

INTERNATIONAL STANDARD

ISO 9001

Fifth edition
2015-09-15

Quality management systems — Requirements

Systèmes de management de la qualité — Exigences



Reference number
ISO 9001:2015(E)

This is a preview. [Click here to purchase the full publication.](#)

© ISO 2015



COPYRIGHT PROTECTED DOCUMENT

© ISO 2015, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Context of the organization	1
4.1 Understanding the organization and its context.....	1
4.2 Understanding the needs and expectations of interested parties.....	2
4.3 Determining the scope of the quality management system.....	2
4.4 Quality management system and its processes.....	2
5 Leadership	3
5.1 Leadership and commitment.....	3
5.1.1 General.....	3
5.1.2 Customer focus.....	3
5.2 Policy.....	4
5.2.1 Establishing the quality policy.....	4
5.2.2 Communicating the quality policy.....	4
5.3 Organizational roles, responsibilities and authorities.....	4
6 Planning	4
6.1 Actions to address risks and opportunities.....	4
6.2 Quality objectives and planning to achieve them.....	5
6.3 Planning of changes.....	5
7 Support	6
7.1 Resources.....	6
7.1.1 General.....	6
7.1.2 People.....	6
7.1.3 Infrastructure.....	6
7.1.4 Environment for the operation of processes.....	6
7.1.5 Monitoring and measuring resources.....	7
7.1.6 Organizational knowledge.....	7
7.2 Competence.....	8
7.3 Awareness.....	8
7.4 Communication.....	8
7.5 Documented information.....	8
7.5.1 General.....	8
7.5.2 Creating and updating.....	9
7.5.3 Control of documented information.....	9
8 Operation	9
8.1 Operational planning and control.....	9
8.2 Requirements for products and services.....	10
8.2.1 Customer communication.....	10
8.2.2 Determining the requirements for products and services.....	10
8.2.3 Review of the requirements for products and services.....	10
8.2.4 Changes to requirements for products and services.....	11
8.3 Design and development of products and services.....	11
8.3.1 General.....	11
8.3.2 Design and development planning.....	11
8.3.3 Design and development inputs.....	11
8.3.4 Design and development controls.....	12
8.3.5 Design and development outputs.....	12
8.3.6 Design and development changes.....	12

8.4	Control of externally provided processes, products and services.....	13
8.4.1	General.....	13
8.4.2	Type and extent of control.....	13
8.4.3	Information for external providers.....	13
8.5	Production and service provision.....	14
8.5.1	Control of production and service provision.....	14
8.5.2	Identification and traceability.....	14
8.5.3	Property belonging to customers or external providers.....	15
8.5.4	Preservation.....	15
8.5.5	Post-delivery activities.....	15
8.5.6	Control of changes.....	15
8.6	Release of products and services.....	15
8.7	Control of nonconforming outputs.....	16
9	Performance evaluation.....	16
9.1	Monitoring, measurement, analysis and evaluation.....	16
9.1.1	General.....	16
9.1.2	Customer satisfaction.....	17
9.1.3	Analysis and evaluation.....	17
9.2	Internal audit.....	17
9.3	Management review.....	18
9.3.1	General.....	18
9.3.2	Management review inputs.....	18
9.3.3	Management review outputs.....	18
10	Improvement.....	19
10.1	General.....	19
10.2	Nonconformity and corrective action.....	19
10.3	Continual improvement.....	19
Annex A (informative) Clarification of new structure, terminology and concepts.....		21
Annex B (informative) Other International Standards on quality management and quality management systems developed by ISO/TC 176.....		25
Bibliography.....		28

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This fifth edition cancels and replaces the fourth edition (ISO 9001:2008), which has been technically revised, through the adoption of a revised clause sequence and the adaptation of the revised quality management principles and of new concepts. It also cancels and replaces the Technical Corrigendum ISO 9001:2008/Cor.1:2009.