

ILNAS

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

ILNAS-EN ISO 9001:2000

Quality management systems - Requirements (ISO 9001:2000)

Qualitätsmanagementsysteme -
Anforderungen (ISO 9001:2000)

Systèmes de management de la qualité -
Exigences (ISO 9001:2000)

12/2000



National Foreword

This European Standard EN ISO 9001:2000 was adopted as Luxembourgish Standard ILNAS-EN ISO 9001:2000.

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
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ILNAS-EN ISO 9001:2000

EUROPEAN STANDARD **EN ISO 9001**

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2000

ICS 00.012.10

Supersedes EN ISO 9001:1994, EN ISO 9002:1994 and
EN ISO 9003:1994

English version

**Quality management systems – Requirements
(ISO 9001:2000)**

Systèmes de management de la qualité – Exigences
(ISO 9001:2000)

Qualitätsmanagementsysteme – Anforderungen
(ISO 9001:2000)

This European Standard was approved by CEN on 15 December 2000.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of the International Standard ISO 9001:2000 has been prepared by Technical Committee ISO/TC 176 "Quality management and quality assurance", Subcommittee 2 "Quality systems". The transposition into a European Standard has been managed by the CEN Management Centre (CMC) with the assistance of CEN/BT WG 107.

This European Standard supersedes EN ISO 9001:1994, EN ISO 9002:1994 and EN ISO 9003:1994.

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 2001, and conflicting national standards shall be withdrawn at the latest by June 2001.

NOTE The following is specifically intended for organizations that need to comply with "New Approach" European Directives in order to affix CE marking on their products and to the other parties involved in that process.

The publication of EN ISO 9001:2000 has implications for Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives. It is important to note that the modules used in individual technical harmonization directives may vary in some respects compared to those described in Council Decision 93/465/EEC. In all cases, it is the annex of the applicable directive(s) which is legally binding. The principles set out in this foreword remain valid regardless of these variations.

Three of the modules cited in Council Decision, i.e. modules E, D and H, require that "the manufacturer must operate an approved quality system". The scope of the quality systems required by these modules addresses:

- Final product inspection and testing (module E)
- Production, final inspection and testing (module D),
- Design manufacture and final product inspection and testing (module H).

Council decision 93/465/EEC specifies that conformity to the harmonized standards EN 29001, EN 29002 or EN 29003 provides a presumption of conformity to the relevant requirements of modules H, D and E.

EN 29001, EN 29002 and EN 29003 were superseded by EN ISO 9001:1994, EN ISO 9002:1994 and EN ISO 9003:1994 respectively, which in turn are now superseded by EN ISO 9001:2000.

Where organizations wish to implement quality management systems in conformance with modules E, D or H, they may use EN ISO 9001:2000. In seeking compliance with modules D, E or H organizations may exclude specific requirements.

Only those requirements in clause 7 of EN ISO 9001:2000 pertaining to the difference between modules E, D and H may be excluded whilst retaining the presumption of conformity.

Module E Permissible exclusions	Module D Permissible exclusions	Module H Permissible exclusions
Sub-clause 7.1: planning of product realization Sub-clause 7.2.3: customer communication Sub-clause 7.3: design and development Sub-clause 7.4 purchasing Sub-clause 7.5.1: control of production and service provision Sub-clause 7.5.2: validation of processes for production and service provision Sub-clause 7.5.3: identification and traceability	Sub-clause 7.3: design and development	NO exclusions permitted

It should be noted that no explicit requirements in modules H, D and E relate to the concepts of "customer satisfaction" and "continual improvement". As a consequence, non compliance with requirements of EN ISO 9001:2000 explicitly related to these concepts does not infringe upon the presumption of conformity to the appropriate module

It should be noted that where the exclusions described in sub-clause 1.2 of EN ISO 9001:2000 are exceeded, conformity to EN ISO 9001:2000 shall not be claimed.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 9001:2000 has been approved by CEN as a European Standard without any modifications.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

(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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This third edition of ISO 9001 cancels and replaces the second edition (ISO 9001:1994) together with ISO 9002:1994 and ISO 9003:1994. It constitutes a technical revision of these documents. Those organizations which have used ISO 9002:1994 and ISO 9003:1994 in the past may use this International Standard by excluding certain requirements in accordance with 1.2.

The title of ISO 9001 has been revised in this edition and no longer includes the term "Quality assurance". This reflects the fact that the quality management system requirements specified in this edition of ISO 9001, in addition to quality assurance of product, also aim to enhance customer satisfaction.

Annexes A and B of this International Standard are for information only.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
ISO 9000	2000	Quality management systems – Fundamentals and vocabulary	EN ISO 9000	2000

ILNAS-EN ISO 9001:2000
**INTERNATIONAL
STANDARD**

**ISO
9001**

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**Quality management systems —
Requirements**

Systèmes de management de la qualité — Exigences



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