PRIJAVA za akreditacijo organA ZA VALIDIRANJE in PREVERJANJE

**Application for accreditation of validation and verification body**

**Izpolnjeno ter podpisano prijavo natisnite in pošljite v tiskani obliki po navadni pošti in v elektronski obliki (Word formatu) po elektronski pošti (prijavo za pridobitev akreditacije na** [**info@slo-akreditacija.si**](mailto:info@slo-akreditacija.si)**, prijavo za širitev pa vašemu koordinatorju).** **Če prijavljate širitev obsega akreditacije, lahko izpolnite le tiste rubrike, ki so specifične za prijavljeno širitev. */*** *Print the completed and signed application form and send it in paper by ordinary mail and in electronic format (Word document) by E-mail (initial application to info@slo-akreditacija.si; application for extension of scope to your coordinator). If you are applying for an extension of accreditation scope, you can only fill in those sections that are specific to the registered extension.*

**VRSTA PRIJAVE / Type of application**:

pridobitev akreditacije / initial application

|  |  |
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| Identifikacijska številka akreditacije / *Accreditation ID no.*: |  |

spremembe pri že akreditiranem strokovnem področju / changes to already accredited technical field

širitev obsega akreditacije / extension of accreditation scope:

novi postopki v okviru že akreditiranega strokovnega področja / *new procedures within already accredited technical field*

širitev na drugo strokovno področje/shemo / *extension to another technical field/scheme*

vključitev drugih lokacij / *inclusion of other sites*

# SPLOŠNI PODATKI O PRIJAVITELJU / General data about the applicant

|  |  |
| --- | --- |
| **Naziv organizacije** / *Company* name |  |
| Naslov / Address |  |
| Matična številka / Registration No. |  |
| Davčna številka / VAT No. |  |
| Naslov za pošiljanje računa / Invoicing Address |  |
| Številka TRR / Account No. |  |
| Odprt pri banki / Opened at Bank |  |
| Telefon / Phone |  |
| Ime in priimek pravnega zastopnika / Name and surname of Legal Representative |  |
| Funkcija/položaj pravnega zastopnika / Function/position of Legal Representative |  |

|  |  |
| --- | --- |
| **Naziv organa za validiranje in preverjanje /** *Name of validation and verification body* |  |
| Naslov / Address |  |
| Telefon / Phone |  |

|  |  |
| --- | --- |
| **Kontaktna oseba /** *Contact Person*  (Ime in priimek / *Name and Surname*) |  |
| Položaj, funkcija / Position, function |  |
| Naslov / Address |  |
| Telefon / Phone |  |
| Elektronski naslov / E-mail Address |  |

# PRAVNA IDENTITETA, POLOŽAJ, ORGANIZACIJA / Legal identity, position, organization

## Organ za validiranje in preverjanje je / *The* *validation and verification* body is:

samostojna pravna oseba / independent legal entity

državni organ / *governmental authority*

samostojni podjetnik / sole trader

drugo (opišite) / other (describe)

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Organ za validiranje in preverjanje dela za / *The* validation and verification body works for:

lastno organizacijo (notranjega naročnika) / own company (internal client)

zunanjega naročnika / external client

## Opišite razloge za pridobitev akreditacije za prijavljeni obseg oziroma posamezne dele obsega. V primeru, da je akreditacija pogoj za pridobitev pooblastila/imenovanja/statusa, ga navedite in opredelite, na katere dele prijavljenega obsega se to nanaša. / *Please describe the reasons for obtaining accreditation for the applied scope or individual parts of the scope. If accreditation is a condition for obtaining the authorization/appointment/notification, please specify it and identify to which parts of the applied scope this refers.*

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## Opišite organizacijsko strukturo organa za validiranje in preverjanje in položaj dejavnosti validiranja in preverjanja v organizaciji (priložite organizacijski diagram). / *Please* describe organizational structure of the validation and verification body and the position of validation and verification activities in the company (attach organizational chart).

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## Navedite pravne subjekte, s katerimi ima organ za validiranje in preverjanje lastniške, finančne, upravljavske in druge povezave, oziroma subjekte, ki so pod organizacijskim nadzorom organa za validiranje in preverjanje ter njihove dejavnosti. / *Please indicate the legal entities with which the validation and verification body has ownership, financial, governmental or other relationships, or entities that are under the organizational control of the validation and verification body and their activities.*

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## Opišite, kakšna je povezava med dejavnostjo validiranja in preverjanja in drugimi dejavnostmi organa za validiranje in preverjanje (priložite izpis dejavnosti iz sodnega registra). / *Please* describe activities of the validation and verification body and *the relationship between validation and verification activities and any other activities in which validation and verification body is engaged* (attach extract of activities from judicial record).

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# SISTEM VODENJA KAKOVOSTI / Quality management system

## Kdaj je bil v organu za validiranje in preverjanje vpeljan sistem vodenja kakovosti po zahtevah standarda SIST EN ISO/IEC 17029? / When was the quality management system according to standard SIST EN ISO/IEC 17029 implemented in the validation and verification body?

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## Je sistem vodenja v organu za validiranje in preverjanje vpeljan skladno s še drugimi standardi? / Is the validation and verification body's management system implemented according to any other standards?

ne / *no*

da / *yes*

v skladu z zahtevami standarda ISO 9001, za kar ima organ za validiranje in preverjanje pridobljen certifikat akreditiranega certifikacijskega organa / *in accordance with the requirements of the standard ISO 9001, for which the validation and verification body holds a certificate from an accredited certification body*

v skladu z zahtevami standarda ISO 9001, za kar organ za validiranje in preverjanje nima pridobljenega certifikata akreditiranega certifikacijskega organa / *in accordance with the requirements of the standard ISO 9001, for which the validation and verification body doesn't hold a certificate from an accredited certification body*

drugo / *other*

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# OSEBJE / Personnel

## Vodja validiranja in preverjanja (izpolniti prilogo 1) / *Head of validation and verification activities (fill in Annex 1)*

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## Namestnik vodje (izpolniti prilogo 1) / *Deputy of head (fill in Annex 1)*

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## Število ostalega osebja organa za validiranje in preverjanje, ki sodeluje pri validiranju in preverjanju / *Number of other personnel of the validation and verification body, which participate in validation and verification activities:*

|  |  |
| --- | --- |
|  | Število osebja / Number of personnel |
| - zaposleni v organu za validiranje in preverjanje / *employed by validation and verification body* |  |
| - pogodbeno zaposleni (preveritelji) / *contracted personnel (verifiers)* |  |
| skupno / total |  |

## Ali je osebje (preveritelji) usposobljeno, da kompetentno pokriva vsa področja validiranja in preverjanja, na katera se nanaša prijava za akreditacijo? (priložiti seznam preveriteljev z informacijo o področju, ki ga posameznik pokriva) / *Is the personnel (verifiers) trained to competently cover all areas of validation and verification referred to in the application for accreditation? (attach a list of verifiers with information about the area which covers the individual)*

