

Qualitätsmanagementsysteme

Leitfaden

(ISO/CD 9004 : 1998)

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Vorgesehen als Ersatz für
DIN EN ISO 9004-1 : 1994-08Quality Management Systems – Guideline
(ISO/CD 9004 : 1998)**Anwendungswarnvermerk**

Dieser Norm-Entwurf wird der Öffentlichkeit zur Prüfung und Stellungnahme vorgelegt.

Weil die beabsichtigte Norm von der vorliegenden Fassung abweichen kann, ist die Anwendung dieses Entwurfes besonders zu vereinbaren.

Stellungnahmen werden erbeten an den Normenausschuß Qualitätsmanagement, Statistik und Zertifizierungsgrundlagen (NQSZ) im DIN Deutsches Institut für Normung e.V., 10772 Berlin (Hausanschrift: Burggrafenstraße 6, 10787 Berlin).

Das internationale Schriftstück ISO/CD 9001 : 1998 "Quality Management Systems – Guideline" ist unverändert in diesen deutschen Norm-Entwurf übernommen worden.

Nationales Vorwort

Der hier veröffentlichte internationale Norm-Entwurf wurde im Technischen Komitee 176 "Qualitätsmanagement und Qualitätssicherung" der Internationalen Normungsorganisation (ISO) unter Mitwirkung des Normenausschusses Qualitätsmanagement, Statistik und Zertifizierungsgrundlagen (NQSZ) im DIN erarbeitet.

Nach DIN 820-15 dürfen DIN-Norm-Entwürfe anstelle der deutschen Übersetzung unter bestimmten Bedingungen den englischen Originaltext enthalten. Diese Bedingungen sind für diesen Norm-Entwurf erfüllt. Der NQSZ bittet, Stellungnahmen auf untenstehendem Formblatt nach Möglichkeit in englischer Sprache mit konkreten Formulierungsvorschlägen einzureichen. Das Formblatt darf kopiert werden. Die später zu veröffentlichende Deutsche Norm (Weißdruck) soll dreisprachig in Deutsch, Englisch und Französisch erscheinen.

Der in dem Norm-Entwurf enthaltene Komitee-Entwurf ISO/CD 9004 : 1998 ist Teil der sogenannten Phase-2-Revision der ISO 9000-Familie. Derzeit ist für die Erarbeitung der neuen ISO 9004 folgender Ablauf vorgesehen:

– ISO/CD 9004 : 1998 gibt das ISO/TC 176/SC 2 (das zuständige Unterkomitee des ISO/TC 176) zur Stellungnahme heraus. Die Stellungnahmen zu dem vorliegenden Entwurf DIN EN ISO 9004 : 1998, die aus Deutschland eingehen, wird der NQSZ zusammenfassen und in seine Stellungnahme zu ISO/CD 9004 : 1998 einbeziehen und im ISO/TC 176/SC 2 vertreten.

– Nach Behandlung der eingegangenen Stellungnahmen wird das ISO/TC 176/SC 2 einen zweiten Komitee-Entwurf ISO/CD 9004.2 im Jahr 1999 zur Abstimmung und Stellungnahme herausgeben.

– Wenn die Abstimmung und Stellungnahme zum zweiten Komitee-Entwurf positiv ausfallen, geht das Normungsprojekt in die nächsten Bearbeitungsstufen über, d. h. Internationalen Norm-Entwurf (ISO/DIS), danach Internationalen Schlußentwurf (ISO/FDIS) und schließlich die Herausgabe der Internationalen Norm (ISO).

Fortsetzung Seite 2 und 3
und 41 Seiten ISO-Original

Normenausschuß Qualitätsmanagement, Statistik und Zertifizierungsgrundlagen (NQSZ) im DIN
Deutsches Institut für Normung e.V.

