SLOVENSKI STANDARD

SIST ISO 10013

druga izdaja
avgust 1997

Smernice za izdelavo poslovnikov kakovosti (istoveten ISO 10013:1995)

Guidelines for developing quality manuals

Lignes directrices pour l'élaboration des manuels qualité

Leitfaden für das Erstellen von Qualitätsmanagement-Handbüchern

Deskriptorji: kakovost, vodenje kakovosti, zagotavljanje kakovosti, sistemi zagotavljanja kakovosti, dokumenti, priročniki, priprava, splošni pogoji

ICS 03.120.10

Referenčna številka
SIST ISO 10013:1997 (sl,en)

Nadaljevanje na straneh od 2 do 28

UVOD

Standard SIST ISO 10013 (sl,en), Smernice za izdelavo poslovnikov kakovosti, druga izdaja, 1997, ima status slovenskega standarda in je istoveten mednarodnemu standardu ISO 10013, Guidelines for developing quality manuals, prva izdaja, 1995.

NACIONALNI PREDGOVOR

Mednarodni standard ISO 10013:1995 je pripravil tehnični odbor Mednarodne organizacije za standardizacijo ISO/TC 176 Vodenje in zagotavljanje kakovosti. Slovenski standard SIST ISO 10013:1997, druga izdaja, je prevod angleškega besedila mednarodnega standarda ISO 10013:1995, First edition. 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 VZK Vodenje in zagotavljanje kakovosti.

Ta slovenski standard je dne 1997-07-02 odobril direktor USM.

ZVEZE S STANDARDI

SIST EN ISO 8402:1997 (sl,en,de,fr) Vodenje in zagotavljanje kakovosti - Slovar

PREDHODNE IZDAJE

- SIST ISO 10013:1996 (en)

OSNOVA ZA IZDAJO STANDARDA

- Prevzem standarda ISO 10013:1995

OPOMBE

- Povsod, kjer se v besedilu standarda uporablja izraz mednarodni standard , v SIST ISO 10013:1997 to pomeni slovenski standard .

- Uvod in nacionalni predgovor nista sestavni del standarda.

- Slovenski standard SIST ISO 10013:1997 je istoveten standardu ISO 10013:1995.

VSEBINA **Stran**

Predgovor 4
Uvod 5
1 Predmet standarda 6
2 Zveza z drugimi standardi 6
3 Definicije 6
4 Dokumentacija sistemov kakovosti 7
5 Proces izdelave poslovnika kakovosti 10
6 Proces odobritve, izdaje in nadzora poslovnika kakovosti 12
7 Kaj vključiti v poslovnik kakovosti 13
Dodatki
A Značilna hierarhija dokumentov sistema kakovosti 20
B Primer oblike poglavja iz poslovnika kakovosti 22
C Primer poglavja v poslovniku kakovosti 24
D Bibliografija 28

Contents **Page**

Foreword 4
Introduction 5
1 Scope 6
2 Normative reference 6
3 Definitions 6
4 Documentation of quality systems 7
5 Process of preparing a quality manual 10
6 Process of quality manual approval, issue and control 12
7 What to include in a quality manual 13
Annexes
A Typical quality system document hiearchy 21
B Example of possible format for a section of quality manual 23
C Example of section of a quality manual 26
D Bibliography 28

PREDGOVOR

ISO (Mednarodna organizacija za standardizacijo) je svetovna zveza nacionalnih organov za standarde (članov ISO). Mednarodne standarde ponavadi pripravljajo tehnični odbori ISO. Vsak član, ki želi sodelovati 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 10013 je pripravil tehnični odbor ISO/TC 176, *Vodenje in zagotavljanje kakovosti*, pododbor SC 3, *Podporne tehnologije*.

Dodatki A, B, C in D tega mednarodnega standarda služijo samo za informacijo.

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 10013 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC, *Supporting technologies*.

Annexes A, B, C and D of this International Standard are for the information only.

UVOD

Skupina mednarodnih standardov ISO 9000 vključuje zahteve za sisteme kakovosti, ki se lahko uporabijo za doseganje enotne razlage, razvoja, izvedbe in uporabe vodenja kakovosti in zagotavljanja kakovosti.

Skupina mednarodnih standardov ISO 9000 zahteva razvoj in izvedbo dokumentiranih sistemov kakovosti, vključno s pripravo poslovnikov kakovosti.

