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Quality management and quality assurance standards —

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

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

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

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Contents

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Annex

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*, Sub-Committee SC 2, *Quality systems*.

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 programme management*

Part 1 is a revision of ISO 9000:1987.

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

Introduction

This part of ISO 9000 gives guidelines for 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 and contains clause-by-clause cross-references to ISO 9001, ISO 9002 and ISO 9003.

In general, the number and scope of the quality system elements and procedures contractually 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 sub-clause 8.3 of ISO 9000 for guidance on the extent and degree of demonstration that may be appropriate.

ISO 9000 provides an overview of the ISO 9000 series of International Standards, and is a "road map" for use of the entire series. ISO 9004 provides extensive quality management guidance to the supplier organization, for designing and installing a quality system appropriate to its needs, without regard to contractual requirements of quality assurance.

This part of ISO 9000 does not duplicate the guidance to users that is provided in other ISO guidance standards such as ISO 9000, ISO 9000-3, ISO 9004 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 to enable its users to have improved consistency, precision, clarity and understanding when applying the requirements of the quality systems standards ISO 9001, ISO 9002 and ISO 9003. This part of ISO 9000 is phrased in terms of guidance to the supplier in order to reflect the requirements of ISO 9001, ISO 9002 or ISO 9003. However, this part of ISO 9000 does not add to, or otherwise change, the requirements of ISO 9001, ISO 9002 and ISO 9003. In a case of conflicting interpretation 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.

This part of ISO 9000 is equally applicable to both manufacturing and service industries seeking to implement quality assurance into organizations.

In particular, this part of ISO 9000 gives guidance for the following users:

a) **suppliers** and **purchasers** involved directly in contractual applications of ISO 9001, ISO 9002 and ISO 9003;

b) **sub-contractors** who provide to the supplier raw materials, intermediate processing, equipment, services, etc., and who are affected by the application of ISO 9001, ISO 9002 or ISO 9003;

c) **auditors** who need to assess and communicate the adequacy of implementation of the requirements of ISO 9001, ISO 9002 or ISO 9003 in a specific situation.

The field of application of this part of ISO 9000 corresponds to the field of application of ISO 9001, ISO 9002 or ISO 9003.

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:—[1], *Quality management and quality assurance — Vocabulary.*

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

ISO 9002:1987, *Quality systems — Model for quality assurance in production and installation.*

ISO 9003:1987, *Quality systems — Model for quality assurance in final inspection and test.*

1) To be published. (Revision of ISO 8402:1986)

3 Definitions

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

In order to clarify the meaning of the terms "supplier", "purchaser" and "sub-contractor", the following usages apply in this part of ISO 9000.

3.1 supplier: Organization to which the requirements of ISO 9001, ISO 9002 or ISO 9003 apply.

3.2 purchaser: Recipient of products (including services) delivered by the supplier.

3.3 sub-contractor: Organization which provides products (including services) to the supplier.

NOTE 1 For any one situation, an organization can, in addition to being *the* supplier, also be *a* purchaser and/or *a* sub-contractor at the same time.

4 Quality system requirements

4.1 Management responsibility

4.1.1 Quality policy

Guidance for ISO 9001 (4.1.1), ISO 9002 (4.1.1) and ISO 9003 (4.1.1)

When defining and documenting its quality policy, quality objectives and commitment to quality, supplier management should consider the following points.

a) The quality policy should be expressed in language which is easy to understand.

b) The quality policy should be relevant to the organization, its other policies, the products or services provided, and the organization's personnel.

c) The objectives should be achievable.

Management should demonstrate commitment visibly and actively on a continuing basis.

Commitment can be demonstrated by activities such as the following:

— ensuring that the organization's personnel understand and implement the quality policy;

— initiating, managing and following up on the implementation of the quality policy, including implementation of the quality system;

— not accepting deviations from quality policy or wasted resources in any part or aspect of the organization;

— providing adequate resources and training to support quality system development and implementation.

