INTERNATIONAL STANDARD

ISO 9000-2

Second edition
1997-06-15

Quality management and quality assurance standards —

Part 2:
Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003

Normes pour le management de la qualité et l'assurance de la qualité —

Partie 2: Lignes directrices génériques pour l'application de l'ISO 9001, l'ISO 9002 et l'ISO 9003

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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 9000-2 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 9000-2:1993), 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 to the development, supply and maintenance of software*

— *Part 4: Guide to dependability management*

Annex A of this part of ISO 9000 is for information only.

Introduction

This part of ISO 9000 gives guidance for the application of ISO 9001, ISO 9002 and ISO 9003. To facilitate cross-reference to those standards, this part of ISO 9000 has the same clause structure as ISO 9001, ISO 9002 and ISO 9003.

In general, the number and scope of the quality system elements and procedures required for quality assurance are greatest in ISO 9001 and least in ISO 9003. For all clauses, the guidelines of this part of ISO 9000 should be applied in a manner consistent with the scope and requirements of the corresponding clause, if present, in the standard involved (i.e. ISO 9001, ISO 9002 or ISO 9003). Reference should be made to subclause 8.3 of ISO 9000-1:1994 for guidance on the appropriate extent and degree of demonstration.

ISO 9000-1 gives an overview of the ISO 9000 series of International Standards, and explains the use of the entire series. ISO 9004-1 gives guidance for designing and installing a quality management system.

This part of ISO 9000 does not duplicate the guidance to users that is given in other ISO guidance standards such as ISO 9000-1, ISO 9000-3, ISO 9004-1 and ISO 9004-2.

Quality management and quality assurance standards —

Part 2:
Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003

1 Scope

This part of ISO 9000 gives guidance on the application of the 1994 versions of ISO 9001, ISO 9002 and ISO 9003.

It does not add to, or otherwise change, the requirements of ISO 9001, ISO 9002 or ISO 9003. In the case of conflicting interpretations of ISO 9001, ISO 9002 or ISO 9003 on the one hand, and ISO 9000-2 on the other, the interpretation of the text in ISO 9001, ISO 9002 or ISO 9003 takes precedence. The use of 'should' in this part of ISO 9000 does not weaken the requirements expressed as 'shall' in ISO 9001, ISO 9002 and ISO 9003.

This part of ISO 9000 gives guidance for the following users:

a) suppliers involved in applications of ISO 9001, ISO 9002 or ISO 9003;

b) customers and third parties.

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 8402:1994, *Quality management and quality assurance — Vocabulary.*

ISO 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing.*

ISO 9002:1994, *Quality systems — Model for quality assurance in production, installation and servicing.*

ISO 9003:1994, *Quality systems — Model for quality assurance in final inspection and test.*

3 Definitions

For the purposes of this part of ISO 9000, the definitions given in ISO 8402 and the following apply.

3.1 contract: Agreed requirements between a supplier and customer transmitted by any means.

[ISO 9001]

3.2 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]

3.3 specified requirements

1) Product requirements prescribed by the customer and agreed by the supplier.

2) Requirements prescribed by the supplier that are perceived as satisfying a market need.

3.4 tender: Offer made by a supplier in response to an invitation to satisfy a contract award to provide product.

[ISO 9001]

4 Quality system requirements

4.1 Management responsibility

4.1.1 Quality policy

The supplier's management with executive responsibility (see 4.1.2.1) is required to develop and define its quality policy, quality objectives and commitment in (a) recorded statement(s). This is required to be relevant to its organizational goals, and the expectations and needs of its customers. The statement(s) should be published throughout the organization and be seen to be fully supported by the management.

All employees, including newly hired, part-time and temporary employees, should be trained so that they understand the objectives of the organization and the commitment required to achieve these objectives. The policy should be expressed in language that is easy to understand and the objectives should be achievable, planned and periodically reviewed.

Management should continuously demonstrate visible commitment to the quality policy by activities which may include, but not be limited to, the following:

- ensuring that the organization's personnel understand and implement the quality policy;
- ensuring that the organization's personnel have quality objectives consistent with the organization's overall objectives;
- initiating, managing and following up on the implementation of the quality policy, including implementation and maintenance of the quality system;
- not accepting deviations from the quality policy in any part or aspect of the organization;
- providing adequate resources and training to support quality system development and implementation. (See 4.1.2.2.)

4.1.2 Organization

4.1.2.1 Responsibility and authority

Management with executive responsibility is that person or group of persons within an organization with the necessary level of authority for making policy and setting objectives, planning their implementation, reviewing achievement and taking corrective action. The supplier should clearly identify those persons having such executive responsibility.

In particular the personnel having the responsibility and authority to make decisions that control all the elements of the quality system and processes should be identified and the job requirements defined and documented (see 4.18).

4.1.2.2 Resources

Consideration needs to be given by the supplier's management to the identification and provision of adequate resources needed to implement its quality policy and achieve its objectives as well as to satisfy customer needs and expectations. The following should be considered:

- personnel to plan, manage, perform work, control and carry out verification activities;
- awareness of standards, procedures and other documented practices that are needed;

- training and qualifications (see 4.18);
- planning design, development and production activities to allow sufficient time to perform the work;
- equipment and processes, including acquisition of new equipment or technology;
- means to access quality records.

4.1.2.3 Management representative

Within the supplier's organization, a management representative with delegated authority is required to be appointed for arranging and overseeing the working of the quality system. This management representative is required to be appointed by management with executive responsibility.

