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
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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.

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.


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.

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


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


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


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


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

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.  


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  


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