SLOVENSKI STANDARD
SIST EN 9100:2004

01-maj-2004

Aerospace series - Quality management systems - Requirements (based on ISO 9001:2000) and Quality systems - Model for quality assurance in design, development, production, installation and servicing (based on ISO 9001:1994)

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Luft- und Raumfahrt - Qualitätsmanagementsysteme - Anforderungen (basiert auf ISO 9001:2000) und Qualitätsmanagementsysteme - Qualitätssicherungsmodelle für Konstruktion, Entwicklung, Produktion, Montage und Wartung (basiert auf ISO 9001:1994)

Série aérospatiale - Systemes de management de la Qualité - Exigences (basé sur ISO 9001:2000) - Systémes qualité - Modele pour l'assurance qualité en conception, developpement, production, installation et exploitation (basé sur ISO 9001:1994)

Ta slovenski standard je istoveten z: **EN 9100:2003**

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

NORME EUROPÉENNE

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English version

Aerospace series - Quality management systems - Requirements (based on ISO 9001:2000) and Quality systems - Model for quality assurance in design, development, production, installation and servicing (based on ISO 9001:1994)

Série aérospatiale - Système de management de la Qualité - Exigences (basé sur ISO 9001:2000) et Système qualité - Modèle pour l'assurance qualité en conception, développement, production, installation et exploitation (basé sur ISO 9001:1994)

Luft- und Raumfahrt - Qualitätsmanagementsysteme - Anforderungen (basiert auf ISO 9001:2000) und Qualitätssysteme - Qualitätssicherungsmodelle für Konstruktion, Entwicklung, Produktion, Montage und Wartung (basiert auf ISO 9001:1994)

This European Standard was approved by CEN on 14 February 2003.

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 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 Management Centre has the same status as the official versions.

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

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 9100:2003 E

Contents

Foreword

This document (EN 9100:2003) has been prepared by the European Association of Aerospace Industries – 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 November 2003, and conflicting national standards shall be withdrawn at the latest by November 2003.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

General

To assure customer satisfaction, aerospace industry organizations must produce, and continually improve, safe, reliable products that meet or exceed customer and regulatory authority requirements. The globalization of the aerospace industry, and the resulting diversity of regional/national requirements and expectations, has complicated this objective. End-product organizations face the challenge of assuring the quality of, and integrating, product purchased from suppliers throughout the world and at all levels within the supply chain. Aerospace suppliers and processors face the challenge of delivering product to multiple customers having varying quality expectations and requirements.

This document standardizes, to the greatest extent possible, quality management system requirements for the aerospace industry. The establishment of common requirements, for use at all levels of the supply-chain, by organizations around the world, should result in improved quality and safety, and decreased costs, due to the elimination or reduction of organization-unique requirements and the resultant variation inherent in these multiple expectations.

Structure and Application

This standard includes aerospace requirements applied to, and integrated with, both the ISO 9001: 2000 and the ISO 9001: 1994 quality management system models. The section of this standard that shall apply is determined by the organization's current quality management system (QMS) status in regards to alignment/compliance with ISO 9001.

Organizations now having a QMS based on ISO 9001: 1994, that are expanding the scope of their QMS to include EN 9100 requirements, shall utilize the section of this standard aligned with ISO 9001: 1994. Upon transition to an ISO 9001: 2000-based QMS, organizations shall use the section of this standard aligned with ISO 9001: 2000. In accordance with the time period established for organizations to transition from ISO 9001: 1994 to ISO 9001: 2000, the section of this standard based on the ISO 9001: 1994 model will be withdrawn on December 15, 2003.

Organizations initially developing an ISO 9001/EN 9100-based QMS after December 15, 2000 must develop a QMS based on ISO 9001:2000 and shall utilize the section of this standard that is based on ISO 9001: 2000.

The ISO 9001 model, and the corresponding EN 9100 section, that is deployed shall be declared in the organization's quality manual.

NOTE This standard is technically equivalent to SAE AS9100

SECTION 1

QUALITY MANAGEMENT SYSTEMS

REQUIREMENTS

(based on ISO 9001:2000)

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 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 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, 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 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 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 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.

