
**Smernice za presojo sistemov kakovosti - 1. del: Presojanje
(identičen z ISO 10011-1:1990)**

Guidelines for auditing quality systems - Part 1: Auditing

Lignes directrices pour l'audit des systèmes qualité - Partie 1: Audit

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Leitfaden für das Audit von Qualitätssicherungssystemen -
Teil 1: Auditdurchführung

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UVOD

Standard SIST ISO 10011-1:1995, Smernice za presojo sistemov kakovosti - 1. del: Presojanje, prva izdaja, 1995, ima status slovenskega standarda in je identičen mednarodnemu standardu ISO 10011-1, Guidelines for auditing quality systems - Part 1: Auditing, First edition, 1990-12-15.

PREDGOVOR

Mednarodni standard ISO 10011-1:1990, Smernice za presojo sistemov kakovosti - 1. del: Presojanje je pripravil tehnični odbor Mednarodne organizacije za standardizacijo ISO/TC 176 Zagotavljanje kakovosti. Slovenski standard SIST ISO 10011-1:1995 je prevod angleškega besedila mednarodnega standarda ISO 10011-1:1990. V primeru spora glede besedila slovenskega prevoda v tem standardu je odločilen izvorni mednarodni standard v angleškem jeziku. Slovensko-angleško izdajo standarda je pripravil tehnični odbor USM/TC QAS Zagotavljanje kakovosti.

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

ZVEZE S STANDARDI

S prevzemom tega mednarodnega standarda veljajo naslednje zveze:

ISO 8402:1986 idt SLS ISO 8402:1993
ISO 10011-2:1991 idt SIST ISO 10011-2:1995
ISO 10011-3:1991 idt SIST ISO 10011-3:1995

Oznake in naslovi navedenih slovenskih standardov so:

SLS ISO 8402:1993 [SIST ISO 10011-1:1995](https://standards.iteh.ai/catalog/standards/sist/01c50d79-591b-4ca9-8d0-a0148cb6813f/sist-iso-10011-1-1995) Kakovost Slovar (identičen z ISO 8402:1986)
SIST ISO 10011-2:1995 Smernice za presojo sistemov kakovosti - 2. del: Kvalifikacijski kriteriji za presojevalce sistemov kakovosti (identičen z ISO 10011-2:1991)
SIST ISO 10011-3:1995 Smernice za presojo sistemov kakovosti - 3. del: Vodenje programov za presoje (identičen z ISO 10011-3:1991)

OSNOVA ZA IZDAJO STANDARDARDA

- Prevzem standarda ISO 10011-1:1990

OPOMBI

- Povsod, kjer se v besedilu standarda uporablja izraz "mednarodni standard", pomeni to v SIST ISO 10011-1:1995 "slovenski standard".
- Uvod in predgovor nista sestavni del standarda.

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UVOD

Skupina standardov ISO 9000 poudarja pomembnost presoje kakovosti in se ocenjuje kot ključno sredstvo vodstva za doseganje ciljev, postavljenih v politiki organizacije.

Presoje naj bi se izvajale z namenom, da se preveri, če so posamezni elementi znotraj sistema kakovosti učinkoviti in primerni za doseganje zastavljenih ciljev kakovosti.

Ta del standarda ISO 10011 predstavlja smernice za izvedbo presoje sistema kakovosti organizacije. Uporabniki lahko prilagodijo predložene smernice v skladu s svojimi potrebami.

Presoja sistema kakovosti prav tako preskrbi stvarne dokaze v zvezi s potrebami po zmanjšanju, odpravljanju in še posebej po preprečevanju neskladnosti.

Rezultate teh presoj lahko vodstvo podjetja uporabi za izboljšanje delovanja organizacije.

INTRODUCTION

The ISO 9000 series emphasizes the importance of quality audit as a key management tool for achieving the objectives set out in an organization's policy.

Audits should be carried out in order to determine that the various elements within a quality system are effective and suitable for achieving the stated quality objectives.

This part of ISO 10011 provides guidelines for performing an audit of a quality system of an organization. It allows users to adjust the guidelines described to suit their needs.

The quality system audit also provides objective evidence concerning the need for the reduction, elimination and, especially, prevention of nonconformities.

The results of these audits can be used by management to improve the performance of the organization.

