
Sistemi vodenja kakovosti – Smernice za izboljšave procesov v zdravstvenih organizacijah

Quality management systems – Guidelines for process improvements in health service organizations

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NACIONALNI UVOD

Tehnična specifikacija SIST-TS IWA 1 (sl, en), Sistemi vodenja kakovosti – Smernice za izboljšave procesov v zdravstvenih organizacijah, 2007, ima status slovenske tehnične specifikacije in je enakovredna dogovoru mednarodne delavnice IWA 1, Quality management systems – Guidelines for process improvements in health service organizations, druga izdaja, 2005.

NACIONALNI PREDGOVOR

Dogovor mednarodne delavnice IWA 1 je bil odobren na delavnici, ki je januarja 2005 potekala v skupni organizaciji Ameriškega združenja za avtomobilsko industrijo (AIAG), Ameriškega združenja za kakovost (ASQ, Oddelek za varovanje zdravja), Kanadskega sveta za standardizacijo (SCC – the Standards Council of Canada) in Mednarodnega kanadskega združenja za standardizacijo (CSA International).

Slovenska tehnična specifikacija SIST-TS IWA 1:2007 je prevod angleškega besedila dogovora mednarodne delavnice IWA 1:2005. V primeru spora glede besedila slovenskega prevoda v tej tehnični specifikaciji je odločilen izvorni dogovor mednarodne delavnice v angleškem jeziku. Slovensko-angleško izdajo tehnične specifikacije je pripravil in potrdil tehnični odbor SIST/TC VZK Vodenje in zagotavljanje kakovosti.

Odločitev za privzem tega sporazuma mednarodne delavnice je 16. novembra 2006 sprejel tehnični odbor SIST/TC VZK Vodenje in zagotavljanje kakovosti.

ZVEZE S STANDARDI

S privzemom te tehnične specifikacije veljajo naslednje zveze:

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| SIST EN ISO 9000:2005 (en) | Sistemi vodenja kakovosti – Osnove in slovar |
| SIST EN ISO 9001:2000 (sl, en) | Sistemi vodenja kakovosti – Zahteve |
| SIST EN ISO 9004:2004 (sl, en) | Vodenje sistemov kakovosti – Smernice za izboljšanje delovanja |
| SIST EN ISO 10012:2003 (sl, en) | Sistemi vodenja meritev – Zahteve za procese merjenja in merilno opremo |
| SIST ISO/TR 10013:2002 (sl, en) | Smernice za dokumentacijo sistema vodenja kakovosti |
| SIST ISO/TR 10014:1998 (en) | Smernice za vodenje ekonomike kakovosti |
| SIST ISO 10015:2002 (en) | Vodenje kakovosti – Smernice za usposabljanje |
| SIST ISO/TR 10017:2003 (en) | Napotki za statistične metode v zvezi z ISO 9001:2000 |
| SIST EN ISO 14001:2005 (sl, en) | Sistemi ravnanja z okoljem – Zahteve z navodili za uporabo |
| SIST ISO 14004:2005 (en) | Sistemi ravnanja z okoljem – Splošne smernice o načelih, sistemih in podpornih tehnikah |
| SIST EN ISO 13485:2003 (en) | Medicinski pripomočki – Sistemi vodenja kakovosti – Zahteve za zakonodajne namene (ISO 13485:2003) |
| SIST EN ISO 15189:2003 (en) | Medicinski laboratoriji – Posebne zahteve za kakovost in usposobljenost (ISO 15189:2003) |
| SIST EN ISO/IEC 17025:2005 (sl, en) | Splošne zahteve za usposobljenost preskuševalnih in kalibracijskih laboratorijev (ISO/IEC 17025:2005) |

| | |
|---------------------------------|--|
| SIST EN ISO 19011:2003 (sl, en) | Smernice za presojanje sistemov vodenja kakovosti in/ali sistemov ravnanja z okoljem |
| SIST EN 60300-1:2004 (en) | Vodenje zagotovitljivosti – 1. del: Sistemi vodenja zagotovitljivosti (IEC 60300-1:2003) |

OSNOVA ZA IZDAJO STANDARDA

- privzem IWA 1:2005

OPOMBA

- Nacionalni uvod in nacionalni predgovor nista sestavni del tehnične specifikacije.

