SLOVENSKI STANDARD

SIST ISO 10005

september 2005

Sistemi vodenja kakovosti – Smernice za plane kakovosti

Quality management systems – Guidelines for quality plans

Systèmes de management de la qualité – Lignes directrices pour les plans qualité

ICS 03.120.10

Referenčna oznaka
SIST ISO 10005:2005 (sl, en)

Nadaljevanje na straneh od 2 do 47

NACIONALNI UVOD

Standard SIST ISO 10005:2005 (sl, en), Sistemi vodenja kakovosti – Smernice za plane kakovosti, 2005, ima status slovenskega standarda in je enakovreden mednarodnemu standardu ISO 10005, Quality management systems – Guidelines for quality plans, 2005.

NACIONALNI PREDGOVOR

Besedilo standarda ISO 10005:2005 je pripravil tehnični odbor ISO/TC 176, *Vodenje in zagotavljanje kakovosti*, pododbor SC 2, *Sistemi kakovosti*. Slovenski standard SIST ISO 10005:2005 je prevod angleškega besedila mednarodnega standarda ISO 10005:2005. V primeru spora glede besedila slovenskega prevoda v tem standardu je odločilen izvirni evropski standard v angleškem jeziku. Slovensko-angleško izdajo standarda je pripravil SIST/TC VZK Vodenje in zagotavljanje kakovosti.

Odločitev za privzem tega standarda je 16. junija 2005 sprejel tehnični odbor SIST/TC VZK Vodenje in zagotavljanje kakovosti.

ZVEZE Z NACIONALNIMI STANDARDI

S privzemom tega evropskega standarda veljajo za omejeni namen referenčnih standardov vsi standardi, navedeni v izvirniku, razen standarda, ki je že sprejet v nacionalno standardizacijo:

SIST EN ISO 9000:2005 (sl,en) Sistemi vodenja kakovosti – Osnove in slovar (ISO 9000:2005)

OSNOVA ZA IZDAJO STANDARDA

– Privzem standarda ISO 10005:2005.

PREDHODNA IZDAJA

– SIST ISO 10005:1998.

OPOMBE

– Povsod, kjer se v besedilu standarda uporablja izraz “mednarodni standard”, v SIST ISO 10005:2005 to pomeni “slovenski standard”.

– Nacionalni uvod in nacionalni predgovor nista sestavni del standarda.

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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 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).

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

Glavna naloga tehničnih odborov je priprava mednarodnih standardov. Osnutki mednarodnih standardov, ki jih sprejmejo tehnični odbori, se pošljejo vsem članom v glasovanje. Za objavo mednarodnega standarda je treba pridobiti soglasje najmanj 75 odstotkov članov, ki se udeležijo glasovanja.

Opozoriti je treba na možnost, da je lahko nekaj elementov tega dokumenta predmet patentnih pravic. ISO ne prevzema odgovornosti za identifikacijo katerihkoli ali vseh takih patentnih pravic.

ISO 10005 je pripravil tehnični odbor ISO/TC 176, *Vodenje in zagotavljanje kakovosti*, pododbor SC 2, *Sistemi kakovosti*.

Ta druga izdaja razveljavlja in nadomešča prvo izdajo (ISO 10005:1995). Predstavlja strokovno prenovo te izdaje, ki upošteva standarde ISO 9000:2000, ISO 9001:2000 in ISO 9004:2000.

Uvod

Ta mednarodni standard je bil pripravljen z namenom, da bi izpolnjeval potrebe po napotkih za plane kakovosti, bodisi v okviru že vzpostavljenega sistema vodenja kakovosti ali kot samostojna aktivnost vodstva. V obeh primerih plani kakovosti zagotavljajo sredstvo za povezovanje specifičnih zahtev procesa, proizvoda, projekta ali pogodbe z delovnimi metodami in praksami, ki podpirajo realizacijo proizvoda. Plan kakovosti naj bo združljiv z morebitnimi drugimi s tem povezanimi plani, ki se pripravljajo.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10005 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 10005:1995). It constitutes a technical revision of that edition, taking into account ISO 9000:2000, ISO 9001:2000 and ISO 9004:2000.

Introduction

This International Standard was prepared to address the need for guidance on quality plans, either in the context of an established quality management system or as an independent management activity. In either case, quality plans provide a means of relating specific requirements of the process, product, project or contract to work methods and practices that support product realization. The quality plan should be compatible with other associated plans that may be prepared.

