INTERNATIONAL STANDARD

ISO 9000-3

Second edition
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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

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

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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*, 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/IEC 12207:1995, 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.

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

4.4.1 General

> 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

> 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,

— users,
— customer representatives,
— quality assurance representative;

e) the identification of, or reference to

— development activities to be carried out,
— required inputs to each activity,
— required outputs from each activity,
— management and supporting activities to be carried out;

f) the analysis of the possible risks, assumptions, dependencies and problems associated with the development;

g) the schedule identifying

— the phases of the project,
— the work to be performed (the inputs to, outputs from and definition of each task),
— the associated resources and timing,
— the associated dependencies,
— the milestones;

h) the identification of

— standards, rules, practices and conventions,
— tools and techniques for development, including the qualification of, and configuration controls placed on, such tools and techniques,
— configuration management practices,
— method of controlling nonconforming products,
— methods of control of nondeliverable software used to support development,
— procedures for archiving, back-up and recovery, including contingency planning,
— methods of control for virus protection;

i) the identification of related plans (including system level plans) such as

— quality plan,
— risk management plan,
— configuration management plan,
— integration plan,
— test plan,
— installation plan,
— migration plan,
— training plan,
— maintenance plan,
— re-use plan.

The development plan and any of these related plans may be an independent document, a part of another document or composed of several documents.

NOTE — For further information, see ISO/IEC 12207:1995, subclause 5.2.4.

4.4.3 Organizational and technical interfaces

> Organizational and technical interfaces between different groups which input into the design process shall be defined and the necessary information documented, transmitted and regularly reviewed.

The boundaries of responsibility for each part of the software product and the way that technical information will be transmitted between all parties should be clearly defined in the development plans of suppliers or subcontractors. The supplier may require submission of a subcontractor's development plan, for review.

In defining interfaces, care should be taken to consider parties, other than the customer and supplier, who need input to the design, installation, maintenance and training activities. These may include subcontractors, regulatory authorities, associated development projects and help-desk staff. In particular, the end-users and any intermediate operations function may need to be involved to ensure that appropriate capacity and training are available to achieve committed service levels.

The customer may have certain responsibilities under the contract. Particular concerns include the need for the customer to cooperate with the supplier, to provide necessary information in a timely manner, and resolve action items. Where a customer representative is appropriate, he/she may represent the eventual user of the product, as well as executive management, and have the authority to deal with contractual matters which include, but are not limited to, the following:

a) defining the customer'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 that the customer's organization observes the agreements made with the supplier;
f) defining the acceptance criteria and procedures;
g) dealing with customer-supplied software items, data, facilities and tools that are found unsuitable for use;
h) defining the customer's responsibility.

Where mutually agreed, joint reviews involving the supplier and customer may be scheduled on a regular basis, or at significant project events, to cover the following aspects, as appropriate:

a) the progress of software development work undertaken by the supplier;
b) the progress of agreed activities being undertaken by the customer;
c) conformance of the development products to the customer's agreed requirements specification;
d) the progress of activities concerning the eventual users of the system under development, such as system conversion and training;
e) verification results;
f) acceptance test results.

NOTE — For further information, see ISO/IEC 12207:1995, subclauses 5.2.6.1 and 6.6.2.

4.4.4 Design input

> Design input requirements relating to the product, including applicable statutory and regulatory requirements, shall be identified, documented and their selection reviewed by the supplier for adequacy. Incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for imposing these requirements.
>
> Design input shall take into consideration the results of any contract review activities.

The requirements specification should be provided by the customer. However, where mutually agreed, the supplier may provide the specification. In such a case, the supplier should, where appropriate:

a) establish documented procedures for developing the requirements specification, including

- methods for agreeing on requirements and authorizing changes, especially during iterative development,
- methods for the evaluation of prototypes or demonstrations, where used,
- recording and reviewing discussion results on both sides,

b) develop the requirements specification in close cooperation with the customer and make efforts to prevent misunderstandings by, for example, provision of definition of terms, explanation of the background of requirements,

c) obtain the customer's approval of the requirements specification.

