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Quality management systems - EN ISO 9001:2015 for healthcare

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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English Version

Quality management systems - EN ISO 9001:2015 for healthcare

Services de santé - Systèmes de management de la qualité - Application de l'EN ISO 9001:2015 aux soins de santé

Qualitätsmanagementsysteme - EN ISO 9001:2015 für die Gesundheitsversorgung

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Contents

European foreword

This document (EN 15224:2016) has been prepared by Technical Committee CEN/TC 362, Health care services – Quality management systems, the secretariat of which is held by SIS.

This document supersedes EN 15224:2012.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2017, and conflicting national standards shall be withdrawn at the latest by June 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Introduction

0.1 General

The adoption of a quality management system is a strategic decision for *a healthcare* organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

The potential benefits to a healthcare organization of implementing a quality management system based on this standard are:

a) the ability to consistently provide *healthcare* products and services that meet customer and applicable statutory and regulatory requirements;

b) facilitating opportunities to enhance customer satisfaction;

c) addressing risks and opportunities associated with its context and objectives;

d) the ability to demonstrate conformity to specified quality management system requirements.

This standard can be used by internal and external parties.

It is not the intent of this standard to imply the need for:

— uniformity in the structure of different quality management systems;

— alignment of documentation to the clause structure of this standard;

— the use of the specific terminology of this standard within the organization.

This standard includes requirements for quality management but does not specify requirements for specific healthcare services. The quality management system requirements specified in this standard are supposed to be complemented by requirements for levels of *healthcare* services .

This standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

The process approach enables an organization to plan its *clinical and other* processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed and opportunities for improvement are identified and acted on.

Risk-based thinking enables a *healthcare* organization to determine the factors that could cause its *clinical and other* processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see A.4).

Consistently meeting requirements and addressing future needs and expectations poses a challenge for *healthcare* organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

In this standard, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.

0.1.1 Quality management in healthcare

This is a sector specific quality management system standard for healthcare. This standard incorporates EN ISO 9001:2015 and adds interpretations, explanations, examples and additional requirements. This standard replaces EN 15224:2012. Additional text specific to healthcare is shown in blue italics in Clause 0 to 10 and in Annex A and C. Information marked as "NOTE" in Clause 4 to 10 is for guidance on understanding or clarifying the associated requirement. In Clause 3 such additional information is written "note to entry" according to CEN rules. However, if the aspect refers to a special cited external document the format follows from that document (e.g. as NOTE from ISO 13940).

This is a standalone standard and can be used for conformity assessment for certification purposes of healthcare organizations.

The requirements in this standard comprehensively incorporate those from EN ISO 9001:2015 with additional requirements, specifications and interpretations for healthcare. Requirements have been added when considered relevant and existing requirements are clarified according to the specific healthcare context. This standard also includes aspects related to clinical risk management throughout the planning, operation and control of processes.

ISO 9001:2008 has been reviewed and important changes were included in EN ISO 9001:2015.

Some examples of major changes are:

- *"Risk-based thinking" is an approach that flows through the new standard in Clauses 4,5,6 8,9 and 10*
- *Two new clauses (4.1, 4.2) relating to the context of the organization are included. These require that the organization determines the issues and requirements that can have impact on the planning of the quality management system*

These changes are important to be aware of when the reviewed standard is applied.

All changes have been considered in this review of EN 15224.

0.1.2 The concept of health

The World Health Organization (WHO) declaration of health is "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." The International Classification of Functioning, Disability and Health (ICF), by WHO, identifies five health components; body function, body structure, activity, participation and environmental factors. These descriptions from WHO are used as the basis and background for the concept of "health" in this standard.

0.1.3 Healthcare in relation to social care

Healthcare is in this standard defined as "care activities, services management or supplies related to the health of an individual". The concept of health relates to both healthcare and social care. This standard is focused on requirements for healthcare.

