
**Smernice za presojo sistemov kakovosti - 3. del: Vodenje programov
za presoje (identičen z ISO 10011-3:1991)**

Guidelines for auditing quality systems - Part 3: Management of audit
programmes

Lignes directrices pour l'audit des systèmes qualité - Partie 3: Gestion
des programmes d'audit

Leitfaden für das Audit von Qualitätssicherungssystemen -
Teil 3: Management von Auditprogramm

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Referenčna številka
SIST ISO 10011-3:1995 (sl, en)

Nadaljevanje na straneh od 2 do 9

UVOD

Standard SIST ISO 10011-3:1995, Smernice za presojo sistemov kakovosti - 3. del: Vodenje programov za presoje, prva izdaja, 1995, ima status slovenskega standarda in je identičen mednarodnemu standardu ISO 10011-3:1991, Guidelines for auditing quality systems - Part 3: Management of audit programmes, First edition, 1991-05-01.

PREDGOVOR

Mednarodni standard ISO 10011-3:1991, Smernice za presojo sistemov kakovosti - 3. del: Vodenje programov za presoje je pripravil tehnični odbor Mednarodne organizacije za standardizacijo ISO/TC 176 Zagotavljanje kakovosti. Slovenski standard SIST ISO 10011-3:1995 je prevod angleškega besedila mednarodnega standarda ISO 10011-3:1991. 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 10011-1:1990 idt SIST ISO 10011-1:1995
ISO 10011-2:1991 idt SIST ISO 10011-2:1995

Oznake in naslovi navedenih slovenskih standardov so:

SLS ISO 8402:1993 Kakovost - Slovar (identičen z ISO 8402:1986)
SIST ISO 10011-1:1995 Smernice za presojo sistemov kakovosti - 1. del: Presojanje (identičen z ISO 10011-1:1990)
SIST ISO 10011-2:1995 Smernice za presojo sistemov kakovosti - 2. del: Kvalifikacijski kriteriji za presojevalce sistemov kakovosti (identičen z ISO 10011-2:1991)

OSNOVA ZA IZDAJO STANDARDA

- Prevzem standarda ISO 10011-3:1991

OPOMBI

- Povsod, kjer se v besedilu standarda uporablja izraz "mednarodni standard", pomeni to v SIST ISO 10011-3:1995 "slovenski standard".
- Uvod in predgovor nista sestavni del standarda.

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[SIST ISO 10011-3:1995](https://standards.iteh.ai/catalog/standards/sist/7f5f0a37-382e-45ad-a3d6-85e1d0c6b242/sist-iso-10011-3-1995)

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UVOD

Organizacija, ki želi stalno izvajati presoje sistemov kakovosti, naj zagotovi možnosti za vodenje celotnega procesa.

Ta del standarda ISO 10011 opisuje aktivnosti, ki naj jih izvaja takšna organizacija.

INTRODUCTION

Any organization which has an ongoing need to carry out audits of quality systems should establish a capability to provide overall management of the entire process.

This part of ISO 10011 describes the activities that should be addressed by such an organization.

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<https://standards.iteh.ai/catalog/standards/sist/7f5f0a37-382e-45ad-a3d6-85e1d0c6b242/sist-iso-10011-3-1995>

Smernice za presojo sistemov kakovosti - 3. del: Vodenje programov za presoje

1 Področje uporabe

Ta del standarda ISO 10011 podaja osnovne smernice za vodenje programov za presoje sistemov kakovosti.

Standard je primeren za vzpostavljanje in vzdrževanje vodenja programov za presoje, kadar se presoje sistemov kakovosti izvajajo v skladu s priporočili, podanimi v standardu ISO 10011-1.

2 Zveza z drugimi standardi

Spodaj navedeni standardi vsebujejo določila, ki v povezavi s tem besedilom tvorijo določila tega dela standarda ISO 10011. V času objave so bile veljavne spodaj navedene izdaje. Vsi standardi se revidirajo in strankam, ki sklenejo pogodbo, zasnovano na tem delu standarda ISO 10011, se priporoča, naj raziščejo možnost uporabe najnovjših izdaj spodaj navedenih standardov. Člani IEC in ISO vzdržujejo register veljavnih mednarodnih standardov.

