
Sistemi vodenja kakovosti – Smernice za uporabo standarda ISO 9001:2015

Quality management systems – Guidelines for the application of ISO 9001:2015

Systèmes de management de la qualité – Lignes directrices pour l'application de l'ISO 9001:2015

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NACIONALNI UVOD

Tehnična specifikacija SIST-TS ISO/TS 9002 (sl, en), Sistemi vodenja kakovosti – Smernice za uporabo standarda ISO 9001:2015, 2016, ima status slovenske tehnične specifikacije in je istovetna mednarodni tehnični specifikaciji ISO/TS 9002, Quality management systems – Guidelines for the application of ISO 9001:2015, 2016.

NACIONALNI PREDGOVOR

Mednarodno tehnično specifikacijo ISO/TS 9002:2016 je pripravil tehnični odbor ISO/TC 176 Vodenje in zagotavljanje kakovosti, pododbor SC 2 Sistemi kakovosti. Slovenska tehnična specifikacija SIST-TS ISO/TS 9002:2016 je prevod angleškega besedila mednarodne tehnične specifikacije ISO/TS 9002:2016. V primeru spora glede besedila slovenskega prevoda v tej tehnični specifikaciji je odločilna izvirna mednarodna tehnična specifikacija v angleškem jeziku. Slovensko-angleško izdajo tehnične specifikacije je pripravil tehnični odbor SIST/TC VZK Vodenje in zagotavljanje kakovosti.

Odločitev za izdajo te tehnične specifikacije je 14. novembra 2016 sprejel SIST/TC VZK Vodenje in zagotavljanje kakovosti.

ZVEZA S STANDARDI

S privzemom te tehnične specifikacije veljajo za omejeni namen referenčnih standardov vsi standardi, navedeni v izvirniku, razen standardov, ki so že sprejeti v nacionalno standardizacijo:

SIST EN ISO 9000:2015 (sl, en) Sistemi vodenja kakovosti – Osnove in slovar (ISO 9000:2015)

SIST EN ISO 9001:2015 (sl, en) Sistemi vodenja kakovosti – Zahteve (ISO 9001:2015)

OSNOVA ZA IZDAJO STANDARDA

- privzem tehnične specifikacije ISO/TS 9002:2016

OPOMBE

- Nacionalni uvod in nacionalni predgovor nista sestavni del tehnične specifikacije.
- Povsod, kjer se v besedilu standarda uporablja izraz “mednarodna tehnična specifikacija”, v SIST-TS ISO/TS 9002:2016 to pomeni “slovenska tehnična specifikacija”.

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Predgovor

Mednarodna organizacija za standardizacijo (ISO) je svetovna zveza nacionalnih organov za standarde (članov ISO). Mednarodne standarde praviloma pripravljajo tehnični odbori ISO. Vsak član, ki ga zanima področje, za katero je bil ustanovljen tehnični odbor, ima pravico biti zastopan v tem odboru. Pri delu sodelujejo tudi 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).

Postopki, uporabljeni pri razvoju tega dokumenta, in postopki, predvideni za njegovo nadaljnje vzdrževanje, so opisani v Direktivah ISO/IEC, 1. del. Posebna pozornost naj se nameni različnim kriterijem odobritve, potrebnim za različne vrste dokumentov ISO. Ta dokument je bil pripravljen v skladu z uredniškimi pravili Direktiv ISO/IEC, 2. del (glej www.iso.org/directives).

Opozoriti je treba na možnost, da je nekaj elementov tega dokumenta lahko predmet patentnih pravic. ISO ne prevzema odgovornosti za identifikacijo katerihkoli ali vseh takih patentnih pravic. Podrobnosti o morebitnih patentnih pravicah, identificiranih med pripravo tega dokumenta, bodo navedene v uvodu in/ali na seznamu patentnih izjav, ki jih je prejela organizacija ISO (glej www.iso.org/patents).

Morebitna trgovska imena, uporabljena v tem dokumentu, so informacije za uporabnike in ne pomenijo podpore blagovni znamki.

Za razlago pomena specifičnih pojmov in izrazov ISO, povezanih z ugotavljanjem skladnosti, ter informacij o tem, kako ISO spoštuje načela Mednarodne trgovinske organizacije (WTO) v Tehničnih ovirah pri trgovanju (TBT), glej naslednji naslov URL: www.iso.org/foreword.html.

Ta dokument je pripravil tehnični odbor ISO/TC 176 Vodenje in zagotavljanje kakovosti, pododbor SC 2 Sistemi 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 176, Quality management and quality assurance, Subcommittee SC 2, Quality systems.

