
Smernice za presojanje sistemov vodenja kakovosti in/ali ravnanja z okoljem (enakovreden ISO 19011:2002)

Guidelines for quality and/or environmental management systems auditing

Lignes directrices pour l'audit des systèmes de management de la qualité et/ou de management environnemental

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NACIONALNI UVOD

Standard SIST EN ISO 19011 (sl,en), Smernice za presojanje sistemov vodenja kakovosti in/ali ravnanja z okoljem, 2003 ima status slovenskega standarda in je enakovreden evropskemu standardu EN ISO 19011, Guidelines for quality and/or environmental management systems auditing, prva izdaja, 2002.

NACIONALNI PREDGOVOR

Besedilo mednarodnega standarda ISO 19011:2002 sta pripravila mednarodna tehnična odbora ISO/TC 176 Vodenje in zagotavljanje kakovosti, pododbor SC3 Podporne tehnologije, in ISO/TC 207 Ravnanje z okoljem, pododbor SC2 Okoljsko presojanje in sorodne okoljske preiskave. Prenos tega standarda v evropski standard je potrdil Centralni sekretariat CEN brez sprememb vsebine mednarodnega standarda ISO 19011.

Slovenski tehnični odbor SIST/TC VZK Vodenje in zagotavljanje kakovosti je dne 2003-01-00 privzel evropski standard EN ISO 19011:2002 po metodi ponatisa. Standard v slovenskem jeziku je le njegova jezikovna različica.

ZVEZA S STANDARDI

S privzemom tega mednarodnega standarda veljajo naslednje zveze:

SIST ISO 9000:2002 (sl,en)	Vodenje sistemov kakovosti – Osnove in slovar
SIST ISO 14050:2000 (en)	Ravnanje z okoljem - Slovar

PREDHODNE IZDAJE **iTeh STANDARD PREVIEW (standards.iteh.ai)**

- SIST EN ISO 14010:1997
- SIST EN ISO 14011:1997
- SIST EN ISO 14012:1997 [SIST EN ISO 19011:2003
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OSNOVA ZA IZDAJO STANDARDA

- Privzem standarda EN ISO 19011:2002.

OPOMBE

- Nacionalni uvod in nacionalni predgovor nista sestavni del standarda.

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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 delovati na določenem področju, za katero je bil ustanovljen tehnični odbor, ima pravico biti zastopan v tem odboru. Pri delu sodelujejo 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).

Mednarodni standardi so pripravljeni v skladu s pravili, podanimi v Direktivah ISO/IEC, 3. del.

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 so glasovali.

Opozoriti je treba na možnost, da je lahko nekaj elementov tega mednarodnega standarda ISO 19011 predmet patentnih pravic in ISO ne je prevzema odgovornosti za identifikacijo katerihkoli ali vseh takih patentnih pravic.

ISO 19011 sta skupaj pripravila tehnična odbora ISO/TC 176 *Vodenje in zagotavljanje kakovosti*, pododbor SC3 *Podporne tehnologije*, in ISO/TC 207, *Ravnanje z okoljem*, pododbor SC2 *Okoljsko presojanje in sorodne okoljske preiskave*.

Ta prva izdaja ISO 19011 razveljavlja in nadomešča ISO 10011-1:1990, ISO 10011-2:1991, ISO 10011-3:1991, ISO 14010:1996, ISO 14011:1996 in ISO 14012:1996.

Uvod

Skupini mednarodnih standardov ISO 9000 in ISO 14000 poudarjata pomembnost presoje kot orodja vodenja za nadzorovanje in overjanje učinkovitega izvajanja politike kakovosti in/ali okoljske politike organizacije. Presoje so tudi bistveni del aktivnosti ugotavljanja skladnosti, kot je zunanjja certifikacija/registracija, in ocenjevanja in nadzorovanja nabavne verige.

Foreword

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

International standards are drafted in accordance with the rules given in the ISO/IEC Directives, part 3.

The main task of technical committees is to prepare International Standards. Draft International Standards accepted 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 members casting a vote.

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

ISO 19011 was prepared jointly by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*, and Technical Committee ISO/TC 207, *Environmental management*, Subcommittee SC 2, *Environmental auditing and related environmental investigations*.

