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INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
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МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

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

Systèmes qualité — Modèle pour l'assurance de la qualité en conception/développement, production, installation et soutien après la vente

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality assurance.*

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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

0 Introduction

This International Standard is one of a series of three International Standards dealing with quality systems that can be used for external quality assurance purposes. The alternative quality assurance models, set out in the three International Standards listed below, represent three distinct forms of "functional or organizational capability" suitable for two-party contractual purposes :

— 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 several stages which may include design/development, production, installation and servicing.

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

For use when conformance to specified requirements is to be assured by the supplier during production and installation.

— 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/service) specified requirements.

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

1 Scope and field of application

1.1 Scope

This International Standard specifies quality system requirements for use where a contract between two parties requires the demonstration of a supplier's capability to design and supply product.

The requirements specified in this International Standard are aimed primarily at preventing nonconformity at all stages from design through to servicing.

1.2 Field of application

This International Standard is applicable in contractual situations when

a) the contract specifically requires design effort and the product requirements are stated principally in performance terms or they need to be established;

b) confidence in product conformance can be attained by adequate demonstration of certain supplier's capabilities in design, development, production, installation and servicing.

2 References

ISO 8402, *Quality — Vocabulary.*

ISO 9000, *Quality management and quality assurance standards — Guidelines for selection and use.*

3 Definitions

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

NOTE — For the purposes of this International Standard, the term "product" is also used to denote "service", as appropriate.

4 Quality system requirements

4.1 Management responsibility

4.1.1 Quality policy

The supplier's management shall define and document its policy and objectives for, and commitment to, quality. The supplier shall ensure that this policy is understood, implemented and maintained at all levels in the organization.

4.1.2 Organization

4.1.2.1 Responsibility and authority

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

a) initiate action to prevent the occurrence of product nonconformity;

b) identify and record any product quality problems;

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 Verification resources and personnel

The supplier shall identify in-house verification requirements, provide adequate resources and assign trained personnel for verification activities (see 4.18).

Verification activities shall include inspection, test and monitoring of the design, production, installation and servicing processes and/or product; design reviews and audits of the quality system, processes and/or product shall be carried out by personnel independent of those having direct responsibility for the work being performed.

4.1.2.3 Management representative

The supplier shall appoint a management representative who, irrespective of other responsibilities, shall have defined authority and responsibility for ensuring that the requirements of this International Standard are implemented and maintained.

4.1.3 Management review

The quality system adopted to satisfy the requirements of this International Standard shall be reviewed at appropriate intervals by the supplier's management to ensure its continuing suitability and effectiveness. Records of such reviews shall be maintained (see 4.16).

NOTE — Management reviews normally include assessment of the results of internal quality audits, but are carried out by, or on behalf of, the supplier's management, *viz* management personnel having direct responsibility for the system. (See 4.17.)

4.2 Quality system

The supplier shall establish and maintain a documented quality system as a means of ensuring that product conforms to specified requirements. This shall include

a) the preparation of documented quality system procedures and instructions in accordance with the requirements of this International Standard;

b) the effective implementation of the documented quality system procedures and instructions.

NOTE — In meeting specified requirements, timely consideration needs to be given to the following activities :

a) the preparation of quality plans and a quality manual in accordance with the specified requirements;

b) the identification and acquisition of any controls, processes, inspection equipment, fixtures, total production resources and skills that may be needed to achieve the required quality;

c) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation;

d) 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;

e) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;

f) the compatibility of the design, the production process, installation, inspection and test procedures and the applicable documentation;

g) the identification and preparation of quality records (see 4.16).

4.3 Contract review

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

Each contract shall be reviewed by the supplier to ensure that

a) the requirements are adequately defined and documented;

b) any requirements differing from those in the tender are resolved;

c) the supplier has the capability to meet contractual requirements.

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

NOTE — The contract review activities, interfaces and communication within the supplier's organization should be coordinated with the purchaser's organization, as appropriate.

4.4 Design control

4.4.1 General

The supplier shall establish and maintain 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 draw up plans that identify the responsibility for each design and development activity. The plans shall describe or reference these activities and shall be updated as the design evolves.

4.4.2.1 Activity assignment

The design and verification activities shall be planned and assigned to qualified personnel equipped with adequate resources.

4.4.2.2 Organizational and technical interfaces

Organizational and technical interfaces between different groups shall be identified and the necessary information documented, transmitted and regularly reviewed.

4.4.3 Design input

Design input requirements relating to the product shall be identified, documented and their selection reviewed by the supplier for adequacy.

Incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for drawing up these requirements.

4.4.4 Design output

Design output shall be documented and expressed in terms of requirements, calculations and analyses.