Uvod

Ta dokument je bil razvit v pomoč uporabnikom pri uporabi zahtev sistema vodenja kakovosti v skladu standardom ISO 9001:2015, *Sistemi vodenja kakovosti – Zahteve*.

Ta dokument daje napotke o korelaciji med točkami 4 do 10 standarda ISO 9001:2015, ne daje pa napotkov o dodatkih A in B k standardu ISO 9001:2015. Kjer obstaja neposredna korelacija med postavkami seznama (tj. alinejami) v določeni točki standarda ISO 9001:2015 in temi smernicami, je to navedeno v ustrezni točki tega dokumenta.

Ta dokument navaja primere, kaj lahko organizacija stori, ne dodaja pa novih zahtev k ISO 9001. Primeri v tem dokumentu niso dokončni, temveč zgolj predstavljajo možnosti, ki pa niso vse nujno primerne za vsako organizacijo.

ISO 9001 vsebuje zahteve, ki jih je mogoče objektivno presoditi ali ovrednotiti. V tem dokumentu so vključeni primeri, opisi in možnosti, ki pomagajo tako pri izvajanju sistema vodenja kakovosti kot pri krepitvi njegovega odnosa do celotnega sistema organizacije. S tem ko so smernice v tem dokumentu skladne z modelom vodenja kakovosti ISO 9001, pa niso namenjene razlagam zahtev standarda ISO 9001 ali uporabi za namene presoje oziroma vrednotenja.

Ker so zahteve ISO 9001 splošne, lahko ta dokument uporabljajo organizacije vseh vrst, velikosti, stopenj zrelosti ter vseh sektorjev in geografskih lokacij. Način, kako bo organizacija uporabila te napotke, pa se lahko razlikuje glede na dejavnike, kot so velikost ali kompleksnost organizacije, sprejeti model upravljanja, obseg dejavnosti organizacije ter tveganja in priložnosti, s katerimi se srečuje.

Tveganje je stopnja negotovosti, povezane s sistemom vodenja kakovosti. Tveganja so prisotna v vseh sistemih, procesih in funkcijah. Razmišljanje na podlagi tveganja zagotavlja, da so ta tveganja opredeljena ter da se upoštevajo in obvladujejo pri vsem snovanju in uporabi sistema vodenja kakovosti.

Razmišljanje na podlagi tveganja je bilo v prejšnjih izdajah standarda ISO 9001 implicitno v zahtevah, kot sta npr. opredeljevanje vrste in obsega nadzora zunanjih ponudnikov na podlagi učinka izdelka, ki bo zagotovljen, ali izvajanje

Introduction

This document has been developed to assist users to apply the quality management system requirements of ISO 9001:2015 *Quality management systems – Requirements*.

This document provides guidance, with a clause by clause correlation to Clauses 4 to 10 of ISO 9001:2015, however it does not provide guidance on ISO 9001:2015, Annexes A and B. Where there is direct correlation between list items (i.e. bullet points) in a clause in ISO 9001:2015 and the guidance, this is indicated within the clause of this document.

This document gives examples of what an organization can do, but it does not add new requirements to ISO 9001. The examples in this document are not definitive and only represent possibilities, not all of which are necessarily suitable for every organization.

ISO 9001 contains requirements that can be objectively audited or evaluated. This document includes examples, descriptions and options that aid both in the implementation of a quality management system and in strengthening its relation to the overall management system of an organization. While the guidelines in this document are consistent with the ISO 9001 quality management system model, they are not intended to provide interpretations of the requirements of ISO 9001 or be used for audit or evaluation purposes.

As the requirements of ISO 9001 are generic, this document can be used by organizations of all types, sizes, levels of maturity and in all sectors and geographic locations. However, the way an organization applies the guidance can vary based on factors such as the size or the complexity of the organization, the management model it adopts, the range of the organization's activities and the nature of the risks and opportunities it encounters.

Risk is the level of uncertainty inherent in a quality management system. There are risks in all systems, processes and functions. Risk-based thinking ensures these risks are determined, considered and controlled throughout the design and use of the quality management system.

Risk-based thinking has been implicit in previous editions of ISO 9001 in such requirements as determining the type and extent of control for external providers based on the effect of the product that is going to be provided, or taking

korektivnih ukrepov na podlagi možnega učinka ugotovljene neskladnosti.

Poleg tega je bila v prejšnjih izdajah ISO 9001 vključena točka o preventivnih ukrepih. Z uporabo razmišljanja na podlagi tveganja pa je upoštevanje tveganja integralno. S pomočjo zgodnjega prepoznavanja in ukrepanja postaja prej proaktivno kot reaktivno pri preprečevanju ali zmanjševanju neželenih učinkov.