This first edition of ISO 19011 cancels and replaces ISO 10011-1:1990, ISO 10011-2:1991, ISO 10011-3:1991, ISO 14010:1996, ISO 14011:1996 and ISO 14012:1996.

Introduction

The ISO 9000 and ISO 14000 series of International Standards emphasize the importance of audits as a management tool for monitoring and verifying the effective implementation of an organization's quality and/or environmental policy. Audits are also an essential part of conformity assessment activities such as external certification/registration and of supply chain evaluation and surveillance.

Ta mednarodni standard podaja napotke za vodenje programov presoja, izvajanje notranjih ali zunanjih presoja sistemov vodenja kakovosti in/ali ravnanja z okoljem in tudi za kompetentnost in ocenjevanje presojevalcev. Uporabljali naj bi ga številni možni uporabniki, vključno presojevalci, organizacije, ki izvajajo sisteme vodenja kakovosti in/ali ravnanja z okoljem, organizacije, ki morajo izvajati presoje sistemov vodenja kakovosti in/ali ravnanja z okoljem iz pogodbenih razlogov, in organizacije, udeležene pri certificiranju ali usposabljanju presojevalcev, pri certifikaciji/registraciji sistemov vodenja, pri akreditaciji ali pri standardizaciji na področju ocenjevanja skladnosti.

Smernice v tem mednarodnem standardu naj bi bile prilagodljive. Kot je nakazano na več mestih v besedilu, se lahko uporaba teh smernic razlikuje glede na velikost, naravo in kompleksnost presojane organizacije in tudi ciljev in predmetov izvajanih presoja. V tem celotnem mednarodnem standardu so podani dodatni napotki ali primeri za specifične teme kot praktična pomoč v okvirju tem besedila. V nekaterih primerih je to namenjeno podpori uporabe tega mednarodnega standarda v majhnih organizacijah.

V točki 4 so opisana načela presojanja. Ta načela pomagajo uporabniku razumeti bistvene značilnosti presojanja in so nujen uvod k točkam 5, 6 in 7.

V točki 5 so podani napotki za vodenje programov presoja in obravnavane teme, kot so določitev odgovornosti za vodenje programov presoja, vzpostavitev ciljev programa presoja, koordiniranje aktivnosti presoja in priskrba zadostnih virov za presojevalne skupine.

V točki 6 so podani napotki za vodenje presoja sistemov vodenja kakovosti in/ali ravnanja z okoljem, vključno z izbiro presojevalnih skupin.

V točki 7 so podani napotki glede potrebne kompetentnosti presojevalca in opisan proces ocenjevanja presojevalcev.

Kjer se sistema vodenja kakovosti in ravnanja z okoljem izvajata hkrati, se uporabnik tega mednarodnega standarda po lastnem preudarku odloči, ali bo izvajal presoje sistemov vodenja kakovosti in ravnanja z okoljem ločeno ali hkrati.

Čeprav je ta mednarodni standard namenjen uporabi za presojanje sistemov vodenja

This International Standard provides guidance on the management of audit programmes, the conduct of internal or external audits of quality and/or environmental management systems, as well as on the competence and evaluation of auditors. It is intended to apply to a broad range of potential users, including auditors, organizations implementing quality and/or environmental management systems, organizations needing to conduct audits of quality and/or environmental management systems for contractual reasons, and organizations involved in auditor certification or training, in certification/registration of management systems, in accreditation or in standardization in the area of conformity assessment.

The guidance in this International Standard is intended to be flexible. As indicated at various points in the text, the use of these guidelines can differ according to the size, nature and complexity of the organizations to be audited, as well as the objectives and scopes of the audits to be conducted. Throughout this International Standard, supplementary guidance or examples on specific topics are provided in the form of practical help in boxed text. In some instances, this is intended to support the use of this International Standard in small organizations.

Clause 4 describes the principles of auditing. These principles help the user to appreciate the essential nature of auditing and they are a necessary prelude to clauses 5, 6 and 7.

Clause 5 provides guidance on managing audit programmes and covers such issues as assigning responsibility for managing audit programmes, establishing the audit programme objectives, coordinating auditing activities and providing sufficient audit team resources.

Clause 6 provides guidance on conducting audits of quality and/or environmental management systems, including the selection of audit teams.