Med koristi vzpostavljanja plana kakovosti se štejejo povečano zaupanje, da bodo zahteve izpolnjene, večje zagotovilo, da so procesi obvladovani, ter motivacija, ki jo lahko daje vsem sodelujočim. Omogoča lahko tudi vpogled v priložnosti za izboljšanje.

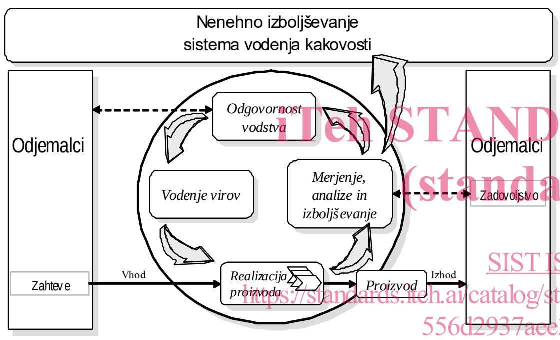
Ta mednarodni standard ne nadomešča napotkov iz standarda ISO 9004 ali iz dokumentov, specifičnih za industrijski sektor. Če so plani kakovosti zahtevani za prijave projektov, so napotki iz tega mednarodnega standarda namenjeni dopolnitvi napotkov iz ISO 10006.

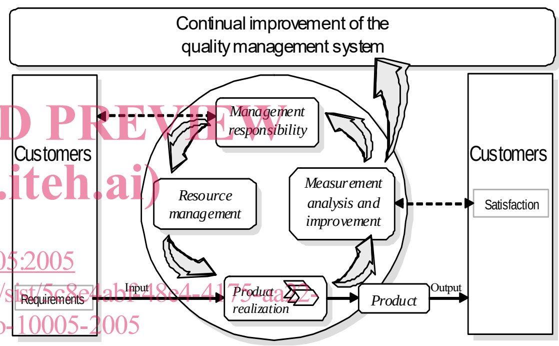
Planiranje sistema vodenja kakovosti se nanaša na celotni procesni model, prikazan na sliki 1, medtem ko se plani kakovosti nanašajo predvsem na pot, ki poteka od zahtev odjemalca preko realizacije proizvoda in samega proizvoda do zadovoljstva odjemalcev.

Among the benefits of establishing a quality plan are the increased confidence that requirements will be met, greater assurance that processes are in control and the motivation it can give to those involved. It may also give insight into opportunities for improvement.

This International Standard does not replace the guidance given in ISO 9004 or in industry-specific documents. Where quality plans are required for project applications, the guidance provided in this International Standard is intended to be complementary to the guidance provided in ISO 10006.

In terms of the process model shown in Figure 1, quality management system planning applies to the whole model. Quality plans, however, apply primarily to the path from customer requirements, through product realization and product, to customer satisfaction.





Legenda

——→ Aktivnosti, ki dodajajo vrednost

- - - - → Pretok informacij

Slika 1: Model na procesih temelječega sistema vodenja kakovosti

Key

——→ Value adding activities

- - - - → Information flow

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

Sistemi vodenja kakovosti – Smernice za plane kakovosti

1 Področje uporabe

Ta mednarodni standard določa smernice za razvoj, pregled, sprejem, uporabo in prenovo planov kakovosti.

Uporablja se lahko ne glede na to, ali ima organizacija sistem vodenja v skladu z ISO 9001 ali ne.

Ta mednarodni standard se nanaša na plane kakovosti za procese, proizvode, projekte ali pogodbe, za katero koli kategorijo proizvodov (materialne proizvode, miselne proizvode, predelane materiale in storitve) ter za katero koli industrijsko dejavnost.

Osredotoča se predvsem na realizacijo proizvoda in ni vodilo za planiranje sistema vodenja kakovosti v organizaciji.

Ta mednarodni standard je usmerjevalni dokument in ni namenjen uporabi v certifikacijske ali registracijske namene.

OPOMBA: Da bi se izognili ponavljanju izrazov "proces, proizvod, projekt ali pogodba", se v tem mednarodnem standardu uporablja izraz "specifičen primer" (glej točko 3.10).

Quality management systems – Guidelines for quality plans

1 Scope

This International Standard provides guidelines for the development, review, acceptance, application and revision of quality plans.

