INTERNATIONAL STANDARD

ISO 9004-1

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Quality management and quality system elements —

Part 1: Guidelines

Management de la qualité et éléments de système qualité —

Partie 1: Lignes directrices

Reference number
ISO 9004-1:1994(E)

Contents

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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 9004-1 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This first edition of ISO 9004-1 cancels and replaces ISO 9004:1987, and has been prepared as a result of comments received on ISO 9004:1977. ISO requires that all its standards be reviewed every five years and, as ISO 9004 has been expanded into a series of standards, it was considered that the revision to the 1987 edition of ISO 9004 should become the first part in the series, i.e. ISO 9004-1.

Comments adopted by Working Group 12 of ISO/TC 176/SC 2 during the review were based on the following considerations.

a) ISO 9004 is a document for internal use by an organization. It is not intended as guidance to ISO 9001, ISO 9002 or ISO 9003, for which ISO 9000-2 is available.

b) For editorial reasons, the 1987 document structure was retained in the 1994 edition. The structure of all four standards ISO 9001, ISO 9002, ISO 9003 and ISO 9004 will be changed and aligned with each other in the next five-year major revision.

c) This edition is essentially an editorial revision to align terminology with ISO 8402 and to reflect the need to serve better not only manufacturing but also process and service industries.

d) This edition also introduces some newer general quality management concepts, such as that all activities can be considered as processes, with input and output.

e) More emphasis has been placed on planning and preventive action. For this reason, activities such as handling, identification and packaging processes are now additionally dealt with under Quality in specifi-

cation and design (clause 8), Quality of processes (clause 10) and Control of processes (clause 11).

f) Figure 1 has been updated to reflect quality activities in the life cycle of a product.

g) New methods for the financial reporting of quality management effectiveness have been introduced.

ISO 9004 consists of the following parts, under the general title *Quality management and quality system elements*:

— *Part 1: Guidelines*

— *Part 2: Guidelines for services*

— *Part 3: Guidelines for processed materials*

— *Part 4: Guidelines for quality improvement*

— *Part 5: Guidelines for quality plans*

— *Part 6: Guidelines on quality assurance for project management*

— *Part 7: Guidelines for configuration management*

— *Part 8: Guidelines on quality principles and their application to management practices*

Annex A of this part of ISO 9004 is for information only.

Introduction

0.1 General

This part of ISO 9004 and all other International Standards in the ISO 9000 family are generic and independent of any specific industry or economic sector. Collectively they provide guidance for quality management and models for quality assurance.

The International Standards in the ISO 9000 family describe what elements quality systems should encompass, but not how a specific organization should implement these elements. Because the needs of organizations vary, it is not the purpose of these International Standards to enforce uniformity of quality systems. The design and implementation of a quality system will be influenced by the particular objectives, products, processes and individual practices of the organization.

A primary concern of any organization should be the quality of its products. (See 3.5 for the definition of "product" which includes service.)

In order to be successful, an organization should offer products that:

a) meet a well-defined need, use or purpose;

b) satisfy customers' expectations;

c) comply with applicable standards and specifications;

d) comply with requirements of society (see 3.3);

e) reflect environmental needs;

f) are made available at competitive prices;

g) are provided economically.

0.2 Organizational goals

In order to meet its objectives, an organization should ensure that the technical, administrative and human factors affecting the quality of its products will be under control, whether hardware, software, processed materials or services. All such control should be oriented towards the reduction, elimination and, most importantly, prevention of nonconformities.

A quality system should be developed and implemented for the purpose of accomplishing the objectives set out in the organization's quality policy.

Each element (or requirement) in a quality system varies in importance from one type of activity to another and from one product to another.

In order to achieve maximum effectiveness and to satisfy customer expectations, it is essential that the quality system be appropriate to the type of activity and to the product being offered.

0.3 Meeting customer/organization needs and expectations

A quality system has two interrelated aspects, as follows.

a) **The customer's needs and expectations**

For the customer, there is a need for confidence in the ability of the organization to deliver the desired quality as well as the consistent maintenance of that quality.

b) **The organization's needs and interests**

For the organization, there is a business need to attain and to maintain the desired quality at an optimum cost; the fulfilment of this aspect is related to the planned and efficient utilization of the technological, human and material resources available to the organization.

Each of the above aspects of a quality system requires objective evidence in the form of information and data concerning the quality of the system and the quality of the organization's products.

0.4 Benefits, costs and risks

Benefit, cost and risk considerations have great importance for both the organization and customer. These considerations are inherent aspects of most products. The possible effects and ramifications of these considerations are given in a) to c).

a) **Benefit considerations**

For the customer, consideration has to be given to reduced costs, improved fitness for use, increased satisfaction and growth in confidence.

