



Quality Management Systems — Requirements for Aviation, Space and Defense Organizations

Qualitätsmanagementsysteme — Anforderungen an Organisationen der
Luftfahrt, Raumfahrt und Verteidigung

Systèmes de management de la Qualité — Exigences des Organisations pour
l'Aviation, l'Espace et la Défense

Publisher and printing

Austrian Standards Institute/
Österreichisches Normungsinstitut (ON)
Heinestraße 38, 1020 Wien

Copyright © Austrian Standards Institute 2010.

All rights reserved. No part of this publication may be
reproduced or utilized in any form or by any means –
electronic, mechanical, photocopying or any other
data carries without prior permission!

E-Mail: publishing@as-plus.at

Internet: www.as-plus.at/nutzungsrechte

Sale and distribution of national and foreign
standards and technical regulations via
Austrian Standards plus GmbH

Heinestraße 38, 1020 Wien

E-Mail: sales@as-plus.at

Internet: www.as-plus.at

24-Hours-Webshop: www.as-plus.at/shop

Tel.: +43 1 213 00-444

Fax: +43 1 213 00-818

ICS 03.120.10; 49.020

Identical (IDT) with EN 9100:2009-08

Supersedes ÖNORM EN 9100:2003-10

responsible Committee 237
Aerospace

English Version

Quality Management Systems - Requirements for Aviation, Space and Defense Organizations

Systèmes de management de la Qualité - Exigences des
Organisations pour l'Aviation, l'Espace et la Défense

Qualitätsmanagementsysteme - Anforderungen an
Organisationen der Luftfahrt, Raumfahrt und Verteidigung

This European Standard was approved by CEN on 3 July 2009.

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 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 Management Centre has the same status as the official versions.

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



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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword.....	4
0 INTRODUCTION	5
0.1 General	5
0.2 Process approach	5
QUALITY MANAGEMENT SYSTEMS – REQUIREMENTS	7
1 SCOPE	7
1.1 General	7
1.2 Application	7
2 NORMATIVE REFERENCES	8
3 TERMS AND DEFINITIONS	8
3.1 <i>Risk</i>	8
3.2 <i>Special requirements</i>	8
3.3 <i>Critical items</i>	8
3.4 <i>Key characteristic</i>	9
4 QUALITY MANAGEMENT SYSTEM.....	9
4.1 General requirements	9
4.2 Documentation Requirements	10
4.2.1 General	10
4.2.2 Quality Manual	10
4.2.3 Control of Documents.....	10
4.2.4 Control of Records	11
5 MANAGEMENT RESPONSIBILITY	11
5.1 Management Commitment	11
5.2 Customer Focus	11
5.3 Quality Policy.....	12
5.4 Planning	12
5.4.1 Quality Objectives	12
5.4.2 Quality Management System Planning	12
5.5 Responsibility, Authority and Communication	12
5.5.1 Responsibility and Authority	12
5.5.2 Management Representative.....	12
5.5.3 Internal Communication	13
5.6 Management Review	13
5.6.1 General	13
5.6.2 Review Input	13
5.6.3 Review Output.....	13
6 RESOURCE MANAGEMENT.....	14
6.1 Provision of Resources	14
6.2 Human Resources	14
6.2.1 General	14
6.2.2 Competence, Training and Awareness	14
6.3 Infrastructure	14
6.4 Work Environment.....	14

7	PRODUCT REALIZATION	15
7.1	Planning of Product Realization	15
7.1.1	<i>Project Management</i>	<i>15</i>
7.1.2	<i>Risk Management</i>	<i>15</i>
7.1.3	<i>Configuration Management</i>	<i>16</i>
7.1.4	<i>Control of Work Transfers</i>	<i>16</i>
7.2	Customer-related processes	16
7.2.1	Determination of Requirements Related to the Product	16
7.2.2	Review of Requirements Related to the Product	16
7.2.3	Customer Communication	17
7.3	Design and Development	17
7.3.1	Design and Development Planning	17
7.3.2	Design and Development Inputs	18
7.3.3	Design and Development Outputs	18
7.3.4	Design and Development Review	19
7.3.5	Design and Development Verification	19
7.3.6	Design and Development Validation	19
7.3.6.1	<i>Design and Development Verification and Validation Testing</i>	<i>19</i>
7.3.6.2	<i>Design and Development Verification and Validation Documentation</i>	<i>19</i>
7.3.7	Control of Design and Development Changes	19
7.4	Purchasing	20
7.4.1	Purchasing Process	20
7.4.2	Purchasing Information	20
7.4.3	Verification of Purchased Product	21
7.5	Production and Service Provision	22
7.5.1	Control of Production and Service Provision	22
7.5.1.1	<i>Production Process Verification</i>	<i>22</i>
7.5.1.2	<i>Control of Production Process Changes</i>	<i>23</i>
7.5.1.3	<i>Control of Production Equipment, Tools and Software Programs</i>	<i>23</i>
7.5.1.4	<i>Post-Delivery Support</i>	<i>23</i>
7.5.2	Validation of Processes for Production and Service Provision	23
7.5.3	Identification and Traceability	24
7.5.4	Customer Property	24
7.5.5	Preservation of Product	24
7.6	Control of Monitoring and Measuring Equipment	25
8	MEASUREMENT, ANALYSIS AND IMPROVEMENT	26
8.1	General	26
8.2	Monitoring and Measurement	26
8.2.1	Customer Satisfaction	26
8.2.2	Internal Audit	26
8.2.3	Monitoring and Measurement of Processes	27
8.2.4	Monitoring and Measurement of Product	27
8.3	Control of Nonconforming Product	28
8.4	Analysis of Data	29
8.5	Improvement	29
8.5.1	Continual Improvement	29
8.5.2	Corrective Action	30
8.5.3	Preventive Action	30
	BIBLIOGRAPHY	31

