
Sistemi vodenja kakovosti – Smernice in izboljšave delovanja

Quality management systems – Guidelines for performance improvements

Systèmes de management de la qualité – Lignes directrices pour l'amélioration des performances

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NACIONALNI UVOD

Standard SIST ISO 9004:2002 (sl,en). Sistemi vodenja kakovosti – Smernice in izboljšave delovanja, druga izdaja, ima status slovenskega stanarda in je enakovreden mednarodnemu standardu ISO 9004, Quality management systems – Guidelines for performance improvements, druga izdaja, 2000.

NACIONALNI PREDGOVOR

Mednarodni standard ISO 9004:2000 je pripravil tehnični odbor Mednarodne organizacije za standardizacijo ISO/TC 176 Vodenje in zagotavljanje kakovosti. Slovenski standard SIST ISO 9004:2002 je prevod angleškega besedila mednarodnega standarda ISO 9004:2000. V primeru spora glede besedila slovenskega prevoda v tem standardu je odločilen izvorni mednarodni standard v angleškem jeziku. Slovensko-angleško izdaja standarda je pripravil in potrdil tehnični odbor SIST/TC VZK Vodenje in zagotavljanje kakovosti.

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PREDHODNA IZDAJA

- SIST EN ISO 9004 -1:1997

OSNOVA ZA IZDAJO STANDARDARDA

- Privzem standarda ISO 9004:2000.

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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 pripravljani skladno s pravili, podanimi v 3. delu Direktiv ISO/IEC.

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 SC 2 Sistemi kakovosti*.

Ta druga izdaja ISO 9004 razveljavlja in nadomešča ISO 9004-1:1994, ki je bil strokovno revidiran. Naslov je bil popravljen, da bi odražal vsestranskost sistema vodenja kakovosti. Veliko obstoječih mednarodnih standardov iz družine ISO 9000 bo ponovno pregledanih, da bi se umaknili iz uporabe ali ponovno izdali kot tehnična poročila, ker so mnoga njihova določila vključena v ta mednarodni standard.

V primerjavi s predhodnima izdajama standarda ISO 9001 in ISO 9004 sedaj tvorita skladni par standardov o vodenju kakovosti. ISO 9001 je usmerjen h kakovosti proizvoda in povečevanju zadovoljstva odjemalca, medtem ko ISO 9004 uporablja širši vidik vodenja kakovosti in podaja napotke za izboljševanje delovanja.

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 9004 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance, Subcommittee SC 2, Quality systems*.

This second edition of ISO 9004 cancels and replaces ISO 9004-1:1994, which has been technically revised. The title has been modified to reflect the comprehensiveness of the quality management system. Many of the existing International Standards within the ISO 9000 family will be reviewed for withdrawal, or for re-issue as Technical Reports, as many of their provisions are incorporated into this International Standard.

In comparison to previous editions, ISO 9001 and ISO 9004 now form a consistent pair of standards on quality management. ISO 9001 aims to give quality assurance of product and to enhance customer satisfaction, while ISO 9004 uses a broader perspective of quality management to give guidance for performance improvement.

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

Uvod

0.1 Splošno

Privzem sistema vodenja kakovosti naj bo strateška odločitev najvišjega vodstva organizacije. Na načrtovanje in izvajanje sistema vodenja kakovosti organizacije vplivajo spreminjajoče se potrebe, posebni cilji, ponujeni proizvodi, izvajani procesi ter velikost in struktura organizacije. Ta mednarodni standard temelji na osmih načelih vodenja kakovosti. Vendar pa ni namen tega mednarodnega standarda, da bi usmerjal v enotno strukturo sistemov vodenja kakovosti ali poenotenost dokumentacije.

Namen organizacije je:

- da identificira in izpolni potrebe in pričakovanja njenih odjemalcev in drugih zainteresiranih strani (zaposleni v organizaciji, dobavitelji, lastniki, družba), da bi dosegla konkurenčno prednost in da bi to storila na učinkovit in uspešen način, ter
- da doseže, vzdržuje in izboljšuje celotno delovanje in sposobnosti organizacije.

