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Quality systems — Model for quality assurance in final inspection and test

Systèmes qualité — Modèle pour l'assurance de la qualité en contrôle et essais finals



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Annex

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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 9003 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 9003:1987), 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 9001 and ISO 9002 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 final inspection and test

1 Scope

This International Standard specifies quality system requirements for use where a supplier's capability to detect and control the disposition of any product nonconformity during final inspection and test needs to be demonstrated.

It is applicable in situations when the conformance of product to specified requirements can be shown with adequate confidence providing that certain suppliers' capabilities for inspection and tests conducted on finished product can be satisfactorily demonstrated.

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 that

is subject to the requirements of this International Standard shall be defined and documented, particularly for personnel who need the organizational freedom and authority to

- a) conduct final inspection and tests, and
- b) ensure that finished product that does not conform to specified requirements is prevented from being used or delivered.

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 on completion 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 of the finished product 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:

- a) the preparation of a quality plan for final inspection and tests;
- b) the identification and acquisition of any final inspection and test equipment, resources and skills that may be needed to achieve the required quality;
- c) the updating, as necessary, of final inspection and testing techniques;
- d) the identification of any final inspection and test measurement requirement involving capability that exceeds the known state of the art in sufficient time for the needed capability to be developed;
- e) the identification of suitable verification at the finished product stage;

- f) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;
- g) the identification and preparation of quality records (see 4.16).

NOTE 8 The quality plan 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 for finished product.

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

The scope of this International Standard does not include quality system requirements for design control. This subclause is included to align the clause numbering with ISO 9001.

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 10 Documents and data may 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

The scope of this International Standard does not include quality system requirements for purchasing. This subclause is included to align the clause numbering with ISO 9001.

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 finished product 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.

4.8 Product identification and traceability

Where and to the extent that traceability is a specified requirement, the supplier shall establish and maintain documented procedures for unique identification of individual product or batches. This identification shall be recorded (see 4.16).

4.9 Process control

The scope of this International Standard does not include quality system requirements for process control. This subclause is included to align the clause numbering with ISO 9001.

4.10 Inspection and testing

4.10.1 General

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

4.10.2 Final inspection and testing

The supplier shall carry out all final inspection and testing in accordance with the quality plan and/or documented procedures and maintain appropriate

records to complete the evidence of conformance of product to the specified requirements. When conformance to the specified requirements cannot be fully verified on the finished product, then a verification of acceptable results of other necessary inspection and tests performed previously shall be included for the purpose of verifying conformance to product requirements at final inspection and test.

Records shall identify the inspection authority responsible for the release of conforming product (see 4.16).

4.11 Control of inspection, measuring and test equipment

4.11.1 General

The supplier shall establish and maintain documented procedures to control, calibrate and maintain final inspection, measuring and test equipment (including test software) used by the supplier to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

Where test software or comparative references such as test hardware are used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product, prior to release for use during final inspection and testing and shall be rechecked at prescribed intervals. The supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 4.16).

Where the availability of technical data pertaining to the inspection, measuring and test equipment is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the inspection, measuring and test equipment is functionally adequate.

NOTE 11 For the purposes of this International Standard, the term "measuring equipment" includes measurement devices.

4.11.2 Control procedure

The supplier shall:

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

- b) identify all inspection, measuring and test equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented;
- c) define the process employed for the calibration of inspection, measuring and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory;
- d) identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status;
- e) maintain calibration records for inspection, measuring and test equipment (see 4.16);
- f) assess and document the validity of previous inspection and test results when inspection, measuring or test equipment is found to be out of calibration;
- g) ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out;
- h) ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use are maintained;
- i) safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

NOTE 12 The metrological confirmation system for measuring equipment given in ISO 10012 may be used for guidance.

4.12 Inspection and test status

The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan and/or documented procedures to ensure that only product that has passed the required final inspection and test [or released under an authorized concession (see 4.13)] is dispatched.

4.13 Control of nonconforming product

The supplier shall establish and maintain control of product that does not conform to specified requirements to ensure that unintended use or delivery is avoided.

Control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product and for notification to the functions concerned.

The description of repairs, and of any nonconformity that has been accepted under authorized concession, shall be recorded to denote the actual condition (see 4.16).

Repaired and/or reworked product shall be re-inspected in accordance with the quality plan and/or documented procedures.

4.14 Corrective action

The supplier shall:

- a) investigate nonconformities that have been identified from the analysis of final inspection and test reports and customer complaints of product;
- b) determine and implement appropriate corrective action on the nonconformities;
- c) ensure that relevant information on the actions taken is submitted for management review (see 4.1.3).

4.15 Handling, storage, packaging, preservation and delivery

4.15.1 General

The supplier shall establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of completed product after final inspection and test.

4.15.2 Handling

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

4.15.3 Storage

The supplier shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending delivery. Appropriate methods for

authorizing receipt to and dispatch from such areas shall be stipulated.

In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.

4.15.4 Packaging

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

4.15.5 Preservation

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

4.15.6 Delivery

The supplier shall arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.

4.16 Control of quality records

The supplier shall establish and maintain control of appropriate quality records to demonstrate conformance of the finished product to specified requirements and the effective operation of the quality system.

Quality records shall be legible and identifiable to the product involved. Quality records that substantiate conformance of the finished product with the specified requirements and the effective operation of the quality system shall be retained for an agreed period and made available on request.

NOTE 13 Records may be in the form of any type of media, such as hard copy or electronic media.

4.17 Internal quality audits

The supplier shall carry out internal quality audits to verify whether quality activities and related results comply with planned arrangements covering the requirements of this International Standard and to determine the effectiveness of the quality system.

Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited.

The results of the audits shall be recorded (see 4.16) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on deficiencies found during the audit.

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (see 4.16).

NOTES

14 The results of internal quality audits form an integral part of the input to management review activities (see 4.1.3).

15 Guidance on quality system audits is given in ISO 10011.

4.18 Training

Personnel performing final inspection and test activities covering the requirements of this International Standard shall have appropriate experience and/or training, including any necessary qualification for specific assigned tasks. Appropriate records of training shall be maintained (see 4.16).

4.19 Servicing

The scope of this International Standard does not include quality system requirements for servicing. This subclause is included to align the clause numbering with ISO 9001.

4.20 Statistical techniques

The supplier shall:

- a) identify the need for statistical techniques required for the acceptability of product characteristics;
- b) implement and control the application of the statistical techniques.