SLOVENSKI STANDARD

SIST EN ISO/IEC 17025

julij 2005

Splošne zahteve za usposobljenost preskuševalnih in kalibracijskih laboratorijev (ISO/IEC 17025:2005)

General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)

Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais (ISO/IEC 17025:2005)

Allgemeine Anforderungen an die Kompetenz von Prüf- und Kalibrierlaboratorien (ISO/IEC 17025:2005)

ICS 03.120.20; 19.020

Referenčna oznaka
SIST EN ISO/IEC 17025:2005 (sl,en)

Nadaljevanje na straneh II in od 1 do 50

NACIONALNI UVOD

Standard SIST EN ISO/IEC 17025 (sl,en), Splošne zahteve za usposobljenost preskuševalnih in kalibracijskih laboratorijev, 2005, ima status slovenskega standarda in je enakovreden evropskemu standardu EN ISO/IEC 17025 (en), General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005), 2005.

NACIONALNI PREDGOVOR

Evropski standard EN ISO/IEC 17025:2005 je pripravil Odbor za ugotavljanje skladnosti CASCO v sodelovanju s tehničnim odborom Evropskega komiteja za standardizacijo CEN/CLC TC 1 Merila za organe za ugotavljanje skladnosti.

Slovenski standard SIST EN ISO/IEC 17025:2005 je prevod evropskega standarda EN ISO/IEC 17025:2005. Ob sporu zaradi besedila slovenskega prevoda v tem standardu je odločilen izvirni evropski standard v angleškem jeziku. Slovensko izdajo standarda je pripravil tehnični odbor SIST/TC UGA Ugotavljanje skladnosti.

V prevodu je uporabljen izraz kalibracija (in izpeljanke), ki ga je po Mednarodnem slovarju osnovnih in splošnih izrazov s področja meroslovja, 1999, mogoče zamenjati z istopomenskim izrazom umerjanje.

ZVEZA S STANDARDOM

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

SIST EN ISO 9001:2000 (sl,en) Sistemi vodenja kakovosti – Zahteve

Mednarodni slovar osnovnih in splošnih izrazov s področja meroslovja, Urad za standardizacijo in meroslovje. Ljubljana 1999.

OSNOVA ZA PRIVZEM STANDARDA

– EN ISO/IEC 17025:2005

PREDHODNA IZDAJA

– SIST EN ISO/IEC 17025:2002 (sl,en) Splošne zahteve za usposobljenost preskuševalnih in kalibracijskih laboratorijev

OPOMBE

– Povsod, kjer se v besedilu standarda uporablja izraz »evropski standard« oziroma »mednarodni standard«, v SIST EN ISO/IEC 17025:2005 to pomeni »slovenski standard«.

– Nacionalni uvod in nacionalni predgovor nista sestavni del standarda.

– Ta nacionalni dokument je enakovreden EN ISO/IEC 17025:2005 in je objavljen z dovoljenjem
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EVROPSKI STANDARD
EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO/IEC 17025

maj 2005

ICS: 03.120.20

Nadomešča EN ISO/IEC 17025:2000

Slovenska izdaja

Splošne zahteve za usposobljenost preskuševalnih in kalibracijskih laboratorijev (ISO/IEC 17025:2005)

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Ta evropski standard sta CEN in CENELEC odobrila dne 15. marca 2005.

Članice CEN in CENELEC morajo izpolnjevati notranje predpise CEN/CENELEC, s katerimi je predpisano, da mora biti ta standard brez kakršnihkoli sprememb sprejet kot nacionalni standard. Seznami najnovejših izdaj teh nacionalnih standardov in njihovi bibliografski podatki so na voljo pri CEN Management Centre ali pri članicah CEN ali CENELEC.

Ta evropski standard obstaja v treh uradnih izdajah (angleški, francoski in nemški). Izdaje v drugih jezikih, ki jih članice CEN in CENELEC na lastno odgovornost prevedejo in izdajo ter prijavijo pri CEN Management Centre, veljajo kot uradne izdaje.