Interviews, surveys, studies, prototypes, demonstrations and analysis methods may be used for developing the requirements specification, as appropriate.

The requirements specification may be provided and agreed in the form of a system specification. In this case, procedures should be in place to ensure the correct allocation of system requirements into hardware and software aspects and also the appropriate interface specifications.

The requirements specification may not be fully defined at contract acceptance, and may be developed during a project. The contract may be amended when the requirements specification changes. Changes to the requirements specification should be controlled.

The requirements should include all aspects necessary to satisfy the customer's agreed needs. The requirements specification may need to take the operational environment into account. The requirements may include, but not be limited to the following characteristics: functionality; reliability; usability; efficiency; maintainability and portability (see also ISO/IEC 9126). Sub-characteristics may be specified, for example security. Safety considerations and statutory obligations may also be specified.

If the software product needs to interface with other software or hardware products, the interfaces between the software product to be developed and other software or hardware products should be specified, as far as possible, either directly or by reference, in the requirements specification.

The requirements should be expressed in terms which allow validation during product acceptance.

NOTE — For further information, see ISO/IEC 12207:1995, subclauses 5.3.2 to 5.3.4.

4.4.5 Design output

> Design output shall be documented and expressed in terms that can be verified and validated against design input requirements.
>
> Design output shall:
>
> a) meet the design input requirements;
>
> b) contain or make reference to acceptance criteria;
>
> c) identify those characteristics of the design that are crucial to the safe and proper functioning of the product (e.g., operating, storage, handling, maintenance and disposal requirements).
>
> Design output documents shall be reviewed before release.

The required output from the design activity should be defined and documented in accordance with the chosen method. This documentation should be correct, complete and consistent with the requirements. Design outputs may include:

- architectural design specification;
- detailed design specification;
- source code;
- user guides.

NOTE — For further information, see ISO/IEC 12207:1995, subclauses 5.3.5 to 5.3.7.

4.4.6 Design review

> At appropriate stages of design, formal documented reviews of the design results shall be planned and conducted. Participants at each design review shall include representatives of all functions concerned with the design stage being reviewed, as well as other specialist personnel, as required. Records of such reviews shall be maintained (see 4.16).

The supplier should plan and implement review processes for all software development projects. The degree of formality and rigour of the activities associated with the review processes should be appropriate to the complexity of the product and the degree of risk associated with the specified use of the software product. The supplier should establish documented procedures for dealing with process and product deficiencies or nonconformities identified during these activities.

During design reviews, aspects inherent to the design activities should be taken into account, for example feasibility, security and safety, programming rules and testability.

The results of review, and any further activities required to ensure that the specified requirements are met, should be recorded and checked when they are completed.

Most design reviews during the development are scheduled, but there may also be unscheduled design reviews.

A documented design review procedure should address the following:

a) what is to be reviewed, when, and the type of review;
b) what functional groups would be concerned in each type of review and, if there is to be a review meeting, who would chair it;
c) what records have to be produced, for example meeting minutes, issues, problems, actions and action status.

Also the following may be addressed in the design review procedure:

a) the methods for monitoring the application of rules, practices and conventions to ensure compliance, such as peer reviews, walkthroughs, code inspections;
b) what has to be done prior to the conduct of a review, such as establishment of objectives, meeting agenda, documents required and roles of review personnel;
c) what has to be done during the review, including the techniques to be used and guidelines for all participants;
d) the success criteria for the review;
e) what follow-up methods are to be used to ensure that issues identified at the review are resolved.

Where specified in the contract, the supplier should conduct design review meetings in cooperation with the customer. Both parties should agree on the results of such reviews.

It is recommended that further design activities should proceed only when the consequences of all known deficiencies are satisfactorily resolved, or the risk of proceeding otherwise is known.

NOTE — For further information, see ISO/IEC 12207:1995, subclauses 5.3.4.2, 5.3.5.6, 5.3.6.7 and 6.6.3.

4.4.7 Design verification

> At appropriate stages of design, design verification shall be performed to ensure that the design stage output meets the design stage input requirements. The design verification measures shall be recorded (see 4.16).
>
> NOTE 10 In addition to conducting design reviews (see 4.4.6), design verification may include activities such as
> — performing alternative calculations,
> — comparing the new design with a similar proven design, if available,
> — undertaking tests and demonstrations, and
> — reviewing the design stage documents before release.