4.1.2 Organization

4.1.2.1 Responsibility and authority

Guidance for ISO 9001 (4.1.2.1), ISO 9002 (4.1.2.1) and ISO 9003 (4.1.2.1)

Individuals in the supplier organization should be aware of the scope, responsibility and authority of their functions and their impact on product or service quality.

Adequate authority should be delegated to individuals to allow them to carry out their designated responsibilities. They should have a clear understanding of their defined authority, and freedom and designated channels to take action. Everyone in the organization should be made aware of, and feel responsibility for, achieving the quality objectives and for fulfilling the requirements for the quality of its products.

It is usual to designate one or more individuals to monitor and to report the quality achieved. It is important that those so designated have access to the highest levels of management in the organization.

4.1.2.2 Verification resources and personnel

Guidance for ISO 9001 (4.1.2.2), ISO 9002 (4.1.2.2) and ISO 9003 (4.1.2.2)

Supplier management should recognize that adequate verification resources and personnel can involve the following:

— people doing the verification;

— awareness of the standards and verification arrangements which exist;

— training (see 4.18);

— sufficient time to do the work;

— production schedules which allow time for activities such as inspection, test and verification;

— equipment;

— documented procedures;

— means to access quality records.

4.1.2.3 Management representative

Guidance for ISO 9001 (4.1.2.3), ISO 9002 (4.1.2.3) and ISO 9003 (4.1.2.3)

The management representative may have other functions. Where this is the case, the responsibilities and authorities for both the quality system and the other functions should be clearly defined. Potential conflicts of interest should be examined to ensure that the effectiveness of the quality system is not degraded.

4.1.2.4 Management review

Guidance for ISO 9001 (4.1.3), ISO 9002 (4.1.3) and ISO 9003 (4.1.3)

The quality system review process and the reasons behind it should be known and understood by the organization. Reviews should include the following:

— the organizational structure, including the adequacy of staffing and resources;

— the structure and degree of implementation of the quality system;

— the achieved quality of the end product or service in relation to the requirements for quality;

— information based on purchaser feedback, internal feedback (such as results of internal audits), process performance and product (including services) performance.

The management should review periodically the appropriateness of the review frequency. The frequency depends on individual circumstances. Many organizations have found that annual management reviews are appropriate, but this interval is not mandatory.

Activities and results may be evaluated on a systematic and/or random basis. Chronic problem areas should receive special attention. Results should be documented and analysed for trends that may indicate systematic problems. These results should be discussed with the individuals concerned.

Required changes to the quality system determined during a management review should be implemented in a timely manner. The effectiveness of any changes should be evaluated.

4.2 Quality system

Guidance for ISO 9001 (4.2), ISO 9002 (4.2) and ISO 9003 (4.2)

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 note to sub-clause 4.2 in ISO 9001 and in ISO 9002 provides guidance. As in all International Standards, the notes given in ISO 9001 and ISO 9002 are not mandatory requirements. The following guidance expands upon item a) in the notes to sub-clause 4.2 in ISO 9001 and in ISO 9002.

The quality system is often documented by means of a quality manual. The quality manual could be one document supported by several tiers of documents, each tier becoming progressively more detailed. For example, there may be an overall system manual and one or more specific procedural manuals. Together these documents define the quality system.

Quality plans may be used to define how the quality system requirements will be met in a specific contract, or for a specific class of products. Most of them will have a sequence of activities in relation to a time-frame. Here again, the plans can be in several tiers, becoming progressively more detailed. An example could include a detailed sequence of inspections, together with the type of inspection equipment and quality record requirements for a particular contract.

4.3 Contract review

Guidance for ISO 9001 (4.3) and ISO 9002 (4.3)

The importance of a thorough understanding of the purchaser's needs during the tendering stage, at the formulation of the contract and in all subsequent stages cannot be overstated. Often dialogue will be necessary to achieve this understanding, that should clearly establish the purchaser's requirements as to the product, delivery and other critical factors. The contract review can be viewed by the supplier as a process of three steps.

