SIST EN 9120:2008

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

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

Qualitätsmanagementsysteme - Anforderungen für Händler und Lagerhalter der Luftfahrt, Raumfahrt und Verteidigung

Systèmes de management de la Qualité - Exigences pour les distributeurs en aéronautique, spatial et défense

Ta slovenski standard je istoveten z: **EN 9120:2010**

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
95.020	Vojaška tehnika. Vojaške zadeve. Orožje	Military engineering. Military affairs. Weapons

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EUROPEAN STANDARD

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

Systèmes de management de la Qualité - Exigences pour les distributeurs en aéronautique, spatial et défense

Qualitätsmanagementsysteme - Anforderungen für Händler und Lagerhalter der Luftfahrt, Raumfahrt und Verteidigung

This European Standard was approved by CEN on 11 March 2010.

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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.

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Foreword

This document (EN 9120:2010) 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of an identical text or by endorsement, at the latest by December 2010, and conflicting national standards shall be withdrawn at the latest by December 2010.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 9120:2005.

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, 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.

FOREWORD

To assure customer satisfaction, aviation and defense organizations must produce, maintain, repair and continually improve, safe, reliable products 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 from suppliers throughout the world and at all levels of the supply chain. Suppliers have the challenge of delivering products to multiple customers having varying quality requirements and expectations.

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 and defense industry, organizations providing maintenance, repair and overhaul services, 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.

REVISION SUMMARY/RATIONALE

This standard has been revised to incorporate the requirements of ISO 9001:2008 and IAQG developed 9100:2009. In addition, industry requirements, definitions and notes have been revised and additional requirements have been included in response to stakeholder needs.

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 European Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

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

This European 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 European Standard.

0.2 Process approach

This European 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;

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 European 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.

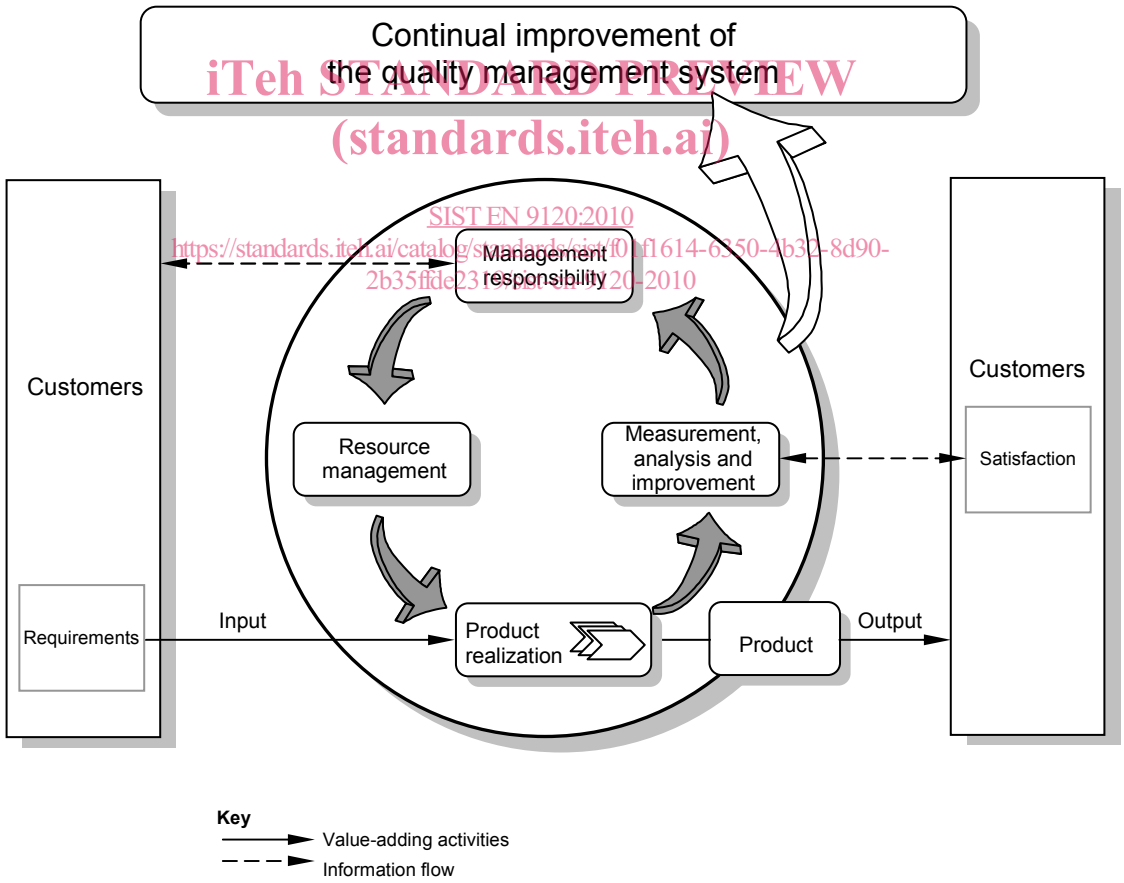

Figure 1 — Model of a process-based quality management system

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 European 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 European 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 European 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 European 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 European 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 for use by organizations that procure parts, materials and assemblies and resells 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 controlled service on the product. This standard is not intended for organizations that maintain or repair products. Organizations that perform work that affect or could affect product characteristics or conformity should use the IAQG-developed 9100 or 9110 standards, as appropriate (see Bibliography).

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1) *With the permission of the International Organization for Standardization (ISO). The complete standard may 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. Copyright remains with ISO.*

Requirements for the aviation, space and defence industries are specified in this standard. Compliance to this standard means the expected exclusions for distributors are already taken for the ISO 9001:2008 standard unless otherwise specified by the organization.

The following ISO 9001:2008 clauses are excluded in their entirety for purposes of this standard:

- ***7.3 Design and development;***
- ***7.5.2 Validation of processes for production and service provision.***

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.

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

3 Terms and definitions

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

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

For the purpose of this standard, the term manufacturer is intentionally used to clearly delineate the relationship between the product creator and the organization. The terms supplier, manufacturer and product creator may be synonymous.

supplier → organization → customer

(manufacturer/product creator)

3.1 *Airworthiness certificate*

A document issued by the cognizant civil aviation authority (e.g. EASA Form 1, FAA Form 8130-3) that certifies that the part conforms to the applicable regulatory requirements.

3.2 *Certificate of conformity*

A document that certifies product conformity to process, design and/or specification requirements; commonly referred to as a "Certificate of Conformance".

3.3 *Counterfeit part*

A product produced or altered to imitate or resemble a product without authority or right to do so, with the intent to mislead or defraud by passing the imitation as original or genuine.

3.4 *Distributor*

Organization carrying out the purchase, storage, splitting or sale of products without affecting product conformity. The term organization in the context of this standard means a distributor.

3.5 *Risk*

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

3.6 *Splitting*

The division of product either physically or by batch quantity, without affecting the product characteristics.

3.7 *Suspected unapproved part*

A product that might not have been or is suspected of not having been produced in accordance with applicable laws and regulations.

3.8 *Test report*

Objective evidence provided by either the manufacturer or a certified testing facility that the product conforms with specific design requirements or properties.

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 European 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 European 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.