ISO 8402:1994, *Vodenje in zagotavljanje kakovosti - Slovar* določa poslovnik kakovosti kot dokument, ki podaja politiko kakovosti in opisuje sistem kakovosti v organizaciji. Lahko se nanaša na vse aktivnosti v organizaciji ali na izbrani del teh aktivnosti, na primer na specificirane zahteve v odvisnosti od narave proizvodov ali storitev, procesov, pogodbenih zahtev, upravnih predpisov ali na samo organizacijo.

Pomembno je, da se zahteve in vsebina sistema kakovosti in poslovnika kakovosti nanašajo na tisti standard kakovosti, ki naj bi ga zadovoljile. Ta mednarodni standard določa smernice za izdelavo takšnega sistema kakovosti.

INTRODUCTION

The ISO 9000 family of International Standards includes requirements for quality systems which can be used to achieve common interpretation, development, implementation and application of quality management and quality assurance.

The ISO 9000 family of International Standards requires the development and implementation of documented quality systems, including the preparation of quality manuals.

ISO 8402:1994, *Quality management and quality assurance - Vocabulary*, defines a quality manual as a document stating the quality policy and describing the quality system of an organization. This may relate to an organization's total activities or to a selected part of those activities; for example, specified requirements depending upon the nature of products or services, processes, contractual requirements, governing regulations or the organization itself.

It is important that the requirements and content of the quality system and quality manual address the quality standard they are intended to satisfy. This International Standard provides guidelines for developing such quality system.

Smernice za izdelavo poslovnikov kakovosti

1 Predmet standarda

Ta mednarodni standard določa smernice za izdelavo, pripravo in nadzor nad poslovniki kakovosti, ki so prikrojeni posebnim potrebam uporabnika. Tako izdelani poslovniki kakovosti bodo odražali dokumentirane postopke sistema kakovosti, ki jih zahteva skupina mednarodnih standardov ISO 9000. Ta mednarodni standard ne obravnava podrobnih delovnih navodil, planov kakovosti, brošur in drugih dokumentov, ki se nanašajo na sistem kakovosti. (Glej dodatek A, nivo C)

Opomba 1: Ta mednarodni standard se lahko uporabi za izdelavo poslovnikov kakovosti, ki se nanašajo na druge standarde za sisteme kakovosti in ne le na skupino ISO 9000.

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 običajno revidirajo. Strankam, ki sklenejo pogodbo, zasnovano na tem mednarodnem standardu, se priporoča, da raziščejo možnost uporabe najnovejše izdaje spodaj navedenega standarda. Člani IEC in ISO vzdržujejo register veljavnih mednarodnih standardov.

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

3 Definicije

V tem mednarodnem standardu se uporabljajo definicije, podane v standardu ISO 8402.

Guidelines for developing quality manuals

1 Scope

This International Standard provides guidelines for the development, preparation and control of quality manuals tailored to the specific needs of the user. The resultant quality manuals will reflect documented quality system procedures required by the ISO 9000 family of International Standards. Detailed work instructions, quality plans, brochures and other quality system related documents are not covered by this International Standard. (See annex A, level C.)

NOTE 1 This International Standard may be used to develop quality manuals relating to quality system standards other than the ISO 9000 family.

2 Normative references

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 Definitions

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

4 Dokumentacija sistemov kakovosti

Dodatek A prikazuje tipično hierarhijo dokumentacije sistema kakovosti. Vrstni red izdelave te hierarhije v posamezni organizaciji je odvisen od razmer v organizaciji, vendar se ponavadi začne z določitvijo njene politike kakovosti in ciljev.

4.1 Dokumentirani postopki sistema kakovosti

Dokumentirani postopki sistema kakovosti naj tvorijo osnovno dokumentacijo, ki se uporablja za celotno planiranje in administriranje aktivnosti, ki vplivajo na kakovost. V skladu s standardi skupine ISO 9000 naj ti dokumentirani postopki obravnavajo vse primerne elemente standarda za sistem kakovosti. Opisujejo naj (tako podrobno, kot je potrebno za ustrezen nadzor obravnavanih aktivnosti) odgovornosti, pooblastila in medsebojne povezave osebja, ki vodi, izvaja, preverja ali pregleduje delo, ki vpliva na kakovost; način izvedbe različnih aktivnosti; dokumentacijo, ki naj bo uporabljena, in nadzor, ki naj bo izveden. (Glej dodatek A)