Daraus wird ersichtlich, daß sich der vorliegende deutsche Norm-Entwurf auf ein frühes Stadium der internationalen Normung bezieht. Die Veröffentlichung jetzt wählt der NQSZ, um der deutschen Öffentlichkeit möglichst frühzeitig Gelegenheit zu geben, durch Stellungnahmen an dem Inhalt der künftigen Norm mitzuwirken. Aus diesem Grunde wurde auch auf die Anfertigung einer deutschen Übersetzung verzichtet, da der dafür notwendige Zeitbedarf einer termingerechten Einbindung der Stellungnahmen aus Deutschland entgegensteht.

An dem Inhalt und der Form des Dokuments sind bis zur Herausgabe der Norm noch erhebliche Änderungen möglich. Die Normanwender sollten daher besondere Vorsicht walten lassen, wenn sie aus dem vorliegenden Entwurf Schlußfolgerungen für die Einrichtung eines neuen oder die Änderung eines bestehenden QM-Systems ziehen wollen. Die derzeitige Norm DIN EN ISO 9004-1 : 1994 bleibt gültig. Der Ersatz wird erst durch Herausgabe der neuen Norm (Weißdruck) wirksam. Der obenstehende Ersatzvermerk ist deshalb als "Vorgesehen" gekennzeichnet.

Um möglichst anwendungsnahe Rückmeldungen darüber zu erhalten, ob der Normentwurf die Bedürfnisse der Anwender erfüllt, hat das ISO/TC 176/SC 2 ein Validierungsprogramm eingerichtet. Jede Organisation, die daran teilnehmen möchte, kann einen entsprechenden Fragebogen ausfüllen. Ein weiteres Arbeitsprogramm des ISO/TC 176/SC 2 betrifft den künftigen Übergang von den derzeitigen Normen ISO 9001, 9002, 9003, 9004-1 auf die neuen Normen. Um einen möglichst reibungslosen Übergang zu erreichen, soll ein unterstützender Leitfaden geschrieben werden. Hierzu sind Mitteilungen der Anwender über zu behandelnde bzw. zu beachtende Aspekte erwünscht. Nähere Einzelheiten zu beiden Programmen sind im Internet abrufbar unter der Adresse:
<http://www.bsi.org.uk/iso-tc176-sc2>.

Änderungen

Gegenüber DIN EN ISO 9004-1 : 1994-08 wurden folgende Änderungen vorgenommen:

Die Norm ist überarbeitet worden, um eine Reihe von Verbesserungen zu erreichen, welche die Anwender gefordert haben. Dazu gehören:

- Konsistenz mit der Struktur von ISO 9001;
- verbesserte Kompatibilität mit anderen Managementsystemen, insbesondere Umwelt;
- Erleichterung der Anwendung in allen Branchen und für alle Arten von Produkten einschließlich Dienstleistungen;
- Erleichterung der Anwendung auch für kleine Organisationen.

Formblatt für die Kommentierung von ISO/CD 9004:1998

Jeder Änderungsvorschlag ist mit einer Begründung zu versehen. Vorschläge ohne Begründung können nicht berücksichtigt werden. Es wäre hilfreich bei der Zusammenfassung der Kommentare und Erarbeitung der deutschen Stellungnahme gegenüber ISO/TC 176/SC 2, wenn Stellungnahmen außer auf dem Formblatt in Papierform nach Möglichkeit auch in elektronischer Form eingereicht werden könnten. (Word 6 oder Word 7 for Windows auf Diskette oder e-mail: graebig@NQSZ.DIN.DE).

Ref. Nr.	Clause no.	Paragraph, bullet, line no.	Text to be changed	Change suggested	Justification for change	Name	Organization
Lfd. Nr.	Abschnitt	Absatz, Unterpunkt, Zeile	Zu verändernder Text	Änderungsvorschlag	Begründung für Änderungsvorschlag	Name	Organisation

Bei Bedarf Formblatt fortsetzen.