Verification of design should be performed as appropriate during the development process. Design verification may comprise reviews of design output, demonstrations including prototypes and simulations, or tests. Verification may be conducted on the output from other development activities. These verification activities should be planned and conducted in accordance with the quality plan or documented procedures to ensure that process outputs meet the process input requirements.

The verification results and any further actions required to ensure that the design stage input requirements are met should be recorded and checked when the actions are completed.

Only verified design outputs should be submitted for acceptance and subsequent use. Any findings should be adequately addressed and resolved.

NOTE — For further information, see ISO/IEC 12207:1995, subclauses 5.3.4.2, 5.3.5.6, 5.3.5.7, 5.3.7.5, 5.3.9 and 6.4.

4.4.8 Design validation

Design validation shall be performed to ensure that product conforms to defined user needs and/or requirements.

NOTES

11 Design validation follows successful design verification (see 4.4.7).

12 Validation is normally performed under defined operating conditions.

13 Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion.

14 Multiple validations may be performed if there are different intended uses.

Before offering the product for customer acceptance, the supplier should validate the product in accordance with its specified intended use, for example during final inspection and test.

In software development, it is important that the validation results and any further actions required to ensure that the specified requirements are met should be recorded and checked when the actions are completed. Only validated products should be submitted for acceptance and subsequent use.

NOTE — For further information, see ISO/IEC 12207:1995, subclauses 5.3.1 and 6.5.

4.4.9 Design changes

All design changes and modifications shall be identified, documented, reviewed and approved by authorized personnel before their implementation.

The supplier should establish and maintain procedures for controlling the implementation of any design changes, which may arise at any time during the product life cycle, in order to:

a) document and justify the change;
b) evaluate consequences of the change;
c) approve or disapprove the change;
d) implement and verify the change.

In the software development environment, control of design changes is usually addressed under the discipline of configuration management.

NOTE — For further information, see ISO/IEC 12207:1995, subclauses 5.5.2, 5.5.3 and 6.2.3.

4.5 Document and data control

4.5.1 General

> The supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this International Standard including, to the extent applicable, documents of external origin such as standards and customer drawings.
>
> NOTE 15 Documents and data can be in the form of any type of media, such as hard copy or electronic media.

Configuration management procedures may be used to implement document and data control. In establishing the procedures to control documents and data, the supplier should identify those documents and data, including those of external origin such as standards and customer data, which should be subject to the control procedures.

The document and data control procedures should be applied to relevant documents and data, including the following:

a) contractual documents including specification of requirements;
b) procedural documents describing the quality system to be applied in the software life cycle;
c) planning documents describing the planning and progress of activities of the supplier and the suppliers interactions with the customer;
d) product documents and data describing or associated with a particular software product.

NOTE — For further information, see ISO/IEC 12207, clause 6.1.

4.5.2 Document and data approval and issue

> The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.
>
> This control shall ensure that:
>
> a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;
> b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;
> c) any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

Where document control is achieved by electronic means, special attention should be given to appropriate approval, access, distribution, media and archiving procedures.

4.5.3 Document and data changes

> Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations shall have access to pertinent background information upon which to base their review and approval.
>
> Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

No further software-related guidance is provided.

4.6 Purchasing

4.6.1 General

> The supplier shall establish and maintain documented procedures to ensure that purchased product (see 3.1) conforms to specified requirements.

In developing, supplying, installing and maintaining software products, purchased products may include:

- commercial off-the-shelf software;
- subcontracted development;
- computer and communications hardware;
- a tool intended to assist in the development of software;
- contract staff;
- maintenance and customer support services;
- training courses and materials.

NOTE — For further information, see ISO/IEC 12207:1995, subclause 5.1.