What is included in healthcare can differ from country to country and this has to be considered in national applications. In this standard healthcare includes e.g. primary healthcare, pre-hospital and hospital care, tertiary care, nursing homes, hospices, preventive healthcare, mental health services, dental services, physiotherapy, occupational health services, rehabilitation and pharmacies.

0.1.4 Quality, quality requirements and quality characteristics in healthcare

Quality in general is defined in EN ISO 9000:2015 as "degree to which a set of inherent characteristics of an object fulfils requirements".

Requirement is defined in EN ISO 9000:2015 as: "needs or expectations that are stated, generally implied or obligatory".

Quality requirements concerning healthcare products and services shall be determined for the quality management system of a healthcare organization according to 8.2.2 and include:

1) any applicable statutory and regulatory requirements. According to national legislation quality requirements may differ;

2) those considered necessary by the organization which may include requirements

a) not stated by the patient but related to the quality level of services offered by the organization;

b) based on scientific evidence and clinical knowledge;

c) from other interested parties, e.g. purchasers of services, insurance companies and funding organizations.

This means that the healthcare organization has to consider a broad variety of quality aspects from several perspectives when determining the quality requirements included in their quality management system. The context of the organization described in 4.1 will set the scope also for the quality requirements.

The main aim for any healthcare organization is to contribute to the health state of the persons that are potential or current patients with different kinds of health needs based on health conditions. Quality requirements should reflect these health needs identified in the patient population. When defining health needs the components of health from the International Classification for Functioning, Disability and Health (ICF) from WHO should be used for categorization and specification of quality requirements. Health needs based on ICF can be specified by the patient and/or by the professional actors interacting with the patients in clinical processes.

Scientific evidence and/or clinical knowledge is another perspective to be considered when determining quality requirements.

This standard identifies eleven basic quality aspects that by clinical experience are known to be relevant in healthcare organizations. To assess fulfilment of quality requirements the organization need to specify quality characteristics related to these requirements. These are also included in the list of complex aspects that shall be considered (assessed if relevant) when a healthcare organization determines the quality requirements for healthcare services as outcomes of clinical processes.

The identified eleven basic quality aspects from this perspective are:

— *appropriate, correct care;*

— *availability;*

— *continuity of care;*

— *effectiveness;*

— *efficiency;*

— *equity;*

— *evidence/knowledge based care;*

— *patient centred care including physical, psychological and social integrity (ICF);*

— *patient involvement;*

— *patient safety;*

— *timeliness/accessibility;*

These basic aspects are not always comprehensive or applicable in total. Other aspects often need to be considered for determining all quality requirements considered relevant by the healthcare organization.

However, these eleven aspects are ensuring that most aspects that are commonly known as relevant will be considered.

If the healthcare organization considers any of the eleven basic aspects not to be relevant or applicable it can exclude that aspect. Reasons for exclusion shall, according to 8.2.2 be retained as documented information.

Other quality requirements can be based on the perspectives from other interested parties. An example of such is insurance companies stating certain levels of accessibility for persons with specific health problems.

Quality characteristic is defined in ISO 9000:2015 as: "inherent characteristic of an object related to a requirement". This means that any quality requirement determined by the organization will also relate to one or more quality characteristics of the processes, services and/or the healthcare system as such.

In 9.1 is stated that: "The organization shall monitor and measure the outcomes of the clinical processes to verify that requirements related to quality aspects have been met."

In summary, identified quality aspects of healthcare services, processes and systems are needed to specify and determine quality characteristics possible to validate. In healthcare with focus on the clinical aspects and the clinical processes, the quality characteristics related to the health needs of patients and the eleven basic quality aspects identified in this standard are of special importance. With a process approach recommended in EN ISO 9001:2015 this can be achieved by systematic clinical process management. Further guidance for such a clinical process approach is given in Annex E.

0.1.5 The concept of "clinical"

The term "clinical" can have different meanings in different countries. In this standard "clinical" refers to all types of interactions between patients and healthcare personnel. "Clinical" always include the patient perspective and the interaction with all types of healthcare personnel, regardless professional entitlement (like doctor, nurse, physiotherapist etc.).