The functions of the management representative may be totally related to quality system activities or be in conjunction with other functions and responsibilities within the organization. If the management representative has other functions to perform, there should be no conflict of interest between the responsibilities for the other functions and those for the quality system. The management representative should have the authority to ensure that the requirements of ISO 9001, ISO 9002 or ISO 9003 are satisfied and that compliance is maintained, together with the responsibility to ensure that they are operated throughout the organization.

The defined role should include reporting on the suitability and effectiveness of the quality system as a basis for improvement, management review, and liaison, as necessary, with customers, subcontractors and any other external parties on quality matters.

4.1.3 Management review

The supplier's management with executive responsibility, should review the quality system. This may include, but not be limited to, the following:

- the adequacy of the organizational structure, including its staffing and other resources;
- conformity to ISO 9001, ISO 9002 or ISO 9003, and effective implementation of the quality system;
- compliance with quality policy;
- information based on customer feedback, internal feedback (such as results of internal audits), process performance and product performance, as well as corrective and preventive actions taken.

The intervals between reviews should be carefully planned and periodically reviewed to ensure the continuing suitability and effectiveness of the quality system. The management

review process, frequency of reviews and levels of inputs will depend on the individual circumstance. Some organizations have found that annual management reviews are acceptable.

Management should focus on trends that may indicate problems. Chronic problem areas should receive special attention. Actions that are required following changes to the quality system determined during management review should be implemented in a timely manner. The effectiveness of any changes should be evaluated. Records of such reviews should be maintained (see 4.16).

4.2 Quality system

4.2.1 General

The implementation of a quality system by the supplier is most effective when those in the organization understand its intention and how it functions, in particular, in the area of their responsibility and its interface with other parts of the system. The quality manual has an important role in this regard, for both internal and external parties. To give a coherent view of the quality system, the quality manual should include the quality policy, a description of the organization, and identify the quality system procedures with appropriate cross-references to more detailed documentation. The quality manual could, for example, be one document supported by several levels of other documents, each level becoming progressively more detailed. There may also be an overall system manual, one or more specific procedural manuals, work instructions and reference documents. Together, these documents define the quality system. Further guidance on development of quality manuals is given in ISO 10013.

4.2.2. Quality system procedures

Documented quality system procedures are required for applicable requirements of ISO 9001, ISO 9002 and ISO 9003 and should be consistent with the supplier's quality policy. It is important to recognise that the structure and level of detail required in these procedures should be tailored to the needs of the organization's personnel, which will depend upon methods used and the training requirements, skills and qualifications of such personnel, as indicated in 4.18.

A documented procedure usually specifies the purpose and scope of an activity:

- what shall be done by whom;
- when, where, and how it shall be done;
- what materials, equipment and documents shall be used; and
- how an activity shall be controlled and recorded.

Documented procedures may make reference to work instructions that define how an activity is performed.

4.2.3 Quality planning

The supplier needs to show that planning activities have been performed, and that they establish the means by which the requirements for quality will be met. Planning should include the application of the quality system elements, and how the product quality requirements will be met.

This may require the following.

a) For managerial and operational planning, preparing the application of the quality system.

b) For product planning, setting out in a quality plan or in any other documented procedures the specific quality practices, resources and sequence of activities relevant to a particular product, project or contract.

More guidance on quality plans is given in ISO 10005.

4.3 Contract review

4.3.1 General

In the situation where a tender is offered or a contract or order is to be established between a supplier and a customer, the means of achieving satisfaction lies in the contract review process.

Contract review is one of the supplier's primary interfaces with its customers. The documented procedures should include a review of customer requirements (whether expressed in a tender, contract or order, which may be written or verbal) and how customer requirements are reviewed and communicated within the organization.

The contract review is prior to accepting a contract or an order.

4.3.2 Review

The importance of a thorough understanding of the customer's needs, from initial contact, through tendering or receiving verbal orders, to the formulation of the contract, or order and in all subsequent stages cannot be overstated. Often, dialogue will be necessary to achieve this understanding, that should clearly establish the customer's requirements as to the product, delivery and other critical factors. Where a verbal statement of requirement is received from the customer, the supplier should ensure that an order (statement of requirements) is understood, adequately documented and agreed to by the customer.

Contract review is a process that includes the following:

a) review of the requirement; this may be appropriate at the tendering or order entry stage and at subsequent stages prior to acceptance of the contract or the order;

b) agreement within the supplier's organization that

- the requirements have been defined,
- the requirements are understood,
- the supplier has the capability to meet the requirements of the contract, by going through a defined process to verify that the necessary resources and facilities are available to fulfil all the requirements of the contract;

c) resolution of any differences with the customer;

d) contract review of a standard product (e.g. "off-the-shelf" items, a "commodity item", a catalogue item with published specification, etc.) can be as simple as verifying the accuracy of the information on the order;

e) the requirements of the contract, where appropriate, may be translated into the terminology, tolerances, and other necessary information for designing, purchasing and process control;

f) preliminary quality plan or documented procedures, where appropriate, may be developed to give an understanding of how to implement the contract successfully and support the contract review process.

It is beneficial for the supplier to adopt a contract or order review procedure that has the following features:

- affected parties have an opportunity and adequate time to review the contract;
- a checklist or some other means (e.g. a standard form) is available for reviewers to verify and record that they have reviewed and understood the requirements of the contract or order;
- a method is available for reviewers to question the requirements of the contract or order, to have their questions considered and to have differences with other affected parties resolved.

4.3.3 Amendment to contract

When customer requirements change, consideration should be given to repeating the contract review procedure (see 4.3.2). It is beneficial for the supplier to have a procedure for reviews by the same departmental functions that reviewed the original contract or accepted order. Before such changes come into effect, there should be methods available to ensure that all relevant changes are communicated to those affected.

