
**Sistemi vodenja kakovosti – Osnove in slovar (ISO 9000:2005)
(istoveten EN ISO 9000:2005)**

Quality management systems – Fundamentals and vocabulary (ISO 9000:2005)

Systèmes de management de la qualité – Principes essentiels et vocabulaire
(ISO 9000:2005)

Qualitätsmanagementsysteme – Grundlagen und Begriffe (ISO 9000:2005)

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NACIONALNI UVOD

Standard SIST EN ISO 9000 (sl,en), Sistemi vodenja kakovosti – Osnove in slovar (ISO 9000:2005), 2005, ima status slovenskega standarda in je istoveten evropskemu standardu EN ISO 9000 (en), Quality management systems – Fundamentals and vocabulary (ISO 9000:2005), 2005-09-01.

NACIONALNI PREDGOVOR

Evropski standard EN ISO 9000:2005 je pripravil tehnični odbor ISO/TC 176 Vodenje in zagotavljanje kakovosti, pododbor 1 Pojmi in izrazi, skupaj s CEN (CMC).

Slovenski standard SIST EN ISO 9000:2005 je prevod evropskega standarda EN ISO 9000:2005. Ob sporu zaradi besedila slovenskega prevoda v tem standardu je odločilen izvorni evropski standard v angleškem jeziku. Slovensko izdajo standarda je pripravil tehnični odbor SIST/TC VZK Vodenje in zagotavljanje kakovosti.

Odločitev za prevzem tega standarda je dne 16. novembra 2005 prevzel SIST/TC VZK Vodenje in zagotavljanje kakovosti.

ZVEZE S STANDARDI

S prevzemom tega evropskega standarda veljajo za omejeni namen referenčnih standardov vsi standardi, navedeni v izvorniku, razen tistih, ki so že sprejeti v nacionalno standardizacijo:

SIST ISO 704:2003 (en)	Terminološko delo – Načela in metode
SIST EN ISO 9001:2000 (sl,en)	Sistemi vodenja kakovosti – Zahteve (ISO 9001:2000)
SIST EN ISO 9004:2004 (sl,en)	Sistemi vodenja kakovosti – Smernice za izboljšanje delovanja (ISO 9004:2000)
SIST EN ISO 10012:2003 (sl,en)	Sistemi vodenja meritev – Zahteve za procese merjenja in merilno opremo (ISO 10012:2003)
SIST ISO/TR 10013:2002 (sl,en)	Smernice za dokumentacijo sistema vodenja kakovosti
SIST ISO/TR 10017:2003 (en)	Napotki za statistične metode v zvezi z ISO 9001:2000
SIST ISO 10019:2005 (en)	Smernice za izbiro svetovalcev za sisteme vodenja kakovosti in uporabo njihovih storitev
SIST EN ISO 14001:2005 (sl,en)	Sistemi ravnanja z okoljem – Zahteve z navodili za uporabo (ISO 14001:2004)
SIST EN ISO/IEC 17000:2005 (sl,en,de,fr)	Ugotavljanje skladnosti – Slovar in splošna načela (ISO/IEC 17000:2004)
SIST EN ISO 19011:2003 (sl,en)	Smernice za presojanje sistemov vodenja kakovosti in/ali sistemov ravnanja z okoljem (ISO 19011:2002)

OSNOVA ZA IZDAJO STANDARDARDA

- privzem EN ISO 9000:2005

PREDHODNA IZDAJA

- SIST EN ISO 9000:2004 (sl,en)

OPOMBE

- Nacionalni uvod in nacionalni predgovor nista sestavni del standarda.
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- Ta nacionalni dokument je istoveten EN ISO 9000:2005 in je objavljen z dovoljenjem

CEN
Rue de Stassart, 36
1050 Bruxelles
Belgija

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Slovenska izdaja

**Sistemi vodenja kakovosti – Osnove in slovar
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Ta evropski standard je CEN sprejel dne 2005-09-12.