Clause 7 provides guidance on the competence needed by an auditor and describes a process for evaluating auditors.

Where quality and environmental management systems are implemented together, it is at the discretion of the user of this International Standard as to whether the quality management system and environmental management system audits are conducted separately or together.

Although this International Standard is applicable to the auditing of quality and/or environmental

kakovosti in/ali ravnanja z okoljem, lahko uporabnik razmisli o prilagoditvi ali razširitvi uporabe podanih napotkov na druge vrste presoj, vključno z drugimi presojami sistema vodenja.

V tem mednarodnem standardu so sicer podani samo napotki, vendar jih lahko uporabniki uporabijo za pripravo njihovih lastnih zahtev v zvezi s presojami.

Poleg tega lahko napotki tega mednarodnega standarda koristijo posameznikom ali organizacijam, ki želijo nadzorovati skladnost z zahtevami, kot so specifikacije proizvodov ali zakoni in predpisi.

management systems, the user can consider adapting or extending the guidance provided herein to apply to other types of audits, including other management system audits.

This International Standard provides only guidance, however, users can apply this to develop their own auditrelated requirements.

In addition, any other individual or organization with an interest in monitoring conformance to requirements, such as product specifications or laws and regulations, may find the guidance in this International Standard useful.

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Smernice za presojanje sistemov vodenja kakovosti in / ali ravnanja z okoljem

1 Predmet

Ta mednarodni standard podaja napotke o načelih presojanja, vodenju programov presoje, izvajjanju presoje sistemov vodenja kakovosti in/ali ravnanja z okoljem in tudi napotke glede kompetentnosti presojevalcev sistemov vodenja kakovosti in ravnanja z okoljem.

Uporaben je v vseh organizacijah, ki morajo izvajati notranje ali zunanje presoje sistemov vodenja kakovosti in/ali ravnanja z okoljem ali voditi program presoje.

Ta mednarodni standard je načeloma mogoče uporabiti pri drugih vrstah presoje, če se pri tem posebna pozornost posveti potrebnim kompetentnostim članov presojevalne skupine.

2 Zveza z drugimi standardi iTeh STANDARD PREVIEW

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Spodaj navedena standarda vsebujeta določila, ki s sklicevanjem v tem besedilu tvorijo določila tega mednarodnega standarda. Pri datiranem sklicevanju se ne upoštevajo poznejši dodatki ali popravki teh dokumentov. Vendar se strankam, ki sklenejo dogovore, zasnovane na tem mednarodnem standardu, priporoča, naj raziščejo možnost uporabe najnovejše izdaje spodaj navedenih standardov. Pri nedatiranem sklicevanju se upošteva zadnja izdaja standarda. Člani ISO in IEC vzdržujejo register veljavnih mednarodnih standardov.

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

ISO 14050:2002, *Ravnanje z okoljem – Slovar*

3 Izrazi in definicije

V tem mednarodnem standardu se uporablajo izrazi in definicije, ki so podani v standardih ISO 9000 in ISO 14050, razen tistih, ki jih zamenjujejo spodnji izrazi in definicije.

Izrazi v definicijah ali opombah, ki so opredeljeni drugje v tej točki, so označeni s poudarjenimi črkami, v oklepaju pa je navedena točka. Tako označen izraz se lahko v definiciji nadomesti z njegovo celotno definicijo.

Guidelines for quality and / or environmental management systems auditing

1 Scope

This International Standard provides guidance on the principles of auditing, managing audit programmes, conducting quality management system audits and environmental management system audits, as well as guidance on the competence of quality and environmental management system auditors.

It is applicable to all organizations needing to conduct internal or external audits of quality and/or environmental management systems or to manage an audit programme.

The application of this International Standard to other types of audit is possible in principle, provided that special consideration is paid to identifying the competence needed by the audit team members in such cases.

2 Normative references

The following normative documents contain provisions which, through references in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative documents indicated below. For undated references, the latest edition of the normative document referred to apply. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems – Fundamentals and vocabulary*

ISO 14050:2002, *Environmental management – Vocabulary*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 and ISO 14050 apply, unless superseded by the terms and definitions given below.

A term in a definition or note which is defined elsewhere in this clause is indicated by boldface followed by its entry number in parentheses. Such a boldface term may be replaced in the definition by its complete definition.

