SLOVENSKI STANDARD
SIST EN 9120:2018

01-julij-2018

Nadomešča:
SIST EN 9120:2010

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 9120:2018**

ICS:

03.100.70	Sistemi vodenja	Management systems
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	Vojaštvo na splošno	Military in general

SIST EN 9120:2018 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 9120

May 2018

ICS 03.100.70; 03.120.10; 49.020; 95.040

Supersedes EN 9120:2010

English Version

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

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

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

This European Standard was approved by CEN on 10 April 2017.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents

Page

Figures

European foreword

This document (EN 9120:2018) 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 9120:2010.

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 *ISO 9001:2015 is reproduced in this document with the permission of the International Organization for Standardization, ISO. No parts of this standard may be reproduced in any form without the prior written consent of ISO at copyright@iso.org. ISO Standards can be obtained from any ISO member and from the web site of the ISO Central Secretariat at www.iso.org. Copyright remains with ISO.*

Intended application

This document is intended for use by organizations that procure parts, materials and assemblies and resell these products to a customer in the aviation, space and defence 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 document 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 defence products and services should use the IAQG-developed EN 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 EN 9110 standard (see bibliography).

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 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.

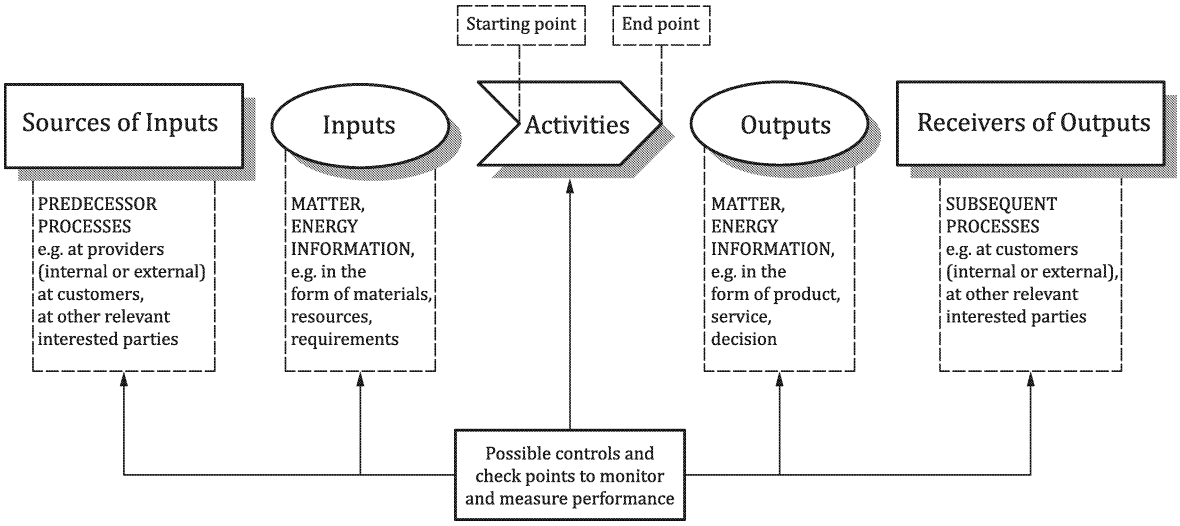

Figure 1 — Schematic representation of the elements of a single process

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 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.

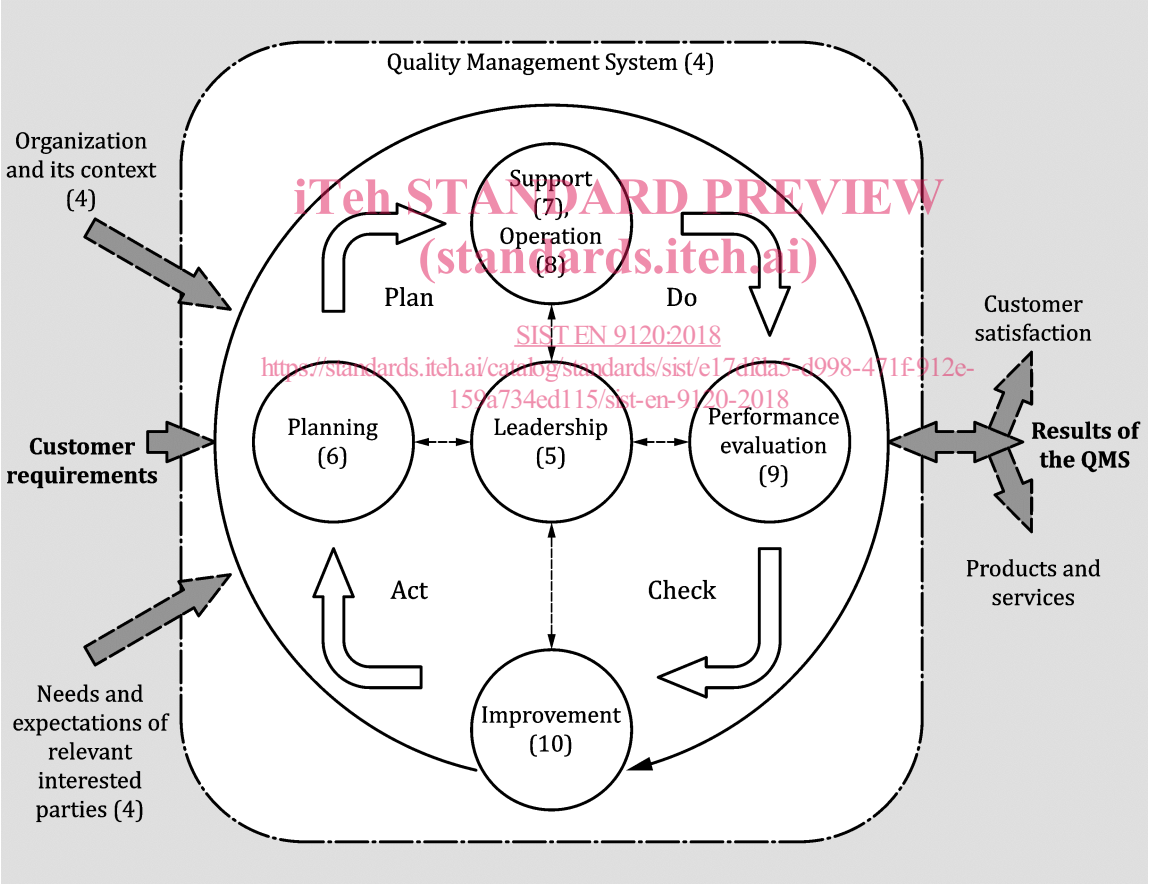

Figure 2 — Representation of the structure of this international standard in the PDCA cycle

0.3.3 Risk-based thinking

Risk-based thinking (see 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 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:

— 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 9100:2016, *Quality Management Systems — Requirements for Aviation, Space and Defence Organizations*

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.

---

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.*

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

3.1
article
material, part, component, assembly or appliance which is listed by the design organization as eligible for installation in/on the product or included in the design data approved by the authority.

3.2
authorized release certificate
document attesting that a product is released for use (e.g. release or return to service) and certifying that the activities performed and the results achieved, conform to established organization, regulatory and customer requirements.

3.3
certificate of conformity (commonly referred to as a 'certificate of conformance')
documented information that attests to product conformity; conformance to defined process, design and specification requirements.

3.4
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 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.

3.5
distributor
an 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.

3.6
product safety
maintaining the state of product so that it is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

3.7
splitting
the division of product either physically or by batch quantity, without affecting the product characteristics or conformity.

3.8
suspected unapproved part
a part for which there is objective and credible evidence indicating that the part is likely an unapproved or counterfeit part.

Note 1 to entry: This includes: articles shipped to an end user by a supplier who does not have direct delivery authorization from the approved production organization; new articles that do not conform to the