Vsi procesi sistema vodenja kakovosti ne predstavljajo enake stopnje tveganja v smislu sposobnosti organizacije, da dosega svoje cilje kakovosti. Nekateri potrebujejo bolj skrbno in formalno planiranje in obvladovanje kot drugi.

V standardu ISO 9001 ni zahteve po formalnem obvladovanju tveganja pri opredeljevanju in obravnavanju tveganj in priložnosti. Organizacija lahko sama izbere metode, ki ustrezajo njenim potrebam. V dokumentu IEC 31010 je seznam orodij in tehnik za ocenjevanje tveganj, ki jih je mogoče upoštevati glede na kontekst organizacije.

V nekaterih primerih ima organizacija lahko vzpostavljen formalni proces obvladovanja tveganja, ki ga zahtevajo stranke ali so zakonske oziroma regulativne zahteve. V takšnih okoliščinah lahko organizacija svoj formalni proces obvladovanja tveganja prilagodi tako, da izpolnjuje namen tistih zahtev standarda ISO 9001, ki zadevajo tveganja in priložnosti.

V dodatku A je ISO dodatno k ISO 9001:2015 objavil številne druge standarde vodenja kakovosti in informativne vire, ki so lahko uporabniku v pomoč in ki zagotavljajo informacije o dodatnih izvedbenih metodah, ter vključujejo:

- priročnik ISO: ISO 9001:2015 *za majhna podjetja – Kaj storiti ? Nasveti tehničnega odbora ISO/TC 176*
- dokumente Skupine ISO 9001 za presojevalsko prakso (APG): www.iso.org/tc176/ISO9001AuditingPracticesGroup
- javno dostopne informacije na spletni strani ISO/TC 176/SC2: <https://committee.iso.org/tc176sc2>
- priročnik ISO: *Celostna uporaba standardov sistema vodenja.*

Dodatni standardi in dokumenti so navedeni v Literaturi.

corrective action based on the potential effect of an identified nonconformity.

In addition, in previous editions of ISO 9001, a clause on preventive action was included. By using risk-based thinking the consideration of risk is integral. It becomes proactive rather than reactive in preventing or reducing undesired effects through early identification and action. Preventive action is built-in when a management system is risk-based.

Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its quality objectives. Some need more careful and formal planning and control than others.

There is no requirement in ISO 9001 to use formal risk management in determining and addressing risks and opportunities. An organization can choose the methods that suit its needs. IEC 31010 provides a list of risk assessment tools and techniques that can be considered, depending on the organization's context.

In some cases, an organization might have a formal risk management process in place that is required by customers or statutory and regulatory requirements. In such circumstances, the organization can adapt its formal risk management process to meet the intent of the requirements in ISO 9001 concerning risks and opportunities.

In addition to ISO 9001:2015, Annex A, ISO has published a number of other quality management standards and informative resources which can assist the user and provide information on additional implementation methods, including:

- the ISO handbook: ISO 9001:2015 *for Small Enterprises – What to do ? Advice from ISO/TC 176*
- the ISO 9001 Auditing Practices Group (APG) papers: www.iso.org/tc176/ISO9001AuditingPracticesGroup
- public information on the ISO/TC 176/SC2 website: <https://committee.iso.org/tc176sc2>
- the ISO handbook: *The Integrated Use of Management System Standards.*

Additional standards and documents are listed in the Bibliography.

Sistemi vodenja kakovosti – Smernice za uporabo standarda ISO 9001:2015

1 Področje uporabe

Ta dokument daje napotke o namenu zahtev v standardu ISO 9001:2015 in navaja primere možnih ukrepov, ki jih organizacija lahko sprejme, da bi izpolnila te zahteve. Dokument tem zahtevam ničesar ne dodaja niti odvzema ali jih kakorkoli spreminja.

Ta dokument ne predpisuje obveznih pristopov k izvedbi oziroma ne zagotavlja kakršnekoli prednostne metode interpretacije.

2 Zveze s standardi

Besedilo se sklicuje na naslednje dokumente na tak način, da njihova vsebina v celoti ali delno predstavlja zahteve tega dokumenta. Pri datiranih sklicevanjih se uporablja le navedena izdaja. Pri nedatiranih sklicevanjih se uporablja zadnja izdaja dokumenta (vključno z dopolnili).

ISO 9000:2015 Sistemi vodenja kakovosti –
Osnove in slovar

ISO 9001:2015 Sistemi vodenja kakovosti –
Zahteve

3 Izrazi in definicije

V tem dokumentu se uporabljajo izrazi in definicije iz ISO 9000:2015.