3.1 Presoja

Sistematičen, neodvisen in dokumentiran proces pridobivanja **dokazov presoje** (3.3) in njihovega objektivnega vrednotenja, da bi se določil obseg, v katerem so izpolnjeni dogovorjeni **kriteriji presoje** (3.2).

- OPOMBA 1: Notranje presoje, ki se včasih imenujejo presoje prve stranke, izvajajo organizacije same ali se izvajajo v imenu organizacije za notranje namene in lahko tvorijo podlago za lastno izjavo organizacije o skladnosti. V mnogih primerih, posebej v manjših organizacijah, se lahko neodvisnost dokazuje s tem, da oseba ni odgovorna za presojane aktivnosti.
- OPOMBA 2: Zunanje presoje vključujejo to, kar se ponavadi imenuje presoje druge ali tretje stranke. Presoje druge stranke izvajajo stranke, ki so zainteresirane za organizacijo, npr. odjemalci, ali pa druge osebe v njihovem imenu. Presoje tretje stranke izvajajo zunanje neodvisne organizacije, kot so organizacije, ki izvajajo certifikacijo ali registracijo skladnosti z zahtevami standardov ISO 9001 in ISO 14001.
- OPOMBA 3: Kadar se sistema vodenja kakovosti in ravnjanja z okoljem presojava hkrati se to imenuje kombinirana presoja.
- OPOMBA 4: Kadar pri presoji enega **presojanca** (3.7) sodelujeta dve ali več presojevalskih organizacij, se to imenuje skupna presoja.

3.2 Kriteriji presoje

Skupek splošnih usmeritev, postopkov ali zahtev

- OPOMBA: Kriteriji presoje se uporabljajo kot referenčna podlaga, s katero se primerja dokaz presoje (3.3).

3.3 Dokaz presoje

Zapisi, ugotovitve o dejstvih ali drugi informaciji v zvezi s **kriteriji presoje** (3.2) in se lahko tudi preverijo.

- OPOMBA: Dokaz presoje je lahko kvalitativen ali kvantitativen.

3.4 Ugotovitve presoje

Rezultati vrednotenja zbranih **dokazov presoje** (3.3) glede na **kriterije presoje** (3.2).

- OPOMBA: Ugotovitve presoje lahko pokažejo bodisi skladnost ali neskladnost s kriteriji presoje ali priložnosti za izboljšave.

3.5 Sklep presoje

Izid presoje (3.1), ki ga poda **presojevalna skupina** (3.9) po premisleku o ciljih in vseh ugotovitvah presoje (3.4).

3.1 audit

systematic, independent and documented process for obtaining **audit evidence** (3.3) and evaluating it objectively to determine the extent to which the **audit criteria** (3.2) are fulfilled

NOTE 1 Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the organization itself for management review and other internal purposes, and may form the basis for an organization's self-declaration of conformity. In many cases, particularly in smaller organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited.

NOTE 2 External audits include those generally termed second- and third-party audits. Second-party audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations, such as those providing registration or certification of conformity to the requirements of ISO 9001 or ISO 14001.

NOTE 3 When a quality management system and an environmental management system are audited together, this is termed a combined audit.

NOTE 4 When two or more auditing organizations cooperate to audit a single **auditee** (3.7), this is termed a joint audit.

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3.2 audit criteria

[3.2 audit criteria](https://standards.iteh.ai/catalog/standards/sist/aa016/03-1339-4e52-9251-2c38617b9db/sist-en-iso-19011-2003)

set of policies, procedures or requirements

NOTE Audit criteria are used as a reference against which audit evidence (3.3) is compared.

3.3 audit evidence

records, statements of fact or other information, which are relevant to the **audit criteria** (3.2) and verifiable

NOTE Audit evidence may be qualitative or quantitative.

3.4 audit findings

results of the evaluation of the collected **audit evidence** (3.3) against **audit criteria** (3.2)

NOTE Audit findings can indicate either conformity or nonconformity with audit criteria or opportunities for improvement.

3.5 audit conclusion

outcome of an **audit** (3.1), provided by the **audit team** (3.9) after consideration of the audit objectives and all **audit findings** (3.4)

3.6 Naročnik presoje

Organizacija ali oseba, ki zahteva **presojo** (3.1).

OPOMBA: Naročnik presoje je lahko **presojanec** (3.7) ali katerakoli druga organizacija, ki ima zakonsko ali pogodbeno pravico zahtevati presojo.

3.7 Presojanec

Presojana organizacija.

3.8 Presojevalec

Oseba, **kompetentna** (3.14) za izvedbo **presoje** (3.1).

3.9 Presojevalna skupina

Eden ali več **presojevalcev** (3.8), ki izvajajo **presojo** (3.1) in so jim po potrebi v pomoč **tehnični izvedenci** (3.10).

OPOMBA 1: En presojevalec v presojevalni skupini je v splošnem določen za vodjo presojevalne skupine.

OPOMBA 2: V presojevalni skupini so lahko presojevalci pripravniki.

3.10 Tehnični izvedenec

Oseba, ki priskrbi **presojevalni skupini** (3.9) personi who provides specific knowledge or expertise to the audit team (3.9)

OPOMBA 1: Specifično znanje ali izkušnje vključujejo znanje ali izkušnje v zvezi z organizacijo, procesom ali presojanimi aktivnostmi ali jezikom ali kulturo.

OPOMBA 2: Tehnični izvedenec v presojevalni skupini ne deluje kot presojevalec (3.8).

3.11 Program presoja

Skupek ene ali več **presa** (3.1), planiranih v specifičnem časovnem okviru in usmerjenih v specifičen namen.

OPOMBA: Program presoja vključuje vse aktivnosti, potrebne za planiranje, organiziranje in izvedbo presoja.

3.12 Plan presoje

Opis aktivnosti in dogоворов за **presojo** (3.1).

3.13 Predmet presoje

Obseg in meje **presa** (3.1).

3.6 audit client

organization or person requesting an **audit** (3.1)

NOTE The audit client may be the **auditee** (3.7) or any other organization which has the regulatory or contractual right to request an audit.

3.7 auditee

organization being audited

3.8 auditor

person with the **competence** (3.14) to conduct an **audit** (3.1)

3.9 audit team

one or more **auditors** (3.8) conducting an **audit** (3.1), supported if needed by **technical experts** (3.10)

NOTE 1 One auditor of the audit team is appointed as the audit team leader.

NOTE 2 The audit team may include auditors-in-training.

3.10 technical expert

set of one or more **audits** (3.1) planned for a specific time frame and directed towards a specific purpose

NOTE An audit programme includes all activities necessary for planning, organizing and conducting the audits.

3.12 audit plan

description of the activities and arrangements for an **audit** (3.1)

3.13 audit scope

extent and boundaries of an **audit** (3.1)

OPOMBA: Predmet presoje navadno vključuje opis fizičnih lokacij, organizacijskih enot, aktivnosti in procesov ter tudi časovni okvir.

NOTE The audit scope generally includes a description of the physical locations, organizational units, activities and processes, as well as the time period covered.

3.14 Kompetentnost

Izkazane osebnostne lastnosti in izkazana sposobnost za uporabo znanja in veščin.

4 Načela presojanja

Za presojanje je značilno zanašanje na številna načela. Ta naredijo presojo za učinkovito in zanesljivo orodje za podporo politikam vodenja in obvladovanja, s tem da priskrbi informacije, na podlagi katerih lahko organizacija ukrepa z namenom izboljšanja svojega delovanja. Upoštevanje teh načel je prvi pogoj za zagotovitev ustreznih in zadostnih sklepov presoje in možnosti presojevalcem, ki delujejo medsebojno neodvisno, da bi prišli do podobnih sklepov v podobnih okoliščinah.

Naslednja načela se nanašajo na presojevalce.

a) **Etično obnašanje:** *temelj strokovno opravljenega dela*

Odgovornost, neoporečnost, zaupnost in preudarnost so bistvene za presojanje.

b) **Korektnost predstavivte:** *dolžnost poročati resnično in točno*

Ugotovitve presoje, sklepi presoje in poročila o presojah odgovorno in natančno odsevajo aktivnosti presoje. Poroča se o pomembnih ovirah, na katere se je naletelo med presojo, in o nerešenih razlikah v mnenjih med presojevalno skupino in presojancem.

c) **Skrb za strokovnost:** *uporaba prizadevnosti in preudarnosti pri presojanju*

Presojevalci skrbijo, da je delo skladno s pomenom naloge, ki jo izvajajo, in zaupanjem, ki ga imajo vanje naročniki presoje in druge zainteresirane strani. Pomemben dejavnik pri tem je potrebna kompetentnost.