For the organization, consideration has to be given to increased profitability and market share.

b) **Cost considerations**

For the customer, consideration has to be given to safety, acquisition cost, operating, maintenance, downtime and repair costs, and possible disposal costs.

For the organization, consideration has to be given to costs due to marketing and design deficiencies, including unsatisfactory product, rework, repair, replacement, reprocessing, loss of production, warranties and field repair.

c) **Risk considerations**

For the customer, consideration has to be given to risks such as those pertaining to the health and safety of people, dissatisfaction with product, availability, marketing claims and loss of confidence.

For the organization, consideration has to be given to risks related to deficient products which lead to loss of image or reputation, loss of market, complaints, claims, liability and waste of human and financial resources.

0.5 Conclusions

An effective quality system should be designed to satisfy customer needs and expectations while serving to protect the organization's interests. A well-structured quality system is a valuable management resource in the optimization and control of quality in relation to benefit, cost and risk considerations.

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Quality management and quality system elements —

Part 1:
Guidelines

1 Scope

This part of ISO 9004 provides guidance on quality management and quality system elements.

The quality system elements are suitable for use in the development and implementation of a comprehensive and effective in-house quality system, with a view to ensuring customer satisfaction.

This part of ISO 9004 is not intended for contractual, regulatory or certification use. Consequently, it is not a guideline for the implementing of ISO 9001, ISO 9002 and ISO 9003. ISO 9000-2 should be used for that purpose.

The selection of appropriate elements contained in this part of ISO 9004 and the extent to which these elements are adopted and applied by an organization depends upon factors such as the market being served, nature of the product, production processes, and customer and consumer needs.

References in this part of ISO 9004 to a "product" should be interpreted as applicable to the generic product categories of hardware, software, processed materials or service (in accordance with the definition of "product" in ISO 8402).

NOTES

1 For further guidance, see ISO 9004-2 and ISO 9004-3.

2 For informative references, see annex A.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 9004. 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 9004 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 9000-1:1994, *Quality management and quality assurance standards — Part 1: Guidelines for selection and use.*

3 Definitions

This revision of ISO 9004 has improved the harmonization of terminology with other International Standards in the ISO 9000 family. Table 1 shows the supply chain terminology used in these International Standards.

Table 1 — Relationships of organizations in the supply chain

ISO 9000-1	Sub-supplier	→	supplier or organization	→ customer
ISO 9001, ISO 9002, ISO 9003	Sub-contractor	→	supplier	→ customer
ISO 9004-1	Sub-contractor	→	organization	→ customer

Thus, the term "subcontractor" is used rather than the term "supplier" in this part of ISO 9004 to avoid confusion with the meaning of the term "supplier", in ISO 9000 and ISO 9001. See ISO 9000-1 for a fuller explanation of the basis for usage of these terms.

For the purposes of this part of ISO 9004, the definitions given in ISO 8402 apply.

For the convenience of users of this part of ISO 9004, the following definitions are quoted from ISO 8402.

3.1 organization: Company, corporation, firm, enterprise or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

3.2 customer: Recipient of a product provided by the supplier.

NOTES

3 In a contractual situation, the customer is called the "purchaser".

4 The customer may be, for example, the ultimate consumer, user, beneficiary or purchaser.

5 The customer can be either external or internal to the organization.

3.3 requirements of society: Obligations resulting from laws, regulations, rules, codes, statutes and other considerations.

NOTES

6 "Other considerations" include notably protection of the environment, health, safety, security, conservation of energy and natural resources.

7 All requirements of society should be taken into account when defining the requirements for quality.

8 Requirements of society include jurisdictional and regulatory requirements. These may vary from one jurisdiction to another.

3.4 quality plan: Document setting out the specific quality practices, resources and sequence of activities relevant to a particular product, project or contract.

NOTES

9 A quality plan usually makes reference to the parts of the quality manual applicable to the specific case.

10 Depending on the scope of the plan, a qualifier may be used, for example, "quality assurance plan", "quality management plan".

3.5 product: Result of activities or processes.

NOTES

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

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

13 A product can be either intended (e.g. offering to customers) or unintended (e.g. pollutant or unwanted effects).

3.6 service: Result generated by activities at the interface between the supplier and the customer and by supplier internal activities to meet the customer needs.

NOTES

14 The supplier or the customer may be represented at the interface by personnel or equipment.

15 Customer activities at the interface with the supplier may be essential to the service delivery.

16 Delivery or use of tangible products may form part of the service delivery.

17 A service may be linked with the manufacture and supply of tangible product.

4 Management responsibility

4.1 General

The responsibility for and commitment to a quality policy belongs to the highest level of management. Quality management encompasses all activities of the overall management function that determine the quality policy, objectives and responsibilities, and implement them by means such as quality planning, quality control, quality assurance and quality improvement within the quality system.

