INTERNATIONAL STANDARD

ISO 9000-2

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Quality management and quality assurance standards —

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

Normes pour le management de la qualité et l'assurance de la qualité —

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

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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 9000-2 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 9000-2:1993), which has been technically revised.

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 management*

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

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Introduction

This part of ISO 9000 gives guidance for the 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, ISO 9002 and ISO 9003.

In general, the number and scope of the quality system elements and procedures 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 subclause 8.3 of ISO 9000-1:1994 for guidance on the appropriate extent and degree of demonstration.

ISO 9000-1 gives an overview of the ISO 9000 series of International Standards, and explains the use of the entire series. ISO 9004-1 gives guidance for designing and installing a quality management system.

This part of ISO 9000 does not duplicate the guidance to users that is given in other ISO guidance standards such as ISO 9000-1, ISO 9000-3, ISO 9004-1 and ISO 9004-2.

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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

1 Scope

This part of ISO 9000 gives guidance on the application of the 1994 versions of ISO 9001, ISO 9002 and ISO 9003.

It does not add to, or otherwise change, the requirements of ISO 9001, ISO 9002 or ISO 9003. In the case of conflicting interpretations 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. The use of 'should' in this part of ISO 9000 does not weaken the requirements expressed as 'shall' in ISO 9001, ISO 9002 and ISO 9003.

This part of ISO 9000 gives guidance for the following users:

a) suppliers involved in applications of ISO 9001, ISO 9002 or ISO 9003;

b) customers and third parties.

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

ISO 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing.*

ISO 9002:1994, *Quality systems — Model for quality assurance in production, installation and servicing.*

ISO 9003:1994, *Quality systems — Model for quality assurance in final inspection and test.*

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3 Definitions

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

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

[ISO 9001]

3.2 product: Result of activities or processes.

NOTE 1 A product may include service, hardware, processed materials, software or a combination thereof.

NOTE 2 A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.

NOTE 3 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.

[ISO 9001]

3.3 specified requirements

1) Product requirements prescribed by the customer and agreed by the supplier.

2) Requirements prescribed by the supplier that are perceived as satisfying a market need.

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

[ISO 9001]

4 Quality system requirements

4.1 Management responsibility

4.1.1 Quality policy

The supplier's management with executive responsibility (see 4.1.2.1) is required to develop and define its quality policy, quality objectives and commitment in (a) recorded statement(s). This is required to be relevant to its organizational goals, and the expectations and needs of its customers. The statement(s) should be published throughout the organization and be seen to be fully supported by the management.

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All employees, including newly hired, part-time and temporary employees, should be trained so that they understand the objectives of the organization and the commitment required to achieve these objectives. The policy should be expressed in language that is easy to understand and the objectives should be achievable, planned and periodically reviewed.

Management should continuously demonstrate visible commitment to the quality policy by activities which may include, but not be limited to, the following:

- ensuring that the organization's personnel understand and implement the quality policy;
- ensuring that the organization's personnel have quality objectives consistent with the organization's overall objectives;
- initiating, managing and following up on the implementation of the quality policy, including implementation and maintenance of the quality system;
- not accepting deviations from the quality policy in any part or aspect of the organization;
- providing adequate resources and training to support quality system development and implementation. (See 4.1.2.2.)

4.1.2 Organization

4.1.2.1 Responsibility and authority

Management with executive responsibility is that person or group of persons within an organization with the necessary level of authority for making policy and setting objectives, planning their implementation, reviewing achievement and taking corrective action. The supplier should clearly identify those persons having such executive responsibility.

In particular the personnel having the responsibility and authority to make decisions that control all the elements of the quality system and processes should be identified and the job requirements defined and documented (see 4.18).

4.1.2.2 Resources

Consideration needs to be given by the supplier's management to the identification and provision of adequate resources needed to implement its quality policy and achieve its objectives as well as to satisfy customer needs and expectations. The following should be considered:

- personnel to plan, manage, perform work, control and carry out verification activities;
- awareness of standards, procedures and other documented practices that are needed;

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- training and qualifications (see 4.18);
- planning design, development and production activities to allow sufficient time to perform the work;
- equipment and processes, including acquisition of new equipment or technology;
- means to access quality records.

4.1.2.3 Management representative

Within the supplier's organization, a management representative with delegated authority is required to be appointed for arranging and overseeing the working of the quality system. This management representative is required to be appointed by management with executive responsibility.

The functions of the management representative may be totally related to quality system activities or be in conjunction with other functions and responsibilities within the organization. If the management representative has other functions to perform, there should be no conflict of interest between the responsibilities for the other functions and those for the quality system. The management representative should have the authority to ensure that the requirements of ISO 9001, ISO 9002 or ISO 9003 are satisfied and that compliance is maintained, together with the responsibility to ensure that they are operated throughout the organization.

The defined role should include reporting on the suitability and effectiveness of the quality system as a basis for improvement, management review, and liaison, as necessary, with customers, subcontractors and any other external parties on quality matters.

4.1.3 Management review

The supplier's management with executive responsibility, should review the quality system. This may include, but not be limited to, the following:

- the adequacy of the organizational structure, including its staffing and other resources;
- conformity to ISO 9001, ISO 9002 or ISO 9003, and effective implementation of the quality system;
- compliance with quality policy;
- information based on customer feedback, internal feedback (such as results of internal audits), process performance and product performance, as well as corrective and preventive actions taken.

The intervals between reviews should be carefully planned and periodically reviewed to ensure the continuing suitability and effectiveness of the quality system. The management

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review process, frequency of reviews and levels of inputs will depend on the individual circumstance. Some organizations have found that annual management reviews are acceptable.