4.3.4 Records

In all cases, it should be sufficient to retain records that the review has been performed (see 4.16). For internal purposes, however, records of the evaluation associated with the contract

review may be retained in cases such as complex or critical projects. These records should give objective evidence for audits, and facilitate the following:

- post-delivery project review;
- process improvement; and
- the generation of proposals for future projects.

4.4 Design control

4.4.1 General

The essential quality aspects and the regulatory requirements such as safety, performance, and dependability of a product are established during the design and development phase. Deficient design can be a major cause of quality problems.

In considering design control, it is important to note that the design process may apply to various activities in differing styles and timescales. Such aspects are related to products, as well as the process associated with product design. The supplier should consider all phases of the design associated with product design and all phases of the design process for which controlled procedures are necessary.

4.4.2 Design and development planning

The supplier should establish procedures for design and development planning and, where appropriate,include the following:

- identification, scope and objectives;
- sequential and parallel work schedules;
- timing, frequency, and nature of design verification and validation activities;
- evaluation of the safety, performance and dependability incorporated in the product design;
- methods of product measurement, test and acceptance criteria;
- assignment of responsibilities.

Design and development plans should be integrated with any other plans and verification procedures related to the product and plans should be updated as necessary.

The supplier should clearly assign responsibilities for specific design leadership and other design work functions to qualified personnel. The personnel in these functions should have access to information and the resources to complete the work.

Design activities should be defined to the level of detail necessary for carrying out the design process.

4.4.3 Organizational and technical interfaces

When input to the design is from a variety of sources, the inter-relationships and interfaces, as well as the pertinent responsibilities and authorities, should be defined, documented, coordinated, and controlled.

Many organizational functions, both internal and external, may contribute to the design process; examples are as follows:

- research and development;
- marketing and sales;
- purchasing;
- quality assurance and quality management;
- engineering;
- materials technology;
- production/manufacturing;
- service groups;
- facilities management;
- warehousing/transportation/logistics;
- communications;
- information systems.

They should also establish, but not limit themselves to, the following:

- what information should be received and transmitted;
- identification of sending and receiving groups;
- the purpose of the information transmitted;
- identification of transmittal methods;
- document transmittal and records maintenance.

4.4.4 Design input

User needs (through marketing) or customer requirements (through contract) should be established during contract review (see 4.3) that, together with relevant statutory legislation, will form the design input requirements.

Design inputs are typically in the form of product requirement specifications and/or product description with specifications relating to configuration, composition, incorporated elements, and other design features.

All pertinent design inputs (such as performance, functional, descriptive, environmental, safety and regulatory requirements) should be defined, reviewed and recorded by the supplier. The design inputs should describe all requirements to the greatest possible extent; they lay the foundation and provide a unified approach to the design. Details agreed between customer and supplier on how customer, statutory and regulatory requirements will be met should be included. The record of the design inputs should also include the resolutions of any incomplete, ambiguous or conflicting requirements that have been identified at the contract review and/or design verification stages or related design control activities.

The design inputs should identify design criteria, materials, and processes requiring development and analysis, including prototype testing to verify their adequacy. Design inputs should be prepared in a way that facilitates periodic updates. They should indicate 'when' or 'what criteria' will cause the inputs to be updated, who is responsible for the update, and under what circumstances the customer will get a copy. Design inputs prepared in this way serve as the definitive up-to-date reference document as the design progresses to completion.

4.4.5 Design output

Throughout the design process, the requirements contained in the design description are translated by the supplier into outputs. Design outputs should be documented in terms that can be verified and validated against design input requirements and need to contain or make reference to acceptance criteria; examples of these can be found in the following:

- drawings and parts list;
- specifications (including process and materials specifications);
- instructions;
- software;
- servicing procedures.

Design outputs are the product requirements used for purchasing, production, installation, inspection and testing, and servicing. Because of their impact on follow-on activities, it is important that the outputs are reviewed and approved before release.

4.4.6 Design review

Design reviews should be planned. In order to achieve a degree of objectivity, they need to involve all functions, both internal and external, concerned with the design stage being reviewed. Design staff and other specialist personnel should also participate as required. Design review may be a regulatory requirement for certain types of product. The timing and frequency of these reviews will be influenced by the maturity, complexity and cost of the product being designed. Records of such reviews should be maintained (see 4.16).

The competence of the participants in the design reviews should be adequate to permit them to examine designs and their implications. Design reviews may consider questions such as the following.

a) Do designs satisfy all specified requirements for the product?

b) Are product design and processing capabilities compatible?

c) Are safety considerations considered?

d) Do designs meet functional and operational requirements, for example, performance and dependability objectives?

e) Have appropriate materials and/or facilities been selected?

f) Is there adequate compatibility of materials, components and/or service elements?

g) Is the design satisfactory for all anticipated environmental and load conditions?

h) Are components or service elements standardized and do they provide for reliability, availability and maintainability?

i) Is there a provision in tolerances, and/or configuration, for interchangeability and replacement?

j) Are plans for implementing the design technically feasible (e.g. purchasing, production, installation, inspection and testing)?

k) Where computer software has been used in design computations, modelling or analyses, has the software been appropriately validated, authorized, verified and placed under configuration control?

l) Have the inputs to such software, and the outputs, been appropriately verified and documented?

m) Are the assumptions made during the design process valid?

n) Are the results of model or prototype testing considered?

4.4.7 Design verification

ISO 9001 describes design control measures (e.g. design reviews, tests and demonstrations, alternative calculations and comparison with a proven design) by which design verification may be established by the supplier. Design verification is a necessary check to ensure that the design outputs conform to specified requirements (design inputs). This is an ongoing activity and in some instances a combination of these measures may be necessary. Design verification measures should be recorded (see 4.16).