Uporaba načel vodenja kakovosti ne nudi samo neposrednih koristi, temveč tudi pomembno prispeva k obvladovanju stroškov in tveganja. Upoštevanje obvladovanja koristi, stroškov in tveganja je pomembno za organizacijo, njene odjemalce in druge zainteresirane strani. To upoštevanje celotnega delovanja organizacije lahko vpliva na:

- lojalnost odjemalcev,
- ponavljajoče se posle in na priporočila,
- operativne rezultate, kot dohodek in tržni delež,
- prilagodljivost in hitrost odziva na tržne priložnosti,
- stroške in trajanje ciklov s pomočjo učinkovite in uspešne uporabe virov,
- usklajevanje procesov, da bodo najboljše dosegali želene rezultate,
- konkurenčne prednosti zaradi izboljšanih sposobnosti organizacije,
- razumevanje in motiviranje zaposlenih v smeri namenov in ciljev organizacije kot tudi sodelovanja pri nenehnem izboljševanju,

Introduction

0.1 General

The adoption of a quality management system should be a strategic decision by the top management of an 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. This International Standard is based on eight quality management principles. However, it is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The purpose of an organization is

- to identify and meet the needs and expectations of its customers and other interested parties (people in the organization, suppliers, owners, society), to achieve competitive advantage, and to do this in an effective and efficient manner, and
- to achieve, maintain, and improve overall organizational performance and capabilities.

The application of quality management principles not only provides direct benefits but also makes an important contribution to managing costs and risks. Benefit, cost and risk management considerations are important for the organization, its customers and other interested parties. These considerations on overall performance of the organization may impact

- customer loyalty,
- repeat business and referral,
- operational results such as revenue and market share,
- flexible and fast responses to market opportunities,
- costs and cycle times through effective and efficient use of resources,
- alignment of processes which will best achieve desired results,
- competitive advantage through improved organizational capabilities,
- understanding and motivation of people towards the organization's goals and objectives, as well as participation in continual improvement,

- zaupanje zainteresiranih strani v učinkovitost in uspešnost organizacije, kot ju dokazuje s finančnimi in socialnimi koristmi od delovanja organizacije, življenjskih ciklov proizvodov in ugleda,
- sposobnost ustvarjati vrednosti za organizacijo in njene dobavitelje z optimizacijo stroškov in virov kot tudi na prilagodljivost in hitrost skupnih odzivov na spreminjajoče se trge.

0.2 Procesni pristop

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

Da bi organizacija delovala učinkovito in uspešno, mora identificirati in voditi številne povezane aktivnosti. Aktivnost, ki porablja vire in je vodena zato, da bi omogočila spremembo vhodov v izhode, obravnavamo kot proces. Izhod enega procesa pogosto tvori vhod v drugi proces.

Uporaba sistema procesov znotraj organizacije, skupaj z njihovo identifikacijo, medsebojnimi vplivi in vodenjem, se lahko poimenuje »procesni pristop«.

Prednost procesnega pristopa je v tem, da omogoča nenehen nadzor nad povezavami med posameznimi procesi znotraj sistema procesov in 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 podlagi objektivnih merjenj.

Slika 1 prikazuje model sistema vodenja kakovosti, ki temelji na procesih. Model ponazarja procesne povezave, kot so predstavljene v točkah

- confidence of interested parties in the effectiveness and efficiency of the organization, as demonstrated by the financial and social benefits from the organization's performance, product life cycle, and reputation,
- ability to create value for both the organization and its suppliers by optimization of costs and resources as well as flexibility and speed of joint responses to changing markets.

0.2 Process approach

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

For an organization to function effectively and efficiently, 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, is 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 and managing of these processes can be referred to as the "process approach".

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as their combination and interaction.