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CEN

Evropski komite za standardizacijo
European Committee for Standardization
Europäisches Komitee für Normung
Comité Européen de Normalisation

Upravni center: Rue de Stassart 36, B-1050 Bruselj

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Predgovor

Mednarodna organizacija za standardizacijo (ISO) 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 tudi vladne in nevladne mednarodne organizacije, povezane z ISO. V vseh zadevah, ki so povezane s standardizacijo na področju elektrotehnike, ISO tesno sodeluje z Mednarodno elektrotehniško komisijo (IEC).

Osnutki mednarodnih standardov so pripravljeni v skladu s pravili, podanimi v 2. delu Direktiv ISO/IEC.

Poglavitna naloga tehničnih odborov je priprava mednarodnih standardov. 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 so nekateri elementi tega mednarodnega standarda lahko predmet patentnih pravic. ISO ne prevzema odgovornosti za identifikacijo katerikoli ali vseh takih patentnih pravic.

Mednarodni standard ISO 9000 je pripravil tehnični odbor ISO/TC 176 *Vodenje in zagotavljanje kakovosti*, pododbor SC1 *Pojmi in izrazi*.

Ta, tretja izdaja preklicuje in nadomešča drugo izdajo (ISO 9000:2000). Vanjo so vključene spremembe, ki so bile sprejete v osnutku dopolnila ISO/DAM 9000:2004.

Dodatek A vsebuje pojmovne diagrame, ki grafično ponazarjajo razmerja med izrazi na specifičnih področjih v zvezi s sistemi vodenja kakovosti.

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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 9000 was prepared by Technical Committee ISO/TC 176, Quality management and quality assurance, Subcommittee SC 1, Concepts and terminology.

This third edition cancels and replaces the second edition (ISO 9000:2000). It includes the changes accepted in the Draft Amendment ISO/DAM 9000:2004.

Annex A includes concept diagrams that provide a graphical representation of the relationships between terms in specific fields relative to quality management systems.

Uvod

0.1 Splošno

V nadaljevanju našeta skupina standardov ISO 9000 je bila razvita z namenom, da pomaga organizacijam vseh vrst in velikosti pri vzpostavitvi in izvajanju uspešnih sistemov vodenja kakovosti.

- ISO 9000 opisuje osnove sistemov vodenja kakovosti in specificira izraze za sisteme vodenja kakovosti.
- ISO 9001 specificira zahteve za sisteme vodenja kakovosti v primerih, ko mora organizacija izkazati svojo zmožnost dobavljati proizvode, ki izpolnjujejo zahteve odjemalcev in zahteve ustrezne regulative, in ko si organizacija prizadeva za večje zadovoljstvo odjemalcev.
- ISO 9004 podaja smernice, ki se nanašajo tako na uspešnost kot na učinkovitost sistema vodenja kakovosti. Namen tega standarda je izboljšati delovanje organizacije ter povečati zadovoljstvo odjemalcev in drugih zainteresiranih strani.
- ISO 19011 podaja napotke za presojanje sistemov vodenja kakovosti in sistemov ravnanja z okoljem.

Skupaj tvorijo skladno celoto standardov za sistem vodenja kakovosti, ki omogoča in podpira medsebojno razumevanje v nacionalni in mednarodni trgovini.

0.2 Načela vodenja kakovosti

Za uspešno vodenje in delovanje je treba organizacijo usmerjati in obvladovati na sistematičen in pregleden način. Uspeh je lahko rezultat izvajanja in vzdrževanja sistema vodenja, zasnovanega tako, da nenehno izboljšuje delovanje ob upoštevanju potreb vseh zainteresiranih strani. Vodenje organizacije obsega med drugimi področji vodenja tudi vodenje kakovosti.