0.1.6 Clinical risk

In EN ISO 9000:2015 risk is defined as "effect of uncertainty". EN 15224:2016 applies the definition from ISO 31000:2009 where risk is defined as "effect of uncertainty on objectives". The definition from ISO 31000:2009 is preferred since EN 15224 explicitly requires clinical risk management.

Clinical risk denotes any risk that could have negative effects on the outcomes for any of the quality aspects in healthcare, even if the risk factors and events itself is categorized to be non-clinical. Aspects of clinical risk management in planning, control and performance of clinical processes are integrated in this standard.

0.1.7 Healthcare specific preconditions

Healthcare is characterized by numerous interactions between patients, healthcare personnel, external providers, insurers, industry and governmental bodies who shall be identified and taken into consideration.

Examples of specific preconditions in healthcare are:

a) Healthcare is delivered through clinical processes that are dependent on the effect/results of a number of management and supporting activities/processes. A clinical process is a continuum of care from the patient's perspective. Depending on the scope of the organization the clinical processes consist of the whole or part of the continuum of care. The results of provided processes in healthcare are mainly services where patients have interacted with healthcare personnel.

b) Patient satisfaction based on needs and expectations is an overall objective in healthcare. The patient cannot always evaluate all aspects of the results of the processes in healthcare. Some aspects of the services have to be evaluated by healthcare professionals.

c) It is the responsibility of the organization to support and balance between the patient's expectations and the professionally assessed needs for care. There may be differences between the expectations expressed by the patient and the patient's needs as judged by the professionals, which has to be considered.

d) In healthcare there are both individual patient records, which contain confidential information about a single patient, and collated records where accumulated information on patients is collected. The protection and privacy of all such information and documentation is subject to national regulation.

e) Clinical risk management is a key component in the quality management system.

f) Quality and management in healthcare are dependent on reliable and unambiguous information. Information management is therefore a key component of quality management in healthcare.

g) National legislation, directives and recommendations from regulatory authorities concerning healthcare services are additional to the requirements in this standard and shall be identified and taken into account.

0.2 Quality management principles

This standard is based on the quality management principles described in EN ISO 9000:2015 *(2.3).* The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of typical actions to improve the organization's performance when applying the principle.

The quality management principles are:

— customer focus;

— leadership;

— engagement of people;

— process approach;

— improvement;

— evidence-based decision making;

— relationship management.

0.3 Process approach

0.3.1 General

This 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. Specific requirements considered essential to the adoption of a process approach are included in 4.4. *Requirements for healthcare are described below in this clause, are specified in 4.4 and are further explored in Annex E.*

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

Process is in EN ISO 9000:2015 defined as: "set of interrelated or interacting activities that use inputs to deliver an intended result". In healthcare the intended results are mainly aimed to improve or maintain the health state of patients who are the main customers. The types of processes to deliver these intended results are clinical processes. The process approach in this standard is thereby focussing clinical processes as well as management and support actions influencing the directly customer oriented clinical processes.

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved

using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results.

The process approach in healthcare should be applied by focusing on the clinical processes. The management and support actions influencing the directly customer oriented clinical processes should also be included in the process approach of the quality management system.

The application of the process approach in a quality management system enables:

a) understanding and consistency in meeting requirements;

b) the consideration of processes in terms of added value. *Added values in clinical processes are positive effects on the health state of the patient;*

c) the achievement of effective process performance;

d) improvement of processes based on evaluation of data and information.

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring checkpoints, which are necessary for control, are specific to each process and will vary depending on the related risks.