The existence of a draft quality plan is sometimes useful to support a contract review.

The process steps include the following.

a) Review of the contract; this may be appropriate at the tendering stage and at subsequent stages.

b) Achievement of agreements within the supplier's organization that

— the requirements have been completely defined;

— the requirements are understood;

— the supplier has the capability to meet contractual requirements.

c) Discussion of the results of the contract review and any draft quality plan with the purchaser in order to achieve agreement.

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

a) All interested parties have an opportunity to review the contract.

b) A checklist or some other means is available for reviewers to verify that they have reviewed and understood the requirements of the contract.

c) A method is available for reviewers to question the requirements of the contract and to have their questions addressed.

d) If appropriate, a draft quality plan is developed to have an understanding of how to implement the contract successfully.

e) There is a provision for reviews in the event that the contract is changed.

4.4 Design control

4.4.1 General

Guidance for ISO 9001 (4.4.1)

The essential quality aspects and the regulatory requirements such as safety, performance and dependability of a product (whether hardware, software, services, or processed materials) are established during the design and development phase. Deficient design can be a major cause of quality problems. ISO 9001 specifies design control requirements for the design process.

In considering design control, it is important to note that the design function may apply to various facets of the operation in differing styles and time-scales. Such facets are related to products, including services and software, as well as to process design associated with product design. The supplier should consider all phases of the design associated with product design. The supplier should consider all phases of the design function process for which controlled procedures are necessary.

4.4.2 Design and development planning

Guidance for ISO 9001 (4.4.2)

The supplier should establish procedures for design and development planning that include the following:

— sequential and parallel work schedules;

— design verification activities;

— plans for evaluating the safety, performance and dependability incorporated in the product design;

— plans for methods of product measurement, test and acceptance criteria;

— assignment of responsibilities.

Design and development planning should recognize the existence of other plans and verification procedures for the implementation of the contract, and be integrated with them.

4.4.2.1 Activity assignment

Guidance for ISO 9001 (4.4.2.1)

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

Design activities should be specified at the level of detail necessary for carrying out the design process and a manner which permits verification that the design meets the requirements.

4.4.2.2 Organizational and technical interfaces

Guidance for ISO 9001 (4.4.2.2)

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 contribute to the design process. These may include

— research and development;

— marketing;

— purchasing;

— quality assurance and quality management;

— engineering;

— materials technology;

— production/manufacturing;

— service groups;

— facilities management;

— warehousing/transportation/logistics;

— communications facilities;

— information systems.

To function effectively, the suppliers' design work groups, both internal and external, should establish

— what information should be received and transmitted;

— identification of sending and receiving groups;

— the purpose of the information transmittal;

— identification of transmittal mechanisms;

— document transmittal records maintenance.

4.4.3 Design input

Guidance for ISO 9001 (4.4.3)

Design inputs are typically in the form of

— product requirements 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 in a design description document.

This design description document should quantify all requirements to the greatest possible extent. It lays the foundation and provides a unified approach to the design. Details agreed between the purchaser and supplier on how purchaser and regulatory requirements will be met should be included. The design description document should also record the resolutions of any incomplete, ambiguous or conflicting requirements that have been uncovered.

The design description document should identify design aspects, materials and processes requiring development and analysis, including prototype testing to verify their adequacy. The design description document should be prepared in a way that facilitates periodic updates. It also should indicate "when" or "what criteria" will cause the document to be updated, who is responsible for the update, and if, and under what circumstances, the purchaser will receive a copy. A design description document prepared in this way serves as the definitive up-to-date reference document as the design progresses to completion.

4.4.4 Design output

Guidance for ISO 9001 (4.4.4)

Throughout the design process, the requirements contained in the design description are translated by the supplier into outputs, such as the following:

— drawings;

— specifications (including process and materials specifications);

— instructions;

— software;

— servicing procedures.