Identificiranih je osem načel vodenja kakovosti, ki jih lahko uporablja najvišje vodstvo zato, da vodi organizacijo k izboljššanemu delovanju.

a) Osredotočenost na odjemalce

Organizacije so odvisne od svojih odjemalcev, zato bi morale razumeti njihove

Introduction

0.1 General

The ISO 9000 family of standards listed below has been developed to assist organizations, of all types and sizes, to implement and operate effective quality management systems.

- ISO 9000 describes fundamentals of quality management systems and specifies the terminology for quality management systems.
- ISO 9001 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide products that fulfil customer and applicable regulatory requirements and aims to enhance customer satisfaction.
- ISO 9004 provides guidelines that consider both the effectiveness and efficiency of the quality management system. The aim of this standard is improvement of the performance of the organization and satisfaction of customers and other interested parties.
- ISO 19011 provides guidance on auditing quality and environmental management systems.

Together they form a coherent set of quality management system standards facilitating mutual understanding in national and international trade.

0.2 Quality management principles

To lead and operate an organization successfully, it is necessary to direct and control it in a systematic and transparent manner. Success can result from implementing and maintaining a management system that is designed to continually improve performance while addressing the needs of all interested parties. Managing an organization encompasses quality management amongst other management disciplines.

Eight quality management principles have been identified that can be used by top management in order to lead the organization towards improved performance.

a) Customer focus

Organizations depend on their customers and therefore should understand current

trenutne in prihodnje potrebe, izpolnjevati njihove zahteve in si prizadevati presežati njihova pričakovanja.

b) Voditeljstvo

Vodje poenotijo namen in usmeritev organizacije. Ustvarijo in vzdržujejo naj tako notranje okolje, v katerem se lahko zaposleni popolnoma vključijo v doseganje ciljev organizacije.

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 med seboj povezanih procesov kot sistem pripomorejo k uspešnosti in učinkovitosti organizacije pri doseganju njenih ciljev.

f) Nenehno izboljševanje

Nenehno izboljševanje celotnega delovanja organizacije naj bo stalen cilj organizacije.

g) Odločanje na podlagi dejstev

Učinkovite odločitve temeljijo na analizi podatkov in informacij.

h) Vzajemno koristni odnosi z dobavitelji

Organizacija in njeni dobavitelji so med seboj odvisni in vzajemno koristen odnos povečuje zmožnost obeh strani za ustvarjanje vrednosti.

Teh osem načel vodenja kakovosti tvori podlago za standarde sistemov vodenja kakovosti znotraj skupine standardov ISO 9000.

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) 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.

These eight quality management principles form the basis for the quality management system standards within the ISO 9000 family.

Sistemi vodenja kakovosti – Osnove in slovar

1 Predmet standarda

Mednarodni standard ISO 9000 opisuje temelje sistemov vodenja kakovosti, ki so predmet skupine standardov ISO 9000, in opredeljuje izraze v zvezi s tem.

Ta mednarodni standard lahko uporabljajo:

- a) organizacije, ki si z uvedbo sistema vodenja kakovosti prizadevajo za prednost;
- b) organizacije, ki želijo zaupati svojim dobaviteljem, da bodo njihove zahteve za proizvod izpolnjene;
- c) uporabniki proizvodov;
- d) tisti, ki se morajo med seboj sporazumeti o izrazih, ki se uporabljajo pri vodenju kakovosti (npr. dobavitelji, odjemalci, zakonodajalci);
- e) tisti znotraj ali zunaj organizacije, ki ocenjujejo sistem vodenja kakovosti ali presojujejo njegovo skladnost z zahtevami ISO 9001 (npr. presojevalci, zakonodajalci, certifikacijski oziroma registracijski organi);
- f) tisti znotraj ali zunaj organizacije, ki svetujejo ali usposablajo za sistem vodenja kakovosti, primeren za organizacijo;
- g) razvijalci sorodnih standardov.

2 Temelji sistemov vodenja kakovosti

2.1 Utemeljitev sistemov vodenja kakovosti

Sistemi vodenja kakovosti lahko pomagajo organizacijam pri povečevanju zadovoljstva odjemalcev.

