



S14d3

**S14 – ANNEX 3:  
SCOPE OF ACCREDITATION IN INSPECTION**

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## 1 PURPOSE AND GENERAL PROVISIONS

The document provides more concrete provisions as to the way of defining the scope in the field of inspection. General requirements and references applicable to all fields of accreditation are provided in general document S14.

This document is one of SA's internal regulations, which lay down the requirements for accreditation and the rules of accreditation, of which SA shall maintain public record. Its provisions constitute a part of the Contracts on establishing and maintaining accreditation, which SA concludes with its clients. Valid copies of SA's internal regulations governing the requirements for accreditation and the rules of accreditation shall be available at SA's head office and published on SA's website.

This document applies *ILAC-G28 Guideline for the formulation of scopes of accreditation for Inspection Bodies*, and the requirements of *EA-2/17 M Document on accreditation for notification purposes*, as well as *EA-2/15 M Requirements for the accreditation of flexible scopes*.

## 2 TECHNICAL FIELDS

Inspection consists in verifying conformity of the item of inspection with specific requirements, or – based on professional judgement – with general requirements.

In internal document D05-11, the fields of inspection are divided into groups, subgroups and sub-subgroups with regard to the item of inspection. The classification only comprises the fields in which Slovenian Accreditation already performs accreditation procedures. When an inspection body applying for accreditation cannot classify its activities into any of the defined fields, it shall define at its discretion the fields in its application, while a final classification will be made during the accreditation procedure and added to the list of fields, where applicable.

Example of classification: The item of inspection under classification code 1.1.3 is defined as Group 1: Industrial machinery and equipment, processes and services, Subgroup 1.1: Pressure equipment, and Sub-subgroup 1.1.3: Piping.

## 3 FIELDS OF INSPECTION

An inspection procedure is defined as a comprehensive process resulting in assessment of conformity or, in exceptional cases, only the result of inspection without assessment of conformity.

Individual parts of inspection cannot represent independent units of the scope of accredited activity such as sampling, or (e.g. internal) calibration, which are carried out within the inspection process, they are not specially indicated in the scope of accreditation, but they are evident from the contents of internal instructions defining the scope.

In inspection, the items of inspection shall be stated as independent items (units) of the scope. An item of inspection can be a product, a process or a service, or an assembly and/or installation or design thereof.

According to the definitions laid down in SIST EN ISO 9000, a process is a set of interrelated or interacting activities which transform inputs into outputs. A product is the result of a process. There are four generic product categories, as follows:



- service (e.g. transport) is the result of at least one activity performed at the interface between the supplier and the customer;
- software (e.g. computer program, report, procedure) consists of information and is generally intangible;
- hardware (e.g. pressure vessel) is generally tangible and its amount is a countable characteristic;
- processed materials (e.g. oil fuels) are generally tangible and their amount is a continuous characteristic.

#### **4 TYPES OF INSPECTION BODY'S SCOPES**

Inspection body's scope can be specified in a fixed or flexible manner.

The inspection body may only change elements of the fixed scope in accordance with the rules applying to extension of scope. These are, in all cases, type of independence; site of inspection; items and types of inspection; and additional information provided in Notes to the scope for accreditation.

The majority of inspection bodies operate in what is called the regulated fields, where the application of latest editions of normative documents is prescribed by law. Due to frequent changes and often short transitory periods for enforcement of the requirements of new editions, changes of indications of normative document editions in the Annex to Accreditation Certificate in surveillance visits only do not always satisfy the needs of accredited inspection bodies. The ability to promptly adjust inspection procedures to new editions of regulations is therefore an essential element of competence for the majority of inspection bodies.

Flexibility of defining the scope means that the inspection body may, without preliminary notification of SA, introduce minor modifications to the accredited procedures. Such modifications do not intervene with the inspection techniques and principles; they are merely intended for adjustment to new editions of normative documents, including standards. In this case, identifying of normative documents and internal procedures shall include the year or other identification of the applicable edition at the time of issue of the Annex. Under the table with detailed description of scope, there shall be a Note explaining the flexibility and the location where the information on currently applicable editions of these documents and procedures is available.

In the case of flexible scope the inspection body shall control and publish an updated list of accredited activities. The list shall, by its structure and elements, to the greatest extent possible follow the method used by SA in specifying inspection bodies' scopes in Annexes to Accreditation Certificates.

Inspection bodies whose scope of accreditation is specified in a flexible way must understand which modifications they can introduce within the framework of flexible scope and which they shall treat according to the procedure for extension of scope. Any major modifications that would entail change of techniques or principles of inspection shall be notified by the inspection body to SA and shall be treated using the procedures which apply in the case of extension of scope. This also applies in cases where such change would be necessary because of changed requirements in normative documents.

In order to adequately control a flexible scope, the inspection body shall further define the responsibilities and perform tasks related to monitoring changes in normative documents and implementing the necessary changes in its management system. The most typical tasks in this respect are: analysing changes with regard to previous edition; updating internal instructions, checklists, inspection reports and

document lists; training and authorising personnel for changed procedures; updating the list of accredited activities with currently applicable editions of normative documents and internal procedures; etc.

In its reports/certificates of inspection, the inspection body should make precise reference to the normative documents (including the version) in use by the inspection body at the time of inspection.

General additional rules regarding accreditation procedure and additional requirements for accreditation in the case of flexible scope are laid down in the document S14, and shall also apply, *mutatis mutandis*, to inspection bodies.

## 5 ELEMENTS OF INSPECTION BODY'S SCOPE

Information on the resources (personnel, equipment, subcontractors ...) used for the performance of inspections within the scope of accreditation need not be stated. Pursuant to the Rules of Accreditation (S03), the inspection body shall inform SA in due time of any substantial changes in resources. Thus, for example, the inspection body shall control the changes of its authorised inspection operators (induction of new inspectors) independently, according to its own procedures.