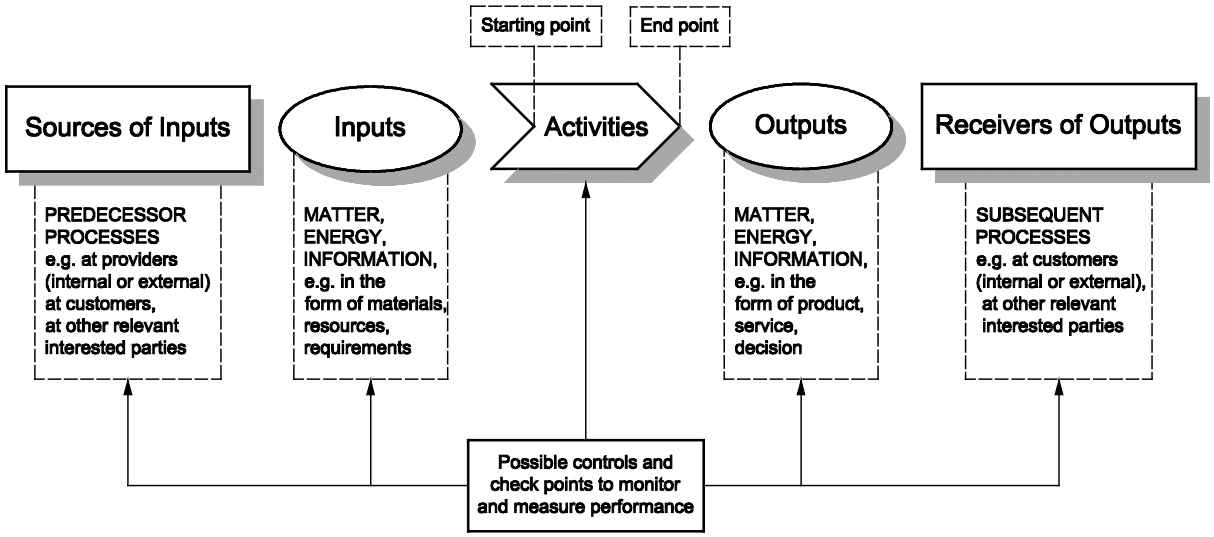

Figure 1 — Schematic representation of the elements of a single process

0.3.1.1 Processes in the provision of healthcare

There are three types of directly customer-oriented processes in healthcare organizations:

— *clinical processes,*

— *research processes and*

— *educational processes*

The main activities in healthcare organizations are related to the interaction between patients and healthcare personnel/professionals. These activities are performed in a wide variety of processes, called clinical processes, which encompasses all healthcare activities related to one or more health issues.

Clinical processes, as processes in general, are influenced by leadership and management activities as well as by resource management (support) activities.

Depending on the scope of the organization, the healthcare services provided can encompass comprehensive clinical processes or parts of it. Depending of the scope of the organization it can deal with any combination of the types and parts of processes mentioned here.

This standard is focussing the clinical processes.

0.3.1.2 Clinical processes

The clinical processes are the main type of processes in healthcare and all healthcare organizations participate in such processes. The clinical process includes all healthcare activities and interactions between the patient and healthcare professionals from the initial healthcare demand to the last activity concerning the specified health issues.

The clinical processes are designed to meet the quality objectives and quality requirements set for the quality aspects.

Clinical processes are designed, developed and controlled in relation to certain specified health issues, for example stroke, diabetes etc. and include all healthcare activities within the complete continuum of care related to that health issue; pre-hospital, emergency care, hospital care, post-hospital care, primary care and rehabilitation.

If the organization includes e.g. both primary care and care in hospital the clinical processes often cross the organizational border between these.

0.3.1.3 Research processes

The objective of the research process is to contribute to knowledge and subsequently improvement in healthcare. Specific requirements for research processes are not included in this standard.

0.3.1.4 Educational processes

The educational process encompasses the processes for basic professional education.

Competence development is not regarded as an educational process but should be integrated in the resource management of all organizations.

Specific requirements for educational processes are not included in this standard.

0.3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle.