Foreword

This document (EN 9100:2009) 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 February 2010, and conflicting national standards shall be withdrawn at the latest by February 2010.

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 9100:2003.

This standard has been revised to incorporate the requirements of ISO 9001:2008. In addition, industry requirements, definitions and notes have been revised and additional requirements have been included in response to stakeholder needs.

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, space and defense industry, 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.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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

- 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 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.

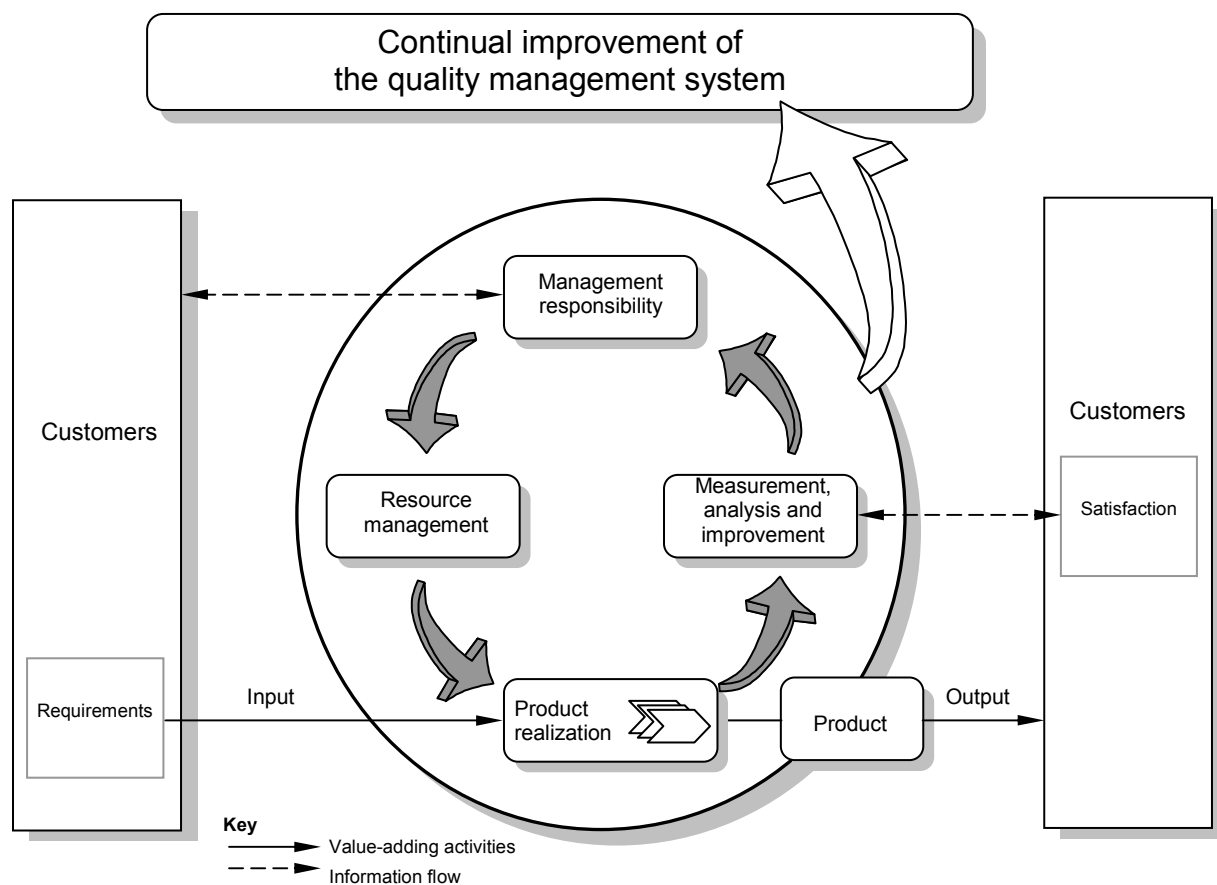


Figure 1 — Model of a process-based quality management system