SVENSK STANDARD
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Ledningssystem för kvalitet – EN ISO 9001:2015 för hälso- och sjukvården

Quality management systems – EN ISO 9001:2015 for healthcare

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Europastandarden EN 15224:2016 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 15224:2016.

Denna standard ersätter SS-EN 15224:2012, utgåva 1.

The European Standard EN 15224:2016 has the status of a Swedish Standard. This document contains the official English version of EN 15224:2016.

This standard supersedes the Swedish Standard SS-EN 15224:2012, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Ledningssystem för kvalitet i hälso- och sjukvården, SIS/TK 457.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 15224

December 2016

ICS 03.100.70; 03.120.10; 11.020.01

Supersedes EN 15224:2012

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

This European Standard was approved by CEN on 20 December 2016.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 15224:2016 E

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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 B. 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.