The timing and personnel involved in these verifications should be considered in the design and development planning phase.

When alternative calculations or comparison with a proven design are employed as forms of design verification, the appropriateness of the alternative calculation method, and/or proven design, should be reviewed in relation to this new application.

When tests and demonstrations are employed as a form of design verification, the safety and performance of the product should be verified under conditions that are representative of the full range of circumstances of actual use. The product units employed for tests and demonstrations should be produced under the expected production conditions.

At any stage before release when the review of design outputs, is employed as a form of design verification, this should be in accordance with relevant standards, practices and predetermined acceptance criteria.

4.4.8 Design validation

Design validation is necessary to confirm that the end product fulfils the specified requirements for its intended use. It may be necessary to involve the customer in design validation.

After successful design verification, a design validation should be performed under defined conditions for the use of the final product. However, it may need to be performed at earlier stages during product development if there are features that it is not possible or practical to validate at the final stage. Conversely, there will be other situations where validation can only be performed by observation during initial use of the product.

The results of the examination, tests and demonstrations carried out under design validation should be included in the design records.

4.4.9 Design changes

Design of a product may be changed or modified for a number of reasons, for example:

- omissions or errors (e.g. in calculation, material selection, etc.) during the design phase which have been identified afterwards;

- manufacturing, installation and/or servicing difficulties found after the design phase;
- the customer or subcontractor requests changes;
- the function or performance of a product is to be improved;
- changes to safety, regulatory, or other requirements;
- design review (see 4.4.6), design verification (see 4.4.7) or design validation (see 4.4.8) requires change;
- corrective or preventive action requires change (see 4.14).

Any changes to design inputs should be identified and reviewed by the supplier to determine whether they influence the previously approved design review, verification or validation results. Design changes in one component of a product should be evaluated for their influence on the whole. Improving one characteristic may have unforeseen adverse influence on another.

When significant design changes are made, the verification procedure should also be reviewed and modified as appropriate.

Procedures should be established to communicate the new design output to all concerned, to record any design changes and to ensure, as well as document, that all authorized design changes and only those are implemented (see 4.5.3).

4.5 Document and data control

4.5.1 General

Document and data control should include those documents and data pertinent to design, purchasing, processing, quality standards, inspection of materials and the quality system documents. Information and/or instructions in documents and data can be recorded, transmitted or received using a variety of media (e.g. hard copy, magnetic disks or tapes). Documents describe or control how things are to be done and should be revised to reflect changing circumstances. Data comprise information upon which a decision may be made; data may be contained in documents or other forms.

4.5.2 Document and data approval and issue

The supplier's system should provide a clear and precise control of procedures and responsibilities for approval, issue, distribution, and administration of internal and external documentation and data, including the removal or identification (to prevent misuse) of obsolete documents. This can be accomplished, for example, by maintaining a master list or equivalent document control procedure of documents or data identifying the level of approval, distribution (location of copies) and revision status. A supplier's internal written procedures should describe the following:

- how the documentation and data for these functions should be controlled;
- who is responsible for the control;
- what is to be controlled;
- where and when the control is to take place.

Applicable documents and data should be accessible in the relevant places of work.

4.5.3 Document and data changes

Recognizing that supplier documentation or data may be subject to revision and change, controls should exist for the preparation, handling, issue and recording of changes. This applies not only to internal documentation and data but also to externally updated documentation (e.g. national standards) and data.

The supplier should establish a procedure for controlling changes in documentation and data, which should

- provide for control of all types of documentation or data media;
- follow documented procedures;
- ensure accurate updating of documents and data;
- provide for using only authorized documents and data when implementing changes;
- preclude confusion, especially where there is a multiplicity of sources authorizing changes and releasing documents and data;
- record the reasons why a change was made.

Consideration should be given to the effect that the proposed changes may have on other parts of the system or the product. Actions may be needed before a change is implemented to assess the effect of the change on other parts of the organization and notify them as appropriate.

Planned circulation of a change proposal to personnel in the affected functions can assist in avoiding disruption. Timing of implementation of the change may be an important factor, particularly when several changes of documentation or data are to be coordinated.

4.6 Purchasing

4.6.1 General

To ensure that purchased products that become part of, or affect the quality of, the supplier's product conform to specified requirements as well as statutory or regulatory requirements, purchasing should be planned and carried out by the supplier under adequate control. This should include, but not be limited to, the following:

- evaluation and selection of subcontractors (see 4.6.2);
- clear and unambiguous purchasing requirements (see 4.6.3);
- the performance of suitable verification (see 4.6.4);
- receiving inspection procedures (see 4.10.2).

The supplier should establish an effective working relationship and feedback system with its subcontractors.

4.6.2 Evaluation of subcontractors

In developing methods to ensure the conformity of purchased product, the supplier is required to establish that all subcontractors have the capability of supplying products meeting the specified requirements.

The supplier should operate a documented procedure to evaluate the capabilities of subcontractors. The extent of the evaluation varies according to the importance of the purchased product and its impact on the final product.

An evaluation may vary from a comprehensive audit of the subcontractor's quality system to the acceptance of an evaluation and approval by reference to historical data (e.g. records of past performance or certified products and quality system registration schemes). In any event, the supplier is required to be able to demonstrate that formal consideration was given to the evaluation and that the selection of a subcontractor was based on an appraisal appropriate to the product being purchased.

The supplier should be able to demonstrate that subcontractors are being evaluated on the basis of performance. Records of acceptable subcontractors should be maintained (see 4.16).