Članice CEN in CENELEC so nacionalni organi za standarde oziroma nacionalni elektrotehniški komiteji Avstrije, Belgije, Cipra, Češke republike, Danske, Estonije, Finske, Francije, Grčije, Irske, Islandije, Italije, Latvije, Litve, Luksemburga, Madžarske, Malte, Nemčije, Nizozemske, Norveške, Poljske, Portugalske, Slovaške, Slovenije, Španije, Švedske, Švice in Združenega kraljestva.

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VSEBINA **Stran**

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Predgovor

Mednarodna organizacija za standardizacijo (ISO – International Organization for Standardization) in Mednarodna elektrotehniška komisija (IEC – International Electrotechnical Commission) tvorita specializiran sistem svetovne standardizacije. Nacionalni organi, člani ISO ali IEC, sodelujejo pri pripravi mednarodnih standardov prek tehničnih odborov, ki jih prva ali druga organizacija ustanovi za obravnavanje posameznega tehničnega področja. Na področjih, ki so v skupnem interesu, tehnični odbori ISO in IEC sodelujejo med seboj. V delo se vključujejo tudi druge vladne in nevladne mednarodne organizacije, ki se povezujejo z ISO in IEC. Za razvoj mednarodnih standardov in vodil s področja ugotavljanja skladnosti je odgovoren Odbor ISO za ugotavljanje skladnosti (CASCO – Committee on conformity assessment).

Mednarodni standardi se pripravljajo v skladu s pravili iz Direktiv ISO/IEC, 2. del.

Osnutki mednarodnih standardov, ki jih sprejmejo tehnični odbori, so posredovani nacionalnim organom, ki o njih glasujejo. Za izdajo mednarodnega standarda je potrebna odobritev vsaj 75 % nacionalnih organov, ki so oddali svoje glasove.

Opozariti je treba na možnost, da so nekateri elementi tega dokumenta lahko predmet patentnih pravic. ISO in IEC ne odgovarjata za prepoznavanje nobene oziroma nobenih takih patentnih pravic.

Standard ISO/IEC 17025 je pripravil *Odbor ISO za ugotavljanje skladnosti (*CASCO – *Committee on conformity assessment)*.

Standard je bil razposlan v glasovanje nacionalnim organom ISO in IEC in sta ga odobrili obe organizaciji.

Ta, druga izdaja preklicuje in nadomešča prvo izdajo (ISO/IEC 17025:1999), ki je tehnično revidirana.

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

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

Draft International Standards are circulated to the national bodies for voting. Publication as an International Standard requires approval by at least 75 % of the national 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/IEC 17025 was prepared by the *ISO Committee on conformity assessment* (CASCO).

It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This second edition cancels and replaces the first edition (ISO/IEC 17025:1999), which has been technically revised.

Uvod

Prva izdaja (1999) tega mednarodnega standarda je bila izdelana na podlagi obsežnih izkušenj pri uporabi vodila ISO/IEC 25 in standarda EN 45001, ki ju je nadomestila. Standard je vseboval vse zahteve, ki jih morajo izpolnjevati preskuševalni in kalibracijski laboratoriji, če želijo dokazati, da imajo vzpostavljen sistem vodenja, da so tehnično usposobljeni in da so sposobni pridobiti tehnično veljavne rezultate.

Prva izdaja se je sklicevala na ISO 9001:1994 in ISO 9002:1994. Ta dva standarda je nadomestil ISO 9001:2000, zaradi česar je bilo treba uskladiti tudi ISO/IEC 17025. V tej, drugi izdaji so poglavja spremenjena ali dodana le, če je bilo to v luči standarda ISO 9001:2000 potrebno.

