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Health services - Quality management systems - Guide for the use of EN ISO 9001:2000

Dienstleistungen in der Gesundheitsversorgung - Qualitätsmanagementsysteme - Anleitung zur Anwendung von EN ISO 9001:2000

Services en santé - Systemes de management de la qualité - Guide d'utilisation de l'EN ISO 9001:2000

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Health services - Quality management systems - Guide for the use of EN ISO 9001:2000

Services en santé - Systèmes de management de la qualité - Guide d'utilisation de l'EN ISO 9001:2000

Dienstleistungen in der Gesundheitsversorgung - Qualitätsmanagementsysteme - Anleitung zur Anwendung von ISO 9001:2000

This Technical Specification (CEN/TS) was approved by CEN on 1 October 2005 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

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Foreword

This Technical Specification (CEN/TS 15224:2005) has been prepared by Working Group CEN/BT/TF 142, the secretariat of which is held by SIS.

This guide for the health services sector is intended to aid the user with the interpretation of the standard *EN ISO 9001:2000 Quality management systems - Requirements* when implementing a quality management system. The guide is not intended for certification purposes on its own.

In Annex A, practical and informative recommendations are provided for all who are involved in the development, implementation and assessment of a quality management system in a health care organisation.

This *Guide for the use of EN ISO 9001:2000 in health services* has been developed by CEN/BT/TF 142, a task force of health experts including experienced physicians, nurses and health administrators, representing different sectors and levels in the European health services sector.

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 Electro technical Commission (IEC) on all matters of electro technical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This third edition of ISO 9001 cancels and replaces the second edition (ISO 9001:1994) together with ISO 9002:1994 and ISO 9003:1994. It constitutes a technical revision of these documents. Those organizations which have used ISO 9002:1994 and ISO 9003:1994 in the past may use this International Standard by excluding certain requirements in accordance with 1.2.

The title of ISO 9001 has been revised in this edition and no longer includes the term “Quality assurance”. This reflects the fact that the quality management system requirements specified in this edition of ISO 9001, in addition to quality assurance of product, also aim to enhance customer satisfaction.

Annexes A and B of this International Standard are for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this CEN Technical Specification: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

0 Introduction

0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer regulatory and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

Health services and quality management systems

In the health services sector, services provided by health care professionals to individuals are central. The professional responsibility of the staff in the care/service provision is critical. Health care professionals are increasingly becoming self regulated: professional groups in this sector implement, guard and promote their professional practice and they guard the quality of their work with codes and standards developed by their professional associations.

In the health services sector requirements for quality management have to be interpreted differently than in industry and other types of business for the following reasons:

- The health services are characterised by the physical and mental involvement of the patient in the process of care provision. Thus, the provision of care is based on the continuous interaction between health care professionals (provider) and customers.

- The customer may have little knowledge of the professional aspects of the service delivered. The relationship between the patient and the professional is an unequal one considering the professional input; choices will be highly influenced by the professional.

- Commonly, the purchase and the receipt of health services are separated (so called “Third party payment”). Thus, the provider may have to satisfy different quality demands from its two main customers: the patient and the purchaser.

- Health services are characterized by complexities such as relations and interactions between patients, health care professionals, health suppliers, insurers, industry and governmental bodies. In addition health services are subject to constant change introduced by evolving technologies.

By the use of a quality management system the processes that are directly or indirectly related to the health services provided, can be controlled to meet these requirements.

In interpreting the EN ISO 9001:2000 standard, the national approaches to improving quality in the health service sector have been found to share a number of common principles. These principles have formed the basis for creating the uniform requirements of this guidance document. These principles are:

Customer focus

A customer centred approach is an important objective in the development of public and private services and it constitutes one of the main drivers for health services reforms. Close co-operation between the customer

and the professional results in genuine and mutual influence and dialogue between equal partners. The heterogeneity of customers means that the understanding of different backgrounds and the development of versatile service capabilities are necessary. Health services need to be tailored to the customer's requirements taking into account their environment and immediate community. Thus, services delivered have to meet both general and individual requirements.

Stakeholder involvement

The definition of care and quality of care requires inputs from all parties involved, which in addition to the provider and purchaser, also include the patient/customer and the professionals. Such input is also instrumental for bringing the stakeholder's perspective of care into the planning process and the periodical and independent assessment of customer satisfaction into the quality improvement process.

Leadership

In health care organisations, leadership is crucial for organisational and quality management with a sharp customer focus that inspires, promotes and supports a quality culture. Quality improvement concerns, equally, professionals and the management. Health care professionals are responsible for their professional practice; the management is however accountable for the safety and quality of all services offered by the organisation.