4.6.2 Evaluation of subcontractors

> The supplier shall:
>
> a) evaluate and select subcontractors on the basis of their ability to meet subcontract requirements including the quality system and any specific quality assurance requirements;
>
> b) define the type and extent of control exercised by the supplier over subcontractors. This shall be dependent upon the type of product, the impact of subcontracted product on the quality of final product and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors;
>
> c) establish and maintain quality records of acceptable subcontractors (see 4.16).

No further software-related guidance is provided.

4.6.3 Purchasing data

> Purchasing documents shall contain data clearly describing the product ordered, including where applicable:
>
> a) the type, class, grade or other precise identification;
>
> b) the title or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel;
>
> c) the title, number and issue of the quality system standard to be applied.
>
> The supplier shall review and approve purchasing documents for adequacy of specified requirements prior to release.

Purchasing documents for software development should contain data clearly describing the product ordered, including, where applicable:

a) precise identification of the product ordered, such as product name and/or product number;
b) requirements specification, or the identity of it (or the procedure to identify requirements specifications where not fixed at the time ordered);
c) standards to be applied (e.g. communications protocol, architectural specification);
d) procedures and/or work instructions;
e) development environment;
f) requirements on personnel.

The considerations under contract review may also be applied to subcontracts.

4.6.4 Verification of purchased product

4.6.4.1 Supplier verification at subcontractor's premises

> Where the supplier proposes to verify purchased product at the subcontractor's premises, the supplier shall specify verification arrangements and the method of product release in the purchasing documents.

No further software-related guidance is provided.

4.6.4.2 Customer verification of subcontracted product

> Where specified in the contract, the supplier's customer or the customer's representative shall be afforded the right to verify at the subcontractor's premises and the supplier's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the supplier as evidence of effective control of quality by the subcontractor.
>
> Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

No further software-related guidance is provided.

4.7 Control of customer-supplied product

> The supplier shall establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities. Any such product that is lost, damaged or is otherwise unsuitable for use shall be recorded and reported to the customer (see 4.16).
>
> Verification by the supplier does not absolve the customer of the responsibility to provide acceptable product.

The supplier may be required to acquire and include product, including data, supplied by the customer. For example:

a) software products including commercial software product supplied by the customer;
b) development tools;
c) development environment including network services;
d) test and operational data;
e) interface or other specifications;
f) hardware;
g) customer proprietary information, including specifications.

Consideration should be given to the requirements of the contract in addressing required licensing and the support of such software product, in any maintenance agreement related to the product to be delivered.

The means by which updates to customer-supplied items are accepted and integrated should be defined. The supplier may apply the same kinds of verification activities to customer-supplied product as to purchased product.

NOTE — For further information, see ISO/IEC 12207:1995, subclause 6.1.

4.8 Product identification and traceability

> Where appropriate, the supplier shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery and installation.
>
> Where and to the extent that traceability is a specified requirement, the supplier shall establish and maintain documented procedures for unique identification of individual product or batches. This identification shall be recorded (see 4.16).

The supplier should establish and maintain procedures for identifying software items during all phases, starting from specification through development, replication and delivery. Where required by contract, these procedures may also apply after delivery of the product.

Throughout the product life cycle, there should be procedures to trace the components of the software item or product. Such tracing may vary in scope according to the requirements of the contract or marketplace, from being able to place a certain change request in a specific release, to recording the destination and usage of each variant of the product.

In software, a means by which identification and traceability may be achieved, is configuration management. Configuration management is a management discipline that applies technical and administrative direction to the development and support life cycle of configuration items, including software items. This discipline is also applicable to related documentation and hardware. Use of configuration management is dependent on the project size and complexity, and the risk level.

One objective of configuration management is to document and provide full visibility of the product's present configuration and on the status of achievement of its requirements. Another objective is that everyone working on the product at any time in its life cycle uses correct and accurate information.

A configuration management system may provide the capability to:

a) identify uniquely the versions of each software item;
b) identify the versions of each software item which together constitute a specific version of a complete product;
c) identify the build status of software products under development, delivered or installed;
d) control simultaneous updating of a given software item by two or more people working independently;
e) provide coordination for the updating of multiple products in one or more locations as required;
f) identify and track all actions and changes resulting from a change request, or problem, from initiation through to release.

