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Quality systems — Model for quality assurance in design, development, production, installation and servicing

iTeh STANDARD PREVIEW

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Systemes qualité — Modèle pour l'assurance de la qualité en conception, développement, production, installation et prestations associées

ISO 9001:1994

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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 9001 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 9001:1987), which has been technically revised.

Annex A of this International Standard is for information only.

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Introduction

This International Standard is one of three International Standards dealing with quality system requirements that can be used for external quality assurance purposes. The quality assurance models, set out in the three International Standards listed below, represent three distinct forms of quality system requirements suitable for the purpose of a supplier demonstrating its capability, and for the assessment of the capability of a supplier by external parties.

- a) ISO 9001, *Quality systems — Model for quality assurance in design, development, production, installation and servicing*

— for use when conformance to specified requirements is to be assured by the supplier during design, development, production, installation and servicing.

- b) ISO 9002, *Quality systems — Model for quality assurance in production, installation and servicing*

— for use when conformance to specified requirements is to be assured by the supplier during production, installation and servicing.

- c) ISO 9003, *Quality systems — Model for quality assurance in final inspection and test*

— for use when conformance to specified requirements is to be assured by the supplier solely at final inspection and test.

It is emphasized that the quality system requirements specified in this International Standard, ISO 9002 and ISO 9003 are complementary (not alternative) to the technical (product) specified requirements. They specify requirements which determine what elements quality systems have to encompass, but it is not the purpose of these International Standards to enforce uniformity of quality systems. They are generic and independent of any specific industry or economic sector. The design and implementation of a quality system will be influenced by the varying needs of an organization, its particular objectives, the products and services supplied, and the processes and specific practices employed.

It is intended that these International Standards will be adopted in their present form, but on occasions they may need to be tailored by adding or deleting certain quality system requirements for specific contractual situations. ISO 9000-1 provides guidance on such tailoring as well as on selection of the appropriate quality assurance model, viz. ISO 9001, ISO 9002 or ISO 9003.

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Quality systems — Model for quality assurance in design, development, production, installation and servicing

1 Scope

This International Standard specifies quality system requirements for use where a supplier's capability to design and supply conforming product needs to be demonstrated.

The requirements specified are aimed primarily at achieving customer satisfaction by preventing non-conformity at all stages from design through to servicing.

This International Standard is applicable in situations when

- a) design is required and the product requirements are stated principally in performance terms, or they need to be established, and
- b) confidence in product conformance can be attained by adequate demonstration of a supplier's capabilities in design, development, production, installation and servicing.

NOTE 1 For informative references, see annex A.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8402 and the following definitions apply.

3.1 product: Result of activities or processes.

NOTES

2 A product may include service, hardware, processed materials, software or a combination thereof.

3 A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.

4 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.

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

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

4 Quality system requirements

4.1 Management responsibility

4.1.1 Quality policy

The supplier's management with executive responsibility shall define and document its policy for quality,

including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organizational goals and the expectations and needs of its customers. The supplier shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

4.1.2 Organization

4.1.2.1 Responsibility and authority

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

- a) initiate action to prevent the occurrence of any nonconformities relating to the product, process and quality system;
- b) identify and record any problems relating to the product, process and quality system;
- c) initiate, recommend or provide solutions through designated channels;
- d) verify the implementation of solutions;
- e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

4.1.2.2 Resources

The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18), for management, performance of work and verification activities including internal quality audits.

4.1.2.3 Management representative

The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for

- a) ensuring that a quality system is established, implemented and maintained in accordance with this International Standard, and
- b) reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system.

NOTE 5 The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system.

4.1.3 Management review

The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the supplier's stated quality policy and objectives (see 4.1.1). Records of such reviews shall be maintained (see 4.16).

4.2 Quality system

4.2.1 General

The supplier shall establish, document and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

NOTE 6 Guidance on quality manuals is given in ISO 10013.

4.2.2 Quality system procedures

The supplier shall

- a) prepare documented procedures consistent with the requirements of this International Standard and the supplier's stated quality policy, and
- b) effectively implement the quality system and its documented procedures.

For the purposes of this International Standard, the range and detail of the procedures that form part of the quality system shall be dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity.

NOTE 7 Documented procedures may make reference to work instructions that define how an activity is performed.

4.2.3 Quality planning

The supplier shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation.