Akreditacijski organi, ki priznavajo usposobljenost preskuševalnih in kalibracijskih laboratorijev, naj bi uporabljali ta mednarodni standard kot podlago za akreditacijo. V 4. točki pa so opisane zahteve za dobro vodenje. V 5. poglavju so navedene zahteve za tehnično usposobljenost za vrste preskušanja in/ali kalibriranja, ki jih laboratorij izvaja.

Vse širša uporaba sistemov vodenja je povečala potrebo, da bi laboratoriji, ki so sestavni del večjih organizacij ali ponujajo druge storitve, lahko delovali po sistemu vodenja kakovosti, skladnem tako s standardom ISO 9001 kot tudi s tem mednarodnim standardom. Zato je bilo poskrbljeno, da so v ta mednarodni standard vključene vse tiste zahteve standarda ISO 9001, ki so pomembne za obseg preskuševalnih in kalibracijskih storitev, zajetih s sistemom vodenja laboratorijev.

Preskuševalni in kalibracijski laboratoriji, ki delujejo v skladu s tem mednarodnim standardom, bodo s tem delovali tudi v skladu z ISO 9001.

Skladnost sistema vodenja kakovosti, po katerem laboratorij deluje, z zahtevami ISO 9001 sama po sebi še ne dokazuje usposobljenosti laboratorija za pridobivanje tehnično veljavnih podatkov in rezultatov. Prav tako pa dokazana skladnost s tem mednarodnim standardom še ne pomeni skladnosti sistema vodenja kakovosti, po katerem laboratorij deluje, z zahtevami ISO 9001.

Introduction

The first edition (1999) of this International Standard was produced as the result of extensive experience in the implementation of ISO/IEC Guide 25 and EN 45001, both of which it replaced. It contained all of the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a management system, are technically competent, and are able to generate technically valid results.

The first edition referred to ISO 9001:1994 and ISO 9002:1994. These standards have been superseded by ISO 9001:2000, which made an alignment of ISO/IEC 17025 necessary. In this second edition, clauses have been amended or added only when considered necessary in the light of ISO 9001:2000.

Accreditation bodies that recognize the competence of testing and calibration laboratories should use this International Standard as the basis for their accreditation. Clause 4 specifies the requirements for sound management. Clause 5 specifies the requirements for technical competence for the type of tests and/or calibrations the laboratory undertakes.

Growth in the use of management systems generally has increased the need to ensure that laboratories which form part of larger organizations or offer other services can operate to a quality management system that is seen as compliant with ISO 9001 as well as with this International Standard. Care has been taken, therefore, to incorporate all those requirements of ISO 9001 that are relevant to the scope of testing and calibration services that are covered by the laboratory's management system.

Testing and calibration laboratories that comply with this International Standard will therefore also operate in accordance with ISO 9001.

Conformity of the quality management system within which the laboratory operates to the requirements of ISO 9001 does not of itself demonstrate the competence of the laboratory to produce technically valid data and results. Nor does demonstrated conformity to this International Standard imply conformity of the quality management system within which the laboratory operates to all the requirements of ISO 9001.

Meddržavno sprejetje rezultatov preskušanja in kalibracije je lažje, če laboratoriji delujejo v skladu s tem mednarodnim standardom in če pridobijo akreditacijo pri organih, ki so podpisniki sporazumov o medsebojnem priznavanju z enakovrednimi organi v drugih državah, ki uporabljajo ta mednarodni standard.

Uporaba tega mednarodnega standarda bo pospešila sodelovanje med laboratoriji in drugimi organi in pomagala pri izmenjavi informacij in izkušenj ter pri usklajevanju standardov in postopkov.

The acceptance of testing and calibration results between countries should be facilitated if laboratories comply with this International Standard and if they obtain accreditation from bodies which have entered into mutual recognition agreements with equivalent bodies in other countries using this International Standard.

The use of this International Standard will facilitate cooperation between laboratories and other bodies, and assist in the exchange of information and experience, and in the harmonization of standards and procedures.