Naslednja načela se nanašajo na presojo, ki je po definiciji neodvisna in sistematična.

d) **Neodvisnost:** *temelj za nepristranost presoje in objektivnost sklepov presoje*

Presojevalci so neodvisni od presojanih aktivnosti, so nepristranski in nimajo navzkrižnih interesov. Presojevalci vzdržujejo objektivno razpoloženje med celotnim procesom presoje, da bi zagotovili,

3.14 competence

demonstrated personal attributes and demonstrated ability to apply knowledge and skills

4 Principles of auditing

Auditing is characterized by reliance on a number of principles. These make the audit an effective and reliable tool in support of management policies and controls, providing information on which an organization can act to improve its performance. Adherence to these principles is a prerequisite for providing audit conclusions that are relevant and sufficient and for enabling auditors working independently from one another to reach similar conclusions in similar circumstances.

The following principles relate to auditors.

a) **Ethical conduct:** *the foundation of professionalism*

Trust, integrity, confidentiality and discretion are essential to auditing.

b) **Fair presentation:** *the obligation to report truthfully and accurately*

Audit findings, audit conclusions and audit reports reflect truthfully and accurately the audit activities. Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and the auditee are reported.

c) **Due professional care:** *the application of diligence and judgement in auditing*

Auditors exercise care in accordance with the importance of the task they perform and the confidence placed in them by audit clients and other interested parties. Having the necessary competence is an important factor.

Further principles relate to the audit, which is by definition independent and systematic.

d) **Independence:** *the basis for the impartiality of the audit and objectivity of the audit conclusions*

Auditors are independent of the activity being audited and are free from bias and conflict of interest. Auditors maintain an objective state of mind throughout the audit process to ensure that the audit findings and

da bodo ugotovitve in sklepi presoje temeljili samo na stvarnih dokazih.

e) Pristop na podlagi dokazov: *racionalna metoda za doseganje zanesljivih in ponovljivih sklepov presoje v sistematičnem procesu presoje*

Dokaz presoje je preverljiv. Temelji na vzorcih informacij, ki so na voljo, saj se presoja izvaja v omejenem času in z omejenimi viri. Ustrezna uporaba vzorčenja je tesno povezana z zaupanjem v sklepe presoje.

Napotki, podani v preostalih točkah tega mednarodnega standarda, temeljijo na gornjih načelih.

5 Vodenje programa presojo

5.1 Splošno

Program presojo lahko vključuje eno ali več presoj, odvisno od velikosti, narave in kompleksnosti presojane organizacije. Te presoje imajo lahko različne cilje in lahko vključujejo skupne ali kombinirane presoje (glej opombi 3 in 4 pri definiciji presoje v 3.1).

Program presojo prav tako vključuje vse aktivnosti, potrebne za planiranje in organiziranje vrst in števila presoje in za zagotavljanje virov za njihovo učinkovito in uspešno izvedbo v danih časovnih okvirih.

Organizacija lahko vzpostavi več kot en program presojo.

Najvišje vodstvo organizacije naj podeli pooblastilo za vodenje programa presojo.

Odgovorne osebe za vodenje programa presojo naj:

- a) vzpostavijo, izvajajo, nadzorujejo, pregledujejo in izboljšujejo program presojo ter
- b) identificirajo in zagotovijo potrebne vire.

Slika 1 prikazuje potek procesa za vodenje programa presojo.

conclusions will be based only on the audit evidence.

e) Evidence-based approach: *the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process*

Audit evidence is verifiable. It is based on samples of the information available, since an audit is conducted during a finite period of time and with finite resources. The appropriate use of sampling is closely related to the confidence that can be placed in the audit conclusions.

The guidance given in the remaining clauses of this International Standard is based on the principles set out above.

5 Managing an audit programme

5.1 General

An audit programme may include one or more audits, depending upon the size, nature and complexity of the organization to be audited. These audits may have a variety of objectives and may also include joint or combined audits (see Notes 3 and 4 to the definition of audit in 3.1).