— Leerseite —

ISO/CD1 9004:2000

Title

**ISO 9004: 2000,
Quality Management Systems -
Guidelines**

Contents

FOREWORD 4

0 INTRODUCTION 6

0.1 GENERAL..... 6

0.2 MEETING NEEDS AND EXPECTATIONS..... 6

0.3 BENEFITS, COSTS AND RISKS 6

1 SCOPE..... 7

2 NORMATIVE REFERENCE..... 7

3 TERMS AND DEFINITIONS 7

4 QUALITY MANAGEMENT SYSTEM GUIDELINES..... 7

4.1 CONCEPTS OF A CONSISTENT PAIR..... 8

4.2 NEED TO INTEGRATE CLAUSE CONTENT 8

4.3 USE OF QUALITY MANAGEMENT PRINCIPLES 8

4.4 EVALUATION OF THE ORGANIZATION'S PROGRESSION TOWARD EXCELLENCE..... 9

4.5 PROCESS MODEL FOR A QUALITY MANAGEMENT SYSTEM..... 9

FIGURE 1 - QUALITY MANAGEMENT PROCESS MODEL..... 10

5 MANAGEMENT RESPONSIBILITY..... 10

5.1 GENERAL..... 10

5.2 INTERESTED PARTY NEEDS AND REQUIREMENTS..... 11

5.3 QUALITY POLICY 11

5.4 QUALITY OBJECTIVES AND PLANNING 12

 5.4.1 *Quality objectives*..... 12

 5.4.2 *Quality planning*..... 12

5.5 QUALITY MANAGEMENT SYSTEM 13

 5.5.1 *General* 13

 5.5.2 *Responsibility and authority*..... 13

 5.5.3 *Management representative*..... 14

 5.5.4 *Documentation*..... 14

 5.5.4.1 *Quality manual*..... 14

 5.5.4.2 *System procedures*..... 14

 5.5.4.3 *Control of documents*..... 15

 5.5.4.4 *Control of quality records*..... 16

5.6 MANAGEMENT REVIEW 16

6 RESOURCE MANAGEMENT 17

6.1 GENERAL..... 17

6.2 HUMAN RESOURCES 17

 6.2.1 *Assignment of personnel*..... 17

 6.2.2 *Training, qualifications and competence*..... 17

 6.2.2.1 *Training*..... 17

 6.2.2.2 *Qualifications and competence*..... 18

 6.2.3 *Awareness and involvement*..... 18

6.3 OTHER RESOURCES..... 19

 6.3.1 *Information*..... 19

 6.3.1.1 *Content*..... 19

 6.3.1.2 *Characteristics*..... 19

 6.3.1.3 *Media*..... 19

 6.3.2 *Infrastructure*..... 20

ISO/CD1 9004:2000

6.3.3 *Work environment*..... 20

6.3.4 *Finance*..... 21

7 PROCESS MANAGEMENT..... 22

7.1 GENERAL..... 22

7.1.1 *Processes and quality*..... 22

7.1.2 *Process network*..... 22

7.1.3 *Process responsibilities*..... 22

7.1.4 *Planning for process control*..... 23

7.1.5 *Process documentation*..... 23

7.2 INTERESTED PARTY RELATED PROCESSES..... 23

7.2.1 *Identification of the needs and expectations of interested parties*..... 23

7.2.2 *Review of the needs and expectations of interested parties*..... 24

7.2.3 *Review of organizational capability to meet defined needs and expectations*..... 24

