SLOVENSKI STANDARD
SIST EN 9110:2008

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Aeronavtika - Sistemi kakovosti - Model zagotavljanja kakovosti za vzdrževalne organizacije

Aerospace series - Quality systems - Model for quality assurance applicable to maintenance organizations

Luft- und Raumfahrt - Qualitätsmanagement - Qualitätssicherungsmodelle für wartungsfirmen

Série aérospatiale - Systèmes qualité - Modèle pour l'assurance qualité applicable aux organismes d'entretien

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ICS:

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
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Aerospace series - Quality systems - Model for quality assurance applicable to maintenance organizations

Série aérospatiale - Systèmes qualité - Modèle pour l'assurance qualité applicable aux organismes d'entretien

Luft- und Raumfahrt - Qualitätsmanagement - Qualitätssicherungsmodelle für wartungsfirmen

This European Standard was approved by CEN on 28 October 2005.

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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 Central Secretariat has the same status as the official versions.

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

EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This European Standard (EN 9110:2005) has been prepared by the European Association of Aerospace Manufacturers - Standardization (AECMA-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 AECMA, 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of an identical text or by endorsement, at the latest by June 2006, and conflicting national standards shall be withdrawn at the latest by June 2006.

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.

In December 1998, the Aerospace Industry established the International Aerospace Quality Group (IAQG) with the purpose of achieving significant improvements in quality and reductions in cost throughout the value stream.

This organization, with representation from Aerospace companies in Americas, Asia and Europe and sponsored by SAE, SJAC and AECMA has agreed to take responsibility for the technical contents of this standard.

This standard was reviewed by the Domain Technical Coordinator of AECMA-STAN's Quality Domain.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland 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 varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

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

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

0.2 Process approach

This 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 identify and manage numerous linked activities. An activity 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, 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 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.

