
Sistemi kakovosti - Model zagotavljanja kakovosti v proizvodnji, vgradnji in servisiranju (identičen z ISO 9002:1994)

Quality systems - Model for quality assurance in production, installation and servicing

Systèmes qualité - Modèle pour l'assurance de la qualité en production, installation et prestations associées

Qualitätsmanagementssysteme - Modell zur Darlegung des Qualitätsmanagementsystems in Produktion, Montage und Wartung

SIST ISO 9002:1995
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Deskriptorji: zagotavljanje kakovosti, program zagotavljanja kakovosti, sistemi zagotavljanja kakovosti, proizvodnja, vgradnja, poprodajne storitve, referenčni modeli

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UVOD

Standard SIST ISO 9002, Sistemi kakovosti - Model zagotavljanja kakovosti v proizvodnji, vgradnji in servisiranju, druga izdaja, 1995, ima status slovenskega standarda in je identičen mednarodnemu standardu ISO 9002, Quality systems - Model for quality assurance in production, installation and servicing, second edition, 1994-07-01.

NACIONALNI PREGOVOR

Mednarodni standard ISO 9002:1994 je pripravil tehnični odbor Mednarodne organizacije za standardizacijo ISO/TC 176 Vodenje kakovosti in zagotavljanje kakovosti. Slovenski standard SIST ISO 9002:1995 je prevod angleškega besedila mednarodnega standarda ISO 9002:1994. V primeru spora glede besedila slovenskega prevoda v tem standardu je odločilen izvirni mednarodni standard v angleškem jeziku. Slovensko-angleško izdajo standarda je pripravil tehnični odbor USM/TC QAS Zagotavljanje kakovosti.

Ta slovenski standard je dne 1995-06-23 odobril direktor USM.

ZVEZE S STANDARDI

S prevzemom tega mednarodnega standarda veljajo naslednje zveze:

SIST ISO 8402:-* idt ISO 8402:1994

SIST ISO 9000-1:-* idt ISO 9000-1:1994

SIST ISO 9001:1995 idt ISO 9001:1994

SIST ISO 9003:1995 idt ISO 9003:1994

SIST ISO 9004-1:-* idt ISO 9004-1:1994

Oznake in naslovi navedenih slovenskih standardov so:

SIST ISO 8402:-*	Vodenje kakovosti in zagotavljanje kakovosti - Slovar (identičen z ISO 8402:1994)
SIST ISO 9000-1:-*	Standardi za vodenje in zagotavljanje kakovosti - 1. del: Smernice za izbiro in uporabo (identičen z ISO 9000-1:1994)
SIST ISO 9001:1995	Sistemi kakovosti - Model zagotavljanja kakovosti v razvoju, proizvodnji, vgradnji in servisiranju (identičen z ISO 9001:1994)
SIST ISO 9003:1995	Sistemi kakovosti - Model zagotavljanja kakovosti v končni kontroli in preskušanju (identičen z ISO 9003:1994)
SIST ISO 9004-1:-*	Vodenje kakovosti in elementi sistema kakovosti - Smernice (identičen z ISO 9004-1:1994)

PREDHODNE IZDAJE

- SLS ISO 9002:1992

* V pripravi.

OSNOVA ZA IZDAJO STANDARDARDA

- Prevzem standarda ISO 9002:1994, druga izdaja

OPOMBE:

- Povsod, kjer se v besedilu standarda uporablja izraz mednarodni standard , pomeni to v SIST ISO 9002:1995 slovenski standard .
- Uvod in nacionalni predgovor nista sestavni del standarda.
- Povsod, kjer se v angleškem besedilu uporabljata besedi design in development , je to v slovenskem besedilu standarda prevedeno kot razvoj .
- Slovenski standard SIST ISO 9002:1995 je identičen tudi EN ISO 9002:1994.

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PREDGOVOR

ISO (Mednarodna organizacija za standardizacijo) je svetovna zveza nacionalnih organov za standarde (članov ISO). Mednarodne standarde običajno pripravljajo tehnični odbori ISO. Vsak član, ki želi delovati na določenem področju, za katero je 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, ki jih sprejmejo tehnični odbori, se pošljejo vsem članicam v glasovanje. Za objavo mednarodnega standarda je treba pridobiti soglasje najmanj 75 odstotkov članic, ki se udeležijo glasovanja.