The supplier should identify the configuration with the following:

a) product structure and selection of configuration items;
b) documentation and computer files;
c) naming conventions;
d) establishment of configuration baselines.

The products that may be managed by a configuration management system include:

a) documents and data pertaining to contract, process, planning and product;
b) source, object and executable code;
c) incorporated products including
   — software tools,

— re-used software including libraries,
— purchased software,
— customer supplied software.

Procedures should be applied to ensure that the following can be identified for each software item:

a) the documentation;
b) any associated development tools;
c) interfaces to other software items and to hardware;
d) the hardware and software environment.

The supplier should establish and maintain configuration status accounting procedures to record, manage and report on the status of software items, of change requests and of the implementation of approved changes.

The supplier should develop and implement a configuration management plan which includes the following:

a) organizations involved in configuration management and responsibilities assigned to each of them;
b) configuration management activities to be carried out;
c) configuration management tools, techniques and methodologies to be used;
d) the point at which items should be brought under configuration control.

NOTE — For further information on configuration management, refer to ISO 10007, and ISO/IEC 12207:1995, subclauses 6.1 and 6.2.

4.9 Process control

The supplier shall identify and plan the production, installation and servicing processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following:

a) documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality;
b) use of suitable production, installation and servicing equipment, and a suitable working environment;
c) compliance with reference standards/codes, quality plans and/or documented procedures;
d) monitoring and control of suitable process parameters and product characteristics;
e) the approval of processes and equipment, as appropriate;
f) criteria for workmanship, which shall be stipulated, in the clearest practicable manner (e.g., written standards, representative samples or illustrations);
g) suitable maintenance of equipment to ensure continuing process capability.

Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met.

The requirements for any qualification of process operations, including associated equipment and personnel (see 4.18), shall be specified.

NOTE 16 Such processes requiring pre-qualification of their process capability are frequently referred to as special processes.

Records shall be maintained for qualified processes, equipment and personnel, as appropriate (see 4.16).

As stated in guidance for the design control element of ISO 9001, a software development project should be organized according to a set of processes which transform the requirements into a software product. The “process control”

element, as applied to software development, is applicable to the replication, delivery and installation of software items or products.

Where required by contract, the supplier should establish and perform the replication procedures, considering the following, to ensure that replication is conducted correctly:

a) identification of the master and the copies including format, variant and version;
b) the number of copies of each software item to be delivered;
c) disaster recovery plans including custody of master and back-up copies where applicable;
d) the period of obligation of the supplier to supply copies and the capability of reading master copies;
e) the type of media for each software item and associated labelling;
f) checks against the possibility of software viruses;
g) the stipulation of required documentation such as manuals and user guides, including identification and packaging;
h) copyright and licensing concerns addressed and agreed;
i) controlling the environment under which the replication is effected to ensure repeatability.

For software product releases, the supplier and customer should agree and document procedures for initial and subsequent releases.

It is recommended that the release of software should establish a baseline that records the tests completed and the resolution of identified deficiencies. Quantitative analysis, to predict system reliability, may be carried out for software with safety and/or security requirements.

These procedures should include the following:

a) descriptions of the types (or classes) of release, depending on the frequency and/or impact on the customer's operations and ability to implement changes at any point in time;
b) methods by which the customer will be advised of current or planned future changes;
c) methods to confirm that changes implemented will not introduce other problems; such methods should include the determination of the level of regression testing to be applied to each release;
d) ground rules to determine where localized temporary fixes may be incorporated or release of a complete updated copy of the software product is necessary;
e) requirements for records indicating which changes have been implemented and at what locations, for multiple products and sites.

When installation of the software product is contractually required, the supplier and customer should agree on their respective roles, responsibilities and obligations, and such agreements should be documented. In providing for installation, consideration should be given to the following:

a) the need for validation at each installation required by contract;
b) an installation procedure;
c) a procedure for approval of each installation upon completion;
d) a schedule;
e) access to customer's facilities (e.g. security badges, passwords, escorts);
f) availability of skilled personnel;
g) availability of and access to customer's systems and equipment;
h) identification of what the customer is to provide at the site;
i) training for the use of new facilities.