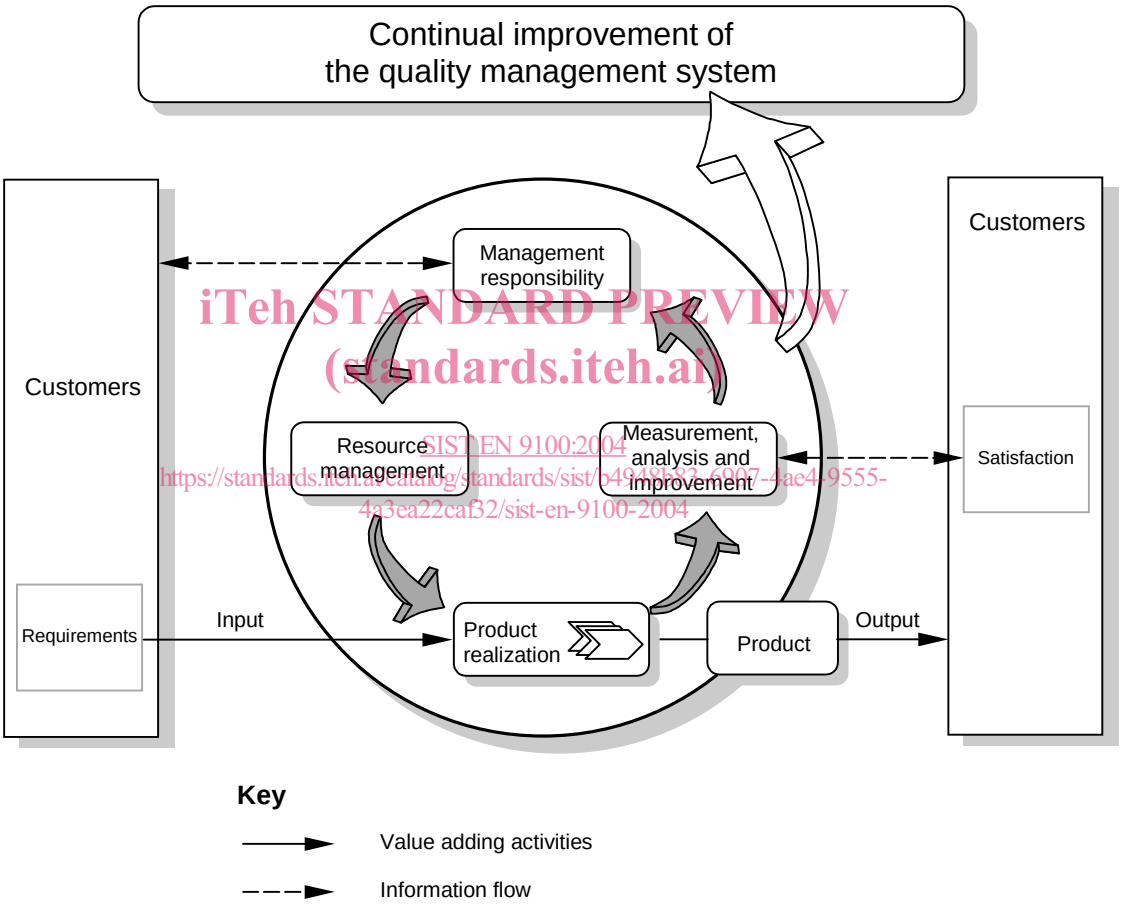

Figure 1 — Model of a process based quality management system

QUALITY MANAGEMENT SYSTEMS – REQUIREMENTS

1 Scope

1.1 General

This standard includes ISO 9001:2000 [1)] ***quality management system requirements and specifies additional requirements for a quality management system for the aerospace industry. 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 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 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 International Standard, the term "product" applies only to the product intended for, or required by, a customer.

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 regulatory requirements.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard***.*** For dated references, subsequent amendments to, or revisions of, any of these publications do not apply***.*** However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO ***(International Organization for Standardization)*** and IEC ***(International Electrotechnical Commission)*** maintain registers of currently valid International Standards.

ISO 9000: 2000 Quality management systems – Fundamentals and vocabulary

ISO 9001: 2000 Quality management systems – Requirements

EN 9130: 2000 Aerospace series – Quality systems – Record retention

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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, Case Postale 56, 1211 Geneva 20, SWITZERLAND. Copyright remains with ISO.

3 Terms and definitions

For the purposes of this International 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″.

Key characteristics:

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

4 Quality management system

0.1 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 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 International 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 International Standard,

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

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

f) quality system requirements imposed by the applicable regulatory authorities.

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

NOTE 1 Where the term "documented procedure" appears within this International 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.

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,