Mednarodni standard ISO 9002 je pripravil tehnični odbor ISO/TC 176 Vodenje kakovosti in zagotavljanje kakovosti, pododbor SC 2 Sistemi kakovosti.

Ta, druga izdaja preklicuje in zamenjuje prvo (ISO 9002:1987), ki je bila tehnično predelana.

Dodatek A tega mednarodnega standarda je podan samo kot informacija.

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.

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.

International Standard ISO 9002 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This second edition cancels and replaces the first edition (ISO 9002:1987), which has been technically revised.

Annex A of this International Standard is for information only.

UVOD

Ta mednarodni standard je eden od treh mednarodnih standardov, ki obravnavajo zahteve za sistem kakovosti in se lahko uporabljajo za zagotavljanje kakovosti navzven. Modeli zagotavljanja kakovosti, opisani v treh spodaj navedenih mednarodnih standardih, predstavljajo tri različne oblike zahtev za sistem kakovosti, ki so primerne tako, kadar dobavitelj želi dokazati svojo sposobnost, kot tudi, kadar želi sposobnosti dobavitelja oceniti zunanja stranka.

- a) ISO 9001, Sistemi kakovosti - Model zagotavljanja kakovosti v razvoju, proizvodnji, vgradnji in servisiranju

Uporablja se, kadar mora dobavitelj zagotoviti skladnost s specificiranimi zahtevami v razvoju, proizvodnji, vgradnji in servisiranju.

- b) ISO 9002, Sistemi kakovosti - Model zagotavljanja kakovosti v proizvodnji, vgradnji in servisiranju

Uporablja se, kadar mora dobavitelj zagotoviti skladnost s specificiranimi zahtevami v proizvodnji, vgradnji in servisiranju.

- c) ISO 9003, Sistemi kakovosti - Model zagotavljanja kakovosti v končni kontroli in preskušanju

Uporablja se, kadar mora dobavitelj zagotoviti skladnost s specificiranimi zahtevami samo v končni kontroli in preskušanju.

Poudariti je treba, da so zahteve za sistem kakovosti, specificirane v tem mednarodnem standardu in v standardih ISO 9001 in ISO 9003, samo dopolnilo (ne zamenjava) tehničnim zahtevam (za proizvod). Podrobno specificirajo zahteve, ki določajo, katere elemente morajo vsebovati sistemi kakovosti, pri čemer ti mednarodni standardi nimajo namena vsiljevati enoličnosti sistemov kakovosti. Ti standardi so splošni in

INTRODUCTION

This International Standard is one of three International Standards dealing with quality system requirements that can be used for external quality assurance purposes. The quality assurance models, set out in the three International Standards listed below, represent three distinct forms of quality system requirements suitable for the purpose of a supplier demonstrating its capability, and for the assessment of the capability of a supplier by external parties.

- a) ISO 9001, Quality systems - Model for quality assurance in design, development, production, installation and servicing

- for use when conformance to specified requirements is to be assured by the supplier during design, development, production, installation and servicing.

- b) ISO 9002, Quality systems - Model for quality assurance in production, installation and servicing

- for use when conformance to specified requirements is to be assured by the supplier during production, installation and servicing.

- c) ISO 9003, Quality systems - Model for quality assurance in final inspection and test

- for use when conformance to specified requirements is to be assured by the supplier solely at final inspection and test.

It is emphasized that the quality system requirements specified in this International Standard, ISO 9001 and ISO 9003 are complementary (not alternative) to the technical (product) specified requirements. They specify requirements which determine what elements quality systems have to encompass, but it is not the purpose of these International Standards to enforce uniformity of quality systems. They are

neodvisni od katerekoli specifične industrije ali gospodarskega sektorja. Na razvoj in izvedbo sistema kakovosti bodo vplivale različne potrebe organizacije, njeni posebni cilji, vrste proizvodov in storitev ter uporabljeni procesi in specifični postopki izvajanja.

Namen je, da se ti mednarodni standardi uporabljajo v izvorni obliki, vendar se v posebnih primerih z dodajanjem ali odvzemanjem določenih zahtev za sistem kakovosti lahko prilagodijo specifičnim pogodbenim situacijam. Vodila za take prilagoditve kakor tudi navodila za izbiro ustreznega modela zagotavljanja kakovosti, to je izbiro standarda ISO 9001, ISO 9002 ali ISO 9003, vsebuje standard ISO 9000-1.

generic and independent of any specific industry or economic sector. The design and implementation of a quality system will be influenced by the varying needs of an organization, its particular objectives, the products and services supplied, and the processes and specific practices employed.