An audit programme also includes all activities necessary for planning and organizing the types and number of audits, and for providing resources to conduct them effectively and efficiently within the specified time frames.

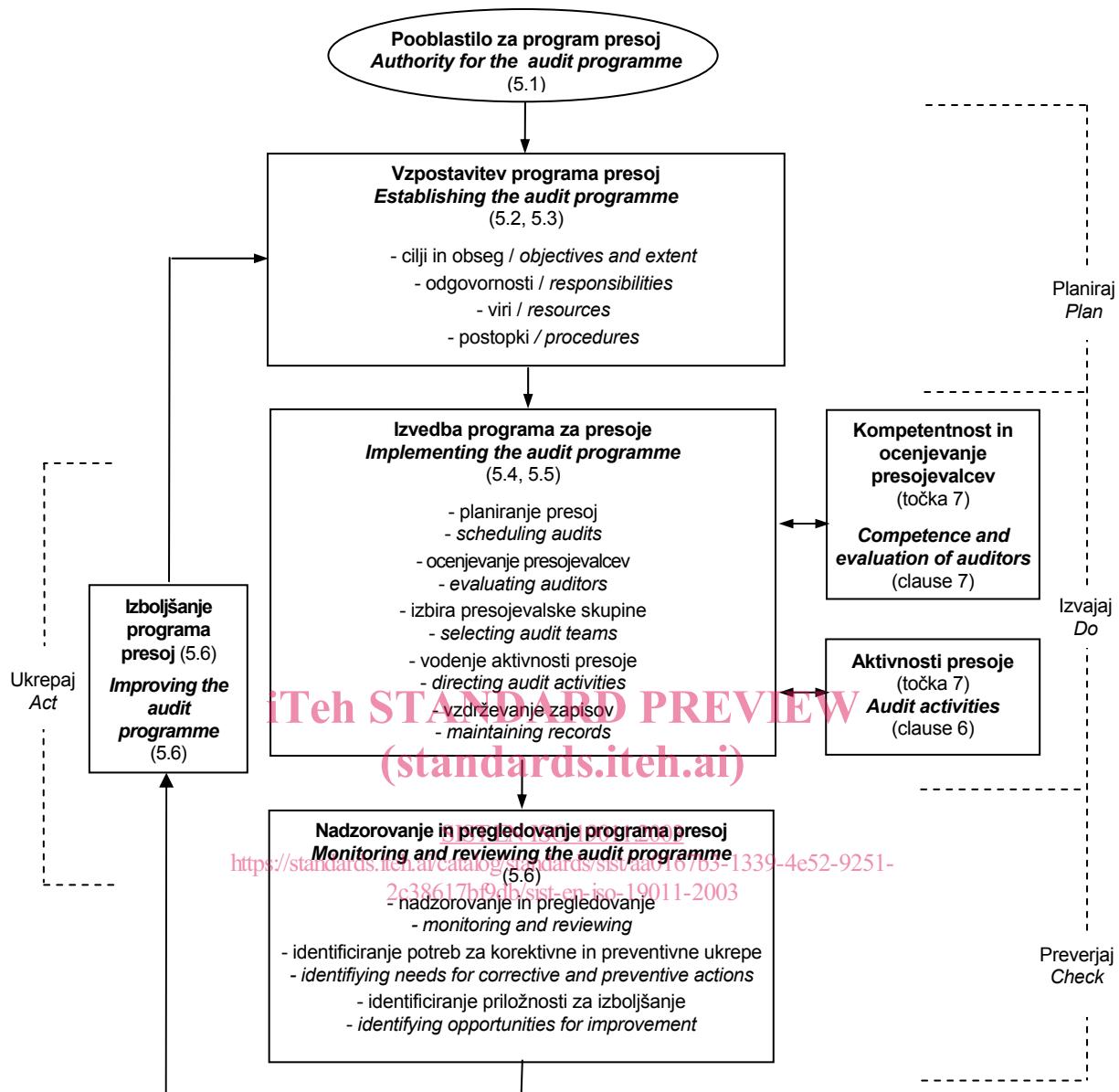
An organization may establish more than one audit programme.

The organization's top management should grant the authority for managing the audit programme.

Those assigned the responsibility for managing the audit programme should

- a) establish, implement, monitor, review and improve the audit programme, and
- b) identify the necessary resources and ensure they are provided.

