

Quality management and quality assurance standards

Part 3. Guidelines for the application of ISO 9001 : 1994 to the development, supply, installation and maintenance of computer software

The European Standard EN ISO 9000-3 : 1997 has the status of a
British Standard

ICS 03.120.10; 35.080



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National foreword

This British Standard is the English language version of EN ISO 9000-3 : 1997. It is identical with ISO 9000-3 : 1997. It supersedes BS 5750 : Part 13 : 1991 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee QS/1, Quality management and quality assurance procedures, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled 'International Standards Correspondence Index', or by using the 'Find' facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

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Summary of pages

The following table identifies the current issue of each page. Issue 1 indicates that a page has been introduced for the first time by amendment. Subsequent issue numbers indicate an updated page. Vertical sidelining on replacement pages indicates the most recent changes (amendment, addition, deletion).

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English version

Quality management and quality assurance standards - Part 3:
Guidelines for the application of ISO 9001:1994 to the
development, supply, installation and maintenance of computer
software (ISO 9000-3:1997)

Normes pour le management de la qualité et l'assurance
de la qualité - Partie 3: Lignes directrices pour l'application
de l'ISO 9001:1994 au développement, à la mise à
disposition, à l'installation et à la maintenance de logiciel
(ISO 9000-3:1997)

This European Standard was approved by CEN on 5 January 1998.

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 Central Secretariat 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 Central Secretariat 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
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Foreword

The text of the International Standard ISO 9000-3 : 1997 has been prepared by Technical Committee ISO/TC 176, Quality management and quality assurance, in collaboration with CEN/CS.

This European Standard supersedes EN 29000-3 : 1993.

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 1998, and conflicting national standards shall be withdrawn at the latest by June 1998.

According to CEN/CENELEC Internal Regulations, 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 9000-3 : 1997 was approved by CEN as a European Standard without any modification.

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

INTERNATIONAL STANDARD

**ISO
9000-3**

Second edition
1997-12-15

Quality management and quality assurance standards —

Part 3:

Guidelines for the application of
ISO 9001:1994 to the development, supply,
installation and maintenance of computer
software

Normes pour le management de la qualité et l'assurance de la qualité —

*Partie 3: Lignes directrices pour l'application de l'ISO 9001:1994 au
développement, à la mise à disposition, à l'installation et à la maintenance
de logiciel*



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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 9000-3 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 9000-3:1991), which has been technically revised.

ISO 9000 consists of the following parts, under the general title *Quality management and quality assurance standards*:

- *Part 1: Guidelines for selection and use*
- *Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003*
- *Part 3: Guidelines for the application of ISO 9001:1994 to the development, supply, installation and maintenance of computer software*
- *Part 4: Guide to dependability programme management.*

Annexes A and B of this part of ISO 9000 are for information only.



Introduction

This part of ISO 9000 provides guidance in applying the requirements of ISO 9001:1994 where computer software design, development, installation and maintenance are an element of the business of a supplier:

- a) as part of a commercial contract with an external organization;
- b) as a product available for a market sector;
- c) in support of the business processes of the supplier;
- d) as software embedded in a hardware product.

It identifies the issues which need to be addressed and is independent of the technology, life cycle models, development processes, sequence of activities, or organization structure used by a supplier.

Where the scope of an organization's activities includes areas other than computer software development, the relationship between the computer software elements of that organization's quality system and the remaining aspects should be clearly documented within the quality system as a whole.

This part of ISO 9000 provides guidelines for the application of ISO 9001:1994. **Where text has been quoted from ISO 9001:1994, that text is enclosed in a box, for ease of identification.**

Throughout this part of ISO 9000, "shall" is used to express a provision that is binding between two or more parties; "will" to express a declaration of purpose, or intent, of one party; "should" to express a recommendation among possibilities; and "may" to indicate a course of action permissible within the limits of this parts of ISO 9000.

Quality management and quality assurance standards —

Part 3:

Guidelines for the application of ISO 9001:1994 to the development, supply, installation and maintenance of computer software

1 Scope

This part of ISO 9000 sets out guidelines to facilitate the application of ISO 9001:1994 for organizations developing, supplying, installing and maintaining computer software. It does not add to, or otherwise change, the requirements of ISO 9001.