It is intended that these International Standards will be adopted in their present form, but on occasions they may need to be tailored by adding or deleting certain quality system requirements for specific contractual situations. ISO 9000-1 provides guidance on such tailoring as well as on selection of the appropriate quality assurance model, viz ISO9001, ISO 9002 or ISO 9003.

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Sistemi kakovosti - Model zagotavljanja kakovosti v proizvodnji, vgradnji in servisiranju

1 Predmet

Ta mednarodni standard specificira zahteve za sistem kakovosti. Uporablja se, kadar mora dobavitelj dokazati sposobnost, da dobavlja že v razvoju osvojen proizvod.

Navedene zahteve so namenjene predvsem doseganju zadovoljstva odjemalca tako, da se neskladnosti preprečujejo v vseh fazah od proizvodnje do servisiranja.

Ta mednarodni standard se uporablja:

- a) ko so zahtevane lastnosti proizvoda izražene z že sprejeto dokumentacijo razvoja ali specifikacijo in
- b) kadar je mogoče doseči zaupanje v skladnost proizvoda s primernim prikazom zmožnosti dobavitelja v proizvodnji, vgradnji in servisiranju.

Opomba 1: Informativne reference glej v dodatku A.

2 Zveza z drugimi standardi

Spodaj navedeni standard vsebuje določila, ki v povezavi s tem besedilom tvorijo določila tega mednarodnega standarda. V času objave je bila veljavna spodaj navedena izdaja. Vsi standardi se revidirajo in strankam, ki sklenejo pogodbo, zasnovano na tem mednarodnem standardu, se priporoča, naj raziščejo možnost uporabe najnovejše izdaje spodaj navedenega standarda. Člani IEC in ISO vzdržujejo register veljavnih mednarodnih standardov.

ISO 8402:1994, *Vodenje kakovosti in zagotavljanje kakovosti - Slovar*

Quality systems - Model for quality assurance in production, installation and servicing

1 Scope

This International Standard specifies quality system requirements for use where a supplier's capability to supply conforming product to an established design needs to be demonstrated.

The requirements specified are aimed primarily at achieving customer satisfaction by preventing nonconformity at all stages from production through to servicing.

This International Standard is applicable in situations when

- a) the specified requirements for product are stated in terms of an established design or specification, and
- b) confidence in product conformance can be attained by adequate demonstration of a supplier's capabilities in production, installation and servicing.

NOTE 1 For informative references, see annex A.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1994, *Quality management and quality assurance - Vocabulary*

3 Definicije

V tem mednarodnem standardu se uporabljajo definicije, podane v standardu ISO 8402, in naslednje definicije:

3.1 Proizvod: Rezultat aktivnosti ali procesov.

Opombe: 2 Proizvod je lahko storitev, strojna oprema, predelani materiali, programska oprema ali njihova kombinacija.

3 Proizvod je lahko materialen (na primer sestavi ali predelani materiali) ali nematerialen (na primer znanje ali zamisli) ali kombinacija obeh.

4 V tem mednarodnem standardu se izraz proizvod nanaša samo na namerni ponujeni proizvod, ki se nudi, in ne na nenamerne "stranske" proizvode, ki vplivajo na okolje. V tem je razlika v primerjavi z definicijo proizvoda, podano v standardu ISO 8402.

3.2 Ponudba na razpis (tender): Ponudba, ki jo pripravi dobavitelj kot odgovor na povabilo za izpolnitev pogodbenih zahtev za dobavo proizvoda.

3.3 Pogodba: Dogovorjene zahteve med dobaviteljem in odjemalcem, sporočene na kakršenkoli način.

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8402 and the following definitions apply.

3.1 product: Result of activities or processes.

NOTES 2 A product may include service, hardware, processed materials, software or a combination thereof.

3 A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.

4 For the purposes of this International Standard, the term product applies to the intended product offering only and not to unintended by-products affecting the environment. This differs from the definition given in ISO 8402.

3.2 tender: Offer made by a supplier in response to an invitation to satisfy a contract award to provide product.

3.3 contract: Agreed requirements between a supplier and customer transmitted by any means.