Odjemalci zahtevajo proizvode s karakteristikami, ki zadovoljujejo njihove potrebe in pričakovanja. Te potrebe in pričakovanja so izraženi v specifikacijah proizvodov in jih skupno imenujemo zahteve odjemalcev. Zahteve odjemalcev lahko določi odjemalec v pogodbi, lahko pa jih določi organizacija sama. V vsakem primeru je odjemalec tisti, ki dokončno odloči o sprejemljivosti proizvoda. Zaradi spreminjanja

Quality management systems – Fundamentals and vocabulary

1 Scope

This International Standard describes fundamentals of quality management systems, which form the subject of the ISO 9000 family, and defines related terms.

This International Standard is applicable to the following:

- a) organizations seeking advantage through the implementation of a quality management system;
- b) organizations seeking confidence from their suppliers that their product requirements will be satisfied;
- c) users of the products;
- d) those concerned with a mutual understanding of the terminology used in quality management (e.g. suppliers, customers, regulators);
- e) those internal or external to the organization who assess the quality management system or audit it for conformity with the requirements of ISO 9001 (e.g. auditors, regulators, certification/registration bodies);
- f) those internal or external to the organization who give advice or training on the quality management system appropriate to that organization;
- g) developers of related standards.

2 Fundamentals of quality management systems

2.1 Rationale for quality management systems

Quality management systems can assist organizations in enhancing customer satisfaction.

Customers require products with characteristics that satisfy their needs and expectations. These needs and expectations are expressed in product specifications and collectively referred to as customer requirements. Customer requirements may be specified contractually by the customer or may be determined by the organization itself. In either case, the customer ultimately determines the acceptability of the product. Because

potreb in pričakovanj odjemalcev ter zaradi pritiska konkurence in tehničnega napredka so organizacije prisiljene, da svoje proizvode in procese nenehno izboljšujejo.

Sistem vodenja kakovosti spodbuja organizacije, da analizirajo zahteve odjemalcev, določijo procese, ki pripomorejo k realizaciji za odjemalca sprejemljivega proizvoda, in da te procese obvladujejo. Sistem vodenja kakovosti lahko daje okvir za nenehno izboljševanje, s čimer se povečuje verjetnost večanja zadovoljstva odjemalcev in zadovoljstva drugih zainteresiranih strani. Organizaciji in njenim odjemalcem vzbuja zaupanje, da je organizacija sposobna zagotoviti proizvode, ki dosledno izpolnjujejo zahteve.

2.2 Zahteve za sisteme vodenja kakovosti in zahteve za proizvode

Skupina ISO 9000 razlikuje med zahtevami za sisteme vodenja kakovosti in zahtevami za proizvode.

Zahteve za sisteme vodenja kakovosti so specificirane v ISO 9001. Zahteve za sisteme vodenja kakovosti so splošne in uporabne za organizacije v katerikoli industrijski ali gospodarski panogi ne glede na kategorijo ponujenega proizvoda. ISO 9001 ne postavlja zahtev za proizvode.

Zahteve za proizvode lahko določijo odjemalci ali organizacija sama ob predvidevanju zahtev odjemalcev ali pa regulativa. Zahteve za proizvode in v nekaterih primerih za pripadajoče procese so lahko vsebovane na primer v tehničnih specifikacijah, standardih za proizvode, standardih za procese, pogodbenih dogovorih in v zahtevah regulative.

2.3 Pristop na podlagi sistemov vodenja kakovosti

Pristop k razvoju in izvajanju sistema vodenja kakovosti sestavlja več korakov, vključno z naslednjimi:

- a) ugotavljanje potreb in pričakovanj odjemalcev in drugih zainteresiranih strani;
- b) vzpostavljanje politike kakovosti in ciljev kakovosti organizacije;
- c) določanje procesov in odgovornosti, potrebnih za doseganje ciljev kakovosti;

customer needs and expectations are changing, and because of competitive pressures and technical advances, organizations are driven to improve continually their products and processes.