It is applicable whether or not the organization has a management system in conformity with ISO 9001.

This International Standard is applicable to quality plans for a process, product, project or contract, any product category (hardware, software, processed materials and services) and any industry.

It is focused primarily on product realization and is not a guide to organizational quality management system planning.

This International Standard is a guidance document and is not intended to be used for certification or registration purposes.

NOTE To avoid undue repetition of “process, product, project or contract”, this International Standard uses the term “specific case” (see 3.10).

2 Zveza s standardi

Za uporabo tega standarda so nujno potrebni spodaj navedeni dokumenti. Pri datiranem sklicevanju se uporablja samo navedena izdaja. Pri nedatiranem sklicevanju se uporablja zadnja izdaja dokumenta (vključno z morebitnimi dopolnili).

ISO 9000:2000, *Sistemi vodenja kakovosti – Osnove in slovar*

2 Normative references

The following referenced documents are indispensable for the application 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 9000:2000, *Quality management systems – Fundamentals and vocabulary*

3 Izrazi in definicije

V tem dokumentu se uporabljajo izrazi in definicije iz standarda ISO 9000 ter naslednji izrazi.

Nekatere od spodnjih definicij so citirane neposredno iz standarda ISO 9000, le da so opombe v nekaterih primerih izpuščene ali dopolnjene.

3.1
stvaren dokaz
podatki, ki potrjujejo obstoj ali verodostojnost nečesa

3 Terms and definitions

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

Some of the definitions below are quoted directly from ISO 9000, but notes are in some cases omitted or supplemented.

3.1
objective evidence
data supporting the existence or verity of something

OPOMBA: Stvaren dokaz se lahko dobi z opazovanjem, meritvami, preskusi ali z drugimi sredstvi.

[ISO 9000:2000, definicija 3.8.1]

3.2
postopek
specificiran način za izvedbo aktivnosti ali **procesa** (3.3)

OPOMBA 1: Postopki so lahko dokumentirani ali ne.

OPOMBA 2: Kadar je postopek dokumentiran, se pogosto uporablja izraz "pisni postopek" ali "dokumentirani postopek". Dokument, ki vsebuje postopek, se lahko imenuje "dokument v postopku".

[ISO 9000:2000, definicija 3.4.5]

3.3
proces
skupek med seboj povezanih ali vzajemno vplivajočih aktivnosti, ki pretvarjajo vhode v izhode

OPOMBA: Prirejeno po ISO 9000:2000, definicija 3.4.1 (opombe niso vključene).

3.4
proizvod
rezultat **procesa** (3.3)

OPOMBA 1: Obstajajo štiri temeljne kategorije proizvodov:

– storitve (npr. transport);
– miselni proizvod (npr. računalniški program, slovar);
– materialni proizvod (npr. mehanski del stroja);
– predelani materiali (npr. mazivo).

Mnogi proizvodi vsebujejo elemente, ki pripadajo različnim temeljnim kategorijam proizvodov. Od prevladujočega elementa je odvisno, ali se bo proizvod imenoval storitev, miselni proizvod, materialni proizvod ali predelan material. Npr. ponujen proizvod “avto” sestoji iz materialnih proizvodov (npr. pnevmatik), predelanih materialov (npr. goriva, hladilne tekočine), miselnih proizvodov (npr. računalniškega programa za obvladovanje motorja, voznikovega priročnika) in storitev (npr. razlage prodajalca, kako deluje).

OPOMBA 2: Storitev je rezultat vsaj ene aktivnosti, obvezno izvedene med dobaviteljem in odjemalcem, in je na splošno neotipljiva. Izvedba storitve lahko npr. vključuje:

– aktivnost, izvedeno na otipljivem proizvodu, ki ga priskrbi odjemalec (npr. popravilo avtomobila);
– aktivnost, izvedeno na neotipljivem proizvodu, ki ga priskrbi odjemalec (npr. prijava dohodkov za povračilo presežka davkov);

NOTE Objective evidence may be obtained through observation, measurement, test, or other means.

[ISO 9000:2000, definition 3.8.1]

3.2
procedure
specified way to carry out an activity or a **process** (3.3)

NOTE 1 Procedures can be documented or not.

NOTE 2 When a procedure is documented, the term “written procedure” or “documented procedure” is frequently used. The document that contains a procedure can be called a “procedure document”.

