
**Sistemi vodenja kakovosti – Osnove in slovar
(enakovreden ISO 9000:2000)**

Quality management systems – Fundamentals and vocabulary

Systèmes de management de la qualité – Principes essentiels et vocabulaire

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NACIONALNI UVOD

Standard SIST ISO 9000:2002 (sl,en), Sistemi vodenja kakovosti – Osnove in slovar, druga izdaja, ima status slovenskega stanarda in je enakovreden mednarodnemu standardu ISO 9000, Quality management systems – Fundamentals and vocabulary, druga izdaja, 2000.

NACIONALNI PREDGOVOR

Mednarodni standard ISO 9000:2000 je pripravil tehnični odbor Mednarodne organizacije za standardizacijo ISO/TC 176 Vodenje in zagotavljanje kakovosti. Slovenski standard SIST ISO 9000:2002 je prevod angleškega besedila mednarodnega standarda ISO 9000:2000. 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-

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- SIST EN ISO 8402:1997

OSNOVA ZA IZDAJO STANDARDARDA

- Privzem standarda ISO 9000:2000.

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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 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 so lahko nekateri elementi tega mednarodnega standarda predmet patentnih pravic. ISO ne prevzema odgovornosti za identifikacijo katerihkoli ali vseh takih patentnih pravic.

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

Ta druga izdaja ISO 9000 razveljavlja in nadomešča ISO 8402:1994.

Dodatek A tega mednarodnega standarda je podan samo informativno. Vsebuje pojmovne diagrame, ki grafično prikazujejo razmerja med izrazi na specifičnih pojmovnih področjih, ki se nanašajo na sisteme 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 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 9000 was prepared by Technical Committee ISO/TC 176, Quality management and quality assurance, Subcommittee SC 1, Concepts and terminology.

This second edition cancels and replaces ISO 8402:1994.

Annex A of this International Standard is for information only. It includes concept diagrams that provide a graphical representation of the relationships between terms in specific concept fields relative to quality management systems.

Uvod

0.1 Splošno

V nadaljevanju našeta družina standardov ISO 9000 je bila razvita z namenom, da pomaga organizacijam vseh vrst in velikosti pri vzpostavitvi in izvajanju učinkovitih 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 dokazati svojo sposobnost, da dobavlja 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 učinkovitost kot uspešnost sistema vodenja kakovosti. Namen tega standarda je izboljševanje delovanja organizacije ter zadovoljstva odjemalcev in drugih zainteresiranih strani.
- ISO 19011 podaja napotke za presojanje sistemov vodenja kakovosti in sistemov ravnanja z okoljem.

Skupno 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 uvedbe 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 bilo 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 naj razumejo njihove trenutne in prihodnje potrebe, izpolnjujejo njihove zahteve in si prizadevajo preseči njihova pričakovanja.

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 and future customer needs, should meet customer requirements and strive to exceed customer expectations.

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.

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

Učinkovite odločitve temeljijo na analizi podatkov in informacij.

h) Vzajemno koristni odnosi z dobavitelji

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

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

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 družine 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 napredek;
- b) organizacije, ki želijo zaupati svojim dobaviteljem, da bodo njihove zahteve za proizvode 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 izven 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, primerne 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 potreb in pričakovanj odjemalcev ter zaradi

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 customer needs and expectations are changing, and because of

pritiska konkurence in tehničnega napredka so organizacije prisiljene, da nenehno izboljšujejo svoje proizvode in procese.

Sistem vodenja kakovosti spodbuja organizacije, da analizirajo zahteve odjemalcev, določijo procese, ki prispevajo k realizaciji za odjemalca sprejemljivega proizvoda, in da 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 omogoča zaupanje, da je organizacija sposobna zagotoviti proizvode, ki dosledno izpolnjujejo zahteve.