The quality management system approach encourages organizations to analyse customer requirements, define the processes that contribute to the achievement of a product which is acceptable to the customer, and keep these processes under control. A quality management system can provide the framework for continual improvement to increase the probability of enhancing customer satisfaction and the satisfaction of other interested parties. It provides confidence to the organization and its customers that it is able to provide products that consistently fulfil requirements.

2.2 Requirements for quality management systems and requirements for products

The ISO 9000 family distinguishes between requirements for quality management systems and requirements for products.

Requirements for quality management systems are specified in ISO 9001. Requirements for quality management systems are generic and applicable to organizations in any industry or economic sector regardless of the offered product category. ISO 9001 itself does not establish requirements for products.

Requirements for products can be specified by customers or by the organization in anticipation of customer requirements, or by regulation. The requirements for products and in some cases associated processes can be contained in, for example, technical specifications, product standards, process standards, contractual agreements and regulatory requirements.

2.3 Quality management systems approach

An approach to developing and implementing a quality management system consists of several steps including the following:

- a) determining the needs and expectations of customers and other interested parties;
- b) establishing the quality policy and quality objectives of the organization;
- c) determining the processes and responsibilities necessary to attain the quality objectives;

- d) določanje in zagotavljanje virov, potrebnih za doseganje ciljev kakovosti;
- e) vzpostavljanje metod za merjenje uspešnosti in učinkovitosti vsakega procesa;
- f) uporaba teh merjenj za ugotavljanje uspešnosti in učinkovitosti vsakega procesa;
- g) določanje načinov preprečevanja neskladnosti in odpravljanja njihovih vzrokov;
- h) vzpostavljanje in uporaba procesa za nenehno izboljševanje sistema vodenja kakovosti.

Takšen pristop je mogoče uporabiti tudi pri vzdrževanju in izboljševanju obstoječega sistema vodenja kakovosti.

Organizacija, ki sprejme gornji pristop, ustvari zaupanje v sposobnost svojih procesov in kakovost svojih proizvodov ter zagotovi temelje za nenehno izboljševanje. To lahko vodi k povečanemu zadovoljstvu odjemalcev in drugih zainteresiranih strani ter k uspehu organizacije.

2.4 Procesni pristop

Vsaka aktivnost ali skupek aktivnosti, ki uporablja vire za pretvorbo vhodov v izhode se lahko obravnava kot proces.

Da bo organizacija lahko učinkovito delovala, mora prepoznavati in obvladovati številne medsebojno povezane in vplivajoče procese. Pogosto je izhod iz enega procesa neposredno vhod v naslednji proces. Sistematično prepoznavanje in obvladovanje procesov, uporabljenih v organizaciji, in zlasti medsebojno vplivanje med takimi procesi imenujemo "procesni pristop".

Namen tega mednarodnega standarda je spodbujati privzem procesnega pristopa za vodenje organizacije.

Slika 1 ponazarja na procesih temelječ sistem vodenja kakovosti, opisan v skupini standardov ISO 9000. Ta ponazoritev kaže, da igrajo zainteresirane strani pomembno vlogo pri opredelitvi vhodov za organizacijo. Spremljanje zadovoljstva zainteresiranih strani terja vrednotenje informacij o tem, kako zainteresirane strani dojemajo, v kolikšnem obsegu so bile izpolnjene njihove potrebe in

- d) determining and providing the resources necessary to attain the quality objectives;
- e) establishing methods to measure the effectiveness and efficiency of each process;
- f) applying these measures to determine the effectiveness and efficiency of each process;
- g) determining means of preventing nonconformities and eliminating their causes;
- h) establishing and applying a process for continual improvement of the quality management system.

Such an approach is also applicable to maintaining and improving an existing quality management system.

An organization that adopts the above approach creates confidence in the capability of its processes and the quality of its products, and provides a basis for continual improvement. This can lead to increased satisfaction of customers and other interested parties and to the success of the organization.

