
**Smernice za presojo sistemov kakovosti - 2. del: Kvalifikacijski
kriteriji za presojevalce sistemov kakovosti
(identičen z ISO 10011-2:1991)**

Guidelines for auditing quality systems - Part 2: Qualification criteria for
quality systems auditors

Lignes directrices pour l'audit des systèmes qualité - Partie 2: Critères de
qualification pour les auditeurs de systèmes qualité

Leitfaden für das Audit von Qualitätssicherungssystemen -
Teil 2: Qualifikationskriterien für Qualitätsauditoren

Deskriptorji: zagotavljanje kakovosti, program zagotavljanja kakovosti, presojanje
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Referenčna številka
SIST ISO 10011-2:1995 (sl, en)

Nadaljevanje na straneh od 2 do 14

UVOD

Standard SIST ISO 10011-2:1995, Smernice za presojo sistemov kakovosti - 2. del: Kvalifikacijski kriteriji za presojevalce sistemov kakovosti, prva izdaja, 1995, ima status slovenskega standarda in je identičen mednarodnemu standardu ISO 10011-2:1991, Guidelines for auditing quality systems - Part 2: Qualification criteria for quality systems auditors, First edition, 1991-05-01.

PREDGOVOR

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

Oznake in naslovi navedenih slovenskih standardov: <https://standards.iteh.ai/catalog/standards/sist/08e8d0f8-96b8-4fd7-974c-1da17d09f8c9/sist-iso-10011-2-1995>

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 10011-3:1995 Smernice za presojo sistemov kakovosti - 3. del: Vodenje programov za presoje (identičen z ISO 10011-3:1991)

OSNOVA ZA IZDAJO STANDARDARDA

- Prevzem standarda ISO 10011-2:1991

OPOMBI

- Povsod, kjer se v besedilu standarda uporablja izraz "mednarodni standard", pomeni to v SIST ISO 10011-2:1995 "slovenski standard".
- Uvod in predgovor nista sestavni del standarda.

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SIST ISO 10011-2:1995

<https://standards.iteh.ai/catalog/standards/sist/08e8d0f8-96b8-4fd7-974c-1da17d0918c9/sist-iso-10011-2-1995>

UVOD

Za učinkovito in poenoteno izvedbo presoj sistemov kakovosti, kot določa ISO 10011-1, se za usposabljanje presojevalcev zahtevajo minimalni kriteriji.

Ta del standarda ISO 10011 podaja te minimalne kriterije.

Podana je tudi metoda, s katero naj se za vsakega posameznega potencialnega kandidata za presojevalca ocenjuje in vzdržuje skladnost s kriteriji. To informacijo vsebuje dodatek A, ki je sestavni del tega dela ISO 10011. Dodatek B podaja informacijo o certificiranju nacionalnih presojevalcev, vendar ni sestavni del tega dela ISO 10011.

INTRODUCTION

In order that quality systems audits are carried out effectively and uniformly as defined in ISO 10011-1, minimum criteria are required to quality auditors.

This part of ISO 10011 describes these minimum criteria.

It also provides the method by which individual potential auditor's compliance to the criteria should be judged and maintained. This information is contained in annex A, which is an integral part of this part of ISO 10011. Annex B contains information on national auditor certification but is not an integral part of this part of ISO 10011.

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Smernice za presojo sistemov kakovosti - 2. del: Kvalifikacijski kriteriji za presojevalce sistemov kakovosti

Guidelines for auditing quality systems - Part 2: Qualification criteria for quality systems auditors

1 Področje uporabe

Ta del ISO 10011 podaja smernice za kvalifikacijske kriterije za presojevalce.

Uporablja se pri izboru presojevalcev za presojo sistemov kakovosti, kot je priporočeno v 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 najnovejših 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 10011-3:1991, Smernice za presojo sistemov kakovosti - 3. del: Vodenje programov za presojo

3 Definicije

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

1 Scope

This part of ISO 10011 gives guidance on qualification criteria for auditors.

It is applicable in the selection of auditors to perform quality systems audits as recommended 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 10011-3:1991, Guidelines for auditing quality systems - Part 3: Management of audit programmes.