Splošne zahteve za usposobljenost preskuševalnih in kalibracijskih laboratorijev

1 Področje uporabe

1.1 Ta mednarodni standard opredeljuje splošne zahteve za usposobljenost za izvajanje preskusov in/ali kalibracij, vključno z vzorčenjem. Standard zajema preskušanje in kalibriranje, ki se izvajata s standardiziranimi in nestandardiziranimi metodami ter z metodami, razvitimi v laboratoriju.

1.2 Ta mednarodni standard je uporaben za vse organizacije, ki izvajajo preskuse in/ali kalibracije. Vključeni so na primer laboratoriji prve, druge in tretje stranke in laboratoriji, kjer preskušanje in/ali kalibriranje sestavljata del kontrole ali certificiranja proizvoda.

Ta mednarodni standard je uporaben za vse laboratorije ne glede na število osebja ali na obseg aktivnosti preskušanja in/ali kalibriranja. Kadar laboratorij ne izvaja ene ali več aktivnosti, zajetih v tem mednarodnem standardu, na primer vzorčenja in snovanja/razvoja novih metod, se zahteve teh točk ne uporabljajo.

1.3 Opombe pojasnjujejo besedilo, navajajo primere in usmerjajo. Ne vsebujejo pa zahtev in niso sestavni del tega mednarodnega standarda.

1.4 Ta mednarodni standard uporabljajo laboratoriji pri razvoju svojih sistemov vodenja kakovosti ter pri upravnem in tehničnem delovanju. Uporabljajo ga lahko tudi odjemalci laboratorija, zakonodajni organi in akreditacijski organi pri potrjevanju ali priznavanju usposobljenosti laboratorijev. Ta mednarodni standard pa se ne more uporabljati kot podlaga za certificiranje laboratorijev.

OPOMBA 1: Izraz "sistem vodenja" v tem mednarodnem standardu pomeni sisteme kakovosti, upravne in tehnične sisteme, s katerimi laboratoriji upravljajo svoje delo.

OPOMBA 2: Certifikacija sistema vodenja se včasih imenuje tudi registracija.

1.5 Ta mednarodni standard ne zajema skladnosti z zahtevami zakonodaje in varnosti za delo laboratorijev.

General requirements for the competence of testing and calibration laboratories

1 Scope

1.1 This International Standard specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.

1.2 This International Standard is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification.

This International Standard is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When a laboratory does not undertake one or more of the activities covered by this International Standard, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

1.3 The notes given provide clarification of the text, examples and guidance. They do not contain requirements and do not form an integral part of this International Standard.

1.4 This International Standard is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. This International Standard is not intended to be used as the basis for certification of laboratories.

NOTE 1 The term 'management system' in this International Standard means the quality, administrative and technical systems that govern the operations of a laboratory.

NOTE 2 Certification of a management system is sometimes also called registration.

1.5 Compliance with regulatory and safety requirements on the operation of laboratories is not covered by this International Standard.

1.6 Če preskuševalni in kalibracijski laboratoriji delujejo skladno z zahtevami tega mednarodnega standarda, pomeni, da imajo za svoje dejavnosti preskušanja in kalibriranja vpeljan sistem vodenja kakovosti, ki izpolnjuje tudi zahteve ISO 9001. V dodatku A so navedene povezave med tem mednarodnim standardom in ISO 9001. Ta mednarodni standard zajema tudi zahteve za tehnično usposobljenost, ki niso zajete z ISO 9001.

OPOMBA 1: Mogoče bo treba določene zahteve tega mednarodnega standarda pojasniti ali razložiti, da bi zagotovili njihovo dosledno uporabo. Napotki za uporabo na posebnih področjih, zlasti za akreditacijske organe (glej ISO/IEC 17011), so navedeni v dodatku B.

OPOMBA 2: Če želi laboratorij akreditacijo za vse svoje preskuševalne in kalibracijske dejavnosti ali za njihov del, naj si izbere akreditacijski organ, ki deluje skladno z ISO/IEC 17011.