The supplier shall give consideration to the following activities, as appropriate, in meeting the specified requirements for products, projects or contracts:

- a) the preparation of quality plans;
- b) the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required quality;
- c) ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation;
- d) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation;
- e) the identification of any measurement requirement involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed;
- f) the identification of suitable verification at appropriate stages in the realization of product;
- g) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;
- h) the identification and preparation of quality records (see 4.16).

NOTE 8 The quality plans referred to [see 4.2.3 a)] may be in the form of a reference to the appropriate documented procedures that form an integral part of the supplier's quality system.

4.3 Contract review

4.3.1 General

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

4.3.2 Review

Before submission of a tender, or the acceptance of a contract or order (statement of requirement), the tender, contract or order shall be reviewed by the supplier to ensure that:

- a) the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by

verbal means, the supplier shall ensure that the order requirements are agreed before their acceptance;

- b) any differences between the contract or order requirements and those in the tender are resolved;
- c) the supplier has the capability to meet the contract or order requirements.

4.3.3 Amendment to a contract

The supplier shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the supplier's organization.

4.3.4 Records

Records of contract reviews shall be maintained (see 4.16).

NOTE 9 Channels for communication and interfaces with the customer's organization in these contract matters should be established.

4.4 Design control

4.4.1 General

The supplier shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met.

4.4.2 Design and development planning

The supplier shall prepare plans for each design and development activity. The plans shall describe or reference these activities, and define responsibility for their implementation. The design and development activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated as the design evolves.

4.4.3 Organizational and technical interfaces

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

4.4.4 Design input

Design input requirements relating to the product, including applicable statutory and regulatory requirements, shall be identified, documented and their selection reviewed by the supplier for adequacy. In-

complete, ambiguous or conflicting requirements shall be resolved with those responsible for imposing these requirements.

Design input shall take into consideration the results of any contract review activities.

4.4.5 Design output

Design output shall be documented and expressed in terms that can be verified and validated against design input requirements.

Design output shall:

- a) meet the design input requirements;
- b) contain or make reference to acceptance criteria;
- c) identify those characteristics of the design that are crucial to the safe and proper functioning of the product (e.g. operating, storage, handling, maintenance and disposal requirements).

Design output documents shall be reviewed before release.

4.4.6 Design review

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

4.4.7 Design verification

At appropriate stages of design, design verification shall be performed to ensure that the design stage output meets the design stage input requirements. The design verification measures shall be recorded (see 4.16).

NOTE 10 In addition to conducting design reviews (see 4.4.6), design verification may include activities such as

- performing alternative calculations,
- comparing the new design with a similar proven design, if available,
- undertaking tests and demonstrations, and
- reviewing the design stage documents before release.

4.4.8 Design validation

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

NOTES

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

12 Validation is normally performed under defined operating conditions.

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

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

4.4.9 Design changes

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

4.5 Document and data control

4.5.1 General

The supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this International Standard including, to the extent applicable, documents of external origin such as standards and customer drawings.

NOTE 15 Documents and data can be in the form of any type of media, such as hard copy or electronic media.

4.5.2 Document and data approval and issue

The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

This control shall ensure that:

- a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;

- b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;
- c) any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

4.5.3 Document and data changes

Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations shall have access to pertinent background information upon which to base their review and approval.

Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

4.6 Purchasing

4.6.1 General

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

4.6.2 Evaluation of subcontractors

The supplier shall:

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

4.6.3 Purchasing data

Purchasing documents shall contain data clearly describing the product ordered, including where applicable:

- a) the type, class, grade or other precise identification;
- b) the title or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel;
- c) the title, number and issue of the quality system standard to be applied.

The supplier shall review and approve purchasing documents for adequacy of the specified requirements prior to release.

4.6.4 Verification of purchased product

4.6.4.1 Supplier verification at subcontractor's premises

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

4.6.4.2 Customer verification of subcontracted product

Where specified in the contract, the supplier's customer or the customer's representative shall be afforded the right to verify at the subcontractor's premises and the supplier's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the supplier as evidence of effective control of quality by the subcontractor.

Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

4.7 Control of customer-supplied product

The supplier shall establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities. Any such product that is lost, damaged or is otherwise unsuitable for use shall be recorded and reported to the customer (see 4.16).

Verification by the supplier does not absolve the customer of the responsibility to provide acceptable product.