4.1.1 Vsebina postopkov

Vsak dokumentiran postopek naj obravnava logično ločljiv del sistema kakovosti, kot na primer celoten element sistema kakovosti ali le njegov del, ali zaporedje medsebojno povezanih aktivnosti, ki jih povezuje več kot en element sistema kakovosti. Število dokumentiranih postopkov, obseg vsakega izmed njih ter njihovo obliko in vrsto predstavitve določi uporabnik tega mednarodnega standarda. Vse navedeno ponavadi odraža kompleksnost procesa, organizacije in vrste poslovanja. Dokumentirani postopki sistema kakovosti naj praviloma ne vsebujejo popolnoma tehničnih podrobnosti take vrste, ki so ponavadi dokumentirane v podrobnih delovnih navodilih.

4 Documentation of quality systems

Annex A describes a typical quality system documentation hierarchy. The order of development of this hierarchy in an individual organization is dependent on that organization's circumstances, but usually starts with development of the organization's quality policy and objectives.

4.1 Documented quality system procedures

Documented quality system procedures should form the basic documentation used for the overall planning and administration of activities which impact on quality. In accordance with the ISO 9000 family, these documented procedures should cover all applicable elements of the quality system standard. They should describe (to the degree of detail required for adequate control of the activities concerned) the responsibilities, authorities and interrelationships of the personnel who manage, perform, verify or review work affecting quality, how the different activities are to be performed, the documentation to be used and the controls to be applied. (See annex A.)

4.1.1 Procedural scope

Each documented procedure should cover a logically separable part of the quality system, such as a complete quality system element or part thereof, or a sequence of interrelated activities connected with more than one quality system element. The quantity of documented procedures, the volume of each and the nature of their format and presentation are to be determined by the user of this International Standard; each usually reflects the complexity of the facility, organization and nature of business. Documented quality system procedures should not, as a rule, enter into purely technical details of the type normally documented in detailed work instructions.

4.1.2 Dosleden pristop

Z uporabo vedno enake oblike in zgradbe dokumentiranih postopkov bodo uporabniki spoznali dosleden pristop, uporabljen pri vsaki zahtevi, in tako povečali verjetnost sistematične skladnosti s standardom.

4.1.2 Consistent approach

By arranging each documented procedure in the same structure and format, the users will become familiar with the consistent approach applied to each requirement and so improve the likelihood of systematic compliance with the standard.

4.2 Poslovniki kakovosti

Poslovnik kakovosti naj vsebuje oziroma se sklicuje na dokumentirane postopke sistema kakovosti, ki so namenjeni za celotno planiranje in administriranje aktivnosti, ki vplivajo na kakovost v organizaciji. Poslovnik kakovosti naj obravnava vse primerne elemente tistega standarda za sistem kakovosti, ki je zahtevan za organizacijo. Do primerne podrobnosti naj opisuje nadzorne vidike, ki so zapisani v podpoglavju 4.1. V nekaterih okoliščinah so lahko določeni deli poslovnika kakovosti popolnoma enaki pripadajočim dokumentiranim postopkom sistema kakovosti. Vsekakor je ponavadi potrebna določena stopnja prikrojitve, da se izberejo samo primerni dokumentirani postopki (ali njihovi deli) za specifične namene poslovnika kakovosti, ki se izdeluje. Vsebina poslovnikov kakovosti je podrobno opisana v poglavju 7. Po potrebi naj se poslovniku kakovosti dodajo dokumentirani postopki ali naj se sklicujejo na dokumentirane postopke, ki so povezani s sistemom kakovosti in kljub temu, da so nujni za primerno obvladovanje aktivnosti, niso vključeni v izbranem standardu za sistem kakovosti. (Glej dodatek B)

Opomba 2: Organizacija se lahko sama odloči o uporabi zaupnih poslovnih informacij.

4.2 Quality manuals

A quality manual should consist of, or refer to, the documented quality system procedures intended for the overall planning and administration of activities which impact on quality within organization. A quality manual should cover all the applicable elements of the quality system standard required for an organization. It should describe, in adequate detail, the same control aspects mentioned in subclause 4.1. In some situations, the related documented quality system procedures and some sections of the quality manual may be identical. However, some degree of tailoring is usually required to ensure that only appropriate documented procedures (or sections thereof) are selected for the specific purposes of the quality manual being developed. The contents of quality manuals are addressed in detail in clause 7. Documented procedures related to the quality system, not dealt with in the selected quality system standard but necessary for the adequate control of the activities, should be added to the quality manual or be referenced as necessary. (See annex B.)

