
**Zdravstvene storitve – Sistemi vodenja kakovosti – Zahteve na osnovi
EN ISO 9001:2015**

Healthcare services – Quality management systems – Requirements based on
EN ISO 9001:2015

Dienstleistungen in der Gesundheitsversorgung – Qualitätsmanagementsysteme
– Anforderungen nach EN ISO 9001:2015

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

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SIST EN 15224:2017

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NACIONALNI UVOD

Standard SIST EN 15224 (sl, en), Zdravstvene storitve – Sistemi vodenja kakovosti – Zahteve na osnovi EN ISO 9001:2015, 2017, ima status slovenskega standarda in je istoveten evropskemu standardu EN 15224 (en), Healthcare services – Quality management systems – Requirements based on EN ISO 9001:2015, 2016.

Ta standard nadomešča SIST EN 15224:2012.

NACIONALNI PREDGOVOR

Besedilo standarda EN 15224:2016 je pripravil tehnični odbor CEN/TC 362 Zdravstvene storitve – Sistemi vodenja kakovosti, katerega sekretariat vodi SIS. Slovenski standard SIST EN 15224:2017 je prevod angleškega besedila evropskega standarda EN 15224:2016. V primeru spora glede besedila slovenskega prevoda v tem standardu je odločilen izvirni evropski standard v angleškem jeziku. Slovensko-angleško izdajo standarda je pripravil SIST/TC VZK Vodenje in zagotavljanje kakovosti.

Odločitev za privzem tega standarda je 4. januarja 2017 sprejel tehnični odbor SIST/TC VZK Vodenje in zagotavljanje kakovosti.

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S privzemom tega evropskega standarda veljajo za omejeni namen referenčnih standardov vsi standardi, navedeni v izvirniku, razen standarda, ki je že sprejet v nacionalno standardizacijo:

SIST EN ISO 9000:2015 (sl, en) Sistemi vodenja kakovosti – Osnove in slovar (ISO 9000:2015)

OSNOVA ZA IZDAJO STANDARDARDA

- privzem standarda EN 15224:2016

PREDHODNA IZDAJA

- SIST EN 15224:2012, Zdravstvene storitve – Sistemi vodenja kakovosti – Zahteve na osnovi EN ISO 9001:2008

OPOMBE

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Slovenska izdaja

Zdravstvene storitve – Sistemi vodenja kakovosti – Zahteve na osnovi EN ISO 9001:2015

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management systems –
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Evropski predgovor

Ta dokument (EN 15224:2016) je pripravil tehnični odbor CEN/TC 362 Zdravstvene storitve – Sistemi vodenja kakovosti, katerega sekretariat vodi SIS.

Ta dokument nadomešča EN 15224:2012.

Ta evropski standard mora dobiti status nacionalnega standarda bodisi z objavo istovetnega besedila ali z razglasitvijo najpozneje do junija 2017, nacionalne standarde, ki so v nasprotju s tem standardom, pa je treba razveljaviti najpozneje do junija 2017.

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European foreword

This document (EN 15224:2016) has been prepared by Technical Committee CEN/TC 362, Healthcare 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.

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Uvod

0.1 Splošno

Privzem sistema vodenja kakovosti je strateška odločitev *zdravstvene* organizacije, ki ji lahko pomaga izboljšati celotno izvajanje in daje trdno podlago pobudam za trajnostni razvoj.

Koristi, ki jih ima lahko zdravstvena organizacija od izvajanja sistema vodenja kakovosti na podlagi tega mednarodnega standarda, so:

- a) zmožnost, da dosledno zagotavlja *zdravstvene* izdelke in storitve, ki izpolnjujejo zahteve odjemalcev ter veljavne zahteve zakonodaje in regulative,
- b) dajanje priložnosti za povečanje zadovoljstva odjemalcev,
- c) obravnavanje tveganj in priložnosti, povezanih z njenim kontekstom in cilji,
- d) zmožnost, da dokaže izpolnjevanje skladnosti s specficiranimi zahtevami sistema vodenja kakovosti.

Ta standard lahko uporabljajo strani v organizaciji in zunaj nje.

Ta standard nima namena nakazovati potrebe po:

- enotni zgradbi različnih sistemov vodenja kakovosti,
- uskladitvi dokumentacije s strukturo točk tega standarda,
- uporabi specifične terminologije tega standarda v organizaciji.

Ta standard vključuje zahteve za vodenje kakovosti, ne določa pa zahtev za specifične zdravstvene storitve. Zahteve sistema vodenja kakovosti, določene v tem standardu, naj bi dopolnjevale zahteve za ravni *zdravstvenih* storitev.