Outputs of the design are the final technical documents used for purchasing, production, installation, inspection and testing, and servicing.

4.4.5 Design verification

Guidance for ISO 9001 (4.4.5)

ISO 9001 describes design control measures (e.g. design reviews, qualification tests, alternative calculations, comparison with a proven design) by which design verification may be established by the supplier. In most instances it is appropriate to employ two or more of these measures. Design reviews typically are the coordinating design control measure. Design review and/or type testing by an authorized external organization may be a regulatory requirement for certain types of product. Even under ordinary circumstances, design verification should involve personnel other than those having direct responsibility for the design work under review.

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

a) Do designs satisfy all specified requirements for the product, process or service?

b) Are product design and processing capabilities compatible?

c) Are safety considerations covered?

d) Do designs meet functional and operational requirements, that is, 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 interchangeability, maintainability and replacement?

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

j) Can the tolerance requirements consistently be met?

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

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?

When qualification tests and demonstrations are employed as a form of design verification, the safety and performance of the product, whether hardware, software, services, or processed materials, should be verified under conditions that are representative of the full range of circumstances of actual use. The product units employed for qualification tests and demonstrations should be ones that were produced under the expected production conditions.

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 the proven design, should be reviewed in relation to this new application.

4.4.6 Design changes

Guidance for ISO 9001 (4.4.6)

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

— omissions or errors (e.g. due to calculation, material selection, etc.) during the design phase have been identified afterwards;

— manufacturing and/or installation difficulties are discovered after the design phase;

— the purchaser or sub-contractor requests changes;

— the function or performance of a product or service is to be improved;

— safety, regulatory or other requirements have been changed;

— design verification necessitates change (see 4.4.5);

— corrective action necessitates change (see 4.14).

Any changes to design inputs should be identified and reviewed by the supplier to determine whether they influence previously approved design verification 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 influences 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 only authorized design changes have been made.

4.5 Document control

Guidance for ISO 9001 (4.5), ISO 9002 (4.4) and ISO 9003 (4.3)

4.5.1 Document approval and issue

Documents and data containing information and/or instructions can be recorded, transmitted or received using a variety of media.

The supplier's system should provide a clear and precise control of procedures and responsibilities for approval, issue, distribution and administration of documentation, including the removal of obsolete documents. This can be accomplished, for example, by maintaining a master list of documents identifying the level of approval, distribution (location of copies) and revision status.

Document control should include those documents and/or computer records pertinent to design, purchasing, work execution, quality standards, inspection of materials and the quality system documents. A supplier's internal written procedures should describe

— how the documentation 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.

Not all documents are needed at each individual place of work.

4.5.2 Document changes/modifications

Recognizing that supplier documentation 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 but also to externally updated documentation (e.g. national standards).

The supplier should establish a continuing mechanism for controlling changes in documentation. The mechanism should

— provide for control irrespective of documentation media;

— follow documentation procedures;

— ensure accurate updating of documents;

— provide for using only authorized documents when implementing changes;

— preclude confusion, especially where there is a multiplicity of sources authorizing changes and releasing documents.

Consideration should be given to the effect that the proposed changes may have on other parts of the procedure, system and product (including service). 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. The timing of the implementation of the change may be an important factor, particularly when several changes of documentation are to be coordinated.

4.6 Purchasing

4.6.1 General

Guidance for ISO 9001 (4.6.1) and ISO 9002 (4.5.1)

To ensure that purchased, sub-contracted products (including services) conform to specified purchaser requirements as well as regulatory requirements, purchasing should be planned and carried out by the supplier under adequate control. This should include the following:

— assessment and selection of sub-contractors (see 4.6.2);

— clear and unambiguous specification of the purchaser requirements (see 4.6.3);

— the performance of suitable verification (see 4.6.4);

— inspection procedures (see 4.10.1).