People and care vision

Health services are 'people working with people'. Quality development in the health service sector therefore requires a shift from authoritative management paradigms to a people-oriented culture that can effect team and group skills for continuous process improvement and intelligent, learning organisations. Guidance and motivation of staff is essential and requires constant and structured communication, not only in between staff members but also between staff and customers.

Process orientation

Modern health services constitute integrated processes that span functions and clinical specialisations and also across different health services providers. Care is delivered through core processes that follow the patient from the time of referral/ request until after the discharge, including follow-up. Core processes, however, depend on a number of vital inputs in the form of supporting processes. Risk management is critical to any health service and is best achieved through an integrated process approach.

Guidance through information

Professional practice is increasingly evidence-based, i.e. scientifically oriented, and best practices are captured in protocols, guidelines and other resources which must keep pace with scientific developments. It is essential that the care provided can be continually evaluated and adjusted according to scientific progress. This requires systematic monitoring of activities and their outcomes.

It is also important to recognise the strong synergies between quality and information technology in an organisation. Information systems are geared to effectively support, control and monitor standardised, integrated processes. On the other hand, quality improvement in the knowledge based, complex and fast evolving health services environment can effectively be carried out only with fully integrated information technology support that links into the organisation's longitudinal work-flows.

Partnerships for quality across health services

Health services are provided over a continuum that spans prevention and health promotion, diagnosis and treatment to rehabilitation and health maintenance. The co-ordination of services between different providers determines the extent of continuity of care that citizens receive within any health services system, over time and across care providers. Eventually, in the regional context, it will be necessary to consider the development of quality management systems encompassing care provider networks.

Demand oriented care

In the health services sector a fundamental change is taking place from supply-oriented care, i.e., care determined by the service provider, to demand-oriented care, in which the expectations and needs of the customer are central. However, the supply of care is not unlimited, one should thus strive for an optimum balance of taking into account needs and wishes of the customer, modified by the professional judgements, and availability of resources. This balance can ideally be determined during a process of open communication and negotiation and must meet both the quality criteria of the purchaser/customer as well as those of the patient and the professional.

Mutually beneficial supplier relationship

Third party services such as technical support, information and communication services, business consulting, recruitment services, sanitation, catering, and training have a critical effect on a health care organisation's quality and its outcomes. Likewise, services provided by clinical laboratories and imaging departments, critically affect treatment decisions made by other departments. Safe and high quality services may be developed only on the grounds of mutual understanding and respect of customer requirements in the numerous internal and external customer-provider relationships.

Continual improvement

Health services organisations are challenged to become continuously evolving learning environments that systematically accept, process and interpret results, and improve performance by learning from past experience. This is one key competence that can allow an organisation to perform successfully in an ever changing environment with escalating pressures for higher quality and better cost containment.

European harmonisation and ISO compatibility

Health services are increasingly becoming international markets. Over the past years, there has been a growing awareness that quality management systems may be applied to the health services sector to improve quality and safety, and ultimately promote public accountability for health care providers and policymakers. National approaches vary and different organisations may choose different methods and approaches to quality management. The ISO standards provide an international standardisation framework for quality management systems and their evaluation. Recognition of quality on the basis of commonly held standards facilitates mutual recognition between organisations. Consequently, there is a strong case for ISO compatibility with national quality management systems in the health services sector, especially in cross-border contracting situations.

Guide to the use of EN ISO 9001:2000 in the health services

This is a guidance document for organisations in the health services sector to aid the user in the interpretation and application of the standard EN ISO 9001:2000, Quality Management Systems - Requirements, when developing and implementing a quality management system. A quality management system is a management system to direct and control an organisation with regard to quality.

Annex A provides practical guidance on the implementation of a quality management system and is meant to be informative and motivating.

The main target groups for this guide are strategic decision-makers at all levels in the health services sector and all staff who are involved in the development, implementation and assessment of a quality management system in a health organisation, including the stakeholders.

In this guide, the term *health services* means *health services provided.* The term *health services* is in other connections used to nominate the health services sector. In this document *health services sector* will be used to differentiate between the health services and the health services sector. The services that are included in the term may vary from country to country; this has to be considered in the national translations. In this guide, health services is considered to include hospital care, primary health care and preventive care, psychiatry and dental services.

The original text of EN ISO 9001:2000 is framed and other referenced source text is marked.

The ISO introduction text to this guide generally explains the requirements in the ISO 9001 standard, clarifying the process approach, the relationship with the ISO 9004 standard and the compatibility with other management systems.

The Scope explains when and where the standard's requirements are applicable.