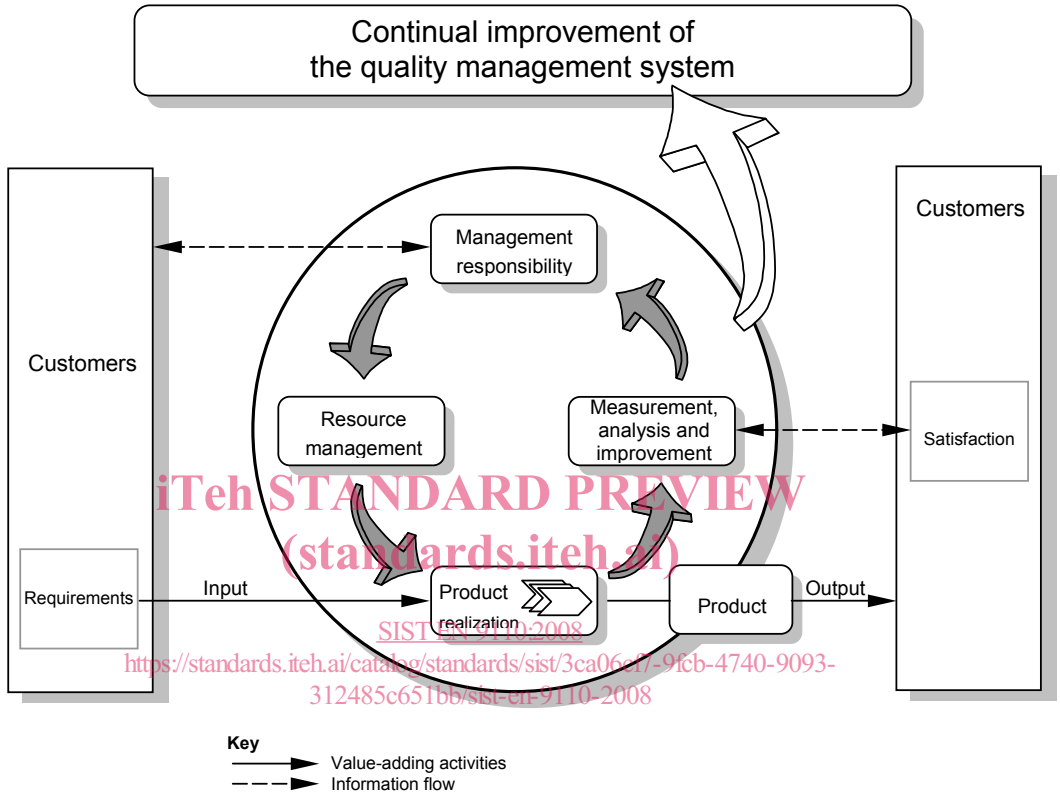

Figure 1 — Model of a process-based quality management system

1 Scope

1.1 General

This standard includes ISO 9001:2000 [1] ***quality management system requirements and specifies additional requirements for a quality management system for aerospace maintenance organizations. The additional aerospace requirements are shown in bold, italic text.***

It is emphasized that the quality management system requirements specified in this standard are complementary (not alternative) to contractual and applicable law and regulatory requirements.

This 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 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 regulatory requirements.

NOTE In this Standard, the term “product” applies only to the product intended for, or required by, a customer.

1.2 Application

All requirements of this 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 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 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 regulatory requirements.

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 9000:2000, *Quality management systems — Fundamentals and vocabulary.*

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3 Terms and definitions

3.1 General

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

The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:

supplier → organization → customer

The term “organization” replaces the term “supplier” used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term “supplier” now replaces the term “subcontractor”.

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

3.2 Additional terms and definitions

3.2.1 Authority

The national aviation authority having jurisdiction over the manufacturer, aircraft owner and operator, maintenance organization; the Authority could be civil or military.

3.2.2 Key Characteristics

The features of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability.

3.2.3 Maintenance

The overhaul, repair, inspection, replacement, modification or defect rectification of an aircraft or an aircraft component that is performed after completion of manufacturing and initial airworthiness certification by the applicable Authority.

3.2.4 Technical data

Data that is necessary to ensure that the aircraft or aircraft component can be maintained in a condition such that serviceability and airworthiness of the aircraft and related operational and emergency equipment, is assured. This data includes maintenance programs, airworthiness directives, service bulletins, major repairs/modifications, operator maintenance manuals, drawings, engineering orders, component maintenance manuals, technical orders, etc.

3.2.5 Human factors

Recognition that personnel performing tasks are affected by physical fitness, physiological characteristics, personality, stress, fatigue, distraction, communication and attitude.

3.2.6 Release certificate

A document certifying that the activities performed, and the results achieved, conform to established organization, Authority, and contract requirements.

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 Standard.

Maintenance organizations shall obtain and maintain any required quality management system approvals and any other approvals, certificates, ratings, licenses, and permits required by the responsible Authority.

The organization shall

a) identify 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 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 Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

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

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 required by this Standard,

d) documents needed by the organization to ensure the effective planning, operation and control of its processes,

e) records required by this Standard (see 4.2.4)***, and***

f) quality system requirements imposed by the applicable Authorities, as well as the standards to which the organization intends to work.

The organization shall ensure that personnel have access to quality management system documentation and are aware of relevant procedures. Customer and/or Authorities representatives shall have access to quality management system documentation.

NOTE 1 Where the term “documented procedure” appears within this Standard, this means that the procedure is established, documented, implemented and maintained.

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
   – ***when referencing the documented procedures, the relationship between the requirements of this International Standard and the documented procedures shall be clearly shown.***
c) a description of the interaction between the processes of the quality management system.

NOTE Guidance on quality manuals is given in ISO/TR 10013.

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,
c) to ensure that changes and the current revision status of documents are identified,
d) to ensure that relevant versions of applicable documents are available at points of use,
e) to ensure that documents remain legible and readily identifiable,
f) to ensure that documents of external origin are identified and their distribution controlled, and
g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The organization shall coordinate document changes with customers and/or Authorities in accordance with contract or regulatory requirements.

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.

Records shall be available for review by customers and Authorities in accordance with contract or regulatory requirements.

4.3 Configuration management

The organization shall establish, document and maintain a configuration management process appropriate to the product.

NOTE Guidance on configuration management is given in ISO 10007.

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

5.3 Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,

b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,

c) provides a framework for establishing and reviewing quality objectives,

d) is communicated and understood within the organization, and

e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and