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Software engineering — Guidelines for the application of ISO 9001:2008 to computer software

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National foreword

This British Standard is the UK implementation of ISO/IEC 90003:2014. It supersedes BS ISO/IEC 90003:2004 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee IST/15, Software and systems engineering.

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

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INTERNATIONAL STANDARD

ISO/IEC 90003

Second edition
2014-12-15

Software engineering — Guidelines for the application of ISO 9001:2008 to computer software

Ingénierie du logiciel — Lignes directrices pour l'application de l'ISO 9001:2008 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. In the field of information technology, ISO and IEC have established a joint technical committee, ISO/IEC JTC 1.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword — Supplementary information.

The committee responsible for this document is ISO/IEC JTC 1, *Information technology*, Subcommittee SC 7, *Software and system engineering*.

This second edition of ISO/IEC 90003 cancels and replaces the first edition. It has been updated for conformity to ISO 9001:2008 and to reference recent editions of other relevant standards.

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Introduction

This International Standard provides guidance for organizations in the application of ISO 9001:2008 to the acquisition, supply, development, operation, and maintenance of computer software.

It identifies the issues that 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 9001:2008 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 9001:2008, "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 9001:2008. This International Standard (ISO/IEC 90003) provides guidance to assist in understanding how the provisions of ISO 9001:2008 apply in the context of software.

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 to support or complement the ISO 9001:2008 process model. The related paragraphs of ISO/IEC 12207:2008 are referenced in each clause of this International Standard; however, they are not intended to imply requirements additional to those in ISO 9001:2008. Further guidance to the use of ISO/IEC 12207 may be found in ISO/IEC 24748–3. For additional guidance, references are provided to the International Standards for software engineering defined by ISO/IEC JTC 1/SC 7. Where these references are specific to a clause or subclause of ISO 9001:2008, 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 9001:2008, that text is enclosed in a box, for ease of identification.

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Software engineering — Guidelines for the application of ISO 9001:2008 to computer software

1 Scope

1.1 General

ISO 9001:2008, 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 statutory and 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 statutory and regulatory requirements.

NOTE 1 In this International Standard, the term "product" only applies to

a) product intended for, or required by, a customer,

b) any intended output resulting from the product realization processes.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

This International Standard provides guidance for organizations in the application of ISO 9001:2008 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 9001:2008.

Annex A (informative) provides a table pointing to additional guidance in the implementation of ISO 9001:2008, available in ISO/IEC JTC 1/SC 7 and ISO/TC 176 International 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 9001:2008, 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 statutory and regulatory requirements.

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

— part of a commercial contract with another organization,

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— 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 9001:2008, Quality management systems requirements

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

ISO 9001:2008, Quality management systems requirements

3 Terms and definitions

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

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 9001:2008, 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 9000:2005 apply.

NOTE ISO/IEC 12207:2008 provides detailed provisions for software life cycle processes. This International Standard will make reference to terms defined in it.

3.1
activity
set of cohesive tasks of a process

[SOURCE: ISO/IEC 12207:2008, 4.3]

3.2
baseline
specification or product that has been formally reviewed and agreed upon, that thereafter serves as the basis for further development, and that can be changed only through formal change control procedures

[SOURCE: ISO/IEC 12207:2008, 4.6]

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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

[SOURCE: ISO/IEC 12207:2008, 4.7]

3.4
COTS
Commercial-Off-The-Shelf
<software product> available for purchase and use without the need to conduct development activities

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

3.6
life cycle model
framework of processes and activities concerned with the life cycle that may be organized into stages, which also acts as a common reference for communication and understanding

Note 1 to entry: The requirements of ISO 9001:2008 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.

[SOURCE: ISO/IEC 12207:2008, 4.17]

3.7
measure
make a measurement

[SOURCE: ISO/IEC 15939:2007, 2.16]

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

[SOURCE: ISO/IEC 15939:2007, 2.15]

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

[SOURCE: ISO/IEC 15939:2007, 2.17]

3.10
process
set of interrelated or interacting activities which transforms inputs into outputs

Note 1 to entry: Inputs to a process are generally outputs of other processes.

[SOURCE: ISO 9000:2005, 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

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3.12
release
particular version of a configuration item that is made available for a specific purpose

Note 1 to entry: The term "release" used in the ISO 9001:2008 text quoted in this International Standard is used in the context of the definition provided in ISO 9000:2005, 3.6.13, which is different from the ISO/IEC 12207 definition quoted above.

EXAMPLE Test release

[SOURCE: ISO/IEC 12207:2008, 4.35]

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 to entry: A software product may be designated for delivery, an integral part of another product, or used in development.

Note 2 to entry: This is different from a product in ISO 9000.