7.2.4 *Interested party communication*..... 24

7.3. DESIGN AND DEVELOPMENT..... 25

7.3.1 *General*..... 25

7.3.2 *Design and development inputs*..... 26

7.3.3 *Design and development outputs*..... 27

7.3.4 *Design and development review*..... 27

7.3.5 *Verification*..... 28

7.3.6 *Validation*..... 28

7.3.7 *Control of changes*..... 28

7.4 PURCHASING..... 29

7.4.1 *General*..... 29

7.4.2 *Supplier relationships*..... 29

7.4.3 *Supplier qualification*..... 30

7.4.4 *Purchasing processes*..... 31

7.5 PRODUCTION AND SERVICE OPERATIONS..... 31

7.5.1 *Services*..... 31

7.5.2 *Hardware and processed materials*..... 31

7.5.3 *Software*..... 32

7.5.4 *Equipment control*..... 32

7.5.5 *Verification activities*..... 32

7.5.6 *Process validation*..... 32

7.5.7 *Process change control*..... 33

7.6 CONTROL OF NONCONFORMITY..... 33

7.6.1 *General*..... 33

7.6.2 *Nonconformity review and disposition*..... 33

7.7 POST-DELIVERY SERVICES..... 33

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT..... 34

8.1 GENERAL..... 34

8.2 MEASUREMENT..... 34

8.2.1 *Measurement of system performance*..... 34

8.2.1.1 *Measurement of customer and interested party satisfaction*..... 34

8.2.1.2 *Internal audit*..... 35

8.2.2 *Measurement of processes*..... 36

8.2.3 *Measurement of product and/or service*..... 36

8.2.4 *Control of measuring, inspection and test equipment*..... 37

8.3 ANALYSIS OF DATA..... 38

8.4 IMPROVEMENT..... 39

8.4.1 *Corrective action*..... 39

8.4.2 *Preventive action*..... 40

8.4.3 *Improvement processes*..... 40

BIBLIOGRAPHY..... 41

ISO/CD1 9004:2000

Foreword

The International Organization for Standardization (ISO) is a world-wide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is 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 a two-thirds majority of the votes cast by the member bodies of the technical committee (or subcommittee) being in favour, and not more than one-quarter of the total number of votes cast being negative.

This International Standard, ISO 9004: 2000, was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*, in accordance with the ISO/IEC Directives, Part 3:1997 *Rules for the structure and drafting of International Standards*.

Upon publication, ISO 9004: 2000 will cancel and replace ISO 9004 -1:1994, which has been technically revised. Also, many of the existing International Standards within the ISO 9000 family will be reviewed for withdrawal (particularly the other Parts of ISO 9004), as their provisions have been incorporated into this International Standard.

This International Standard has been developed to be one part of a consistent pair of quality management system standards, the other being ISO 9001 : 2000, *Quality management systems - Requirements*. The two International Standards are designed to be used together, but are also capable of being used as stand-alone documents. The two International Standards have similar structures, for ease of use, but have different scopes. ISO 9004 gives guidance on the total aspects of a quality management system, to improve organizations' overall quality performance, while ISO 9001 addresses the quality management system requirements for an organization to demonstrate its capability to meet customer requirements.

The ISO 9041 and ISO 9001 consistent pair of quality management system standards address all generic product categories. They also provide the basis for addressing those requirements which may be developed by specific sectors of affected users.

This International Standard references ISO 9000: 2000, *Quality management systems - Concepts and vocabulary*. ISO 9000 gives guidance on the quality management principles and concepts which provide the foundation for ISO 9004 and ISO 9001, as well as establishing the terminology and definitions applied in them.

The development of this International Standard has been coordinated with the work of Technical Committee ISO/TC 207, *Environmental management*, Subcommittee SC 1 *Environmental management systems*, to achieve greater compatibility with the ISO 14000

ISO/CD1 9004:2000

series of environmental management systems standards, for the benefit of the user community

0 Introduction

0.1 General

This International Standard provides guidelines to organizations for achieving excellence through continual improvement of the performance of their business.

It gives comprehensive guidance on the application of quality management and describes what processes quality management systems should encompass.

When used with ISO 9001, it forms part of a consistent pair of International Standards that together incorporate all aspects of a quality management system.

The focus of this International Standard is directed towards improving the internal processes of an organization to enhance business performance.

Because the needs of organizations vary, it is not the purpose of this International Standard to imply uniformity of quality management systems. The design and implementation of a quality management system is influenced by the objectives of the organization, product and/or services provided, and the processes employed.

It is not the intention that organizations should be obliged to change the structure of their quality management system and/or its documentation to align with the structure of this International Standard. The documentation of an organization's quality management system should be configured in a manner that is appropriate to its unique activities.

0.2 Meeting needs and expectations

The role of an organization is to:

- a) meet the needs and expectations of its customers and interested parties (i.e. employees, suppliers, owners, society) and to do this in a effective and effective manner;
- b) attain, and maintain the fulfilment of the objectives of the business.