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Smernice za presojo sistemov kakovosti -

1. del: Presojanje

1 Področje uporabe

Ta del standarda ISO 10011 postavlja osnovne principe presoje, kriterije in izvedbo, v njem so podane tudi smernice za vzpostavljanje, planiranje, izvajanje in dokumentiranje presoj sistemov kakovosti.

Ta del standarda podaja smernice za preverjanje obstoja in izvajanja elementov sistema kakovosti in sposobnosti sistema, da doseže zastavljene cilje kakovosti. Standard je dovolj splošen, da omogoča uporabnost ali prilagajanje različnim vrstam industrije in drugim organizacijam. Za izvajanje teh smernic naj vsaka organizacija razvije lastne specifične postopke.

2 Zveza z drugimi standardi (standards reference)

Spodaj navedeni standard vsebuje določila, ki v povezavi s tem besedilom tvorijo določila tega dela standarda ISO 10011. V času objave je bila veljavna spodaj navedena izdaja. Vsi standardi se revidirajo in strankam, ki sklenejo pogodbo, zasnovano na tem delu standarda ISO 10011, se priporoča, naj raziščejo možnost uporabe najnovejše izdaje spodaj navedenega standarda. Člani IEC in ISO vzdržujejo register veljavnih mednarodnih standardov.

ISO 8402:1986, Kakovost - Slovar.

3 Definicije

V tem delu standarda ISO 10011 se uporabljajo definicije, podane v standardu ISO 8402, skupaj z naslednjimi definicijami.

Opomba 1: Nekateri izrazi v ISO 8402 se tukaj ponavljajo, zato je vir zapisan v oklepaju.

Guidelines for auditing quality systems -

Part 1: Auditing

1 Scope

This part of ISO 10011 establishes basic audit principles, criteria and practices, and provides guidelines for establishing, planning, carrying out and documenting audits of quality systems.

It provides guidelines for verifying the existence and implementation of elements of a quality system and for verifying the system's ability to achieve defined quality objectives. It is sufficiently general in nature to permit it to be applicable or adaptable to different kinds of industries and organizations. Each organization should develop its own specific procedures for implementing these guidelines.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 10011. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10011 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 8402:1986, Quality - Vocabulary.

3 Definitions

For the purposes of this part of ISO 10011, the definitions given in ISO 8402, together with following definitions, apply.

NOTE 1 Some terms in ISO 8402 are repeated here and the source is indicated in brackets.

3.1 Presoja kakovosti: Sistematična in neodvisna preiskava, katere namen je ugotoviti, ali ukrepi za kakovost in njihovi rezultati ustrezajo načrtovanim ureditvam ter ali se te ureditve izvajajo učinkovito in ali so primerne za doseganje ciljev.

[ISO 8402]

Opombe: 2 Praviloma se presoja kakovosti uporablja za sisteme kakovosti in njihove elemente, za procese, proizvode ali storitve, vendar to ni omejitev. Te vrste presoje se pogosto imenujejo "presoja sistema kakovosti", "presoja procesa kakovosti", "presoja kakovosti proizvodov", "presoja kakovosti storitve".

3 Presoja kakovosti izvaja osebje, ki nima neposredne odgovornosti na področjih, ki se presojajo, vendar pa je priporočljivo sodelovanje z odgovornimi osebami področja.

4 Eden od ciljev presoje kakovosti je ovrednotenje potrebe po izboljšavah ali korektivnih ukrepih. Presoja naj se ne zamenjuje z aktivnostmi "nadzora" ali "kontrol", katerih namen je zgolj obvladovanje procesa ali sprejemljivost proizvoda.

5 Presoja kakovosti se lahko izvaja za notranje in zunanje potrebe.

3.2 Sistem kakovosti: Organizacijska struktura, odgovornosti, postopki, procesi in sredstva za izvajanje vodenja kakovosti.

[ISO 8402]

Opombi: 6 Sistem kakovosti naj bo le toliko obsežen, da omogoča doseganje zastavljenih ciljev.

7 Za pogodbene, zakonske in ocenjevalne potrebe se lahko zahteva predstavitev izpolnjevanja določenih elementov sistema.

3.3 Presojevalec (kakovosti): Oseba, ki je usposobljena za opravljanje presoj kakovosti.

Opombi: 8 Za opravljanje presoje kakovosti mora biti presojevalec pooblaščen za vsako posamezno presoj.