[ISO 9000:2000, definition 3.4.5]

3.3
process
set of interrelated or interacting activities which transforms inputs into outputs

NOTE Adapted from ISO 9000:2000, definition 3.4.1 (the Notes have not been included).

3.4
product
result of a **process** (3.3)

NOTE 1 There are four generic product categories, as follows:

– services (e.g. transport);
– software (e.g. computer program, dictionary);
– hardware (e.g. engine mechanical part);
– processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example the offered product “automobile” consists of hardware (e.g. tyres), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman).

NOTE 2 Service is the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible. Provision of a service can involve, for example, the following:

– an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);
– an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);

– dobavo neotipljivega proizvoda (npr. dobava informacij v zvezi s prenosom znanja);

– ustvarjanje okolja za odjemalca (npr. v hotelih in restavracijah).

Miselni proizvod sestoji iz informacij, je na splošno neotipljiv in je lahko v obliki pristopov, strokovnih poročil ali **postopkov** (3.2).

Materialni proizvod je na splošno otipljiv in njegova količina je števna karakteristika. Predelani materiali so na splošno otipljivi in njihova količina je zvezna karakteristika. Materialni proizvodi in predelani materiali se pogosto imenujejo blago.

[ISO 9000:2000, definicija 3.4.2]

3.5
projekt
enkraten **proces** (3.3), ki sestoji iz skupka koordiniranih in obvladanih aktivnosti s časovno določenim začetkom in koncem. Sprožen je za doseganje cilja, skladnega s specifičnimi zahtevami, vključno z omejitvami časa, stroškov in virov.

OPOMBA 1: Posamezen projekt je lahko del večje projektne strukture.

OPOMBA 2: V nekaterih projektih se cilji podrobneje opredelijo in karakteristike proizvoda sproti definirajo med projektom.

OPOMBA 3: Rezultat projekta je lahko ena ali več enot proizvoda (3.4).

[ISO 9000:2000, definicija 3.4.3]

3.6
sistem vodenja kakovosti
sistem vodenja za usmerjanje in obvladovanje organizacije v zvezi s kakovostjo

[ISO 9000:2000, definicija 3.2.3]

3.7
cilj kakovosti
nekaj, za kar se prizadeva ali na kar se meri v zvezi s kakovostjo

OPOMBA 1: Cilji kakovosti so na splošno zasnovani na podlagi politike kakovosti organizacije.

OPOMBA2: Cilji kakovosti so na splošno specificirani za ustrezne funkcije in ravni organizacije.

[ISO 9000:2000, definicija 3.2.5]

– the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);

– the creation of ambience for the customer (e.g. in hotels and restaurants).

Software consists of information and is generally intangible and can be in the form of approaches, transactions or **procedures** (3.2)

Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.

[ISO 9000:2000, definition 3.4.2]

3.5
project
unique **process** (3.3) consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost and resources

NOTE 1 An individual project can form part of a larger project structure.

NOTE 2 In some projects, the objectives are refined and the product characteristics defined progressively as the project proceeds.

NOTE 3 The outcome of a project may be one or several units of product (3.4).

[ISO 9000:2000, definition 3.4.3]

3.6
quality management system
management system to direct and control an organization with regard to quality

[ISO 9000:2000, definition 3.2.3]

3.7
quality objective
something sought, or aimed for, related to quality

NOTE 1 Quality objectives are generally based on the organization's quality policy.

NOTE 2 Quality objectives are generally specified for relevant functions and levels in the organization.

[ISO 9000:2000, definition 3.2.5]

3.8
plan kakovosti
dokument, ki specificira, kdo in kdaj bo uporabil katere **procese** (3.3), **postopke** (3.2) in pripadajoče vire za izpolnjevanje zahtev specifičnega **projekta** (3.5), **proizvoda** (3.4), procesa ali pogodbe

OPOMBA 1: Ti postopki navadno vključujejo tiste, ki se nanašajo na procese vodenja kakovosti in na procese realizacije proizvoda.

OPOMBA 2: Plan kakovosti se pogosto sklicuje na dele poslovnika kakovosti ali na dokumente v postopku.

OPOMBA 3: Plan kakovosti je na splošno eden od rezultatov planiranja kakovosti.

3.8
quality plan
document specifying which **processes** (3.3), **procedures** (3.2) and associated resources will be applied by whom and when, to meet the requirements of a specific **project** (3.5), **product** (3.4), process or contract

NOTE 1 These procedures generally include those referring to quality management processes and to product realization processes.

