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Zdravstvene storitve - Sistemi vodenja kakovosti - Zahteve na osnovi EN ISO 9001:2008

Health care services - Quality management systems - Requirements based on EN ISO 9001:2008

Dienstleistungen in der Gesundheitsversorgung - Qualitätsmanagementsysteme - Anforderungen nach EN ISO 9001:2008

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Services de santé - Systèmes de management de la qualité - Exigences selon l'EN ISO 9001:2008

Dienstleistungen in der Gesundheitsversorgung - Qualitätsmanagementsysteme - Anforderungen nach EN ISO 9001:2008

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Foreword

This document (EN 15224:2012) has been prepared by Technical Committee CEN/TC 362, "Health services - Quality management systems", the secretariat of which is held by SIS.

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of an identical text or by endorsement, at the latest by April 2013, and conflicting national standards shall be withdrawn at the latest by April 2013.

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.

This document supersedes CEN/TS 15224:2005.

This document includes the text of ISO 9001 as published in 2008 by the International Organization for Standardization, ISO, and therefore may not be the last version published.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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Introduction

0.1 Quality in health care

0.1.1 General

This is a sector specific quality management system standard for health care organizations. This standard incorporates EN ISO 9001:2008 and replaces CEN/TS 15224:2005 Health services – Quality management systems – Guide for the use of EN ISO 9001:2000. The text from EN ISO 9001:2008 in Clause 3 to Clause 8 is shown in black in this European Standard and *additional text specific to health care services is in Clause 3 to Clause 8 shown in blue italics.*

This is a stand alone standard and can be used for certification in health care.

The requirements in this standard incorporate those from EN ISO 9001:2008 with additional interpretations and specifications for health care. Requirements have been added to and clarified according to the specific health care context. New requirements have been added when considered relevant. This standard also includes aspects related to clinical risk management throughout the planning, operation and control of processes.

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This quality management system does not include requirements specific to environmental management. Therefore, it is recommended that organisations that apply a management system also apply an environmental management.

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The congruence and difference between this standard and EN ISO 9001:2008 is explained in this introduction and in cross reference table (Annex A).

The congruence and difference between CEN/TS 15224:2005 and this standard is explained in cross reference table (Annex C).

A practical guide for the implementation of this standard in health care organizations is presented in Annex B.

Further guidance for quality improvement approaches can be found in *CEN/TR 15592:2007, Health services - Quality management systems - Guide for the use of EN ISO 9004:2000 in health services for performance Improvement.*

The following quality management principles from EN ISO 9000:2005 are applied in this standard:

a) Customer focus

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

b) Leadership

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

c) Involvement of personnel

Staff at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization’s benefit.

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d) Process approach

A desired result is achieved more efficiently when activities and related resources are managed as a process.

e) System approach to management

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

f) Continual improvement

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

g) Factual approach to decision making

Effective decisions are based on the analysis of data and information.

h) Mutually beneficial supplier relationships

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

These eight quality management principles form the basis for the quality management system standards within the ISO 9000 family.

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0.1.2 The concept of "health"

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The World Health Organization (WHO) definition 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.

0.1.3 Health care

In this standard health is not a stand alone concept but is used in several terms as a prefix. When used as a prefix the concept of health is based on the health components in of ICF by WHO. The concept of health relates to both health care and social care. This standard is focused on requirements for health care.

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

0.1.4 Quality in health care

Quality in general is defined as "degree to which a set of inherent characteristics fulfils requirements". To make quality in health care measurable and testable the quality characteristics of clinical processes must be identified and described. In this standard the requirements of the patients or customers for health care services must be specified according to effectiveness, safety, availability, timeliness/accessibility, continuity of care, respect of patient values and preferences and appropriateness, Aspects of efficiency; fair distribution and evidence must be considered (3.14, Note 2). Where any of the above mentioned requirements can not be applied due to the nature of an organisation and its product this can be considered for exclusion. The requirements can be specified in quality objectives according to 3.11.

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To be able to define and describe the quality in health care the quality characteristics need to be identified and described. A quality characteristic always relates to a quality requirement. Therefore eleven quality characteristics of health care services with interrelated quality requirements are identified as:

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;

timeliness/accessibility.

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The health care organisation defines their quality vision/policy and it identifies the quality characteristics for their context / situation.

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A quality management system is a system to direct and control an organization with regard to quality. The requirements for a quality management system in this standard are consequently focused on the quality characteristics.