4.6.3 Purchasing data

The supplier's purchasing data should define the specified requirements to the subcontractor to ensure the quality of the purchased product, including technical product requirements, calibration services, special processes and inspection and test activities. This may be done, in part, by reference to other applicable technical information such as national or international standards, test methods, etc. Another approach is for information to be clearly and precisely stated to the subcontractor on the purchase order. Responsibilities for reviewing and

approving the purchasing data should be clearly assigned to appropriate personnel. The revision status of documents referenced in the purchasing data should be identified.

4.6.4 Verification of purchased product

4.6.4.1 Supplier verification at subcontractor's premises

When contractually specified, the supplier may be involved with verification activities at the subcontractor's premises.

The supplier should include in purchasing documents special clauses or statements regarding verification procedures, and product release methods (e.g. product shipment should have prior approval of the supplier) when verification is to be carried out at the subcontractor's facilities.

4.6.4.2 Customer verification of subcontracted product

When specified by the customer, the supplier should include in subcontracts special clauses or statements when verification is contractually required at source (e.g. the subcontractor's facilities).

When specified in the contract, the customer may extend verification activities to the facilities of the subcontractor to assure that the product fulfils the specified requirements. In such cases, the supplier should arrange for the customer to verify the quality of the subcontractor's product and, if necessary, the effectiveness of the process.

Where the contract provides, the customer may use the supplier's data to decide which of the products to be purchased will require verification at source and to decide the nature and extent of such verification.

If the customer, on verification of the subcontractor's product, expresses satisfaction, the supplier should not take this as an opportunity to relax controls. The supplier retains full responsibility for the quality of the product being supplied to the customer.

4.7 Control of customer-supplied product

The supplier, upon receipt of customer-supplied product that is furnished to the supplier for use in meeting the requirements of the contract, accepts responsibilities for prevention of damage and for identification, preservation, storage, handling and use while that product is in the supplier's possession.

The supplier should therefore establish arrangements, as necessary, for the following:

- examination of the product upon receipt to check the quantity received and its identity, and to detect any damage in transit;

- periodic inspection during storage to detect any signs of deterioration, to check the limitations on time in storage, to assure maintenance of proper conditions and to determine the current state of the product;

- compliance with any contractual requirements;

- identification and safeguarding of the supplied product to prevent any unauthorized use or improper disposal.

The responsibility should be defined for reporting unsuitability to the customer, who is responsible for providing acceptable product within the terms of the contract. Records of products that are lost, damaged or otherwise unsuitable for use should be maintained (see 4.16).

The supplier should consider the significance of customer-supplied product during contract review, particularly when the customer-supplied product is a service (e.g. the use of a customer's transport for delivery). The supplier should be able to show documentary evidence that this is being done, where appropriate. The supplier should obtain from the customer, as appropriate, information or requirements concerning handling, storage and maintenance of customer-supplied product.

When necessary, the need for calibration of customer-supplied tools and equipment should be specified by the customer.

4.8 Product identification and traceability

Where appropriate the supplier should define the means for product identification This may be done by marking, tagging or the location of the product or its container. For example, on visually identical parts where the functional characteristics are different, different colours may be used. For bulk products or product from continuous processes, the identification may be by marking of batches or well-defined lots and accompanying documents. Service identification may be achieved by documentation that accompanies the service.

Product traceability involves the ability to trace the history, application or location of an item or activity by means of recorded identification. Traceability is typically required when there is a need to track a nonconformity back to its source and to determine the location of the remainder of the affected batch. Traceability may entail additional cost and, when specified in a contract, the extent of quality records should be stated.

The supplier can achieve traceability by each individual product having an identifier (e.g. serial number, date code, batch code, lot number) unique to the source of operation. Separate identifiers could be required for changes in operative personnel, changes in raw materials, changes in tooling, new or different machine set-ups, changes in process methods, etc. Traceability identifiers should appear on applicable inspection and stock records (see 4.16). There may be situations where traceability requires identification of the specific personnel involved in each phase of product processing or delivery. A sequence of individuals may perform successive service functions, each of which is to be traceable. The recording of identification evidence through signatures on serially numbered documents in invoicing and

banking operations are examples. Here there is no tangible product as such, but each individual's identification evidence should be traceable.

4.9 Process control

The supplier's planning for the production, installation and servicing processes should consider each of the controlled conditions described in subclause 4.9 of ISO 9001:1994 and ISO 9002:1994. Control within the process to prevent nonconformities from occurring is preferable to inspection of finished product or servicing alone. The characteristics that are most critical to the product and/or servicing quality should be identified and subjected to process control procedures

Process control activities may include procedures for accepting materials or items into the process and determining their characteristics while in-process. The amount of in-process testing and inspection performed will depend partly on the effect of nonconformities on the following processes. The adequacy of measurement processes should be considered when reviewing the effectiveness of production process control.

The supplier should include within the scope of the quality system the proper maintenance of process equipment and essential materials. It is the supplier's responsibility to establish process capability and define the maintenance activities that will ensure continuing process capability.

Some processes are such that the product quality characteristics cannot be fully verified after the completion of the processes. These are frequently referred to as 'special processes'. Although these processes are found in all generic product categories (hardware, software, processed materials and services), they are particularly common in the production of processed materials. Examples include circumstances where:

- certain product characteristics do not exist until later in the process;
- the method of measurement does not exist or is destructive to the product;
- it is not possible or practical to measure a characteristic in later inspections or tests.

Some examples where critical product quality characteristics fall within one or more of the three process circumstances above include the following:

- strength, ductility, fatigue life, corrosion resistance of a metal part, following welding, soldering, heat treatment or plating;
- dyeability, shrinkage, tensile properties of a polymerized plastic;
- taste, texture, appearance of a bakery product;
- correctness of a software product or a financial or legal document.

