
geregistreeerde
Belgische norm

NBN EN ISO 9001 E

2e uitg., juli 1994

Normklasse : X 50

Kwaliteitssystemen - Model voor de kwaliteitsborging bij het ontwerpen, het ontwikkelen, het vervaardigen, het installeren en de nazorg (ISO 9001:1994)

Quality systems - Model for quality assurance in design, development, production, installation and servicing (ISO 9001:1994)

Toelating tot publikatie : 26 juli 1994.

Vervangt NBN-EN 29001 (1990).

Deze Europese norm EN ISO 9001 : 1994 heeft de status van een Belgische norm.

Deze Europese norm bestaat in drie officiële versies (Duits, Engels, Frans).



Belgisch instituut voor normalisatie (BIN), vereniging zonder winstoogmerk
Brabançonnelaan 29 - 1040 BRUSSEL - telefoon (02) 734 92 05 - prk. 000-0063310-66

norme belge
enregistrée

NBN EN ISO 9001 E

2e éd., juillet 1994

Indice de classement : X 50

Systèmes qualité - Modèle pour l'assurance de la qualité en conception, développement, production, installation et prestations associées (ISO 9001:1994)

Quality systems - Model for quality assurance in design, development, production, installation and servicing (ISO 9001:1994)

Autorisation de publication : 26 juillet 1994.

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La présente norme européenne EN ISO 9001 : 1994 a le statut d'une norme belge.

La présente norme européenne existe en trois versions officielles (allemand, anglais, français).



Institut belge de normalisation (IBN), association sans but lucratif
avenue de la Brabançonne 29 - 1040 BRUXELLES - Tél. (02) 734 92 05 - CCP 000-0063310-66

EUROPEAN STANDARD

EN ISO 9001

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 1994

UDC

Supersedes EN 29001:1987

Descriptors:

English version

**Quality systems - Model for quality assurance in
design, development, production, installation and
servicing (ISO 9001:1994)**

Systèmes qualité - Modèle pour l'assurance de
la qualité en conception, développement,
production, installation et prestation
associées (ISO 9001:1994)

Qualitätsmanagementsysteme - Modell zur
Darlegung des Qualitätsmanagementsystems in
Design, Entwicklung, Produktion, Montage und
Kundendienst (ISO 9001:1994)

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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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.

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.

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

This second edition cancels and replaces the first edition (ISO 9001:1987), which has been technically revised.

Annex A of this International Standard is for information only.

Introduction

This International Standard is one of three International Standards dealing with quality system requirements that can be used for external quality assurance purposes. The quality assurance models, set out in the three International Standards listed below, represent three distinct forms of quality system requirements suitable for the purpose of a supplier demonstrating its capability, and for the assessment of the capability of a supplier by external parties.

- a) ISO 9001, *Quality systems — Model for quality assurance in design, development, production, installation and servicing*
 - for use when conformance to specified requirements is to be assured by the supplier during design, development, production, installation and servicing.
- b) ISO 9002, *Quality systems — Model for quality assurance in production, installation and servicing*
 - for use when conformance to specified requirements is to be assured by the supplier during production, installation and servicing.
- c) ISO 9003, *Quality systems — Model for quality assurance in final inspection and test*
 - for use when conformance to specified requirements is to be assured by the supplier solely at final inspection and test.

It is emphasized that the quality system requirements specified in this International Standard, ISO 9002 and ISO 9003 are complementary (not alternative) to the technical (product) specified requirements. They specify requirements which determine what elements quality systems have to encompass, but it is not the purpose of these International Standards to enforce uniformity of quality systems. They are generic and independent of any specific industry or economic sector. The design and implementation of a quality system will be influenced by the varying needs of an organization, its particular objectives, the products and services supplied, and the processes and specific practices employed.

It is intended that these International Standards will be adopted in their present form, but on occasions they may need to be tailored by adding or deleting certain quality system requirements for specific contractual situations. ISO 9000-1 provides guidance on such tailoring as well as on selection of the appropriate quality assurance model, viz. ISO 9001, ISO 9002 or ISO 9003.

Quality systems — Model for quality assurance in design, development, production, installation and servicing

1 Scope

This International Standard specifies quality system requirements for use where a supplier's capability to design and supply conforming product needs to be demonstrated.

The requirements specified are aimed primarily at achieving customer satisfaction by preventing non-conformity at all stages from design through to servicing.

This International Standard is applicable in situations when

- a) design is required and the product requirements are stated principally in performance terms, or they need to be established, and
- b) confidence in product conformance can be attained by adequate demonstration of a supplier's capabilities in design, development, production, installation and servicing.

NOTE 1 For informative references, see annex A.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1994, *Quality management and quality assurance — Vocabulary*.

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8402 and the following definitions apply.

3.1 product: Result of activities or processes.

NOTES

2 A product may include service, hardware, processed materials, software or a combination thereof.

3 A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.

4 For the purposes of this International Standard, the term "product" applies to the intended product offering only and not to unintended "by-products" affecting the environment. This differs from the definition given in ISO 8402.

3.2 tender: Offer made by a supplier in response to an invitation to satisfy a contract award to provide product.

3.3 contract: Agreed requirements between a supplier and customer transmitted by any means.

4 Quality system requirements

4.1 Management responsibility

4.1.1 Quality policy

The supplier's management with executive responsibility shall define and document its policy for quality,