ISO in IEC vzdržujeta terminološke baze za uporabo v standardizaciji na naslednjih naslovih:

- platforma za spletno brskanje ISO: dostopna na: <http://www.iso.org/obp>
- Elektropedija IEC: dostopna na: <http://www.electropedia.org/>

4 Kontekst organizacije

4.1 Razumevanje organizacije in njenega konteksta

Namen te podtočke je razumeti, katera zunanja in notranja vprašanja so relevantna za namen organizacije in njeno strateško usmeritev ter katera lahko pozitivno ali negativno vplivajo na njeno zmožnost dosegati predvidene rezultate njenega sistema vodenja kakovosti. Organiza-

Quality management systems – Guidelines for the application of ISO 9001:2015

1 Scope

This document provides guidance on the intent of the requirements in ISO 9001:2015, with examples of possible steps an organization can take to meet the requirements. It does not add to, subtract from, or in any way modify those requirements.

This document does not prescribe mandatory approaches to implementation, or provide any preferred method of interpretation.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015, Quality management systems –
Fundamentals and
vocabulary

ISO 9001:2015, Quality management systems
– Requirements

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

4 Context of the organization

4.1 Understanding the organization and its context

The intent of this subclause is to understand the external and internal issues that are relevant to the organization's purpose and strategic direction and that can affect, either positively or negatively, the organization's ability to achieve the intended results of its quality management

cija naj se zaveda, da se zunanja in notranja vprašanja lahko spremenijo, zato jih je treba spremljati in pregledovati. Organizacija lahko preglede svojega konteksta izvaja v planiranih časovnih presledkih in z aktivnostmi, kot je npr. vodstveni pregled.

Informacije o zunanjih in notranjih vprašanjih je mogoče pridobiti iz številnih virov, na primer preko notranjih dokumentiranih informacij in sestankov, nacionalnega in mednarodnega tiska, spletnih strani, publikacij nacionalnih statističnih uradov in drugih vladnih služb, strokovnih in tehničnih publikacij, konferenc in srečanj z ustreznimi agencijami ter srečanj s strankami in z relevantnimi zainteresiranimi stranmi in strokovnimi združenji.

Primeri zunanjih in notranjih vprašanj, relevantnih za kontekst organizacije, so med drugim lahko:

- a) zunanja vprašanja v zvezi z:
- 1) ekonomskimi dejavniki, kot so npr. menjalni tečaji, gospodarske razmere, napoved inflacije, razpoložljivost kreditov,
 - 2) socialnimi dejavniki, kot so npr. lokalne stopnje brezposelnosti, dojemanje varnosti, stopnje izobrazbe, državni prazniki in delavniki,
 - 3) političnimi dejavniki, kot so npr. politična stabilnost, javne investicije, lokalna infrastruktura, mednarodni trgovinski sporazumi,
 - 4) tehnološkimi dejavniki, kot so npr. nova tehnologija, materiali in oprema v sektorju, iztek trajanja patentov, kodeks poklicne etike,
 - 5) tržnimi dejavniki, kot so npr. konkurenca, vključno s tržnim deležem organizacije, podobni izdelki ali storitve, vodilni trendi na trgu, trendi rasti kupcev, stabilnost trga, razmerja v dobavni verigi,
 - 6) zakonskimi in regulativnimi dejavniki, ki vplivajo na delovno okolje (glej ISO 9001:2015, točka 7.1.4), kot so npr. sindikalni predpisi in predpisi, povezani z določeno industrijo,
- b) notranja vprašanja v zvezi s:
- 1) splošno uspešnostjo organizacije,
 - 2) dejavniki virov, kot so npr. infrastruktura (glej ISO 9001:2015, točka 7.1.3), okolje

system. The organization should be aware that external and internal issues can change, and therefore, should be monitored and reviewed. An organization might conduct reviews of its context at planned intervals and through activities such as management review.

Information about external and internal issues can be found from many sources, such as through internal documented information and meetings, in the national and international press, websites, publications from national statistics offices and other government departments, professional and technical publications, conferences and meetings with relevant agencies, meetings with customers and relevant interested parties, and professional associations.