2.2 Zahteve za sisteme vodenja kakovosti in zahteve za proizvode

Družina 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) določitev potreb in pričakovanj odjemalcev in drugih zainteresiranih strani;
- b) določitev politike kakovosti in ciljev kakovosti organizacije;
- c) določitev procesov in odgovornosti, potrebnih za doseganje ciljev kakovosti;
- d) določitev in zagotovitev virov, potrebnih za doseganje ciljev kakovosti;

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) determining and providing the resources necessary to attain the quality objectives;

- | | |
|--|--|
| <p>e) vzpostavitev metod za merjenje učinkovitosti in uspešnosti vsakega procesa;</p> <p>f) uporaba teh merjenj za določanje učinkovitosti in uspešnosti vsakega procesa;</p> <p>g) določitev načinov preprečevanja neskladnosti in odpravljanja njihovih vzrokov;</p> <p>h) vzpostavitev in uporaba procesa za nenehno izboljševanje sistema vodenja kakovosti.</p> | <p>e) establishing methods to measure the effectiveness and efficiency of each process;</p> <p>f) applying these measures to determine the effectiveness and efficiency of each process;</p> <p>g) determining means of preventing nonconformities and eliminating their causes;</p> <p>h) establishing and applying a process for continual improvement of the quality management system.</p> |
|--|--|

Podoben pristop je možno uporabiti pri vzdrževanju in izboljševanju obstoječega sistema vodenja kakovosti.

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

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

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 Procesni pristop

2.4 The process approach

Vsako aktivnost ali skupek aktivnosti, ki uporablja vire za pretvorbo vhodov v izhode, lahko obravnavamo kot proces.

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

Organizacija mora identificirati in obvladovati številne medsebojno povezane in vzajemno vplivajoče procese, da bi delovala učinkovito. Izhod enega procesa pogosto tvori neposredni vhod v naslednji proces. Sistematično identifikacijo in obvladovanje procesov, uporabljenih znotraj organizacije, in posebej medsebojnih vplivov med takimi procesi, lahko imenujemo "procesni pristop".

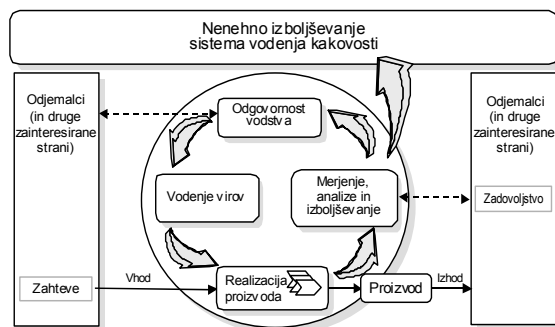
For organizations to function effectively, they have to identify and manage numerous interrelated and interacting processes. Often, the output from one process will directly form the input into the next process. The systematic identification and management of the processes employed within an organization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

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

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

Slika 1 prikazuje procesno utemeljen sistem vodenja kakovosti, opisan v družini standardov ISO 9000. Ta prikaz kaže, da zainteresirane strani igrajo pomembno vlogo pri opredelitvi vhodov za organizacijo. Spremljanje zadovoljstva zainteresiranih strani terja vrednotenje informacij o tem, kako zainteresirane strani dojemajo, v kakšnem obsegu so bile izpolnjene njihove potrebe in pričakovanja. Model na sliki 1 ne prikazuje procesov na ravni podrobnega prikaza.

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

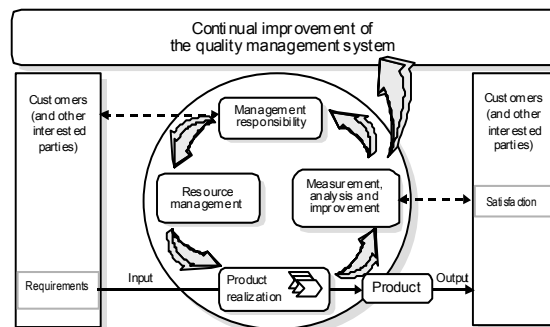


Legenda

- > Aktivnosti, ki dodajajo vrednost
 -----> Pretok informacij

OPOMBA: Besedilo v oklepaju se ne nanaša na ISO 9001.

Slika 1: Model, osnovan na procesih sistema vodenja kakovosti



Key

- > Value-adding activities
 -----> Information flow

NOTE Statements in parentheses do not apply to ISO 9001.