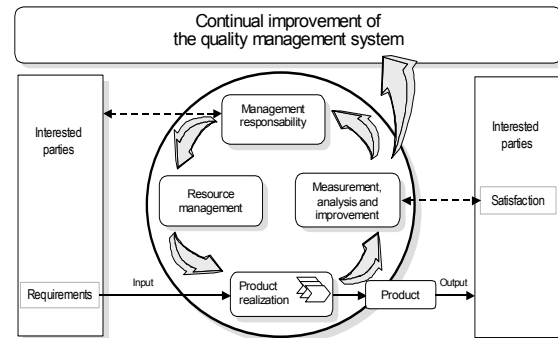
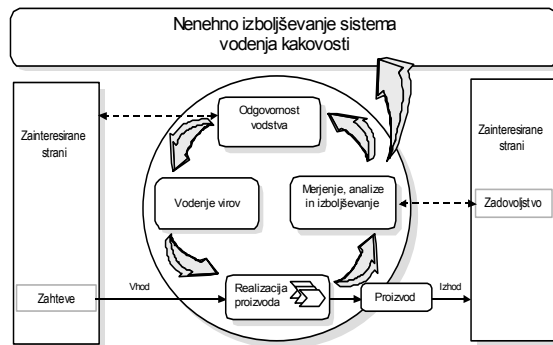
When used within a quality management system, such an approach emphasizes the importance of

- a) understanding and fulfilling the 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.

od 4 do 8. Razvidno je, da imajo zainteresirane strani pomembno vlogo pri določanju vhodnih zahtev. Spremljanje zadovoljstva zainteresiranih strani zahteva ocenjevanje njihovega zaznavanja, ali je organizacija izpolnila njihove zahteve. Model, prikazan na sliki 1, ne prikazuje procesov na podrobnejši ravni.

This illustration shows that interested parties play a significant role in defining requirements as inputs. Monitoring the satisfaction of interested parties requires the evaluation of information relating to the perception of interested parties as to whether the organization has met their requirements. The model shown in Figure 1 does not show processes at a detailed level.



Legenda

- Aktivnosti, ki dodajajo vrednost
- > Tok informacij

Key

- Value-adding activities
- > Information flow

Slika 1: Model sistema vodenja kakovosti, zasnovan na procesih

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

0.3 Razmerje do ISO 9001

Ta izdaja ISO 9001 in ISO 9004 je bila razvita kot skladni par standardov za sistem vodenja kakovosti, in sta 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 njihovi uporabi kot skladni par.

ISO 9001 podrobneje določa zahteve za sistem vodenja kakovosti za uporabo v organizaciji, certificiranje ali v pogodbeno namene. Osredotoča se na učinkovitost sistema vodenja kakovosti pri izpolnjevanju zahtev odjemalcev.

ISO 9004 podaja napotke na podlagi širšega obsega ciljev sistema vodenja kakovosti kot ISO 9001, zlasti za nenehno izboljševanje celotnega delovanja in uspešnosti organizacije in tudi njene učinkovitosti. ISO 9004 se priporoča kot vodilo za organizacije, katerih najvišje vodstvo želi v prizadevanju za nenehnim izboljševanjem delovanja preseči okvire zahtev ISO 9001. Vendar pa ni namenjen certificiranju ali uporabi v pogodbenih odnosih.

0.3 Relationship with ISO 9001

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been 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 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 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 for contractual purposes.

V dodatno pomoč uporabnikom je temeljna vsebina zahtev ISO 9001 vključena v okvirjenem besedilu, ki sledi primerljivi točki v tem mednarodnem standardu. Informacija, označena kot »OPOMBA«, je napotek za razumevanje ali razlago.

0.4 Združljivost z drugimi sistemi vodenja

Ta mednarodni standard ne vsebuje napotkov, ki so značilni za druge sisteme vodenja, npr. tiste za ravnanje z okoljem, vodenje varovanja zdravja in varstva pri delu, finančno vodenje ali obvladovanje tveganja. Kljub temu ta mednarodni standard omogoča organizaciji, da združi ali poveže svoj lastni sistem vodenja kakovosti s sorodnimi sistemi vodenja. Organizacija lahko prilagodi svoj(e) obstoječi(e) sistem(e) vodenja in tako vzpostavi sistem vodenja kakovosti, ki sledi smernicam tega mednarodnega standarda.

For further benefit to the user, the basic content of the ISO 9001 requirements are included in boxed text following the comparable clause in this International Standard. Information marked "NOTE" is for guidance in understanding or clarification.

0.4 Compatibility with other management systems

This International Standard does not include guidance 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 systems. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that follows the guidelines of this International Standard.