DA / YES  NE / NO

# LOKACIJE / Sites

## Lokacije (v Sloveniji in/ali v tujini), kjer izvajate aktivnosti postopka validiranja in preverjanja iz prijavljenega obsega akreditacije (npr. prejem prijave, pregled prijave, odločanje o preveriteljih …). Podajte informacije za lokacije ne glede na to, za kakšno pravno obliko gre (npr. pravna oseba, podpogodbeno razmerje z izvajalcem, predstavništvo, zastopnik). / Sites (in Slovenia and/or foreign) where validation and verification activities are performed for applied accreditation scope (e.g. receipt of the application, review of application, decision-making on auditors …). Please state the sites regardless of their legal form (e.g. legal entity, sub-contractual relationship with operator, representation, agency).

|  |  |
| --- | --- |
| Naziv in naslov lokacije /  Name and address of site | Aktivnosti postopka validiranja in preverjanja, ki se jih tam izvaja /  Activities of the validation and verification process carried out there |
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## Ali se za katero od vaših strank/naročnikov izvaja validiranje in preverjanje iz prijavljenega obsega akreditacije v tujini (npr. na lokaciji stranke/naročnika oziroma na terenu)? / *Is validation and verification from the applied scope of accreditation carried out for any of your clients abroad (e.g. at the client's location or in the field)?*

ne / *no*

da / *yes*

|  |  |
| --- | --- |
| Država, v kateri izvajate validiranje/preverjanja / Country in which you are performing validations/verifications | Področja dejavnosti\*, ki se jih tam izvaja /  Fields of activities\* carried out in this country |
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\* pri navedbi področij izhajajte iz opredelitev v dokumentu D05-11 oz. v vaši Prilogi k akreditacijski listini / *for specifying fields of accreditation activities see the definitions in the document D05-11 or in your Annex to Accreditation Certificate*

# PODPOGODBENIKI / *Outsourcing*

## Ali organ za validiranje in preverjanje oddaja dejavnost validiranja in preverjanja drugemu organu? */ Does the verification and validation body subcontract to another organization to provide the validation/verification activity on behalf of validation/verification body?*

DA / YES  NE / NO

Če je odgovor da, prosimo, da navedete, katere aktivnosti v postopku validiranja/preverjanja izvajajo vaši podpogodbeniki, kateri so vaši podpogodbeniki in kako ugotavljate njihovo usposobljenost. / *If yes, please, list the activities that verification/validation body subcontract, your subcontractors and describe how does verification/validation body verify subcontractor’s competence.*

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# PRIJAVLJENI OBSEG AKREDITACIJE / *Scope applied for accreditation*

**Navodila / *Instructions***

Pri opredelitvi obsega upoštevajte določila dokumentov S14 – Obseg akreditacije in S14d2 – Obseg akreditacije pri certifikacijskih organih in organih za validiranje in preverjanje. / *In specifying the scope, please observe the provisions of the documents S14 – Scope of accreditation and S14d2 – Scope of accreditation in certification bodies and validation and verification bodies.*

Navedite **naslov lokacije** (v Sloveniji ali v tujini), kjer se dejavnost izvaja. Če se aktivnosti validiranja/preverjanja izvajajo na različnih lokacijah, tudi če so te del iste organizacije, podajte ločen seznam za vsako od lokacij. / *Please indicate the address of the site (in Slovenia or another country) at which the activity is performed. When the validation/verification activities are performed at different sites, even if they are part of the same organization**,* *provide a separate list for each location.*

V spodnjih tabelah jasno in nedvoumno definirajte oziroma označite obseg želene akreditacije. Zgledujte se po obsegih že akreditiranih organov za validiranje in preverjanje, dostopnih na: / *In the tables below, clearly and unambiguously define or indicate the scope of the desired accreditation. Check the scopes of already accredited validation and verification bodies available at:* <https://www.slo-akreditacija.si/?s=&post_type=lpacreditation>.

Za dele obsega, za katere veljajo **dodatne zahteve za usposobljenost** (dodatni standard, normativni dokument nivoja 4), le-te navedite v prvi vrstici tabele, kjer pa to ni relevantno, v tabelah to vrstico izbrišite. V drugi vrstici tabele navedite identifikacijo programa validiranja/preverjanja in oznako vašega dokumenta oz. njegovih relevantnih delov. / *For parts of the scope that are subject to additional requirements for competence (additional standard, normative document of level 4), list them in the first row of the table, but where it is not relevant, delete this row in tables. In the second row of the table, state the validation/verification program and the designation of your document or its relevant parts.*

V **drugem stolpcu** tabele navedite tip trditve, ki jo želite validirati/preverjati. / *In the second column of the table, indicate the type of claim you want to validate/verify.*

V **tretjem stolpcu** tabele podajte oznako in originalen naslov programa validiranja/preverjanja (v celoti ali delno, npr. poglavje, del, točka). / *In the third column of the table, indicate the designation and original title of the validation/verification programme (in full or in part, e.g. chapter, section, paragraph).*

Obseg želene akreditacije vpisujte tako, da bo vsak program validiranja ali preverjanja vpisan v eno vrstico. Dodajte toliko vrstic, kot jih potrebujete. / *Please enter the applied accreditation scope so that each validation/verification programme occupies one raw in the table. Add as many rows as you need.*

V glavi vsake tabele opredelite, ali prijavljate obseg **fiksnega ali fleksibilnega tipa** (glej S14). Pri delih obsega s fleksibilnostjo dodajte tudi opis, na kaj se fleksibilnost nanaša (glej primere v S14d2). / *In the header of each table, specify whether you are applying for fixed or flexible type of scope (see S14). For parts of the flexible scope, add a description of limitations of flexible scope (see examples in S14d2).*

Za področje preverjanja poročil o emisijah toplogrednih plinov po Izvedbeni uredbi Komisije (EU) 2018/2067 označite, za katera področja preverjanja želite pridobiti akreditacijo. / *For the verification of GHG emissions reports according to Commission implementing Regulation (EU) 2018/2067, indicate verification areas/scope of the applied accreditation*.

Prosimo, da v poševni pisavi dodate tudi angleški prevod besedila. */ Please add also the English translations of text and use italics format.*

# Naslov lokacije, kjer se izvajajo aktivnosti / *Site address where activities are performed*

## **Validiranje trditve / *Validation of claim***

### Validiranje po programu / *Validation programme*

Tabela / *Table* 1

| Dodatne zahteve za usposobljenost / *Additional requirements for competence*: **oznaka referenčnega dokumenta oz. njegovih delov / *identification of reference document/its parts*** | | |
| --- | --- | --- |
| Validiranje v skladu s programom / *Validation in accordance with programme*: **opredelitev programa validiranja in oznaka dokumenta sheme oz. njegovih delov / *description of validation programme and identification of scheme document/its parts*** | | |
| Tip obsega: **fiksni / fleksibilni (opis)\*** / *Type of scope:* ***fixed / flexible (description)\**** | | |
| Št.  *No.* | **Vrsta trditve**  **Type of Claim** | **Oznaka in naslov normativnega dokumenta** (v celoti ali delno, npr. poglavje, del, točka)  **Reference** **and title of normative** **document** (entirely or partly, e.g. part, chapter, article) |
|  |  |  |
|  |  |  |

\* opis omejitev fleksibilnega obsega / *description of limitations of flexible scope*

