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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*



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Contents

	Page
1 Scope	1
2 Normative references	1
3 Definitions	1
4 Management responsibility	2
5 Quality system elements	3
6 Financial considerations of quality systems	7
7 Quality in marketing	8
8 Quality in specification and design	9
9 Quality in purchasing	12
10 Quality of processes	14
11 Control of processes	15
12 Product verification	16
13 Control of inspection, measuring and test equipment	16
14 Control of nonconforming product	17
15 Corrective action	18
16 Post-production activities	19
17 Quality records	19
18 Personnel	20
19 Product safety	21
20 Use of statistical methods	22

Annex

A Bibliography	23
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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.