SLOVENSKI STANDARD

SIST ISO 9001

tretja izdaja
december 2000

Sistemi vodenja kakovosti – Zahteve
(enakovreden ISO 9001:2000)

Quality management systems – Requirements

Systèmes de management de la qualité – Exigences

Qualitätsmanagementsysteme – Forderungen

ICS 01.120.10

SIST ISO 9001:2000 (sl, en)

Nadaljevanje na straneh od 2 do 47

NACIONALNI UVOD

Standard SIST ISO 9001:2000 (sl,en), Sistemi vodenja kakovosti - Zahteve, tretja izdaja, 2000, ima status slovenskega standarda in je enakovreden mednarodnemu standardu ISO 9001, Quality management systems - Requirements, tretja izdaja, 2000.

NACIONALNI PREDGOVOR

Mednarodni standard ISO 9001:2000 je pripravil tehnični odbor Mednarodne organizacije za standardizacijo ISO/TC 176 Vodenje in zagotavljanje kakovosti. Slovenski standard SIST ISO 9001:2000 je prevod angleškega besedila mednarodnega standarda ISO 9001:2000. V primeru spora glede besedila slovenskega prevoda v tem standardu je odločilen izvirni mednarodni standard v angleškem jeziku. Slovensko-angleško izdajo standarda je pripravil in potrdil tehnični odbor USM/TC VZK Vodenje in zagotavljanje kakovosti.

Ta slovenski standard je dne 2001-02-16 odobril direktor USM.

ZVEZE S STANDARDI

S privzemom tega mednarodnega standarda veljajo naslednje zveze:

ISO 9000:2000 (en)	Vodenje sistemov kakovosti – Osnove in slovar
ISO 9004:2000 (en)	Vodenje sistemov kakovosti – Smernice za izboljšanje delovanja
SIST EN ISO 14001:1997(sl,en)	Sistemi ravnanja z okoljem – Razčlenitev z navodili za uporabo

PREDHODNA IZDAJA

- SIST ISO 9001:1995 (sl,en)

OSNOVA ZA IZDAJO STANDARDA

- Privzem standarda ISO 9001:2000.

OPOMBE

- Povsod, kjer se v besedilu standarda uporablja izraz “mednarodni standard”, v SIST ISO 9001 to pomeni “slovenski standard”.
- Nacionalni uvod in nacionalni predgovor nista sestavni del standarda.
- V povezavi s kakovostjo prevajamo izraz “management” kot “vodenje”, v povezavi z drugimi pojmi pa npr. kot “ravnanje” z okoljem, “obvladovanje” tveganja itd. Če gre za skupino ljudi, ki vodi organizacijo, prevajamo “management” kot “vodstvo”.
- Povsod, kjer se v angleškem besedilu uporablja izraz “design and development”, je to v slovenskem besedilu standarda SIST ISO 9001:2000 (sl,en) prevedeno kot “načrtovanje in razvoj”.

Vsebina

Contents

Predgovor

ISO (Mednarodna organizacija za standardizacijo) je svetovna zveza nacionalnih organov za standarde (članov ISO). Mednarodne standarde ponavadi pripravljajo tehnični odbori ISO. Vsak član, ki želi delovati na določenem področju, za katero je bil ustanovljen tehnični odbor, ima pravico biti zastopan v tem odboru. Pri delu sodelujejo mednarodne vladne in nevladne organizacije, povezane z ISO. V vseh zadevah, ki so povezane s standardizacijo na področju elektrotehnike, ISO tesno sodeluje z Mednarodno elektrotehniško komisijo (IEC).

Mednarodni standardi so pripravljeni v skladu s pravili, podanimi v Direktivah ISO/IEC, 3. del.

Osnutki mednarodnih standardov, ki jih sprejmejo tehnični odbori, se pošljejo vsem članom v glasovanje. Za objavo mednarodnega standarda je treba pridobiti soglasje najmanj 75 odstotkov članov, ki se udeležijo glasovanja. Opozoriti je treba na možnost, da je lahko nekaj elementov tega mednarodnega standarda predmet patentnih pravic. ISO ne prevzema odgovornosti za identifikacijo katerihkoli ali vseh takih patentnih pravic.

Mednarodni standard ISO 9001 je pripravil tehnični odbor ISO/TC 176 *Vodenje kakovosti in zagotavljanje kakovosti*, pododbor SC2 *Sistemi kakovosti*.

Ta tretja izdaja ISO 9001 razveljavlja in nadomešča drugo izdajo (ISO 9001:1994) hkrati z ISO 9002:1994 in ISO 9003:1994. Predstavlja strokovno revizijo teh dokumentov. Organizacije, ki so v preteklosti uporabljale ISO 9002:1994 in ISO 9003:1994, lahko uporabljajo ta mednarodni standard tako, da opustijo določene zahteve v skladu s točko 1.2.