1.6 If testing and calibration laboratories comply with the requirements of this International Standard, they will operate a quality management system for their testing and calibration activities that also meets the principles of ISO 9001. Annex A provides nominal cross-references between this International Standard and ISO 9001. This International Standard covers technical competence requirements that are not covered by ISO 9001.

NOTE 1 It might be necessary to explain or interpret certain requirements in this International Standard to ensure that the requirements are applied in a consistent manner. Guidance for establishing applications for specific fields, especially for accreditation bodies (see ISO/IEC 17011) is given in Annex B.

NOTE 2 If a laboratory wishes accreditation for part or all of its testing and calibration activities, it should select an accreditation body that operates in accordance with ISO/IEC 17011.

2 Zveza z drugimi standardi

V nadaljevanju navedeni dokumenti so za uporabo tega dokumenta nujni. Pri datiranem sklicevanju se uporablja samo navedena izdaja; pri nedatiranem sklicevanju se uporablja zadnja izdaja dokumenta (vključno z morebitnimi spremembami).

ISO/IEC 17000, *Ugotavljanje skladnosti – Slovar in splošna načela*

VIM, *Mednarodni slovar osnovnih in splošnih izrazov s področja meroslovja*, ki so ga izdali BIPM, IEC, IFCC, ISO, IUPAC, IUPAP in OIML

OPOMBA: Nadaljnji sorodni standardi, vodila itd., katerih tematika je vključena v ta mednarodni standard, so navedeni v bibliografiji.

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/IEC 17000, *Conformity assessment-Vocabulary and general principles*

VIM, *International vocabulary of basic and general terms in metrology,* issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML

NOTE Further related standards, guides, etc. on subjects included in this International Standard are given in the Bibliography.

3 Izrazi in definicije

V tem mednarodnem standardu se uporabljajo ustrezni izrazi in definicije, navedeni v ISO/IEC 17000 in VIM.

OPOMBA: Splošne definicije, povezane s kakovostjo, so navedene v ISO 9000, medtem ko so v ISO/IEC 17000 navedene definicije, ki so v posebni zvezi s certifikacijo in z akreditacijo laboratorijev. Kadar so v ISO 9000 navedene drugačne definicije, imajo prednost definicije iz ISO/IEC 17000 in VIM.

3 Terms and definitions

For the purposes of this document, the relevant terms and definitions given in ISO/IEC 17000 and VIM apply.

NOTE General definitions related to quality are given in ISO 9000, whereas ISO/IEC 17000 gives definitions specifically related to certification and laboratory accreditation. Where different definitions are given in ISO 9000, the definitions in ISO/IEC 17000 and VIM are preferred.

4 Zahteve za vodenje

4.1 Organizacija

4.1.1 Laboratorij ali organizacija, katere sestavni del je laboratorij, mora biti pravno odgovorna oseba.

4.1.2 Laboratorij je odgovoren, da izvaja svoje dejavnosti preskušanja in kalibriranja tako, da izpolnjuje zahteve tega standarda in zadovoljuje potrebe odjemalca, zakonodajnih oblasti ali organizacij, ki izvajajo postopke priznavanja.

4.1.3 Sistem vodenja mora vključevati dela, ki se izvajajo na stalni lokaciji laboratorija, na terenu zunaj njegove stalne lokacije ali v pripadajočih začasnih oziroma premičnih enotah.

4.1.4 Če je laboratorij del organizacije, ki poleg preskušanja in/ali kalibriranja izvaja tudi druge aktivnosti, morajo biti določene odgovornosti ključnega osebja, ki vpliva na preskušanje in/ali kalibriranje ali je vanju vključeno, da bi se ugotovilo morebitno nasprotje interesov.

OPOMBA 1: Če je laboratorij del večje organizacije, naj bo organizacijska struktura taka, da oddelki z nasprotnimi interesi, kot so npr. proizvodnja, trženje ali vodenje financ, ne vplivajo škodljivo na izpolnjevanje zahtev tega mednarodnega standarda v laboratoriju.