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Sistemi vodenja kakovosti – Smernice za izboljševanje delovanja

1 Predmet standarda

Ta mednarodni standard podaja smernice, ki presegajo zahteve ISO 9001, da bi bilo mogoče upoštevati tako učinkovitost kot tudi uspešnost sistema vodenja kakovosti in posledično potencial za izboljšanje delovanja organizacije. V primerjavi z ISO 9001 so cilji glede zadovoljstva odjemalcev in kakovosti proizvoda razširjeni tako, da vključujejo zadovoljstvo zainteresiranih strani in delovanje organizacije.

Ta mednarodni standard je mogoče uporabiti pri procesih organizacije in zato se lahko načela vodenja organizacije, na katerih je zasnovan, uporabijo v celotni organizaciji. Osredotoča se na doseganje nenehnega izboljševanja, merjeno z zadovoljstvom odjemalcev in drugih zainteresiranih strani.

Ta mednarodni standard vsebuje napotke in priporočila in ni namenjen certificiranju, uporabi v regulativi ali v pogodbah niti kot vodilo za izvajanje ISO 9001.

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

3 Izrazi in definicije

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

Quality management systems – Guidelines for performance improvements

1 Scope

This International Standard provides guidelines beyond the requirements given in ISO 9001 in order to consider both the effectiveness and efficiency of a quality management system, and consequently the potential for improvement of the performance of an organization. When compared to ISO 9001, the objectives of customer satisfaction and product quality are extended to include the satisfaction of interested parties and the performance of the organization.

This International Standard is applicable to the processes of the organization and consequently the quality management principles on which it is based can be deployed throughout the organization. The focus of this International Standard is the achievement of ongoing improvement, measured through the satisfaction of customers and other interested parties.

This International Standard consists of guidance and recommendations and is not intended for certification, regulatory or contractual use, nor as a guide to the implementation of ISO 9001.

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. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

3 Terms and definitions

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

Da bi odražali trenutno uporabljano izrazoslovje, so bili v tej izdaji ISO 9004 spremenjeni naslednji izrazi, ki opisujejo nabavno verigo:

dobavitelj → **organizacija** → **odjemalec**
(zainteresirane strani)

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

4 Sistem vodenja kakovosti

4.1 Vodenje sistemov in procesov

Da bi bili vodenje in delovanje organizacije uspešni, jo je treba voditi sistematično in pregledno. Uspeh naj bi bil rezultat izvajanja in vzdrževanja sistema vodenja, zasnovanega tako, da nenehno izboljšuje učinkovitost in uspešnost delovanja organizacije z upoštevanjem potreb zainteresiranih strani. Vodenje organizacije vključuje med drugimi vidiki tudi vodenje kakovosti.

Najvišje vodstvo naj vzpostavi organizacijo, usmerjeno k odjemalcu, tako, da:

- a) opredeli sisteme in procese, ki jih je mogoče jasno razumeti, voditi in izboljševati tako njihovo učinkovitost kot tudi uspešnost, in
- b) zagotovi učinkovito in uspešno delovanje in obvladovanje procesov ter merila in podatke, ki se uporabljajo za zadovoljivo opredelitev delovanja organizacije.

Aktivnosti za vzpostavitev organizacije, usmerjene k odjemalcu, vključujejo na primer:

- opredelitev in promoviranje procesov, ki vodijo k izboljššanemu delovanju organizacije,
- nenehno pridobivanje in uporabo podatkov in informacij o procesih,
- usmerjanje napredka k nenehnemu izboljševanju,
- uporabo primernih metod za vrednotenje izboljševanja procesa, kot sta samoocenitev in vodstveni pregled.

Primeri procesov samoocenjevanja in nenehnega izboljševanja so podani v dodatku A oziroma B.

The following terms, used in this edition of ISO 9004 to describe the supply-chain, have been changed to reflect the vocabulary currently used:

supplier → **organization** → **customer**
(interested parties)

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

4 Quality management system

4.1 Managing systems and processes

Leading and operating an organization successfully requires managing it in a systematic and visible manner. Success should result from implementing and maintaining a management system that is designed to continually improve the effectiveness and efficiency of the organization's performance by considering the needs of interested parties. Managing an organization includes quality management, among other management disciplines.

Top management should establish a customer-oriented organization

- a) by defining systems and processes that can be clearly understood, managed and improved in effectiveness as well as efficiency, and
- b) by ensuring effective and efficient operation and control of processes and the measures and data used to determine satisfactory performance of the organization.