Such products are typically the final result of a series of operations and require close adherence to specified in-process procedures and sequences such as the following.

a) For a hardware or processed materials product, these can involve starting materials, temperature profiles, physical deformations, mixing and environmental conditions.

b) For a software or service product, these can involve source data and documents that are subject to regulatory and copyright requirements.

Comprehensive measurement assurance and calibration of equipment used to produce or measure the product should be required for such processes. Where suitable, process control should include statistical process control methods, supplemented by procedures to maintain the suitability of software, of in-process materials and of activities needed for appropriate storage, handling and segregation.

Special skills, capabilities and training of personnel (see 4.18) may be needed. The qualification requirements (e.g. skills, knowledge, physical capabilities) of personnel should be stated and conformity to the requirements demonstrated.

Process knowledge can be considered as a basis to differentiate finished product characteristics from measurable in-process characteristics. Such processes should have stated qualification requirements and should be qualified in advance, by examination, inspection, measurement or test to verify that the process can meet the specified requirements. Records of these requirements should be maintained (see 4.16).

4.10 Inspection and testing

4.10.1 General

This subclause considers all of those inspection and test activities carried out from receiving inspection to product delivery, installation and servicing as appropriate. It requires that the supplier establish and maintain documented procedures for these activities, in order to verify conformity to specified requirements and that the appropriate records are kept.

4.10.2 Receiving inspection and testing

4.10.2.1 Receiving inspection is one method for the supplier to verify that purchased items delivered to the supplier's facilities fulfil specified requirements for quality.

The supplier's procedures or quality plan should specify the method of verifying that shipments received are in accordance with specifications, are complete, have proper identity and are undamaged. The procedures should also include provisions for verifying that incoming items, materials or services are accompanied by the required supporting documentation (e.g. certificates of conformity, mill test reports and acceptance test reports). Appropriate action in the event of nonconformities should be specified (see 4.13). Analysis of previous receiving inspection data, in-plant rejection history or customer complaints should influence the supplier's decisions regarding the amount of inspection required, and the need to reassess a subcontractor.

4.10.2.2 This subclause does not imply that incoming items have to be inspected and tested by the supplier, if the necessary confidence in the product can be obtained by other defined procedures, particularly in cases where the information given by a subcontractor is considered sufficient (see 4.6.4).

4.10.2.3 Release of incoming product subject to recall should be discouraged as a matter of good quality management practice. Product should only be released subject to recall if

- an objective evaluation of quality status and solution of any nonconformities can still be implemented;
- correction of nonconformities cannot compromise the quality of adjacent, attached or incorporated product.

The supplier's procedures should define who is authorized to allow incoming product(s) to be used without prior demonstration of conformity to specified requirements for quality. The supplier's procedures should also define how such product will be positively identified and controlled in the event that subsequent inspection finds nonconformities.

4.10.3 In-process inspection and testing

In-process inspection and testing applies to all forms of product. It allows early recognition of nonconformities and their timely disposition.

Where appropriate, statistical control techniques should be used to identify adverse trends for both product and process before nonconformities actually occur.

Early identification of nonconformities, before arriving at the final inspection stage, increases the efficiency of the entire operation by avoiding further processing of nonconforming items.

The supplier's procedures or quality plan should ensure the validity of the inspection and test results including situations where in-process inspection is carried out by production personnel.

4.10.4 Final inspection and testing

Final inspection involves activities (examination, inspection, measurement or test) upon which the final release of product is based. Records of previously performed inspection and testing results may also be reviewed.

4.10.5 Inspection and test records

The supplier's inspection and test records (see 4.16) should facilitate assessment of products having fulfilled the requirements for quality. Records are useful for showing compliance with statutory and regulatory requirements and may also give supporting evidence in product liability considerations. Records of process failure are useful in improving the process (see 4.14.3).

4.11 Control of inspection, measuring and test equipment

4.11.1 General

This subclause applies to inspection, measuring and test equipment used to demonstrate conformity of the product to specified requirements. Some products in the service sector are not subject to the use of equipment for inspection, measuring and test, as is typical for suppliers of hardware and processed materials; in which case the requirements of this subclause may not apply.

Although the requirements pertain explicitly to inspection, measuring and test equipment, including test software, it is helpful to approach the subject from the perspective that measuring is itself a process involving materials, equipment and procedures. The requirements explicitly involve elements of the measurement process; elements whose collective purpose is to choose suitable measurements, suitable inspection, measuring and test equipment, and suitable measurement procedures. These elements are specified to give confidence in the ability of the supplier's measuring systems to control adequately the production and inspection of the product.

Statistical methods are valuable tools for achieving and demonstrating fulfilment of requirements. In particular, statistical methods are the important tools in fulfilling the requirement that "Inspection, measuring and test equipment shall be used in a manner which ensures that measurement uncertainty is known and is consistent with the required measurement capability".

The requirements of this subclause also should be applied by the supplier when demonstrating the conformity of the product to the specified requirements. This may contractually involve measurements subsequent to production and inspection of a product, for example, during handling, storage, packaging, preservation, delivery or servicing.

4.11.2 Control procedure

This subclause defines the extent of control to be exercised with regard to inspection, measuring and test equipment. Records of calibration should be maintained (see 4.16). For general background and guidance on the management of inspection, measuring and test equipment, it is recommended that ISO 10012-1 be consulted.

NOTE — It should be recognised that the requirements and guidance in ISO 10012-1 are not mandatory and do not add to, or otherwise change, the requirements of ISO 9001, ISO 9002 or ISO 9003.