Ta standard uporablja procesni pristop, ki vključuje cikel "planiraj-izvedi-preveri-ukrepaj" (PDCA) in razmišljanje na podlagi tveganja.

Procesni pristop pomaga organizaciji planirati njene *klinične in druge* procese ter njihovo interakcijo.

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.

Cikel PDCA pomaga organizaciji zagotavljati, da so njeni procesi ustrezno podprti in vodeni ter da so priložnosti za izboljšanje prepoznane in izvedene.

Razmišljanje na podlagi tveganja pomaga *zdravstveni* organizaciji opredeliti dejavnike, ki bi lahko povzročili odstopanje njenih *kliničnih in drugih* procesov ter njenega sistema vodenja kakovosti od planiranih rezultatov, sprejeti preventivne ukrepe za zmanjšanje negativnih vplivov in kar najboljše izkoristiti priložnosti, ko se ponudijo (glej točko A.4).

Dosledno izpolnjevanje zahtev ter obravnavanje prihodnjih potreb in pričakovanj v vse bolj dinamičnem in kompleksnem okolju predstavlja za *zdravstvene* organizacije velik izziv. Da bi organizacija dosegla ta cilj, se ji lahko zdi potrebno, da poleg korekcij in nenehnega izboljševanja sprejme različne oblike izboljšav, kot so na primer prebojne spremembe, inovacije in reorganizacija.

V tem standardu so uporabljene naslednje glagolske oblike:

- "treba je" ali "mora" označuje zahtevo;
- "naj" označuje priporočilo;
- "sme" označuje dovoljenje;
- "lahko" označuje možnost ali sposobnost.

Informacije, označene kot "OPOMBA", so namenjene usmerjanju pri razumevanju ali pojasnjevanju pripadajoče zahteve.

0.1.1 Vodenje kakovosti v zdravstvenem varstvu

To je področno specifičen standard sistema vodenja kakovosti za zdravstveno varstvo. Standard vključuje standard EN ISO 9001:2015 in dodaja interpretacije, razlage, primere in dodatne zahteve. Ta standard nadomešča standard EN 15224:2012. Dodatno besedilo, posebej namenjeno zdravstvenemu varstvu, je v točkah od 0 do 10 ter v dodatkih A in B prikazano v modrem poševnem tisku. Informacije, ki so v točkah od 4 do 10 označene kot "OPOMBA", so namenjene usmerjanju pri razumevanju ali pojasnjevanju ustrezne zahteve. V točki 3 so take dodatne informacije v skladu s pravili CEN zapisane kot "opomba k vnosu". Če pa se neki vidik nanaša na posebej navedeni zunanji dokument, oblika izhaja iz tega dokumenta (npr. kot OPOMBA iz ISO 13940).

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).

To je samostojen standard in se lahko uporablja za ugotavljanje skladnosti za namene certificiranja v zdravstvenih organizacijah.

Zahteve v tem standardu celovito vključujejo zahteve iz standarda EN ISO 9001:2015 z dodatnimi zahtevami, specifikacijami in razlagami za zdravstveno varstvo. Po potrebi so dodane nove zahteve, obstoječe zahteve pa so razjasnjene v skladu s posebnostmi v zdravstvenem varstvu. Ta standard vključuje tudi vidike, povezane z obvladovanjem kliničnega tveganja med planiranjem, delovanjem in obvladovanjem procesov.

ISO 9001:2008 je bil revidiran in v EN ISO 9001:2015 so bile vključene pomembne spremembe.

Nekateri primeri večjih sprememb so:

- "razmišljanje na podlagi tveganja" je pristop, ki poteka skozi novi standard v točkah 4, 5, 6, 8, 9 in 10,
- vključeni sta dve novi točki (4.1, 4.2), povezani s kontekstom organizacije. Zahtevata, da organizacija opredeli vprašanja in zahteve, ki lahko vplivajo na planiranje sistema vodenja kakovosti.

Teh sprememb se je pomembno zavedati, ko se uporablja revidirani standard.

V tej reviziji standarda EN 15224 so upoštewane vse spremembe.

0.1.2 Pojem zdravja

Deklaracija Svetovne zdravstvene organizacije (WHO) definira zdravje kot "stanje popolne telesne, duševne in socialne blaginje, in ne le kot odsotnost bolezni ali invalidnosti". V Mednarodni klasifikaciji funkcioniranja, zmanjšane zmožnosti in zdravja (MKF), ki jo je izdelala WHO, je identificiranih pet sestavin zdravja: telesna funkcija, telesna zgradba, aktivnost, sodelovanje in okoljski dejavniki. Ti opisi WHO so v tem standardu uporabljeni kot osnova in ozadje pojma "zdravje".