Figure 1 illustrates the process flow for the management of an audit programme.



**Slika 1: Prikaz poteka procesa za vodenje programa presoja
Figure 1: Illustration of the process flow for the management of an audit programme**

OPOMBA 1: Slika 1 prikazuje tudi uporabo metodologije Planiraj - Izvajaj - Preverjaj – Ukrepaj v tem mednarodnem standardu.

OPOMBA 2: Številke v tej in vseh nadaljnjih slikah se sklicujejo na ustrezone točke tega mednarodnega standarda.

Če presojana organizacija izvaja sistem vodenja kakovosti in sistem ravnjanja z okoljem, se lahko v program presoju vključijo kombinirane presoje. V takem primeru naj se posebna pozornost posveti kompetentnosti presojevalne skupine.

NOTE 1 Figure 1 also illustrates the application of the Plan-Do-Check-Act methodology in this International Standard.

NOTE 2 The numbers in this and all subsequent figures refer to the relevant clauses of this International Standard.

If an organization to be audited operates both quality management and environmental management systems, combined audits may be included in the audit programme. In such a case, special attention should be paid to the competence of the audit team.

Dve ali več presojevalskih organizacij lahko sodeluje, kot del njihovih programov presoj, pri izvedbi skupne presoje. V takem primeru naj se posebna pozornost posveti razdelitvi odgovornosti, priskrbi kakršnihkoli dodatnih virov, kompetentnosti presojevalne skupine in primernim postopkom. Dogovor o tem naj se doseže pred začetkom presoje.

Praktična pomoč – Primeri programov presoj

Primeri programov presoj vključujejo:

- a) niz notranjih presoj, ki v tekočem letu zajamejo sistem vodenja kakovosti v celotni organizaciji;
- b) presoje sistema vodenja potencialnih dobaviteljev kritičnih proizvodov, ki jih izvaja druga stranka v 6-mesečnem obdobju;
- c) certifikacijske/registracijske in nadzorne presoje sistema ravnjanja z okoljem, ki jih izvaja certifikacijski/registracijski organ kot tretja stranka znotraj časovnega obdobja, pogodbeno dogovorenega med certifikacijskim organom in stranko.

Program presoj vključuje tudi primerno planiranje, priskrbo virov in vzpostavitev postopkov za izvedbo presoje znotraj programa.

<http://www.iteh.si/standards/iso/19011/standards.iteh.ai>

5.2 Cilji in obseg programa presoj

5.2.1 Cilji programa presoj

Vzpostavijo naj se cilji programa presoj za usmerjanje planiranja in izvajanja presoj.

Ti cilji naj temeljijo na premisleku o:

- a) vodstvenih prioritetah,
- b) poslovnih namerah,
- c) zahtevah za sistem vodenja,
- d) zahtevah zakonodaje in regulative ter pogodbenih zahtevah,
- e) potrebi po ocenjevanju dobaviteljev,
- f) zahtevah odjemalcev,
- g) potreba drugih zainteresiranih strani in
- h) tveganju za organizacijo.

Two or more auditing organizations may cooperate, as part of their audit programmes, to conduct a joint audit. In such a case, special attention should be paid to the division of responsibilities, the provision of any additional resources, the competence of the audit team and the appropriate procedures. Agreement on these should be reached before the audit commences.

Practical help — Examples of audit programmes

Examples of audit programmes include the following:

- a) a series of internal audits covering an organization-wide quality management system for the current year;
- b) second-party management system audits of potential suppliers of critical products to be conducted within 6 months;
- c) certification/registration and surveillance audits conducted by a third-party certification/registration body on an environmental management system within a time period agreed contractually between the certification body and the client.

An audit programme also includes appropriate planning, the provision of resources and the establishment of procedures to conduct audits within the programme.

5.2 Audit programme objectives and extent

5.2.1 Objectives of an audit programme

Objectives should be established for an audit programme, to direct the planning and conduct of audits.

These objectives can be based on consideration of

- a) management priorities,
- b) commercial intentions,
- c) management system requirements,
- d) statutory, regulatory and contractual requirements,
- e) need for supplier evaluation,
- f) customer requirements,
- g) needs of other interested parties, and
- h) risks to the organization.