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

2.5 Politika kakovosti in cilji kakovosti

Politika kakovosti in cilji kakovosti se postavljajo zato, da se ustvari žarišče, ki usmerja organizacijo. Oboje določa želene rezultate in pomaga organizaciji uporabiti njene vire za doseganje teh rezultatov. Politika kakovosti daje okvir za določitev in pregledovanje ciljev kakovosti. Cilji kakovosti morajo biti skladni s politiko kakovosti in zavezanostjo nenehnemu izboljševanju. Doseganje ciljev kakovosti mora biti merljivo. Doseganje ciljev kakovosti lahko pozitivno vpliva na kakovost proizvodov, učinkovitost delovanja in finančne učinke ter s tem na zadovoljstvo in zaupanje zainteresiranih strani.

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:

- določiti in vzdrževati politiko kakovosti in cilje kakovosti organizacije;
- propagirati politiko kakovosti in cilje kakovosti v celotni organizaciji, da bi se povečale zavest, motivacija in vključenost;
- v celotni organizaciji zagotoviti osredotočenost na zahteve odjemalcev;

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.

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;
- to promote the quality policy and quality objectives throughout the organization to increase awareness, motivation and involvement;
- to ensure focus on customer requirements throughout the organization;

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| <p>d) zagotoviti, da se izvajajo ustrezni procesi, ki omogočajo izpolnjevanje zahtev odjemalcev in drugih zainteresiranih strani ter doseganje ciljev kakovosti;</p> <p>e) zagotoviti, da je učinkovit in uspešen sistem vodenja kakovosti vzpostavljen, da se le-ta za doseganje teh ciljev kakovosti izvaja in vzdržuje;</p> <p>f) zagotoviti, da so na voljo potrebni viri;</p> <p>g) periodično pregledovati sistem vodenja kakovosti;</p> <p>h) odločati o ukrepih glede politike kakovosti in ciljev kakovosti;</p> <p>i) odločati o ukrepih za izboljševanje sistema vodenja kakovosti.</p> | <p>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;</p> <p>e) to ensure that an effective and efficient quality management system is established, implemented and maintained to achieve these quality objectives;</p> <p>f) to ensure the availability of necessary resources;</p> <p>g) to review the quality management system periodically;</p> <p>h) to decide on actions regarding the quality policy and quality objectives;</p> <p>i) to decide on actions for improvement of the quality management system.</p> |
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2.7 Dokumentacija

2.7 Documentation

2.7.1 Pomen dokumentacije

2.7.1 Value of documentation

Dokumentacija omogoča sporočanje namena in konsistentnosti ukrepa. Njena uporaba prispeva k:

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

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| <p>a) doseganju skladnosti z zahtevami odjemalcev in izboljševanju kakovosti;</p> <p>b) pripravi primerne usposabljanja;</p> <p>c) ponovljivosti in sledljivosti;</p> <p>d) preskrbi objektivnih dokazov in</p> <p>e) vrednotenju učinkovitosti in trajne ustreznosti sistema vodenja kakovosti.</p> | <p>a) achievement of conformity to customer requirements and quality improvement,</p> <p>b) provision of appropriate training,</p> <p>c) repeatability and traceability,</p> <p>d) provision of objective evidence, and</p> <p>e) evaluation of the effectiveness and continuing suitability of the quality management system.</p> |
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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 sistemu 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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| <p>a) dokumenti, ki tako navznoter kot tudi navzven, podajajo konsistentne informacije o sistemu vodenja kakovosti organizacije; taki dokumenti se imenujejo poslovniki kakovosti;</p> <p>b) dokumenti, ki opisujejo, kako se sistem vodenja kakovosti uporablja pri specifičnem</p> | <p>a) documents that provide consistent information, both internally and externally, about the organization's quality management system; such documents are referred to as quality manuals;</p> <p>b) documents that describe how the quality management system is applied to a specific</p> |
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| <p>proizvodu, projektu ali pogodbi; taki dokumenti se imenujejo plani kakovosti;</p> <p>c) dokumenti, ki vsebujejo zahteve; taki dokumenti se imenujejo specifikacije;</p> <p>d) dokumenti, ki vsebujejo priporočila ali predloge; taki dokumenti se imenujejo smernice;</p> <p>e) dokumenti, ki podajajo informacije o tem, kako konsistentno izvajati aktivnosti in procese; taki dokumenti lahko vključujejo dokumentirane postopke, delovna navodila in risbe;</p> <p>f) dokumenti, ki podajajo objektivne dokaze o izvedenih aktivnostih ali doseženih rezultatih; taki dokumenti se imenujejo zapisi.</p> | <p>product, project or contract; such documents are referred to as quality plans;</p> <p>c) documents stating requirements; such documents are referred to as specifications;</p> <p>d) documents stating recommendations or suggestions; such documents are referred to as guidelines;</p> <p>e) documents that provide information about how to perform activities and processes consistently; such documents can include documented procedures, work instructions and drawings;</p> <p>f) documents that provide objective evidence of activities performed or results achieved; such documents are referred to as records.</p> |
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Vsaka organizacija določi obseg potrebne dokumentacije in medij, ki ga bo uporabljala. To je odvisno od faktorjev, kot so vrsta in velikost organizacije, kompleksnost in medsebojno vplivanje procesov, kompleksnost proizvodov, zahteve odjemalcev, zahteve ustrezne regulative, dokazane sposobnosti osebja in obsega, v katerem je treba dokazovati 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 Ocenjevanje sistemov vodenja kakovosti

