



Institut luxembourgeois de la normalisation  
de l'accréditation, de la sécurité et qualité  
des produits et services

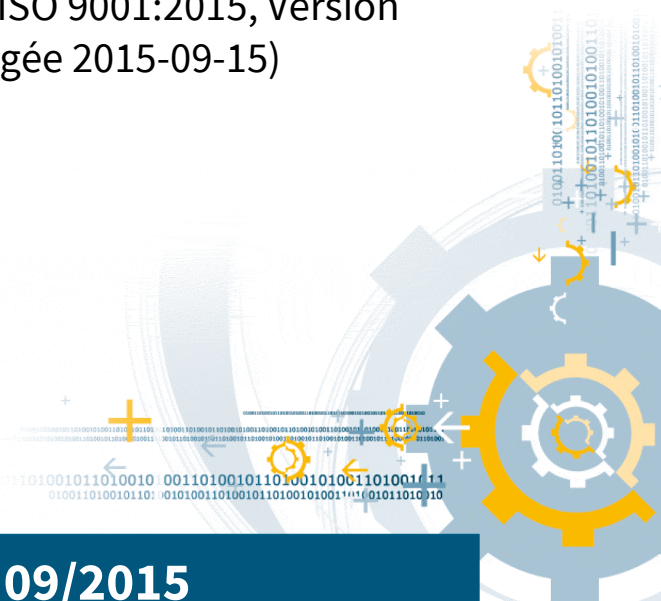
## ILNAS-EN ISO 9001:2015

### Quality management systems - Requirements (ISO 9001:2015)

Qualitätsmanagementsysteme -  
Anforderungen (ISO 9001:2015)

Systèmes de management de la qualité -  
Exigences (ISO 9001:2015, Version  
corrigée 2015-09-15)

09/2015



## National Foreword

This European Standard EN ISO 9001:2015 was adopted as Luxembourgish Standard ILNAS-EN ISO 9001:2015.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

<https://portail-qualite.public.lu/fr/normes-normalisation/participer-normalisation.html>

### **THIS PUBLICATION IS COPYRIGHT PROTECTED**

Nothing from this publication may be reproduced or utilized in any form or by any mean - electronic, mechanical, photocopying or any other data carries without prior permission!

ILNAS-EN ISO 9001:2015

EUROPEAN STANDARD **EN ISO 9001**

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2015

ICS 03.120.10

Supersedes EN ISO 9001:2008

English Version

**Quality management systems - Requirements (ISO 9001:2015)**

Systèmes de management de la qualité - Exigences (ISO 9001:2015)

Qualitätsmanagementsysteme - Anforderungen (ISO 9001:2015)

This European Standard was approved by CEN on 14 September 2015.

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**

Contents	Page
European foreword.....	3

## European foreword

This document (EN ISO 9001:2015) has been prepared by Technical Committee ISO/TC 176 "Quality management and quality assurance".

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 March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.

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 ISO 9001:2008.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

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.

## Endorsement notice

The text of ISO 9001:2015 has been approved by CEN as EN ISO 9001:2015 without any modification.

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)

© 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

<b>Foreword</b>	<b>v</b>
<b>Introduction</b>	<b>vi</b>
<b>1 Scope</b>	<b>1</b>
<b>2 Normative references</b>	<b>1</b>
<b>3 Terms and definitions</b>	<b>1</b>
<b>4 Context of the organization</b>	<b>1</b>
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
<b>5 Leadership</b>	<b>3</b>
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
<b>6 Planning</b>	<b>4</b>
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
<b>7 Support</b>	<b>6</b>
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
<b>8 Operation</b>	<b>9</b>
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
<b>9</b>	<b>Performance evaluation .....</b>	<b>16</b>
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
<b>10</b>	<b>Improvement.....</b>	<b>19</b>
10.1	General.....	19
10.2	Nonconformity and corrective action.....	19
10.3	Continual improvement.....	19
	<b>Annex A (informative) Clarification of new structure, terminology and concepts.....</b>	<b>21</b>
	<b>Annex B (informative) Other International Standards on quality management and quality management systems developed by ISO/TC 176 .....</b>	<b>25</b>
	<b>Bibliography .....</b>	<b>28</b>

## 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](http://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](http://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](http://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.