

SLOVENSKI STANDARD SIST EN 9120:2008

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Aerospace series - Quality management systems - Requirements for stockist distributors (based on ISO 9001:2000)

Luft- und Raumfahrt - Qualitätsmanagementsysteme - Anforderungen an Händler und Lagerhalter (basiert auf 1SO 9001 2000) DARD PREVIEW

Série aérospatiale - Systèmes de management de la qualité - Exigences pour les distributeurs stockistes (basé sur ISO 9001:2000),008

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Aerospace series - Quality management systems -Requirements for stockist distributors (based on ISO 9001:2000)

Série aérospatiale - Systèmes de management de la qualité - Exigences pour les distributeurs stockistes (basé sur ISO 9001:2000) Luft- und Raumfahrt - Qualitätsmanagementsystems -Anforderungen für Händler und Lagerhalter (basiert auf ISO 9001:2000)

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

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austra, 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. SIST EN 9120:2008

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

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Foreword

This European Standard (EN 9120:2005) 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.

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

To assure customer satisfaction, aerospace industry organizations must produce, and continually improve, safe, reliable products that meet or exceed customer and regulatory agency 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.

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 STANDARD PREVIEW

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.

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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.

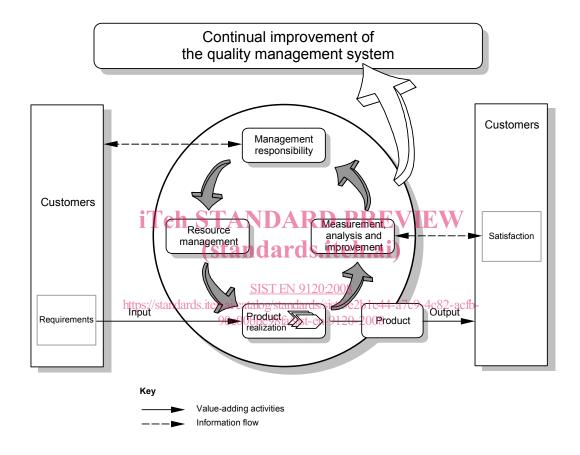


Figure 1 — Model of a Process-Based Quality Management System

1 Scope

1.1 General

This standard includes ISO 9001:2000¹⁾ quality management system requirements and specifies additional requirements for a quality management system for the aerospace industry applicable to stockist distributors. 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.

This standard is for use by organizations that procure parts, materials and assemblies and sells these products to a customer in the aerospace industry. This includes organizations that procure products and split them into smaller quantities. This standard is not intended for organizations that rework or repair products. Organizations that perform work that affect or could affect product characteristics or conformity shall use EN 9100 or another quality management system standard.

The following ISO 9001:2000 clauses are excluded in their entirety for purposes of the EN 9120 requirements for stockist distributors: 7.1, 7.3, and 7.5.2.

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.

ISO 9001:2000, Quality management systems – Requirements.

EN 9100:2001, Aerospace series – Quality management systems – Requirements (based on ISO 9001:2000).

EN 9130:2000, Aerospace series – Quality systems – Record retention. ²⁾

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.

²⁾ Published as AECMA Prestandard at the date of publication of this standard.

3 Terms and definitions

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 \rightarrow organization \rightarrow customer manufacturer

For the purpose of this document, the term manufacturer is intentionally used to clearly delineate the product creator.

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

Airworthiness Certificate: A document issued by the cognizant civil aviation authority (e.g., JAA Form 1, FAA Form 8130-3) that certifies that the part has been manufactured, overhauled, or repaired in accordance with, and conforms to, the applicable airworthiness regulations.

Manufacturer's Certificate/Test Report: A document issued by the product manufacturer that certifies product conformance to process, design, and/or specification requirements.

Splitting:

- batch splitting the separation of entities, such as sheets, bars, components, parts, fasteners, and containers belonging to the same production batch.
- product splitting physically dividing a solid entity such as bar, sheet, plate (metallic or nonmetallic material) or partial decanting of a gaseous or liquid entity, where the physical and metallurgical properties or chemical characteristics are not altered.

Splitting shall not affect the conformance of the product as defined by the original product specification.

Stockist Distributors: Organization carrying out the purchase, storage, splitting, and sale of products without affecting product conformance. The term organization in the context of this standard means a stockist distributor.

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.

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

The organization^{htt}shall^{an}ensure^h that personnel^{si}have^{b1}access⁹-to⁸²quality management system documentation and are aware of relevant procedures.⁰⁰⁸Customer and/or regulatory 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 Standard and the documented procedures shall be clearly shown.
- c) a description of the interaction between the processes of the quality management system.