0.1.3 Zdravstveno varstvo v povezavi s socialnim varstvom

Zdravstveno varstvo je v tem standardu definirano kot "aktivnosti oskrbe, upravljanje storitev ali dobave v zvezi z zdravjem posameznika". Pojem zdravja je povezan tako z zdravstvenim varstvom kot s socialnim. Ta

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

standard je osredotočen na zahteve za zdravstveno varstvo.

V različnih državah lahko zdravstveno varstvo vključuje različne stvari in to je pri nacionalni rabi treba upoštevati. V tem standardu zdravstveno varstvo vključuje npr. primarno zdravstveno varstvo, predbolnišnično in bolnišnično oskrbo, terciarno oskrbo, negovalne domove, hospice, preventivno zdravstveno varstvo, psihiatrične zdravstvene storitve, zobozdravstvene storitve, fizioterapijo, storitve zdravja pri delu, rehabilitacijo in lekarne.

0.1.4 Kakovost, zahteve kakovosti in karakteristike kakovosti v zdravstvenem varstvu

V standardu EN ISO 9000:2015 je kakovost na splošno definirana kot "stopnja, na kateri skupek svojstvenih karakteristik predmeta izpolnjuje zahteve".

Zahteva je v EN ISO 9000:2015 definirana kot "potrebe ali pričakovanja, ki so izraženi, na splošno samoumevni ali obvezni".

Za sistem vodenja kakovosti zdravstvene organizacije so zahteve kakovosti za zdravstvene izdelke in storitve opredeljene v skladu s točko 8.2.2 in vključujejo:

- 1) vse ustrezne zahteve zakonodaje in regulative. Zahteve kakovosti se lahko razlikujejo glede na nacionalno zakonodajo,
- 2) tiste zahteve, ki jih organizacija šteje za potrebne in lahko vključujejo zahteve:
 - a) ki jih pacient ne navaja, a so povezane z ravno kakovosti storitev, ki jih nudi organizacija,
 - b) temelječe na znanstvenih dokazih in kliničnem znanju,
 - c) drugih zainteresiranih strani, npr. kupcev storitev, zavarovalnic in organizacij za financiranje.

To pomeni, da mora zdravstvena organizacija pri opredeljevanju zahtev kakovosti, ki jih bo vključila v svoj sistem vodenja kakovosti, upoštevati raznolike vidike kakovosti, gledano z več zornih kotov. Kontekst organizacije, opisan v točki 4.1, bo določal tudi obseg zahtev kakovosti.

Glavni cilj vsake zdravstvene organizacije je prispevati k zdravstvenemu stanju potencialnih

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

ali trenutnih pacientov z različnimi zdravstvenimi potrebami glede na zdravstveno kondicijo. Zahteve kakovosti naj odražajo te zdravstvene potrebe, ugotovljene pri populaciji pacientov. Pri določanju zdravstvenih potreb naj se za kategorizacijo in specifikacijo zahtev kakovosti uporabijo sestavine zdravja iz Mednarodne klasifikacije funkcioniranja, zmanjšane zmožnosti in zdravja (MKF) organizacije WHO. Zdravstvene potrebe lahko na podlagi MKF specifikirajo pacient in/ali strokovni akterji, ki interaktivno delujejo s pacienti v kliničnih procesih.

Znanstveni dokazi in klinično znanje so drugi vidiki, ki jih je treba upoštevati pri opredeljevanju zahtev kakovosti.

V tem standardu je identificiranih enajst osnovnih vidikov kakovosti, ki so po kliničnih izkušnjah relevantni v zdravstvenih organizacijah. Da bi organizacija ocenila izpolnjevanje zahtev kakovosti, mora določiti karakteristike kakovosti, povezane s temi zahtevami. Te karakteristike so vključene tudi v seznam kompleksnih vidikov, ki jih mora zdravstvena organizacija upoštevati (če je relevantno, oceniti), kadar opredeljuje zahteve kakovosti za zdravstvene storitve kot rezultate kliničnih procesov.

Enajst identificiranih osnovnih vidikov kakovosti iz te perspektive je:

- ustrezna, korektna oskrba,
- razpoložljivost,
- neprekinjenost oskrbe,
- uspešnost,
- učinkovitost,
- enakost,
- na dokazih/znanju temelječa oskrba,
- na pacienta osredotočena oskrba, vključno s telesno, psihološko in socialno integriteto (MKF),
- vključenost pacientov,
- varnost pacientov,
- pravočasnost/dostopnost.

