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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

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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 sup*port 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?