Examples of external and internal issues relevant to the organization's context can include, but are not limited to:

- a) external issues related to:
- 1) economic factors such as money exchange rates, economic situation, inflation forecast, credit availability;
 - 2) social factors such as local unemployment rates, safety perception, education levels, public holidays and working days;
 - 3) political factors such as political stability, public investments, local infrastructure, international trade agreements;
 - 4) technological factors such as new sector technology, materials and equipment, patent expirations, professional code of ethics;
 - 5) market factors such as competition, including the organization's market share, similar products or services, market leader trends, customer growth trends, market stability, supply chain relationships;
 - 6) statutory and regulatory factors which affect the work environment (see ISO 9001:2015, 7.1.4) such as trade union regulations and regulations related to an industry;
- b) internal issues related to:
- 1) overall performance of the organization;
 - 2) resource factors, such as infrastructure (see ISO 9001:2015, 7.1.3),

za delovanje procesov (glej ISO 9001:2015, točka 7.1.4), organizacijsko znanje (glej ISO 9001:2015, točka 7.1.6),

- 3) človeškimi vidiki, kot so npr. kompetentnost osebja, organizacijsko vedenje in kultura, odnosi s sindikati,
- 4) operativnimi dejavniki, kot so npr. procesne ali proizvodne zmogljivosti in zmožnost zagotavljanja storitev, uspešnost sistema vodenja kakovosti, spremljanje zadovoljstva kupcev,
- 5) dejavniki pri upravljanju organizacije, kot so npr. pravila in postopki za odločanje ali organizacijska struktura.

environment for the operation of the processes (see ISO 9001:2015, 7.1.4), organizational knowledge (see ISO 9001:2015, 7.1.6);

- 3) human aspects such as competence of persons, organizational behaviour and culture, relationships with unions;
- 4) operational factors such as process or production and service provision capabilities, performance of the quality management system, monitoring customer satisfaction;
- 5) factors in the governance of the organization, such as rules and procedures for decision making or organizational structure.

Na strateški ravni se lahko uporabijo orodja, kot sta analiza prednosti, slabosti, priložnosti in tveganj (SWOT) ter analiza političnih, ekonomskih, socioloških, tehnoloških, pravnih in okoljskih dejavnikov (PESTLE). Odvisno od velikosti in kompleksnosti organizacije je lahko uporaben enostaven pristop, kot sta viharjenje možganov (brainstorming) ali zastavljanje vprašanj "kaj če".

4.2 Razumevanje potreb in pričakovanih zainteresiranih strani

Namen te podtočke je zagotoviti, da organizacija upošteva relevantne zahteve relevantnih zainteresiranih strani, ki presegajo tiste od njenih neposrednih odjemalcev. Namen je osredotočiti se samo na tiste relevantne zainteresirane strani, ki lahko vplivajo na zmožnost organizacije, da zagotavlja izdelke in storitve, ki izpolnjujejo zahteve. Čeprav to ni neposredno navedeno v standardu ISO 9001, bi lahko organizacija pred opredelitvijo svojih relevantnih zainteresiranih strani in za pomoč pri tem upoštevala svoja zunanja in notranja vprašanja (glej ISO 9001:2015, točka 4.1).

Seznam relevantnih zainteresiranih strani je lahko edinstven za organizacijo. Organizacija lahko razvije kriterije za opredeljevanje relevantnih zainteresiranih strani, tako da upošteva:

- a) njihov možni vpliv na delovanje ali odločitve organizacije,
- b) njihovo zmožnost ustvarjati tveganja in priložnosti,
- c) njihove možne vplive na trg,
- d) njihovo zmožnost, da s svojimi odločitvami ali aktivnostmi vplivajo na organizacijo.

At the strategic level, tools such as Strengths, Weaknesses, Opportunities and Threats analysis (SWOT) and Political, Economic, Social, Technological, Legal, Environmental analysis (PESTLE) can be used. A simple approach can be useful for organizations dependent on the size and complexity of their operations, such as brainstorming and asking "what if" questions.

4.2 Understanding the needs and expectations of interested parties

The intent of this subclause is to ensure that the organization considers the relevant requirements of relevant interested parties, beyond just those of its direct customers. The intention is to focus on only those relevant interested parties which can have an impact on the organization's ability to provide products and services that meet requirements. While not directly stated in ISO 9001, the organization could consider its external and internal issues (see ISO 9001:2015, 4.1) before, and to assist in, determining its relevant interested parties.

The list of relevant interested parties can be unique to the organization. The organization can develop criteria for determining relevant interested parties by considering their:

- a) possible influence or impact on the organization's performance or decisions;
- b) ability to create risks and opportunities;
- c) possible influences or impact on the market;
- d) ability to affect the organization through their decisions or activities.