Ti osnovni vidiki niso vedno celoviti ali v celoti uporabni. Pri opredelitvi vseh zahtev kakovosti, ki jih zdravstvena organizacija šteje za relevantne, je pogosto treba upoštevati tudi druge vidike.

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.

Vendar pa teh enajst vidikov zagotavlja, da bo upoštevana večina vidikov, ki so na splošno znani kot relevantni.

Če zdravstvena organizacija meni, da kateri od enajstih vidikov ni relevanten ali uporaben, lahko ta vidik izključi. V skladu s točko 8.2.2 je treba razloge za izključitev hraniti kot dokumentirane informacije.

Druge zahteve kakovosti lahko temeljijo na vidikih drugih zainteresiranih strani. Tak primer so zavarovalnice, ki navajajo določene ravni dostopnosti za osebe s posebnimi zdravstvenimi težavami.

Karakteristika kakovosti je v standardu ISO 9000:2015 definirana kot "svojstvena karakteristika predmeta, ki se nanaša na zahtevo". To pomeni, da se bo vsaka zahteva kakovosti, ki jo organizacija opredeli, nanašala tudi na eno ali več karakteristik kakovosti procesov, storitev in/ali zdravstvenega sistema kot takega.

V točki 9.1 je navedeno: "Organizacija mora nadzorovati in meriti rezultate kliničnih procesov, da preveri, ali so izpolnjene zahteve glede vidikov kakovosti."

Skratka, identificirani vidiki kakovosti zdravstvenih storitev, procesov in sistemov so potrebni za določitev in opredelitev karakteristik kakovosti, ki jih je mogoče validirati. V zdravstvenem varstvu, osredotočenem na klinične vidike in klinične procese, so posebej pomembne karakteristike kakovosti, povezane z zdravstvenimi potrebami pacientov in enajstimi osnovnimi vidiki kakovosti, identificiranimi v tem standardu. S procesnim pristopom, ki ga priporoča standard EN ISO 9001:2015, je to mogoče doseči s sistematičnim upravljanjem kliničnih procesov. Nadaljnji napotki za tak pristop vodenja kliničnih procesov so podani v dodatku E.

0.1.5 Pojem "kliničen"

Izraz "kliničen" ima lahko v različnih državah različen pomen. V tem standardu se "kliničen" nanaša na vse vrste interaktivnosti med pacienti in zdravstvenim osebjem. "Kliničen" vedno vključuje pacientov pogled in interakcijo z vsemi vrstami zdravstvenega osebja ne glede na strokovni naziv (npr. doktor, medicinska sestra, fizioterapevt itd.).

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 Klinično tveganje

V standardu EN ISO 9000:2015 je tveganje definirano kot "učinek negotovosti". EN 15224:2016 uporablja definicijo iz standarda ISO 31000:2009, kjer je tveganje definirano kot "učinek neskladnosti na cilje". Definicija iz ISO 31000:2009 je ustrenejša, saj EN 15224 izrecno zahteva obvladovanje kliničnega tveganja.

Klinično tveganje označuje vsako tveganje, ki bi lahko negativno vplivalo na rezultate za katerikoli vidik kakovosti v zdravstvenem varstvu, tudi če so dejavniki tveganja in sami dogodki kategorizirani kot neklinični. V ta standard so vključeni vidiki obvladovanja kliničnega tveganja pri planiranju, obvladovanju in izvajanju kliničnih procesov.

0.1.7 Predpogoji, specifični za zdravstveno varstvo

Za zdravstveno varstvo so značilne številne interaktivnosti med pacienti, zdravstvenim osebjem, zunanjimi ponudniki, zavarovalnicami, industrijo in državnimi organi, ki jih je treba identificirati in upoštevati.

Primeri specifičnih predpogojev v zdravstvenem varstvu so:

- a) Zdravstveno varstvo se izvaja s kliničnimi procesi, ki so odvisni od učinka oziroma rezultatov številnih vodstvenih in podpornih aktivnosti oziroma procesov. S pacientovega zornega kota pomeni klinični proces celoten potek oskrbe. Odvisno od obsega organizacije je klinični proces sestavljen iz celotnega ali delnega poteka oskrbe. Rezultati izvajanih procesov v zdravstvenem varstvu so v glavnem storitve, kjer so pacienti v interakciji z zdravstvenim osebjem.
- b) Splošni cilj zdravstvenega varstva je zadovoljstvo pacientov, ki temelji na njihovih potrebah in pričakovanjih. Pacient ne more vedno ovrednotiti vseh vidikov rezultatov procesov v zdravstvenem varstvu. Nekatere vidike storitev morajo ovrednotiti strokovnjaki.
- c) Organizacija je tista, ki je odgovorna za podporo in uravnoveženost med pacientovimi pričakovanji in strokovno ocenjenimi potrebami oskrbe. Med pričakovanji, ki jih izrazi pacient, in pacientovimi potrebami, kot jih presodijo strokovnjaki, so lahko razlike, ki jih je treba

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

upoštevati.