2.4 The process approach

Any activity, or set of activities, that uses resources to transform inputs to outputs can be considered as a process.

For organizations to function effectively, they have to identify and manage numerous interrelated and interacting processes. Often, the output from one process will directly form the input into the next process. The systematic identification and management of the processes employed within an organization and particularly the interactions between such processes is referred to as the "process approach".

The intent of this International Standard is to encourage the adoption of the process approach to manage an organization.

Figure 1 illustrates the process-based quality management system described in the ISO 9000 family of standards. This illustration shows that interested parties play a significant role in providing inputs to the organization. Monitoring the satisfaction of interested parties requires the evaluation of information relating to the perception of interested parties as to the extent to which their needs and expectations have

pričakovanja. Model na sliki 1 procesov ne kaže v podrobnosti.

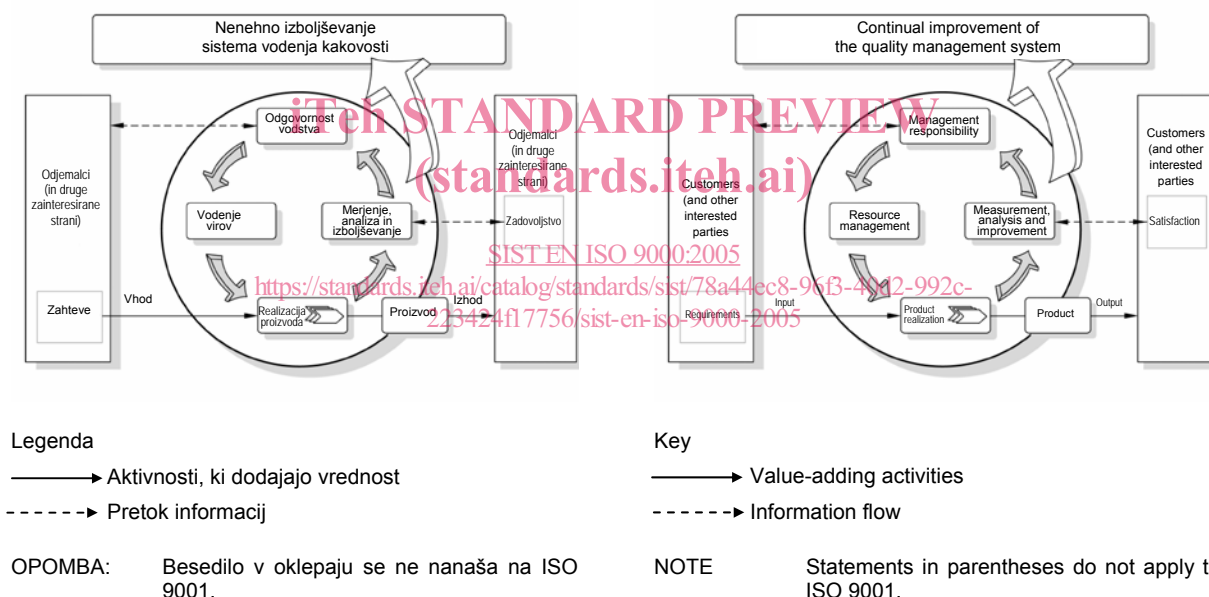
2.5 Politika kakovosti in cilji kakovosti

Politika kakovosti in cilji kakovosti se postavijo zato, da organizacija ve, kam naj se usmeri. Oboje določa želene rezultate in pomaga organizaciji uporabiti njene vire za doseganje teh rezultatov. Politika kakovosti daje okvir za določanje in pregledovanje ciljev kakovosti. Cilji kakovosti morajo biti skladni s politiko kakovosti in zavezanostjo nenehnemu izboljševanju, njihovo doseganje pa mora biti merljivo. Doseganje ciljev kakovosti lahko pozitivno vpliva na kakovost proizvodov, uspešnost delovanja in finančno delovanje ter s tem na zadovoljstvo in zaupanje zainteresiranih strani.

been met. The model shown in Figure 1 does not show processes at a detailed level.