The supplier should establish an effective working relationship and feedback system with the sub-contractor.

4.6.2 Assessment of sub-contractors

Guidance for ISO 9001 (4.6.2) and ISO 9002 (4.5.2)

The supplier may employ several ways of choosing satisfactory sub-contractors, given that technical capabilities are satisfactory for the product to be delivered, for example:

— a review of previous performance in supplying similar products, processes or services;

— a satisfactory assessment to an appropriate quality system standard by a body considered to be competent for the purpose;

— an assessment of the sub-contractor by the supplier to an appropriate quality system standard.

The supplier's quality records concerning the assessment should be sufficiently comprehensive to demonstrate the ability of sub-contractors to meet contract requirements and should allow for selection on the basis of quality capability.

Factors such as product compliance with specified requirements, the total cost for the supplier, delivery arrangements, and the sub-contractor's own quality systems may be pertinent in this context. The performance of sub-contractors should be reviewed at intervals consistent with the complexity and technical requirements of the product and demonstrated sub-contractor performance.

4.6.3 Purchasing data

Guidance for ISO 9001 (4.6.3) and ISO 9002 (4.5.3)

The supplier's purchasing data should define the specified technical product requirements to the sub-contractor to ensure the quality of the purchased product, process or service. This may be done, in part, by reference to other applicable technical information such as national or international standards, test methods, etc. Well-defined purchase orders can provide documented evidence. Another option is for essential information to be clearly and precisely stated in the sub-contract. Responsibilities for reviewing and approving the purchasing data should be clearly assigned to appropriate personnel. Arrangements should be made to identify the revision status of documents referenced in the purchasing data.

4.6.4 Verification of purchased product

Guidance for ISO 9001 (4.6.4) and ISO 9002 (4.5.4)

The supplier should include in sub-contracts special clauses or statements when verification is required at source (e.g. the sub-contractor's facilities) by the purchaser.

When specified in the contract to assure that the product (including service) fulfils the specified re-

quirements, the purchaser may extend verification activities to the facilities of the sub-contractor for this purpose. In such cases, the supplier should arrange for the purchaser to assess the quality of the sub-contractor's product (including service) and/or the effectiveness of the process.

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

If the purchaser, on verification of the sub-contractor's product, expresses satisfaction, the supplier should not take this as an opportunity to relax vigilance. The supplier retains full responsibility for the quality of the products (including services) being supplied to the purchaser.

4.7 Purchaser-supplied product

Guidance for ISO 9001 (4.7) and ISO 9002 (4.6)

"Purchaser-supplied product" is product owned by the purchaser and furnished to the supplier for use in meeting the requirements of the contract. The supplier, upon delivery, accepts responsibilities for prevention from damage and for identification, maintenance, storage, handling and use while that product is in the supplier's possession.

The supplier should therefore establish arrangements 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 for reinspection;

— 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 purchaser who is responsible for providing acceptable product within the terms of the contract.

The purchaser-supplied product could be a service, for example the use of a purchaser's transport for delivery. The supplier should make sure of the suitability of that service and the maintenance of its effectiveness. The supplier should be able to show documentary evidence that this is being done, where appropriate. The supplier should obtain from the purchaser, as appropriate, information or requirements concerning handling, storage and maintenance of purchaser-supplied product.

When necessary, the need for calibration of equipment of "purchaser-supplied products" should be specified.

4.8 Product identification and traceability

Guidance for ISO 9001 (4.8), ISO 9002 (4.7) and *ISO 9003* (4.4)

The supplier can achieve product identification by marking or tagging the product or its container. For example, on visually identical parts where the functional characteristics are different, different colours can be used. For bulk products or product from continuous processes, the identification may be limited to identification of batches or well-defined lots.

Service identification can be achieved by documentation that accompanies the service. (Only this paragraph of this guidance clause applies to ISO 9003.)