Note 3 to entry: For the purposes of this International Standard, "software" is synonymous with "software product".

[SOURCE: ISO/IEC 12207:2008, definition 4.42]

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4 Quality management system

4.1 General requirements

ISO 9001:2008, 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) determine 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 where applicable, 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 to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.

NOTE 2 An "outsourced process" is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,

b) the degree to which the control for the process is shared,

c) the capability of achieving the necessary control through the application of 7.4.

Guidance is provided for items a) and b) of ISO 9001:2008, 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

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

NOTE For further information, see the following:

— ISO/IEC 12207:2008[5] (Software Life Cycle Processes) which defines a set of software life cycle processes that may be used for reference;

— ISO/IEC/TR 24748–1[21] and ISO/IEC/TR 24748–3[22] which provide guidance on how to use processes from ISO/IEC 12207 in different life cycles.

4.2 Documentation requirements

4.2.1 General

ISO 9001:2008, 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 and records required by this International Standard, and

d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

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 9001:2008, 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.

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4.2.2 Quality manual

ISO 9001:2008, 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 9001:2008, 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 determined by the organization to be necessary for the planning and operation of the quality management system 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 9001:2008, Quality management systems requirements

4.2.4 Control of records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

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,

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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 guidance related to ISO 9001:2008, 4.2, see ISO/IEC 12207:2008,[5] 6.3.6 (Information Management Process) and 7.2.1 (Software Documentation Management Process).

5 Management responsibility

5.1 Management commitment

ISO 9001:2008, 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.

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5.2 Customer focus

ISO 9001:2008, 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 9001:2008, 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 9001:2008, 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 1 Information on attributes of software processes suitable for setting objectives may be found in ISO/IEC 15504–1.[10] ISO/IEC 15504 (all parts) may be used for assessing process capabilities and for setting objectives for improving process capabilities.

NOTE 2 Information on quality characteristics, subcharacteristics and attributes of a software product suitable for setting quality objectives are defined in ISO/IEC 25010.[24] The ISO/IEC 25000 series of standards are useful for defining quality requirements and for setting quality objectives of a software product.

5.4.2 Quality management system planning

ISO 9001:2008, 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.

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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;

c) defining the content of software management plans, such as software project management plans, software configuration management plans, software verification and validation plans, software quality assurance plans and training plans;

d) defining how software engineering methods are tailored for the organization's projects within the life cycle (see 1.2);

e) identifying the tools and environment for software development, operations or maintenance;

f) specifying conventions for the use of programming languages, e.g. coding rules, software libraries and frameworks;

g) identifying any software reuse (see also 7.5.4).

The organization's management representative should consider any change to a software life cycle model which may affect the quality management system and should ensure that such changes do not compromise any quality management system controls.

Software quality planning at the project/product level is discussed in 7.1.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

ISO 9001:2008, Quality management systems requirements

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management representative

ISO 9001:2008, Quality management systems requirements

5.5.2 Management representative

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained,

b) reporting to top management on the performance of the quality management system and any need for improvement, and

c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

For a software-producing organization, there is benefit if the management representative has had experience with software development.

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5.5.3 Internal communication

ISO 9001:2008, Quality management systems requirements

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

ISO 9001:2008, Quality management systems requirements

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

5.6.2 Review input

ISO 9001:2008, Quality management systems requirements

5.6.2 Review input

The input to management review shall include information on

a) results of audits,

b) customer feedback,

c) process performance and product conformity,

d) status of preventive and corrective actions,

e) follow-up actions from previous management reviews,

f) changes that could affect the quality management system, and

g) recommendations for improvement.

Guidance is provided for ISO 9001:2008, 5.6.2, item c) as follows.

One way to measure process performance is to perform software process assessments (see 8.2.3). The outcomes of software process assessments should be considered as input to management reviews.

One way to measure product conformity is to perform software product evaluation (see 8.2.4). The outcomes of software product evaluation should be considered as input to management review.

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5.6.3 Review output

ISO 9001:2008, Quality management systems requirements **5.6.3 Review output** The output from the management review shall include any decisions and actions related to a) improvement of the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.

6 Resource management

6.1 Provision of resources

ISO 9001:2008, Quality management systems requirements **6.1 Provision of resources** The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General

ISO 9001:2008, Quality management systems requirements **6.2.1 General** Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience. NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

NOTE For further information, see ISO/IEC 12207:2008,[5] 6.2.4, Human Resource Management Process.

6.2.2 Competence, awareness and training

ISO 9001:2008, Quality management systems requirements **6.2.2 Competence, training, and awareness** The organization shall a) determine the necessary competence for personnel performing work affecting conformity to product requirements, b) where applicable, provide training or take other actions to achieve the necessary competence, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

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