INTERNATIONAL STANDARD

ISO/IEC 90003

First edition
2004-02-15

Software engineering — Guidelines for the application of ISO 9001:2000 to computer software

Ingénierie du logiciel — Lignes directrices pour l'application de l'ISO 9001:2000 aux logiciels informatiques

Reference number
ISO/IEC 90003:2004(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

In the field of information technology, ISO and IEC have established a joint technical committee, ISO/IEC JTC 1. Draft International Standards adopted by the joint technical committee are circulated to national bodies for voting. Publication as an International Standard requires approval by at least 75 % of the national bodies casting a vote.

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

ISO/IEC 90003 was prepared by Joint Technical Committee ISO/IEC JTC 1, *Information technology*, Subcommittee SC 7, *Software and system engineering*.

This first edition of ISO/IEC 90003 cancels and replaces ISO 9000-3:1997, which has been updated for conformity with ISO 9001:2000. ISO 9000-3:1997 was under the responsibility of ISO/TC 176/SC 2.

Introduction

This International Standard provides guidance for organizations in the application of ISO 9001:2000 to the acquisition, supply, development, operation and maintenance of computer software.

It identifies the issues which should be addressed and is independent of the technology, life cycle models, development processes, sequence of activities and organizational structure used by an organization. The guidance and identified issues are intended to be comprehensive but not exhaustive. 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 management system and the remaining aspects should be clearly documented within the quality management system as a whole.

Clauses 4, 5 and 6 and parts of clause 8 of ISO 9001:2000 are applied mainly at the "global" level in the organization, although they do have some effect at the "project/product level". Each project or product development may tailor the associated parts of the organization's quality management system, to suit project/product-specific requirements.

Throughout ISO 9001:2000, "shall" is used to express a provision that is binding between two or more parties, "should" to express a recommendation among possibilities and "may" to indicate a course of action permissible within the limits of ISO 9001:2000. In this International Standard (ISO/IEC 90003), "should" and "may" have the same meaning as in ISO 9001:2000, i.e. "should" to express a recommendation among possibilities and "may" to indicate a course of action permissible within the limits of this International Standard.

Organizations with quality management systems for developing, operating or maintaining software based on this International Standard may choose to use processes from ISO/IEC 12207 and ISO/IEC 12207:1995/Amd.1:2002 to support or complement the ISO 9001:2000 process model. It should be noted that the quality management process defined in ISO/IEC 12207:1995/Amd.1:2002, F.3.1.4 is not consistent with the definition of quality management in ISO 9000, ISO 9001 and other ISO/TC 176 standards. The related paragraphs of ISO/IEC 12207:1995/Amd.1:2002 are referenced in each clause of this International Standard; however, they are not intended to imply requirements additional to those in ISO 9001:2000. Further guidance to the use of ISO/IEC 12207 may be found in ISO/IEC TR 15271. For additional guidance, frequent references are provided to the International Standards for software engineering defined by ISO/IEC JTC 1/SC 7 and in particular ISO/IEC 9126-1, ISO/IEC TR 9126-2, ISO/IEC TR 9126-3, ISO/IEC TR 9126-4, ISO/IEC 15939 and ISO/IEC 15504 (all parts). Where these references are specific to a clause or subclause of ISO 9001:2000 they appear after the guidance for that clause or subclause. Where they apply generally across the parts of a clause or subclause, the references are included at the end of the last part of the clause or subclause.

Where text has been quoted from ISO 9001:2000, that text is enclosed in a box, for ease of identification.

Software engineering — Guidelines for the application of ISO 9001:2000 to computer software

1 Scope

1.1 General

ISO 9001:2000, Quality management systems — Requirements

1.1 General

This International Standard specifies requirements for a quality management system where an organization

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

NOTE In this International Standard, the term "product" applies only to the product intended for, or required by, a customer.

This International Standard provides guidance for organizations in the application of ISO 9001:2000 to the acquisition, supply, development, operation and maintenance of computer software and related support services. It does not add to or otherwise change the requirements of ISO 9001:2000.

Annex A (informative) provides a table pointing to additional guidance in the implementation of ISO 9001:2000 available in ISO/IEC JTC 1/SC 7 and ISO/TC 176 standards.

The guidelines provided in this International Standard are not intended to be used as assessment criteria in quality management system registration/certification.

1.2 Application

ISO 9001:2000, Quality management systems — Requirements

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

The application of this International Standard is appropriate to software that is

— part of a commercial contract with another organization,

— a product available for a market sector,

— used to support the processes of an organization,

— embedded in a hardware product, or

— related to software services.

Some organizations may be involved in all of the above activities; others may specialize in one area. Whatever the situation, the organization's quality management system should cover all aspects (software related and non-software related) of the business.

2 Normative references

ISO 9001:2000, Quality management systems — Requirements

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*.

3 Terms and definitions

ISO 9001:2000, Quality management systems — Requirements

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.

The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:

supplier → **organization** → **customer**

The term "organization" replaces the term "supplier" used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor".

Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".

For the purposes of this document, the terms and definitions given in ISO 9001:2000, and certain terms (repeated here for convenience) given in ISO/IEC 12207 apply.

However, in the event of a conflict in terms and definitions, the terms and definitions specified in ISO 9000:2000 apply.

NOTE ISO/IEC 12207:1995 provides detailed provisions for seventeen software life cycle processes. ISO/IEC 12207:1995/Amd.1:2002 provides high-level provisions for many additional processes. This International Standard will make reference to terms defined in both.

3.1
activity
collection of related tasks

3.2
baseline
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 12207:1995, definition 3.5]

3.3
configuration item
entity within a configuration that satisfies an end use function and that can be uniquely identified at a given reference point

[ISO/IEC 12207:1995, definition 3.6]

3.4
COTS
Commercial-Off-The-Shelf (acronym)
⟨software product⟩ available for purchase and use without the need to conduct development activities

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

3.6
life cycle model
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 12207:1995, definition 3.11]

NOTE The requirements of ISO 9001:2000 would apply to maintenance, only if contractually required, after acceptance of the product by the customer. However, generally the requirements do not apply to maintenance.

3.7
measure, verb
make a measurement

[ISO/IEC 14598-1:1999, definition 4.17]

3.8
measure, noun
variable to which a value is assigned as the result of measurement

[ISO/IEC 15939:2002, definition 3.14]

3.9
measurement
set of operations having the object of determining a value of a measure

[ISO/IEC 15939:2002, definition 3.17]

3.10

process

set of interrelated or interacting activities which transforms inputs into outputs

NOTE 1 Inputs to a process are generally outputs of other processes.

NOTE 2 Adapted from ISO 9000:2000, definition 3.4.1.

3.11

regression testing

testing required to determine that a change to a system component has not adversely affected functionality, reliability or performance and has not introduced additional defects

3.12

release

particular version of a configuration item that is made available for a specific purpose

EXAMPLE A test release.

[ISO/IEC 12207:1995, definition 3.22]

NOTE The term “release” used in the ISO 9001:2000 text quoted in this International Standard is used in the context of the definition provided in ISO 9000:2000, 3.6.13, which is different from the ISO/IEC 12207 definition quoted above.

3.13

replication

copying a software product from one medium to another

3.14

software item

identifiable part of a software product

3.15

software product

set of computer programs, procedures, and possibly associated documentation and data

[ISO/IEC 12207:1995, definition 3.26]

NOTE 1 A software product may be designated for delivery, an integral part of another product, or used in development.

NOTE 2 This is different from a product in ISO 9000[2].

NOTE 3 For the purposes of this International Standard, “software” is synonymous with “software product”.

3.16

software service

performance of activities, work, or duties connected with a software product, such as its development, maintenance and operation

[ISO/IEC 12207:1995, definition 3.27]

4 Quality management system

4.1 General requirements

ISO 9001:2000, Quality management systems — Requirements

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure and analyse these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

Guidance is provided for items a) and b) of ISO 9001:2000, 4.1, in relation to the organizational processes as follows (see 5.4.2, and 7.4.1 for additional guidance on outsourcing).

a) ***Process identification and application***

The organization should also identify the processes for software development, operation or maintenance.

b) ***Process sequence and interaction***

The organization should also define the sequence and interaction of the processes in

1) life cycle models for software development, e.g. waterfall, incremental and evolutionary, and

2) quality and development planning, which should be based upon a life cycle model.