OPOMBA 2: Če želi biti laboratorij priznan kot tretja stranka, mora biti sposoben dokazati, da je nepristranski in da njegovo osebje ni pod vplivom nobenih poslovnih, finančnih ali drugih pritiskov, ki bi lahko vplivali na njegovo strokovno presojo. Preskuševalni ali kalibracijski laboratorij, ki nastopa kot tretja stranka, naj ne bi bil vključen v kakršnekoli aktivnosti, ki bi lahko ogrozile zaupanje v neodvisnost njegovih razsodb in poštenost v zvezi z njegovimi preskuševalnimi ali kalibracijskimi aktivnostmi.

4.1.5 Laboratorij mora:

a) imeti tako vodstveno in tehnično osebje, ki ima ne glede na druge odgovornosti potrebna pooblastila in vire za opravljanje svojih dolžnosti, vključno z izvajanjem, vzdrževanjem in izboljševanjem sistema vodenja, ter za prepoznavanje odstopanj od sistema vodenja ali od postopkov za izvajanje preskusov in/ali kalibracij ter za vpeljavo ukrepov, ki preprečujejo oziroma

4 Management requirements

4.1 Organization

4.1.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.

4.1.2 It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.

4.1.3 The management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

4.1.4 If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.

NOTE 1 Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this International Standard.

NOTE 2 If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgement. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its testing or calibration activities.

4.1.5 The laboratory shall

a) have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests

zmanjšujejo takšna odstopanja (glej tudi 5.2);

b) imeti tako ureditev, ki zagotavlja, da njegovo vodstvo in osebje ni pod kakršnimi koli notranjimi in zunanjimi poslovnimi, finančnimi ali drugimi pritiski in vplivi, ki bi lahko škodljivo vplivali na kakovost njihovega dela;

c) imeti politiko in postopke za varovanje odjemalčevih zaupnih informacij in lastninskih pravic, vključno s postopki za zaščito elektronskega shranjevanja in prenosa rezultatov;

d) imeti politiko in postopke, ki preprečujejo vpletenost v katere koli dejavnosti, ki bi lahko zmanjšale zaupanje v njegovo usposobljenost, nepristranskost, presojo ali integriteto delovanja;

e) določiti organizacijsko in vodstveno strukturo laboratorija, njegov položaj v morebitni matični organizaciji in razmerja med vodenjem kakovosti, tehničnim delovanjem in podpornimi storitvami;

f) določiti odgovornosti, pooblastila in medsebojna razmerja za vse osebje, ki vodi, izvaja ali preverja delo, ki vpliva na kakovost preskusov in/ali kalibracij;

g) zagotoviti ustrezen nadzor nad osebjem, ki izvaja preskušanje in kalibriranje, vključno s pripravniki. Nadzorno osebje mora poznati metode in postopke, namen vsakega preskusa in/ali kalibracije ter ocenjevanje rezultatov preskusov ali kalibracij;

h) imeti strokovno vodstvo, ki je v celoti odgovorno za tehnično delovanje in zagotovitev virov, potrebnih za doseganje zahtevane kakovosti dela laboratorija;

i) imenovati člana osebja za vodjo kakovosti (naziv je lahko poljuben), ki ima ne glede na druge dolžnosti in odgovornosti določeno odgovornost in pooblastilo, da zagotovi neprekinjeno izvajanje in spremljanje sistema vodenja, povezanega s kakovostjo; vodja kakovosti mora imeti neposreden dostop do najvišje ravni vodstva, kjer se sprejemajo odločitve o politiki ali virih laboratorija;

j) imenovati namestnike za ključno vodilno osebje (glej opombo);

and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);

b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;

e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;

f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;

g) provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;

h) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;

i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;

j) appoint deputies for key managerial personnel (see Note);

k) zagotavljati, da se njegovo osebje zaveda pomembnosti svojih aktivnosti in tega, kako sami prispevajo k doseganju ciljev sistema vodenja.