Management should focus on trends that may indicate problems. Chronic problem areas should receive special attention. Actions that are required following changes to the quality system determined during management review should be implemented in a timely manner. The effectiveness of any changes should be evaluated. Records of such reviews should be maintained (see 4.16).

4.2 Quality system

4.2.1 General

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 quality manual has an important role in this regard, for both internal and external parties. To give a coherent view of the quality system, the quality manual should include the quality policy, a description of the organization, and identify the quality system procedures with appropriate cross-references to more detailed documentation. The quality manual could, for example, be one document supported by several levels of other documents, each level becoming progressively more detailed. There may also be an overall system manual, one or more specific procedural manuals, work instructions and reference documents. Together, these documents define the quality system. Further guidance on development of quality manuals is given in ISO 10013.

4.2.2. Quality system procedures

Documented quality system procedures are required for applicable requirements of ISO 9001, ISO 9002 and ISO 9003 and should be consistent with the supplier's quality policy. It is important to recognise that the structure and level of detail required in these procedures should be tailored to the needs of the organization's personnel, which will depend upon methods used and the training requirements, skills and qualifications of such personnel, as indicated in 4.18.

A documented procedure usually specifies the purpose and scope of an activity:

- what shall be done by whom;
- when, where, and how it shall be done;
- what materials, equipment and documents shall be used; and
- how an activity shall be controlled and recorded.

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

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4.2.3 Quality planning

The supplier needs to show that planning activities have been performed, and that they establish the means by which the requirements for quality will be met. Planning should include the application of the quality system elements, and how the product quality requirements will be met.

This may require the following.

a) For managerial and operational planning, preparing the application of the quality system.

b) For product planning, setting out in a quality plan or in any other documented procedures the specific quality practices, resources and sequence of activities relevant to a particular product, project or contract.

More guidance on quality plans is given in ISO 10005.

4.3 Contract review

4.3.1 General

In the situation where a tender is offered or a contract or order is to be established between a supplier and a customer, the means of achieving satisfaction lies in the contract review process.

Contract review is one of the supplier's primary interfaces with its customers. The documented procedures should include a review of customer requirements (whether expressed in a tender, contract or order, which may be written or verbal) and how customer requirements are reviewed and communicated within the organization.

The contract review is prior to accepting a contract or an order.

4.3.2 Review

The importance of a thorough understanding of the customer's needs, from initial contact, through tendering or receiving verbal orders, to the formulation of the contract, or order and in all subsequent stages cannot be overstated. Often, dialogue will be necessary to achieve this understanding, that should clearly establish the customer's requirements as to the product, delivery and other critical factors. Where a verbal statement of requirement is received from the customer, the supplier should ensure that an order (statement of requirements) is understood, adequately documented and agreed to by the customer.

Contract review is a process that includes the following:

a) review of the requirement; this may be appropriate at the tendering or order entry stage and at subsequent stages prior to acceptance of the contract or the order;

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b) agreement within the supplier's organization that

- the requirements have been defined,
- the requirements are understood,
- the supplier has the capability to meet the requirements of the contract, by going through a defined process to verify that the necessary resources and facilities are available to fulfil all the requirements of the contract;

c) resolution of any differences with the customer;

d) contract review of a standard product (e.g. "off-the-shelf" items, a "commodity item", a catalogue item with published specification, etc.) can be as simple as verifying the accuracy of the information on the order;

e) the requirements of the contract, where appropriate, may be translated into the terminology, tolerances, and other necessary information for designing, purchasing and process control;

f) preliminary quality plan or documented procedures, where appropriate, may be developed to give an understanding of how to implement the contract successfully and support the contract review process.

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

- affected parties have an opportunity and adequate time to review the contract;
- a checklist or some other means (e.g. a standard form) is available for reviewers to verify and record that they have reviewed and understood the requirements of the contract or order;
- a method is available for reviewers to question the requirements of the contract or order, to have their questions considered and to have differences with other affected parties resolved.

4.3.3 Amendment to contract

When customer requirements change, consideration should be given to repeating the contract review procedure (see 4.3.2). It is beneficial for the supplier to have a procedure for reviews by the same departmental functions that reviewed the original contract or accepted order. Before such changes come into effect, there should be methods available to ensure that all relevant changes are communicated to those affected.

4.3.4 Records

In all cases, it should be sufficient to retain records that the review has been performed (see 4.16). For internal purposes, however, records of the evaluation associated with the contract

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review may be retained in cases such as complex or critical projects. These records should give objective evidence for audits, and facilitate the following:

- post-delivery project review;
- process improvement; and
- the generation of proposals for future projects.

4.4 Design control

4.4.1 General

The essential quality aspects and the regulatory requirements such as safety, performance, and dependability of a product are established during the design and development phase. Deficient design can be a major cause of quality problems.

In considering design control, it is important to note that the design process may apply to various activities in differing styles and timescales. Such aspects are related to products, as well as the process associated with product design. The supplier should consider all phases of the design associated with product design and all phases of the design process for which controlled procedures are necessary.

4.4.2 Design and development planning

The supplier should establish procedures for design and development planning and, where appropriate,include the following:

- identification, scope and objectives;
- sequential and parallel work schedules;
- timing, frequency, and nature of design verification and validation activities;
- evaluation of the safety, performance and dependability incorporated in the product design;
- methods of product measurement, test and acceptance criteria;
- assignment of responsibilities.

Design and development plans should be integrated with any other plans and verification procedures related to the product and plans should be updated as necessary.

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