The terms and definitions described in Clause 3 of this guide are from the ISO 9000:2000 standard. In addition, terms of special interest, importance and understanding for the health services sector are included.

In Clause 4, the general ISO requirements on quality management systems are specified complemented with specifications of these requirements for the health services sector, when necessary.

In Clause 5 the management's responsibility is made explicit through the requirements in the standard and complemented with specifications of these for the health services sector.

Clause 6 specifies requirements on the resource management in the organisation and these requirements are also specified for the health services sector when needed.

Clause 7 specifies requirements for the realisation of the product that include the planning, the customer-related processes, design and development, purchasing, service provision and the control of monitoring and measuring devices. When needed, these requirements are also specified for the health services sector.

In Clause 8 the requirements on measurement, analysis and improvement processes are made explicit and complemented with specifications when needed.

Annex A, "*Practical guide for the implementation of EN ISO 9001:2000 in health care organisations*", provides practical and informative recommendations for all who are involved in the development, implementation and assessment of a quality management system in a health care organisation.

The Bibliography has two parts. The first part consists of reference literature related to the EN ISO 9001:2000 standard. The second part contains reference documents supplied by the European CEN BT Task Force, that has been used as background documents for the development of this guide for the health services. The list of references to the guide does not claim to be comprehensive or covering all possible European or International documents in the field. This part of the Bibliography should be considered as giving examples of documents provided by the members of the task force.

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and meeting requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

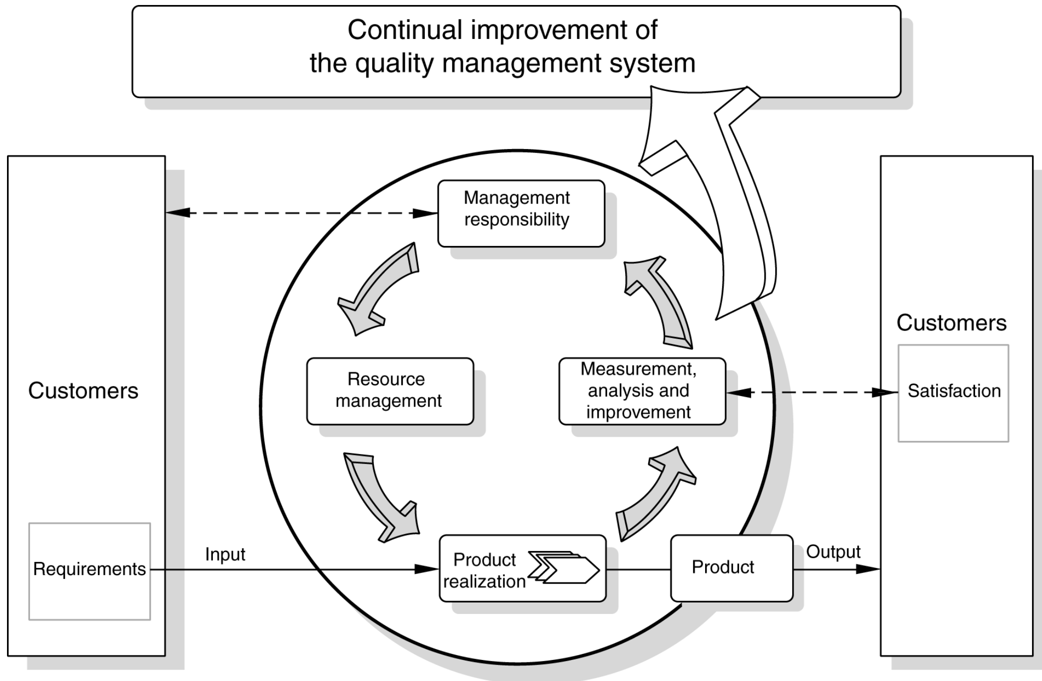
NOTE In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.



Key

——► Value-adding activities

– – –► Information flow

Figure 1 – Model of a process-based management system

The process approach in the health service sector is discussed and explained in Clause 3.8 and in Annex A.

0.3 Relationship with ISO 9004

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

0.4 Compatibility with other management systems

This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

In the health services sector there are two other European management system standards covering medical devices and medical laboratories:

EN ISO 13485, Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003)

EN ISO 15189, Medical laboratories — Particular requirements for quality and competence (ISO 15189:2003)

Health services - Quality management systems - Guide for the use of EN ISO 9001:2000

1 Scope

A quality management system is a management system to direct and control an organisation with regard to quality (ISO 9000:2000).

The guide is generally applicable to the health services sector and will complement national legislation. Furthermore other national requirements, sector specific requirements and standards (including professional standards) may complement the guide or be used in parallel.