2.8 Evaluating quality management systems

2.8.1 Ocenjevanje procesov znotraj sistema vodenja kakovosti

2.8.1 Evaluating processes within the quality management system

Pri ocenjevanju sistemov vodenja kakovosti obstajajo štiri osnovna vprašanja o vsakem procesu, ki je predmet ocene.

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

- Ali je proces prepoznan in primerno opredeljen?
- Ali so odgovornosti določene?
- Ali so postopki uvedeni in se vzdržujejo?
- Ali je proces učinkovit pri doseganju zahtevanih rezultatov?

- Is the process identified and appropriately defined?
- Are responsibilities assigned?
- Are the procedures implemented and maintained?
- Is the process effective in achieving the required results?

Skupni odgovori na zgornja vprašanja lahko določijo rezultat ocenjevanja. Obseg ocenjevanja sistema vodenja kakovosti se lahko spreminja in lahko obsega vrsto aktivnosti, kot so presojanje in pregledovanje sistema vodenja kakovosti ter samoocenjevanje.

The collective answers to the above questions can determine the result of the evaluation. Evaluation of a quality management system can vary in scope and encompass a range of activities, such as auditing and reviewing the quality management system, and self-assessments.

2.8.2 Presojanje sistema vodenja kakovosti

Presoje se uporabljajo za določanje obsega, v katerem so zahteve sistema vodenja kakovosti izpolnjene. Izsledki presoj se uporabljajo za ocenjevanje učinkovitosti sistema vodenja kakovosti in za identificiranje možnosti za izboljševanje.

Presoje prve stranke izvaja organizacija sama ali nekdo v njenem imenu v interne namene in so lahko podlaga za lastno izjavo organizacije o skladnosti.

Presoje druge stranke izvajajo odjemalci ali druge osebe v imenu odjemalca.

Presoje tretje stranke izvajajo zunanje neodvisne presojevalske organizacije. Take organizacije, ki so ponavadi akreditirane, izstavijo certifikat ali registracijo o skladnosti z zahtevami, kot so na primer zahteve ISO 9001.

ISO 19011 podaja napotke za izvajanje presoj.

2.8.3 Pregledovanje sistema vodenja kakovosti

Ena izmed vlog najvišjega vodstva je v tem, da izvaja redne sistematične ocenitve primernosti, ustreznosti, učinkovitosti in uspešnosti sistema vodenja kakovosti glede na politiko in cilje kakovosti. Ta pregled lahko vključuje premislek o potrebi po prilagoditvi politike in ciljev kakovosti kot odgovor na spreminjajoče se potrebe in pričakovanja zainteresiranih strani. Pregled vključuje določitev potrebnih ukrepov.

Med drugimi viri informacij se za pregled sistema vodenja kakovosti uporabljajo tudi poročila o presojah.

2.8.4 Samoocenjevanje

Samoocenjevanje organizacije je vseobsežen in sistematičen pregled aktivnosti in rezultatov organizacije v primerjavi s sistemom vodenja kakovosti ali modelom odličnosti.

Samoocenjevanje lahko zagotovi celovit pregled delovanja organizacije in stopnjo zrelosti sistema vodenja kakovosti. Prav tako lahko pomaga določiti področja, ki terjajo izboljševanje v organizaciji, in določiti prioritete.