1. PRIMER: Primeri zainteresiranih strani, ki jih organizacija lahko šteje za relevantne, med drugim vključujejo:

- odjemalce,
- končne uporabnike ali koristnike,
- partnerje v skupnem podjetju,
- dajalce franšize,
- lastnike intelektualne lastnine,
- matične ali hčerinske organizacije,
- lastnike, delničarje,
- bankirje,
- sindikate,
- zunanje ponudnike,
- zaposlene in druge, ki delajo v imenu organizacije,
- zakonodajne in regulativne organe (lokalne, regionalne, nacionalne ali mednarodne),
- trgovinska in strokovna združenja,
- lokalne skupnosti,
- nevladne organizacije,
- sosednje organizacije,
- konkurente.

Da bi razumeli potrebe in pričakovanja relevantnih zainteresiranih strani, se lahko izvedejo številne aktivnosti in metode. Te vključujejo sodelovanje s tistimi, ki so odgovorni za procese, ali uporabo metod, ki omogočajo zbiranje informacij. Te metode med drugim vključujejo:

- pregledovanje prejetih naročil,
- pregledovanje zahtev zakonodaje in regulative z oddelki za ugotavljanje skladnosti ali pravnimi oddelki,
- lobiranje in mreženje,
- sodelovanje v ustreznih združenjih,
- primerjalne analize,
- tržni nadzor,
- pregledovanje odnosov v dobavnih verigah,
- izvajanje anket odjemalcev ali uporabnikov,
- spremljanje potreb, pričakovanj in zadovoljstva odjemalcev.

2. PRIMER: Primeri zahtev relevantnih zainteresiranih strani med drugim vključujejo:

- zahteve odjemalcev glede skladnosti, cene, razpoložljivosti ali dostave,
- pogodbe, sklenjene z odjemalci ali zunanjimi ponudniki,

EXAMPLE 1 Examples of relevant interested parties that can be considered relevant by an organization include, but are not limited to:

- customers;
- end users or beneficiaries;
- joint venture partners;
- franchisors;
- owners of intellectual property;
- parent and subsidiary organizations;
- owners, shareholders;
- bankers;
- unions;
- external providers;
- employees and others working on behalf of the organization;
- statutory and regulatory authorities (local, regional, national or international);
- trade and professional associations;
- local community groups;
- non-governmental organizations;
- neighbouring organizations;
- competitors.

To understand the needs and expectations of relevant interested parties, several activities and methods can be carried out. They include working with those responsible for the processes or by using methods that allow the gathering of information. Methods include, but are not limited to:

- reviewing orders received;
- reviewing statutory and regulatory requirements with compliance or legal departments;
- lobbying and networking;
- participating in relevant associations;
- benchmarking;
- market surveillance;
- reviewing supply chain relationships;
- conducting customer or user surveys;
- monitoring customer needs, expectations and satisfaction.

EXAMPLE 2 Examples of relevant interested party requirements include, but are not limited to:

- customer requirements regarding conformity, price, availability or delivery;
- contracts which have been entered into with customer or external providers;

- | | |
|---|---|
| <ul style="list-style-type: none"> – industrijske kodekse ravnanja in standarde, – sporazume z lokalnimi skupnostmi ali nevladnimi organizacijami, – zahteve zakonodaje in regulative za izdelke ali storitve, ki jih organizacija zagotavlja, ter tiste, ki vplivajo na njeno zmožnost zagotavljanja teh izdelkov ali storitev, – memorandume o soglasju, – dovoljenja, licence ali druge oblike pooblastil, – ukaze, ki jih izdajo regulativne agencije, – pogodbe, konvencije in protokole, – sporazume z javnimi organi in odjemalci, – načela prostovoljnosti ali kodekse ravnanja, – prostovoljno označevanje ali okoljske zaveze, – obveznosti, izhajajoče iz pogodbenih dogovorov z organizacijo, – politik za zaposlene. | <ul style="list-style-type: none"> – industry codes and standards; – agreements with community groups or non-governmental organizations; – statutory and regulatory requirements for the product or service provided, and those that affect the organization's ability to provide that product or service; – memoranda of understanding; – permits, licenses or other forms of authorization; – orders issued by regulatory agencies; – treaties, conventions and protocols; – agreements with public authorities and customers; – voluntary principles or codes of practice; – voluntary labelling or environmental commitments; – obligations arising under contractual arrangements with the organization; – policies for employees. |
|---|---|

Informacije, ki izhajajo iz teh dejavnosti, naj se upoštevajo pri planiranju sistema vodenja kakovosti (glej ISO 9001:2015, točka 6).

The information resulting from these activities should be considered in planning the quality management system (see ISO 9001:2015, Clause 6).

Organizacija naj se zaveda, da so relevantne zainteresirane strani in njihove relevantne zahteve lahko različne za različne ponujene izdelke in storitve in da se lahko spremenijo zaradi nepredvidenih okoliščin ali namernih odzivov na trgih.

