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# INTERNATIONAL STANDARD

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## Quality management and quality assurance standards —

## Part 3:

## Guidelines for the application of ISO 9001 to the development, supply and maintenance of software



*Normes pour la gestion de la qualité et l'assurance de la qualité —*

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

Reference number
ISO 9000-3:1991(E)

# Contents







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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.



International Standard ISO 9000-3 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*.

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 to the development, supply and maintenance of software*

Part 1 will be a revision of ISO 9000:1987. Part 2 is to be published.

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

## Introduction

With the progress of information technology, the amount of software products has been increasing and the quality management of software products is essential. One of the means of establishing a quality management system is to provide guidance for software quality assurance.

The requirements for a generic quality system for two-party contractual situations have already been published: ISO 9001:1987, *Quality systems — Model for quality assurance in design/development, production, installation and servicing.*

However, the process of development and maintenance of software is different from that of most other types of industrial products. In such a rapidly evolving technology field it is therefore necessary to provide additional guidance for quality systems where software products are involved, taking into account the present status of this technology.



The nature of software development is such that some activities are related to particular phases of the development process, while others may apply throughout the process. These guidelines have therefore been structured to reflect these differences. This document thus does not correspond directly in format with ISO 9001 and cross-reference indexes (annex A and annex B) are provided to give assistance when referring to that standard.



Contracts between two parties for software product development may occur in many variations. In certain cases of two-party contracts, these guidelines might not be applicable even if "tailored". It is therefore important to determine the adequacy of the application of this part of ISO 9000 to the contract.

This part of ISO 9000 deals primarily with situations where specific software is developed as part of a contract according to purchaser's specifications. However, the concepts described may be equally of value in other situations.

NOTES

1 In English, use of the masculine gender in this part of ISO 9000 is not meant to exclude the feminine gender where applied to persons. Similarly, use of the singular does not exclude the plural (and vice versa) when the sense allows.

2 Throughout this part of ISO 9000 where there is no further guidance, the text of the relevant ISO 9001 clause is given and printed in italics.

3 In this part of ISO 9000 there are a number of lists; none of these is presumed to be exhaustive — they are intended as examples.

# Quality management and quality assurance standards —

# Part 3:
Guidelines for the application of ISO 9001 to the development, supply and maintenance of software

## 1 Scope

This part of ISO 9000 sets out guidelines to facilitate the application of ISO 9001 to organizations developing, supplying and maintaining software.

It is intended to provide guidance where a contract between two parties requires the demonstration of a supplier's capability to develop, supply and maintain software products.

The guidelines in this part of ISO 9000 are intended to describe the suggested controls and methods for producing software which meet a purchaser's requirements. This is done primarily by preventing nonconformity at all stages from development through to maintenance.

The guidelines in this part of ISO 9000 are applicable in contractual situations for software products when

a) the contract specifically requires design effort and the product requirements are stated principally in performance terms, or they need to be established;

b) confidence in the product can be attained by the adequate demonstration of a certain supplier's capabilities in development, supply and maintenance.

## 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 editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 2382-1:1984, *Data processing — Vocabulary — Part 01: Fundamental terms.*

ISO 8402:1986, *Quality — Vocabulary.*

ISO 9001:1987, *Quality systems — Model for quality assurance in design/development, production, installation and servicing.*

ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing.*

## 3 Definitions

For the purposes of this part of ISO 9000, the definitions given in ISO 2382-1 and ISO 8402 apply, together with the following definitions.

**3.1 software:** Intellectual creation comprising the programs, procedures, rules and any associated documentation pertaining to the operation of a data processing system.

[ISO 2382-1:1984, 01.04.04]

NOTE 4 Software is independent of the medium on which it is recorded.

**3.2 software product:** Complete set of computer programs, procedures and associated documentation and data designated for delivery to a user.

**3.3 software item:** Any identifiable part of a software product at an intermediate step or at the final step of development.

**3.4 development:** All activities to be carried out to create a software product.

**3.5 phase:** Defined segment of work.

NOTE 5 A phase does not imply the use of any specific life-cycle model, nor does it imply a period of time in the development of a software product.

**3.6 verification** (for software)**:** The process of evaluating the products of a given phase to ensure correctness and consistency with respect to the products and standards provided as input to that phase.

**3.7 validation** (for software)**:** The process of evaluating software to ensure compliance with specified requirements.

