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)

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)



# **EESTI STANDARDI EESSÕNA**

# **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN
9100:2003 sisaldab Euroopa standardi EN
9100:2003 ingliskeelset teksti.

Käesolev dokument on jõustatud 14.08.2003 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN 9100:2003 consists of the English text of the European standard EN 9100:2003.

This document is endorsed on 14.08.2003 with the notification being published in the official publication of the Estonian national standardisation organisation.

The standard is available from Estonian standardisation organisation.

#### Käsitlusala:

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

### Scope:

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

ICS 03.120.10, 49.020

Võtmesõnad:

# **EUROPEAN STANDARD**

# **EN 9100**

# NORME EUROPÉENNE

**EUROPÄISCHE NORM** 

May 2003

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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

# Contents

		page
Forew	ord	6
Structi	ure and Application	7
SECT	TION 1: Quality management systems - Requirements (based on ISO 9001:2000)	8
n .	Introduction	
0 0.1	General	
0.2	Process approach	9
Quality	y management systems - Requirements	11
1	Scope	11
1.1	General	
1.2	Application	
2	Normative reference	11
3	Terms and definitions	12
4	Quality management system	12
4.1	General requirements	12
4.2	Documentation requirements	
4.2.1 4.2.2	Quality manual	
4.2.3	Control of documents	
4.2.4	Control of records	
4.3	Configuration management	
5	Management responsibility	
5.1 5.2	Management commitment	
5.2 5.3	Quality policy	
5.4	Planning	15
5.4.1	Quality objectives	
5.4.2 5.5	Quality management system planning  Responsibility, authority and communication	
5.5.1	Responsibility and authority	
5.5.2	Management representative	
5.5.3 5.6	Internal communication Management review	
5.6.1	General	
5.6.2	Review input	16
5.6.3	Review output	16
6	Resource management	
6.1 6.2	Provision of resources	
6.2.1	General	
6.2.2	Competence, awareness and training	
6.3	Infrastructure	
6.4	Work environment	17

		Seite
7	Product realization	17
7.1	Planning of product realization	17
7.2	Customer-related processes	18
7.2.1	Determination of requirements related to the product	18
7.2.2	Review of requirements related to the product	18
7.2.3	Customer communication	18
7.3	Design and development	19
7.3.1	Design and development planning	
7.3.2	Design and development inputs	
7.3.3	Design and development outputs	
7.3.4	Design and development review	20
7.3.5	Design and development verification	20
7.3.6	Design and development validation	21
7.3.6.1	Documentation of design and/or development verification and validation	21
7.3.6.2	Design and/or development verification and validation testing	21
7.3.7	Control of design and development changes	21
7.4	Purchasing	22
7.4.1	Purchasing process	22
7.4.2	Purchasing information	22
7.4.3	Verification of purchased product	23
7.5	Production and service provision	23
7.5.1	Control of production and service provision	23
7.5.1.1	Production documentation	24
7.5.1.2	Control of production process changes	24
7.5.1.3	Control of production equipment, tools and Numerical Control (N.C.) machine programs	
7.5.1.4	Control of work transferred, on a temporary basis, outside the organization's facilities	25
7.5.1.5	Control of service operations	
7.5.2	Validation of processes for production and service provision	25
7.5.3	Identification and traceability	
7.5.4	Customer property	26
7.5.5	Preservation of product	26
7.6	Control of monitoring and measuring devices	27
8	Measurement, analysis and improvement	29
8.1	General	
8.2	Monitoring and measurement	
8.2.1	Customer satisfaction	
8.2.2	Internal audit	
8.2.3	Monitoring and measurement of processes	
8.2.4	Monitoring and measurement of product	
8.2.4.1	Inspection documentation	
8.2.4.2	First article inspection	
8.3	Control of nonconforming product	
8.4	Analysis of data	
8. <del>5</del>	Improvement	
8.5.1	Continual improvement	
8.5.2	Corrective action	
8.5.3	Preventive action	
<b>Bibliog</b>	raphy	33