Product (including service) traceability involves the ability to trace the history, application or location of an item or activity by means of recorded identification. Traceability can entail high costs and, when called up in a contract, the extent of quality records required should be included.

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.

There may be situations where traceability requires identification of the specific personnel involved in each phase of the operation or service delivery process. 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, *per se*, but each individual's identification evidence should be traceable.

4.9 Process control

4.9.1 General

Guidance for ISO 9001 (4.9.1) and ISO 9002 (4.8.1)

The supplier's planning for the production and, where applicable, installation processes should consider each of the controlled conditions described in the rel-

evant clause of the International Standard. Control within the process to prevent nonconformities from occurring is preferable to inspection of finished product or service alone. The characteristics that are most critical to the product/service quality should be identified and should be under the closest process control.

Both written and electronic media documentation methods should be recognized for documented procedures.

Process-control activities may include procedures for accepting materials or items into the process and determining their characteristics while in the process. The amount of testing and inspecting needed for process control may bear a relationship to the influence of nonconformities on the downstream process. The adequacy of measurement processes should be considered in assessing the adequacy of production process control.

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.

Where the achievement of desired levels of process control is dependent upon consistent and stable operation of process equipment and essential materials, the supplier should include within the scope of the quality system the proper maintenance of such process equipment and essential materials.

4.9.2 Special processes

Guidance for ISO 9001 (4.9.2) and ISO 9002 (4.8.2)

The supplier should give special consideration to "special processes". These are processes in which the product quality characteristics cannot be fully verified in the finished product.

Examples include circumstances where

— the characteristics of interest do not exist until further downstream in the process;

— the method of measurement does not exist or is destructive to the product;

— results within the process cannot be measured in later inspections or tests.

All products are produced by processes, and special processes are found in all generic product categories: hardware, software, processed materials and services. However, special processes are particularly common in the production of processed materials.

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

— 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, intellectual and clerical correctness.

Comprehensive measurement assurance and calibration of equipment used to produce or measure the product may be required for such "special processes". The use of statistical process control is often most advantageous.

Special skills, capabilities and training of personnel may be needed and should be demonstrated.

Process knowledge can be considered as a basis to distinguish finished-product characteristics from measurable in-process characteristics. Such processes should be qualified in advance by tests to make sure that the process can meet the specified requirements.

4.10 Inspection and testing

4.10.1 Receiving inspection and testing

Guidance for ISO 9001 (4.10.1) and ISO 9002 (4.9.1)

4.10.1.1 Receiving inspection is one means for the supplier to verify that sub-contractors have fulfilled their contractual obligations relating to quality and that procured items entering the supplier's facilities fulfil specified requirements for quality.

This sub-clause in ISO 9001 and ISO 9002 does not imply that incoming items have to be inspected and tested by the supplier, if the necessary confidence in the product (including service) can be obtained by other defined procedures.

The supplier's procedures or quality plan should specify the means of verifying that shipments received are in accordance with specifications, are complete, have the proper identity and are undamaged. The procedures should also include provisions for verifying that incoming items, materials or services are accompanied by supporting documentation as, and if, required (e.g. mill test reports, non-destructive examination reports). Appropriate action in the event of nonconformities should be specified. Analysis of past receiving inspection data, in-plant rejection history or customer complaints can influence the supplier's decisions regarding the need to reassess a sub-contractor.

4.10.1.2 Release of incoming product(s) subject to recall should be discouraged as a matter of good quality management practice. Items 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 items.

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

4.10.2 In-process inspection and testing

Guidance for ISO 9001 (4.10.2) and ISO 9002 (4.9.2)

In-process inspection and testing applies to all forms of products, including services. It allows early recognition of nonconformities and timely disposition of the nonconforming items.

Where appropriate, statistical control techniques should be used to identify 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 objectivity of the inspection and test results, including situations where in-process inspection is carried out by production personnel.