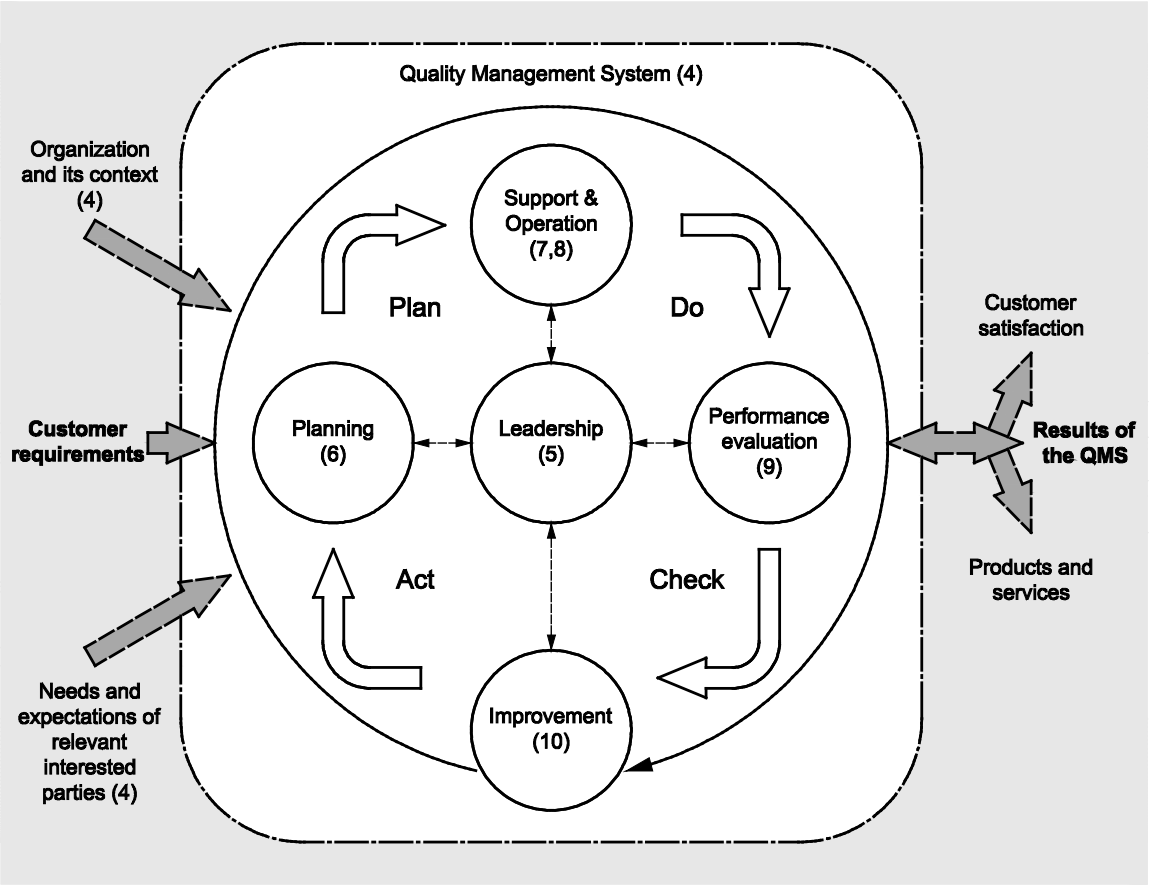

Figure 2 — Representation of the structure of this standard in the PDCA cycle

The PDCA cycle can be briefly described as follows:

— **Plan**: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies; and identify and address risks and opportunities;

— **Do**: implement what was planned;

— **Check**: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives and requirements and planned activities, and report the results;

— **Act**: take actions to improve performance, as necessary.

0.3.3 Risk-based thinking

Risk-based thinking (see Clause A.4) is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of this standard *(referring to EN ISO 9001:2008)* including, for example, carrying out preventive action to eliminate potential nonconformities, analysing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

To conform to the requirements of this standard, an organization needs to plan and implement actions to address risks and opportunities. *In healthcare approaches for clinical risk management in planning and performing clinical processes is the essential aspect of risk-based thinking*. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.

Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and

services, reduce waste or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

0.4 Relationship with other management system standards

This standard incorporates EN ISO 9001:2015 and replaces EN ISO 15224:2012 Health services – Quality management systems – Requirements based on EN ISO 9001:2008.

This international standard applies the framework developed by ISO to improve alignment among its International standards for management systems (see Clause A.1).

This standard enables an organization to use the process approach, *including focus on clinical processes*, coupled with the PDCA cycle and risk-based thinking, to align or integrate its quality management system with the requirements of other management system standards.

This standard relates to EN ISO 9000 and EN ISO 9004 as follows:

— EN ISO 9000 *Quality management systems — Fundamentals and vocabulary* provides essential background for the proper understanding and implementation of this standard;

— EN ISO 9004 *Managing for the sustained success of an organization — A quality management approach* provides guidance for organizations that choose to progress beyond the requirements of this standard.

Annex B provides details of other International Standards on quality management and quality management systems that have been developed by ISO/TC 176.

This international standard does not include requirements specific to other management systems, such as those for environmental management, *medical device management*, occupational health and safety management, or financial management.

This standard is a quality management system standard and can be applied together with other standards, for example,

– *EN ISO 14001, Environmental management systems — Requirements with guidance for use;*

– *EN ISO 13940:2016. Health informatics - System of concepts to support continuity of care*

– *EN ISO 27002 Information technology – Security*

– *ISO 31000, Risk Management — Principles and guidelines*

– *EN 80001-1 Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities*

– *EN ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes*

This standard enables an organization to align or integrate its own quality management system with related management system requirements. This standard also enables a healthcare organization to be conformant to the generic system of concepts and clinical process model in EN ISO 13940:2016. It is possible to adapt the organization's existing management system(s) in order to comply with the requirements of this standard.

Annex C provides a cross-reference table with details on the congruence and difference between this standard, EN ISO 9001:2015 and EN 15224:2012.

Sector-specific quality management system standards based on the requirements of this International Standard have been developed for a number of sectors. Some of these standards specify additional quality management system requirements, while others are limited to providing guidance to the application of this International Standard within the particular sector.

A matrix showing the correlation between the clauses of this edition of this International Standard and the previous edition (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access web site at: www.iso.org/tc176/sc02/public

1 Scope

This international standard specifies requirements for a quality management system when a *healthcare* organization:

a) needs to demonstrate its ability to consistently provide *healthcare* product or service that meets customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer requirements, *applicable statutory and regulatory requirements and requirements related to the quality aspects; appropriate, correct care; availability; continuity of care; effectiveness; efficiency; equity; evidence/knowledge based care; patient centred care including physical, psychological and social integrity; patient involvement; patient safety and timelines/accessibility*.

All the requirements of this International Standard are generic and are intended to be applicable to any *health care* organization, regardless of its type or size, or the products and services it provides.

NOTE 1 In this standard the terms “product” or “service” only apply to products and services intended for, or required by, a customer.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

Requirements related to material outputs such as tissue, blood products, pharmaceuticals, cell culture products and medical devices are not the focus of the scope of this standard as they are regulated elsewhere.

This standard is focused on requirements for management of clinical processes. Organizations that also include research or education processes in their quality management system could use the requirements in this standard where applicable.

This standard aims to specify and complement the requirements in EN ISO 9001:2015 to the specific conditions for healthcare providing mainly services and where customers are mainly patients.

1.1 *Application*

This standard:

a) gives requirements for systematic approaches for the organization’s ability to produce good quality healthcare services;

b) can be used at all levels in the healthcare organization to implement and maintain a quality management system or by internal and external parties, including certification bodies, to assess the organization’s ability to meet patients’ needs and expectations as well as those from other customers;

c) is applicable to healthcare organizations, regardless of structure, organization, owner, size or types of healthcare services provided;

d) is focused on requirements for clinical processes. Organizations that also include research or education processes, in the scope of their quality management system could use the requirements in this standard where applicable.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary (ISO 9000:2015)*