2.5 Quality policy and quality objectives

Quality policy and quality objectives are established to provide a focus to direct the organization. Both determine the desired results and assist the organization to apply its resources to achieve these results. The quality policy provides a framework for establishing and reviewing quality objectives. The quality objectives need to be consistent with the quality policy and the commitment to continual improvement, and their achievement needs to be measurable. The achievement of quality objectives can have a positive impact on product quality, operational effectiveness and financial performance and thus on the satisfaction and confidence of interested parties.



Slika 1: Model na procesih temelječega sistema vodenja kakovosti

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

2.6 Vloga najvišjega vodstva znotraj sistema vodenja kakovosti

Z voditeljstvom in ukrepi lahko najvišje vodstvo ustvari okolje, v katerem so zaposleni popolnoma vključeni in v katerem lahko sistem vodenja kakovosti učinkovito deluje. Načela vodenja kakovosti (glej 0.2) lahko najvišje vodstvo uporabi kot podlago za svojo vlogo, ki je naslednja:

- vzpostaviti in vzdrževati politiko kakovosti in cilje kakovosti organizacije;

2.6 Role of top management within the quality management system

Through leadership and actions, top management can create an environment where people are fully involved and in which a quality management system can operate effectively. The quality management principles (see 0.2) can be used by top management as the basis of its role, which is as follows:

- to establish and maintain the quality policy and quality objectives of the organization;

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| b) propagirati politiko kakovosti in cilje kakovosti v celotni organizaciji, da bi se povečale zavest, motivacija in vključenost; | b) to promote the quality policy and quality objectives throughout the organization to increase awareness, motivation and involvement; |
| c) v celotni organizaciji zagotoviti osredotočenost na zahteve odjemalcev; | c) to ensure focus on customer requirements throughout the organization; |
| d) zagotoviti, da se izvajajo ustrezni procesi, ki omogočajo izpolnjevanje zahtev odjemalcev in drugih zainteresiranih strani ter doseganje ciljev kakovosti; | d) to ensure that appropriate processes are implemented to enable requirements of customers and other interested parties to be fulfilled and quality objectives to be achieved; |
| e) zagotoviti, da je vzpostavljen uspešen in učinkovit sistem vodenja kakovosti, ki se izvaja in vzdržuje za doseganje teh ciljev kakovosti; | e) to ensure that an effective and efficient quality management system is established, implemented and maintained to achieve these quality objectives; |
| f) zagotoviti, da so na voljo potrebni viri; | f) to ensure the availability of necessary resources; |
| g) periodično pregledovati sistem vodenja kakovosti; | g) to review the quality management system periodically; |
| h) odločati o ukrepih glede politike kakovosti in ciljev kakovosti; | h) to decide on actions regarding the quality policy and quality objectives; |
| i) odločati o ukrepih za izboljševanje sistema vodenja kakovosti. | i) to decide on actions for improvement of the quality management system. |

2.7 Dokumentacija

2.7 Documentation

2.7.1 Pomen dokumentacije

2.7.1 Value of documentation

Dokumentacija omogoča sporočanje namena in konsistentnost ukrepa. Njena uporaba pripomore k:

Documentation enables communication of intent and consistency of action. Its use contributes to

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| a) doseganju skladnosti z zahtevami odjemalcev in izboljševanju kakovosti; | a) achievement of conformity to customer requirements and quality improvement, |
| b) zagotavljanju ustreznega usposabljanja; | b) provision of appropriate training, |
| c) ponovljivosti in sledljivosti; | c) repeatability and traceability, |
| d) preskrbi objektivnih dokazov; | d) provision of objective evidence, and |
| e) vrednotenju uspešnosti in trajne ustreznosti sistema vodenja kakovosti. | e) evaluation of the effectiveness and continuing suitability of the quality management system. |

Izdelava dokumentacije naj ne bo sama sebi namen, temveč naj bo aktivnost, ki dodaja vrednost.