4.12 Inspection and test status

The supplier's quality system and procedures should ensure that required inspections and tests are performed. The system should provide a way of knowing the inspection and test status of a product throughout production, installation and servicing. Status may be indicated by marking, location, tagging or signing, either physically or by electronic means.

The status should indicate whether or not a product has been inspected and tested and either:

- accepted as fully meeting requirements, or

- accepted with identified nonconformities under concession, or

- put on hold awaiting further analysis/decision, or

- rejected as unsatisfactory.

Separate physical location of these categories of a product is often the most certain method of assuring both the status and accurate disposition. However, in an automated process accurate disposition may equally be achieved by other means, such as a computer database.

4.13 Control of nonconforming product

4.13.1 General

When any intermediate or final product is found (e.g. by test or inspection) not to conform to the specified requirements, inadvertent use should be prevented. This is applicable to nonconforming product occurring in the supplier's own facilities as well as to nonconforming product received by the supplier. Procedures should be established and maintained by the supplier for the following purposes:

- to determine which product is involved in the nonconformity, for example, what production time interval, production machines or products are involved;

- to identify the nonconforming product to make sure that it can be distinguished from the conforming product (see 4.12);

- to document the existence and source of the nonconformity;

- to evaluate the nature of the nonconformity;

- to consider the alternatives for disposition of the nonconforming product, to decide and record what disposition should be made;

- to control (e.g. by physical segregation) the subsequent processing of the nonconforming product consistent with the disposition decision;

- to notify others that may be affected by the nonconformity including, where appropriate, the customer.

4.13.2 Review and disposition of nonconforming product

The supplier should have a nonconformity handling process with designated disposition authority for technical specifications, rework processes and contractual requirements. Repaired and reworked product should be re-inspected in accordance with the documented procedures or the quality plan.

Information concerning nonconforming items should be provided to all appropriate personnel, so that action is taken if necessary to identify and correct the cause of the nonconformity and prevent recurrence (see 4.14). These records (see 4.16) and their analysis form a measure of the effectiveness of the quality system.

Requests by the supplier for concessions or changes in specification should be processed in accordance with documented procedures. The supplier should ensure that such requests are clear and accurate. Any additional information, comment or recommendation that might assist the customer to arrive at a decision should be given. Concessions requested by subcontractors may be agreed by the supplier. The customer's agreement to these concessions may form part of the contract with the supplier.

The foregoing guidance is equally applicable to product purchased from subcontractors that is found to depart from the specified requirements.

While ISO 9003 does not have a subclause dealing explicitly with the review and disposition of nonconforming product, the guidance presented here may be helpful in the implementation of sublause 4.13 of ISO 9003:1994.

4.14 Corrective and preventive action

4.14.1 General

The supplier should have documented procedures for identifying and eliminating the causes of actual or potential nonconformities in products, processes or the quality system.

Causes of detected nonconformities should promptly be identified so that corrective action may be taken and recurrence prevented. These causes may include the following:

- failures, malfunctions or nonconformities in incoming materials, processes, tools, equipment or facilities in which products are processed, stored or handled, including the equipment and systems therein;
- inadequate or non-existent procedures and documentation;
- non-compliance with procedures;
- inadequate process control;
- poor scheduling;
- lack of training;
- inadequate working conditions;
- inadequate resources (human or material);
- inherent process variability.

The conditions resulting from these causes may be revealed by analysis of the following:

- inspection and test records;
- nonconformity records;
- observations during process monitoring;
- audit observations;
- field, service or customer complaints;
- regulatory authority or customer observations;
- observations and reports by personnel;
- subcontract problems;
- management review results;
- inherent process variability.

The same causes and conditions may be involved in preventive action, where patterns or trends that may indicate the potential for occurrence of nonconformities should be investigated. The degree of corrective or preventive action taken should be dependent upon and directly related to the risk, size and nature of the problems and their direct effects on product quality.

It should be noted that the requirement for corrective action is less comprehensive in ISO 9003, and preventive action is not required in ISO 9003.

4.14.2 Corrective action

Documented procedures should be established to determine corrective actions and how this should be carried out and their effectiveness verified. It may be beneficial to take into account information concerning corrective actions when carrying out management reviews (see 4.1.3).

It is useful to implement procedures to deal with nonconformities discovered in product that has already been shipped as satisfactory. Such procedures can include investigations to establish whether the nonconformity is an isolated or a repetitive problem and any actions to be taken, if necessary.

Corrective action to eliminate the cause of a nonconformity is not necessarily required for every occurrence or for isolated incidents of a minor nature, but periodic analysis of patterns of nonconformities should be considered to identify opportunities for process improvement.

4.14.3 Preventive action

It should be noted that corrective action is taken after nonconformities are identified. Preventive action is taken when a potential nonconformity is identified as a result of the analysis of records and other relevant sources of information, such as the following:

- statistical process control documents;
- customer complaints;
- internal and subcontractor-sourced product, process and quality system information (see 4.14.1).

Records relating to the performance of the product should be analysed regularly, to detect any trends and to identify areas of risk that may lead to potential nonconformities. The analyses should also determine the actions necessary to prevent any identified potential problems.

Information on preventive actions taken is required to form an integral part of the management review process (see 4.1.3), to maintain and improve the effectiveness of the quality system.

Preventive action to eliminate a potential nonconformity is not necessarily required for every potential nonconformity identified, but should be considered for system improvement.

4.15 Handling, storage, packaging, preservation and delivery

4.15.1 General

The supplier's system should provide adequate planning, control and documentation for handling, storage, packaging, preservation and delivery of product. This applies to materials in-process and finished product.