This part of ISO 9000 is not intended to be used as assessment criteria in quality system registration/certification.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 9000. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 9000 are encouraged to investigate the possibility of applying the most recent edition of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

ISO 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing*.

3 Definitions

For the purposes of this part of ISO 9000, the definitions given in ISO 8402 and the following definitions apply.

3.1 product: Result of activities or processes.

NOTE 1 A product may include service, hardware, processed materials, software or a combination thereof.

NOTE 2 A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.

NOTE 3 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.

[ISO 9001]

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

[ISO 9001]



3.3 contract: Agreed requirements between a supplier and customer transmitted by any means.
[ISO 9001]

3.4 baseline: A formally approved version of a configuration item, regardless of media, formally designated and fixed at a specific time during the configuration item's life cycle.
[ISO/IEC 12207]

3.5 development: Software life cycle process that comprises the activities of requirements analysis, design, coding, integration, testing, installation and support for acceptance of software products.

3.6 life cycle model: A framework containing the processes, activities, and tasks involved in the development, operation, and maintenance of a software product, spanning the life of the system from the definition of its requirements to the termination of its use.
[ISO/IEC 12207]

3.7 phase: Defined segment of work.

NOTE — A phase does not imply the use of any specific life cycle model.

3.8 regression testing: Testing to determine that changes made in order to correct defects have not introduced additional defects.

3.9 replication: Copying a software product from one medium to another.

3.10 software: See software product (3.11).

NOTE — In this part of ISO 9000, the term “software” is confined to computer software.

3.11 software product: The set of computer programs, procedures, and possibly associated documentation and data.
[ISO/IEC 12207]

NOTE — A software product may be designated for delivery, an integral part of another product, or used in the development process.

3.12 software item: Any identifiable part of a software product.

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 including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organizational goals and the expectations and needs of its customers. The supplier shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

No further software-related guidance is provided.

4.1.2 Organization

4.1.2.1 Responsibility and authority

The responsibility, authority and the interrelation of personnel who manage, perform and verify work affecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to:

- a) initiate action to prevent the occurrence of any nonconformities relating to product, process and quality system;
- b) identify and record any problems relating to the product, process and quality system;
- c) initiate, recommend or provide solutions through designated channels;
- d) verify the implementation of solutions;
- e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

No further software-related guidance is provided.

4.1.2.2 Resources

The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18), for management, performance of work and verification activities including internal quality audits.

No further software-related guidance is provided.

NOTE — For further information see ISO/IEC 12207:1995, subclause 7.2.

4.1.2.3 Management representative

The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for:

- a) ensuring that a quality system is established, implemented and maintained in accordance with this International Standard, and;
- b) reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system.

NOTE 5 The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system.

No further software-related guidance is provided.

NOTE — For further information, see ISO/IEC 12207:1995, subclause 6.3.1.6.

4.1.3 Management review

The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the supplier's stated quality policy and objectives (see 4.1.1). Records of such reviews shall be maintained (see 4.16).



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No further software-related guidance is provided.

NOTE — For further information, see ISO/IEC 12207:1995, subclause 7.1.4.

4.2 Quality system

4.2.1 General

The supplier shall establish, document and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

NOTE 6 Guidance on quality manuals is given in ISO 10013.

No further software-related guidance is provided.

4.2.2 Quality system procedures

The supplier shall:

- a) prepare documented procedures consistent with the requirements of this International Standard and the supplier's stated quality policy, and;
- b) effectively implement the quality system and its documented procedures.

For the purpose of this International Standard, the range and detail of the procedures that form part of the quality system shall be dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity.

NOTE 7 Documented procedures may make reference to work instructions that define how an activity is performed.

No further software-related guidance is provided.

4.2.3 Quality planning

The supplier shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation. The supplier shall give consideration to the following activities, as appropriate, in meeting the specified requirements for products, projects or contracts:

- a) the preparation of quality plans;
- b) the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required quality;
- c) ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation.
- d) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation;
- e) the identification of any measurement requirement involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed;