

STN	Systémy manažérstva kvality. Požiadavky na organizácie vykonávajúce údržbu v letectve.	STN EN 9110 31 0432
------------	---	---------------------------------------

Quality Management Systems - Requirements for Aviation Maintenance Organizations

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 07/15

Obsahuje: EN 9110:2015

Oznámením tejto normy sa ruší
STN EN 9110 (31 0432) z novembra 2010

121017

English Version

Quality Management Systems - Requirements for Aviation Maintenance Organizations

Systèmes de management de la Qualité - Exigences pour
les Organismes d'Entretien de l'Aéronautique

Qualitätsmanagementsysteme - Anforderungen für
Luffahrt-Instandhaltungsbetriebe

This European Standard was approved by CEN on 29 November 2014.

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 CEN-CENELEC 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 CEN-CENELEC Management Centre has the same status as the official versions.

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



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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

RATIONALE

This standard has been revised to address stakeholder needs through the addition of definitions and clarification of existing requirements to resolve interpretation issues, and incorporate editorial corrections.

FOREWORD

To assure customer satisfaction, aviation and defence organizations must produce, maintain, repair and continually improve, safe, reliable products that meet or exceed customer and applicable statutory and regulatory requirements. The globalization of the industry and the resulting diversity of regional and national requirements and expectations have complicated this objective. Organizations have the challenge of purchasing products from suppliers throughout the world and at all levels of the supply chain. Suppliers have the challenge of delivering products to multiple customers having varying quality requirements and expectations.

Industry has established the International Aerospace Quality Group (IAQG), with representatives from companies in the Americas, Asia/Pacific and Europe, to implement initiatives that make significant improvements in quality and reductions in cost throughout the value stream. This standard has been prepared by the IAQG.

This document standardizes quality management system requirements to the greatest extent possible and can be used at all levels of the supply chain by organizations around the world. Its use should result in improved quality, schedule, and cost performance by the reduction or elimination of organization-unique requirements and wider application of good practice. While primarily developed for the aviation and defence industry organizations providing maintenance services, this standard can also be used in other industry sectors where a quality management system with additional requirements over an ISO 9001 system is needed.

Contents

Page

RATIONALE	2
FOREWORD	2
Foreword	5
Introduction.....	6
0.1 General	6
0.2 Process approach	6
Quality management systems — Requirements	8
1 Scope	8
1.1 General	8
1.2 Application	8
2 Normative references	9
3 Terms and definitions	9
4 Quality management system.....	11
4.1 General requirements	11
4.2 Documentation requirements.....	12
4.2.1 General	12
4.2.2 Quality manual	12
4.2.3 Control of documents	13
4.2.4 Control of records	13
5 Management responsibility	14
5.1 Management commitment	14
5.2 Customer focus	14
5.3 Quality policy	14
5.4 Planning.....	14
5.4.1 Quality objectives	14
5.4.2 Quality management system planning.....	15
5.4.3 Safety objectives	15
5.5 Responsibility, authority and communication	15
5.5.1 Responsibility and authority	15
5.5.1.1 Accountable manager.....	15
5.5.1.2 Maintenance manager(s)	15
5.5.2 Management representative	15
5.5.3 Internal communication	16
5.6 Management review	16
5.6.1 General	16
5.6.2 Review input	16
5.6.3 Review output	16
5.7 Safety policy	16
6 Resource management.....	17
6.1 Provision of resources.....	17
6.2 Human resources	17
6.2.1 General	17
6.2.2 Competence, training and awareness.....	17

6.3	Infrastructure.....	18
6.4	Work environment	18
7	Product realization.....	18
7.1	Planning of product realization	18
7.1.1	Project management	19
7.1.2	Risk management	19
7.1.3	Configuration management	19
7.1.4	Control of work transfers	20
7.2	Customer-related processes	20
7.2.1	Determination of requirements related to the product	20
7.2.2	Review of requirements related to the product	20
7.2.3	Customer communication	21
7.3	Design and development	21
7.3.1	Design and development planning	21
7.3.2	Design and development inputs	21
7.3.3	Design and development outputs	22
7.3.4	Design and development review	22
7.3.5	Design and development verification	22
7.3.6	Design and development validation	23
7.3.6.1	Design and development verification and validation testing.....	23
7.3.6.2	Design and development verification and validation documentation.....	23
7.3.7	Control of design and development changes.....	23
7.4	Purchasing	23
7.4.1	Purchasing process	23
7.4.2	Purchasing information	24
7.4.3	Verification of purchased product	25
7.5	Production and service provision.....	25
7.5.1	Control of production and service provision.....	25
7.5.1.1	Maintenance process verification	27
7.5.1.2	Control of maintenance process changes	27
7.5.1.3	Control of maintenance equipment, tools, and software programs.....	27
7.5.1.4	Post-delivery support.....	27
7.5.2	Validation of processes for production and service provision	27
7.5.3	Identification and traceability	28
7.5.4	Customer property.....	28
7.5.5	Preservation of product	29
7.6	Control of monitoring and measuring equipment.....	29
8	Measurement, analysis and improvement	30
8.1	General.....	30
8.2	Monitoring and measurement	30
8.2.1	Customer satisfaction	30
8.2.2	Internal audit	31
8.2.3	Monitoring and measurement of processes	31
8.2.4	Monitoring and measurement of product	31
8.3	Control of nonconforming product.....	32
8.4	Analysis of data	33
8.5	Improvement	34
8.5.1	Continual improvement.....	34
8.5.2	Corrective action.....	34
8.5.3	Preventive action	34
9	Notes	35
	Bibliography.....	36