## **Preverjanje trditve / *Verification of claim***

### Preverjanje poročil o emisijah toplogrednih plinov / *Verification of greenhouse gas emission reports*

Tabela / *Table* 2

| Označite prijavljen obseg / *Tick applied scope* | **Št. skupine dejavnosti / *Activity group No*.** | **Skupina dejavnosti / *Activity group*** |
| --- | --- | --- |
|  | 1a | Izgorevanje goriv v napravah, v katerih se uporabljajo samo komercialna standardna goriva, kot so opredeljena v Izvedbeni uredbi (EU) 2018/2066, ali če se v napravah kategorije A ali B uporablja zemeljski plin / *Combustion of fuels in installations, where only commercial standard fuels as defined in Commission Implementing Regulation (EU) 2018/2066 are used, or where natural gas is used in category A or B installations* |
|  | 1b | Izgorevanje goriv v napravah, brez omejitev / *Combustion of fuels in installations, without restrictions* |
|  | 2 | Rafiniranje mineralnega olja / *Refining of mineral oil* |
|  | 3 | Proizvodnja koksa / *Production of coke*  Praženje ali sintranje kovinskih rud, vključno s peletiranjem (vključno s sulfidnimi rudami) / *Metal ore (including sulphide ore) roasting or sintering, including pelletisation*  Proizvodnja surovega železa ali jekla (primarno ali sekundarno taljenje), vključno s kontinuiranim litjem / *Production of pig iron or steel (primary or secondary fusion) including continuous casting* |
|  | 4 | Proizvodnja ali predelava železnih kovin (vključno z železovimi zlitinami) / *Production or processing of ferrous metals (including ferro-alloys)*  Proizvodnja sekundarnega aluminija / *Production of secondary aluminium*  Proizvodnja ali predelava neželeznih kovin, vključno s proizvodnjo zlitin / *Production or processing of non-ferrous metals, including production of alloys* |
|  | 5 | Proizvodnja primarnega aluminija (emisije CO2 in PFC) / *Production of primary aluminium (CO2 and PFC emissions)* |
|  | 6 | Proizvodnja cementnega klinkerja / *Production of cement clinker*  Proizvodnja apna ali žganje dolomita ali magnezita / *Production of lime or calcination of dolomite or magnesite*  Proizvodnja stekla, vključno s steklenimi vlakni / *Manufacture of glass including glass fibre*  Izdelava keramičnih izdelkov z žganjem / *Manufacture of ceramic products by firing*  Proizvodnja izolacijskega materiala iz mineralne volne / *Manufacture of mineral wool insulation material*  Sušenje ali žganje mavca ali proizvodnja mavčnih plošč in drugih mavčnih proizvodov / *Drying or calcination of gypsum or production of plaster boards and other gypsum products* |
|  | 7 | Proizvodnja papirne kaše iz lesa ali drugih vlaknatih materialov / *Production of pulp from timber or other fibrous materials*  Proizvodnja papirja ali kartona / *Production of paper or cardboard* |
|  | 8 | Proizvodnja industrijskega oglja / *Production of carbon black*  Proizvodnja amonijaka / *Production of ammonia*  Proizvodnja organskih kemikalij v rinfuzi s krekingom, reformingom, delno ali polno oksidacijo ali s podobnimi procesi / *Production of bulk organic chemicals by cracking, reforming, partial or full oxidation or by similar processes*  Proizvodnja vodika (H2) in sinteznega plina z reformingom ali delno oksidacijo / *Production of hydrogen (H2) and synthesis gas by reforming or partial oxidation*  Proizvodnja natrijevega karbonata (Na2CO3) in natrijevega bikarbonata (NaHCO3) / *Production of soda ash (Na2CO3) and sodium bicarbonate (NaHCO3)* |
|  | 9 | Proizvodnja dušikove kisline (emisije CO2 in N2O) / *Production of nitric acid (CO2 and N2O emissions)*  Proizvodnja adipinske kisline (emisije CO2 in N2O) / *Production of adipic acid (CO2 and N2O emissions)*  Proizvodnja glioksala in glioksilne kisline (emisije CO2 in N2O) / *Production of glyoxal and glyoxylic acid (CO2 and N2O emissions)* |
|  | 10 | Zajemanje toplogrednih plinov iz naprav, ki jih ureja Direktiva 2003/87/ES, za transport in geološko shranjevanje na območju shranjevanja, dovoljenem v skladu z Direktivo 2009/31/ES / *Capture of greenhouse gases from installations covered by Directive 2003/87/EC for the purpose of transport and geological storage in a storage site permitted under Directive 2009/31/EC*  Transport toplogrednih plinov s cevovodi za geološko shranjevanje na območju shranjevanja, dovoljenem v skladu z Direktivo 2009/31/ES / *Transport of greenhouse gases by pipelines for geological storage in a storage site permitted under Directive 2009/31/EC* |
|  | 11 | Geološko shranjevanje toplogrednih plinov na območju shranjevanja, dovoljenem v skladu z Direktivo 2009/31/ES / *Geological storage of greenhouse gases in a storage site permitted under Directive 2009/31/EC* |
|  | 12 | Dejavnosti letalstva (podatki o emisijah in tonskih kilometrih) / *Aviation activities (emissions and tonne-kilometre data)* |
|  | 98 | Druge dejavnosti v skladu s členom 10a Direktive 2003/87/ES / *Other activities pursuant to Article 10a of Directive 2003/87/EC* |
|  | 99 | Druge dejavnosti, ki jih država članica vključi v skladu s členom 24 Direktive 2003/87/ES in jih je treba podrobno navesti v akreditacijski listini / *Other activities, included by a Member State pursuant to Article 24 of Directive 2003/87/EC, to be specified in detail in the accreditation certificate* |

### Preverjanje po drugih programih / *Verification according to other programmes*

Tabela / *Table* 3

| Dodatne zahteve za usposobljenost / *Additional requirements for competence*: **oznaka referenčnega dokumenta oz. njegovih delov / *identification of reference document/its parts*** | | |
| --- | --- | --- |
| Preverjanje v skladu s programom / *Verification in accordance with programme*: **opredelitev programa preverjanja in oznaka dokumenta sheme oz. njegovih delov / *description of validation programme and identification of scheme document/its parts*** | | |
| Tip obsega: **fiksni / fleksibilni (opis)\*** / *Type of scope:* ***fixed / flexible (description)\**** | | |
| Št.  *No.* | **Vrsta trditve**  **Type of Claim** | **Oznaka in naslov normativnega dokumenta** (v celoti ali delno, npr. poglavje, del, točka)  **Reference** **and title of normative** **document** (entirely or partly, e.g. part, chapter, article) |
|  |  |  |
|  |  |  |

\* opis omejitev fleksibilnega obsega */ description of limitations of flexible scope*

# INFORMACIJA O IZDANIH IZJAVAH ORGANA ZA VALIDIRANJE IN PREVERJANJE / *Information on* *issued validation and verification statements*

## Ali obstaja spisek prejemnikov Izjave organa za validiranje in preverjanje? / *Is there a list of issued validation and verification statements?*

DA / YES  NE / NO

Kako je ta spisek dostopen? / *How is this list accessible?*

na voljo je na internetni strani / *available on the Internet*:

|  |
| --- |
|  |

na voljo je pri organu za validiranje in preverjanje (prosimo, da priložite seznam) / *available at validation and verification body (please attach a list)*