9 Presojevalec, imenovan za vodenje presoje kakovosti, se imenuje "vodja presoje".

3.1 quality audit: A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

[ISO 8402]

NOTES 2 The quality audit typically applies to, but is not limited to, a quality system or elements thereof, to processes, to products, or to services. Such audits are often called "quality system audit", "process quality audit", "product quality audit", "service quality audit".

3 Quality audits are carried out by staff not having direct responsibility in the areas being audited but, preferably, working in cooperation with the relevant personnel.

4 One purpose of the quality audit is to evaluate the need for improvement or corrective action. An audit should not be confused with "surveillance" or "inspection" activities performed for the sole purpose of process control or product acceptance.

5 Quality audits can be conducted for internal or external purposes.

3.2 quality system: The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

[ISO 8402]

NOTES 6 The quality system should only be as comprehensive as is needed to meet the quality objectives.

7 For contractual, mandatory and assessment purposes, demonstration of the implementation of identified elements in the system may be required.

3.3 auditor (quality): A person who has the qualification to perform quality audits.

NOTES 8 To perform a quality audit, the auditor must be authorized for that particular audit.

9 An auditor designated to manage a quality audit is called a "lead auditor".

3.4 Naročnik: Oseba ali organizacija, ki presojo naroča.

Opomba 10: Naročnik je lahko:

- a) presojanec, ki želi preverjanje skladnosti lastnega sistema kakovosti glede na zahteve enega od standardov sistema kakovosti;
- b) stranka, ki želi, da se preveri sistem kakovosti dobavitelja, za kar lahko uporablja svoje presojevalce ali tretjo stranko;
- c) neodvisna agencija, pooblaščenca za ugotavljanje, ali sistem kakovosti zagotavlja primerno obvladovanje kakovosti proizvodov ali storitev (z zakoni določeni organi, kot na primer za živilske proizvode, zdravila, jedrsko energijo, ali drugi);
- d) neodvisna agencija, imenovana za izvedbo presoje z namenom, da se sistem kakovosti presojane organizacije vnese v register.

3.4 client: A person or organization requesting the audit.

NOTE 10 The client may be:

- a) the auditee wishing to have its own quality system audited against some quality system standard;
- b) a customer wishing to audit the quality system of a supplier using his own auditors or a third party;
- c) an independent agency authorized to determine whether the quality system provides adequate control of the products or services being provided (such as food, drug, nuclear, or other regulatory bodies);
- d) an independent agency assigned to carry out an audit in order to list the audited organization's quality system in a register.

3.5 Presojanec: Organizacija, ki se presoja.

3.6 Ugotovitev: Poročilo o ugotovljenih dejstvih, sestavljeno v času presoje in podkrepljeno s stvarnimi dokazi.

3.7 Stvarni dokaz: Kvalitativne ali kvantitativne informacije, zapisi ali izjave o dejstvih, vezanih na kakovost posameznega proizvoda ali storitve ali na obstoj in izvajanje elementa sistema kakovosti, temelječe na ugotovitvah, merjenjih ali preskušanjih, ki se lahko preverijo.

3.8 Neskladnost: Neizpolnitev specificiranih zahtev.

[ISO 8402]

Opomba 11: Definicija obsega izostanek ali odstopanje ene ali več karakteristik kakovosti ali elementov sistema kakovosti od postavljenih zahtev.

3.5 auditee: An organization to be audited.

3.6 observation: A statement of fact made during an audit and substantiated by objective evidence.

3.7 objective evidence: Qualitative or quantitative information, records or statements of fact pertaining to the quality of an item or service or to the existence and implementation of a quality system element, which is based on observation, measurement or test and which can be verified.

3.8 nonconformity: The nonfulfilment of specified requirements.

[ISO 8402]

NOTE 11 The definition covers the departure or absence of one or more quality characteristics or quality system elements from specified requirements.

4 Cilji presoje in odgovornosti

4.1 Cilji presoje

Presoja je običajno načrtovana z vsaj enim od naslednjih namenov:

- za ugotavljanje skladnosti ali neskladnosti elementov sistema kakovosti s specificiranimi zahtevami;
- za ugotavljanje učinkovitosti uporabljenega sistema kakovosti pri doseganju zastavljenih ciljev kakovosti;
- da presojanču daje priložnost za izboljšanje sistema kakovosti;
- da se izpolnijo zahteve zakonskih predpisov;
- da se omogoči vpis sistema kakovosti presojane organizacije v register.