2.8.2 Auditing the quality management system

Audits are used to determine the extent to which the quality management system requirements are fulfilled. Audit findings are used to assess the effectiveness of the quality management system and to identify opportunities for improvement.

First-party audits are conducted by, or on behalf of, the organization itself for internal purposes and can form the basis for an organization's self-declaration of conformity.

Second-party audits are conducted by customers of the organization or by other persons on behalf of the customer.

Third-party audits are conducted by external independent organizations. Such organizations, usually accredited, provide certification or registration of conformity with requirements such as those of ISO 9001.

ISO 19011 provides guidance on auditing.

2.8.3 Reviewing the quality management system

One role of top management is to carry out regular systematic evaluations of the suitability, adequacy, effectiveness and efficiency of the quality management system with respect to the quality policy and quality objectives. This review can include consideration of the need to adapt the quality policy and objectives in response to changing needs and expectations of interested parties. The review includes determination of the need for actions.

Amongst other sources of information, audit reports are used for review of the quality management system.

2.8.4 Self-assessment

An organization's self-assessment is a comprehensive and systematic review of the organization's activities and results referenced against the quality management system or a model of excellence.

Self-assessment can provide an overall view of the performance of the organization and the degree of maturity of the quality management system. It can also help to identify areas requiring improvement in the organization and to determine priorities.

2.9 Nenehno izboljševanje

Namen nenehnega izboljševanja sistema vodenja kakovosti je izboljšati možnosti za povečanje zadovoljstva odjemalcev in drugih zainteresiranih strani. Ukrepi za izboljševanje vključujejo:

- a) analiziranje in ocenjevanje obstoječe situacije, da bi se identificirala področja izboljševanja;
- b) določitev ciljev za izboljšave;
- c) iskanje možnih rešitev za doseg ciljev;
- d) vrednotenje teh rešitev in izbiro;
- e) uvedbo izbrane rešitve;
- f) merjenje, overjanje, analiziranje in vrednotenje rezultatov uvedbe, da se ugotovi, ali so bili cilji doseženi;
- g) formalizacijo sprememb.

Rezultati se po potrebi pregledujejo, da bi se določile nadaljnje možnosti za izboljšave. Na ta način je izboljševanje nenehna aktivnost. Odziv odjemalcev in drugih zainteresiranih strani, presoje in pregled sistema vodenja kakovosti lahko prav tako služijo za prepoznavanje priložnosti za izboljševanje.

2.10 Vloga statističnih metod

Uporaba statističnih metod lahko pomaga pri razumevanju variabilnosti in s tem pomaga organizacijam rešiti probleme ter izboljšati učinkovitost in uspešnost. Te metode prav tako omogočajo in podpirajo boljšo uporabo podatkov, ki so na voljo, kot pomoč pri odločanju.

Variabilnost se lahko opazi v obnašanju in rezultatih mnogih aktivnosti, celo v pogojih navidezne stabilnosti. Taka variabilnost se lahko opazuje v merljivih karakteristikah proizvodov in procesov in se lahko vidi pri različnih fazah življenjskega cikla proizvoda: od raziskav trga do oskrbe odjemalcev in njegove dokončne odstranitve.

Statistične metode lahko pomagajo meriti, opisati, analizirati, tolmačiti in modelirati tako variabilnost celo z relativno omejeno količino podatkov. Statistične analize takih podatkov lahko prispevajo k boljšemu razumevanju narave, obsega in vzrokov variabilnosti in na ta način

2.9 Continual improvement

The aim of continual improvement of a quality management system is to increase the probability of enhancing the satisfaction of customers and other interested parties. Actions for improvement include the following:

- a) analysing and evaluating the existing situation to identify areas for improvement;
- b) establishing the objectives for improvement;
- c) searching for possible solutions to achieve the objectives;
- d) evaluating these solutions and making a selection;
- e) implementing the selected solution;
- f) measuring, verifying, analysing and evaluating results of the implementation to determine that the objectives have been met;
- g) formalizing changes.

Results are reviewed, as necessary, to determine further opportunities for improvement. In this way, improvement is a continual activity. Feedback from customers and other interested parties, audits and review of the quality management system can also be used to identify opportunities for improvement.