The main target groups for this guide are strategic decision-makers at all levels in the health services sector and all staff who are involved in the development, implementation and assessment of a quality management system in a health care organisation, including the stakeholders.

This guide is generally applicable to all health care organisations regardless of structure, organisation, owner, size, type of service provided, locally used approaches or location. When using and adapting this guide every organisation needs to consider the nature, culture, complexity, legislation, regulation, etc. of their organisation and further specify their own requirements and use complementary national and local information.

The guide also applies to the requirements of patient organisations, owners, users, insurers, inspectorates and to relevant legislation. In this manner the guide provides a basis for national requirements on health services, e.g. Provisions and Recommendations, for purchasers of health services, for contracts and agreements, and for supervision, audit, certification and accreditation in the health services sector.

1.1 General

This International Standard specifies requirements for a quality management system where an organization

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

NOTE In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possi-bility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary.*

3 Terms and definitions

For the purposes of this document the following terms and definitions from [EN ISO 9000:2000] and [ENV 13940:2001,CONTsys] apply.

The terms and definitions are of special interest and importance for the health services sector and for the understanding of this guide. For the complete terminology, see EN ISO 9000:2000.

The terminology is presented with the original definitions and notes from the [EN ISO 9000:2000] standard within boxes, together with interpretation, explanation and necessary examples specific for health services. The origin from [EN ISO 9000:2000] and [ENV 13940:2001,CONTsys] is shown in [brackets]. Correspondence to the numbering of the terminology in this document is shown in (brackets).

To be easily accessible, the terms from [EN ISO 9000:2000] are presented in alphabetical order.

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

The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:

supplier organization customer

The term “organization” replaces the term “supplier” used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term “supplier” now replaces the term “subcontractor”.

Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

The health services sector carries out a wide variety of processes. The results of these processes could in general be called **health services**. The result of processes that include patients/subjects of care could be called **health care services**, as in Contsys.

In this guide, the term **health services** has the meaning health services produced. The term health services could in other circumstances also be used to nominate the health services sector, In that case the term **health services sector** will be used.

The services that are included in the term may vary from country to country and this has to be considered in national translations. In this guide, health services include hospital care, primary health care and preventive health care, psychiatry and dental services.

3.1
customer

organization or person that receives a product

EXAMPLE Consumer, client, end-user, retailer, beneficiary and purchaser.

NOTE A customer can be internal or external to the organization.

[EN ISO 9000:2000, 3.3.5]

The patient/**subject of care** (3.1.1) is the key customer and the recipient of the **health services** provision. In the health services sector, the citizens in the affiliated area or target group must be taken into consideration in dimensioning health care resources as an act of quality management.

Examples of other customers could be other health care providers (3.5.3) or department/part of the organisation receiving products/services produced. It can also be insurance companies asking for services from the **health care organisation** (3.6.1) etc.

Concerning relatives/next of kin see **stakeholder (3.5.1)**

3.1.1
subject of care
person scheduled to receive, receiving, or having received health care services

[ENV 13940:2001, CONTsys]

3.2
customer satisfaction

customer's perception of the degree to which the customer's requirements have been fulfilled

EXAMPLE Consumer, client, end-user, retailer, beneficiary and purchaser.

NOTE 1 Customer complaints are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction.

NOTE 2 Even when customer requirements have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction.

[EN ISO 9000:2000, 3.1.4]

The primary customer in health services is the patient/subject of care i.e. the degree to which the needs of and expectations on health care services have been fulfilled, as judged by the patient/subject of care/health care third parties

Cf. **customer** [EN ISO 9000:2000 3.3.5] (3.1), **subject of care** [ENV 13940:2001,CONTsys] (3.1,1)

3.3
defect

non-fulfilment of a requirement (3.1.2) related to an intended or specified use

NOTE 1 The distinction between the concepts defect and nonconformity is important as it has legal connotations, particularly those associated with product liability issues. Consequently the term “defect” should be used with extreme caution.

NOTE 2 The intended use as intended by the customer can be affected by the nature of the information, such as operating or maintenance instructions, provided by the supplier.

[EN ISO 9000:2000, 3.6.3]

3.3.1
adverse event
event which is not consistent with the desired, normal or usual operation of the organisation (Cf.IWA-1:2001)

This may include: Injury or accidental death, accidents involving patient, personnel or third parties; medication variances (delays, incorrect dose, wrong medication); unexpected results from a treatment or procedure; mistaken identity; medical devices that malfunction/or incorrect use of medical devices, with or without injury to patient, personnel etc.