4.10.3 Final inspection and testing

Guidance for ISO 9001 (4.10.3), ISO 9002 (4.9.3) and ISO 9003 (4.5)

Final inspection involves the activities (examination, inspection, measurement or test) upon which the final release of product (including service) is based with respect to specified characteristics. The specified requirements forming the basis of final inspection and test should include all designated release characteristics.

4.10.4 Inspection and test records

Guidance for ISO 9001 (4.10.4), ISO 9002 (4.9.4) and ISO 9003 (4.5)

The supplier's inspection and test records should facilitate assessment of products having fulfilled the requirements for quality. Helpful supporting evidence may be available from records of other inspections and tests (e.g. raw materials, in-process). Regulatory requirements and product liability should also be taken into consideration.

4.11 Inspection, measuring and test equipment

Guidance for ISO 9001 (4.11), ISO 9002 (4.10) and ISO 9003 (4.6)

The requirements of this sub-clause in ISO 9001 and ISO 9002 specify what is to be implemented; ISO 9003 has less specific requirements. Although the requirements pertain explicitly to inspection, measuring and test equipment, it is helpful to approach the subject from the perspective that measuring is itself a process involving raw materials, equipment and procedures. The requirements of ISO 9001 and ISO 9002 explicitly involve elements of the measurement process; elements whose collective purpose is to choose suitable measurements, suitable measuring equipment, and suitable measurement procedures. These elements are specified to provide confidence in the ability of the supplier's measuring systems to control adequately the production and inspection of the product.

Measurements may include less tangible measuring instruments, such as polling or questionnaires. For both product- and process-measurement systems, statistical methods are valuable tools for achieving and demonstrating fulfilment of requirements. In particular, statistical methods are the preferred tools in fulfilling the requirement that "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 sub-clause also should be applied by the supplier in so far as "demonstrating the conformance of product to the specified requirements" contractually involves measurements subsequent to production and inspection of a product (e.g. during subsequent handling, storage, packaging, delivery or servicing) as may be required under other clauses of the applicable International Standard (ISO 9001, ISO 9002 or ISO 9003).

NOTE 2 For general background on the management of measuring equipment, it is recommended that reference is made to ISO 10012-1, but the requirements and guidance in ISO 10012-1 do not add to, or otherwise change, the requirements of ISO 9001, ISO 9002 or ISO 9003, except in situations where conformance to ISO 10012-1 is required by certification bodies, or where required by the contract.

4.12 Inspection and test status

Guidance for ISO 9001 (4.12), ISO 9002 (4.11) and ISO 9003 (4.7)

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 product (including service) status. Status may be indicated by marking or tagging or signing, either physically or by electronic means. Status should indicate whether a product has not been inspected, has been inspected and rejected and on-hold awaiting decision, or has been inspected and rejected. Separate physical location of these categories of product units is often the most certain method of assuring both the status and accurate disposition. However, in an automated environment, accurate disposition may equally be achieved by other means, such as a computer database.

4.13 Control of nonconforming product

4.13.1 General

Guidance for ISO 9001 (4.13), ISO 9002 (4.12) and ISO 9003 (4.8)

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

— to determine which product units are involved in the nonconformity, for example, what production time interval, or production machines or product lots are involved;

— to mark the nonconforming product units to make sure that they can be distinguished from conforming product units (see 4.12);

— to document the existence of the nonconformity and, for example, which product units, production machines or product lots are involved;

— to evaluate the nature of the nonconformity;

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

— physically to control (e.g. by physical segregation) the movements, storage and subsequent processing of the nonconforming product consistent with the disposition decision;

— to notify other functions that may be affected by the nonconformity, including, where appropriate, the purchaser.

4.13.2 Nonconformity review and disposition

Guidance for ISO 9001 (4.13.1), ISO 9002 (4.12.1) and ISO 9003 (4.8)

It is suggested that nonconformity disposition decisions made by the supplier take into consideration the seven purposes listed under 4.13, in relationship to the risk of failure to meet the purchaser's requirements. Actions a), b), c) and d) in ISO 9001 and ISO 9002 all carry degrees of risk.