3 Definitions

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

4 Izobrazba

Kandidati za presojevalce naj imajo najmanj srednjo izobrazbo, to je tisti del splošnega šolanja, ki pride po osnovni stopnji izobrazbe, vendar pred tisto, ki šteje za diplomu, oziroma kot jo drugače določi ocenjevalna komisija, opisana v dodatku A. Kandidati naj svojo usposobljenost dokažejo z jasnimi in tekočimi izražanjem pojmov ter zamisli tako ustno kot pisno in to v svojem, uradno priznanem jeziku.

5 Usposabljanje

Kandidati za presojevalce naj se usposabljujejo v obsegu, potrebnem za zagotovitev usposobljenosti za veščine, ki se zahtevajo za izvajanje in vodenje presoj. Posebej pomembno je usposabljanje na naslednjih področjih:

- poznavanje in razumevanje standardov na podlagi katerih se presojajo sistemi kakovosti;
- ocenjevalne tehnike, kot so pregledovanje, spraševanje, vrednotenje in poročanje;
- dodatne veščine, potrebne za vodenje presoje, kot so planiranje, organiziranje, sporočanje in usmerjanje.

Takšna usposobljenost naj se dokaže s pisnimi ali ustnimi izpiti ali na drugačen sprejemljiv način.

6 Izkušnje

Kandidati za presojevalce naj imajo najmanj štiri leta praktičnih izkušenj na delovnem mestu s polnim delovnim časom (čas usposabljanja ne šteje), od tega vsaj dve leti izkušenj v dejavnosti zagotavljanja kakovosti.

4 Education

Auditor candidates should have completed at least secondary education, that is, that part of the national educational system that comes after the primary or elementary stage but prior to that which qualifies for a degree, or as otherwise determined by the evaluation panel described in annex A. Candidates should have demonstrated competence in clearly and fluently expressing concepts and ideas orally and in writing in their officially recognised language.

5 Training

Auditor candidates should have undergone training to the extent necessary to ensure their competence in the skills required for carrying out audits, and for managing audits. Training in the following areas should be regarded as particularly relevant:

- knowledge and understanding of the standards against which quality systems audits may be performed;
- assessment techniques of examining, questioning, evaluating and reporting;
- additional skills required for managing an audit, such as planning, organizing, communicating and directing.

Such competence should be demonstrated through written or oral examinations, or other acceptable means.

6 Experience

Auditor candidates should have a minimum of four years' full-time appropriate practical workplace experience (not including training), at least two years of which should have been in quality assurance activities.

Pred prevzemom odgovornosti za opravljanje presoj kot presojevalec naj kandidat pridobi izkušnje v celotnem procesu presoje, kot je opisano v ISO 10011-1. Izkušnje lahko pridobi s sodelovanjem pri najmanj štirih presojah, ki skupaj trajajo najmanj dvajset dni in vključujejo pregled dokumentacije, praktične aktivnosti pri presoji in poročanje o presoji.

Vse te izkušnje naj bodo primerno aktualne.

7 Osebnostne lastnosti

Kandidati za presojevalca naj bodo dojemljive in zrele osebnosti, sposobne pravilne, analitične presoje, ter vztrajne, imajo naj sposobnost realističnega opazovanja stanja, da razumejo zapletene operacije širše perspektive in da razumejo vlogo posameznih enot v sklopu celotne organizacije.

Presojevalec naj bo sposoben uporabljati te lastnosti z namenom, da:

- pridobi stvarne dokaze in jih pošteno oceni;
- ostane zvest namenu presoje brez strahu ali pristranosti;
- nenehno ocenjuje ugotovitve presoje ter osebnih stikov med presoj;
- ravna z osebjem tako, da bo čim boljše dosegel namen presoje;
- z občutkom upošteva šege in navade države, v kateri se izvaja presoja;
- kljub motnjam izvaja postopek presoje brez odstopanj;
- posveča vso pozornost in daje vso podporo postopku presoje;
- v stresnih okoliščinah deluje učinkovito;
- na podlagi ugotovitev presoje pride do splošno sprejemljivih zaključkov;
- ostaja zvest zaključkom kljub pritiskom za spremembe, ki ne izhajajo iz dokazov.

Prior to assuming responsibility for performing audits as an auditor, the candidate should have gained experience in the entire audit process as described in ISO 10011-1. This experience should have been gained by participating in a minimum of four audits, for a total of at least 20 days, including documentation review, actual audit activities and audit reporting.