- d) *V zdravstvenem varstvu obstajajo tako zapisi o posameznih pacientih, ki vsebujejo zaupne podatke o posameznem pacientu, kakor tudi zbrani zapisi, kjer se zbirajo nakopičeni podatki o pacientih. Zaščita in zasebnost vseh takih informacij in dokumentacije sta predmet nacionalnih predpisov.*
- e) *Obvladovanje kliničnega tveganja je ključni sestavni del sistema vodenja kakovosti.*
- f) *Kakovost in vodenje v zdravstvenem varstvu sta odvisna od zanesljivih in nedvoumnih informacij. Upravljanje informacij je zato ključna sestavina vodenja kakovosti v zdravstvenem varstvu.*
- g) *Nacionalna zakonodaja, direktive in priporočila regulativnih organov, ki se nanašajo na zdravstvene storitve, so dodane k zahtevam tega standarda ter jih je treba identificirati in upoštevati.*

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 Načela vodenja kakovosti

Ta standard temelji na načelih vodenja kakovosti, opisanih v standardu EN ISO 9000:2015 (2.3). Opisi vključujejo trditev za posamezno načelo, utemeljitev, zakaj je načelo pomembno za organizacijo, nekaj primerov koristi, povezanih z načelom, ter primere tipičnih ukrepov za izboljšanje učinkov delovanja organizacije pri izvajanju načela.

Načela vodenja kakovosti so:

- osredotočenost na odjemalce,
- voditeljstvo,
- angažiranost ljudi,
- procesni pristop,
- izboljševanje,
- odločanje na podlagi dokazov,
- upravljanje odnosov.

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 Procesni pristop

0.3.1 Splošno

Ta mednarodni standard spodbuja privzem procesnega pristopa pri razvijanju, izvajanju in izboljševanju uspešnosti sistema vodenja kakovosti, da bi se z izpolnjevanjem zahtev odjemalcev povečalo njihovo zadovoljstvo. V točko 4.4 so vključene posebne zahteve, ki se štejejo za bistvene za privzem procesnega pristopa. *V nadaljevanju te točke so opisane zahteve za zdravstveno varstvo, določene v točki 4.4 in nadalje raziskane v dodatku E.*

Razumevanje in vodenje medsebojno povezanih procesov kot sistema prispevata k uspešnosti in učinkovitosti organizacije pri doseganju predvidenih rezultatov. Ta pristop pomaga organizaciji obvladovati medsebojne povezave in soodvisnost med procesi v sistemu, tako da se lahko izboljša celotno delovanje organizacije.

V standardu EN ISO 9000:2015 je proces definiran kot "skupek med seboj povezanih ali interaktivnih aktivnosti, ki uporabljajo vhode za doseganje predvidenega rezultata". V zdravstvenem varstvu so predvideni rezultati v glavnem namenjeni izboljšanju ali vzdrževanju zdravstvenega stanja pacientov, ki so glavni odjemalci. Vrsta procesov za doseganje teh predvidenih rezultatov so klinični procesi. Procesni pristop v tem standardu je s tem osredotočen na klinične procese ter tudi na upravljalvske in podporne ukrepe, ki vplivajo na klinične procese, neposredno usmerjene k odjemalcu.

Procesni pristop vključuje sistematično določitev in vodenje procesov ter njihove interakcije za doseganje predvidenih rezultatov v skladu s politiko kakovosti in strateško usmeritvijo organizacije. Procese in celotni sistem je mogoče voditi z uporabo cikla PDCA (glej točko 0.3.2) s splošnim poudarkom na razmišljanju na podlagi tveganja (glej točko 0.3.3), namenjenem preprečevanju neželenih rezultatov.

Procesni pristop v zdravstvenem varstvu naj se izvaja z osredotočanjem na klinične procese. V procesni pristop sistema vodenja kakovosti naj bodo vključeni tudi upravljalvske in podporni ukrepi, ki vplivajo na klinične procese in so neposredno usmerjeni k odjemalcu.

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.