# ŽELIMO, DA SA IZVEDE PREDOCENJEVANJE / *We want that SA performs pre-assessment*

DA / YES  NE / NO

**ŽELIMO, DA SA OCENJEVANJE ZA ŠIRITEV OBSEGA AKREDITACIJE IZVEDE IZVEN TERMINA REDNEGA NADZORA KOT IZREDNO OCENJEVANJE (to možnost lahko izkoristite le enkrat v akreditacijskem ciklu) / *We want that SA performs assessment for extension of accreditation scope outside the regular surveillance period as an extraordinary assessment (this option can be used only once in accreditation cycle)***

DA / YES  NE / NO

1. **IZJAVA / Statement**

**Izjavljamo, da smo seznanjeni z naslednjimi pogoji za izvedbo postopka akreditiranja in jih sprejemamo / We hereby declare that we are aware of and accepting the following conditions for the performance of accreditation procedure:**

* vzpostavljen in delujoč sistem vodenja kakovosti, ki omogoča izpolnjevanje vseh zahtev standarda SIST EN ISO/IEC 17029 / implemented and operational quality management system which fulfils all requirements of the standard SIST EN ISO/IEC 17029;
* sistem vodenja kakovosti dokumentiran v obsegu, ki ga zahteva standard SIST EN ISO/IEC 17029 / management system documented as required by the standard SIST EN ISO/IEC 17029;
* izvedena najmanj ena notranja presoja v celotnem obsegu in najmanj en vodstveni pregled, upoštevajoč zahteve standarda SIST EN ISO/IEC 17029 / *performed* at least one complete internal audit and at least one management review respecting all requirements of the standard SIST EN ISO/IEC 17029;
* aktivno izvajanje postopkov validiranja/preverjanja v celotnem obsegu, ki je naveden v tej prijavi / *active performance of validations/verifications specified in the applied scope of accreditation*;
* izpolnjevanje zahtev za akreditacijo in obveznosti do SA v zvezi z akreditacijo / fulfilling the requirements for accreditation and other obligations to SA relating to accreditation.

**Poleg tega izjavljamo, da smo seznanjeni s splošnimi pogoji za izvedbo postopka akreditiranja, vezanimi na informacije in dostop do osebnih podatkov, ki so dostopni na spletni strani SA:** [**https://www.slo-akreditacija.si/o-nas/o-slovenski-akreditaciji/politika-varstva-osebnih-podatkov/**](https://www.slo-akreditacija.si/o-nas/o-slovenski-akreditaciji/politika-varstva-osebnih-podatkov/)**, in jih sprejemamo. / We in addition hereby declare that we are aware of and accepting the conditions for the performance of accreditation procedure regarding information and access to personal data, which are available at SA website:** [**https://www.slo-akreditacija.si/about-us/about-sa/personal-data-protection-policy-in-carrying-out-accreditation-procedures-2/?lang=en**](https://www.slo-akreditacija.si/about-us/about-sa/personal-data-protection-policy-in-carrying-out-accreditation-procedures-2/?lang=en)**.**

# PRILOGE / Attachments

**Ob prvi prijavi za akreditacijo** priložiti vsa navedena dokazila, v ostalih primerih pa le tista, ki so relevantna za prijavljeno širitev obsega: / *When first applying for accreditation attach all listed evidence, and in other cases only those that are relevant to the applied scope for extension*:

Potrdilo o nekaznovanosti pravne osebe oz. Potrdilo o nekaznovanosti fizične osebe, kadar gre za samostojnega podjetnika (za pridobitev se obrnite na Ministrstvo za pravosodje RS) (opomba: dokazila ne priložite, če spadate med državne organe) / *Certificate of non-conviction for legal person or – in the case of sole trader – certificate of impunity of natural person* (contact the Ministry of Justice of the Republic of Slovenia) *(note: no certificate needed if you belong to state authority)*

Izpisek iz evidence o pravnomočnih odločbah o prekrških, iz katerega izhaja, da niste bili pravnomočno spoznani za odgovorno za storitev prekrška, ki je v povezavi s področji dejavnosti, prijavljenimi za akreditacijo (za pridobitev se obrnite na Ministrstvo za pravosodje RS) / *Extract from the Criminal Record to certifiy that the client has not been finally held liable for committing an offence related to the fields of activities applied for accreditation* (contact the Ministry of Justice of the Republic of Slovenia)

Organizacijski diagram / Organizational chart

Izpis dejavnosti iz sodnega registra / *Extract of activities from judicial record*

Podatki odgovornega osebja organa za validiranje in preverjanje (Priloga 1 tega dokumenta) / *Information regarding responsible personnel of validation and verification body (Annex 1 of this document)*

Seznam osebja z informacijo o področju, ki ga posameznik pokriva / A list of verifiers with information about the area, which covers the individual

Seznam prejemnikov Izjave organa za validiranje in preverjanje / *A list of issued validation and verification statements*

Samoocena skladnosti programa validiranja/preverjanja z zahtevami za program / *Self-assessment* *of the compliance of the validation/verification programme with the requirements for the programme*

Korelacijska tabela dokumentacije sistema vodenja z zahtevami standarda SIST EN ISO/IEC 17029:2019 (Priloga 2 tega dokumenta) / *Cross reference list of management system documentation with requirements of the standard SIST EN ISO/IEC 17029:2019 (Annex 2 of this document)*

Korelacijska tabela dokumentacije sistema vodenja z zahtevami standarda SIST EN ISO 14065:2022 (istoveten z ISO 14065:2020) (Priloga 3 tega dokumenta) / *Cross reference list of management system documentation with requirements of the standard SIST EN ISO 14065:2022 (identical to ISO 14065:2020) (Annex 3 of this document)*

Primer izjave o validaciji/preverjanju / *An example of a validation/verification statement*

|  |  |  |
| --- | --- | --- |
| , |  |  |
| Kraj, datum  *Place, date* |  | Ime in podpis odgovorne osebe  *Name and signature of responsible person* |

Žig

*Stamp*

PRILOGA / *ANNEX* 1: Podatki odgovornega osebja organa za validiranje in preverjanje / *Information regarding responsible personnel of validation and verification body*

|  |  |
| --- | --- |
| **Vodja aktivnosti validiranja/preverjanja** /*Head of validation/verification activities*  (Ime in priimek / *Name and Surname*) |  |
| Datum in kraj rojstva / *Date and place of birth* |  |
| Izobrazba / Education |  |
| Delovne izkušnje (leta) / Working experience (years) |  |
| Položaj, funkcija v organizaciji / Position, function in organization |  |
| Izkušnje na področju validiranja/preverjanja (leta) / Experience in the field of validation/verification (years) |  |

|  |  |
| --- | --- |
| **Namestnik vodje /** *Deputy of head*  (Ime in priimek / *Name and Surname*) |  |
| Datum in kraj rojstva / *Date and place of birth* |  |
| Izobrazba / Education |  |
| Delovne izkušnje (leta) / Working experience (years) |  |
| Položaj, funkcija v organizaciji / Position, function in organization |  |
| Izkušnje na področju validiranja/preverjanja (leta) / Experience in the field of validation/verification (years) |  |

**PRILOGA / *ANNEX* 2:**

**Korelacijska tabela dokumentacije sistema vodenja z zahtevami standarda SIST EN ISO/IEC 17029:2019 / *Cross reference list of management system documentation with requirements of the standard SIST EN ISO/IEC 17029:2019***

**Navodila / *Instructions*:**

1. Namen te korelacijske tabele je pomoč organu za validiranje in preverjanje pri pregledu, ali so vse zahteve standarda SIST EN ISO/IEC 17029 zajete v dokumentaciji sistema vodenja. Korelacijska tabela omogoča SA večjo učinkovitost pri oceni ustreznosti dokumentacije sistema vodenja. / *The purpose of this matrix is to assist the validation and verification body in verifying whether all the requirements of the SIST EN ISO/IEC 17029 standard have been processed in the relevant documents. Furthermore, the matrix allows SA increased efficiency in evaluating the documentation of the management system.*
2. V stolpec »Zakoni, predpisi« vpišite oznako relevantnega predpisa z ustrezno točko/poglavjem. / *Adequate code of the respective law, rule, regulation, or similar should be entered in column marked “Legislation”.*
3. V ostale stolpce vpišite odgovarjajoči dokument, del dokumenta, poglavje, ki se nanaša na izpolnjevanje zahteve standarda. / *In other columns please enter the codes of respective documents that deal with individual standard requirements, and their chapters/sections.*

| Zahteva standarda  S*tandard requirement* | Zahteva  *Requirement* | Zakoni, predpisi *Legislation* | Poslovnik kakovosti  *Quality*  *manual* | | | Postopki sistema vodenja  *System procedures* | | Delovna navodila  *Work instructions* | | Obrazci  *Forms* |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **5 SPLOŠNE ZAHTEVE /** *GENERAL REQUIREMENTS* | | | | | | | | | | |
| **5.1 Pravni status**  *Legal entity* | 5.1 |  |  | | |  | |  | |  |
| **5.2 Odgovornost za izdajo izjave**  *Responsibility for validation/verification statements* | 5.2 |  |  | | |  | |  | |  |
| **5.3 Obvladovanje nepristranskosti** *Management of impartiality* | 5.3.1 |  |  | | |  | |  | |  |
| 5.3.2 |  |  | | |  | |  | |  |
| 5.3.3 |  |  | | |  | |  | |  |
| 5.3.4 |  |  | | |  | |  | |  |
| 5.3.5 |  |  | | |  | |  | |  |
| 5.3.6 |  |  | | |  | |  | |  |
| 5.3.7 |  |  | | |  | |  | |  |
| 5.3.8 |  |  | | |  | |  | |  |
| 5.3.9 |  |  | | |  | |  | |  |
| 5.3.10 |  |  | | |  | |  | |  |
| 5.3.11 |  |  | | |  | |  | |  |
| 5.3.12 |  |  | | |  | |  | |  |
| 5.3.13 |  |  | | |  | |  | |  |
| **5.4 Zavarovanje**  *Liability* | 5.4 |  |  | | |  | |  | |  |
| **6 STRUKTURNE ZAHTEVE** / *STRUCTURAL REQUIREMENTS* | | | | | | | | | | |
| **6.1 Organizacijska struktura in najvišje vodstvo**  *Organizational structure and top management* | 6.1.1 |  |  | | |  | |  | |  |
| 6.1.2 |  |  | | |  | |  | |  |
| 6.1.3 |  |  | | |  | |  | |  |
| 6.1.4 a) |  |  | | |  | |  | |  |
| 6.1.4 b) |  |  | | |  | |  | |  |
| 6.1.4 c) |  |  | | |  | |  | |  |
| 6.1.4 d) |  |  | | |  | |  | |  |
| 6.1.4 e) |  |  | | |  | |  | |  |
| 6.1.4 f) |  |  | | |  | |  | |  |
| 6.1.4 g) |  |  | | |  | |  | |  |
| 6.1.4 h) |  |  | | |  | |  | |  |
| 6.1.4 i) |  |  | | |  | |  | |  |
| 6.1.4 j) |  |  | | |  | |  | |  |
| 6.1.4 k) |  |  | | |  | |  | |  |
| 6.1.4 l) |  |  | | |  | |  | |  |
| 6.1.4 m) |  |  | | |  | |  | |  |
| **6.2 Operativni nadzor**  *Operational control* | 6.2.1 |  |  | | |  | |  | |  |
| 6.2.2 |  |  | | |  | |  | |  |
| 6.2.3 |  |  | | |  | |  | |  |
| **7 ZAHTEVE GLEDE VIROV /** *RESOURCE REQUIREMENTS* | | | | | | | | | | |
| **7.1 Splošno**  *General* | 7.1 |  |  | | |  | |  | |  |
| **7.2 Osebje**  *Personnel* | 7.2.1 |  |  | | |  | |  | |  |
| 7.2.2 a) |  |  | | |  | |  | |  |
| 7.2.2 b) |  |  | | |  | |  | |  |
| 7.2.2 c) |  |  | | |  | |  | |  |
| 7.2.3 |  |  | | |  | |  | |  |
| 7.2.4 |  |  | | |  | |  | |  |
| 7.2.5 |  |  | | |  | |  | |  |
| 7.2.6 |  |  | | |  | |  | |  |
| 7.2.7 |  |  | | |  | |  | |  |
| **7.3 Vodenje kompetenc osebja**  *Management process for the competence of personnel* | 7.3.1 |  |  | | |  | |  | |  |
| 7.3.2 a) |  |  | | |  | |  | |  |
| 7.3.2 b) |  |  | | |  | |  | |  |
| 7.3.2 c) |  |  | | |  | |  | |  |
| 7.3.2 d) |  |  | | |  | |  | |  |
| 7.3.2 e) |  |  | | |  | |  | |  |
| 7.3.3 |  |  | | |  | |  | |  |
| **7.4 Podpogodbeniki**  *Outsourcing* | 7.4 a) |  |  | | |  | |  | |  |
| 7.4 b) |  |  | | |  | |  | |  |
| 7.4 c) |  |  | | |  | |  | |  |
| 7.4 d) |  |  | | |  | |  | |  |
| 7.4 e) |  |  | | |  | |  | |  |
| **8 PROGRAM VALIDIRANJA/PREVERJANJA /** *VALIDATION/VERIFICATION PROGRAMME* | | | | | | | | | | |
| **Program V&P**  *V&V Programme* |  |  |  | | |  | |  | |  |
| **9 ZAHTEVE GLEDE PROCESOV /** *PROCESS REQUIREMENTS* | | | | | | | | | | |
| **9.1 Splošno**  *General* | 9.1 |  |  | | |  | |  | |  |
| **9.2 Predhodne aktivnosti**  *Pre-engagement* | 9.2.1 a) |  |  | | |  | |  | |  |
| 9.2.1 b) |  |  | | |  | |  | |  |
| 9.2.1 c) |  |  | | |  | |  | |  |
| 9.2.1 d) |  |  | | |  | |  | |  |
| 9.2.1 e) |  |  | | |  | |  | |  |
| 9.2.1 f) |  |  | | |  | |  | |  |
| 9.2.1 g) |  |  | | |  | |  | |  |
| 9.2.2 a) |  |  | | |  | |  | |  |
| 9.2.2 b) |  |  | | |  | |  | |  |
| 9.2.2 c) |  |  | | |  | |  | |  |
| 9.2.2 d) |  |  | | |  | |  | |  |
| 9.2.2 e) |  |  | | |  | |  | |  |
| 9.2.2 f) |  |  | | |  | |  | |  |
| 9.2.2 g) |  |  | | |  | |  | |  |
| 9.2.2 h) |  |  | | |  | |  | |  |
| 9.2.2 i) |  |  | | |  | |  | |  |
| 9.2.3 |  |  | | |  | |  | |  |
| **9.3 Dogovor**  *Engagement* | 9.3.1 a) |  |  | | |  | |  | |  |
| 9.3.1 b) |  |  | | |  | |  | |  |
| 9.3.2 a) |  |  | | |  | |  | |  |
| 9.3.2 b) |  |  | | |  | |  | |  |
| 9.3.2 c) |  |  | | |  | |  | |  |
| 9.3.2 d) |  |  | | |  | |  | |  |
| 9.3.3 a) |  |  | | |  | |  | |  |
| 9.3.3 b) |  |  | | |  | |  | |  |
| 9.3.4 |  |  | | |  | |  | |  |
| **9.4 Planiranje**  *Planning* | 9.4.1 a) |  |  | | |  | |  | |  |
| 9.4.1 b) |  |  | | |  | |  | |  |
| 9.4.1 c) |  |  | | |  | |  | |  |
| 9.4.1 d) |  |  | | |  | |  | |  |
| 9.4.1 e) |  |  | | |  | |  | |  |
| 9.4.1 f) |  |  | | |  | |  | |  |
| 9.4.1 g) |  |  | | |  | |  | |  |
| 9.4.2 a) |  |  | | |  | |  | |  |
| 9.4.2 b) |  |  | | |  | |  | |  |
| 9.4.2 c) |  |  | | |  | |  | |  |
| 9.4.2 d) |  |  | | |  | |  | |  |
| 9.4.3 |  |  | | |  | |  | |  |
| 9.4.4 |  |  | | |  | |  | |  |
| 9.5 **Izvajanje validacije / preverjanja**  *Validation/verification execution* | 9.5.1 |  |  | | |  | |  | |  |
| 9.5.2 |  |  | | |  | |  | |  |
| 9.5.3 |  |  | | |  | |  | |  |
| 9.5.4 a) |  |  | | |  | |  | |  |
| 9.5.4 b) |  |  | | |  | |  | |  |
| 9.5.4 c) |  |  | | |  | |  | |  |
| 9.5.5 a) |  |  | | |  | |  | |  |
| 9.5.5 b) |  |  | | |  | |  | |  |
| 9.5.5 c) |  |  | | |  | |  | |  |
| **9.6 Pregled**  *Review* | 9.6.1 |  |  | | |  | |  | |  |
| 9.6.2 |  |  | | |  | |  | |  |
| 9.6.3 a) |  |  | | |  | |  | |  |
| 9.6.3 b) |  |  | | |  | |  | |  |
| 9.6.3 c) |  |  | | |  | |  | |  |
| 9.6.4 |  |  | | |  | |  | |  |
| 9.6.5 |  |  | | |  | |  | |  |
| **9.7 Odločitev in izdaja izjave o validaciji / preverjanju**  *Decision and issue of the validation / verification statement* |  |  |  | | |  | |  | |  |
| **9.7.1 Odločitev**  *Decision* | 9.7.1.1 |  |  | | |  | |  | |  |
| 9.7.1.2 |  |  | | |  | |  | |  |
| 9.7.1.3 |  |  | | |  | |  | |  |
| 9.7.1.4 |  |  | | |  | |  | |  |
| **9.7.2 Izdaja izjave o validaciji / preverjanju**  *Issue of the validation / verification statement* | 9.7.2 a) |  |  | | |  | |  | |  |
| 9.7.2 b) |  |  | | |  | |  | |  |
| 9.7.2 c) |  |  | | |  | |  | |  |
| 9.7.2 d) |  |  | | |  | |  | |  |
| 9.7.2 e) |  |  | | |  | |  | |  |
| 9.7.2 f) |  |  | | |  | |  | |  |
| 9.7.2 g) |  |  | | |  | |  | |  |
| 9.7.2 h) |  |  | | |  | |  | |  |
| 9.7.2 i) |  |  | | |  | |  | |  |
| 9.7.2 j) |  |  | | |  | |  | |  |
| 9.7.2 k) |  |  | | |  | |  | |  |
| **9.8 Dejstva, ugotovljena po izdaji Izjave o preverjanju / validaciji**  *Facts discovered after the issue of the validation/verification statement* | 9.8.1 a) |  |  | | |  | |  | |  |
| 9.8.1 b) |  |  | | |  | |  | |  |
| 9.8.2 |  |  | | |  | |  | |  |
| 9.8.3 |  |  | | |  | |  | |  |
| **9.9 Prizivi**  *Handling of**appeals* | 9.9.1 |  |  | | |  | |  | |  |
| 9.9.2 a) |  |  | | |  | |  | |  |
| 9.9.2 b) |  |  | | |  | |  | |  |
| 9.9.2 c) |  |  | | |  | |  | |  |
| 9.9.3 |  |  | | |  | |  | |  |
| 9.9.4 |  |  | | |  | |  | |  |
| 9.9.5 |  |  | | |  | |  | |  |
| 9.9.6 |  |  | | |  | |  | |  |
| 9.9.7 |  |  | | |  | |  | |  |
| 9.9.8 |  |  | | |  | |  | |  |
| **9.10 Pritožbe**  *Handling of complaints* | 9.10.1 |  |  | | |  | |  | |  |
| 9.10.2 a) |  |  | | |  | |  | |  |
| 9.10.2 b) |  |  | | |  | |  | |  |
| 9.10.2 c) |  |  | | |  | |  | |  |
| 9.10.3 |  |  | | |  | |  | |  |
| 9.10.4 |  |  | | |  | |  | |  |
| 9.10.5 |  |  | | |  | |  | |  |
| 9.10.6 |  |  | | |  | |  | |  |
| 9.10.7 |  |  | | |  | |  | |  |
| 9.10.8 |  |  | | |  | |  | |  |
| **9.11 Zapisi**  *Records* | 9.11.1 a) |  |  | | |  | |  | |  |
| 9.11.1 b) |  |  | | |  | |  | |  |
| 9.11.1 c) |  |  | | |  | |  | |  |
| 9.11.1 d) |  |  | | |  | |  | |  |
| 9.11.1 e) |  |  | | |  | |  | |  |
| 9.11.1 f) |  |  | | |  | |  | |  |
| 9.11.1 g) |  |  | | |  | |  | |  |
| 9.11.1 h) |  |  | | |  | |  | |  |
| 9.11.2 |  |  | | |  | |  | |  |
| 9.11.3 |  |  | | |  | |  | |  |
| **10 ZAHTEVE ZA INFORMACIJE /** *INFORMATION REQUIREMENTS* | | | | | | | | | | |
| **10.1 Javno dostopne informacije**  *Publicly available information* | 10.1.1 a) |  | | |  | |  | |  |  |
| 10.1.1 b) |  | | |  | |  | |  |  |
| 10.1.1 c) |  | | |  | |  | |  |  |
| 10.1.1 d) |  | | |  | |  | |  |  |
| **10.2 Druge dostopne informacije**  *Other information to be available* | 10.2.1 |  | | |  | |  | |  |  |
| 10.2.2 |  | | |  | |  | |  |  |
| 10.2.3 a) |  | | |  | |  | |  |  |
| 10.2.3 b) |  | | |  | |  | |  |  |
| 10.2.3 c) |  | | |  | |  | |  |  |
| 10.2.3 d) |  | | |  | |  | |  |  |
| **10.3 Sklicevanje na validiranje / preverjanje in uporaba znaka**  *Reference to validation / verification and use of marks* | 10.3.1 |  | |  | | |  | |  |  |
| 10.3.2 |  | |  | | |  | |  |  |
| **10.4 Zaupnost**  *Confidentiality* | 10.4.1 |  | |  | | |  | |  |  |
| 10.4.2 |  | |  | | |  | |  |  |
| 10.4.3 |  | |  | | |  | |  |  |
| 10.4.4 |  | |  | | |  | |  |  |
| 10.4.5 |  | |  | | |  | |  |  |
| **11 ZAHTEVE ZA SISTEM VODENJA /** *MANAGEMENT SYSTEM REQUIREMENTS* | | | | | | | | | | |
| **11.1 Splošno**  *General* | 11.1.1 |  |  | | |  | |  | |  |
| 11.1.2 |  |  | | |  | |  | |  |
| 11.1.3 |  |  | | |  | |  | |  |
| **11.2 Vodstveni pregled**  *Management review* | 11.2.1 |  |  | | |  | |  | |  |
| 11.2.2 a) |  |  | | |  | |  | |  |
| 11.2.2 b) |  |  | | |  | |  | |  |
| 11.2.2 c) |  |  | | |  | |  | |  |
| 11.2.2 d) |  |  | | |  | |  | |  |
| 11.2.2 e) |  |  | | |  | |  | |  |
| 11.2.2 f) |  |  | | |  | |  | |  |
| 11.2.2 g) |  |  | | |  | |  | |  |
| 11.2.2 h) |  |  | | |  | |  | |  |
| 11.2.2 i) |  |  | | |  | |  | |  |
| 11.2.2 j) |  |  | | |  | |  | |  |
| 11.2.2 k) |  |  | | |  | |  | |  |
| 11.2.2 l) |  |  | | |  | |  | |  |
| 11.2.2 m) |  |  | | |  | |  | |  |
| 11.2.2 n) |  |  | | |  | |  | |  |
| 11.2.3 a) |  |  | | |  | |  | |  |
| 11.2.3 b) |  |  | | |  | |  | |  |
| 11.2.3 c) |  |  | | |  | |  | |  |
| 11.2.3 d) |  |  | | |  | |  | |  |
| **11.3 Notranje presoje**  *Internal audits* | 11.3.1 a) |  |  | | |  | |  | |  |
| 11.3.1 b) |  |  | | |  | |  | |  |
| 11.3.2 a) |  |  | | |  | |  | |  |
| 11.3.2 b) |  |  | | |  | |  | |  |
| 11.3.2 c) |  |  | | |  | |  | |  |
| 11.3.2 d) |  |  | | |  | |  | |  |
| 11.3.2 e) |  |  | | |  | |  | |  |
| 11.3.3 |  |  | | |  | |  | |  |
| **11.4 Korektivni ukrepi**  *Corrective action* | 11.4 a) |  |  | | |  | |  | |  |
| 11.4 b) |  |  | | |  | |  | |  |
| 11.4 c) |  |  | | |  | |  | |  |
| 11.4 d) |  |  | | |  | |  | |  |
| 11.4 e) |  |  | | |  | |  | |  |
| 11.4 f) |  |  | | |  | |  | |  |
| 11.4 g) |  |  | | |  | |  | |  |
| **11.5 Ukrepi za obravnavanje tveganj in priložnosti**  *Actions to address risks and opportunities* | 11.5.1 a) |  |  | | |  | |  | |  |
| 11.5.1 b) |  |  | | |  | |  | |  |
| 11.5.1 c) |  |  | | |  | |  | |  |
| 11.5.1 d) |  |  | | |  | |  | |  |
| 11.5.2 a) |  |  | | |  | |  | |  |
| 11.5.2 b) |  |  | | |  | |  | |  |
| 11.5.2 c) |  |  | | |  | |  | |  |
| 11.5.3 |  |  | | |  | |  | |  |
| **11.6 Dokumentirane informacije**  *Documented information* | 11.6.1 a) |  |  | | |  | |  | |  |
| 11.6.1 b) |  |  | | |  | |  | |  |
| 11.6.2 a) |  |  | | |  | |  | |  |
| 11.6.2 b) |  |  | | |  | |  | |  |
| 11.6.2 c) |  |  | | |  | |  | |  |
| 11.6.2 d) |  |  | | |  | |  | |  |
| 11.6.3 |  |  | | |  | |  | |  |
| 11.6.4 |  |  | | |  | |  | |  |

**PRILOGA / *ANNEX 3*:**

**Korelacijska tabela dokumentacije sistema vodenja z zahtevami standarda SIST EN ISO 14065:2022 (istoveten z ISO 14065:2020) / *Cross reference list of management system documentation with requirements of the standard SIST EN ISO 14065:2022 (identical to ISO 14065:2020)***

**Navodila / *Instructions*:**

1. Tabelo izpolnijo organi za validiranje in preveranje, ki preverjajo okoljske informacije. / *Table to be completed by validation and verification bodies verifying environmental information.*
2. Namen te korelacijske tabele je pomoč organu za validiranje in preverjanje pri pregledu, ali so vse zahteve standarda SIST EN ISO 14065 zajete v dokumentaciji sistema vodenja. Korelacijska tabela omogoča SA večjo učinkovitost pri oceni ustreznosti dokumentacije sistema vodenja. / *The purpose of this matrix is to assist the validation and verification body in verifying whether all the requirements of the SIST EN ISO 14065 standard have been processed in the relevant documents. Furthermore, the matrix allows SA increased efficiency in evaluating the documentation of the verifier management system.*
3. V stolpec »Zakoni, predpisi« vpišite oznako relevantnega predpisa z ustrezno točko/poglavjem. / *Adequate code of the respective law, rule, regulation, or similar should be entered in column marked “Legislation”.*
4. V ostale stolpce vpišite odgovarjajoči dokument, del dokumenta, poglavje, ki se nanaša na izpolnjevanje zahteve standarda. / *In other columns please enter the codes of respective documents that deal with individual standard requirements, and their chapters/sections.*