# 4 Quality system — Framework

## 4.1 Management responsibility

### 4.1.1 Supplier's management responsibility

#### 4.1.1.1 Quality policy

*The supplier's management shall define and document its policy and objectives for, and commitment to, quality. The supplier shall ensure that this policy is understood, implemented and maintained at all levels in the organization.*

[ISO 9001:1987, 4.1.1]

#### 4.1.1.2 Organization

##### 4.1.1.2.1 Responsibility and authority

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

a) *initiate action to prevent the occurrence of product nonconformity;*

b) *identify and record any product quality problems;*

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.*

[ISO 9001:1987, 4.1.2.1]

##### 4.1.1.2.2 Verification resources and personnel

*The supplier shall identify in-house verification requirements, provide adequate resources and assign trained personnel for verification activities.*

*Verification activities shall include inspection, test and monitoring of the design, production, installation and servicing processes and/or product; design reviews and audits of the quality system, processes and/or product shall be carried out by personnel independent of those having direct responsibility for the work being performed.*

[ISO 9001:1987, 4.1.2.2]

##### 4.1.1.2.3 Management representative

*The supplier shall appoint a management representative who, irrespective of other responsibilities, shall have defined authority and responsibility for ensuring that the requirements of* [ISO 9001] *are implemented and maintained.*

[ISO 9001:1987, 4.1.2.3]

#### 4.1.1.3 Management review

*The quality system adopted to satisfy the requirements of* [ISO 9001] *shall be reviewed at appropriate intervals by the supplier's management to ensure its continuing suitability and effectiveness. Records of such reviews shall be maintained.*

*NOTE — Management reviews normally include assessment of the results of internal quality system audits, but are carried out by, or on behalf of, the supplier's management viz management personnel having direct responsibility for the system.*

[ISO 9001:1987, 4.1.3]

### 4.1.2 Purchaser's management responsibility

The purchaser should cooperate with the supplier to provide all necessary information in a timely manner and resolve pending items.

The purchaser should assign a representative with the responsibility for dealing with the supplier on contractual matters. This representative should have the authority commensurate with the need to deal with contractual matters which include, but are not limited to, the following:

a) defining the purchaser's requirements to the supplier;

b) answering questions from the supplier;

c) approving the supplier's proposals;

d) concluding agreements with the supplier;

e) ensuring the purchaser's organization observes the agreements made with the supplier;

f) defining acceptance criteria and procedures;

g) dealing with the purchaser-supplied software items that are found unsuitable for use.

#### 4.1.3 Joint reviews

Regular joint reviews involving the supplier and purchaser should be scheduled to cover the following aspects, as appropriate:

a) conformance of the software to the purchaser's agreed requirements specification;

b) verification results;

c) acceptance test results;

The results of such reviews should be agreed and documented.



### 4.2 Quality system



#### 4.2.1 General

The supplier should establish and maintain a documented quality system. The quality system should be an integrated process throughout the entire life cycle, thus ensuring that quality is being built in as development progresses, rather than being discovered at the end of the process. Problem prevention should be emphasized rather than depending on correction after occurrence.

The supplier should ensure the effective implementation of the documented quality system.

#### 4.2.2 Quality system documentation

All the quality system elements, requirements and provisions should be clearly documented in a systematic and orderly manner.

#### 4.2.3 Quality plan

The supplier should prepare and document a quality plan to implement quality activities for each software development on the basis of the quality system, and ensure that it is understood and observed by the organizations concerned.

### 4.3 Internal quality system audits

*Internal quality audits*

*The supplier shall carry out a comprehensive system of planned and documented internal quality* [system] *audits to verify whether quality activities comply with planned arrangements and to determine the effectiveness of the quality system.*

*Audits shall be scheduled on the basis of the status and importance of the activity.*

*The audits and follow-up actions shall be carried out in accordance with documented procedures.*

*The results of the audits shall be documented and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on the deficiencies found by the audit.*

[ISO 9001:1987, 4.17]

See ISO 10011-1.

### 4.4 Corrective action

*The supplier shall establish, document and maintain procedures for*

a) *investigating the cause of nonconforming product and the corrective action needed to prevent recurrence;*

b) *analysing all processes, work operations, concessions, quality records, service reports and customer complaints to detect and eliminate potential causes of nonconforming product;*

c) *initiating preventive actions to deal with problems to a level corresponding to the risks encountered;*

d) *applying controls to ensure that corrective actions are taken and that they are effective;*

e) *implementing and recording changes in procedures resulting from corrective action.*

[ISO 9001:1987, 4.14]

## 5 Quality system — Life-cycle activities

### 5.1 General

A software development project should be organized according to a life-cycle model. Quality-related activities should be planned and implemented with respect to the nature of the life-cycle model used.

This part of ISO 9000 is intended for application irrespective of the life-cycle model used. Should any description, guidance, requirement or structure be read differently, this is unintended and should not be read as indicating that the requirement or guidance is restricted to a specific life-cycle model only.