Design output shall

a) meet the design input requirements;

b) contain or reference acceptance criteria;

c) conform to appropriate regulatory requirements whether or not these have been stated in the input information;

d) identify those characteristics of the design that are crucial to the safe and proper functioning of the product.

4.4.5 Design verification

The supplier shall plan, establish, document and assign to competent personnel functions for verifying the design.

Design verification shall establish that design output meets the design input requirement (see 4.4.4) by means of design control measures such as :

a) holding and recording design reviews (see 4.16);

b) undertaking qualification tests and demonstrations;

c) carrying out alternative calculations;

d) comparing the new design with a similar proven design, if available.

4.4.6 Design changes

The supplier shall establish and maintain procedures for the identification, documentation and appropriate review and approval of all changes and modifications.

4.5 Document control

4.5.1 Document approval and issue

The supplier shall establish and maintain procedures to control all documents and data that relate to the requirements of this International Standard. These documents shall be reviewed and approved for adequacy by authorized personnel prior to issue. 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) obsolete documents are promptly removed from all points of issue or use.

4.5.2 Document changes/modifications

Changes to documents shall be reviewed and approved by the same functions/organizations that performed the original review and approval unless specifically designated otherwise. The designated 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.

A master list or equivalent document control procedure shall be established to identify the current revision of documents in order to preclude the use of non-applicable documents.

Documents shall be re-issued after a practical number of changes have been made.

4.6 Purchasing

4.6.1 General

The supplier shall ensure that purchased product conforms to specified requirements.

4.6.2 Assessment of sub-contractors

The supplier shall select sub-contractors on the basis of their ability to meet sub-contract requirements, including quality

requirements. The supplier shall establish and maintain records of acceptable sub-contractors (see 4.16).

The selection of sub-contractors, and the type and extent of control exercised by the supplier, shall be dependent upon the type of product and, where appropriate, on records of sub-contractors' previously demonstrated capability and performance.

The supplier shall ensure that quality system controls are effective.

4.6.3 Purchasing data

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

a) the type, class, style, grade or other precise identification;

b) the title or other positive identification, and applicable issue 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 International Standard to be applied to the product.

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

4.6.4 Verification of purchased product

Where specified in the contract, the purchaser or his representative shall be afforded the right to verify at source or upon receipt that purchased product conforms to specified requirements. Verification by the purchaser shall not absolve the supplier of the responsibility to provide acceptable product nor shall it preclude subsequent rejection.

When the purchaser or his representative elects to carry out verification at the sub-contractor's plant, such verification shall not be used by the supplier as evidence of effective control of quality by the sub-contractor.

4.7 Purchaser supplied product

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

NOTE — Verification by the supplier does not absolve the purchaser of the responsibility to provide acceptable product.

4.8 Product identification and traceability

Where appropriate, the supplier shall establish and maintain procedures for identifying the product from applicable drawings, specifications or other documents, during all stages of production, delivery and installation.

Where, and to the extent that, traceability is a specified requirement, individual product or batches shall have a unique identification. This identification shall be recorded (see 4.16).

4.9 Process control

4.9.1 General

The supplier shall identify and plan the production and, where applicable, installation processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following :

a) documented work instructions defining the manner of production and installation, where the absence of such instructions would adversely affect quality, use of suitable production and installation equipment, suitable working environment, compliance with reference standards/codes and quality plans;

b) monitoring and control of suitable process and product characteristics during production and installation;

c) the approval of processes and equipment, as appropriate;

d) criteria for workmanship which shall be stipulated, to the greatest practicable extent, in written standards or by means of representative samples.

4.9.2 Special processes

These are processes, the results of which cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use. Accordingly, continuous monitoring and/or compliance with documented procedures is required to ensure that the specified requirements are met. These processes shall be qualified and shall also comply with the requirements of 4.9.1.

Records shall be maintained for qualified processes, equipment and personnel, as appropriate.

4.10 Inspection and testing

4.10.1 Receiving inspection and testing

4.10.1.1 The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.1.2) until it has been inspected or otherwise verified as conforming to specified requirements. Verification shall be in accordance with the quality plan or documented procedures.

4.10.1.2 Where incoming product is released for urgent production purposes, it shall be positively identified and recorded (see 4.16) in order to permit immediate recall and replacement in the event of nonconformance to specified requirements.

NOTE — In determining the amount and nature of receiving inspection, consideration should be given to the control exercised at source and documented evidence of quality conformance provided.

4.10.2 In-process inspection and testing

The supplier shall

a) inspect, test and identify product as required by the quality plan or documented procedures;

b) establish product conformance to specified requirements by use of process monitoring and control methods;

c) hold product until the required inspection and tests have been completed or necessary reports have been received and verified except when product is released under positive recall procedures (see 4.10.1). Release under positive recall procedures shall not preclude the activities outlined in 4.10.2a);

d) identify nonconforming product.