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Predgovor

ISO (Mednarodna organizacija za standardizacijo) je svetovna zveza nacionalnih organov za standarde (članov ISO). Tehnično delo ISO ponavadi opravljajo tehnični odbori ISO, v katerih ima pravico biti zastopan vsak član ISO. Pri delu sodelujejo tudi mednarodne vladne in nevladne organizacije, povezane z ISO.

V odgovor na vse glasnejše zahteve trga je ISO uvedel možnost, da se dokumenti pripravijo v delavnicah, in to zunaj postopkov, običajnih za delo v odborih. ISO te dokumente objavlja kot dogovore mednarodnih delavnic (International Workshop Agreements – IWA). Izvedbo take delavnice lahko predlaga kdorkoli, potrditi pa jo mora Strokovni odbor ISO (ISO Technical Management Board), ki tudi imenuje člana ISO za pomoč predlagatelju pri organizaciji delavnice. Dogovore mednarodnih delavnic s konsenzom potrdijo sodelujoči na delavnicah. Čeprav lahko obstaja več konkurenčnih dogovorov mednarodnih delavnic na isto temo, le-ti ne smejo biti v nasprotju z obstoječim standardom ISO ali IEC.

Član, ki ga je imenoval Strokovni odbor, je odgovoren, da po treh letih pregleda dogovor mednarodne delavnice in odloči, ali naj bo potrjen še za nadaljnja tri leta, poslan tehničnemu odboru ISO v revizijo ali umaknjen. Če je dogovor mednarodne delavnice potrjen, je ponovno pregledan čez tri leta. Takrat ga mora ustrezni tehnični odbor ISO revidirati ali umakniti.

Opozarjamo, da so nekateri elementi tega dogovora mednarodne delavnice lahko predmet patentnih pravic. ISO ne prevzema odgovornosti za identificiranje nobene od takih patentnih pravic.

Dogovor mednarodne delavnice IWA 1 je bil potrjen januarja 2001 na delavnici, ki je potekala v skupni organizaciji Ameriškega združenja za avtomobilsko industrijo (AIAG), Oddelka za zdravstvo Ameriškega združenja za kakovost (ASQ), Kanadskega sveta za standardizacijo

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). ISO's technical work is normally carried out through ISO technical committees in which each ISO member body has the right to be represented. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

In order to respond to urgent market requirements, ISO has also introduced the possibility of preparing documents through a workshop mechanism, external to its normal committee processes. These documents are published by ISO as International Workshop Agreements. Proposals to hold such workshops may come from any source and are subject to approval by the ISO Technical Management Board which also designates an ISO member body to assist the proposer in the organization of the workshop. International Workshop Agreements are approved by consensus amongst the individual participants in such workshops. Although it is permissible that competing International Workshop Agreements exist on the same subject, an International Workshop Agreement shall not conflict with an existing ISO or IEC standard.

An International Workshop Agreement is reviewed after three years, under the responsibility of the member body designated by the Technical Management Board, in order to decide whether it will be confirmed for a further three years, transferred to an ISO technical body for revision, or withdrawn. If the International Workshop Agreement is confirmed, it is reviewed again after a further three years, at which time it must be either revised by the relevant ISO technical body or withdrawn.

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

International Workshop Agreement IWA 1 was approved at a workshop organized jointly by the Automotive Industry Action Group (AIAG), the American Society for Quality (ASQ) (Healthcare Division), the Standards Council of Canada (SCC) and CSA International, and

(SCC – the Standards Council of Canada) in Mednarodnega kanadskega združenja za standardizacijo (CSA International). Za organizacijo delavnice in pripravo tega dogovora se iskreno zahvaljujemo Ameriškemu združenju za avtomobilsko industrijo (AIAG), Oddelku za zdravstvo Ameriškega združenja za kakovost (ASQ), Kanadskemu svetu za standardizacijo (SCC) in Mednarodnemu kanadskemu združenju za standardizacijo (CSA International).