OPOMBA: Posamezniki imajo lahko več funkcij; imenovati namestnike za vsako funkcijo bi bilo nepraktično.

4.1.6 Najvišje vodstvo mora zagotoviti vzpostavitev ustreznih komunikacijskih procesov v laboratoriju in komunikacijo, povezano z uspešnostjo sistema vodenja.

4.2 Sistem vodenja

4.2.1 Laboratorij mora vzpostaviti, izvajati in vzdrževati tak sistem vodenja, ki je primeren za področje njegovih dejavnosti. Laboratorij mora dokumentirati svojo politiko, sisteme, programe, postopke in navodila do take mere, da je zagotavljena kakovost rezultatov preskusov in/ali kalibracij. Dokumentacija sistema vodenja mora biti posredovana, razumljiva in dostopna ustreznemu osebju, ki naj jo uporablja.

4.2.2 Laboratorij mora svojo politiko sistema vodenja v zvezi s kakovostjo, vključno z izjavo o politiki kakovosti, opredeliti v poslovniku kakovosti (naslov je lahko poljuben). Zastaviti si mora splošne cilje in jih pregledovati na vodstvenem pregledu. Izjavo o politiki kakovosti izda najvišje vodstvo. Izjava mora vključevati najmanj:

a) zavezanost vodstva laboratorija dobri poklicni praksi ter kakovosti preskušanja in kalibriranja pri opravljanju storitev za odjemalce;

b) izjavo vodstva o ravni kakovosti storitev laboratorija;

c) namen sistema vodenja v zvezi s kakovostjo;

d) zahtevo, da se mora vse osebje, vključeno v preskuševalne in kalibracijske aktivnosti v laboratoriju, podrobno seznaniti z dokumentacijo sistema kakovosti in pri svojem delu upoštevati njegovo politiko ter postopke;

e) zavezanost vodstva laboratorija, da bo delovalo skladno s tem mednarodnim standardom in stalno izboljševalo uspešnost sistema vodenja.

k) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

NOTE Individuals may have more than one function and it may be impractical to appoint deputies for every function.

4.1.6 Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

4.2 Management system

4.2.1 The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programmes, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

4.2.2 The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:

a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;

b) the management's statement of the laboratory's standard of service;

c) the purpose of the management system related to quality;

d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and

e) the laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system.

OPOMBA: Izjava o politiki kakovosti naj bo kratka in lahko vključuje zahtevo, da se morajo preskusi in kalibracije vedno izvajati v skladu z določenimi metodami in zahtevami odjemalca. Če je preskuševalni in/ali kalibracijski laboratorij del večje organizacije, so lahko posamezni elementi politike kakovosti navedeni v drugih dokumentih.

4.2.3 Najvišje vodstvo mora zagotoviti dokaze o zavezanosti razvoju in izvajanju sistema vodenja ter stalnemu izboljševanju njegove uspešnosti.

4.2.4 Najvišje vodstvo mora posredovati organizaciji pomen izpolnjevanja zahtev odjemalcev ter tudi statutarnih in zakonskih zahtev.

4.2.5 Poslovnik kakovosti mora vsebovati dodatne postopke, tudi tehnične, ali se nanje sklicevati. Vsebovati mora tudi pregled dokumentacije, ki se uporablja v sistemu vodenja.

4.2.6 V poslovniku kakovosti morajo biti določeni vloga in odgovornosti tehničnega vodstva in vodje kakovosti ter njihova odgovornost za zagotavljanje skladnosti s tem mednarodnim standardom.

4.2.7 Najvišje vodstvo mora zagotavljati, da se ob načrtovanju in izvajanju sprememb sistema vodenja ohranja njegova integriteta.