NOTE 2 Inclusion of proprietary information is at the discretion of organization.

4.2.1 Namen poslovnikov kakovosti

Poslovnike kakovosti lahko organizacija izdela in uporabi za namene, ki vključujejo naslednje, niso pa na to omejeni:

a) sporočanje politike kakovosti organizacije

b) opisovanje in izvedbo učinkovitega sistema kakovosti

4.2.1 Purposes of quality manuals

Quality manuals may be developed and used by an organization for purposes including, but not limited to, the following:

a) communicating the organization's quality policy;

b) describing and implementing an effective quality system;

c) zagotavljanje obvladovanja izboljšav v praksi in pospeševanje aktivnosti za zagotavljanje kakovosti

d) zagotavljanje dokumentirane osnove za presojo sistema kakovosti

e) zagotavljanje stalnosti sistema kakovosti in njegovih zahtev tudi v spreminjajočih se razmerah,

f) usposabljanje osebja s področja zahtev sistema kakovosti in metod za skladnost

g) predstavitev sistema kakovosti za zunanje namene, kot na primer dokazovanje skladnosti z ISO 9001, 9002 ali 9003

h) dokazovanje skladnosti sistema kakovosti z zahtevami kakovosti v pogodbenih razmerah.

c) providing improvement control of practices and facilitating assurance activities;

d) providing the documented bases for auditing the quality system;

e) providing continuity of quality system and its requirements during changing circumstances;

f) training personnel in the quality system requirements and methods of compliance;

g) presenting the quality system for external purposes, such as demonstrating compliance with ISO 9001, 9002 or 9003;

h) demonstrating compliance of the quality system with quality requirements in contractual situations.

4.2.2 Zgradba in oblika

Čeprav struktura poslovnika kakovosti ni predpisana, naj le-ta natančno, popolno in jedrnato izraža politiko kakovosti, cilje in določa glavne dokumentirane postopke v organizaciji (glej poglavje 6). Ena izmed metod, ki zagotavlja, da je določena tema primerno obravnavana in umeščena, je prilagoditev poglavij v poslovniku kakovosti elementom kakovosti glavnega standarda za sistem kakovosti. Enako sprejemljivi so tudi drugi pristopi, kot na primer takšno strukturiranje poslovnika, ki odraža naravo organizacije.

Opomba 3: Zaradi jasnosti sistema in njegovega ocenjevanja naj bo razloženo vsako namerno izpuščanje kateregakoli elementa sistema kakovosti iz poslovnika kakovosti v primerjavi z glavnim standardom za sistem kakovosti.

4.2.2 Structure and format

Although there is no required structure for quality manual, it should convey accurately, completely and concisely the quality policy, objectives and governing documented procedures of the organization (see clause 6). One of the methods of assuring that the subject matter is adequately addressed and located would be to key the sections of the quality manual to the quality elements of the governing quality system standard. Other approaches, such as structuring the manual to reflect the nature of the organization, are equally acceptable.

NOTE 3 For system clarity and assessment purposes, the intentional omission of any quality system element from the quality manual compared to the governing quality system standard should be explained.

4.2.3 Izvor poslovnika kakovosti

Poslovnik kakovosti je lahko:

a) neposredno sestavljen iz dokumentiranih postopkov sistema kakovosti

b) razvrstitev ali del dokumentiranih

4.2.3 Derivation of a quality manual

A quality manual may:

a) be a direct compilation of documented quality system procedures;

b) be a grouping or section of the

postopkov sistema kakovosti

c) niz dokumentiranih postopkov za specifične priložnosti in uporabe

d) več kot en dokument ali nivo

e) takšen, da ima skupno jedro s prilagojenimi dodatki

f) samostojen ali ne

g) takšen, da ima vrsto drugih mogočih izpeljav, glede na potrebe organizacije.

4.2.4 Posebne uporabe poslovnika kakovosti

Preprost izraz "poslovnik kakovosti" je uporabljen, kadar se isti poslovnik uporablja tako za vodenje kot za zagotavljanje kakovosti. To je najpogostejša uporaba poslovnika kakovosti. Kadar pa je po mnenju organizacije potrebna porazdelitev vsebine ali uporabe, je zagotovo zelo pomembno, da si poslovniki, ki opisujejo isti sistem kakovosti, ne nasprotujejo.