NOTE For further information, see the following:

— ISO/IEC 12207[11] and ISO/IEC 12207:1995/Amd.1:2002[12] (software life cycle processes) which define a set of software life cycle processes that may be used for reference;

— ISO/IEC TR 15271:1998[21], Annex C (guide to ISO/IEC 12207) which provides guidance on how to use processes from ISO/IEC 12207 in different life cycles.

4.2 Documentation requirements

4.2.1 General

ISO 9001:2000, Quality management systems — Requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures required by this International Standard,

d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and

e) records required by this International Standard (see 4.2.4).

NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

Documents for the effective planning, operation, and control of processes for software [ISO 9001:2000, 4.2.1, item d)] may cover the following:

1) descriptions of processes, such as those identified in implementing 4.1;

2) descriptions of procedural instructions and/or templates used;

3) descriptions of life cycle models used, such as waterfall, incremental and evolutionary;

4) descriptions of tools, techniques, technologies, and methods such as those identified in implementing 4.1;

5) technical topics such as standards or guidance documents for coding, design and development, and testing.

NOTE For further information on document identification as part of configuration management, see 7.5.3.

4.2.2 Quality manual

ISO 9001:2000, Quality management systems — Requirements

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

4.2.3 Control of documents

ISO 9001:2000, Quality management systems — Requirements

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

NOTE For further information on document control as part of configuration management, see 7.5.3.

4.2.4 Control of records

ISO 9001:2000, Quality management systems — Requirements

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

4.2.4.1 Evidence of conformity to requirements

Evidence of conformity to requirements may include

a) documented test results,

b) problem reports, including those related to tools problems,

c) change requests,

d) documents marked with comments,

e) audit and assessment reports, and

f) review and inspection records, such as those for design reviews, code inspections, and walk-throughs.

4.2.4.2 Evidence of effective operation

Examples of evidence of effective operation of the quality management system may include, but are not limited to

a) changes (and the reasoning) to resources (people, software and equipment),

b) estimates, e.g. project size and effort (people, cost, schedule),

c) how and why tools, methodologies and suppliers were selected and qualified,

d) software license agreements (both for software supplied to customers and software procured to aid development),

e) minutes of meetings, and

f) software release records.

4.2.4.3 Retention and disposition

When determining the retention periods for records, consideration should be given to statutory and regulatory requirements. Where records are held on electronic media, consideration of the retention times and accessibility of the records should take into account the rate of media degradation, the availability of the devices, and software needed to access the records. Records may include information held in email systems. Protection from computer viruses and unapproved or illegal access, should be considered.

The proprietary nature of the information stored on records should be assessed, in determining the methods of data erasure from the media, at the end of its required retention period.

NOTE For further general guidance related to ISO 9001:2000, 4.2, see ISO/IEC 12207:1995[11], 6.1, and ISO/IEC 12207:1995/Amd.1:2002[12], F.2.1 (documentation process).

5 Management responsibility

5.1 Management commitment

ISO 9001:2000, Quality management systems — Requirements

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

5.2 Customer focus

ISO 9001:2000, Quality management systems — Requirements

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

5.3 Quality policy

ISO 9001:2000, Quality management systems — Requirements

5.3 Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,

b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,

c) provides a framework for establishing and reviewing quality objectives,

d) is communicated and understood within the organization, and

e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

ISO 9001:2000, Quality management systems — Requirements

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

NOTE Information on attributes of software processes suitable for setting objectives may be found in ISO/IEC 15504-1[22]. ISO/IEC 15504 (all parts) may be used for assessing process capabilities and for setting objectives for improving process capabilities.

5.4.2 Quality management system planning

ISO 9001:2000, Quality management systems — Requirements

5.4.2 Quality management system planning

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Planning may occur at organizational and project/product levels.

Quality management system planning at the organizational level may include the following:

a) defining appropriate software life cycle models to be used for the types of project that the organization undertakes, including how the organization normally implements software life cycle processes;

b) defining the work products of software development, such as software requirements documents, architectural design documents, detailed design documents, program code, and software user documentation;