SLOVENSKI STANDARD
SIST EN 9110:2015

01-april-2015

Nadomešča:
SIST EN 9110:2012

Sistemi vodenja kakovosti - Zahteve za organizacije za vzdrževanje letal

Quality Management Systems - Requirements for Aviation Maintenance Organizations

Qualitätsmanagementsysteme - Anforderungen für Luftfahrt-Wartungsfirmen

Systèmes de management de la Qualité - Exigences pour les Organismes d'Entretien de l'Aéronautique

Ta slovenski standard je istoveten z: EN 9110:2015

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 9110:2015 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 9110

February 2015

ICS 03.120.10; 49.020

Supersedes EN 9110:2010

English Version

Quality Management Systems - Requirements for Aviation Maintenance Organizations

Systèmes de management de la Qualité - Exigences pour les Organismes d'Entretien de l'Aéronautique

Qualitätsmanagementsysteme - Anforderungen für Luftfahrt-Instandhaltungsbetriebe

This European Standard was approved by CEN on 29 November 2014.

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Ref. No. EN 9110:2015 E

RATIONALE

This standard has been revised to address stakeholder needs through the addition of definitions and clarification of existing requirements to resolve interpretation issues, and incorporate editorial corrections.

FOREWORD

To assure customer satisfaction, aviation and defence 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 defence industry organizations providing maintenance 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.

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Foreword

This document (EN 9110:2015) 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 August 2015, and conflicting national standards shall be withdrawn at the latest by August 2015.

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 9110:2010.

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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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 on-going 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 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.

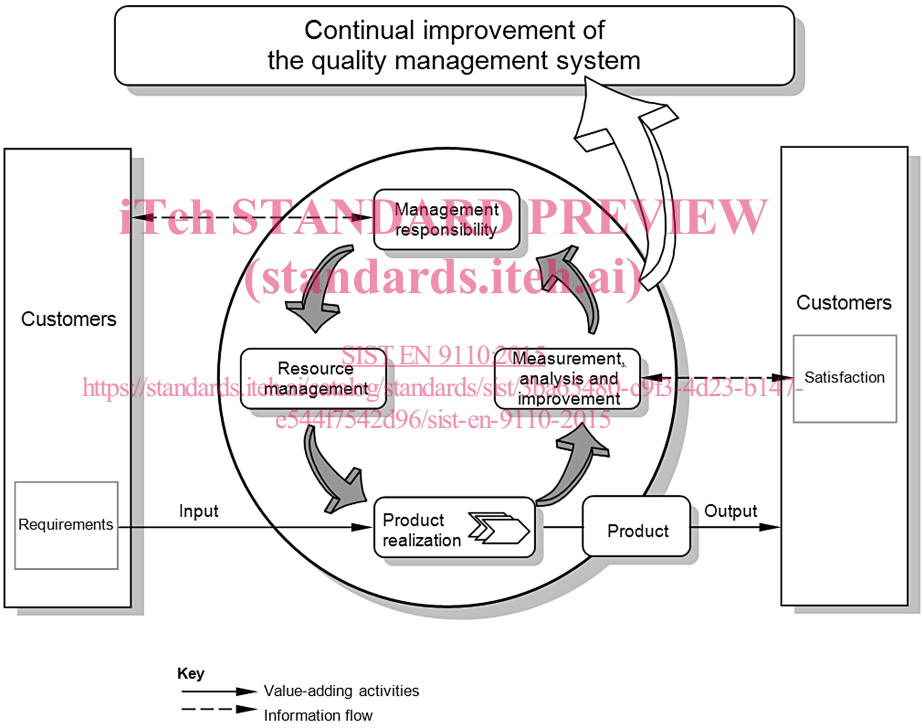

Figure 1 — Model of a process-based quality management system

Quality management systems — Requirements

1 Scope

1.1 General

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

NOTE 1 Baseline aviation maintenance requirements originate from IAQG developed 9100:2009 standard; modifications were made, as required, to address maintenance industry specific requirements.

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 2 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 3 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 has been developed to benefit maintenance organizations that choose to adopt it, whether or not holders of a National Aviation Authority (NAA) repair station certificate. This standard is intended for use by maintenance organizations whose primary business is providing maintenance services for aviation commercial and military products; and for Original Equipment Manufacturer (OEM) organizations with maintenance operated autonomously or that are substantially different from their manufacturing/production operations.

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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.*

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

3 Terms and definitions

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

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

NOTE In the context of this standard, the term "product" is synonymous with the term "maintenance service".

3.1
Airworthy
state of an article conforming to its type design and being in a condition for safe operation

3.2
Article
material, part, component, assembly, appliance, propeller, aircraft engine, airframe, or aircraft which is listed by the design organization as eligible for installation in product or included in the design data approved by the authority

3.3
Authority
the aviation authority having jurisdiction over the manufacturer, aircraft owner/operator or maintenance organization; the authority could be civil or military

3.4
Certified personnel
personnel qualified by an external/internal competent body to carry out special tasks (e.g., non-destructive testing certified personnel, licensed maintenance personnel)

3.5
Certifying staff
personnel authorized by the maintenance organization to sign the release certificate for an article after maintenance

3.6
Counterfeit part
an article produced or altered to imitate or resemble an “approved article” without authority or right to do so, with the intent to mislead or defraud by passing the imitation as original or genuine

NOTE 1 to entry: Commonly referred to within the industry as a "bogus part".

3.7
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, airworthiness limitations items, key characteristics, and maintenance tasks critical for safety.

3.8
Human factors
the study of human behaviour (physically and psychologically) in relation to particular environments, products, or services and the potential effect on safety. Recognition that personnel performing tasks are affected by physical fitness, physiological characteristics, personality, stress, fatigue, distraction, communication, and attitude in order to ensure a safe interface between the personnel and all other environmental elements such as other personnel, equipment, facilities, organizations, procedures, and data.

3.9
Key characteristic
an attribute or feature whose variation has a significant effect on product fit, form, function, performance, or service life, that requires specific actions for the purpose of controlling variation

NOTE 1 to entry: ***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.***

3.10
Maintenance
performance of tasks required to ensure the continuing airworthiness of an article, including any one or combination of overhaul, inspection, testing, replacement, defect rectification, and the embodiment of a modification or repair

NOTE 1 to entry: ***This term applies to the overhaul, repair, inspection, replacement, modification, or defect rectification of an article that is performed after completion of manufacturing and initial airworthiness certification by or on behalf of the relevant authority.***

3.11
Release certificate
document attesting that a product is released for use (release/return to service) and certifying that the activities performed, and the results achieved, conform to established organization, regulatory, and customer requirements with no known nonconformities that would endanger flight safety

3.12
Risk
an undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence

3.13
Safety policy
top management formally expressed commitment to product safety. This policy should reflect the organization's philosophy of safety management and outlines the methods and processes that the organization will use to achieve desired safety outcomes.

3.14
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.