4.15.2 Handling

The supplier's method for handling product should consider providing equipment such as anti-static wrist straps, gloves and protective clothing, also transportation units such as pallets, containers, conveyors, vessels, tanks, rigging, pipelines and vehicles. This is necessary so that damage, deterioration or contamination (due to vibration, shock, abrasion, corrosion, temperature variation, electrostatic discharge, radiation or any other conditions occurring during handling and storage) may be prevented. Maintenance of handling equipment is another factor to be considered.

4.15.3 Storage

The supplier should provide suitable storage facilities, considering not only physical security but also environmental conditions (e.g. temperature and humidity). It may be appropriate to check periodically items in storage to detect possible deterioration. The methods for identification should give legible, durable information in accordance with the specified

requirements. Consideration may need to be given to administrative procedures for product expiration dates, stock rotation and lot segregation.

4.15.4 Packaging

The supplier's packaging, materials, packing and labelling should provide adequate protection against damage to the product. The various forms of storage and the types of transportation that can be encountered should be considered.

The packaging should provide a clear description of the contents or ingredients of the product where regulations or the contract specify.

Provisions should be made for checking the effectiveness of the packaging.

4.15.5 Preservation

The supplier's preservation methods should include appropriate protection against deterioration and contamination during storage, transportation or any later period until the supplier's responsibility ceases.

Examples of preservation measures are as follows:

- maintenance of sterile conditions for medical equipment;

- maintenance of dust and static free conditions for semiconductors;

- protection for fragile products;

- controlled temperature/humidity and hygienic conditions for handling foodstuffs.

4.15.6 Delivery

The supplier should provide for protection of the quality of product after final inspection and test. Where contractually specified, the supplier should provide for the protection of the quality of the product during shipping and other phases of delivery. For some products, delivery time is a critical factor. Consideration should be given to the various types of delivery and variations in environmental conditions that may be encountered.

4.16 Control of quality records

Quality records should give evidence directly or indirectly as to whether or not the product meets specified requirements. These records may be confidential and should be treated appropriately.

The supplier's quality records should give evidence that quality system elements falling within the requirements of ISO 9001, ISO 9002 or ISO 9003 have been implemented. If the results have not proved satisfactory, quality records should indicate what has been done to correct the situation.

Quality records should be prepared, stored safely, protected from unauthorized access, protected from alteration and maintained by the supplier. Quality records should be properly identified, collected, indexed and filed, and readily accessible as and where needed. They may be stored or copied in any suitable form, for example hard copy or electronic media. Where records are held on electronic media, consideration of the retention times and accessibility of the records should take into account the rate of degradation of the electronic images and the availability of the devices and software needed to access the records Such copies of quality records should contain all the relevant information in the original quality records. The supplier should consider how to translate the requirements of the contract into the needs for submission and retention and disposition of quality records.

There may be circumstances in which the customer is required to store and maintain selected quality records attesting to the quality of products for a specified part of the operating lifetime. The supplier should make due allowance for the provision of such documents to the customer.

ISO 9001, ISO 9002 and ISO 9003 do not specify a minimum time period for the retention of quality records. There may be circumstances where it is the supplier's responsibility to verify with regulatory authorities what their requirements are. The aspects of product liability and legality of various forms of record-keeping should be taken into consideration. If a specific period of time is required, it should be specified in the contract. If time periods are not prescribed by legislation or in the contract, the supplier should consider the expected lifetime of the product and should document the appropriate retention times. Records may be disposed of after the specified retention period. The supplier may also take into account the nature of the product and determine an appropriate retention time.

A number of clauses throughout ISO 9001 make reference to records and to this subclause (4.16). Some examples of quality records are

- management review records,
- contract review,
- inspection and test records,
- internal quality audit records.

4.17 Internal quality audits

Internal quality audits should be carried out by the supplier in order to determine whether the various quality system elements are effective and suitable to achieve the stated quality objectives. The frequency of periodic audits should be defined in an internal audit schedule.

The supplier should select and assign qualified auditors for the activity being audited. The requirement for the audit activity to be carried out by personnel independent of those having direct responsibility for the activity being audited does not preclude persons who have specific functions and responsibilities within the organization from being internal auditors of other functions and areas within the organization.

Periodic internal audits may be performed on parts of the quality system or the whole quality system

- to determine the adequacy and conformity of the quality system elements with the requirements for their documentation and implementation requirements;
- to determine the effectiveness of the implemented quality system;
- to give an opportunity to improve the supplier's quality system;
- to facilitate external quality audits.

In addition to the periodic internal audits, an internal audit may be initiated for the following reasons:

- initially to evaluate the quality system where there is a desire to establish a contractual relationship;
- within the framework of a contractual relationship, to verify that the quality system continues to meet specified requirements and is being implemented;
- when significant changes have been made in functional areas, for example, reorganizations and procedures revisions;
- when safety, performance or dependability of the products are in, or are suspected to be in, jeopardy due to nonconformities;
- when it is necessary to verify that required corrective actions have been taken and have been effective.

The results of audits should be stated in a written report (see 4.16) and the records should indicate the deficiencies found and corrective action(s) required.

Target dates for responding to audit findings should also be included. The audit result should be communicated as follows:

- given to the management personnel responsible for the department or function being audited; and
- an input to management reviews (see 4.1.3).

It is important that follow-up audit activities demonstrate and confirm that corrective action has been taken and is effective (see 4.16).

For general guidelines for auditing quality systems, it is recommended that ISO 10011-1, ISO 10011-2 and ISO 10011-3 be consulted.

NOTE — The guidance in the ISO 10011 series does not add to, or otherwise change, the requirements of ISO 9001, ISO 9002 and ISO 9003.