NOTE — For further information, see ISO/IEC 12207:1995, subclauses 5.3.12 and 6.3.3.

4.10 Inspection and testing

4.10.1 General

> The supplier shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan or documented procedures.

Testing may be required at several levels, from the individual software item to the complete software product. There are several different approaches to testing, and the extent of testing, the degree of controls on the test environment, test inputs and test outputs, may vary with the approach, complexity of the product, and the risks. Software testing is also performed during software integration. The techniques described under Design review may also be relevant in inspection and testing activities.

The supplier should establish, document and review plans for unit, integration, system and acceptance tests, in accordance with the quality plan or documented procedures, covering, as appropriate:

a) test objectives;
b) configurations to be tested;
c) types of tests to be performed (e.g. functional tests, boundary tests, performance tests, usability tests);
d) sequence of tests, test cases, test procedures, test data and expected results;
e) scope of tests to be performed, in terms of coverage and volumes;
f) relevancy of the tests to the test objectives and to operational use;
g) special concerns such as security and safety;
h) test environment, tools and test software, including any associated qualification and controls;
i) testing of end-user documentation;
j) personnel required and associated training requirements, including training material;
k) the degree of independence between the personnel developing the software and the personnel performing the tests;
l) the responsibilities for specification and performance of the tests;
m) the test completion criteria;
n) the method of recording results;
o) procedures for analysing and approving results;
p) procedures for handling problems found during test execution, including suspension criteria and resumption requirements;
q) the need for, and extent of, regression tests;
r) the repeatability of the tests.

NOTE — For further information, see ISO/IEC 12207:1995, subclauses 5.1.5, 5.3.5.5, 5.3.6.5, 5.3.6.6, 5.3.7, 5.3.11 and 5.3.13.

4.10.2 Receiving inspection and testing

4.10.2.1 The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.2.3) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of conformance to the specified requirements shall be in accordance with the quality plan and/or documented procedures.

4.10.2.2 In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the subcontractor's premises and recorded evidence of conformance provided.

4.10.2.3 Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded (see 4.16) in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.

The supplier may be required to acquire and include software product, including data, supplied by a third party. The supplier should establish and maintain documented procedures for verification (upon receipt) of such product, taking into account the requirements of the contract.

The supplier may apply the same kinds of verification activities to customer-supplied product as to purchased product.

4.10.3 In-process inspection and testing

The supplier shall:

a) inspect and test product as required by the quality plan and/or documented procedures;

b) hold product until the required inspection and tests have been completed or necessary reports have been received and verified, except when product is released under positive-recall procedures (see 4.10.2.3). Release under positive-recall procedures shall not preclude the activities outlined in 4.10.3a).

The general considerations for testing apply.

4.10.4 Final inspection and testing

The supplier shall carry out all final inspection and testing in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

The quality plan and/or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements.

No product shall be dispatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.

Before offering the product for customer acceptance, the supplier should validate the operation of the product in accordance with its specified intended use, under conditions similar to the application environment, as specified in the contract. Any differences between the validation environment and the actual application environment, and the risks associated with such differences, should be identified and justified as early in the life cycle as possible, and recorded.

In the course of validation, configuration audits or evaluations may be performed, where appropriate, before release of a configuration baseline to confirm, by examination of the review, inspection and test records, that the software product complies with its contractual or specified requirements.

When considering the test environment, the following concerns should be addressed:

a) the features to be tested;
b) the controls to be placed on the test environment, including the test tools;
c) any limitations placed on the tests, by the environment.

Where testing in the target environment is required, the following concerns should be addressed:

a) the specific responsibilities of the supplier and customer for carrying out and evaluating the test;
b) restoration of the user environment (after test).

Acceptance test support may be required when the supplier is ready to deliver the validated product. The customer should judge whether or not the product is acceptable according to previously agreed criteria and in a manner specified in the contract. Acceptance tests should be performed by the customer or may be performed on behalf of the customer by the supplier or a third party. The supplier should cooperate in acceptance activities with the customer as stipulated in the contract.