Vsak poslovnik kakovosti naj določi vodilne funkcije, obravnava ali se sklicuje na dokumentiran sistem kakovosti in postopke ter na kratko obdela vse ustrezne zahteve standarda, ki si ga za sistem kakovosti izbere organizacija.

5 Proces izdelave poslovnika kakovosti

5.1 Odgovornost za izdelavo

Ko vodstvo sprejme odločitev, da bo sistem kakovosti dokumentiran v poslovniku kakovosti, naj se začne dejanski proces tako, da vodstvo zadolži pristojno telo za koordiniranje. To je lahko posameznik ali skupina posameznikov iz ene ali več funkcionalnih enot.

Dejansko pisanje naj izvaja in nadzira, kot je to primerno: pooblaščeno pristojno telo ali različne posamezne funkcionalne enote. Uporaba obstoječih dokumentov in referenc

documented quality system procedures;

c) be a series of documented procedures for specific facilities or applications;

d) be more than one document or level;

e) have a common core with tailored appendices;

f) stand alone or otherwise;

g) have other numerous possible derivations based upon organizational need.

4.2.4 Special applications of quality manual

The simple term "quality manual" is used when the same manual is employed for both quality management and quality assurance purposes. This usage is the most common application of a quality manual. However, in situations where an organization believes that a distinction of content or usage is needed, it is essential that manuals describing the same quality system are not in conflict.

Any quality manual should identify the management functions, address or reference the documented quality system and procedures and briefly cover all the applicable requirements of the quality system standard selected by the organization.

5 Process of preparing a quality manual

5.1 Responsibility for preparation

Once the management decision has been made to document a quality system in a quality manual, the actual process should begin with assignment of the coordination task to a management-delegated competent body, which may be an individual or a group of individuals from one or more functional organizations.

The actual writing activity should be performed and controlled from within the delegated competent body or from within various individual functional units, as appropri-

lahko bistveno skrajša čas izdelave poslovnika kakovosti, prav tako je v pomoč pri določanju tistih področij, na katerih je potrebno obravnavati in odpraviti neustreznosti v sistemu kakovosti.

Pristojno telo lahko spodbudi naslednje akcije, če so te primerne:

a) urediti in izdelati seznam obstoječih uporabnih politik sistema kakovosti, ciljev in dokumentiranih postopkov oziroma izdelati plane zanje

b) odrediti, kateri elementi sistema kakovosti so primerni glede na izbran standard za sistem kakovosti

c) na različne načine (na primer z vprašalniki ali pogovori) priskrbeti podatke o obstoječem sistemu kakovosti in praksah

d) od operacijskih enot zahtevati ali priskrbeti dodatno izvorno dokumentacijo ali sklicevanje

e) določiti zgradbo in obliko predvidenega poslovnika

f) razporediti obstoječe dokumente glede na predvideno zgradbo in obliko

g) uporabiti katerokoli drugo primerno metodo v organizaciji za dokončanje osnutka poslovnika kakovosti.

5.2 Uporaba referenc

Kjerkoli je to primerno in zaradi preprečevanja nepotrebne obsežnosti dokumenta naj se vključi sklicevanje na obstoječe priznane standarde ali dokumente, ki so dostopni uporabniku poslovnika kakovosti.

5.3 Natančnost in popolnost

Pooblaščeno telo naj bo odgovorno za zagotavljanje natančnosti in popolnosti osnutka poslovnika kakovosti kakor tudi za stalnost in vsebino dokumentov.

ate. The use of existing documents and references can significantly shorten the quality manual development time, as well as being an aid to identifying those areas where quality system inadequacies need to be addressed and corrected.

The competent body may initiate the following actions as applicable:

a) establish and list existing applicable quality system policies, objectives and documented procedures, or develop plans for such;

b) decide which quality system elements apply according to the quality system standard selected;

c) obtain data about the existing quality system and practices by various means, such as questionnaires and interviews;

d) request and obtain additional source documentation or references from operational units;

e) determine the structure and format for the intended manual;

f) classify existing documents in accordance with the intended structure and format;

g) use any other method suitable within the organization to complete the quality manual draft.

5.2 Use of references

Wherever appropriate, and to avoid unnecessary document volume, reference to existing recognized standards or documents available to the quality manual user should be incorporated.

5.3 Accuracy and completeness

The delegated competent body should be responsible for assuring the accuracy and completeness of the quality manual draft, as well as for the continuity and contents of documents.