Figure

Figure 1 — Model of a process-based quality management system	7
---	---

Foreword

This document (EN 9110:2015) has been prepared by the Aerospace and Defence Industries Association of Europe - Standardization (ASD-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 ASD, 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 August 2015, and conflicting national standards shall be withdrawn at the latest by August 2015.

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.

This document supersedes EN 9110:2010.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey 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:

- a. its organizational environment, changes in that environment, and the risks associated with that environment,
- b. its varying needs,
- c. its particular objectives,
- d. the products it provides,
- e. the processes it employs,
- f. its size and organizational structure.

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, statutory, and regulatory requirements applicable to the product, 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 determine and manage numerous linked activities. An activity or set of activities 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 to produce the desired outcome, can be referred to as the "process approach".

An advantage of the process approach is the on-going 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.

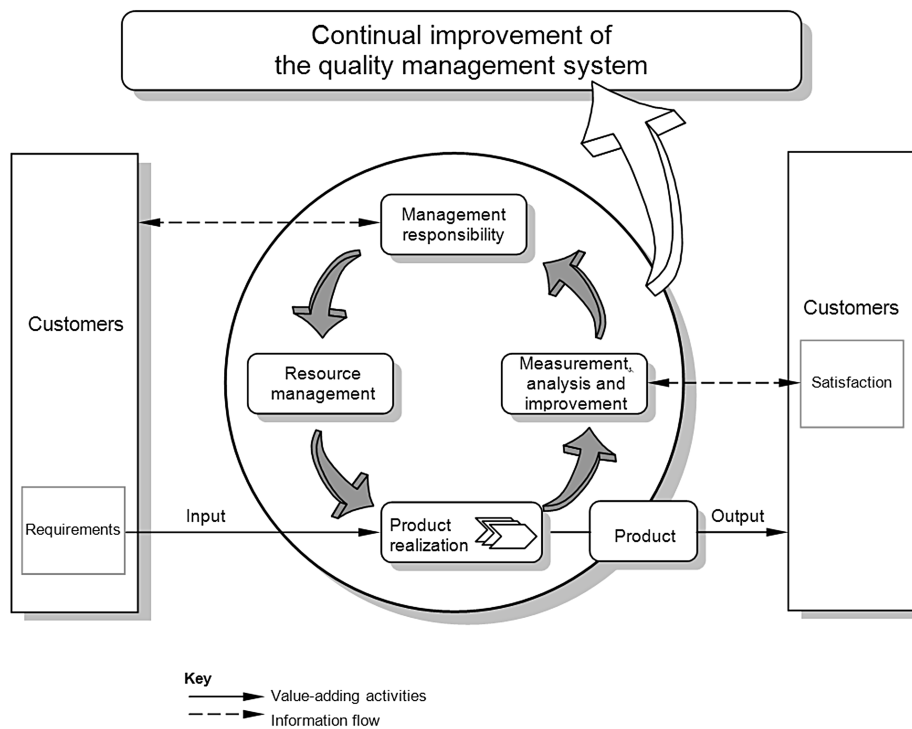


Figure 1 — Model of a process-based quality management system

Quality management systems — Requirements

1 Scope

1.1 General

This standard includes ISO 9001:2008 ¹⁾ quality management system requirements and specifies additional aviation maintenance industry requirements, definitions and notes as shown in bold, italic text.

NOTE 1 *Baseline aviation maintenance requirements originate from IAQG developed 9100:2009 standard; modifications were made, as required, to address maintenance industry specific requirements.*

It is emphasized that the requirements specified in this standard are complementary (not alternative) to contractual and applicable statutory and regulatory requirements. Should there be a conflict between the requirements of this standard and applicable statutory or regulatory requirements, the latter shall take precedence.

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 statutory and 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 statutory and regulatory requirements.

NOTE 2 In this International Standard, the term "product" only applies to:

- a. product intended for, or required by, a customer,
- b. any intended output resulting from the product realization processes.

NOTE 3 Statutory and regulatory requirements can be expressed as legal requirements.

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 statutory and regulatory requirements.

This standard has been developed to benefit maintenance organizations that choose to adopt it, whether or not holders of a National Aviation Authority (NAA) repair station certificate. This standard is intended for use by maintenance organizations whose primary business is providing maintenance services for aviation commercial and military products; and for Original Equipment Manufacturer (OEM) organizations with maintenance operated autonomously or that are substantially different from their manufacturing/production operations.

1) With the permission of the International Organization for Standardization (ISO). The complete standard can be obtained from any ISO member or from the ISO Central Secretariat: 1, Ch. de la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, SWITZERLAND, or visit www.iso.org. Copyright remains with ISO.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN