SLOVENSKA AKREDITACIJA

OA14

UPORABA STANDARDA ISO/IEC 17020:2012 ZA AKREDITACIJO KONTROLNIH ORGANOV

APPLICATION OF ISO/IEC 17020:2012 FOR THE ACCREDITATION OF INSPECTION BODIES (ILAC-P15:05/2020)

ILAC – Mednarodno združenje za akreditacijo laboratorijev

ILAC je globalno združenje za akreditacijo laboratorijev, kontrolnih organov, izvajalcev preskusov strokovne usposobljenosti in proizvajalcev referenčnih materialov, katerega članstvo sestavljajo akreditacijski organi in organizacije zainteresiranih strani po vsem svetu.

Je predstavniška organizacija, ki se vključuje v:

- razvoj akreditacijskih praks in postopkov,
- promocijo akreditacije kot orodja za spodbujanje trgovine,
- podporo zagotavljanju lokalnih in nacionalnih storitev,
- pomoč pri razvoju akreditacijskih sistemov,
- priznavanje kompetentnih preskuševalnih (tudi medicinskih) in kalibracijskih laboratorijev, kontrolnih organov, izvajalcev preskusov strokovne usposobljenosti in proizvajalcev referenčnih materialov po vsem svetu.

Pri zasledovanju teh ciljev ILAC aktivno sodeluje z drugimi relevantnimi mednarodnimi organizacijami.

Z upravljanjem mednarodnega dogovora o medsebojnem priznavanju med akreditacijskimi organi (AO) – Dogovora ILAC – ILAC pospešuje trgovino in nudi podporo regulatorjem. Preko tega dogovora so podatki in rezultati preskusov, ki jih izdajo laboratoriji in kontrolni organi s skupnim imenom organi za ugotavljanje skladnosti (OUS), akreditirani pri akreditacijskih organih, članih ILAC, globalno sprejeti. S tem so zmanjšane tehnične ovire pri trgovanju, kot npr. ponovno preskušanje izdelkov z vsakim njihovim vstopom v novo gospodarstvo, v podporo sprostitvi cilja proste trgovine: “enkrat akreditirano, sprejeto povsod”.

Poleg tega akreditacija z zagotavljanjem, da so akreditirani OUS kompetentni za izvajanje dela, ki ga v svojem obsegu akreditacije opravljajo, zmanjša tveganje podjetij in njihovih strank.

Nadalje rezultate akreditiranih organov v javno korist široko uporabljajo regulatorji pri zagotavljanju storitev, ki promovirajo neonesnaženo okolje, varno hrano, čisto vodo, energetske in zdravstvene storitve ter storitve socialnega varstva.

Od akreditacijskih organov, ki so člani združenja ILAC, in od OUS, ki jih ti akreditirajo, se zahteva, da delujejo v skladu z ustreznimi mednarodnimi standardi in z veljavnimi navodili ILAC za dosledno izvajanje teh standardov.

Akreditacijski organi podpisniki dogovora ILAC so pred podpisom dogovora podvrženi zunanji evalvaciji (peer evaluation), ki jo opravijo uradno ustanovljeni in priznani organi regionalnega sodelovanja z uporabo pravil in postopkov ILAC.

Na spletni strani ILAC je objavljena vrsta informacij na teme, povezane z akreditacijo, ugotavljanjem skladnosti, spodbujanjem trgovine, pa tudi kontaktni podatki članov. Na strani www.publicsectorassurance.org se najdejo tudi nadaljnje informacije, ki preko študij primerov in neodvisnih raziskav ponazarjajo, kako pomembno je akreditirano ugotavljanje skladnosti za regulatorje in javni sektor.

ILAC – International Laboratory Accreditation Cooperation

ILAC is the global association for the accreditation of laboratories, inspection bodies, proficiency testing providers and reference material producers, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world.

It is a representative organisation that is involved with:

- the development of accreditation practices and procedures,
- the promotion of accreditation as a trade facilitation tool,
- supporting the provision of local and national services,
- the assistance of developing accreditation systems,
- the recognition of competent testing (including medical) and calibration laboratories, inspection bodies, proficiency testing providers and reference material producers around the world.

ILAC actively cooperates with other relevant international organisations in pursuing these aims.

ILAC facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement – the ILAC Arrangement - among Accreditation Bodies (ABs). The data and test results issued by laboratories, and inspection bodies, collectively known as Conformity Assessment Bodies (CABs), accredited by ILAC Accreditation Body members are accepted globally via this Arrangement. Thereby, technical barriers to trade, such as the re-testing of products each time they enter a new economy is reduced, in support of realising the free-trade goal of “accredited once, accepted everywhere”.

In addition, accreditation reduces risk for business and its customers by assuring that accredited CABs are competent to carry out the work they undertake within their scope of accreditation.

Further, the results from accredited facilities are used extensively by regulators for the public benefit in the provision of services that promote an unpolluted environment, safe food, clean water, energy, health and social care services.

Accreditation Bodies that are members of ILAC and the CABs they accredit are required to comply with appropriate international standards and the applicable ILAC application documents for the consistent implementation of those standards.

Accreditation Bodies having signed the ILAC Arrangement are subject to peer evaluation via formally established and recognised regional cooperation bodies using ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

The ILAC website provides a range of information on topics covering accreditation, conformity assessment, trade facilitation, as well as the contact details of members. Further information to illustrate the value of accredited conformity assessment to regulators and the public sector through case studies and independent research can also be found at www.publicsectorassurance.org.

Za več informacij se obrnite na:

ILAC Secretariat
PO Box 7507
Silverwater NSW 2128
Australia
Tel.: +61 2 9736 8374
E-pošta: ilac@nata.com.au
Spletna stran: www.ilac.org @ILAC_Official
https://www.youtube.com/user/IAFandILAC

For more information, please contact:

The ILAC Secretariat
PO Box 7507
Silverwater NSW 2128
Australia
Phone: +61 2 9736 8374
Email: ilac@nata.com.au
Website: www.ilac.org @ILAC_Official
https://www.youtube.com/user/IAFandILAC

KAZALO

1. UVOD 5
2. AVTORSTVO 5
3. IZVAJANJE 5
4. TERMINOLOGIJA 5
5. UPORABE STANDARDA ISO/IEC 17020:2012 6
   - Izrazi in definicije 6
   - Splošne zahteve – Nepristranskost in neodvisnost 6
   - Strukturne zahteve – Upravne zahteve 7
   - Strukturne zahteve – Organizacija in vodenje 7
   - Zahteve glede virov – Osebje 8
   - Zahteve glede virov – Zmogljivosti in oprema 10
   - Zahteve glede virov – Sklepanje podpogodb 11
   - Zahteve glede procesov – Metode in postopki kontrole 11
   - Zahteve glede procesov – Zapisi o kontroli 12
   - Zahteve glede procesov – Poročila in potrdila/ certifikati o kontroli 12
   - Zahteve glede sistema vodenja – Možnosti 12
   - Zahteve glede sistema vodenja – Dokumentacija sistema vodenja (možnost A) 13
   - Zahteve glede sistema vodenja – Obvladovanje zapisov (možnost A) 13
   - Zahteve glede sistema vodenja – Vodstveni pregled (možnost A) 13
   - Zahteve glede sistema vodenja – Notranje presoje (možnost A) 13
   - Zahteve glede sistema vodenja – Preventivni ukrepi (možnost A) 14
   - Dodatek A: Zahteve za neodvisnost kontrolnih organov 14
6. DODATEK 1: MOŽNA OBLIKA ANALIZE TVEGANJA ZA NEPRISTRANSKOST 14
7. DODATEK 2:RAZMERJE MED ZAHTEVAMI ZA NEPRISTRANSKOST IN ZA NEODVISNOST TIPA A 15
8. LITERATURA 17

LIST OF CONTENTS

1. INTRODUCTION 5
2. AUTHORSHIP 5
3. IMPLEMENTATION 5
4. TERMINOLOGY 5
5. APPLICATIONS OF ISO/IEC 17020:2012 6
   - Terms and definitions 6
   - General requirements – Impartiality and independence 6
   - Structural requirements – Administrative requirements 7
   - Structural requirements – Organisation and management 7
   - Resource requirements – Personnel 8
   - Resource requirements – Facilities and equipment 10
   - Resource requirements – Subcontracting 11
   - Process requirements - Inspection methods and procedures 11
   - Process requirements - Inspection records 12
   - Process requirements - Inspection reports and inspection certificates 12
   - Management system requirements – Options 12
   - Management system requirements – Management system documentation (Option A) 13
   - Management system requirements – Control of records (Option A) 13
   - Management system requirements – Management review (Option A) 13
   - Management system requirements – Internal audits (Option A) 13
   - Management system requirements – Preventive actions (Option A) 14
   - Annex A Independence requirements for inspection bodies 14
6. ANNEX 1: POSSIBLE FORMAT FOR AN IMPARTIALITY RISK ANALYSIS 14
7. ANNEX 2: RELATIONSHIP BETWEEN IMPARTIALITY AND TYPE A INDEPENDENCE REQUIREMENTS 15
8. REFERENCES 17

1. UVOD

V tem dokumentu so podane informacije za uporabo standarda ISO/IEC 17020:2012 Ugotavljanje skladnosti – Zahteve za delovanje različnih tipov organov, ki izvajajo kontrolo za akreditacijo kontrolnih organov. Namenjen je akreditacijskim organom, ki ocenjujejo kontrolne organe za akreditacijo, kakor tudi kontrolnim organom, ki želijo delovati na način, da izpolnjujejo zahteve za akreditacijo.

Za lažje sklicevanje je vsaka opomba glede uporabe označena s številko pripadajoče točke standarda ISO/IEC 17020 ter z ustrezno pripono, npr. 4.1.4 n1 bi bila prva opomba glede uporabe zahtev točke 4.1.4 standarda.

Izraz “mora” (shall) se v celotnem dokumentu uporablja za označevanje tistih določb, ki se štejejo za obvezne, ker odražajo zahteve ISO/IEC17020, oziroma v nekaj primerih zahteve za delovanje akreditacijskih organov iz ISO/IEC 17011.

Izraz "naj" (should) se v celotnem dokumentu uporablja za označevanje tistih določb, ki sicer niso obvezne, a jih ILAC navaja kot priznan način izpolnjevanja zahtev. Izraz "sme" (may) se uporablja za označevanje nečesa, kar je dovoljeno, izraz »lahko« (can) za označevanje možnosti ali sposobnosti. Kontrolni organi, katerih sistemi ne sledijo napotkom "naj" iz tega dokumenta ILAC, bodo do akreditacije upravičeni samo, če bodo akreditacijskemu organu lahko dokazali, da njihove rešitve enakovredno ali bolje izpolnjujejo ustrezno točko standarda ISO/IEC 17020.

V posameznih kontrolnih shemah so lahko navedene dodatne zahteve za akreditacijo. Ta dokument ne poskuša ugotoviti, katere bi lahko bile te zahteve oziroma kako se morajo izvajati.

Ta različica dokumenta vključuje smernice za porajajoče se tehnologije, ki v standardu ISO/IEC 17020:2012 niso obravnavane, in upošteva, da je lahko kontrola aktivnost, vključena v širši proces, vključno s preskušanjem in certificiranjem.

Pri uporabi ISO/IEC 17020 in tega dokumenta naj akreditacijski organi zahtevam ISO/IEC 17020 ničesar ne dodajajo niti odvzemajo. Akreditacijski organi pa morajo še vedno izpolnjevati tudi zahteve ISO/IEC 17011.

Primeri, ki so bili vključeni v prejšnji različici tega dokumenta, so bili odstranjeni in dodani v podatkovno bazo za pogosta vprašanja (FAQ) Odbora za kontrolo na spletni strani ILAC: https://ilac.org/about-ilac/faqs/

2. AVTORSTVO

To publikacijo je pripravil Odbor ILAC za kontrolo (IC) in je bila potrjena za objavo na podlagi uspešnega glasovanja članov ILAC leta 2020.

3. IZVAJANJE

Zaradi izpolnjevanja določb točke 2.1.1 dokumenta IAF/ILAC A2 morajo podpisniki dogovora o medsebojnem priznavanju ILAC MRA ta dokument uveljaviti v 18 mesecih od dneva izdaje.

4. TERMINOLOGIJA

V tem dokumentu se uporabljajo izrazi in definicije iz standardov ISO/IEC 17000 in ISO/IEC 17020.

1. INTRODUCTION

This document provides information for the application of ISO/IEC 17020:2012 Conformity assessment – Requirements for the operation of various types of bodies performing inspection for the accreditation of inspection bodies. It is intended to be used by accreditation bodies assessing inspection bodies for accreditation as well as by inspection bodies seeking to manage their operations in a manner fulfilling the requirements for accreditation.

For ease of reference, each application note is identified by the relevant clause number of ISO/IEC 17020 and an appropriate suffix, e.g. 4.1.4 n1 would be the first application note on the requirements of clause 4.1.4 of the standard.

The term “shall” is used throughout this document to indicate those provisions which, reflecting the requirements of ISO/IEC17020, or in a few cases requirements for the operation of accreditation bodies in ISO/IEC 17011, are considered to be mandatory.

The term “should” is used throughout this document to indicate those provisions which, although not mandatory, are provided by ILAC as a recognized means of meeting the requirements. The term “may” is used to indicate something which is permitted. The term “can” is used to indicate a possibility or a capability. Inspection bodies whose systems do not follow the “should” guidance in this ILAC document will only be eligible for accreditation if they can demonstrate to the accreditation body that their solutions meet the relevant clause of ISO/IEC 17020 in an equivalent or better way.

Individual inspection schemes may specify additional requirements for accreditation. This document does not try to identify what such requirements may be or how they shall be implemented.

This version of the document includes guidance on emerging technologies that are not addressed in ISO/IEC 17020:2012 and takes in consideration that inspection can be an activity embedded in a larger process including testing and certification.

When using ISO/IEC 17020 and this application document the accreditation bodies should neither add to, nor subtract from, the requirements in ISO/IEC 17020. Note, however, that accreditation bodies must still fulfill the requirements of ISO/IEC 17011.

The examples that were included in the previous version of the document were removed and added to the Inspection Committee FAQ database on the ILAC website: https://ilac.org/about-ilac/faqs/

2. AUTHORSHIP

This publication was prepared by the ILAC Inspection Committee (IC) and endorsed for publication following a successful ballot of the ILAC voting membership in 2020.

3. IMPLEMENTATION

In order to comply with the provisions of IAF/ILAC A2 clause 2.1.1, signatories to the ILAC MRA shall implement this document within 18 months from the date of publication.

4. TERMINOLOGY

For the purposes of this document the terms and definitions given in ISO/IEC 17000 and ISO/IEC 17020 apply.

5. UPORABE STANDARDA ISO/IEC 17020:2012

Izrazi in definicije

3.1 n1 Izraz "inštalacija" se lahko definira kot "zbirka sestavnih delov, ki so sestavljeni zato, da bi skupaj dosegli namen, ki ga ločeno ne morejo doseči".

Splošne zahteve – Nepristranskost in neodvisnost

ISO/IEC 17020 pripisuje največji pomen preprečevanju neupravičenega vpliva na aktivnosti kontrole. Poglavje (4.1.2) zahteva, da komercialni, finančni in drugi pritiski ne smejo ogrožati nepristranskosti, in priznava, da lahko osebni in organizacijski odnosi (4.1.3) ogrožajo nepristranskost in bi za vzdrževanje nepristranskosti lahko bil potreben nadzor (4.1.4). Na koncu je obravnavana neodvisnost in so za opozarjanje na naravo odnosov med kontrolnim organom in predmeti kontrole organi razvrščeni po tipih neodvisnosti A, B in C.
V dodatku 2 so podane dodatne smernice.

4.1.3 n1 "stalno" pomeni, da kontrolni organ prepoznava tveganje, kadarkoli se zgodijo dogodki, ki bi lahko vplivali na nepristranskost kontrolnega organa.

4.1.3 n2 Kontrolni organ naj s pomočjo organigramov ali z drugimi sredstvi opiše vse svoje morebitne odnose oziroma odnose svojega osebja, ki bi lahko pomembno vplivali na njegovo nepristranskost.

4.1.3 n3 V dodatku 1 je naveden primer možne oblike analize tveganja za nepristranskost.

4.1.4 n1 Grožnje in neprimerne spodbude, namenjene kontrolorjem ali drugemu osebju kontrolnega organa, lahko predstavljajo resno tveganje za nepristranskost. Grožnje in spodbude lahko nastanejo znotraj ali zunaj kontrolnega organa in se lahko zgodijo kadarkoli. Kontrolni organ naj si zaznana in očitna tveganja za nepristranskost kontrol zapisuje. Vse osebje, ki dela v imenu kontrolnega organa, naj se zaveda odgovornosti za nepristransko delovanje, se temu primerno vključuje v ukrepe kontrolnega organa in ima ustrezen dostop za zagotavljanje zapisov, kadar se pojavijo vprašanja. Kontrolni organ naj v svojo analizo tveganj za nepristranskost vključi podrobnosti o svojih odzivih na taka tveganja.

4.1.5 n1 Kontrolni organ naj ima dokumentirano izjavo, v kateri poudarja svojo zavezanost nepristranskosti pri izvajanju svojih aktivnosti kontrole, obvladovanju nasprotij interesov in zagotavljanju objektivnosti svojih aktivnosti kontrole. Ukrepi najvišjega vodstva naj ne bodo v nasprotju s to izjavo.

4.1.5 n2 Eden od načinov, kako najvišje vodstvo poudari svojo zavezanost nepristranskosti, je, da relevantne izjave in politike javno objavi.

4.1.6 n1 Kontrolni organ lahko ima za različne aktivnosti kontrole različne vrste neodvisnosti (tip A, B ali C), navedene v obsegu akreditacije. Ne more pa kontrolni organ za isto aktivnost kontrole ponuditi različne vrste neodvisnosti.

4.1.6 n2 Skladnost z zahtevami A.1b in A.1c za neodvisnost tipa A je binarna (da ali ne), kar pomeni, da delna skladnost z zahtevami za neodvisnost tipa A ni

5. APPLICATIONS OF ISO/IEC 17020:2012

Terms and definitions

3.1 n1 The term "installation" may be defined as "a collection of components assembled to jointly achieve a purpose not achievable by the components separately".

General requirements – Impartiality and independence

ISO/IEC 17020 places the highest importance on preventing the undue influencing of inspection activities. (4.1.2) requires that commercial, financial and other pressures do not compromise impartiality, and recognises that personal and organisational relationships (4.1.3) potentially compromise impartiality and may need controls (4.1.4) to maintain impartiality. Finally, it considers independence and classifies bodies into Independence Types A, B and C to signal the nature of the relationships between inspection body and the items inspected.
Annex 2 provides additional guidance.

4.1.3 n1 "on an ongoing basis" means that the inspection body identifies a risk whenever events occur which might have a bearing on the impartiality of the inspection body.

4.1.3 n2 The inspection body should describe any of its relationships or its personnel's that could affect its impartiality, to the extent relevant, using organisational diagrams or other means.

4.1.3 n3 Annex 1 gives an example of a possible format for impartiality risk analysis.

4.1.4 n1 Threats and inducements aimed at inspectors or other inspection body personnel may represent serious risks to impartiality. Threats and inducements may originate from inside or outside the inspection body and may happen at any time. The inspection body should record perceived and explicit risks to impartiality of inspections. All personnel working on behalf of the inspection body, should be aware of the responsibility to act impartially, be involved accordingly in the inspection body's impartiality measures and have appropriate access to provide records as issues arise. The inspection body's analysis of risks to impartiality should include details of the inspection body's responses to such risks.

4.1.5 n1 The inspection body should have a documented statement emphasising its commitment to impartiality in carrying out its inspection activities, managing conflicts of interest and ensuring the objectivity of its inspection activities. Actions emanating from the top management should not contradict this statement.

4.1.5 n2 One way for the top management to emphasise its commitment to impartiality is to make relevant statements and policies publicly available.

4.1.6 n1 An inspection body may have different types of independence (Type A, B or C) for different inspection activities listed on the scope of accreditation. However, it is not possible for an inspection body to offer different independence types for the same inspection activity.

4.1.6 n2 Complying with the Type A independence requirements A.1b and A.1.c is binary (yes or no) meaning that partly complying with Type A

možna. To tudi pomeni, da v situaciji, ko ni skladnosti s temi zahtevami tipa A, ni možna analiza tveganja, ki ima za posledico nadzorne ukrepe za zmanjšanje tveganj za nepristranskost. Torej je možna samo odprava situacije, ki ni v skladu s temi zahtevami tipa A.

independence requirements is not possible. This also means that a risk analysis resulting in control measures to minimize the impartiality risks of a situation where there is no compliance with these Type A requirements is not possible. Hence, only elimination of the situation that is not compliant with these Type A requirements is possible.

Strukturne zahteve – Upravne zahteve

5.1.3 n1 Kontrolni organ naj opiše svoje aktivnosti z opredelitvijo splošnega področja in obsega kontrole (npr. kategorije/podkategorije proizvodov, procesov, storitev ali inštalacij) in stopnje kontrole (glej opombo k poglavju standarda) ter predpisov, standardov ali specifikacij z zahtevami, po katerih se bo izvajala kontrola, če je primerno. V dokumentu ILAC G28 so smernice za oblikovanje obsegov akreditacije za kontrolne organe.

5.1.4 n1 Velikost rezervacij naj bo sorazmerna z ravnijo in naravo obveznosti, ki lahko izhajajo iz aktivnosti kontrolnega organa.

5.1.4 n2 Ocena 'ustreznosti' lahko temelji na dokazih o dogovoru med pogodbenicama in upoštevanju vseh relevantnih zakonskih zahtev oziroma pravil sheme. Kontrolni organ naj bo sposoben dokazati, katere dejavnike je upošteval pri določanju, kaj sestavlja "ustrezno rezervacijo". Ni pa naloga akreditacijskega organa, da odobri rezervacijo kontrolnega organa.

Structural requirements – Administrative requirements

5.1.3 n1 The inspection body should describe its activities by defining the general field and range of inspection (e.g. categories/sub-categories of products, processes, services or installations) and the stage of inspection, (see note to clause 1 of the standard) and, where applicable, the regulations, standards or specifications containing the requirements against which the inspection will be performed. ILAC G28 gives guidance for the Formulation of Scopes of Accreditation for Inspection Bodies.

5.1.4 n1 The level of provisions should be commensurate with the level and nature of liabilities that may arise from the inspection body's activities.

5.1.4 n2 An assessment of 'adequacy' may be based on evidence of agreement between the parties to the contract and consideration of any relevant statutory requirements or scheme rules. The inspection body should be able to show what factors have been taken into account when determining what constitutes "adequate provision". It is not the role of an accreditation body to approve the provision held by an inspection body.

Strukturne zahteve – Organizacija in vodenje

5.2.2 n1 Velikost, struktura, sestava in vodenje kontrolnega organa morajo skupaj biti primerni za kompetentno izvajanje aktivnosti znotraj obsega, za katerega je kontrolni organ akreditiran.

5.2.2 n2 "Vzdrževanje sposobnosti izvajanja aktivnosti kontrole" pomeni, da mora kontrolni organ poskrbeti za to, da je ustrezno informiran o veljavnih tehničnih, spremembah shem in/ali zakonodajnih spremembah, ki zadevajo njegove aktivnosti.

5.2.2 n3 Kontrolni organi morajo vzdrževati svojo sposobnost in kompetentnost za izvajanje kontrol, ki niso pogoste (praviloma s presledki, daljšimi od enega leta). Kontrolni organ lahko dokaže svojo sposobnost in kompetentnost za kontrole, ki se ne izvajajo pogosto, z "navideznimi kontrolami" in/ali z izvajanjem aktivnosti kontrole na podobnih proizvodih.

5.2.3 n1 Kontrolni organ mora vzdrževati posodobljen organigram oziroma dokumente, ki jasno označujejo funkcije in linije vodenja za osebje znotraj kontrolnega organa. Iz organigrama oziroma dokumentov naj bo jasno razviden položaj tehničnega vodje oziroma vodij in člana vodstva, omenjenega v točki 8.2.3.

5.2.4 n1 Pomembno je lahko tudi zagotavljanje informacij o osebju, ki izvaja delovne naloge tako za kontrolni organ kakor tudi za druge enote in oddelke, da bi upoštevali njihovo vključenost in vpliv, ki bi ga lahko imeli na aktivnosti kontrole.

5.2.5 n1 Da bi se za osebo štelo, da je "na voljo", mora biti

Structural requirements – Organisation and management

5.2.2 n1 The size, structure, composition and management of an inspection body, taken together, shall be suitable for the competent performance of the activities within the scope for which the inspection body is accredited.

5.2.2 n2 "To maintain the capability to perform the inspection activities" implies that the inspection body shall take steps to keep it appropriately informed about applicable technical, scheme and/or legislative developments concerning its activities.

5.2.2 n3 Inspection bodies shall maintain their capability and competence to carry out inspection activities performed infrequently (normally with intervals longer than one year). An inspection body may demonstrate its capability and competence for inspection activities performed infrequently through 'dummy inspections' and/or through inspection activities conducted on similar products.

5.2.3 n1 The inspection body shall maintain an up-to-date organisational chart or documents clearly indicating the functions and lines of authority for staff within the inspection body. The position of the technical manager(s) and the member of management referenced in clause 8.2.3 should be clearly shown in the chart or documents.

5.2.4 n1 It may be relevant to provide information concerning personnel which carry out work tasks for both the inspection body and for other units and departments in order to take into account the involvement and the influence they may have over the inspection activities.

5.2.5 n1 In order to be considered as "available", the person

bodisi zaposlena bodisi kako drugače pogodbeno vezana.

5.2.5 n2 Da bi zagotovili, da je izvajanje aktivnosti kontrole v skladu z ISO/IEC 17020, morajo imeti tehnični vodja(-e) in morebitni namestnik(-i) strokovno kompetentnost, potrebno za razumevanje pomembnih vprašanj in tehnologij, ki se porajajo pri izvajanju aktivnosti kontrole.

5.2.6 n1 Za organizacijo, v kateri odsotnost ključne osebe povzroči prekinitev dela, zahteva glede namestnikov ne velja.

5.2.7 n1 Delovna mesta, vključena v aktivnosti kontrole, zajemajo kontrolorje in druga delovna mesta, ki lahko vplivajo na vodenje, izvajanje, zapisovanje ali poročanje o kontrolah.

5.2.7 n2 V opisu del ali drugi dokumentaciji morajo biti podrobno opisane dolžnosti, odgovornosti in pooblastila za vsako delovno mesto, omenjeno v točki 5.2.7 n1.

Zahteve glede virov – Osebje

6.1.1 n1 Če je primerno, morajo kontrolni organi določiti in dokumentirati zahteve za kompetentnost za vsako aktivnost kontrole, opisano v točki 5.1.3n1. Lahko da so nekatere vidike zahtev za kompetentnost določili že regulatorji in lastniki shem, ali pa so jih določili naročniki. V takem primeru naj kontrolni organ te zahteve vključi v svoje splošne opredelitve kompetentnosti oziroma se tam sklicuje nanje. Kontrolni organ ostaja odgovoren za ustreznost opredelitev kompetentnosti in njihovo skladnost z zahtevami standarda ISO/IEC 17020.

6.1.1 n2 Glede "osebja, vključenega v aktivnosti kontrole" glej 5.2.7n1.

6.1.1 n3 Zahteve za kompetentnost naj vključujejo poznavanje sistema vodenja kontrolnega organa in sposobnost izvajanja tako upravnih kot tehničnih postopkov, ki se uporabljajo pri izvajanih aktivnostih.

6.1.1 n4 Če je za ugotavljanje skladnosti potrebna strokovna presoja, je to treba upoštevati pri določanju zahtev za kompetentnost.

6.1.2 n1 Vse zahteve standarda ISO/IEC 17020 veljajo enako za zaposlene kot za pogodbene osebe.

6.1.5 n1 V postopku za formalno pooblaščanje kontrolorjev naj bo opredeljeno, da so dokumentirane relevantne podrobnosti, npr. za katere aktivnosti kontrole je oseba pooblaščena, začetek veljavnosti pooblastila, identiteta osebe, ki je dala pooblastilo, in če je primerno, datum prenehanja pooblastila.

6.1.6 n1 "Obdobje dela pod mentorstvom", omenjeno pod točko b), naj vključuje sodelovanje pri kontrolah na lokacijah, kjer se te kontrole izvajajo.

6.1.7 n1 Ugotavljanje potreb po usposabljanju posamezne osebe naj se izvaja v rednih časovnih presledkih. Izbere naj se tak presledek, da se zagotovi izpolnjevanje točke c) v točki 6.1.6. Rezultati pregleda usposabljanja, npr. plani nadaljnjega usposabljanja ali izjava, da nadaljnje usposabljanje ni potrebno, naj se dokumentirajo.

shall be either employed or otherwise contracted.

5.2.5 n2 In order to ensure that the inspection activities are carried out in accordance with ISO/IEC 17020, the technical manager(s) and any deputy(ies), shall have the technical competence necessary to understand all significant issues and technologies involved in the performance of inspection activities.

5.2.6 n1 In an organization where the absence of a key person causes the cessation of work, the requirement for having deputies is not applicable.

5.2.7 n1 The position categories involved in inspection activities are inspectors and other positions which could have an effect on the management, performance, recording or reporting of inspections.

5.2.7 n2 The job description or other documentation shall detail the duties, responsibilities and authorities for each position category referred to in 5.2.7 n1.

Resource requirements – Personnel

6.1.1 n1 Where appropriate, inspection bodies shall define and document competence requirements for each inspection activity, as described in 5.1.3 n1. Some aspects of competence requirements may already be defined by regulators and scheme owners or specified by clients. Where this is the case, the inspection body should incorporate/reference these requirements into their overall competence definitions. The inspection body remains responsible for the appropriateness of competence definitions and their compliance with the requirements of ISO/IEC 17020.

6.1.1 n2 For “personnel involved in inspection activities”, see 5.2.7 n1.

6.1.1 n3 Competence requirements should include knowledge of the inspection body’s management system and ability to implement administrative as well as technical procedures applicable to the activities performed.

6.1.1 n4 When professional judgment is needed to determine conformity, this shall be considered when defining competence requirements.

6.1.2 n1 All requirements of ISO/IEC 17020 apply equally for both employed and contracted persons.

6.1.5 n1 The procedure for formally authorising inspectors should specify that the relevant details are documented, e.g. the authorised inspection activity, the beginning of the authorisation, the identity of the person who performed the authorisation and, where appropriate, the termination date of the authorisation.

6.1.6 n1 The “mentored working period” mentioned in item b should include participation in inspections at the locations where these inspections are performed.

6.1.7 n1 Identification of training needs for each person should take place at regular intervals. The interval should be selected to ensure fulfilment of clause 6.1.6 item c. The results of the review of training, e.g. plans for further training or a statement that no further training is required, should be documented.

6.1.8 n1 Glavni cilj zahtev za nadzorovanje je, da se kontrolnemu organu zagotovi orodje, s katerim zagotavlja doslednost in zanesljivost rezultatov kontrole, vključno z morebitnimi strokovnimi presojami po splošnih kriterijih. Rezultat nadzorovanja je lahko identifikacija potreb po usposabljanju posameznikov ali potreb po pregledu sistema vodenja kontrolnega organa.

6.1.8 n2 Za "drugo osebje, vključeno v aktivnosti kontrole" glej 5.2.7 n1.

6.1.9 n1 Da bi se dokazi o tem, da kontrolor stalno kompetentno deluje, šteli za zadostne, naj bodo utemeljeni s kombinacijo informacij, kot so:

- zadovoljivo izvajanje pregledov in ugotavljanj skladnosti,
- pozitivni rezultati nadzorovanja (glej opombo k točki 6.1.8),
- pozitivni rezultati ločenih vrednotenj za potrditev rezultatov kontrol (to je lahko možno in primerno npr. v primeru kontrole gradbene dokumentacije),
- pozitivni rezultati dela pod mentorstvom in usposabljanja,
- odsotnost upravičenih prizivov ali pritožb in
- zadovoljivi rezultati opazovanja, ki ga izvede kompetenten organ, npr. certifikacijski organ za osebje.

6.1.9 n2 Učinkovit program za opazovanje kontrolorjev na terenu lahko prispeva k izpolnjevanju zahtev iz točk 5.2.2 in 6.1.3. Program naj bo zasnovan z upoštevanjem:

- tveganja in kompleksnosti kontrol,
- rezultatov predhodnih aktivnosti nadzorovanja in
- tehničnih, postopkovnih ali zakonodajnih sprememb, pomembnih za kontrolo.

Pogostnost opazovanj na terenu je odvisna od zgoraj naštetih vprašanj, vendar naj se opravijo najmanj enkrat v ocenjevalnem obdobju*, glej tudi točko 6.1.9 n1. Če ravni tveganja ali zahtevnosti ali rezultati predhodnih opazovanj to nakazujejo, ali če je prišlo do tehničnih, postopkovnih ali zakonodajnih sprememb, potem je treba razmisliti o večji pogostnosti. Odvisno od področij, vrst in obsegov kontrol, zajetih v pooblastilih kontrolorja, je lahko potrebnih več opazovanj kontrolorja, da se ustrezno pokrije celotni obseg zahtevanih kompetenc. Pogostejše opazovanje na terenu bi lahko bilo potrebno tudi, če je pomanjkanje dokazov o stalnem zadovoljivem delovanju.

**OPOMBA SA: ocenjevalno obdobje v postopkih SA vključuje praviloma 3 nadzorna ocenjevanja in ponovno ocenjevanje.*

6.1.9 n3 Ta zahteva velja tudi v primeru, da ima kontrolni organ samo eno strokovno usposobljeno osebo.

6.1.10 n1 Zapisi o pooblastilu naj navajajo, na kakšni podlagi je bilo pooblastilo podeljeno (npr. opazovanje kontrol na terenu).

6.1.12 n1 Politike in postopki naj osebju kontrolnega organa pomagajo identificirati in obravnavati komercialne, finančne in druge grožnje ali prisile, ki bi lahko vplivale na njihovo nepristranskost, ne glede na to, ali nastajajo znotraj ali zunaj kontrolnega organa. Taki postopki naj obravnavajo, kako se o morebitnih nasprotjih interesov, ki jih osebje kontrolnega organa identificira, poroča in kako se zapisujejo. Treba pa je

6.1.8 n1 A major aim of the monitoring requirement is to provide the inspection body with a tool to ensure the consistency and reliability of inspection outcomes, including any professional judgments against general criteria. Monitoring may result in the identification of needs for individual training or needs for review of the inspection body's management system.

6.1.8 n2 For "other personnel involved in inspection activities", see 5.2.7 n1.

6.1.9 n1 To be considered sufficient, the evidence that the inspector is continuing to perform competently should be substantiated by a combination of information such as;

- satisfactory performance of examinations and determinations,
- positive outcome of monitoring (see note to clause 6.1.8),
- positive outcome of separate evaluations to confirm the outcome of the inspections (this may be possible and appropriate in the case of e.g. the inspection of construction documentation),
- positive outcome of mentoring and training,
- absence of legitimate appeals or complaints, and
- satisfactory results of witnessing by a competent body, e.g. a certification body for persons.

6.1.9 n2 An effective program for the on-site observation of inspectors may contribute to fulfil the requirements in clauses 5.2.2 and 6.1.3. The program should be designed considering;

- the risks and complexities of the inspections,
- results of previous monitoring activities, and
- technical, procedural or legislative developments relevant to the inspections.

The frequency of on-site observations depends on the issues listed above, but should be at least once during the accreditation re-assessment cycle, however see application note 6.1.9 n1. If the levels of risks or complexities, or the results from previous observations, so indicate, or if technical, procedural or legislative changes have occurred, then a higher frequency should be considered. Depending on the fields, types and ranges of inspection covered by the inspector's authorisations, there may be more than one observation per inspector necessary to adequately cover the whole range of required competencies. Also, more frequent on-site observations may be necessary if there is lack of evidence of continuing satisfactory performance.

6.1.9 n3 This requirement applies even in the case the inspection body has only one technically competent person.

6.1.10 n1 Records of authorisation should specify the basis on which authorisation was granted (e.g. the on-site observation of inspections).

6.1.12 n1 Policies and procedures should assist inspection body personnel in identifying and addressing commercial, financial or other threats or inducements which could affect their impartiality, whether they originate inside or outside the inspection body. Such procedures should address how any conflicts of interests identified by personnel of the inspection body are reported and recorded. Note, however, that while

opozoriti na to, da so pričakovanja za integriteto kontrolorjev sicer sporočena v politiki in postopkih, vendar obstoj takih dokumentov ne pomeni nujno prisotnosti integritete in nepristranskosti, ki ju zahteva ta točka.

expectations for inspector integrity can be communicated by policies and procedures, the existence of such documents may not signal the presence of integrity and impartiality required by this clause.

Zahteve glede virov – Zmogljivosti in oprema

Resource requirements – Facilities and equipment

6.2.3 n1 Če so potrebni kontrolirani pogoji okolja, npr. za pravilno izvajanje kontrole, mora kontrolni organ te nadzorovati in zapisati rezultate. Če so bile razmere zunaj sprejemljivih meja za izvedbo kontrole, mora kontrolni organ zapisati, kakšne ukrepe je sprejel. Glej tudi točko 8.7.4.

6.2.3 n1 If controlled environmental conditions are needed, e.g. for the correct performance of the inspection, the inspection body shall monitor these and record the results. If conditions were outside acceptable limits for the inspection to be performed, the inspection body shall record what action was taken. See also clause 8.7.4.

6.2.3 n2 Stalna ustreznost se lahko preveri z vizualno kontrolo, preverjanjem delovanja in/ali ponovno kalibracijo. Ta zahteva je še posebno pomembna za opremo, ki ni več pod neposrednim nadzorom kontrolnega organa.

6.2.3 n2 Continued suitability may be established by visual inspection, functional checks and/or re-calibration. This requirement is particularly relevant for equipment that has left the direct control of the inspection body.

6.2.4 n1 Kontrolni organi naj dokumentirajo in hranijo razloge za odločitve o pomembnosti vpliva opreme na rezultate kontrole, saj so te odločitve bistvena podlaga za poznejše odločitve glede kalibracije in sledljivosti.

6.2.4 n1 Inspection bodies should document and retain the rationale for decisions on the significance of influence of equipment on the inspection results as these decisions are critical foundations for subsequent decisions on calibration and traceability.

6.2.4 n2 Da bi se omogočilo sledenje ob zamenjavi opreme, bi lahko bilo primerno enoznačno identificirati vsak kos opreme, tudi če je na voljo en sam kos..

6.2.4 n2 In order to enable tracking when items are replaced, the unique identification of an item of equipment may be appropriate even when there is only one item available.

6.2.4 n3 Če so potrebni kontrolirani pogoji okolja, naj se oprema, uporabljena za nadzorovanje takih razmer, šteje kot oprema, ki pomembno vpliva na rezultat kontrol.

6.2.4 n3 When controlled environmental conditions are needed, the equipment used to monitor such conditions should be considered as equipment that significantly influences the result of inspections.

6.2.6 n1 Utemeljitev, zakaj oprema, ki pomembno vpliva na izid kontrole (glej točko 6.2.4), ni kalibrirana, je treba zapisati.

6.2.6 n1 The justification for not calibrating equipment that has a significant influence on the outcome of inspection (see clause 6.2.4) shall be recorded.

6.2.6 n2 Smernice za določanje kalibracijskih intervalov je mogoče najti v vodilu ILAC G24.

6.2.6 n2 Guidelines on how to determine calibration intervals can be found in ILAC G24.

6.2.6 n3 Če je primerno (praviloma za opremo, ki je zajeta v točki 6.2.6), mora opredelitev opreme vključevati zahtevano točnost in merilni obseg.

6.2.6 n3 When appropriate (normally for the equipment covered by clause 6.2.6) the definition shall include the required accuracy and measurement range.

6.2.7 n1 V skladu s publikacijo ILAC P10 je mogoče kalibracijo opreme, ki se uporablja za meritve, opraviti interno. Od akreditacijskih organov se zahteva, da imajo politiko za zagotavljanje, da se take interne kalibracijske storitve izvajajo v skladu z ustreznimi kriteriji za meroslovno sledljivost v standardu ISO/IEC 17025.

6.2.7 n1 According to ILAC P10 it is possible to perform in-house calibration of equipment used for measurements. It is a requirement for accreditation bodies to have a policy to ensure that such in-house calibration services are performed in accordance with the relevant criteria for metrological traceability in ISO/IEC 17025.

6.2.7 n2 Prednostne poti za kontrolne organe, ki za kalibracijo svoje opreme najemajo zunanje storitve, so določene v dokumentu ILAC P10.

6.2.7 n2 The preferred routes for inspection bodies who seek external services for calibration of their equipment are defined in ILAC P10.

6.2.9 n1 Če se v času med rednimi ponovnimi kalibracijami na opremi izvajajo vmesna preverjanja, se morajo določiti narava takih preverjanj, pogostnost in kriteriji sprejemljivosti.

6.2.9 n1 Where equipment is subjected to in-service checks between regular re-calibrations, the nature of such checks, the frequency and acceptance criteria shall be defined.

6.2.10 n1 Podatki iz točk 6.2.7 n1, 6.2.7 n2 in 6.2.9 n1 za programe kalibracije opreme veljajo tudi za programe kalibracije referenčnih materialov.

6.2.10 n1 The information provided in 6.2.7 n1, 6.2.7 n2 and 6.2.9 n1 for programs of calibration of equipment is valid also for programs of calibration of reference materials.

6.2.11 n1 Če kontrolni organ najame dobavitelje za izvajanje aktivnosti, ki ne vključujejo izvajanja dela kontrole, ki

6.2.11 n1 When the inspection body engages suppliers to perform activities which do not include the performance

pa so pomembne za rezultat kontrole, npr. registracija naročil, arhiviranje, dobava pomožnih storitev med kontrolo, urejanje poročil o kontroli ali kalibracijske storitve, so take storitve zajete v izrazu "storitve", ki se uporablja v tej točki.

6.2.11 n2 Postopek preverjanja naj zagotavlja, da se vhodno blago in storitve ne uporabijo, dokler ni preverjena skladnost s specifikacijo.

Zahteve glede virov – Sklepanje podpogodb

6.3.1 n1 Po definiciji (ISO/IEC 17011, točka 3.1) je akreditacija omejena na naloge ugotavljanja skladnosti, za katere je kontrolni organ dokazal kompetentnost, da jih izvaja sam. Tako akreditacije ni mogoče podeliti za aktivnosti iz četrte alineje pod opombo 1, če kontrolni organ nima zahtevanih kompetenc in/ali virov. Vendar pa se naloga ocenjevanja in razlage rezultatov takih aktivnosti za namen ugotavljanja skladnosti lahko vključijo v obseg akreditacije pod pogojem, da je za to dokazana ustrezna kompetentnost.

6.3.3 n1 V opombi 2 k definiciji "kontrole" v točki 3.1 je navedeno, da je kontrola v nekaterih primerih lahko omejena samo na pregled, ne da bi bilo potrebno naknadno ugotavljati skladnost. V takih primerih se točka 6.3.3 ne uporablja, saj ni ugotavljanja skladnosti.

6.3.4 n1 Čeprav je prednostni način dokazovanja kompetentnosti podpogodbenika akreditacija, bi se v utemeljenih primerih (na podlagi kvalificiranega vrednotenja oziroma strokovne presoje) lahko sprejeli tudi rezultati neakreditiranih organov.

6.3.4 n2 Če ovrednotenje kompetentnosti podpogodbenika delno ali v celoti temelji na njegovi akreditaciji, mora kontrolni organ zagotoviti, da obseg akreditacije podpogodbenika zajema aktivnosti, za katere je sklenjena podpogodba.

Zahteve glede procesov – Metode in postopki kontrole

7.1.1 n1 Če kontrola vključuje meritve, so v dokumentu ILAC G27 podane smernice o tem, katere zahteve so lahko relevantne.

7.1.1 n2 Za razvoj posebnih metod in postopkov kontrole se lahko uporabijo smernice iz standarda ISO/IEC 17007.

7.1.1 n3 Številne metode kontrole uporabljajo človeško oko za izvajanje vizualnega pregleda. Za uporabo pri kontrolah se uvaja tudi vedno več nove tehnologije (npr. droni, kamere, posebna stekla, IT, umetna inteligenca itd.). To bi lahko bilo kot (delno) nadomestilo za obstoječo metodo kontrole (kot npr. človeško oko) ali kot nova metoda kontrole.

7.1.3 n2 Vidiki, na katere je treba biti pozoren pri uvajanju nove tehnologije, so:

- Validacija nove oziroma spremenjene metode kontrole z uporabo nove tehnologije. V primeru (delne) nadomestitve obstoječe metode kontrole je treba raziskati, ali je izid kontrole enako (ali bolj) zanesljiv kot izid obstoječe metode;
- Veljavne zakonske in varnostne zahteve (npr.

of part of the inspection, but which are relevant for the outcome of inspection activities, e.g. order registration, archiving, delivery of auxiliary services during an inspection, the editing of inspection reports or calibration services, such activities are covered by the term "services" used in this clause.

6.2.11 n2 The verification procedure should ensure that incoming goods and services are not used until conformance with specification has been verified.

Resource requirements – Subcontracting

6.3.1 n1 By definition (ISO/IEC 17011, clause 3.1), accreditation is limited to conformity assessment tasks which the inspection body has demonstrated competence to perform itself. Thus, accreditation cannot be granted for activities referred to in the fourth bullet point under note 1, if the inspection body does not have the required competence and/or resources. However, the task of assessing and interpreting the results of such activities for the purpose of determining conformity may be included in the scope of accreditation, provided adequate competence for this has been demonstrated.

6.3.3 n1 In note 2 to the definition of "inspection" in clause 3.1 it is indicated that in some cases inspection may be examination only, without a subsequent determination of conformity. In such cases clause 6.3.3 does not apply since there is no determination of conformity.

6.3.4 n1 Accreditation is the preferred means to demonstrate the competence of the subcontractor, but in justified situations (on the basis of qualified evaluation/professional judgement) results from non-accredited bodies could be accepted.

6.3.4 n2 If the evaluation of the competence of the subcontractor is based partly or in full on its accreditation, the inspection body shall ensure that the scope of the subcontractor's accreditation covers the activities to be sub-contracted.

Process requirements - Inspection methods and procedures

7.1.1 n1 If the inspection includes measurements, ILAC G27 provides guidance on how to determine which requirements may be relevant.

7.1.1 n2 For the development of specific inspection methods and procedures the guidance in ISO/IEC 17007 can be used.

7.1.1 n3 Many inspection methods use the human eye to perform visual inspections. Increasingly new technology (e.g drones, cameras, special glasses, IT, artificial intelligence, etc.) is introduced to be used during inspections. This could be as a (partly) replacement of an existing inspection method (like the human eye) or as a new inspection method.

7.1.3 n2 Aspects that require attention with the introduction of new technology are:

- Validation of the new or changed inspection method using new technology. In case of (partly) replacement of an existing inspection method, it should be investigated whether the inspection outcome is equally (or more) reliable than the outcome of the existing method;
- The applicable legal and safety requirements (like

dovoljenja), zakonske omejitve in pravni pogoji;
- Veljavne omejitve in pogoji za metodo kontrole, kadar se uporabi nova tehnologija;
- Ali naj bo uporaba nove tehnologije omenjena v poročilu o kontroli;
- Ali naj bo uporaba nove tehnologije omenjena v obsegu kontrole in/ali akreditacije.

permits), legal limitations and legal conditions;
- The applicable limitations and conditions for the inspection method when new technology is used;
- Whether the use of new technology should be mentioned in the inspection report;
- Whether the use of new technology should be mentioned on the inspection and/or accreditation scope.

7.1.5 n1 Kjer je primerno, naj sistem za obvladovanje pogodb ali delovnih nalogov zagotavlja tudi:
- da so dogovorjeni pogodbeni pogoji,
- da so kompetence osebja ustrezne,
- da so prepoznane morebitne zakonske zahteve,
- da so prepoznane zahteve glede varnosti,
- da je prepoznan obseg vseh potrebnih podpogodbenih dogovorov

Pri zahtevah za rutinsko ali ponavljajoče se delo je pregled lahko omejen na upoštevanje časa in človeških virov. V takih primerih bi bil sprejem pogodbe, ki jo je podpisala ustrezno pooblaščena oseba, sprejemljiv zapis.

7.1.5 n1 Where appropriate the contract or work order control system should also ensure that;
- contract conditions are agreed
- personnel competence is adequate
- any statutory requirements are identified
- safety requirements are identified
- the extent of any subcontracting arrangements required is identified

For routine or repeat work requests the review may be limited to considerations of time and human resources. An acceptable record in such cases would be an acceptance of the contract signed by an appropriately authorised person.

7.1.5 n2 V situacijah, ko so sprejemljivi ustni delovni nalogi, mora kontrolni organ hraniti zapise o vseh prejetih ustnih zahtevkih in navodilih. Če je primerno, naj se zapišejo tudi ustrezni datumi in identiteta naročnikovega predstavnika.

7.1.5 n2 In situations where verbal work orders are acceptable, the inspection body shall keep a record of all requests and instructions received verbally. Where appropriate, the relevant dates and the identity of the client's representative should be recorded.

7.1.5 n3 Sistem za obvladovanje pogodb ali delovnih nalogov naj zagotavlja, da bo med kontrolnim organom in njegovim naročnikom jasen in dokazljiv dogovor glede obsega kontrolnega dela, ki ga bo izvedel kontrolni organ.

7.1.5 n3 The contract or work order control system should ensure that there is a clear and demonstrable understanding between the inspection body and its client of the scope of the inspection work to be undertaken by the inspection body.

7.1.6 n1 Informacije, omenjene v te točki, niso tiste, ki jih zagotovi podpogodbenik, temveč informacije, prejete od drugih strani, npr. od regulatornega organa ali naročnika kontrolnega organa. V teh informacijah so lahko zajeti splošni podatki za aktivnost kontrole, ki pa niso rezultat aktivnosti kontrole.

7.1.6 n1 The information referred to in this clause is not information provided by a sub-contractor, but information received from other parties, e.g. a regulating authority or the client of the inspection body. The information may include background data for the inspection activity, but not results of the inspection activity.

Zahteve glede procesov – Zapisi o kontroli

Process requirements - Inspection records

7.3.1 n1 V zapisih naj bo označeno, kateri kos opreme, ki pomembno vpliva na rezultat kontrole, je uporabljen v posamezni aktivnosti kontrole.

7.3.1 n1 The records should indicate which particular item of equipment, having a significant influence on the result of the inspection, has been used for each inspection activity.

Zahteve glede procesov – Poročila in potrdila/certifikati o kontroli

Process requirements - Inspection reports and inspection certificates

7.4.2 n1 V dokumentu ILAC P8 so podane zahteve za uporabo akreditacijskih znakov in za sklicevanje na status akreditacije.

7.4.2 n1 ILAC P8 provides requirements for the use of accreditation symbols and for claims of Accreditation status.

Zahteve glede sistema vodenja – Možnosti

Management system requirements – Options

8.1.3 n1 Izraz "ta mednarodni standard" se nanaša na ISO/IEC 17020.

8.1.3 n1 The expression "this International Standard" is a reference to ISO/IEC 17020.

8.1.3 n2 Možnost B ne zahteva, da je vodenje kontrolnega organa certificirano po ISO 9001. Vendar pa mora akreditacijski organ pri določanju obsega zahtevanega ocenjevanja upoštevati, ali je kontrolni organ po ISO 9001 certificiral certifikacijski organ, ki ga je akreditiral akreditacijski organ, podpisnik IAF MLA oziroma regionalnega MLA za certificiranje sistemov vodenja.

8.1.3 n2 Option B does not require that the inspection body's management is certified to ISO 9001. However, when determining the extent of required assessment, the accreditation body should take into consideration whether the inspection body has been certified against ISO 9001 by a certification body accredited by an accreditation body which is a signatory to the IAF MLA, or to a regional MLA, for the certification of management systems.

Zahteve glede sistema vodenja – Dokumentacija sistema vodenja (možnost A)

8.2.1 n1 Politike in cilji morajo vključevati kompetentnost, nepristranskost in dosledno delovanje kontrolnega organa.

8.2.4 n1 Za lažje sklicevanje se priporoča, da kontrolni organ označi, npr. s preglednico za navzkrižno sklicevanje, kje so obravnavane zahteve ISO/IEC 17020.

Zahteve glede sistema vodenja – Obvladovanje zapisov (možnost A)

8.4.1 n1 Ta zahteva pomeni, da morajo biti vsi zapisi, potrebni za dokazovanje skladnosti z zahtevami standarda, vzpostavljeni in ohranjeni.

8.4.1 n2 V primerih, ko se za odobritev uporabljajo elektronski pečati ali pooblastila, naj bo dostop do elektronskih medijev ali pečata varovan in nadzorovan.

Zahteve glede sistema vodenja – Vodstveni pregled (možnost A)

8.5.2 n1 Del vsakoletnega vodstvenega pregleda naj bo tudi pregled procesa identifikacije tveganja za nepristranskost in njegovi zaključki (točki 4.1.3/4.1.4).

8.5.2 n2 Vodstveni pregled naj upošteva informacije o ustreznosti trenutnih človeških virov in opreme, predvidenih delovnih obremenitvah in potrebi po usposabljanju novega in obstoječega osebja.

8.5.2 n3 Vodstveni pregled naj vključuje pregled uspešnosti sistemov, vzpostavljenih za zagotavljanje ustrezne kompetentnosti osebja.

Zahteve glede sistema vodenja – Notranje presoje (možnost A)

8.6.4 n1 Kontrolni organ naj zagotovi, da v akreditacijskem ciklu program notranje presoje zajame vse zahteve standarda ISO/IEC 17020. Zahteve, ki morajo biti zajete, je treba obravnavati za vsa področja kontrole in za vse prostore, v katerih se vodijo ali izvajajo aktivnosti kontrole.

Kontrolni organ mora kot del planiranja izvedbe presoje utemeljiti izbiro pogostnosti presoje za različne vrste zahtev, področij kontrole in prostorov. Utemeljitev lahko temelji na upoštevanju:

- kritičnosti,
- zrelosti,
- predhodnega delovanja,
- organizacijskih sprememb,
- postopkovnih sprememb in
- učinkovitosti sistema za prenos izkušenj med različnimi lokacijami in različnimi področji delovanja.

8.6.4 n2 Notranja presoja je bistveno orodje, ki naj ga kontrolni organ uporablja dovolj pogosto, da nadzoruje svojo sposobnost za dosledno izpolnjevanje zahtev standarda ISO/IEC 17020. Kadar kontrolni organ odkrije težave, ki vplivajo na izpolnjevanje katerekoli zahteve standarda ISO/IEC 17020 (npr. povečanje števila pritožb in prizivov, nezadovoljivi rezultati na zunanjih presojah,

Management system requirements – Management system documentation (Option A)

8.2.1 n1 The policies and objectives shall address the competence, impartiality and consistent operation of the inspection body.

8.2.4 n1 For easy reference, it is recommended that the inspection body indicates where the requirements of ISO/IEC 17020 are addressed, e.g., by means of a cross reference table.

Management system requirements – Control of records (Option A)

8.4.1 n1 This requirement means that all records needed to demonstrate compliance with the requirements of the standard shall be established and retained.

8.4.1 n2 In cases where electronic seals or authorizations are used for approvals, access to the electronic media or seal should be secure and controlled.

Management system requirements – Management review (Option A)

8.5.2 n1 A review of the impartiality risk identification process and its conclusions (clauses 4.1.3/4.1.4) should be part of the annual management review.

8.5.2 n2 The management review should take into account information on the adequacy of current human and equipment resources, projected workloads and the need for training of both new and existing staff.

8.5.2 n3 The management review should include a review of the effectiveness of systems established to ensure adequate competence of the personnel.

Management system requirements – Internal audits (option A)

8.6.4 n1 The inspection body should ensure that all requirements of ISO/IEC 17020 are covered by the internal audit program within the accreditation cycle. The requirements to be covered shall be considered for all fields of inspection and for all premises where inspectionactivities are managed or performed.

The inspection body shall justify the choice of audit frequency for different types of requirements, fields of inspection and premises as part of audit planning performed. The justification may be based on considerations such as;

- criticality,
- maturity,
- previous performance,
- organisational changes,
- procedural changes, and
- efficiency of the system for transfer of experience between different operational sites and between different fields of operation.

8.6.4 n2 The internal audit is an essential tool the inspection body should apply with a frequency short enough to monitor its capacity to consistently fulfil the requirements in ISO/IEC 17020. When an inspection body detects problems that affect the fulfilment of any ISO/IEC 17020 requirement (e.g. a rise in complaints and appeals; unsatisfactory results at external audits;

vprašanja glede kvalifikacij osebja itd.), naj razmisli o povečanju pogostnosti in globine svojih notranjih presoj, oziroma o razširitvi njihove pokritosti z vključitvijo drugih lokacij in področij kontrole.

8.6.5 n1 Notranje presoje lahko izvaja kompetentno zunanje pogodbeno osebje.

Zahteve glede sistema vodenja – Preventivni ukrepi (možnost A)

8.8.1 n1 Preventivni ukrepi se sprejemajo v proaktivnem procesu identificiranja možnih neskladnosti in možnosti za izboljšave, in ne kot odziv na identifikacijo neskladnosti, težav ali pritožb.

Dodatek A: Zahteve za neodvisnost kontrolnih organov

A n1 V Dodatkih A.1 in A.2 k standardu ISO/IEC 17020 se izraz "predmeti kontrole" nanaša na kontrolne organe tipov A in B. (v točki 4.1.6 n1 so razjasnjeni primeri, ko ima kontrolni organ lahko različne vrste neodvisnosti). V dodatku A.1 b je navedeno, da "zlasti ne smeta biti vključena v snovanje, proizvodnjo, dobavo, montažo, nabavo, lastništvo, uporabo ali vzdrževanje predmetov kontrole". V dodatku A.2 c je navedeno, da "zlasti ne smeta biti vključena v snovanje, proizvodnjo, dobavo, montažo, nabavo, lastništvo, uporabo ali vzdrževanje predmetov kontrole". Tretja oseba dvojine v zgornjih stavkih pomeni sklicevanje na zadevni kontrolni organ in njegovo osebje. Predmeti kontrole so v tem primeru tisti predmeti, ki so specificirani v akreditacijski listini akreditacijskega organa oziroma v prilogi k njej (npr. tlačne posode).

A n2 Kot konfliktna aktivnost se šteje tudi svetovanje pri snovanju, proizvodnji, dobavi, montaži, nabavi, lastništvu, uporabi ali vzdrževanju predmetov kontrole.

A n3 'Regulatorna zahteva' pomeni, da je izjema zapisana v ustrezni zakonodaji in/ali kadar regulator zagotavlja javno dostopne smernice, ki navajajo, da je ta izjema dopustna, če se izvaja kot del regulirane aktivnosti kontrole.

6. DODATEK 1: MOŽNA OBLIKA ANALIZE TVEGANJA ZA NEPRISTRANSKOST (INFORMATIVNO)

V točki 4.1.3 je zahteva, da mora kontrolni organ stalno prepoznavati tveganja za svojo nepristranskost, v točki4.1.4 pa, da mora kontrolni organ dokazati, kako taka tveganja odpravlja ali zmanjšuje. V praksi kombinacija teh dveh poglavij pomeni, da je potrebna "analiza tveganja za nepristranskost". Čeprav izraz "analiza tveganja za nepristranskost" v standardu ISO/IEC 17020 ni omenjen, se v teh smernicah uporablja kot razširjen izraz, s katerim lahko kontrolni organ obravnava zahteve poglavij 4.1.3 in 4.1.4.

Ukrepi, s katerimi kontrolni organ dokaže, kako v praksi odpravi ali zmanjša prepoznana tveganja za nepristranskost, se pogosto imenujejo "nadzorni ukrepi". Tudi ta izraz ni omenjen v ISO/IEC 17020.

V spodnji preglednici je prikazana možna oblika analize tveganja za nepristranskost.

issues with personnel qualification, etc.), it should consider increasing the frequency and depth of its internal audits, and/or to extend their coverage to include other locations and fields of inspection.

8.6.5 n1 Competent externally contracted personnel may carry out internal audits.

Management system requirements – Preventive actions (Option A)

8.8.1 n1 Preventive actions are taken in a pro-active process of identifying potential non-conformities and opportunities for improvement rather than as a reaction to the identification of non-conformities, problems or complaints.

Annex A Independence requirements for inspection bodies

A n1 Annex A.1 and A.2 of ISO/IEC 17020 refer to the phrase "items inspected" with respect to Type A and Type B inspection bodies (4.1.6 n1 clarifies the cases where an inspection body may have different types of independence). In Annex A.1 b it is stated that "In particular they shall not be engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected". In Annex A.2 c it is stated that "In particular they shall not be engaged in the design, manufacture, supply, installation, use or maintenance of the items inspected". The reference to "they" in the above sentences is a reference to the inspection body concerned and its personnel. The items in this case are those items that are specified in the accreditation body's certificate/annex with respect to the accredited scope of the inspection body (e.g. pressure vessels).

A n2 It is also considered as a conflicting activity the provision of consultancy in the design, manufacture, supply, installation, purchase, use or maintenance of the items inspected.

A n3 A 'regulatory requirement' means that the exception has been written into relevant legislation and/or where a Regulator provides publicly available guidance stating that this exception is permissible when undertaken as part of the regulated inspection activity.

6. ANNEX 1: POSSIBLE FORMAT FOR AN IMPARTIALITY RISK ANALYSIS (INFORMATIVE)

Clause 4.1.3 requires the inspection body to identify risks to impartiality on an ongoing basis and clause 4.1.4 requires the inspection body to demonstrate how it eliminates or minimizes such risks. In practice the combination of these two clauses indicates that "an impartiality risk analysis" is required. Although this term "impartiality risk analysis" is not mentioned in ISO/IEC 17020, in this application note it is used as a widely spread term through which the requirements of clauses 4.1.3 and 4.1.4 may be addressed by the inspection body.

The actions through which the inspection body demonstrates how it eliminates or minimizes the identified impartiality risks in practice are often called "control measures". Also this term is not mentioned in ISO/IEC 17020.

A possible format for an impartiality risk analysis is shown in the table below.

Situacija	Tveganje za nepristranskost	Nadzorni ukrep in njegovo spremljanje	Kje je nadzorni ukrep vključen v sistem vodenja (postopek, navodilo, obrazec, izjava)?
1. Aktivnosti kontrolnega organa			
2. Odnosi kontrolnega organa			
3. Odnosi osebja			

Preglednica 1. Možna oblika analize tveganja za nepristranskost

Situation	Impartiality risk	Control measure and its monitoring	Where in the management system is control measure embedded (procedure, instruction, form, statement)?
1. Activities of the inspection body			
2. Relationships of the inspection body			
3. Relationships of personnel			

Table 1. Possible format TTable 1. Possible format for an impartiality risk analysis

7. DODATEK 2: RAZMERJE MED ZAHTEVAMI ZA NEPRISTRANSKOST IN ZA NEODVISNOST TIPA A (INFORMATIVNO)

- Nepristranskost (definirana kot prisotnost objektivnosti) je vodilna zahteva;
- Nepristranskost kontrolorja je prisotna, kadar kontrolor pri svoji presoji v vseh primerih dokazuje objektivnost;

1 – Odpravljanje tveganj z izpolnjevanjem zahtev za neodvisnost tipa A

- Z izpolnjevanjem zahtev za neodvisnost tipa A se odpravijo tveganja za nepristranskost, povezana z vključevanjem v aktivnosti, ki bi lahko bile v nasprotju z neodvisnostjo presoje in integriteto v povezavi z aktivnostmi kontrole;
- Zahteve za neodvisnost tipa A so namenjene povečanju zaupanja v nepristranskost in izključujejo samo določena tveganja za nepristranskost. Torej izpolnjevanje teh zahtev za neodvisnost tipa A ne odpravlja vseh tveganj za nepristranskost;
- Preostala tveganja za nepristranskost je treba prepoznati (točka 4.1.3) in zmanjšati ali odpraviti (točka 4.1.4);

2 – Analiza tveganja za nepristranskost in nadzorni ukrepi

- V praksi se prepoznavanje možnih tveganj za nepristranskost pogosto imenuje “analiza tveganja za nepristranskost”; zmanjševanje ali odpravljanje tveganj za neskladnost v skladu s točko4.1.4 pa se v praksi pogosto imenuje “nadzorni ukrepi”;
- Analiza tveganja za nepristranskost se zahteva za vse tri vrste neodvisnosti (tip A, tip B in tip C);
- Izpolnjevanje zahtev A.1b in A.1c za neodvisnost tipa A je binarno (da ali ne), kar pomeni, da delno izpolnjevanje zahtev za neodvisnost tipa A ni možno. To tudi pomeni, da tam, kjer ni izpolnjevanja teh zahtev tipa A, analiza tveganja, ki ima za posledico nadzorne ukrepe za zmanjšanje tveganj za nepristranskost, ni možna. Torej je situacijo, ki ne izpolnjuje zahtev za neodvisnost tipa A, podanih v zahtevah A1 b in c, dopustno edino odpraviti;
- Zahteve A.1d za neodvisnost tipa A se lahko obravnavajo preko nadzornih ukrepov, ki so posledica analize tveganja;
- Ocenjevanje, ali kontrolni organ izpolnjuje zahteve A.1b in A.1c za neodvisnost tipa A, je lahko v nekaterih

7. ANNEX 2: RELATIONSHIP BETWEEN IMPARTIALITY AND TYPE A INDEPENDENCE REQUIREMENTS (INFORMATIVE)

- Impartiality (defined as presence of objectivity) is the leading requirement;
- Impartiality of an inspector is present when the inspector in all cases demonstrates objectivity in his/ her judgement;

1 - Risks Eliminated by complying to Type A independence requirements

- Complying with the Type A independence requirements eliminates the impartiality risks related to engaging in activities that may conflict with the independence of judgment and integrity in relation to inspection activities;
- The Type A independence requirements are meant to increase confidence in impartiality and exclude only certain impartiality risks. Hence, complying with these Type A independence requirements does not eliminate all impartiality risks;
- The remaining impartiality risks have to be identified (4.1.3) and minimized or eliminated (4.1.4);

2 - Impartiality Risk Analysis and Control Measures

- In practice, the identification of the potential risks to impartiality is often called “impartiality risk analysis”; the minimization or elimination of impartiality risks according to 4.1.4 in practice is often called “control measures”;
- An impartiality risk analysis is required for all three types of independence (Type A, Type B and Type C);
- Complying with the Type A independence requirements A.1b and A.1.c is binary (yes or no) meaning that partly complying with these Type A independence requirements is not possible. This also means that a risk analysis resulting in control measures to minimize the impartiality risks of a situation where there is no compliance with these Type A requirements is not possible. Hence, only elimination of the situation that is not compliant with these Type A requirements is possible;
- The Type A independence requirements A.1d could be addressed through control measures resulting from the risk analysis;
- The assessment whether an inspection body complies with the Type A independence requirements A.1b and A.1c can be complex in some specific situations

posebnih situacijah zapleteno (odvisno od predmetov kontrole, ki so pri roki, in od značilnosti trga), izid pa mora biti da ali ne;

3 – Predmeti kontrole

- Izraz "predmeti kontrole" je omenjen v zahtevah za neodvisnost tipa A v Dodatku A.1b/c k standardu ISO/IEC 17020 in je pojasnjen v tem dokumentu ILAC-P15 pod A n1.
- Obrazložitev pojasnila v dokumentu ILAC-P15 je, da je treba preprečiti možen vpliv na trg oziroma možen vpliv trga, tako da se preprečijo tudi komercialni oziroma finančni pritiski na kontrolni organ in/ali njegovo osebje (npr. kontrolorje);
- Kontrolni organi lahko delujejo na trgih z različnimi karakteristikami v smislu števila dobaviteljev oziroma proizvajalcev, in sicer:
    - na trgih z omejenim številom dobaviteljev/proizvajalcev, na primer dvigal, avtomobilov, tlačne opreme;
    - na trgih z zelo velikim številom dobaviteljev/proizvajalcev, na primer v agroživilstvu.

Takšna razlika v tržnih razmerah nima nikakršnega vpliva na razlago ILAC-P15 A n1: Kontrolni organi in njihovi kontrolorji se ne smejo ukvarjati s predmeti kontrole, navedenimi v obsegu akreditacije, torej na splošno in neomejeno le na posebne/edinstvene/posamezne predmete, ki so predmet kontrole kontrolnega organa.

4 - Tip A / Tip C

- V nekaterih sektorjih gospodarske dejavnosti bi utegnilo biti težko izpolnjevati zahteve A.1b in A.1c za neodvisnost tipa A, saj se potencialni zunanji kontrolorji v teh sektorjih v večini primerov ukvarjajo s predmeti kontrole; v takih primerih je alternativa tipu A tip C.
- Treba je opozoriti, da so zahteve za nepristranskost in kompetentnost enake za tip A in tip C; različne so samo zahteve za neodvisnost.

(depending on the items inspected at hand and market characteristics), but the outcome must be yes or no;

3 - Items Inspected

- The term "items inspected" is mentioned in the Type A independence requirements of Annex A.1b/c of ISO/IEC 17020 and is clarified in this document ILAC-P15 under A n1.
- The reasoning behind the ILAC-P15 clarification is that possible influence on the market or possible influence from the market should be prevented, thus also preventing commercial/ financial pressures on the inspection body and/ or its personnel (e.g. inspectors);
- Inspection bodies may operate in markets with different characteristics in terms of the number of suppliers/ producers:
    - Markets where there is a limited number of suppliers/ producers. For instance, elevators, cars, pressure equipment;
    - Markets where there is a very large number of suppliers/ producers. For instance, in the agro/ food sector.

This kind of difference in the market situation has no influence on the interpretation of ILAC-P15 A n1: Inspection Bodies and its inspectors shall not be engaged with the items inspected as mentioned on the scope of accreditation, thus in general and not restricted to only the specific/ unique/ individual items that are subject of an inspection by the Inspection Body.

4 - Type A / Type C

- It may be difficult to comply with the Type A independence requirements A.1b and A.1c in some sectors of economic activity where potential external inspectors in those sectors are, in most cases, engaged with the items inspected; In such cases Type C is an alternative for Type A.
- It should be noted that the impartiality and competence requirements for Type A and Type C are the same; only the independence requirements are different.

8. LITERATURA

8.1 ISO/IEC 17000:2004 Ugotavljanje skladnosti – Slovar in splošna načela.

8.2 ISO/IEC 17011:2017 Ugotavljanje skladnosti – Splošne zahteve za akreditacijske organe, ki akreditirajo organe za ugotavljanje skladnosti.

8.3 ISO/IEC 17020:2012 Ugotavljanje skladnosti – Zahteve za delovanje različnih tipov organov, ki izvajajo kontrolo.

8.4 ISO/IEC 17025:2017 Splošne zahteve za usposobljenost preskuševalnih in kalibracijskih laboratorijev.

8.5 ISO 15189:2012 Medicinski laboratoriji – Zahteve za kakovost in kompetentnost.

8.6 ISO 9001:2015 Sistemi vodenja kakovosti – Zahteve.

8.7 IAF/ILAC A2:01/2018 IAF/ILAC Večstranski dogovori o medsebojnem priznavanju (Dogovori): Zahteve in postopki za vrednotenje enega samega akreditacijskega organa.

8.8 ISO/IEC 17007:2009 Ugotavljanje skladnosti – Smernice za pripravo normativnih dokumentov, primernih za uporabo na področju ugotavljanja skladnosti.

8.9 ILAC P8/03:2019 Večstranski dogovor ILAC o medsebojnem priznavanju (Dogovor): Dopolnilne zahteve za akreditacijske organe za uporabo akreditacijskih znakov in za sklicevanje na status akreditacije..

8.10 ILAC P10:01/2013 Politika ILAC o sledljivosti rezultatov meritev.

8.11 ILAC G24:2007 Smernice za določanje kalibracijskih intervalov merilnih instrumentov.

8.12 ILAC G27:06/2017 Smernice o meritvah, ki se izvajajo kot del procesa kontrole.

8.13 ILAC G28:07/2018 Smernice za oblikovanje obsegov akreditacije za kontrolne organe.

8. REFERENCES

8.1 ISO/IEC 17000:2004 Conformity assessment – Vocabulary and general principles.

8.2 ISO/IEC 17011:2017 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

8.3 ISO/IEC 17020:2012 Conformity assessment – Requirements for the operation of various types of bodies performing inspection.

8.4 ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories.

8.5 ISO 15189:2012 Medical laboratories – Requirements for quality and competence.

8.6 ISO 9001:2015 Quality management systems – Requirements.

8.7 IAF/ILAC A2:01/2018 IAF/ILAC Multi-lateral mutual recognition arrangements (Arrangements): Requirements and procedures for evaluation of a single accreditation body.

8.8 ISO/IEC 17007:2009 Conformity assessment - Guidance for drafting normative documents suitable for use for conformity assessment..

8.9 ILAC P8/03:2019 ILAC Mutual recognition arrangement (Arrangement): Supplementary requirements for the use of accreditation symbols and for claims of accreditation status by Accredited Conformity Assessment Bodies.

8.10 ILAC P10:01/2013 ILAC policy on traceability of measurement results.

8.11 ILAC G24:2007 Guidelines for the determination of calibration intervals of measuring instruments.

8.12 ILAC G27:06/2017 Guidance on measurements performed as part of an inspection process.

8.13 ILAC G28:07/2018 Guideline for the Formulation of Scopes of Accreditation for Inspection Bodies.