

Quality systems — Model for quality assurance applicable to maintenance organizations

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British Standard

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National foreword

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English Version

**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

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Contents

Page

Foreword	3
Introduction	4
0.1 General	4
0.2 Process approach	4
1 Scope	6
1.1 General	6
1.2 Application	6
2 Normative references	6
3 Terms and definitions	7
4 Quality management system	8
4.1 General requirements	8
4.2 Documentation requirements	8
5 Management responsibility	10
5.1 Management commitment	10
5.2 Customer focus	10
5.3 Quality policy	10
5.4 Planning	10
5.5 Responsibility, authority and communication	11
5.6 Management review	11
6 Resource management	12
6.1 Provision of resources	12
6.2 Human resources	12
6.3 Infrastructure	13
6.4 Work environment	13
7 Product realization	13
7.1 Planning of product realization	13
7.2 Customer-related processes	14
7.3 Design and development	14
7.4 Purchasing	17
7.5 Production and service provision	19
7.6 Control of monitoring and measuring devices	22
8 Measurement, analysis and improvement	23
8.1 General	23
8.2 Monitoring and measurement	23
8.3 Control of nonconforming product	25
8.4 Analysis of data	26
8.5 Improvement	27
<i>Bibliography</i>	28

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of an identical text or by endorsement, at the latest by June 2006, and conflicting national standards shall be withdrawn at the latest by June 2006.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.

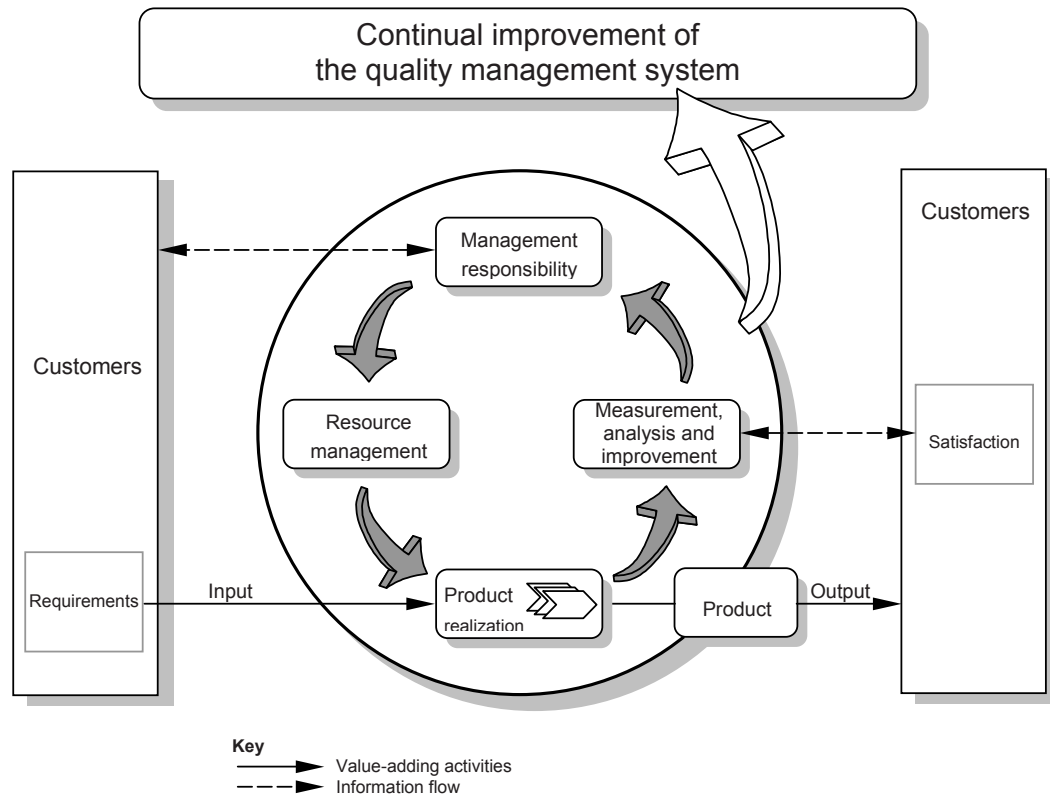


Figure 1 — Model of a process-based quality management system

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.