The organization should be aware that the relevant interested parties and their relevant requirements can be different for the different products and services provided, and can change due to unforeseen circumstances or intentional reactions to markets.

Organizacija naj ima vzpostavljene zanesljive sisteme za nadzor in pregled relevantnih zahtev svojih zainteresiranih strani. Nadzorovanje in pregledovanje se lahko izvajata s pomočjo procesov organizacije, povezanih z zahtevami odjemalcev, s snovanjem in razvojem izdelkov in storitev ter (na bolj strateški ravni) med vodstvenim pregledom.

The organization should have robust systems in place to monitor and review the relevant requirements of its interested parties. Monitoring and reviewing can be done by using the organization's processes related to customer requirements, design and development of products and services, and (at a more strategic level) during management review.

4.3 Opredeljevanje področja uporabe sistema vodenja kakovosti

4.3 Determining the scope of the quality management system

Namen te podtočke je opredeliti meje sistema vodenja kakovosti tako, da je določen na tak način, da organizaciji pomaga izpolnjevati zahteve in dosegati predvidene rezultate sistema.

The intent of this subclause is to determine the boundaries of the quality management system so that it is defined in a manner that helps the organization meet requirements and the intended results of the system.

V skladu z ISO 9001:2015, točka 4.3, alineje a) do c), naj se področje uporabe ugotovi na podlagi:

For ISO 9001:2015, 4.3, bullets a) to c), the scope should be established based on:

- a) zunanjih in notranjih vprašanj, opredeljenih z zahtevami ISO 9001:2015, točka 4.1,

- a) the external and internal issues as determined by the requirements of ISO 9001:2015, 4.1;

b) relevantnih zahtev relevantnih zainteresiranih strani (kot so npr. regulatorji, pa tudi odjemalci), opredeljenih v skladu z zahtevami ISO 9001:2015, točka 4.2,

c) izdelkov in storitev, ki jih organizacija zagotavlja.

Pri opredeljevanju področja uporabe naj organizacija vzpostavi tudi meje sistema vodenja kakovosti, s tem ko upošteva vprašanja, kot so npr.:

- infrastruktura organizacije,
- različne lokacije in aktivnosti organizacije,
- trgovinske politike in strategije,
- centralizirane ali od zunaj dobljene funkcije, aktivnosti, procesi, izdelki in storitve.

Vse zahteve iz ISO 9001 se štejejo za veljavne, razen če nimajo učinka na zmožnost organizacije, da zagotavlja izdelek ali storitev, ki izpolnjuje zahteve, oziroma na povečanje zadovoljstva odjemalcev.

Pri opredeljevanju glede uporabnosti zahtev iz standarda ISO 9001 naj organizacija upošteva vsako posamezno zahtevo in ne le odloči, da celotna točka ni uporabna. Včasih so lahko uporabne nekatere zahteve v točki ali pa so uporabne oziroma neuporabne vse zahteve znotraj točke.

Področje uporabe naj se vzdržuje v obliki dokumentiranih informacij. V področje uporabe naj bodo vključeni podatki o izdelkih in storitvah, ki jih zajema. Vključuje naj tudi utemeljitev za vsako zahtevo, ki je opredeljena kot neprimerna. Te dokumentirane informacije se lahko vzdržujejo pri katerikoli metodi, ki jo organizacija opredeli za izpolnjevanje svojih potreb, bodisi ročni ali spletni.

4.4 Sistem vodenja kakovosti in njegovi procesi

4.4.1 Namen te podtočke je zagotoviti, da organizacija opredeli procese, ki so v skladu s standardom ISO 9001 potrebni za njen sistem vodenja kakovosti. To vključuje ne samo procese za proizvodnjo in zagotavljanje storitev, temveč tudi procese, potrebne za uspešno izvajanje sistema, kot so npr. notranja presoja, vodstveni pregled in drugi (vključno s procesi, ki jih izvajajo zunanji ponudniki). Na primer, če organizacija kot potreben opredeli proces za nadzorovanje in merjenje virov, bo moral tak

b) the relevant requirements of relevant interested parties (such as regulators as well as customers) as determined in accordance with the requirements in ISO 9001:2015, 4.2;

c) the products and services provided by the organization.

In determining the scope, the organization should also establish the boundaries of the quality management system by considering such issues as:

- the infrastructure of the organization;
- the organization's different sites and activities;
- commercial policies and strategies;
- centralized or externally provided functions, activities, processes, products and services.

All requirements of ISO 9001 are considered applicable unless they do not have an effect on the organization's ability to provide a product or deliver a service that meets requirements or on its enhancement of customer satisfaction.