4.10.3 Final inspection and testing

The quality plan or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the data meets specified requirements.

The supplier shall carry out all final inspection and testing in accordance with the quality plan or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

No product shall be despatched until all the activities specified in the quality plan or documented procedures have been satisfactorily completed and the associated data and documentation is available and authorized.

4.10.4 Inspection and test records

The supplier shall establish and maintain records which give evidence that the product has passed inspection and/or test with defined acceptance criteria (see 4.16).

4.11 Inspection, measuring and test equipment

The supplier shall control, calibrate and maintain inspection, measuring and test equipment, whether owned by the supplier, on loan, or provided by the purchaser, to demonstrate the conformance of product to the specified requirements. Equipment shall be used in a manner which ensures that measurement uncertainty is known and is consistent with the required measurement capability.

The supplier shall

a) identify the measurements to be made, the accuracy required and select the appropriate inspection, measuring and test equipment;

b) identify, calibrate and adjust all inspection, measuring and test equipment and devices that can affect product quality at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to nationally recognized standards — where no such standards exist, the basis used for calibration shall be documented;

c) establish, document and maintain calibration procedures, including details of equipment type, identification number, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory;

d) ensure that the inspection, measuring and test equipment is capable of the accuracy and precision necessary;

e) identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status;

f) maintain calibration records for inspection, measuring and test equipment (see 4.16);

g) assess and document the validity of previous inspection and test results when inspection, measuring and test equipment is found to be out of calibration;

h) ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out;

i) ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use is maintained;

j) safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

Where test hardware (e.g. jigs, fixtures, templates, patterns) or test software is 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 production and installation 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). Measurement design data shall be made available, when required by the purchaser or his representative, for verification that it is functionally adequate.

4.12 Inspection and test status

The inspection and test status of product shall be identified by using markings, authorized stamps, tags, labels, routing cards, inspection records, test software, physical location or other 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 necessary, throughout production and installation of the product to ensure that only product that has passed the required inspections and tests is despatched, used or installed.

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

4.13 Control of nonconforming product

The supplier shall establish and maintain procedures to ensure that product that does not conform to specified requirements is

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

4.13.1 Nonconformity review and disposition

The responsibility for review and authority for the disposition of nonconforming product shall be defined.

Nonconforming product shall be reviewed in accordance with documented procedures. It may be

a) reworked to meet the specified requirements, or

b) accepted with or without repair by concession, or

c) re-graded for alternative applications, or

d) rejected or scrapped.

Where required by the contract, the proposed use or repair of product [see 4.13.1b)] which does not conform to specified requirements shall be reported for concession to the purchaser or his representative. The description of nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition (see 4.16).

Repaired and reworked product shall be re-inspected in accordance with documented procedures.

4.14 Corrective action

The supplier shall establish, document and maintain procedures for

a) investigating the cause of nonconforming product and the corrective action needed to prevent recurrence;

b) analysing all processes, work operations, concessions, quality records, service reports and customer complaints to detect and eliminate potential causes of nonconforming product;

c) initiating preventative actions to deal with problems to a level corresponding to the risks encountered;

d) applying controls to ensure that corrective actions are taken and that they are effective;

e) implementing and recording changes in procedures resulting from corrective action.

4.15 Handling, storage, packaging and delivery

4.15.1 General

The supplier shall establish, document and maintain procedures for handling, storage, packaging and delivery of product.

4.15.2 Handling

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

4.15.3 Storage

The supplier shall provide secure storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt and the despatch to and 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, preservation and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements and shall identify, preserve and segregate all product from the time of receipt until the supplier's responsibility ceases.

4.15.5 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 Quality records

The supplier shall establish and maintain procedures for identification, collection, indexing, filing, storage, maintenance and disposition of quality records.

Quality records shall be maintained to demonstrate achievement of the required quality and the effective operation of the quality system. Pertinent sub-contractor quality records shall be an element of these data.

All quality records shall be legible and identifiable to the product involved. Quality records shall be stored and maintained in such a way that they are readily retrievable in facilities that provide a suitable environment to minimize deterioration or damage and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the purchaser or his representative for an agreed period.

4.17 Internal quality audits

The supplier shall carry out a comprehensive system of planned and documented internal quality audits to verify whether quality activities comply with planned arrangements and to determine the effectiveness of the quality system.

Audits shall be scheduled on the basis of the status and importance of the activity.

The audits and follow-up actions shall be carried out in accordance with documented procedures.