		Seite
SECT	ION 2: Quality systems –Model for Quality Assurance in design, development, production, installation and servicing (based on ISO 9001:1994)	34
Quality	systems –Model for Quality Assurance in design, development, production, installation and servicing.	35
1	Scope	35
2	Normative reference	35
2	Definitions	
3 3.1	Product	
3.2	Tender	
3.3	Contract	36
3.4	Key characteristics	36
4	Quality system requirements	36
4.1	Management responsibility	
4.1.1	Quality policy	
4.1.2	Organization	
4.1.2.1 4.1.2.2	Responsibility and authorityResources	
4.1.2.3	Management representative	
4.1.2.4	Process performer	
4.1.3	Management review	
4.2	Quality system	
4.2.1	General	
4.2.2	Quality system procedures	
4.2.3	Quality planning	
4.2.4 4.3	Configuration management  Contract review	
4.3.1	General	
4.3.2	Review	
4.3.3	Amendment to a contract	
4.3.4	Records	
4.4	Design control	
4.4.1 4.4.2	General  Design and development planning	
4.4.2.1	Design and development management planning	
4.4.2.2	Reliability, maintainability, safety	
4.4.3	Organizational and technical interfaces	40
4.4.4	Design input	
4.4.5	Design output	
4.4.6	Design review	41
4.4.7 4.4.8	Design verification	
+.4.8.1	Documentation of design verification and validation	
4.4.8.2	Design verification and validation testing	
4.4.9	Design changes	42
4.5	Document and data control	
4.5.1	General	
4.5.2	Document and data approval and issue	
4.5.3 4.6	Document and data changes  Purchasing	
4.6 4.6.1	General	
4.6.2	Evaluation of subcontractors	
4.6.3	Purchasing data	43
4.6.4	Verification of purchased product	44
4.6.4.1	Supplier verification at subcontractor's premises	
4.6.4.2	Customer verification of subcontracted product	44

		Seite
4.7	Control of customer-supplied product	44
4.8	Product identification and traceability	
4.9	Process control	45
4.9.1	General	
4.9.1.1	Production documentation	46
4.9.1.2	Control of production process changes	46
4.9.1.3	Control of production equipment, tools and Numerical Control (N.C.) machine programs	46
4.9.1.4	Control of work occasionally performed outside the supplier's facilities	
4.9.2	Special processes	
4.10	Inspection and testing	47
4.10.1	General	47
4.10.2	Receiving inspection and testing	47
4.10.3	In-process inspection and testing	48
4.10.4	Final inspection and testing	
4.10.5	Inspection and test records	48
4.10.6	First article inspection	48
4.11	Control of inspection, measuring and test equipment	
4.11.1	General	
4.11.2	Control procedure	49
4.12	Inspection and test status	
4.12.1	Authorized personnel	
4.12.2	Acceptance authority media	50
4.13	Control of nonconforming product	50
4.13.1		
4.13.2	Review and disposition of nonconforming product	51
4.13.2.	Material review authority	51
4.13.2.2	Regrading material	51
4.13.2.3		
4.13.2.4	Notification	51
4.14	Corrective and preventive action	52
4.14.1	General	52
4.14.2	Corrective action	52
4.14.3	Preventive action	52
4.15	Handling, storage, packaging, preservation and delivery	52
4.15.1	General	52
4.15.2	Handling	53
4.15.3	Storage	53
4.15.4	Packaging	53
4.15.5	Preservation	53
4.15.6	Delivery	53
4.16	Control of quality records	53
4.17	Internal quality audits	
4.18	Training	54
4.19	Servicing	
4.20	Statistical techniques	55
	Identification of need	
4.20.2	Procedures	55
Diblic	raphy	<i></i>
policia	rapny	ət

# **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, e d, li ne Unit. 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.

# { INHALT "Structure and Application" \f m} 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 { INHALT "SECTION 1: Quality management systems - Requirements (based on ISO 9001:2000)" \f m} SECTION 1

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# 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.

# EN 9100:2003 (E)

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.

> 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.

take actions to continually improve process performance.

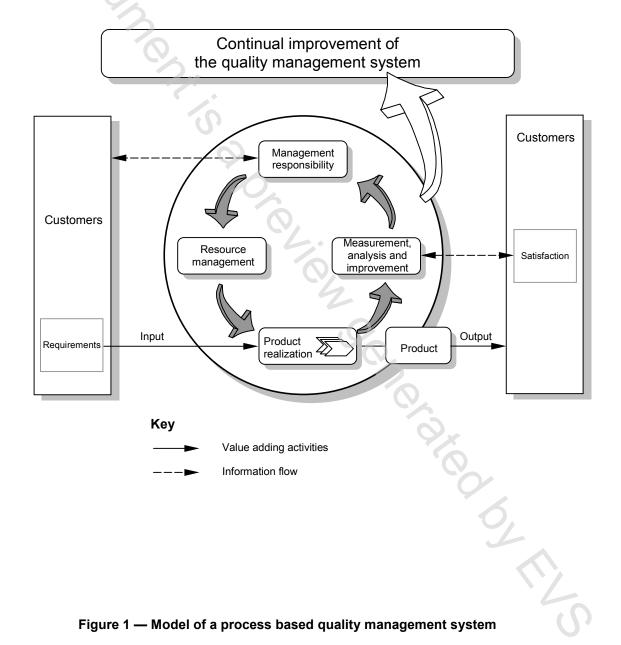


Figure 1 — Model of a process based quality management system

# { INHALT "Quality management systems - Requirements" \f m}QUALITY MANAGEMENT SYSTEMS - REQUIREMENTS

# 1 Scope

#### 1.1 General

This standard includes ISO 9001:2000 <sup>1)</sup> 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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