Naslov ISO 9001 je bil popravljen in ne vsebuje več izraza »Zagotavljanje kakovosti«. To odraža dejstvo, da je namen zahtev za sistem vodenja kakovosti, specificiranih v tej izdaji ISO 9001, poleg zagotavljanja kakovosti proizvoda tudi povečevanje zadovoljstva odjemalcev.

Dodatka A in B tega mednarodnega standarda sta podana samo informativno.

Foreword

ISO (The International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote. Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This third edition of ISO 9001 cancels and replaces the second edition (ISO 9001:1994) together with ISO 9002:1994 and ISO 9003:1994. It constitutes a technical revision of these documents. Those organizations which have used ISO 9002:1994 and ISO 9003:1994 in the past may use this International Standard by excluding certain requirements in accordance with 1.2.

The title of ISO 9001 has been revised in this edition and no longer includes the term “Ouality Assurance”. This reflects the fact that the quality management system requirements specified in this edition of ISO 9001, in addition to quality assurance of product, also aim to enhance customer satisfaction.

Annexes A and B of this International Standard are for information only.

0 Uvod

0.1 Splošno

Privzem sistema vodenja kakovosti naj bo strateška odločitev organizacije. Na načrtovanje in izvajanje sistema vodenja kakovosti organizacije vplivajo spreminjajoče se potrebe, posebni cilji, ponujeni proizvodi, izvajani procesi ter velikost in struktura organizacije. Ni namen tega mednarodnega standarda, da bi zahteval enotno strukturo sistemov vodenja kakovosti ali poenotenost dokumentacije.

Zahteve za sistem vodenja kakovosti, specificirane v tem mednarodnem standardu, so dopolnilo zahtevam za proizvode. Besedilo, označeno z »OPOMBA«, predstavlja napotek pri razumevanju ali razjasnitvi zahtev.

Ta mednarodni standard lahko uporabljajo notranje ali zunanje stranke, vključno s certifikacijskimi organi, za ocenjevanje sposobnosti organizacije glede izpolnjevanja zahtev odjemalcev, regulative ali zahtev, ki si jih postavi organizacija sama.

Pri razvoju tega mednarodnega standarda so bila upoštevana načela vodenja kakovosti, pojasnjena v ISO 9000 in ISO 9004.

0.2 Procesni pristop

Ta mednarodni standard spodbuja privzem procesnega pristopa pri razvijanju, izvajanju in izboljševanju učinkovitosti sistema vodenja kakovosti z namenom, da bi se z izpolnjevanjem zahtev odjemalcev povečalo njihovo zadovoljstvo.

Da bi organizacija delovala učinkovito, mora identificirati in voditi številne povezane aktivnosti. Aktivnost, ki uporablja vire in ki jo vodimo z namenom, da omogoči spremembo vhodov v izhode, lahko obravnavamo kot proces. Izhod enega procesa pogosto tvori vhod v drugi proces.

Uporabo sistema procesov znotraj organizacije, vključno z njihovo identifikacijo in medsebojnimi vplivi, lahko poimenujemo »procesni pristop«.

Prednost procesnega pristopa je v tem, da omogoča nenehni nadzor nad povezavami med

0 Introduction

0.1 General

The adoption of a quality management system should be a strategic decision of the organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked »NOTE« is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during development of this International Standard.

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfacion by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the »process approach«.

An advantage of the process aproach is the ongoing control that it provides over the linkage

posameznimi procesi znotraj sistema procesov, kot tudi nad njihovimi kombinacijami in medsebojnimi vplivi.

Pri uporabi znotraj sistema vodenja kakovosti tak pristop poudari pomen:

a) razumevanja in izpolnjevanja zahtev,

b) potrebe po obravnavanju procesov z vidika dodane vrednosti,

c) pridobivanja rezultatov delovanja in učinkovitosti procesov,

d) nenehnega izboljševanja procesov na osnovi objektivnih merjenj.

Slika 1 prikazuje model sistema vodenja kakovosti, ki je osnovan na procesih. Model ponazarja procesne povezave, kot so predstavljene v točkah od 4 do 8. Slika prikazuje, da imajo odjemalci pomembno vlogo pri določanju vhodnih zahtev. Spremljanje zadovoljstva odjemalca zahteva ocenjevanje njegovega zaznavanja, ali je organizacija izpolnila njegove zahteve. Model, prikazan na sliki 1, pokriva vse zahteve tega mednarodnega standarda, vendar ne prikazuje procesov podrobneje.

between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and meeting requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

OPOMBA: Poleg zgoraj opisanega se lahko pri vseh procesih uporabi metodologija, poznana kot "Planiraj-Izvedi-Preveri-Ukrepaj" (PDCA).
PDCA lahko na kratko opišemo na spodaj navedeni način.