| Zahteva standarda  S*tandard requirement* | Zahteva  *Requirement* | Zakoni, Predpisi  *Legislation* | Poslovnik kakovosti  *Quality*  *manual* | Postopki sistema vodenja  *System*  *procedures* | Delovna navodila  *Work instructions* | Obrazci  *Forms* |
| --- | --- | --- | --- | --- | --- | --- |
| **5 SPLOŠNE ZAHTEVE /** *GENERAL REQUIREMENTS* | | | | | | |
| **5.1 Pravna oseba**  *Legal entity* | 5.1 |  |  |  |  |  |
| **5.2 Odgovornost za izdajo izjave**  *Responsibility for validation/verification statements* | 5.2 |  |  |  |  |  |
| **5.3 Obvladovanje nepristranskosti** *Management of impartiality* | 5.3 |  |  |  |  |  |
| **5.4 Zavarovanje**  *Liability* | 5.4 |  |  |  |  |  |
| **6 STRUKTURNE ZAHTEVE /** *STRUCTURAL REQUIREMENTS* | | | | | | |
| **6.1 Organizacijska struktura in najvišje vodstvo**  *Organizational structure and top management* | 6.1 |  |  |  |  |  |
| **6.2 Operativni nadzor**  *Operational control* | 6.2 |  |  |  |  |  |
| **7 ZAHTEVE GLEDE VIROV /** *RESOURCE REQUIREMENTS* | | | | | | |
| **7.1 Splošno**  *General* | 7.1 |  |  |  |  |  |
| **7.2 Osebje**  *Personnel* | 7.2 |  |  |  |  |  |
| **7.3 Vodenje kompetenc osebja**  *Management process for the competence of personnel* | 7.3.1 |  |  |  |  |  |
| 7.3.2 a) |  |  |  |  |  |
| 7.3.2 b) |  |  |  |  |  |
| 7.3.2 c) |  |  |  |  |  |
| 7.3.3 |  |  |  |  |  |
| 7.3.4 |  |  |  |  |  |
| 7.3.5 a) |  |  |  |  |  |
| 7.3.5 b) |  |  |  |  |  |
| 7.3.5 c) |  |  |  |  |  |
| 7.3.6 a) |  |  |  |  |  |
| 7.3.6 b) |  |  |  |  |  |
| 7.3.7 a) |  |  |  |  |  |
| 7.3.7 b) |  |  |  |  |  |
| 7.3.7 c) |  |  |  |  |  |
| 7.3.7 d) |  |  |  |  |  |
| 7.3.7 e) |  |  |  |  |  |
| 7.3.8 |  |  |  |  |  |
| 7.3.9 a) |  |  |  |  |  |
| 7.3.9 b) |  |  |  |  |  |
| 7.3.9 c) |  |  |  |  |  |
| **7.4 Podpogodbeniki**  *Outsourcing* | 7.4 |  |  |  |  |  |
| **8 PROGRAM VALIDIRANJA/ PREVERJANJA /** *VALIDATION/VERIFICATION PROGRAMME* | | | | | | |
| **Program V&P**  *V&V Programme* |  |  |  |  |  |  |
| **9 ZAHTEVE GLEDE PROCESOV /** *PROCESS REQUIREMENTS* | | | | | | |
| **9.1 Splošno**  *General* | 9.1 |  |  |  |  |  |
| **9.2 Predhodne aktivnosti**  *Pre-engagement* | 9.2 |  |  |  |  |  |
| **9.3 Dogovor**  *Engagement* | 9.3 |  |  |  |  |  |
| **9.4 Planiranje**  *Planning* | 9.4.1 |  |  |  |  |  |
| 9.4.2 a) |  |  |  |  |  |
| 9.4.2 b) |  |  |  |  |  |
| 9.4.3 |  |  |  |  |  |
| 9.4.4 |  |  |  |  |  |
| 9.4.5 a) |  |  |  |  |  |
| 9.4.5 b) |  |  |  |  |  |
| 9.4.5 c) |  |  |  |  |  |
| 9.4.5 d) |  |  |  |  |  |
| **Izvajanje validacije / preverjanja** *Validation / verification execution* | 9.5 |  |  |  |  |  |
| **9.6 Pregled**  *Review* | 9.6.1 |  |  |  |  |  |
| 9.6.2 |  |  |  |  |  |
| 9.6.3 |  |  |  |  |  |
| 9.6.4 a) |  |  |  |  |  |
| 9.6.4 b) |  |  |  |  |  |
| 9.6.4 c) |  |  |  |  |  |
| 9.6.4 d) |  |  |  |  |  |
| 9.6.4 e) |  |  |  |  |  |
| 9.6.5 |  |  |  |  |  |
| 9.6.6 |  |  |  |  |  |
| **9.7 Odločitev in izdaja izjave o validaciji / preverjanju**  *Decision and issue of the validation / verification statement* |  |  |  |  |  |  |
| **9.7.1 Odločitev**  *Decision* | 9.7.1.1 |  |  |  |  |  |
| 9.7.1.2 |  |  |  |  |  |
| 9.7.1.3 |  |  |  |  |  |
| 9.7.1.4 |  |  |  |  |  |
| 9.7.1.5 |  |  |  |  |  |
| 9.7.1.6 a) |  |  |  |  |  |
| 9.7.1.6 b) |  |  |  |  |  |
| 9.7.1.6 c) |  |  |  |  |  |
| 9.7.1.7 |  |  |  |  |  |
| 9.7.1.8 |  |  |  |  |  |
| 9.7.1.9 |  |  |  |  |  |
| **9.7.2 Izdaja izjave o validaciji / preverjanju**  *Issue of the validation / verification statement* | 9.7.2 |  |  |  |  |  |
| **Dejstva, ugotovljena po izdaji Izjave o preverjanju / validaciji** *Facts discovered after the issue of the validation/verification statement* | 9.8 |  |  |  |  |  |
| **9.9 Prizivi**  *Handling of**appeals* | 9.9 |  |  |  |  |  |
| **9.10 Pritožbe**  *Handling of complaints* | 9.10 |  |  |  |  |  |
| **9.11 Zapisi**  *Records* | 9.11 |  |  |  |  |  |
| **10 ZAHTEVE ZA INFORMACIJE /** *INFORMATION REQUIREMENTS* | | | | | | |
| **10.1 Javno dostopne informacije**  *Publicly available information* | 10.1 |  |  |  |  |  |
| **10.2 Druge dostopne informacije**  *Other information to be available* | 10.2.1 |  |  |  |  |  |
| 10.2.2 |  |  |  |  |  |
| 10.2.3 |  |  |  |  |  |
| **10.3 Sklicevanje na validiranje / preverjanje in uporaba znaka**  *Reference to validation / verification and use of marks* | 10.3.1 |  |  |  |  |  |
| 10.3.2 |  |  |  |  |  |
| 10.3.3 |  |  |  |  |  |
| **10.4 Zaupnost**  *Confidentiality* | 10.4 |  |  |  |  |  |
| **11 ZAHTEVE ZA SISTEM VODENJA /** *MANAGEMENT SYSTEM REQUIREMENTS* | | | | | | |
| **11.1 Splošno**  *General* | 11.1 |  |  |  |  |  |
| **11.2 Vodstveni pregled**  *Management review* | 11.2 |  |  |  |  |  |
| **11.3 Notranje presoje**  *Internal audits* | 11.3 |  |  |  |  |  |
| **11.4 Korektivni ukrepi**  *Corrective action* | 11.4 |  |  |  |  |  |
| **11.5 Ukrepi za obravnavanje tveganj in priložnosti**  *Actions to address risks and opportunities* | 11.5 |  |  |  |  |  |
| **11.6 Dokumentirane informacije**  *Documented information* | 11.6 |  |  |  |  |  |