While ISO 9003 does not have a sub-clause dealing explicitly with nonconformity review and disposition, the guidance presented here may be helpful in the implementation of sub-clause 4.8 of ISO 9003.

4.14 Corrective action

Guidance for ISO 9001 (4.14) and ISO 9002 (4.13)

Causes of detected (or potential) nonconformities should promptly be identified so that corrective action may be taken and recurrence (or occurrence) may be 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 purchaser complaints;

— regulatory authority or customer observations;

— observations and reports by personnel;

— sub-contract problems;

— management review results;

— inherent process variability.

NOTE 3 Corrective action is not necessarily required for every occurrence of a nonconformance, but periodic analysis of patterns of nonconformance should be considered to uncover opportunities for process improvement.

Procedures should be developed by the supplier to establish responsibility for taking corrective action and how this action will be carried out and the verification of the effectiveness of the corrective action.

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 chronic problem;

— actions to be taken, if necessary.

4.15 Handling, storage, packaging and delivery

4.15.1 General

Guidance for ISO 9001 (4.15.1), ISO 9002 (4.14.1) and ISO 9003 (4.9)

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

4.15.2 Handling

Guidance for ISO 9001 (4.15.2), ISO 9002 (4.14.2) and ISO 9003 (4.9)

The supplier's method for handling materials should consider providing transportation units (such as pallets, containers, conveyors, vessels, tanks, pipelines and vehicles) so that damage, deterioration or contamination (due to vibration, shock, abrasion, corrosion, temperature variation, 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

Guidance for ISO 9001 (4.15.3), ISO 9002 (4.14.3) and ISO 9003 (4.9)

The supplier should plan for 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 marking and labelling should give legible, durable information in accordance with the specifications. Consideration may need to be given to administrative procedures for expiry dates, and stock rotation and lot segregation.

NOTE 4 Storage and packaging requirements should consider the tiering, layering or stacking of product as part of the design parameters.

4.15.4 Packaging

Guidance for ISO 9001 (4.15.4), ISO 9002 (4.14.4) and ISO 9003 (4.9)

The supplier's packaging procedures, materials, packaging and labelling designs should provide appropriate protection against damage, deterioration or contamination during storage, transportation or any later period until the supplier's responsibility ceases. 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 where regulations or the contract specify.

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

4.15.5 Delivery

Guidance for ISO 9001 (4.15.5), ISO 9002 (4.14.5) and ISO 9003 (4.9)

The supplier should provide for protection of the quality of product during shipping and other phases of delivery. For some products, including services, 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 Quality records

Guidance for ISO 9001 (4.16), ISO 9002 (4.15) and ISO 9003 (4.10)

Quality records should contain evidence testifying directly and indirectly whether the product (including service) meets technical requirements.

The supplier's quality records should provide 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 and protected from alteration and maintained by the supplier. Quality records should be readily accessible as and where needed. They may be stored or copied in any suitable form, for example hard copy or electronic media. 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, retention and disposition of quality records.

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

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 the 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.

4.17 Internal quality audits

Guidance for ISO 9001 (4.17) and ISO 9002 (4.16)

Internal quality audits as required by ISO 9001 and ISO 9002 should be carried out by the supplier in order to determine whether the various quality system elements of the organization are effective and suitable for achieving the stated quality objectives. The internal audit plan should include the frequency of periodic audits.

The supplier should select and assign competent auditors for the activity being audited, taking into consideration the criteria for auditor selection given in sub-clause 4.1.2.2 of both ISO 9001 and ISO 9002.

Periodic internal audits should be performed

— 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 in meeting the specified quality objectives;

— to meet regulatory requirements;

— to provide 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 any of 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 (including services) are in, or are suspected to be in, jeopardy due to nonconformities;