All relevant experience should be reasonably current.

7 Personal attributes

Auditor candidates should be open-minded and mature; possess sound judgement, analytical skills and tenacity; have the ability to perceive situations in a realistic way, to understand complex operations from a broad perspective, and to understand the role of individual units within the overall organization.

The auditor should be able to apply these attributes in order to

- obtain and assess objective evidence fairly;
- remain true to the purpose of the audit without fear or favour;
- evaluate constantly the effects of audit observations and personal interactions during an audit;
- treat concerned personnel in a way that will best achieve the audit purpose;
- react with sensitivity to the national conventions of the country in which the audit is performed;
- perform the audit process without deviating due to distractions;
- commit full attention and support to the audit process;
- react effectively in stressful situations;
- arrive at generally acceptable conclusions based on audit observations;
- remain true to a conclusion despite pressure to change that is not based on evidence.

8 Vodstvene sposobnosti

Kandidati za presojevalce naj na ustrezen način dokažejo svoje poznavanje in zmožnost uporabljanja potrebnih vodstvenih veščin, ki se zahtevajo pri izvajanju presoje, kot je priporočeno v ISO 10011-1.

9 Vzdrževanje usposobljenosti

Presojevalci naj vzdržujejo svojo usposobljenost:

- z zagotavljanjem, da je njihovo poznavanje standardov in zahtev za sisteme kakovosti ažurno;
- z zagotavljanjem, da je njihovo poznavanje postopkov in metod presojanja ažurno;
- z udeležbo pri obnavljanju usposobljenosti, kadar je to potrebno;
- s tem, da ocenjevalna komisija najmanj vsaka tri leta pregleda njihovo delo (glej dodatek A).

Ti ukrepi naj zagotovijo, da presojevalec nenehno izpolnjuje vse zahteve tega dela standarda ISO 10011. Pri pregledih presojevalca naj se upoštevajo vse dodatne informacije, pozitivne ali negativne, nastale po zadnjem pregledu.

10 Jezik

Nihče izmed presojevalcev naj ne sodeluje pri presojah brez pomoči, če dogovorjenega jezika presoje ne obvlada tekoče. Ta pomoč pomeni, da imajo presojevalci ves čas na voljo osebo s potrebnim tehničnim poznavanjem jezika, nedovzetno za pritiske, ki bi vplivali na izvajanje presoje.

8 Management capabilities

Auditor candidates should demonstrate through suitable means their knowledge of, and capability of using, the necessary management skills required in the execution of an audit as recommended in ISO 10011-1.

9 Maintenance of competence

Auditors should maintain their competence by

- ensuring that their knowledge of quality systems standards and requirements is current;
- ensuring that their knowledge of auditing procedures and methods is current;
- participating in refresher training where necessary;
- having their performance reviewed at least every three years by an evaluation panel (see annex A).

These measures should ensure that the auditor continues to meet all the requirements of this part of ISO 10011. Auditor reviews should take into account any additional information, positive or negative, developed subsequent to the previous review.

10 Language

No audit personnel should participate in unsupported audits where they are not fluent in the agreed language of the audit. Support in these terms means the audit personnel have at all times available to them a person with the necessary technical language skills, who is not subject to pressures that would affect the performance of the audit.

11 Izbira vodje presoje

Vodstvo programa presoje naj izbere vodjo presoje za določeno presojo med kvalificiranimi presojevalci z uporabo dejavnikov, opisanih v ISO 10011-3, ter ob upoštevanju naslednjih dodatnih kriterijev:

- da so kandidati sodelovali kot kvalificirani presojevalci pri najmanj treh celotnih presojah, izvedenih v skladu s priporočili, podanimi v ISO 10011-1;
- da so kandidati dokazali sposobnost učinkovitega sporočanja tako ustno kot pisno v dogovorjenem jeziku presoje.

11 Selection of lead auditor

The lead auditor for a specific audit should be selected by audit programme management from qualified auditors using the factors described in ISO 10011-3, taking into account the following additional criteria:

- the candidates should have acted as qualified auditors in at least three complete audits performed in accordance with the recommendations given in ISO 10011-1;
- the candidates should have demonstrated the capability to communicate effectively both orally and in writing in the agreed language of the audit.

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