4 Zahteve za sistem kakovosti

4.1 Odgovornost vodstva

4.1.1 Politika kakovosti

Vodstvo dobavitelja z izvršilno odgovornostjo mora določiti in dokumentirati svojo politiko kakovosti, vključno s cilji kakovosti in s svojo zavezanostjo za kakovost. Politika kakovosti mora biti primerna dobaviteljevim organizacijskim ciljem ter pričakovanjem in potrebam njegovih odjemalcev. Dobavitelj mora zagotoviti, da politiko kakovosti razumejo, izvajajo in vzdržujejo na vseh ravneh organizacije.

4 Quality system requirements

4.1 Management responsibility

4.1.1 Quality policy

The supplier's management with executive responsibility shall define and document its policy for quality, including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organizational goals and the expectations and needs of its customers. The supplier shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

4.1.2 Organizacija

4.1.2.1 Odgovornosti in pooblastila

Odgovornosti, pooblastila in medsebojni odnos osebja, ki vodi, izvaja in overja delo, ki vpliva na kakovost, morajo biti določeni in dokumentirani, še posebej za tisto osebje, ki potrebuje organizacijsko svobodo in pooblastila za:

- a) uvajanje ukrepov, s katerimi se preprečuje pojavljanje neskladnosti pri proizvodih, v procesih in v sistemih kakovosti;
- b) identificiranje in zapisovanje vseh problemov, povezanih s proizvodom, procesom in sistemom kakovosti;
- c) uvajanje, priporočanje ali omogočanje izvedbe rešitev po ustaljenih poteh;
- d) overjanje izvajanja rešitev;
- e) nadzor nadaljnje obdelave, dostave ali vgradnje neskladnega proizvoda, dokler pomanjkljivost ali nezadovoljivo stanje ni odpravljeno.

4.1.2.2 Viri

Dobavitelj mora identificirati zahteve v zvezi z viri in zagotoviti primerno vire, vključno z imenovanjem usposobljenega osebja (glej 4.18) za vodenje, izvajanje dela in overitvene aktivnosti, vključno z notranjimi presojami kakovosti.

4.1.2.3 Predstavniki vodstva

Dobaviteljevo vodstvo z izvršilno odgovornostjo mora imenovati člana dobaviteljevega lastnega vodstva, ki mora imeti ne glede na druge odgovornosti določena pooblastila za:

- a) zagotavljanje, da je sistem kakovosti vzpostavljen, da se izvaja in vzdržuje v skladu s tem mednarodnim standardom, in
- b) poročanje o delovanju sistema kakovosti dobaviteljevemu vodstvu za pregled in kot osnovo za izboljšanje sistema kakovosti.

4.1.2 Organization

4.1.2.1 Responsibility and authority

The responsibility, authority and the interrelation of personnel who manage, perform and verify work affecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to:

- a) initiate action to prevent the occurrence of any nonconformities relating to the product, process and quality system;
- b) identify and record any problems relating to the product, process and quality system;
- c) initiate, recommend or provide solutions through designated channels;
- d) verify the implementation of solutions;
- e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

4.1.2.2 Resources

The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18), for management, performance of work and verification activities including internal quality audits.

4.1.2.3 Management representative

The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for

- a) ensuring that a quality system is established, implemented and maintained in accordance with this International Standard, and
- b) reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system.

Opomba 5: Odgovornost predstavnika vodstva lahko vključuje tudi sodelovanje z zunanjimi strankami v zadevah, povezanih z dobaviteljevim sistemom kakovosti.

NOTE 5 The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system.

4.1.3 Pregled s strani vodstva

Dobaviteljevo vodstvo z izvršilno odgovornostjo mora pregledovati sistem kakovosti v določenih časovnih presledkih, zadostnih da sta zagotovljeni stalna ustreznost in učinkovitost v izpolnjevanju zahtev tega mednarodnega standarda ter izraženi politika in cilji kakovosti dobavitelja (glej 4.1.1). Vzdrževati se morajo zapisi o pregledih (glej 4.16).

4.1.3 Management review

The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the supplier's stated quality policy and objectives (see 4.1.1). Records of such reviews shall be maintained (see 4.16).