4.3 Obvladovanje dokumentov

4.3.1 Splošno

Laboratorij mora vzpostaviti in vzdrževati postopke za obvladovanje vseh dokumentov (notranjega ali zunanjega izvora), ki so del njegovega sistema vodenja. To so lahko predpisi, standardi, drugi normativni dokumenti, preskusne in/ali kalibracijske metode ter tudi risbe, programska oprema, specifikacije, navodila in priročniki.

OPOMBA 1: V tej povezavi so "dokument" lahko izjave o politiki, postopki, specifikacije, kalibracijske preglednice, preglednice, učbeniki, posterji, opombe, zaznamki, programska oprema, risbe, načrti itd. Dokumenti so lahko na različnih medijih, bodisi kot papirnate ali elektronske kopije, in so lahko v digitalni, analogni, fotografski ali pisni obliki.

OPOMBA 2: Obvladovanje podatkov, povezanih s preskušanjem in kalibriranjem, je opisano v točki 5.4.7. Obvladovanje zapisov je opisano v točki 4.13.

NOTE The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents.

4.2.3 Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

4.2.4 Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

4.2.5 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the management system.

4.2.6 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual.

4.2.7 Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

4.3 Document control

4.3.1 General

The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.

NOTE 1 In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.

NOTE 2 The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.13.

4.3.2 Odobritev in izdaja dokumentov

4.3.2.1 Vse dokumente, izdane osebju v laboratoriju kot del sistema vodenja, mora pred izdajo pregledati pooblaščeno osebje in odobriti njihovo uporabo. Laboratorij mora vzpostaviti lahko dostopen seznam ali enakovreden postopek za obvladovanje dokumentov, ki omogoča prepoznavanje trenutnega stanja in razdelitev dokumentov v sistemu vodenja, da bi se preprečila uporaba neveljavnih in/ali zastarelih dokumentov.

4.3.2.2 Sprejeti postopek(-ki) mora(-jo) zagotoviti, da:

a) so povsod, kjer se izvajajo aktivnosti, pomembne za učinkovito delovanje laboratorija, na voljo odobrene izdaje ustreznih dokumentov;

b) se dokumenti periodično pregledujejo in po potrebi revidirajo, tako da sta zagotovljeni stalna ustreznost in skladnost z veljavnimi zahtevami;

c) se neveljavni ali zastareli dokumenti takoj odstranijo z vseh izdajateljskih ali uporabniških mest ali se drugače prepreči njihova nenamerna uporaba;

d) so zastareli dokumenti, ki so shranjeni zaradi zakonskih zahtev ali zaradi ohranitve znanja, primerno označeni.

4.3.2.3 Dokumenti sistema vodenja, izdani v laboratoriju, morajo biti enoumno prepoznavni. Takšna identifikacija vključuje datum izdaje in/ali oznako za revidirano izdajo, oštevilčenje strani, skupno število strani ali označbo za konec dokumenta in pristojne za izdajo.

4.3.3 Spremembe dokumentov

4.3.3.1 Spremembe dokumentov morajo pregledati in odobriti osebe z enakimi funkcijami kot tiste, ki so opravile prvotni pregled in odobritev, razen če ni posebej določeno drugače. Imenovano osebje mora imeti dostop do ustreznih informacij, na katerih temeljita njihov pregled in odobritev.

4.3.3.2 Kjer je to izvedljivo, mora biti spremenjeno ali novo besedilo razpoznavno v dokumentu ali v ustreznih prilogah.

4.3.3.3 Če laboratorijski sistem za obvladovanje dokumentov dovoljuje ročno spreminjanje dokumentov do njihove ponovne izdaje, mora laboratorij določiti postopke in

4.3.2 Document approval and issue

4.3.2.1 All documents issued to personnel in the laboratory as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and shall be readily available to preclude the use of invalid and/or obsolete documents.

4.3.2.2 The procedure(s) adopted shall ensure that:

a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;

b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;

c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

4.3.2.3 Management system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

4.3.3 Document changes

4.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.

4.3.3.3 If the laboratory's document control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such