0.3 Benefits, costs and risks

Benefit, cost and risk considerations are important for the organization, its customers and interested parties. Some possible impacts of these considerations on overall performance are:

- a) revenue (turnover) and market share. These may be increased by such things as improved employee performance, increased efficiency, employee and customer satisfaction;
- b) costs due to resources needed for business. The absence of resource funding is likely to cause potential production losses, and a competitive disadvantage in the market place through the sale of deficient produce and/or service. Additional losses may be incurred through a loss of market share, poor image and/or reputation, customer complaints, increased liability and a waste of human and financial resources.

Quality management systems - Guidelines

1 Scope

This International Standard provides guidance on quality management, and the continual improvement of processes that contribute to the satisfaction of an organization's customers and interested parties.

This International Standard is based on quality management principles to provide understanding of quality management and its application to enhancing the internal performance of an organization. Consequently, it is not a guideline for implementing ISO 9001, and is not intended for certification, regulatory or contractual use.

The selection of the appropriate quality related processes described in this International Standard and the extent to which these processes are adopted and applied by an organization depends upon factors such as the market being served, the operational processes and resource requirements.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 9000: 2000, Quality management systems - Concepts and vocabulary.

3 Terms and definitions

For the purposes of this International Standard the terms and definitions given in ISO 9000: 2000 apply.

Note 1 The supply-chain terminology used in this edition of this International Standard, is shown as follows:

supplier-----organization-----customer

Note 2 The term 'organization' used in this International Standard replaces the term 'supplier' which was used previously to mean the unit to which this International Standard applied. The term 'supplier' is now used instead of the term 'subcontractor'. The changes have been introduced to reflect the current vocabulary used by organizations.

4 Quality management system guidelines

ISO/CD1 9004:2000

4.1 Concepts of a consistent pair

This International Standard has been developed so as to have identical major clause structure with ISO 9001:2000. This identical structure permits ease of use of the two documents as a complementary consistent pair of standards. ISO 9001 is a requirement standard, it focuses on the managing of those processes necessary to meet customer requirements.

Although utilising the same major clause structure as the ISO 9001 standard, this guideline International Standard presents the user organization with those quality management system elements to be considered for the improvement of performance of the organization.

4.2 Need to integrate clause content

This International Standard has been developed under four major clause headings:

- Management responsibility
- Resource management
- Process management
- Measurement, analysis and improvement

The topic clause headings have been chosen as a simple way of presenting the content of a quality management system. The content of the individual clauses do not stand alone but need to be integrated to achieve the complete quality management system. For example, the requirement for a documented quality management system is covered from:

- a) a need or policy viewpoint under management responsibility (clause 5);
- b) development of the documentation and its implementation under process management (clause 7);
- c) need for records of results in measurement, analysis and improvement (clause 8).

As stated in clause 5 Management responsibility, the nature and extent of the documentation is to be determined by the user organization, based on the organization needs.

4.3 Use of quality management principles

The eight quality management principles identified in ISO publication ISO/TC 176/SC 2/N 376 have been integrated into the text of this International Standard. They are simple but powerful considerations in the success of a quality management system. They are directed toward the management of the organization but implementation of the principles will ultimately benefit the organization's customers and interested parties. These quality management principles are:

- Customer focused organizations
- Leadership
- Involvement of people
- Process approach
- Systems approach to management

ISO/CD1 9004:2000

- Factual approach to decision making
- Continual improvement
- Mutually beneficial supplier relationships

4.4 Evaluation of the organization's progression toward excellence

The quality management system content of this International Standard is presented to guide the management of an organization in the pursuit of increased performance and excellence. Since the document is generic in nature and intent, only generic guidance is presented. Each organization will need to select and employ the most appropriate methods and tools from the content of this International Standard. The management of the prudent organization will closely monitor the movement toward performance improvement and excellence. Initially identification of those elements, steps or processes which will define excellence for the organization must be determined by management. Second, the appropriate steps or thresholds in the movement toward excellence will need to be determined and sufficiently described so as to permit management to evaluate where the organization improvement status is located in regard to each of the defined excellence elements.