4.2 Sistem kakovosti

4.2 Quality system

4.2.1 Splošno

Dobavitelj mora vzpostaviti, dokumentirati in vzdrževati sistem kakovosti, s katerim zagotavlja, da je proizvod skladen s specificiranimi zahtevami. Dobavitelj mora izdelati poslovnik kakovosti, ki pokriva zahteve tega mednarodnega standarda. Poslovnik kakovosti mora vsebovati postopke sistema kakovosti ali se nanje sklicevati in povzeti strukturo dokumentacije, ki se uporablja v sistemu kakovosti.

4.2.1 General

The supplier shall establish, document and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

Opomba 6: Napotki za poslovnik kakovosti so podani v standardu ISO 10013.

NOTE 6 Guidance on quality manuals is given in ISO 10013.

4.2.2 Postopki sistema kakovosti

4.2.2 Quality system procedures

Dobavitelj mora:

The supplier shall

- a) izdelati dokumentirane postopke, skladne z zahtevami tega mednarodnega standarda in izraženo politiko kakovosti dobavitelja, in
- b) učinkovito izvajati sistem kakovosti in njegove dokumentirane postopke.

- a) prepare documented procedures consistent with the requirements of this International Standard and the supplier's stated quality policy, and
- b) effectively implement the quality system and its documented procedures.

Za namene tega mednarodnega standarda morajo biti obseg in podrobnosti postopkov, ki so sestavni del sistema kakovosti, odvisni od zahtevnosti dela in uporabljenih metod ter od potrebnih veščin in usposobljenosti osebja, ki aktivnosti izvaja.

For the purposes of this International Standard, the range and detail of the procedures that form part of the quality system shall be dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity.

Opomba 7: V pisnih postopkih se lahko sklicuje na navodila za delo, ki določajo, kako se aktivnost izvede.

NOTE 7 Documented procedures may make reference to work instructions that define how an activity is performed.

4.2.3 Planiranje kakovosti

Dobavitelj mora opredeliti in dokumentirati, kako bodo zahteve za kakovost izpolnjene. Planiranje kakovosti mora biti usklajeno z vsemi drugimi zahtevami dobaviteljevega sistema kakovosti in mora biti dokumentirano v obliki, primerni dobaviteljevemu načinu dela.

Dobavitelj mora pri izpolnjevanju specificiranih zahtev za proizvode, projekte ali pogodbe upoštevati naslednje dejavnosti, če je to primerno:

- a) pripravo planov kakovosti;
- b) identifikacijo potreb in preskrbo krmilne opreme, procesov, opreme (vključno s kontrolno in preskusno opremo), pripomočkov, virov in veščin, ki bi lahko bile potrebne za doseganje zahtevane kakovosti;
- c) zagotavljanje usklajenosti razvoja, proizvodnega procesa, vgradnje, servisiranja, postopkov kontroliranja in preskušanja ter uporabljene dokumentacije;
- d) potrebno posodabljanje metod obvladovanja kakovosti ter tehnik kontroliranja in preskušanja, vključno z razvojem novih orodij;
- e) pravočasno identifikacijo vseh zahtev za merjenja, ki presegajo obstoječe možnosti in za katera je potreben določen čas za razvoj;
- f) identifikacijo ustreznih overjanj na primernih stopnjah v izvedbi proizvoda;
- g) razčiščevanje kriterijev sprejemljivosti za vse značilnosti in zahteve, vključno s takimi, ki vsebujejo subjektivne elemente;
- h) identifikacija in priprava zapisov o kakovosti (glej 4.16).

Opomba 8: Na omenjene plane kakovosti [glej 4.2.3 a)] se lahko sklicuje v ustreznih dokumentiranih postopkih, ki tvorijo celoto dobaviteljevega sistema kakovosti.

4.2.3 Quality planning

The supplier shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation.

The supplier shall give consideration to the following activities, as appropriate, in meeting the specified requirements for products, projects or contracts:

- a) the preparation of quality plans;
- b) the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required quality;
- c) ensuring the compatibility of the production process, installation, servicing, inspection and test procedures and the applicable documentation;
- d) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation;
- e) the identification of any measurement requirement involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed;
- f) the identification of suitable verification at appropriate stages in the realization of product;
- g) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;
- h) the identification and preparation of quality records (see 4.16).

NOTE 8 The quality plans referred to [see 4.2.3a)] may be in the form of a reference to the appropriate documented procedures that form an integral part of the supplier's quality system.