
**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

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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*



Contents	Page
1 Scope	1
2 Normative references	1
3 Definitions	1
4 Quality system requirements	2
4.1 Management responsibility	2
4.2 Quality system	4
4.3 Contract review	5
4.4 Design control	7
4.5 Document and data control	14
4.6 Purchasing	15
4.7 Control of customer-supplied product	16
4.8 Product identification and traceability	17
4.9 Process control	18
4.10 Inspection and testing	19
4.11 Control of inspection, measuring and test equipment	22
4.12 Inspection and test status	23
4.13 Control of nonconforming product	24
4.14 Corrective and preventive action	25
4.15 Handling, storage, packaging, preservation and delivery	25
4.16 Control of quality records	27
4.17 Internal quality audits	28
4.18 Training	28
4.19 Servicing	28
4.20 Statistical techniques	30
Annex A Bibliography	31
Annex B Cross-references to ISO/IEC 12207	32

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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.

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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 9000-3:1997](https://www.iso.org/standard/561580c-4285-a15d-0c7b5d4d0f3d/iso-9000-3-1997), 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).

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;

- f) the identification of suitable verification at appropriate stages in the realization of product;
- g) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;
- h) the identification and preparation of quality records (see 4.16).

NOTE 8 The quality plans referred to [see 4.2.3a)] may be in the form of a reference to the appropriate documented procedures that form an integral part of the supplier's quality system.

Quality planning should address the following items, as appropriate:

- a) quality requirements, expressed in measurable terms, where appropriate;
- b) the life cycle model to be used for software development;
- c) defined criteria for starting and ending each project phase;
- d) identification of types of reviews, tests and other verification and validation activities to be carried out;
- e) identification of configuration management procedures to be carried out;
- f) detailed planning (including schedules, procedures, resources and approval) and specific responsibilities and authorities for:
 - configuration management,
 - verification and validation of developed products,
 - verification and validation of purchased products,
 - verification of customer-supplied products,
 - control of nonconforming product and corrective action,
 - assuring that activities described in the quality plan are carried out.

A quality plan provides the means for tailoring the application of the quality system to a specific project, product or contract.

A quality plan may include or reference generic and/or project/product/contract-specific procedures, as appropriate. A quality plan should be updated along with the progress of the development, and items concerned with each phase should be completely defined when starting that phase.

A quality plan should be reviewed and agreed by all organizations concerned in its implementation.

The document that describes a quality plan may be an independent document (entitled quality plan), a part of another document, or composed of several documents.

A quality plan may include, or reference, the plans for unit, integration, system and acceptance tests. Guidance on test planning and the test environment is provided as part of inspection and testing .

NOTE — Guidance on quality plans is given in ISO 10005 and on configuration management in ISO 10007. For further information, see ISO/IEC 12207:1995, subclauses 6.2 to 6.5.

4.3 Contract review

4.3.1 General

The supplier shall establish and maintain documented procedures for contract review and for the coordination of these activities.

Software may be developed as part of a contract, as a product available for a market sector, as software embedded in a hardware product, or in support of the business processes of the supplier. Contract review is applicable in all these circumstances.

4.3.2 Review

Before submission of a tender, or the acceptance of a contract or order (statement of requirement), the tender, contract or order shall be reviewed by the supplier to ensure that:

- a) the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the supplier shall ensure that the order requirements are agreed before their acceptance;
- b) any differences between the contract or order requirements and those in the tender are resolved;
- c) the supplier has the capability to meet the contract or order requirements.

The following concerns may also be relevant during the supplier's review of software tenders, contracts, or orders.

a) Customer-related concerns:

- the terminology to be used, is agreed by the relevant parties;
- the customer has the capability and resources to meet the defined contractual obligations;
- agreed criteria for customer to accept or reject product;
- the customer's responsibilities in the provision of data and related facilities;
- the extent to which the customer is to participate in joint development or in subcontracted work;
- the arrangements for joint reviews to monitor progress of the contract;
- the agreed procedure for handling changes in customer's requirements during the development and/or maintenance;
- life-cycle processes imposed by the customer;
- handling of problems detected after acceptance, including customer complaints and claims;
- the responsibility for removal of nonconformities after any warranty period;
- any obligations for the customer to upgrade to a subsequent version when the supplier dictates, or for the supplier to maintain historic versions;
- deployment and associated user training. [ISO 9000-3:1997](https://standards.iteh.ai/catalog/standards/sist/a859b6b1-580c-4285-a15d-0c7b5d4d0f3d/iso-9000-3-1997)

<https://standards.iteh.ai/catalog/standards/sist/a859b6b1-580c-4285-a15d-0c7b5d4d0f3d/iso-9000-3-1997>

b) Technical concerns:

- the feasibility of meeting the requirements;
- the software development standards and procedures to be used;
- facilities, tools, software items and data, to be provided by the customer, are identified and methods defined and documented to assess their suitability for use;
- the operating system or hardware platform;
- agreement on the control of interfaces with the software product;
- replication and distribution requirements.