S to drugo izdajo IWA 1 se razveljavi in nadomesti prva izdaja (IWA 1:2001). V njej je podana enaka vsebina kot v prvi izdaji z nekaj izboljšavami.

held in January 2001. Appreciation is extended to the Automotive Industry Action Group (AIAG), the American Society for Quality (ASQ) (Healthcare Division), the Standards Council of Canada (SCC) and CSA International for both the organization of the workshop and the preparation of this International Workshop Agreement.

This second edition of IWA 1 cancels and replaces the first edition (IWA 1:2001). It provides the content of the first edition but with improved appearance.

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Predgovor k drugi izdaji IWA 1 – Dopolnilo

Namen druge izdaje IWA 1 je bil podati enako, a izboljšano in uporabnejšo vsebino kot v prvi izdaji. Seveda ta dokument ni edini način za interpretacijo skupine standardov ISO 9000 za zdravstvene organizacije. Navedeni primeri, definicije in besedilo zgolj nakazujejo, kako se v kontekstu tega dokumenta uporabljajo različne definicije. Specifično izrazje organizacij se lahko uporablja tudi tukaj. Dodane spremembe so rezultat razvoja in komentarjev, ki smo jih po prvi izdaji IWA 1 prejeli od recenzentov, ki so bili v glavnem izvajalci zdravstvenih storitev, nekaj pa je tudi komentarjev s prvotne delavnice, ki v prvi izdaji niso bili vključeni.

Postavitev te izdaje:

Besedilo v okvirju s polno črto je vzeto iz ISO 9001:2000. Črno besedilo zunaj okvirja je vzeto iz ISO 9004:2000. To so splošni napotki in veljajo za vse organizacije. Besedilo v poševni pisavi Times New Roman je gradivo, ki so ga ALAG, ASQ ali Delavnica IWA-1 dodali v posebno pomoč zdravstvenim organizacijam.

Novost te izdaje so tudi napotki pod naslovom "Kaj iskati?" in primeri, kdaj naj se napotki IWA 1 upoštevajo.

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Po izkušnjah z drugih področij naj bi z upoštevanjem teh napotkov ter discipliniranim in energičnim vzdrževanjem sistema v vsej organizaciji dosegli uspeh in učinkovitost skupaj s stroškovno učinkovitostjo v razmerju do 17:1. Ta dokument se lahko uporabi za izvajanje sistema kakovosti, ki je v skladu z ISO 9001, in ga lahko tretja stran po tem standardu tudi certificira, če organizacija to želi.

Za prispevek k tej izdaji se iskreno zahvaljujemo:

Marvinu "Mickeyu" Christensenu, TQM Systems (Odbor za standardizacijo, Oddelek za zdravstvo ASQ)

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Foreword to IWA 1, 2nd Edition – Supplemental

The IWA 1 2nd Edition is intended to provide the IWA 1, 1st Edition content with the same intent, but with improved appearance and usefulness. This is not the only way to interpret the ISO 9000 series of standards for health service organizations. The examples, definitions, and text given are only representative of how the wording is used within the context of this document. Organization-specific terminology can be used as applicable. These changes were the compilation of developments or comments received since the original workshop from IWA 1, from reviewers who were primarily providers, and some of the comments from the original workshop not previously incorporated.

Layout of this Edition:

Text in the solid box is from ISO 9001:2000. Black text outside the box is from ISO 9004:2000, which is both generic guidance and applicable to all organizations. *Italicized text in Times New Roman font is material added by ALAG, ASQ or the IWA-1 Workshop aimed at assisting health service organizations specifically.*

Also new in this Edition is guidance on "What to look for" as well as examples when implementing IWA 1 guidance.

Implementing this guidance and maintaining the system with discipline and rigor throughout the organization should produce effectiveness and efficiencies with a cost benefit up to 17:1 based on experience of other sectors. This document can be used to implement a quality system that is compliant with and can be third party certified to ISO 9001 if the organization desires.

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Predgovor – dopolnilo

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