NOTE 2 A quality plan often makes reference to parts of the quality manual or to procedure documents.

NOTE 3 A quality plan is generally one of the results of quality planning.

3.9
zapis
dokument, ki navaja dosežene rezultate ali predstavlja dokaz o izvedenih aktivnostih

OPOMBA: Prirejeno po ISO 9000:2000, definicija 3.7.6 (opombe niso vključene).

3.9
record
document stating results achieved or providing evidence of activities performed

NOTE Adapted from ISO 9000:2000, definition 3.7.6 (the Notes have not been included).

3.10
specifičen primer
predmet **plana kakovosti** (3.8)

OPOMBA: Ta izraz se v tem mednarodnem standardu uporablja, da bi se izognili ponavljanju izrazov "proces, proizvod, projekt ali pogodba".

3.10
specific case
subject of the **quality plan** (3.8)

NOTE This term is used to avoid repetition of “process, product, project or contract” within this International Standard.

4 Razvoj plana kakovosti

4.1 Identificiranje potrebe po planu kakovosti

Organizacija naj identificira morebitno potrebo po planih kakovosti. Plani kakovosti so lahko koristni ali potrebni v številnih primerih, na primer:

a) da bi pokazali, kako se sistem vodenja kakovosti organizacije uporablja v specifičnem primeru;

b) da bi izpolnili zakonske, regulativne ali odjemalčeve zahteve;

c) pri razvijanju in validiranju novih proizvodov ali procesov;

d) da bi znotraj in/ali zunaj organizacije dokazali, kako bodo izpolnjene zahteve glede kakovosti;

e) da bi organizirali in vodili aktivnosti za izpolnjevanje zahtev glede kakovosti in ciljev kakovosti;

f) da bi optimizirali uporabo virov pri izpolnjevanju ciljev kakovosti;

4 Development of a quality plan

4.1 Identifying the need for the quality plan

The organization should identify what need there may be for quality plans. There are a number of situations where quality plans may be useful or necessary, for example:

a) to show how the organization's quality management system applies to a specific case;

b) to meet statutory, regulatory or customer requirements;

c) in developing and validating new products or processes;

d) to demonstrate, internally and/or externally, how quality requirements will be met;

e) to organize and manage activities to meet quality requirements and quality objectives;

f) to optimize the use of resources in meeting quality objectives;

g) da bi čim bolj zmanjšali tveganje neizpolnjevanja zahtev glede kakovosti;

h) kot podlaga za nadzorovanje in ocenjevanje skladnosti z zahtevami glede kakovosti;

i) če ni dokumentiranega sistema vodenja kakovosti.

OPOMBA: Pri specifičnem primeru se potreba po pripravi plana kakovosti lahko pokaže ali pa tudi ne. Organizacija z vzpostavljenim sistemom vodenja kakovosti je lahko sposobna izpolnjevati vse svoje potrebe po planih kakovosti z obstoječim sistemom; v takem primeru se lahko organizacija odloči, da ni potrebe po pripravi posebnih planov kakovosti.

4.2 Vhodni podatki za plan kakovosti

Ko se organizacija odloči, da bo razvila plan kakovosti, naj identificira vhodne podatke za njegovo pripravo, na primer:

a) zahteve specifičnega primera;

b) zahteve za plan kakovosti, vključno z zahtevami iz specifikacij odjemalcev, z zakonskimi, regulativnimi in industrijskimi zahtevami;

c) zahteve sistema vodenja kakovosti organizacije;

d) ocene tveganja v specifičnem primeru;

e) zahtevo glede virov in njihove razpoložljivosti;

f) informacije o potrebah tistih, ki sodelujejo pri izvajanju aktivnosti iz plana kakovosti;

g) informacije o potrebah drugih zainteresiranih strani, ki bodo uporabljale plan kakovosti;

h) druge ustrezne plane kakovosti;

i) druge ustrezne plane, kot so na primer drugi projektni plani, okoljski, zdravstveni in varnostni plani, varnostni načrti ter plani upravljanja informacij.

4.3 Obseg plana kakovosti

Organizacija naj določi, kaj naj bi obsegal plan kakovosti in kaj obsegajo oziroma naj bi obsegali drugi dokumenti. Nepotrebnemu podvajanju naj bi se izogibali.