c) Management concerns:

- possible contingencies or risks are identified and the impact of these on subsequent activities are assessed;
- the supplier's responsibility with regard to subcontracted work;
- scheduling of progress, technical reviews and deliverables;
- installation, maintenance and support requirements;
- the timely availability of technical, human and financial resources.

d) Legal, security and confidentiality concerns:

- information handled under the contract may be subject to concerns regarding Intellectual Property Rights, licence agreements, confidentiality and the protection of such information;
- guardianship of the master copy of the product and the rights of the customer to access or verify that master copy;
- the level of information disclosure to the customer needs to be mutually agreed to by the parties;
- definition of warranty terms;
- liabilities/penalties associated with the contract.

NOTE — For further information, see ISO/IEC 12207:1995, subclauses 5.2.1, 5.2.6 and 6.4.2.1.

4.3.3 Amendment to a contract

The supplier shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the supplier's organization.

No further software-related guidance is provided.

NOTE — For further information, see ISO/IEC 12207:1995, subclauses 5.1.3.5 and 5.2.3.2.

4.3.4 Records

Records of contract reviews shall be maintained (see 4.16).

NOTE 9 Channels for communication and interfaces with the customer's organization in these contract matters should be established.

No further software-related guidance is provided.

4.4 Design control

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4.4.1 General

ISO 9000-3:1997

The supplier shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met.

This subclause provides guidance on the development activities of requirements analysis, architectural design, detailed design and coding. This subclause also contains guidance on development planning.

A software development project should be organized according to one or more life cycle models. Processes, activities and tasks should be planned and performed according to the nature of the life cycle model used. The life cycle model used may be adapted to suit particular project needs. This part of ISO 9000 is intended for application irrespective of the life cycle model used and is not intended to indicate a specific life cycle model.

A life cycle model identifies a set of processes and specifies when and how the processes are invoked. The sequence in which the processes are described in this part of ISO 9000 does not suggest in any way the sequence in which they are performed.

The development process is that which transforms the requirements into a software product. This process should be carried out in a disciplined manner, in order to prevent the introduction of errors. This approach reduces dependence on the verification and validation processes as the sole methods for identifying problems. The supplier should therefore establish and maintain documented procedures that ensure that the software products are developed in compliance with specified requirements and in accordance with the development plan and/or quality plan.

The following aspects inherent to the design activities should be taken into account:

- a) Design method: a design method should be systematically used. Consideration should be given to the suitability of that method for the type of task, product or project and the compatibility of the application, the methods and the tools to be used.

- b) Use of past experiences: utilizing lessons learned from past experiences, the supplier should avoid recurrences of the same or similar problems by applying lessons learned from previous projects, analysis of metrics and post-project reviews.
- c) Subsequent processes: to the extent practical, the software product should be designed to facilitate testing, installation, maintenance and use.
- d) Security and safety: special consideration should be given to the design for testability or validation. For products where failure may cause damage to people, property or the environment, design of such software should ensure definition of specific design requirements that specify desired immunity from, and system response to, potential failure conditions.

For coding, rules for the use of programming languages, consistent naming conventions, coding and adequate commentary rules should be specified and observed. Such rules should be documented and controlled.

The supplier may use tools, facilities and techniques in order to make the quality system guidelines in this part of ISO 9000 effective. These tools, facilities and techniques can be effective for management purposes as well as for product development and/or servicing. Whether these tools and techniques are developed internally, or purchased, the supplier should evaluate whether or not they are fit for purpose. Tools used in the implementation of the product, such as analysis and design tools, compilers, and assemblers should be approved and placed under an appropriate level of configuration management control, prior to use. The scope of use of such tools and techniques should be documented and their use reviewed as appropriate, to determine whether there is a need to improve and/or upgrade them.

Personnel may need training in the use of such tools and techniques, at commencement of usage, or after any improvements/upgrades.

4.4.2 Design and development planning

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The supplier shall prepare plans for each design and development activity. The plans shall describe or reference these activities, and define responsibility for their implementation. The design and development activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated as the design evolves.

For software products, development planning should determine the activities of requirements analysis, design, coding, integration, testing, installation and support for acceptance of software products. Development planning should be documented in a development plan.

A development plan should be reviewed and approved. A development plan may have other names such as “software development plan” or “software project plan”.

A development plan may define how the project is to be managed, the progress reviews required and the type and frequency of reports to management, the customer, and other relevant parties, taking into account any contractual requirements.

Development planning should address the following items, as appropriate:

- a) the definition of the project, including a statement of its objectives and reference to any related customer or supplier projects;
- b) the definition of input and output of the project as a whole;
- c) the organization of the project resources, including the team structure, responsibilities, use of subcontractors and material resources to be used;
- d) organizational and technical interfaces between different individuals or groups, such as
 - sub-project teams,
 - subcontractors,