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 all kinds of health care professionals. In this standard “clinical” is not restricted to the hospital context.

0.1.6 Clinical risk

Clinical risk denotes any risk that could have negative effects on the outcomes for any of the quality requirements. The risk factors could be non-clinical, but the risk is considered a clinical risk if it could have any negative impact on any of the quality requirements. Aspects of clinical risk management are integrated in this standard.

0.1.7 Health care specific preconditions

Health care is characterised by numerous interactions between patients, health care personnel, suppliers, insurers, industry and governmental bodies which shall be identified and taken into consideration.

Examples of such specific preconditions in health care are given below:

a) Health care is delivered through clinical processes which are dependent on a number of management and supporting activities/processes. A clinical process is a continuum of care from the patient's

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perspective. Depending on the scope of the organization the clinical processes consists of the whole or part of the continuum of care. The results of processes in health care are mainly services.

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

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

d) In health care there are both individual patient records, which contain confidential information about a single patient, and collated records where accumulated information on patients are collected. The 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) National legislation, directives and recommendations from regulatory authorities concerning health care services are additional to the requirements in this standard and shall be identified and taken into account. An example of a national directive is implementation of clinical governance where organizations are accountable for continuously monitoring and improving the quality of their care and services.

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0.2 Process approach

0.2.1 General

There are three types of directly customer oriented processes in health care organizations:

- clinical processes,
- research processes and,
- educational processes

0.2.1.1 Processes in the provision of health care

The main activities in health care organizations are related to the interaction between patients and health care professionals. These activities are performed in a wide variety of processes, called clinical processes, which encompasses all health care 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 activities.

Depending on the scope of the organization, the health care 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 of processes mentioned here.

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This standard focuses on the clinical processes.

0.2.1.2 Clinical processes

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The clinical processes are the main type of processes in health care services and all health care organizations participate in such processes. The clinical process includes all health care activities and interactions between the patient and health care professionals from the initial health request to the last activity concerning that health issue.

The clinical processes shall be designed to meet the quality objectives and quality requirements set for the quality characteristics.

Clinical processes shall be designed and developed in relation to certain specified health issues, for example stroke, and includes all care within the complete continuum of care related to that health issue; pre-hospital, emergency care, hospital care, primary care and rehabilitation.

Clinical processes may cross organizational borders depending on the scope of the organization.

0.2.1.3 Research processes

The objective of the research process is to contribute to knowledge and subsequently improvement in health care.

0.2.1.4 Educational processes

The educational process encompasses the processes for basic professional education.

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

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0.2.2 Process approach and improvements

This standard and EN ISO 9001:2008 are based on a process approach when developing, implementing and improving the quality management system.

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

Clauses 1 to 4 in the standard constitute the basis for the quality management system. The relevance of Clauses 5 to 8 are shown in the improvement figure below. The PDCA (plan-do-check-act) cycle is applicable to the improvement of the health care organization's processes encompassed in the quality management system, Figure 1.