When acceptance testing, if required by the contract, is performed by the supplier, the acceptance test activities may be recognized as relating to final inspection and test, and validation. In some instances, validation, field testing and acceptance testing may be one and the same activity.

Before carrying out acceptance activities, the supplier should assist the customer to identify the following:

a) time schedule;
b) procedures for evaluation, including acceptance criteria;
c) software/hardware environments, including the controls on them;
d) human resources required and associated training.

The method of handling problems detected during the acceptance procedure and their disposition should be agreed between the customer and supplier and documented.

4.10.5 Inspection and test records

> The supplier shall establish and maintain records which provide evidence that the product has been inspected and/or tested. These records shall show clearly whether te product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply (see 4.13).
>
> Records shall identify the inspection authority responsible for the release of product (see 4.16).

The supplier should ensure that the test results are recorded as defined in the relevant specification.

4.11 Control of inspection, measuring and test equipment

4.11.1 General

> The supplier shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software), used by the supplier to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.
>
> Where test software or comparative references such as test hardware are used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product, prior to release for use during production, installation or servicing and shall be rechecked at prescribed intervals. The supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 4.16).
>
> Where the availability of technical data pertaining to the inspection, measuring and test equipment is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the inspection, measuring and test equipment is functionally adequate.
>
> NOTE 17 For the purposes of this International Standard, the term "measuring equipment" includes measurement devices.

Where the supplier uses tools, facilities and techniques, in the conduct of any tests verifying conformance of the software product to specified requirements, the supplier should consider the effect of such tools on the quality of the software product, when approving them. In addition, such tools may be placed under configuration management prior to use.

The scope of use of test tools and techniques should be documented and their use reviewed at defined intervals, to determine if there is a need to improve and/or upgrade them.

NOTE — For further information, see ISO/IEC 12207:1995, subclause 7.2.

4.11.2 Control procedure

The supplier shall:

a) determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision;

b) identify all inspection, measuring and test equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented;

c) define the process employed for the calibration of inspection, measuring and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory;

d) identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status;

e) maintain calibration records for inspection, measuring and test equipment (see 4.16);

f) assess and document the validity of previous inspection and test results when inspection, measuring and test equipment is found to be out of calibration;

g) ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out;

h) ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use are maintained;

i) safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

NOTE 18 The metrological confirmation system for measuring equipment given in ISO 10012 may be used for guidance.

Calibration is a verification technique that is not directly applicable to software. However, it may be applicable to hardware and tools used to test and validate the software. Consequently, items b) to f) above are not applicable to the software itself but may be applicable to the environment used when testing the software.

4.12 Inspection and test status

The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation and servicing of the product to ensure that only product that has passed the required inspections and tests [or released under an authorized concession (see 4.13.2)] is dispatched, used or installed.

The supplier should have a means of identifying the stage of development of the components of the product and the test status. For example: untested; tested with error; tested successfully or approved for release to any further development activity. The creation of builds or the movement of software items between development, test and operational environments may serve to indicate this status. Inspection and test records may be used to identify inspection and test status.

NOTE — For further information, see ISO/IEC 12207:1995, subclause 6.2.

4.13 Control of nonconforming product

4.13.1 General

> The supplier shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. This control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and for notification to the functions concerned.

In software development, segregation of nonconforming items may be effected by transferring the item out of a production or a testing environment, into a separate environment. In the case of embedded software it may become necessary to segregate the nonconforming item (hardware) which contains the nonconforming software.

The supplier should identify at what points control and recording of nonconforming product is required. Where a software item manifests a defect during the development or maintenance process, the investigation and resolution of such defects should be controlled and recorded.

A configuration management process may be invoked to implement part or the whole of this requirement.

NOTE — For further information, see ISO/IEC 12207:1995, subclauses 6.2 and 6.8.

4.13.2 Review and disposition of nonconforming product

> The responsibility for review and authority for the disposition of nonconforming product shall be defined.
>
> Nonconforming product shall be reviewed in accordance with documented procedures. It may be:
>
> a) reworked to meet the specified requirements;
> b) accepted with or without repair by concession;
> c) regraded for alternative applications; or
> d) rejected or scrapped.
>
> Where required by the contract, the proposed use or repair of product [see 4.13.2b)] which does not conform to specified requirements shall be reported for concession to the customer or customer's representative. The description of the nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition (see 4.16).
>
> Repaired and/or reworked product shall be re-inspected in accordance with the quality plan and/or documented procedures.