Planiraj : Vzpostavi cilje in procese, potrebne za doseganje rezultatov, v skladu z zahtevami odjemalcev in načeli organizacije.

Izvedi: Izvajaj procese.

Preveri: Nadzoruj in meri procese in proizvod glede načel, ciljev in zahtev za proizvod ter poročaj o rezultatih.

Ukrepaj: Ukrepaj tako, da se delovanje procesa nenehno izboljšuje.

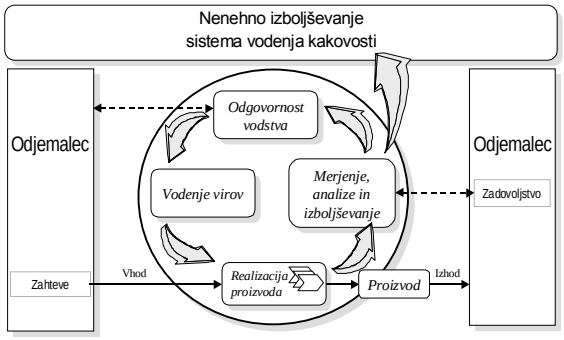
NOTE In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

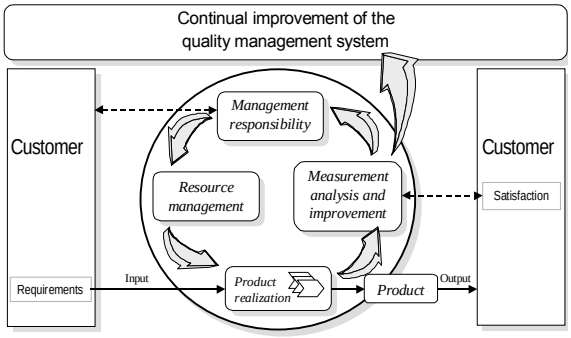
Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.





Legenda

Aktivnosti, ki dodajajo vrednost

Tok informacij

Slika 1: Model sistema vodenja kakovosti, osnovan na procesih

Key

Value adding activities

Information flow

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

0.3 Razmerje do ISO 9004

Ta izdaja ISO 9001 in ISO 9004 je bila razvita kot skladni par standardov za sistem vodenja kakovosti, ki sta bila zasnovana tako, da drug drugega dopolnjujeta, vendar pa se lahko uporabljata tudi samostojno. Ta dva mednarodna standarda imata kljub različnemu namenu podobno strukturo, da bi bilo to v pomoč pri njuni uporabi.

ISO 9001 specificira zahteve za sistem vodenja kakovosti za uporabo znotraj organizacije, certificiranje ali pogodbene namene. Osredotoča se na učinkovitost sistema vodenja kakovosti pri izpolnjevanju zahtev odjemalcev.

ISO 9004:2000 daje navodila na podlagi širšega obsega ciljev sistema vodenja kakovosti kot ISO 9001, zlasti za nenehno izboljševanje celotnega delovanja in uspešnosti organizacije kot tudi njene učinkovitosti. ISO 9004:2000 se priporoča kot vodilo za organizacije, katerih najvišje vodstvo želi v prizadevanju za nenehno izboljševanje delovanja preseči okvire zahtev ISO 9001. Vendar pa ni namenjen za certificiranje ali uporabo v pogodbenih odnosih.

0.3 Relationship with ISO 9004

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004:2000 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004:2000 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or contractual use.

0.4 Združljivost z ostalimi sistemi vodenja

Ta mednarodni standard je usklajen z ISO 14001:1996 z namenom, da se poveča združljivost obeh standardov v korist skupnosti uporabnikov.

Ta mednarodni standard ne vključuje zahtev, specifičnih za ostale sisteme vodenja, kot na primer specifičnih zahtev za ravnanje z okoljem, varovanje zdravja in varnost pri delu, finančno vodenje ali obvladovanje tveganj. Kljub temu ta mednarodni standard organizaciji omogoča, da uskladi ali združi svoj sistem vodenja kakovosti z zahtevami sorodnih sistemov vodenja. Da bi organizacija vzpostavila sistem vodenja kakovosti, ki izpolnjuje zahteve tega mednarodnega standarda, lahko prilagodi svoj(e) obstoječi(e) sistem(e) vodenja.

