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**Kwaliteitszorg en elementen van het kwaliteitssysteem - Deel 1 :
Richtlijnen (ISO 9004-1:1994)**

Quality management and quality system elements - Part 1 : Guidelines (ISO 9004-1:1994)

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**Management de la qualité et éléments de système qualité - Partie 1 :
Lignes directrices (ISO 9004-1:1994)**

Quality management and quality system elements - Part 1 : Guidelines (ISO 9004-1:1994)

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La présente norme européenne EN ISO 9004-1 : 1994 a le statut d'une norme belge.

La présente norme européenne existe en trois versions officielles (allemand, anglais, français).



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EUROPEAN STANDARD

EN ISO 9004-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 1994

UDC

Supersedes EN 29004:1987

Descriptors:

English version

**Quality management and quality system elements
- Part 1: Guidelines (ISO 9004-1:1994)**

Management de la qualité et éléments de système
qualité - Partie 1: Lignes directrices
(ISO 9004-1:1994)

Qualitätsmanagement und Elemente eines
Qualitätsmanagementsystems - Teil 1: Leitfaden
(ISO 9004-1:1994)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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ISO 9004-1:1994(E)

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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.

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.