Generation of documentation should not be an end in itself but should be a value-adding activity.

2.7.2 Vrste dokumentov, ki se uporabljajo v sistemih vodenja kakovosti

2.7.2 Types of document used in quality management systems

V sistemih vodenja kakovosti se uporabljajo naslednje vrste dokumentov:

The following types of document are used in quality management systems:

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| a) dokumenti, ki tako navznoter kot tudi navzven podajajo konsistentne informacije o sistemu vodenja kakovosti organizacije; | a) documents that provide consistent information, both internally and externally, about the organization's quality management |
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| taki dokumenti se imenujejo poslovniki kakovosti; | system; such documents are referred to as quality manuals; |
| b) dokumenti, ki opisujejo, kako se sistem vodenja kakovosti uporablja pri specifičnem proizvodu, projektu ali pogodbi; taki dokumenti se imenujejo plani kakovosti; | b) documents that describe how the quality management system is applied to a specific product, project or contract; such documents are referred to as quality plans; |
| c) dokumenti, ki navajajo zahteve; taki dokumenti se imenujejo specifikacije; | c) documents stating requirements; such documents are referred to as specifications; |
| d) dokumenti, ki navajajo priporočila ali predloge; taki dokumenti se imenujejo smernice; | d) documents stating recommendations or suggestions; such documents are referred to as guidelines; |
| e) dokumenti, ki podajajo informacije o tem, kako konsistentno izvajati aktivnosti in procese; taki dokumenti lahko vključujejo dokumentirane postopke, delovna navodila in risbe; | e) documents that provide information about how to perform activities and processes consistently; such documents can include documented procedures, work instructions and drawings; |
| f) dokumenti, ki podajajo objektivne dokaze o izvedenih aktivnostih ali o doseženih rezultatih; taki dokumenti se imenujejo zapisi. | f) documents that provide objective evidence of activities performed or results achieved; such documents are referred to as records. |

Vsaka organizacija določi obseg potrebne dokumentacije in medij, ki ga bo uporabljala. To je odvisno od dejavnikov, kot so vrsta in velikost organizacije, kompleksnost in medsebojno vplivanje procesov, kompleksnost proizvodov, zahteve odjemalcev, zahteve ustrezne regulative, izkazane zmožnosti osebja in obsega, v katerem je treba izkazovati izpolnjevanje zahtev sistema vodenja kakovosti.

Each organization determines the extent of documentation required and the media to be used. This depends on factors such as the type and size of the organization, the complexity and interaction of processes, the complexity of products, customer requirements, the applicable regulatory requirements, the demonstrated ability of personnel, and the extent to which it is necessary to demonstrate fulfilment of quality management system requirements.

2.8 Vrednotenje sistemov vodenja kakovosti

2.8 Evaluating quality management systems

2.8.1 Vrednotenje procesov znotraj sistema vodenja kakovosti

2.8.1 Evaluating processes within the quality management system

Pri vrednotenju sistemov vodenja kakovosti si je o vsakem procesu, ki se vrednoti, treba zastaviti štiri osnovna vprašanja.

When evaluating quality management systems, there are four basic questions that should be asked in relation to every process being evaluated.

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| a) Ali je proces prepoznan in primerno opredeljen? | a) Is the process identified and appropriately defined? |
| b) Ali so odgovornosti določene? | b) Are responsibilities assigned? |
| c) Ali se postopki izvajajo in vzdržujejo? | c) Are the procedures implemented and maintained? |
| d) Ali je proces učinkovit pri doseganju zahtevanih rezultatov? | d) Is the process effective in achieving the required results? |

Odgovori na gornja vprašanja skupaj lahko določijo rezultat vrednotenja. Obseg vrednotenja

The collective answers to the above questions can determine the result of the evaluation.