Obseg plana kakovosti je odvisen od več dejavnikov, vključno:

a) s procesi in karakteristikami kakovosti, ki so značilni za specifični primer, in jih je zato treba vključiti;

g) to minimize the risk of not meeting quality requirements;

h) to use as a basis for monitoring and assessing compliance with the requirements for quality;

i) in the absence of a documented quality management system.

NOTE There may or may not be a need to prepare a quality plan for a specific case. An organization with an established quality management system may be able to fulfil all of its needs for quality plans under its existing system; the organization may then decide that there is no need to prepare separate quality plans.

4.2 Inputs to the quality plan

Once the organization has decided to develop a quality plan, the organization should identify the inputs for preparation of the quality plan, for example:

a) the requirements of the specific case;

b) the requirements for the quality plan, including those in customer, statutory, regulatory and industry specifications;

c) the quality management system requirements of the organization;

d) risk assessments on the specific case;

e) the requirement for and availability of resources;

f) information on the needs of those engaged in carrying out activities covered by the quality plan;

g) information on the needs of other interested parties who will use the quality plan;

h) other relevant quality plans;

i) other relevant plans, such as other project plans, environmental, health and safety, security and information management plans.

4.3 Scope of the quality plan

The organization should determine what is to be covered by the quality plan and what is covered or to be covered by other documents. Unnecessary duplication should be avoided.

The scope of the quality plan will depend on several factors, including the following:

a) the processes and quality characteristics that are particular to the specific case, and will therefore need to be included;

b) z zahtevami odjemalcev ali drugih zainteresiranih strani (notranjih ali zunanjih) za vključitev procesov, ki niso značilni za specifični primer, a jih potrebujejo zato, da zaupajo v izpolnitev svojih zahtev;

c) s tem, v kolikšnem obsegu je plan kakovosti podprt z dokumentiranim sistemom vodenja kakovosti.

Če postopki vodenja kakovosti niso vzpostavljeni, jih bo za podporo plana kakovosti morda treba razviti.

Pregledovanje obsega plana kakovosti skupaj z odjemalci ali drugimi zainteresiranimi stranmi bi bilo lahko koristno, da bi jim tako na primer olajšali uporabo plana kakovosti za nadzorovanje in merjenje.

4.4 Priprava plana kakovosti

4.4.1 Začetek

Oseba, odgovorna za pripravo plana kakovosti, naj bo jasno identificirana. Plan kakovosti naj se pripravi v sodelovanju z ljudmi, ki so vključeni v specifični primer, tako znotraj organizacije in, kjer je primerno, tudi v zunanjih organizacijah.

Med pripravo plana kakovosti naj se določijo in, kjer je potrebno, dokumentirajo aktivnosti vodenja kakovosti, ki se uporabljajo v specifičnem primeru.

4.4.2 Dokumentiranje plana kakovosti

V planu kakovosti naj bo navedeno, kako se bodo zahtevane aktivnosti izvajale bodisi neposredno ali s sklicevanjem na ustrezne dokumentirane postopke ali druge dokumente (npr. projektni načrt, delovno navodilo, kontrolni seznam, računalniška aplikacija). Če ima kakšna zahteva za posledico odstopanje od sistemov vodenja organizacije, naj se to odstopanje upraviči in dovoli.

Veliko potrebne splošne dokumentacije je morda že vsebovane v dokumentaciji sistema vodenja kakovosti organizacije, vključno z njenim poslovnikom kakovosti in dokumentiranimi postopki. To dokumentacijo bo morda treba izbrati, prilagoditi in/ali dopolniti. Iz plana kakovosti naj bo razvidno, kako se dokumentirani splošni postopki organizacije uporabljajo oziroma kako so spremenjeni ali nadomeščeni s postopki v planu kakovosti.

b) the requirements of customers or other interested parties (internal or external) for inclusion of processes not particular to the specific case, but necessary for them to have confidence that their requirements will be met;

c) the extent to which the quality plan is supported by a documented quality management system.

Where quality management procedures have not been established, they may need to be developed to support the quality plan.

There may be benefits from reviewing the scope of the quality plan with the customer or other interested parties, for example in order to facilitate their use of the quality plan for monitoring and measurement.

4.4 Preparation of the quality plan

4.4.1 Initiation

The person responsible for preparing the quality plan should be clearly identified. The quality plan should be prepared with the participation of people who are involved in the specific case, both within the organization and, where appropriate, external parties.