2.10 Role of statistical techniques

The use of statistical techniques can help in understanding variability, and thereby can help organizations to solve problems and improve effectiveness and efficiency. These techniques also facilitate better use of available data to assist in decision making.

Variability can be observed in the behaviour and outcome of many activities, even under conditions of apparent stability. Such variability can be observed in measurable characteristics of products and processes, and may be seen to exist at various stages over the life cycle of products from market research to customer service and final disposal.

Statistical techniques can help to measure, describe, analyse, interpret and model such variability, even with a relatively limited amount of data. Statistical analysis of such data can help to provide a better understanding of the nature, extent and causes of variability, thus

pomagajo reševati in celo preprečevati probleme, ki lahko izhajajo iz take variabilnosti, obenem pa podpirajo tudi nenehno izboljševanje.

Napotki o statističnih metodah v sistemu vodenja kakovosti so dani v ISO/TR 10017.

2.11 Osredotočenost sistemov vodenja kakovosti in drugih sistemov vodenja

Sistem vodenja kakovosti je tisti del sistema vodenja organizacije, ki je osredotočen na doseganje rezultatov glede na cilje kakovosti za zadovoljevanje potreb, pričakovanj in zahtev zainteresiranih strani. Cilji kakovosti dopolnjujejo druge cilje organizacije, kot so npr. cilji, povezani z rastjo, vlaganji, donosnostjo, okoljem ter varovanjem zdravja in varstvom pri delu. Različni deli sistema vodenja organizacije so lahko združeni s sistemom vodenja kakovosti v en sam sistem vodenja s skupnimi elementi. To lahko olajša planiranje, razporeditev virov, določitev dopolnjujočih se ciljev in ocenjevanje celotne učinkovitosti organizacije. Sistem vodenja organizacije lahko ocenjuje organizacija glede na lastne zahteve za sistem vodenja. Sistem vodenja se prav tako lahko presoja glede na zahteve mednarodnih standardov, kot sta na primer ISO 9001 in ISO 14001:1996. Te presoje sistema vodenja se lahko izvajajo ločeno ali v kombinaciji.

2.12 Razmerje med sistemi vodenja kakovosti in modeli odličnosti

Pristopi sistemov vodenja kakovosti, navedeni v družini standardov ISO 9000 in v modelih organizacijske odličnosti, temeljijo na skupnih načelih. Oba pristopa:

- a) omogočata, da organizacija identificira svoje prednosti in slabosti,
- b) vsebujeta določila za ocenjevanje glede na splošne modele,
- c) podajata podlago za nenehno izboljševanje in
- d) vsebujeta podlago za zunanje priznanje.

Razlika med sistemi vodenja kakovosti po družini ISO 9000 in modeli odličnosti je v njihovem področju uporabe. Družina standardov ISO 9000 daje zahteve za sisteme vodenja kakovosti in napotke za izboljševanje

helping to solve and even prevent problems that may result from such variability, and to promote continual improvement.

Guidance on statistical techniques in a quality management system is given in ISO/TR 10017.

2.11 Quality management systems and other management system focuses

The quality management system is that part of the organization's management system that focuses on the achievement of results, in relation to the quality objectives, to satisfy the needs, expectations and requirements of interested parties, as appropriate. The quality objectives complement other objectives of the organization such as those related to growth, funding, profitability, the environment and occupational health and safety. The various parts of an organization's management system might be integrated, together with the quality management system, into a single management system using common elements. This can facilitate planning, allocation of resources, definition of complementary objectives and evaluation of the overall effectiveness of the organization. The organization's management system can be assessed against the organization's management system requirements. The management system can also be audited against the requirements of International Standards such as ISO 9001 and ISO 14001:1996. These management system audits can be carried out separately or in combination.

2.12 Relationship between quality management systems and excellence models

The approaches of quality management systems given in the ISO 9000 family of standards and in organizational excellence models are based on common principles. Both approaches

- a) enable an organization to identify its strengths and weaknesses,
- b) contain provision for evaluation against generic models,
- c) provide a basis for continual improvement, and
- d) contain provision for external recognition.

The difference between the approaches of the quality management systems in the ISO 9000 family and the excellence models lies in their scope of application. The ISO 9000 family of standards provides requirements for quality