Examples of activities to establish a customer-oriented organization include

- defining and promoting processes that lead to improved organizational performance,
- acquiring and using process data and information on a continuing basis,
- directing progress towards continual improvement, and
- using suitable methods to evaluate process improvement, such as self-assessments and management review.

Examples of self-assessment and continual improvement processes are given in annexes A and B respectively.

**ISO 9001:2000, Sistemi vodenja kakovosti –
Zahteve****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.

Organizacija mora:

- 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 nadziranja 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.

4.2 Dokumentacija

Vodstvo naj določi dokumentacijo skupaj z ustreznimi zapisi, potrebnimi za vzpostavitev, izvajanje in vzdrževanje sistema vodenja kakovosti in za podporo učinkovitemu in uspešnemu delovanju procesov organizacije.

**ISO 9001:2000, Quality management systems –
Requirements****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.

The organization shall

- a) identify the processes needed for the quality management system and their application throughout the organization,
- 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 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 the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

4.2 Documentation

Management should define the documentation, including the relevant records, needed to establish, implement and maintain the quality management system and to support an effective and efficient operation of the organization's processes.

Narava in obseg dokumentacije naj zadovoljujeta pogodbene in zakonske zahteve in zahteve regulative, potrebe in pričakovanja odjemalcev in drugih zainteresiranih strani ter naj bosta primerna organizaciji. Dokumentacija je lahko v katerikoli obliki ali mediju, primernem potrebam organizacije.

Da vodstvo zagotovi dokumentacijo, ki zadovoljuje potrebe in pričakovanja zainteresiranih strani, naj upošteva:

- pogodbene zahteve odjemalcev in drugih zainteresiranih strani,
- sprejete mednarodne, nacionalne, regionalne in industrijske panožne standarde,
- ustrezne zahteve zakonodaje in regulative,
- odločitve organizacije,
- vire zunanjih informacij, primernih za razvoj kompetentnosti organizacije, in
- informacije o potrebah in pričakovanjih zainteresiranih strani.

Izdelava, uporaba in obvladovanje dokumentacije naj se ocenijo glede na učinkovitost in uspešnost organizacije po kriterijih, kot so:

- funkcionalnost (kot je npr. hitrost procesiranja),
- prijaznost za uporabnika,
- potrebni viri,
- politike in cilji,
- trenutne in prihodnje zahteve, povezane z obvladovanjem znanja,
- primerjava sistemov dokumentacije z drugimi,
- medsebojne povezave, ki jih uporabljajo odjemalci, dobavitelji in druge zainteresirane strani.

Politika komuniciranja v organizaciji naj zagotovi dostop do dokumentacije tako zaposlenim v organizaciji kot drugim zainteresiranim stranem.

The nature and extent of the documentation should satisfy the contractual, statutory and regulatory requirements, and the needs and expectations of customers and other interested parties and should be appropriate to the organization. Documentation may be in any form or medium suitable for the needs of the organization.

In order to provide documentation to satisfy the needs and expectations of interested parties management should consider

- contractual requirements from the customer and other interested parties,
- acceptance of international, national, regional and industry sector standards,
- relevant statutory and regulatory requirements,
- decisions by the organization,
- sources of external information relevant for the development of the organization's competencies, and
- information about the needs and expectations of interested parties.

The generation, use and control of documentation should be evaluated with respect to the effectiveness and efficiency of the organization against criteria such as

- functionality (such as speed of processing),
- user friendliness,
- resources needed,
- policies and objectives,
- current and future requirements related to managing knowledge,
- benchmarking of documentation systems,
- interfaces used by organization's customers, suppliers and other interested parties.

Access to documentation should be ensured for people in the organization and to other interested parties, based on the organization's communication policy.

**ISO 9001: 2000, Sistemi vodenja kakovosti –
Zahteve****4.2 Zahteve glede dokumentacije****4.2.1 Splošno**

Dokumentacija sistema vodenja kakovosti mora vključevati:

- a) dokumentirane izjave o politiki kakovosti in ciljnih 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

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.

4.2.3 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:

**ISO 9001:2000, Quality management systems –
Requirements****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.

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 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,
- b) the documented procedures established for the quality management system, or reference to them,
- c) a description of the interaction between the processes of the quality management system.

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) 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.