## 5.2 Contract review

### 5.2.1 General

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

Each contract should be reviewed by the supplier to ensure that

a) the scope of the contract and requirements are defined and documented;

b) possible contingencies or risks are identified;

c) proprietary information is adequately protected;

d) any requirements differing from those in the tender are resolved;

e) the supplier has the capability to meet contractual requirements;

f) the supplier's responsibility with regard to subcontracted work is defined;

g) the terminology is agreed by both parties;

h) the purchaser has the capability to meet contractual obligations.

Records of such contract reviews should be maintained.

### 5.2.2 Contract items on quality

Among others, the following items are frequently found to be relevant in the contract:

a) acceptance criteria;

b) handling of the changes in purchaser's requirements during the development;

c) handling of problems detected after acceptance, including quality-related claims and purchaser complaints;

d) activities carried out by the purchaser, especially the purchaser's role in requirements specification, installation and acceptance;

e) facilities, tools and software items to be provided by the purchaser;

f) standards and procedures to be used;

g) replication requirements (see 5.9).

## 5.3 Purchaser's requirements specification

### 5.3.1 General

In order to proceed with software development, the supplier should have a complete, unambiguous set of functional requirements. In addition, these requirements should include all aspects necessary to satisfy the purchaser's need. These may include, but are not limited to, the following: performance, safety, reliability, security and privacy. These requirements should be stated precisely enough so as to allow validation during product acceptance.

The purchaser's requirements specification records these requirements. In some cases, this document is provided by the purchaser. If not, the supplier should develop these requirements in close cooperation with the purchaser, and the supplier should obtain the purchaser's approval before entering the development stage. The purchaser's requirements specification should be subject to documentation control and configuration management as part of the development documentation.



All interfaces between the software product and other software or hardware products should be fully specified, either directly or by reference, in the purchaser's requirements specification.

### 5.3.2 Mutual cooperation

During the development of the purchaser's requirements specification, attention to the following issues is recommended:

a) assignment of persons (on both sides) responsible for establishing the purchaser's requirements specification;

b) methods for agreeing on requirements and approving changes;

c) efforts to prevent misunderstandings such as definition of terms, explanations of background of requirements;

d) recording and reviewing discussion results on both sides.

## 5.4 Development planning

### 5.4.1 General

The development plan should cover the following:

a) the definition of the project, including a statement of its objectives and with reference to related purchaser or supplier projects;

b) the organization of the project resources, including the team structure, responsibilities, use of sub-contractors and material resources to be used;

c) development phases (as defined in 5.4.2.1);

d) the project schedule identifying the tasks to be performed, the resources and time required for each and any interrelationships between tasks;

e) identification of related plans, such as

— quality plan,

— configuration management plan,

— integration plan,

— test plan.

The development plan should be updated as development progresses and each phase should be defined as in 5.4.2.1 before activities in that phase are started. It should be reviewed and approved before execution.

### 5.4.2 Development plan

#### 5.4.2.1 Phases

The development plan should define a disciplined process or methodology for transforming the purchaser's requirements specification into a software product. This may involve dividing the work into phases, and the identification of

a) development phases to be carried out;

b) required inputs for each phase;

c) required outputs from each phase;

d) verification procedures to be carried out at each phase;

e) analysis of the potential problems associated with the development phases and with the achievment of the specified requirements.

#### 5.4.2.2 Management

The development plan should define how the project is to be managed, including the identification of

a) schedule of development, implementation and associated deliveries;

b) progress control;

c) organizational responsibilities, resources and work assignment;

d) organizational and technical interfaces between different groups.

#### 5.4.2.3 Development methods and tools

The development plan should identify methods for ensuring that all activities are carried out correctly. This may include

a) rules, practices and conventions for development;

b) tools and techniques for development;

c) configuration management.

### 5.4.3 Progress control

Progress reviews should be planned, held and documented to ensure that outstanding resource issues are resolved and to ensure effective execution of development plans.

### 5.4.4 Input to development phases

The required input to each development phase should be defined and documented. Each requirement should be defined so that its achievement can be verified. Incomplete, ambiguous or conflicting requirements should be resolved with those responsible for drawing up the requirements.

### 5.4.5 Output from development phases

The required output from each development phase should be defined and documented. The output from each development phase should be verified and should

a) meet the relevant requirements;

b) contain or reference acceptance criteria for forwarding to subsequent phases;

c) conform to appropriate development practices and conventions, whether or not these have been stated in the input information;

d) identify those characteristics of the product that are crucial to its safe and proper functioning;

e) conform to applicable regulatory requirements.

### 5.4.6 Verification of each phase

The supplier should draw up a plan for verification of all development phase outputs at the end of each phase.