ISO 8402:1986, Kakovost - Slovar

ISO 10011-1:1990, Smernice za presojo sistemov kakovosti - 1. del: Presojanje

ISO 10011-2:1991, Smernice za presojo sistemov kakovosti - 2. del: Kvalifikacijski kriteriji za presojevalce sistemov kakovosti

3 Definicije

V tem delu standarda ISO 10011 se uporabljajo definicije, podane v standardih ISO 8402 in ISO 10011-1, ter naslednja definicija.

Guidelines for auditing quality systems - Part 3: Management of audit programmes

1 Scope

This part of ISO 10011 gives basic guidelines for managing quality audit programmes.

It is applicable to the establishment and maintenance of an audit programme management function when performing quality systems audits in accordance with the recommendations given in ISO 10011-1.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10011. At the time of publication, the editions indicated were 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 editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1986, Quality - Vocabulary.

ISO 10011-1:1990, Guidelines for auditing quality systems - Part 1: Auditing.

ISO 10011-2:1991, Guidelines for auditing quality systems - Part 2: Qualification criteria for quality systems auditors.

3 Definitions

For the purposes of this part of ISO 10011, the definitions given in ISO 8402 and ISO 10011-1 and the following definition apply.

3.1 Vodstvo programa za presoje:

Organizacija ali funkcija znotraj organizacije, kateri je naložena odgovornost za planiranje in izvedbo načrtovanega zaporedja presoj.

4 Vodenje programa presoje

4.1 Organizacija

Organizacija, ki želi stalno izvajati presoje sistemov kakovosti, naj zagotovi možnosti za vodenje celotnega procesa. Ta funkcija naj bo neodvisna od neposredne odgovornosti za izvajanje sistemov kakovosti, ki se presojujejo.

4.2 Standardi

Vodstvo programa za presoje naj določi standarde za sisteme kakovosti, glede na katere naj se presoja, in naj razvije možnosti za učinkovito presojo glede na te standarde.

4.3 Kvalifikacija osebja

4.3.1 Vodstvo programa za presoje

Program za presoje naj vodi osebje, ki ima praktično znanje v zvezi s postopki in izvajanjem presoj kakovosti.

4.3.2 Presojevalci

Vodstvo programa za presoje naj zaposli presojevalce, ki ustrezajo priporočilom, podanim v standardu ISO 10011-2. Te presojevalce naj potrdi ocenjevalna komisija, ki je sprejemljiva za vodstvo programa za presoje in ki ustreza priporočilom, podanim v standardu ISO 10011-2.

4.4 Ustreznost članov skupine

Vodstvo programa za presoje naj pri izbiri presojevalcev in vodij presoj za določene naloge upošteva naslednje dejavnike, s katerimi zagotovi za vsako nalogo primerne veščine:

3.1 audit programme management:

Organization, or function within an organization, given the responsibility to plan and carry out a programmed series of quality systems audits.

4 Managing an audit programme

4.1 Organization

Any organization which has an ongoing need to carry out audits of quality systems should establish a capability to provide overall management of the entire process. This function should be independent of direct responsibility for implementing the quality systems being audited.

4.2 Standards

Audit programme management should determine the quality system standards they may be expected to audit against and develop capabilities to enable them to audit effectively against such standards.

4.3 Qualification of staff

4.3.1 Audit programme management

Management of the audit programme should be carried out by those who have practical knowledge of quality audit procedures and practices.

4.3.2 Auditors

Audit programme management should employ auditors who comply with the recommendations given in ISO 10011-2. Such auditors should be approved by an evaluation panel, acceptable with the recommendations given in ISO 10011-2.

4.4 Suitability of team members

Audit programme management should consider the following factors when selecting auditors and lead auditors for particular assignments in order to ensure that the skills brought to each assignment are appropriate:

- | | |
|--|--|
| <ul style="list-style-type: none"> - tip standarda za sistem kakovosti, glede na katerega se bo izvajala presoja (na primer standardi za proizvodnjo, računalniško programsko opremo ali za storitve); - tip storitve ali proizvoda in z njim povezane zakonske zahteve (na primer zdravstvo, živila, zavarovanje, računalniki, instrumentarij, jedrske naprave); - potreba po poklicni usposobljenosti ali tehničnem strokovnem znanju v določeni stroki; - velikost in sestava skupine presojevalcev; - potreba po veščini vodenja skupine; - sposobnost za učinkovito uporabo veščin posameznih članov skupine; - osebne veščine, potrebne za delo z določenim presojevalcem; - zahtevano znanje jezika; - ne sme biti nikakršnega dejanskega ali možnega nasprotja interesov; - drugi zadevni dejavniki. | <ul style="list-style-type: none"> - the type of quality system standard against which the audit is to be conducted (for example, manufacturing, computer software or service standards); - the type of service or product and its associated regulatory requirements (for example, health care, food, insurance, computers, instrumentation, nuclear devices); - the need for professional qualifications or technical expertise in a particular discipline; - the size and composition of the audit team; - the need for skill in managing the team; - the ability to make effective use of the skills of the various audit team members; - the personal skills needed to deal with a particular auditee; - the required language skills; - the absence of any real or perceived conflict of interest; - other relevant factors. |
|--|--|

4.5 Spremljanje in vzdrževanje dela presojevalcev

4.5.1 Ocenjevanje dela

Vodstvo programa za presoje naj stalno ocenjuje delo presojevalcev bodisi z opazovanjem presoj ali kako drugače. Te informacije naj se uporabijo za izboljšanje izbire presojevalcev in njihovega dela, kakor tudi za ugotavljanje neustreznega dela.

Vodstvo programa za presoje naj to informacijo posreduje ocenjevalnim komisijam, kadar je to potrebno.

4.5 Monitoring and maintenance of auditor performance

4.5.1 Performance evaluations

Audit programme management should continually evaluate the performance of their auditors, either through observation of audits or other means. Such information should be used to improve auditor selection and performance and to identify unsuitable performance.

Audit programme management should make this information available to evaluation panels, where required.

4.5.2 Skladnost med presojevalci

Presoje, ki so jih izvedli različni presojevalci, naj imajo podobne zaključke, če je enaka operacija presojana pod enakimi pogoji. Vodstvo programa za presoje naj vzpostavi metode za merjenje in primerjavo dela presojevalcev za doseganje skladnosti med presojevalci. Takšne metode naj vključujejo:

- delavnice za usposabljanje presojevalcev;
- primerjave dela presojevalcev;
- preglede poročil presoj;
- ocene dela;
- menjave presojevalcev med skupinami presojevalcev.

4.5.3 Usposabljanje

Vodstvo programa za presoje naj redno ocenjuje potrebe po usposabljanju presojevalcev in ustrezno ukrepa, da se vzdržujejo in izboljšujejo veščine za presojo.

4.6 Operativni dejavniki**4.6.1 Splošno**

Vodstvo programa za presoje naj upošteva naslednje dejavnike in kjer je potrebno, vzpostavi postopke, s katerimi zagotovi, da osebje lahko deluje skladno in ima tudi primerno podporo.

4.6.2 Zagotovitev virov

Vzpostavljeni naj bodo postopki, s katerimi se zagotovijo primerni viri za doseganje ciljev programa za presoje.

4.6.3 Planiranje programa presoje

Vzpostavijo naj se postopki za planiranje programov presoj.

4.6.4 Poročanje o presoji

Oblika poročila naj bo formalno določena do takšne mere, kolikor je to praktično.

4.5.2 Consistency of auditors

Audits conducted by different auditors should arrive at similar conclusions when the same operation is audited under the same conditions. Audit programme management should establish methods to measure and compare auditor performance to achieve consistency among auditors. Such methods should include:

- auditor training workshops;
- auditor performance comparisons;
- reviews of audit reports;
- performance appraisals;
- rotation of auditors between audit teams.

4.5.3 Training

Audit programme management should regularly assess the training needs of auditors and take appropriate action to maintain and improve audit skill.

4.6 Operational factors**4.6.1 General**

Audit programme management should consider the following factors and, where necessary, establish procedures to ensure that their staff can operate in a consistent manner and are adequately supported.

4.6.2 Commitment of resources

Procedures should be established to ensure that adequate resources are available to accomplish audit programme objectives.

4.6.3 Audit programme planning and scheduling

Procedures should be established for planning and scheduling the programme of audits.

4.6.4 Audit reporting

Audit report formats should be formalized to the extent practicable.