0.4 Compatibility with other management systems

This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Vodenje sistemov kakovosti – Zahteve

Quality management systems – Requirements

1 Predmet standarda

1.1 Splošno

Ta mednarodni standard specificira zahteve za sistem vodenja kakovosti. Uporablja se, kadar organizacija:

a) mora dokazati svojo sposobnost, da dosledno dobavlja proizvode, ki izpolnjujejo zahteve odjemalcev in zahteve ustrezne zakonodaje,

b) namerava izboljšati zadovoljstvo odjemalcev z učinkovito uporabo sistema, vključno s procesi za nenehno izboljševanje sistema in zagotavljanje skladnosti z zahtevami odjemalcev in ustreznimi zahtevami regulative.

OPOMBA: V tem mednarodnem standardu se izraz »proizvod« nanaša samo na proizvod, ki je namenjen odjemalcu ali ki ga odjemalec zahteva.

1.2 Uporaba

Vse zahteve, specificirane v tem mednarodnem standardu, so splošne in namenjene za uporabo v vseh organizacijah, ne glede na vrsto in velikost ter preskrbljeni proizvod.

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

NOTE In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.

1.2 Application

All the requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Kjer se zahteva(e) tega mednarodnega standarda ne more(jo) uporabiti zaradi narave organizacije in njenih proizvodov, se lahko preuči možnost za njihovo opustitev.

Sklicevanje na skladnost s tem mednarodnim standardom v primeru opustitev ni sprejemljivo, razen če so te opustitve omejene na zahteve znotraj točke 7 in ne vplivajo na sposobnost ali odgovornost organizacije, da preskrbi proizvod, ki izpolnjuje zahteve odjemalcev in ustrezne zahteve regulative.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for an exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that fulfils customer and applicable regulatory requirements.

2 Zveza z drugimi standardi

Spodaj navedeni standard vsebuje določila, ki s sklicevanjem v tem besedilu tvorijo določila tega mednarodnega standarda. Pri datiranem sklicevanju se ne upoštevajo poznejši dodatki ali popravki teh dokumentov. Vendar se strankam, ki sklenejo dogovore, zasnovane na tem mednarodnem standardu, priporoča, naj raziščejo možnost uporabe najnovejše izdaje spodaj navedenega standarda. Člani ISO in IEC vzdržujejo register veljavnih mednarodnih standardov.

ISO 9000:2000, *Sistemi vodenja kakovosti – Osnove in slovar*

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems - Fundamentals and vocabulary.*

3 Izrazi in definicije

V tem mednarodnem standardu se uporabljajo izrazi in definicije, ki so podani v standardu ISO 9000.

Da bi se odrazilo trenutno uporabljano izrazoslovje, so bili v tej izdaji ISO 9001 spremenjeni naslednji izrazi, ki opisujejo nabavno verigo:

dobavitelj → organizacija → odjemalec

Izraz »organizacija« nadomešča predhodno uporabljan izraz »dobavitelj« in se nanaša na enoto, v kateri se uporablja ta mednarodni standard. Prav tako izraz »dobavitelj« sedaj nadomešča izraz »podpogodbenik«.

Kjerkoli se v besedilu tega mednarodnega standarda pojavi izraz »proizvod«, lahko ta izraz pomeni tudi »storitev«.

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.

The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:

supplier → organization → customer

The term "organization" replaces the term "supplier" used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor".

Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".

4 Sistem vodenja kakovosti

4.1 Splošne zahteve

Organizacija mora vzpostaviti, dokumentirati, izvajati in vzdrževati sistem vodenja kakovosti ter nenehno izboljševati njegovo učinkovitost v skladu z zahtevami tega mednarodnega standarda.

Pri izvajanju sistema vodenja kakovosti mora organizacija:

a) identificirati procese, potrebne za sistem vodenja kakovosti, in njihovo uporabo v celotni organizaciji (glej 1.2),

b) določiti zaporedje in medsebojne vplive teh procesov,

c) določiti kriterije in metode, potrebne za zagotovitev tako učinkovitega delovanja kot tudi učinkovitega obvladovanja teh procesov,

d) zagotoviti, da so na voljo viri in informacije, potrebne za podporo delovanja in nadzorovanja teh procesov,

e) nadzorovati, meriti in analizirati te procese,

f) izvajati ukrepe, potrebne za doseganje planiranih rezultatov in za nenehno izboljševanje teh procesov.

Organizacija mora voditi te procese skladno z zahtevami tega mednarodnega standarda.

V primeru, da se organizacija odloči predati zunanjim izvajalcem v izvajanje katerikoli proces, ki vpliva na skladnost proizvoda z zahtevami, mora organizacija zagotoviti obvladovanje teh procesov. Obvladovanje teh procesov mora biti vključeno v sistem vodenja kakovosti.