4.2.4 Obvladovanje zapisov

Zapise je treba izdelati in vzdrževati, da bi se z njimi dokazali 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.

- 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 and 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 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 identifiable 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.

SIST ISO 9004:2002

4.3 Uporaba načel vodenja kakovosti

Da bi bili vodenje in delovanje organizacije uspešni, jo je treba voditi sistematično in pregledno. Napotki za vodenje, ki jih ponuja ta mednarodni standard, temeljijo na osmih načelih vodenja kakovosti.

Ta načela so bila razvita zato, da jih uporablja najvišje vodstvo, da vodi organizacijo v smeri izboljšane delovanja. Ta načela vodenja kakovosti so vključena v vsebino tega mednarodnega standarda in so navedena v nadaljevanju.

a) Osredotočenost na odjemalce

Organizacije so odvisne od svojih odjemalcev in naj zato razumejo njihove trenutne in prihodnje potrebe, izpolnjujejo njihove zahteve in si prizadevajo preseči njihova pričakovanja.

b) Voditeljstvo

Vodje vzpostavijo enotnost namena in usmeritve organizacije. Ustvarijo in vzdržujejo naj notranje okolje, v katerem se lahko zaposleni popolnoma vključijo v doseganje ciljev organizacije.

SIST ISO 9004:2002

4.3 Use of quality management principles

To lead and operate an organization successfully, it is necessary to manage it in a systematic and visible manner. The guidance to management offered in this International Standard is based on eight quality management principles.

These principles have been developed for use by top management in order to lead the organization toward improved performance. These quality management principles are integrated in the contents of this International Standard and are listed below

a) Customer focus

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

b) Leadership

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

c) Vključenost zaposlenih

Zaposleni na vseh ravneh so jedro organizacije in njihova popolna vključenost omogoča, da se njihove sposobnosti uporabijo v korist organizacije.

d) Procesni pristop

Želeni rezultat se doseže uspešneje, kadar se aktivnosti in z njimi povezani viri vodijo kot proces.

e) Sistemski pristop k vodenju

Identificiranje, razumevanje in vodenje medsebojno povezanih procesov kot sistem prispevajo k učinkovitosti in uspešnosti organizacije pri doseganju njenih ciljev.

f) Nenehno izboljševanje

Nenehno izboljševanje vsesplošnega delovanja organizacije naj bo stalen cilj organizacije.

g) Odločanje na podlagi dejstev

Uspešne rešitve temeljijo na analizi podatkov in informacij.

h) Vzajemno koristni odnosi z dobaviteljem

Organizacija in njeni dobavitelji so medsebojno odvisni in vzajemno koristni odnos povečuje sposobnost obeh za ustvarjanje vrednosti.

Uspešna uporaba osmih načel vodenja bo koristila zainteresiranim stranem, npr. z izboljšano donosnostjo, ustvarjanjem vrednosti in povečano stabilnostjo.

5 Odgovornost vodstva**5.1 Splošni napotki****5.1.1 Uvod**

Voditeljstvo, zavezanost in aktivna vključenost najvišjega vodstva so bistveni za razvoj in vzdrževanje učinkovitega in uspešnega sistema vodenja kakovosti, ki naj dosega koristi za zainteresirane strani. Za doseganje teh koristi je treba doseči, vzdrževati in povečevati zadovoljstvo odjemalcev. Najvišje vodstvo naj pretehta ukrepe, kot so:

- vzpostavitev vizije, politik in strateških ciljev, skladnih z namenom organizacije,
- vodenje organizacije z zgledom, da bi se

c) Involvement of people

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

d) Process approach

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

e) System approach to management

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

f) Continual improvement

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

g) Factual approach to decision making

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

h) Mutually beneficial supplier relationships

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

Successful use of the eight management principles by an organization will result in benefits to interested parties, such as improved monetary returns, the creation of value and increased stability.

5 Management responsibility**5.1 General guidance****5.1.1 Introduction**

Leadership, commitment and the active involvement of the top management are essential for developing and maintaining an effective and efficient quality management system to achieve benefits for interested parties. To achieve these benefits, it is necessary to establish, sustain and increase customer satisfaction. Top management should consider actions such as

- establishing a vision, policies and strategic objectives consistent with the purpose of the organization,
- leading the organization by example, in