Presoja običajno spodbudi vsaj eden od naslednjih razlogov:

- da se pred sklepanjem pogodbe oceni dobavitelj;
- da se preveri, ali lasten sistem kakovosti organizacije še ustreza postavljenim zahtevam in se tudi izvaja;
- da se v okviru pogodbenega odnosa potrdi, da sistem kakovosti dobavitelja še ustreza postavljenim zahtevam in se tudi izvaja;
- da se oceni skladnost sistema kakovosti organizacije s standardom za sistem kakovosti.

Te presoje so lahko rutinske ali pa jih spodbudijo pomembne spremembe v sistemu kakovosti organizacije, v procesu, v kakovosti proizvoda ali storitve kakor tudi potrebe po spremljanju korektivnih ukrepov.

Opombi: 12 Rezultat presoj kakovosti naj ne prenaša odgovornosti za doseganje kakovosti z operativnega osebja na organizacijo, ki presoje izvaja.

4 Audit objectives and responsibilities

4.1 Audit objectives

Audits are normally designed for one or more of the following purposes:

- to determine the conformity or nonconformity of the quality system elements with specified requirements;
- to determine the effectiveness of the implemented quality system in meeting specified quality objectives;
- to provide the auditee with an opportunity to improve the quality system;
- to meet regulatory requirements;
- to permit the listing of the audited organization's quality system in a register.

Audits are generally initiated for one or more of the following reasons:

- to initially evaluate a supplier where there is a desire to establish a contractual relationship;
- to verify that an organization's own quality system continues to meet specified requirements and is being implemented;
- within the framework of a contractual relationship, to verify that the supplier's quality system continues to meet specified requirements and is being implemented;
- to evaluate an organization's own quality system against a quality system standard.

These audits may be routine, or may be prompted by significant changes in the organization's quality system, process, product or service quality, or by a need to follow up on corrective action.

NOTES 12 Quality audits should not result in a transfer of the responsibility to achieve quality from operating staff to the auditing organization.

13 Presoja kakovosti naj ne vodi k povečanju obsega funkcije kakovosti prek tistega, ki je nujen za doseganje ciljev kakovosti.

13 Quality audits should not lead to an increase in the scope of quality functions over and above those necessary to meet quality objectives.

4.2 Vloge in odgovornosti

4.2 Roles and responsibilities

4.2.1 Presojevalci

4.2.1 Auditors

4.2.1.1 Presojevalna skupina

4.2.1.1 Audit team

Kadar presajo izvajajo skupina ali posameznik, mora biti imenovan vodja presoje z vsemi pooblastili.

Whether an audit is carried out by a team or an individual, a lead auditor should be placed in overall charge.

Ovisno od okoliščin lahko ekipa presojevalcev vključuje strokovnjake s specializiranim osnovnim znanjem, presojevalce - pripravnike ali opazovalce, ki so sprejemljivi za naročnika, presojanca in vodjo presoje.

Depending upon the circumstances, the audit team may include experts with specialized background, auditor trainees or observers who are acceptable to the client, auditee and lead auditor.

4.2.1.2 Odgovornosti presojevalca

4.2.1.2 Auditor's responsibilities

Presojevalci so odgovorni za:

Auditors are responsible for

- podrejanje ustreznim zahtevam presoje;
 - sporočanje in pojasnjevanje zahtev presoje;
 - uspešno in učinkovito planiranje in izvajanje dodeljenih nalog;
 - dokumentiranje ugotovitev;
 - poročanje o rezultatih presoje;
 - overjanje (verificiranje) učinkovitosti korektivnih ukrepov, ki so posledica presoje (če stranka to zahteva);
 - shranjevanje in zaščito dokumentov, ki se nanašajo na presajo:
 - predložitev teh dokumentov na zahtevo,
 - zagotavljanje tajnosti teh dokumentov,
 - diskretno ravnanje s posebnimi podatki;
 - sodelovanje in pomoč vodji presoje.
- complying with the applicable audit requirements;
 - communicating and clarifying audit requirements;
 - planning and carrying out assigned responsibilities effectively and efficiently;
 - documenting the observations;
 - reporting the audit results;
 - verifying the effectiveness of corrective actions taken as a result of the audit (if requested by the client);
 - retaining and safeguarding documents pertaining to the audit:
 - submitting such documents as required,
 - ensuring such documents remain confidential,
 - treating privileged information with discretion;
 - cooperating with and supporting the lead auditor.