OPOMBA: Procesi, potrebni za sistem vodenja kakovosti, na katere se sklicuje zgornje besedilo, naj vključujejo procese za vodstvene aktivnosti, priskrbo virov, realizacijo proizvoda in merjenje.

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

To implement the quality management system, the organization shall

a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure and analyse these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE Processes needed for quality management system reffered to above should include processes for management activities, provision of resources, product realization and measurement.

4.2 Zahteve glede dokumentacije

4.2.1 Splošno

Dokumentacija sistema vodenja kakovosti mora vključevati:

a) dokumentirane izjave o politiki kakovosti in ciljih kakovosti,

b) poslovnik kakovosti,

c) dokumentirane postopke, ki jih zahteva ta mednarodni standard,

d) dokumente, ki jih organizacija potrebuje, da bi zagotovila učinkovito planiranje, delovanje in obvladovanje njenih procesov,

e) zapise, ki jih zahteva ta mednarodni standard (glej 4.2.4).

OPOMBA 1: Kjer se v tem mednarodnem standardu pojavlja izraz »dokumentiran postopek«, to pomeni, da je postopek vzpostavljen, dokumentiran, da se izvaja in vzdržuje.

OPOMBA 2: Obseg dokumentacije sistema vodenja kakovosti se lahko razlikuje od ene do druge organizacije zaradi:

a) velikosti organizacije in vrste aktivnosti,

b) kompleksnosti procesov in njihovih medsebojnih vplivov,

c) kompetentnosti osebja.

OPOMBA 3: Dokumentacija je lahko v kakršnikoli obliki ali v kateremkoli mediju.

4.2.2 Poslovnik kakovosti

Organizacija mora izdelati in vzdrževati poslovnik kakovosti, ki vključuje:

a) predmet sistema vodenja kakovosti, vključno z razlogi in s podrobnostmi glede morebitnih opustitev (glej 1.2),

b) dokumentirane postopke, vzpostavljene za sistem vodenja kakovosti, ali sklicevanje nanje,

c) opis medsebojnega vpliva procesov sistema vodenja kakovosti.

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures required by this International Standard,

d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and

e) records required by this International Standard (see 4.2.4).

NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

a) the size of the organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction of the processes of the quality management system.

4.2.3 Obvladovanje dokumentov

Dokumente, ki jih zahteva sistem vodenja kakovosti, je treba obvladovati. Zapisi so posebna vrsta dokumentov in jih je treba obvladovati v skladu z zahtevami, podanimi v 4.2.4.

Vzpostaviti je treba dokumentiran postopek, ki opredeljuje potreben način obvladovanja za:

a) odobritev primernosti dokumentov pred njihovo izdajo,

b) pregled in posodobitev ter ponovno odobritev dokumentov, ko je to potrebno,

c) zagotovitev, da so identificirane spremembe in trenutni status popravkov dokumentov,

d) zagotovitev, da so ustrezne izdaje primernih dokumentov na voljo na mestih uporabe,

e) zagotovitev, da dokumenti ostanejo čitljivi in prepoznavni brez težav,

f) zagotovitev, da so dokumenti zunanjega izvora identificirani, njihovo razdeljevanje pa obvladovano,

g) preprečitev nenamerne uporabe zastarelih dokumentov in uporabo primerne identifikacije zanje, če se obdržijo za kakršenkoli namen.

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible, readily identifiable,

f) to ensure that documents of external origin are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Obvladovanje zapisov

Zapise je treba izdelati in vzdrževati, da bi se z njimi dokazala skladnost z zahtevami in učinkovitost delovanja sistema vodenja kakovosti. Zapisi morajo ostati čitljivi, prepoznavni brez težav in dostopni. Vzpostaviti je treba dokumentiran postopek, ki opredeljuje potrebne načine obvladovanja za identifikacijo, shranjevanje, zaščito, dostopnost, čas hranjenja in odstranjevanje zapisov.

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identidiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

5 Odgovornost vodstva

5.1 Zavezanost vodstva

Najvišje vodstvo mora priskrbeti dokaze o svoji zavezanosti razvoju in izvajanju sistema vodenja kakovosti ter nenehnemu izboljševanju njegove učinkovitosti, tako da:

a) sporoča organizaciji, kako pomembno je izpolnjevanje zahtev odjemalcev kot tudi zahtev zakonodaje in pravnih zahtev,

b) določi politiko kakovosti,

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

a) communicating to the organization the importance of meeting customer as well as regulatory and legal requirements,

b) establishing the quality policy,