4.2 Quality policy

The management of an organization should define and document its quality policy. This policy should be consistent with other policies within the organization. Management should take all necessary measures to ensure that its quality policy is understood, implemented and reviewed, at all levels of the organization.

4.3 Quality objectives

4.3.1 Management should document objectives and commitments pertaining to key elements of quality, such as fitness for use, performance, safety and dependability.

4.3.2 The calculation and evaluation of costs associated with all quality elements and objectives should always be an important consideration, with the objective of minimizing quality losses.

4.3.3 Appropriate levels of management should document specific quality objectives consistent with quality policy as well as other objectives of the organization.

4.4 Quality system

4.4.1 A quality system is the organizational structure, procedures, processes and resources needed to implement quality management.

4.4.2 The organization's management should develop, establish and implement a quality system to accomplish the stated policies and objectives.

4.4.3 The quality system should be structured and adapted to the organization's particular type of business and should take into account the appropriate elements outlined in this part of ISO 9004.

4.4.4 The quality system should function in such a manner as to provide confidence that:

a) the system is understood, implemented, maintained and effective;

b) the products actually do satisfy customer needs and expectations;

c) the needs of both society and the environment have been addressed;

d) emphasis is placed on problem prevention rather than dependence on detection after occurrence.

5 Quality system elements

5.1 Extent of application

5.1.1 The quality system typically applies to, and interacts with, all activities pertinent to the quality of a product. It will involve all phases in the life cycle of a product and processes, from initial identification of market needs to final satisfaction of requirements. Typical phases are:

a) marketing and market research;

b) product design and development;

c) process planning and development;

d) purchasing;

e) production, or provision of services;

f) verification;

g) packaging and storage;

h) sales and distribution;

i) installation and commissioning;

j) technical assistance and servicing;

k) after sales;

l) disposal or recycling at the end of useful life.

NOTE 18 Figure 1 gives a schematic representation of the typical life-cycle phases of a product.

5.1.2 In the context of interacting activities within an organization, marketing and design should be emphasized as especially important for

— determining and defining customer needs, expectations and other product requirements, and

— providing the concepts (including supporting data) for producing a product to documented specifications at optimum cost.

5.2 Structure of the quality system

5.2.1 General

Input from the market should be used to improve new and existing products and to improve the quality system.

Management is ultimately responsible for establishing the quality policy and for decisions concerning the initiation, development, implementation and maintenance of the quality system.

5.2.2 Responsibility and authority

Activities contributing to quality, whether directly or indirectly, should be defined and documented, and the following actions taken.

a) General and specific quality-related responsibilities should be explicitly defined.

b) Responsibility and authority delegated to each activity contributing to quality should be clearly established. Responsibility, organizational freedom and authority to act should be sufficient to attain the assigned quality objectives with the desired efficiency.

c) Interface control and coordination measures between different activities should be defined.

d) In organizing a well-structured and effective quality system, emphasis should be placed on the identification of potential or actual quality problems and the implementation of preventive or corrective action (see clauses 14 and 15).

5.2.3 Organizational structure

Functions related to the quality system should be clearly established within the overall organizational structure. The lines of authority and communication should be defined.

5.2.4 Resources and personnel

Management should identify resource requirements, and provide sufficient and appropriate resources essential to the implementation of the quality policy and the achievement of quality objectives. For example, these resources can include:

a) human resources and specialized skills;

b) design and development equipment;

c) manufacturing equipment;

d) inspection, test and examination equipment;

e) instrumentation and computer software.

Management should determine the level of competence, experience and training necessary to ensure the capability of personnel (see clause 18).

Management should identify quality-related factors affecting market position and objectives relative to products, processes or associated services, in order to allocate organization resources on a planned and timely basis.

Programmes and schedules covering these resources and skills should be consistent with the organization's overall objectives.

5.2.5 Operational procedures

The quality system should be organized in such a way that adequate and continuous control is exercised over all activities affecting quality.

The quality system should emphasize preventive actions that avoid occurrence of problems, while maintaining the ability to respond to and correct failures should they occur.

Documented operational procedures coordinating different activities with respect to an effective quality system should be developed, issued and maintained to implement the quality policy and objectives. These documented procedures should specify the objectives and performance of the various activities having an impact on quality (see figure 1).

All documented procedures should be stated simply, unambiguously and understandably, and should indicate methods to be used and criteria to be satisfied.

5.2.6 Configuration management

The quality system should include documented procedures for configuration management to the extent appropriate. This discipline is initiated early in the design phase and continues through the whole life cycle of a product. It assists in the operation and control of design, development, production and use of a product, and gives management visibility of the state of documentation and product during its life-time.

Configuration management can include: configuration identification, configuration control, configuration status accounting and configuration audit. It relates to several of the activities described in this part of ISO 9004.