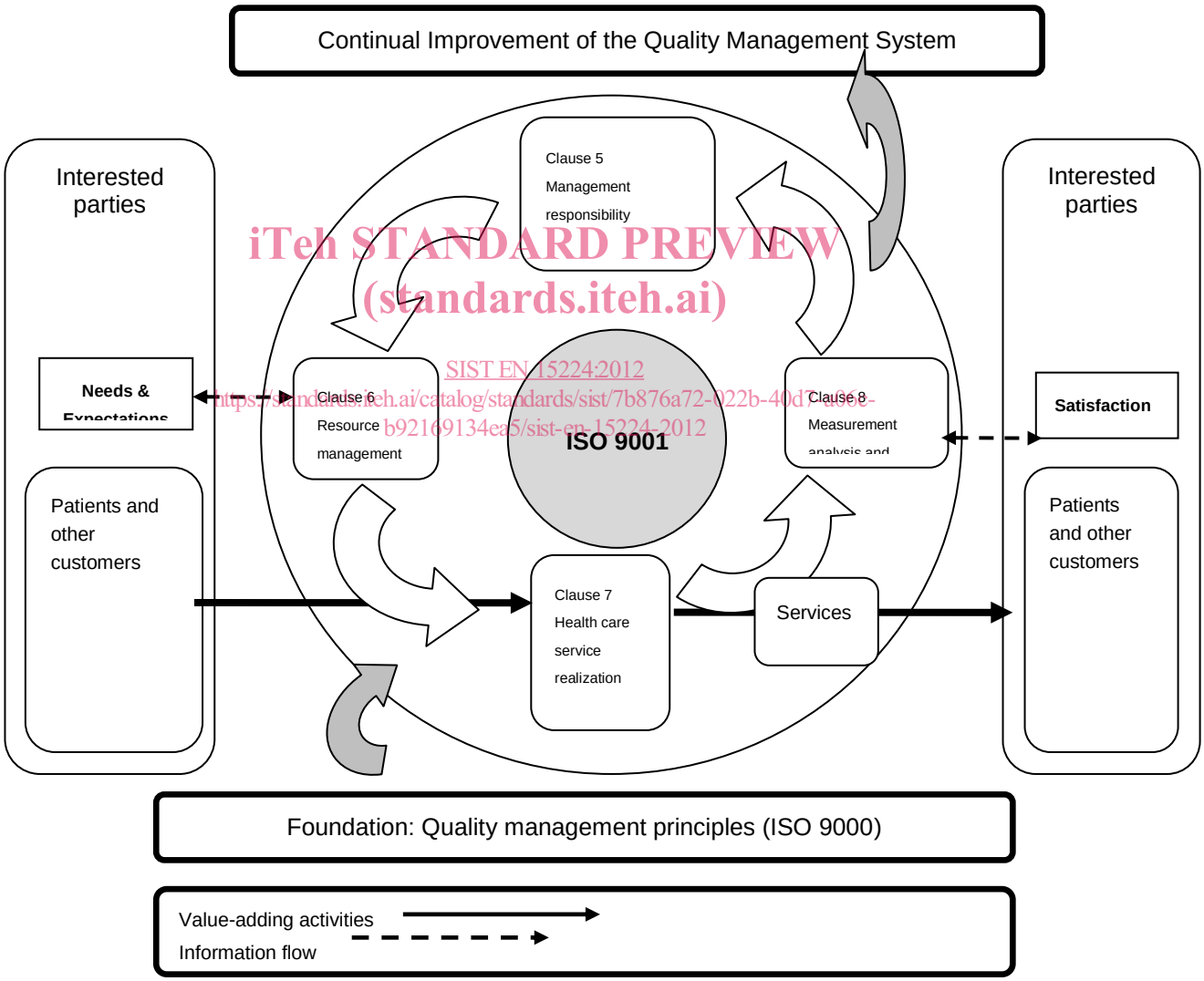

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Figure 1 — Model of a process-based quality management system

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0.3 Compatibility with other standards

This standard is based on EN ISO 9001:2008 and is a development of CEN/TS 15224:2005 Health services – Quality management systems – Guide for the use of EN ISO 9001:2000.

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 27799:2008, Health informatics — Information security management in health using ISO/IEC 27002,

ISO 31000, Risk Management — Principles and guidelines.

This standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible to adapt the organization's existing management system(s) in order to comply with the requirements of this standard

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1 Scope

1.1 General

This European standard specifies requirements for a quality management system where an organization:

a) needs to demonstrate its ability to consistently provide health care services that meet requirements from customers as well as applicable statutory and regulatory requirements, and professional standards

b) aims to enhance customer satisfaction through the effective application of the system, including continual improvement of the management system, the clinical processes and the assurance of conformity to requirements related to the quality characteristics ; 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.

Material products such as tissue, blood products, pharmaceuticals, cell culture products and medical devices have not been focused in the scope of the standard as they are regulated elsewhere.

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

This European Standard aims to adjust and specify the requirements, as well as the “product” concept and customer perspectives in EN ISO 9001:2008 to the specific conditions for health care where products are mainly services and customers are mainly patients.

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The focus of this European Standard is the clinical processes and their risk management in order to promote good quality health care.

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1.2 Application

This European Standard

a) gives requirements for systematic approaches for the organization’s ability to produce good quality health care.

b) can be used by management at all levels in the health care 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 those from other customers.

c) is applicable to health care organizations, regardless of structure, organization, owner, size or type of health care services provided.

d) is applicable to e.g. primary health care, pre-hospital and hospital care, tertiary care, nursing homes, hospices, preventive health care, mental health services, dental services, physiotherapy, occupational health services and pharmacies.

e) 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.

Where any requirement(s) of this European Standard cannot be applied due to the nature of a health care organization and its product (including services), this can be considered for exclusion.