Attention should be paid to the following aspects, in the disposition of nonconformities:

a) any discovered problems and their possible impacts to any other parts of the software should be noted and those responsible notified so the problems can be tracked until they are resolved;
b) areas impacted by any modifications should be identified and re-tested, and the method for determining the scope of re-testing should be identified in a documented procedure;
c) the priority of the nonconformities.

With software, repair or rework to achieve fulfilment of specified requirements creates a new software version. In software development, disposition of nonconforming product may be achieved by:

a) repair or rework (i.e. to fix defects) to meet the requirement;
b) acceptance with or without repair by concession;
c) treatment as a conforming product after the amendment of requirements;
d) rejection.

4.14 Corrective and preventive action

4.14.1 General

> The supplier shall establish and maintain documented procedures for implementing corrective and preventive action.
>
> Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.
>
> The supplier shall implement and record any changes to the documented procedures resulting from corrective and preventive action.

Where corrective action directly affects the software product, the configuration management process may be invoked to manage the changes. Corrective actions that involve changes to the software life cycle processes should be reviewed by management and implemented by means of document and data control procedures.

NOTE — For further information, see ISO/IEC 12207:1995, subclauses 6.2, 6.8 and 7.3.

4.14.2 Corrective action

> The procedures for corrective action shall include:
>
> a) the effective handling of customer complaints and reports of product nonconformities;
>
> b) investigation of the cause of nonconformities relating to product, process and quality system, and recording the results of the investigation (see 4.16);
>
> c) determination of the corrective action needed to eliminate the cause of nonconformities;
>
> d) application of controls to ensure that corrective action is taken and that it is effective.

No further software-related guidance is provided.

4.14.3 Preventive action

> The procedures for preventive action shall include:
>
> a) the use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports and customer complaints to detect, analyze and eliminate potential causes of nonconformities;
>
> b) determination of the steps needed to deal with any problems requiring preventive action;
>
> c) initiation of preventive action and application of controls to ensure that it is effective;
>
> d) ensuring that relevant information on actions taken is submitted for management review (see 4.1.3).

Analysis of the root causes of nonconformities may provide input to preventive action. The measures taken to reverse unfavourable trends in metric levels may be considered as preventive actions.

4.15 Handling, storage, packaging, preservation and delivery

4.15.1 General

> The supplier shall establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product.

No further software-related guidance is provided.

NOTE — For further information, see ISO/IEC 12207:1995, subclauses 5.2.7.1, 5.3.13.2 and 6.2.6.

4.15.2 Handling

> The supplier shall provide methods of handling product that prevent damage or deterioration.

Damage to software means alteration of contents. Software infection by computer virus should be treated as damaged software.

Software information does not deteriorate; however, the media on which it is stored may be subject to deterioration, and appropriate precautions should be taken by the supplier.

Virus protection requirements, as applicable to software products designated for delivery, are described as part of the guidance on replication.

4.15.3 Storage

> The supplier shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated.
>
> In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.

A system should be established for:

a) storing software items;
b) controlling access to software items;
c) maintaining versions of products in established baselines.

To protect the integrity of the product and provide a basis for the control of change, it is essential that software items be held in an environment which:

a) protects them from unauthorized change or corruption;
b) permits the controlled access to and retrieval of the master and any copies.

Consideration should be given to the storage of computer media, particularly with respect to the electromagnetic and electrostatic environment.

4.15.4 Packaging

> The supplier shall control packing, packaging and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

Packaging requirements, as applicable to software products, designated for delivery, are described as part of the guidance on replication. In cases where electronic storage is used there may be no physical activity related to this clause. During packaging, software may be compressed and/or encrypted.

4.15.5 Preservation

> The supplier shall apply appropriate methods for preservation and segregation of product when the product is under the supplier's control.