4.5 Process model for a quality management system

The process model displayed in Figure 1 reflects graphically the integration of the four major clause headings.

Since it is a model of the complete quality management process, it is capable of demonstrating both vertical and horizontal process integration.

For a vertical loop example, management sets requirements under *Management responsibility*; necessary resources are identified and employed within *Resource management*; processes are created and driven under *Process management*; results are measured, analysed, and improved through *Measurement, analysis and improvement*. *Management review* closes the loop, as the cycle returns to *Management responsibility* for change authorisation and initiation of improvement.

As an example of a major horizontal loop, the model recognises the fact that customers play a significant role during process input of needs, the identified realization processes are then exercised and customer satisfaction is evaluated at process output. Output data are used to improve the customer inputs, completing the horizontal process loop.

Subordinate vertical and horizontal process loops will be encountered or created as the organization's major processes are exercised.

The process model displayed is conceptual and not intended to reflect processes at the detailed level, however all elements of a complete quality management system may be placed within the model.

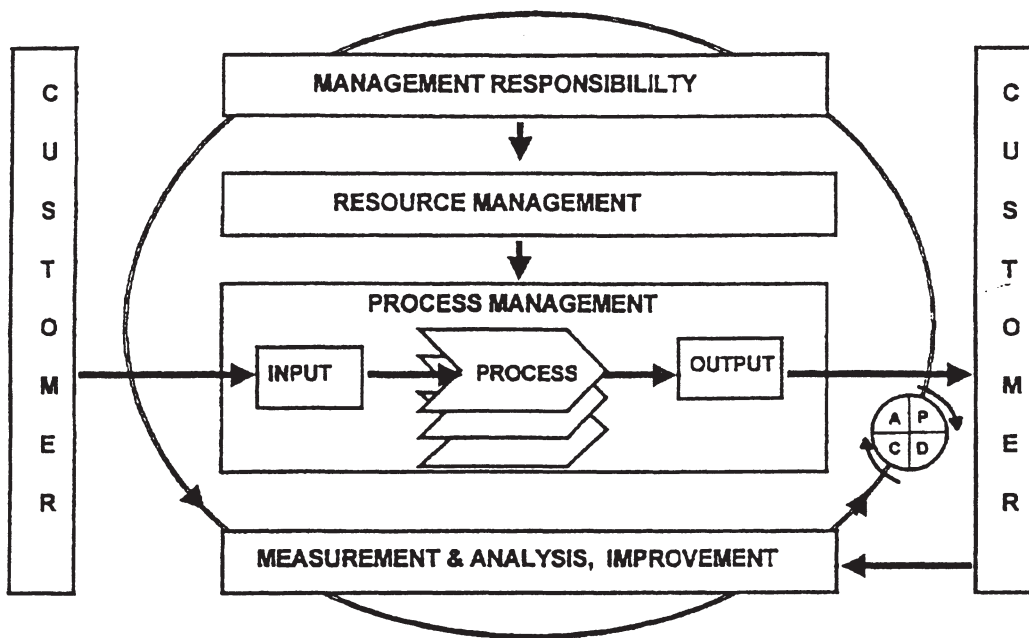


Figure 1 - Quality Management Process Model

5 Management responsibility

5.1 General

The commitment and involvement of the top management are essential for developing and implementing an effective and efficient quality management system.

The top management should focus the organization on sustained customer satisfaction while giving benefits to the other interested parties.

Top management should:

- a) provide visible personal leadership;
- b) plan for the future of the organization (change management);
- c) develop a culture of continual improvement;
- d) set and communicate directions related to achieving interested party satisfaction, including:
 - creating valued relationships with suppliers;
 - encouraging employee efforts;
 - being sensitive to the community;
 - improving financial results;
- e) define quality policy and quality objectives;
- f) provide resources;
- g) carry out periodic reviews of the quality results.