In determining the application of requirements in ISO 9001, the organization should consider each individual requirement, and not just decide that a whole clause is not applicable. At times, some of the requirements may be applicable in a clause, or all of the requirements within a clause may, or may not, be applicable.

The scope should be maintained as documented information. The scope should include details of the products and services covered. It should also include justification for any requirements that are determined not to be applicable. This documented information can be maintained in whatever method the organization determines to meet its needs, such as a manual or a website.

4.4 Quality management system and its processes

4.4.1 The intent of this subclause is to ensure that the organization determines the processes needed for its quality management system in accordance with ISO 9001. This includes not only the processes for production and service provision, but also the processes that are needed for the effective implementation of the system, such as internal audit, management review and others (including processes that are performed by external providers). For example, if the organization determines the need for a

proces izpolnjevati zahteve točke 7.1.5 iz ISO 9001:2015. Raven, na kateri je treba procese opredeliti in podrobno opisati, se lahko razlikuje v skladu s kontekstom organizacije in z uporabo razmišljanja na podlagi tveganja – ob upoštevanju obsega vpliva procesa na zmožnost organizacije doseči predvidene rezultate, verjetnosti, da bo pri procesu prišlo do težav, in možnih posledic takih težav.

Proces je niz medsebojno povezanih in medsebojno delujočih aktivnosti, ki uporabljajo vhode za zagotavljanje predvidenih rezultatov. V skladu z ISO 9001:2015, 4.4.1, točke a) do h):

- a) organizacija naj opredeli potrebne vhode v svoje procese in predvidene izhode iz njih; potrebni vhodi za procese naj se obravnavajo z vidika, kaj se zahteva za izvedbo planiranih procesov; pričakovani izhodi naj se obravnavajo z vidika, kaj pričakujejo bodisi odjemalci bodisi nadaljnji procesi; vhodi in izhodi so lahko oprijemljivi (npr. materiali, komponente ali oprema) ali neoprijemljivi (npr. podatki, informacije ali znanje);
- b) pri opredeljevanju zaporedja in interakcij teh procesov naj se upoštevajo povezave z vhodi in izhodi predhodnih in nadaljnjih procesov; metode za zagotavljanje podatkov o zaporedju in interakciji procesov so odvisne od narave organizacije; uporabijo se lahko različne metode, kot je npr. hranjenje oziroma vzdrževanje dokumentiranih informacij (npr. zemljevidi procesov ali diagrami poteka), ali pa enostavnejši pristop, kot je npr. ustna razlaga zaporedja in interakcije procesov;
- c) da bi se organizacija prepričala, ali so procesi uspešni (tj. da dajejo planirane rezultate), naj opredeli kriterije in metode za obvladovanje procesov; kriteriji za nadzorovanje in merjenje so lahko parametri procesov ali specifikacije za izdelke in storitve; kazalniki delovanja naj bodo povezani z nadzorovanjem in merjenjem, lahko pa so povezani tudi s cilji (kriteriji) kakovosti organizacije; druge metode za kazalnike delovanja med drugim vključujejo poročila, grafikone ali rezultate presoje;

process for monitoring and measuring resources, the process will need to meet the requirements of ISO 9001:2015, 7.1.5. The level to which processes need to be determined and detailed can vary according to the context of the organization and the application of risk-based thinking – taking into consideration the extent to which the process affects the organization's ability to achieve its intended results, the likelihood of problems occurring with the process and the potential consequences of such problems.

A process is a set of interrelated or interacting activities that use inputs in order to deliver intended results. For ISO 9001:2015, 4.4.1, bullets a) to h):

- a) the organization should determine the inputs required and the outputs expected from its processes; inputs required for the processes should be considered from the viewpoint of what is required for the implementation of the processes as planned; expected outputs should be considered from the viewpoint of what is expected either by the customers or the subsequent processes; inputs and outputs can be tangible (e.g. materials, components or equipment) or intangible (e.g. data, information or knowledge);
- b) when determining the sequence and interaction of these processes, the links with the inputs and outputs of the previous and subsequent processes should be considered; the methods for providing details of the sequence and interaction of the processes depends on the nature of the organization; different methods can be used, such as retaining or maintaining documented information (e.g. process maps or flow diagrams), or a more simple approach, such as a verbal explanation of the sequence and interaction of the processes;
- c) to make sure that processes are effective (i.e. deliver the planned results), the process control criteria and methods should be determined and applied by the organization; criteria for monitoring and measurement could be process parameters, or specifications for products and services; performance indicators should be related to monitoring and measurement, or can be related to the organization's quality objectives (criteria); other methods for performance indicators include, but are not limited to, reports, charts or the results of audits;