When preparing a quality plan, quality management activities applicable to the specific case should be defined and, where necessary, documented.

4.4.2 Documenting the quality plan

The quality plan should indicate how the required activities will be carried out, either directly or by reference to appropriate documented procedures or other documents (e.g. project plan, work instruction, checklist, computer application). Where a requirement results in a deviation from the organization's management systems, this deviation should be justified and authorized.

Much of the generic documentation needed may already be contained in the organization's quality management system documentation, including its quality manual and documented procedures. This documentation may need to be selected, adapted and/or supplemented. The quality plan should show how the organization's generic documented procedures are applied, or alternatively modified or overridden by procedures in the quality plan.

Plan kakovosti je lahko vključen kot del drugega dokumenta ali dokumentov; tako so na primer plani kakovosti projekta pogosto vključeni v plane vodenja projekta (glej ISO 10006).

4.4.3 Odgovornosti

Organizacija naj pri pripravi plana kakovosti uskladi in določi ustrezne vloge, odgovornosti in obveznosti tako znotraj organizacije kakor tudi z odjemalcem, regulativnimi organi in drugimi zainteresiranimi stranmi. Tisti, ki upravljajo plan kakovosti, naj zagotovijo, da se bodo osebe, na katere se nanaša, zavedale ciljev kakovosti in kakršnihkoli specifičnih vidikov kakovosti ali ukrepov, ki jih plan kakovosti zahteva.

4.4.4 Usklajenost in združljivost

Vsebina in oblika plana kakovosti naj bosta usklajeni z obsegom plana kakovosti, z vhodnimi podatki za plan in s potrebami predvidenih uporabnikov. Raven podrobnosti v planu kakovosti naj bo usklajena z morebitnimi dogovorjenimi zahtevami odjemalcev, načinom delovanja organizacije in kompleksnostjo aktivnosti, ki naj bi se izvajale. Upošteva naj se tudi potreba po združljivosti z drugimi plani.

4.4.5 Predstavitev in struktura

Plan kakovosti je lahko predstavljen v različnih oblikah, na primer kot enostavno opisno besedilo, preglednica, matrični dokument, shema procesov, diagram poteka del ali priročnik. Vsaka ali vse te oblike so lahko podane v elektronski obliki ali na tiskanem mediju.

OPOMBA: Primeri planov kakovosti so podani v dodatku A.

Plan kakovosti je lahko razdeljen v več dokumentov, od katerih vsak predstavlja plan za poseben vidik. Obvladovanje povezav med različnimi dokumenti mora biti jasno opredeljeno. Primeri takih vidikov vključujejo snovanje, nabavo, proizvodnjo, obvladovanje procesov ali posamezne aktivnosti (npr. preskušanje sprejemljivosti).

Organizacija morda želi pripraviti plan kakovosti, ki je v skladu z veljavnimi zahtevami ISO 9001. Kot navodilo je v dodatku B podana matrika za navzkrižno sklicevanje.

A quality plan may be included as part of another document or documents, for example project quality plans are often included in project management plans (see ISO 10006).

4.4.3 Responsibilities

In preparing the quality plan, the organization should agree and define the respective roles, responsibilities and obligations both within the organization and with the customer, regulatory authorities or other interested parties. Those administering the quality plan should ensure that the persons it refers to are aware of the quality objectives and any specific quality issues or controls required by the quality plan.

4.4.4 Consistency and compatibility

The contents and format of the quality plan should be consistent with the scope of the quality plan, the inputs to the plan and the needs of the intended users. The level of detail in the quality plan should be consistent with any agreed customer requirement, the organization's method of operation and the complexity of the activities to be performed. The need for compatibility with other plans should also be considered.

4.4.5 Presentation and structure

The presentation of the quality plan may have any of several forms, for example a simple textual description, a table, a document matrix, a process map, a work flow chart or a manual. Any or all of these may be presented in electronic or hard-copy formats.

NOTE Examples of quality plans are provided in Annex A.

The quality plan may be broken up into several documents, each of which represents a plan for a distinct aspect. Control of the interfaces between the different documents needs to be clearly defined. Examples of these aspects include design, purchasing, production, process control or particular activities (such as acceptance testing).

An organization may wish to prepare a quality plan that conforms to applicable requirements of ISO 9001. A cross-reference matrix is provided in Annex B for guidance.