### Inspection body's independence type

The inspection body may maintain different types of independence (Type A, B or C) for different items of inspection; however, it is not possible to offer different types of independence for the same item of inspection. Activities with different independence types shall be listed in separate tables of the scope.

### Site (indicated above the table with detailed description of scope)

When the inspection is performed by different internal organisational units of the accredited body, or when the activities are performed at different sites, the scope shall be given separately for each of the units and for each site.

### Type of scope (indicated in the head of the table with detailed description of scope)

In the head of the table, the following types of scope are indicated:

- Type of scope: **fixed**
- Type of scope: **flexible (possibility of introducing minor modifications of methods)\***

and in this case, the following text shall be added in a Note under the Table: *\*In column 4 of the Table ("Methods and procedures") the editions of normative documents and internal procedures in force at the time of issuing this Annex are defined. The inspection body may introduce minor modifications to these procedures (e.g. adjustment to a new edition of normative/internal document). Information on the current status of editions is maintained by the inspection body and published on its website (state the link) / on the bulletin board on inspection body's premises / in the document (state the document identification number), which is available on request.*

### Item of inspection

Precise designation of the item of inspection shall be given in accordance with the classification list in D05-11. The given level (group, subgroup, sub-subgroup) shall depend on individual case.

Where applicable, a more detailed definition can be given than that on the classification list, all by trying to preserve the classification that may have already been in use in the relevant technical field (e.g. by the regulator in technical regulations ...).

### **Type of inspection**

Wherever possible, the distribution used in normative documents should be stated (e.g. initial, periodic, extraordinary inspection). In cases where the inspection body is not performing inspection against a normative document, or when this does not define inspection types, an appropriate description shall be provided under the inspection type, deriving from the purpose, method or requests for inspection, e.g. "inspection of opening pressure", "inspection of functionality"; etc.

### **Methods and procedures**

Inspection bodies often perform the inspection in the fields where inspection is prescribed by normative documents (called "mandatory inspection"). In most cases these are legislative acts (e.g. rules, decrees), which define, directly or via reference to (international) standards, the methods, types, frequency and other parameters of inspection. Stating of subordinated documents (e.g. standards) in the scope for accreditation of inspection bodies is not necessary when their application is defined in the umbrella normative document, which is stated in the scope.

In the scope of accreditation, the normative documents shall be stated by their full name (e.g. Rules on measuring instruments), the name of issuing authority (e.g. RS OG), and indication of edition and any revisions thereof (e.g. 42/06, 97/10). After that, the part of the normative document defining the specific field of inspection (e.g. Annex I, Chapter MI-001 – Water meters) shall be stated.

In the case that the inspection body wishes, on reasonable grounds, to obtain or maintain accreditation against a normative document (e.g. standard) which is no longer applicable, appropriate identification of the document shall be made and the inscription "cancelled" added.

All internal procedures defining the inspection procedure shall be stated in the scope as well, including the date or other identification of publication. In cases where the inspection method is described in sufficient detail in the normative documents, the internal instructions need not be stated in the scope.

### **Notes**

Any limitations to the scope (e.g. as to the item of inspection: a certain type, manufacturer or other properties), as well as any performance of inspection on site or in a mobile unit, and other relevant data regarding the inspection, shall be given under Notes.

## **5.1 Scope of accreditation for notification purposes**

In inspection bodies which are accredited for notification purposes, the scope of accreditation shall be given in a separate table entitled "Detailed description of scope of accreditation for notification purposes".

Presenting of the scope for notification purposes shall be aligned with the needs of the notification body in such a way that the information needed for entry into the base of notified bodies is provided to the greatest extent possible, and the same terminology is used (e.g. conformity assessment modules in types of inspection).



## 6 EXAMPLES OF PRESENTING SCOPES

### a) Fixed scope:

Inspection body, Mala ulica 1, 0000 Malo mesto

Tip obsega: <b>fiksn</b> i / <i>Type of scope: fixed</i>				
Št. No.	Predmet kontrole (proizvod, storitev, proces) <i>Item of inspection (product, service, process)</i>	Vrsta kontrole <i>Inspection type</i>	Metode in postopki (normativni dokumenti, interni postopki) <i>Methods and procedures (normative documents, internal procedures)</i>	Opombe <i>Notes</i>
1.	Avtomatski merilni sistemi za trajne meritve emisije snovi v zrak	- prva uporaba - periodična kontrola med uporabo	SIST EN 14181:2015, poglavje 6 v povezavi z internim postopkom: - Kontrola merilnih sistemov, 20. 12. 2023	Kontrola po postopku ABC. Izvedba na terenu.
			SIST EN 14181:2015, točke 6.3 do 6.7 v povezavi z internim postopkom: Kontrola merilnih sistemov, 20. 12. 2023	Kontrola po postopku ABC – primerjalne meritve. Izvedba na terenu.

### b) Flexible scope:

Inspection body, Mala ulica 2, 0000 Veliko mesto

Tip obsega: <b>fleksibilni</b> (možnost uvajanja manjših sprememb metod)* <i>Type of scope: flexible (possibility of introducing minor modifications to the methods)*</i>				
Št. No.	Predmet kontrole (proizvod, storitev, proces) <i>Item of inspection (product, service, process)</i>	Vrsta kontrole <i>Inspection type</i>	Metode in postopki (normativni dokumenti, interni postopki) <i>Methods and procedures (normative documents, internal procedures)</i>	Opombe <i>Notes</i>
2.	Zapisovalna oprema v cestnem prometu – analogni tahografi	- pred namestitvijo - ob namestitvi - redna - med uporabo	Uredba (EU) št. 165/2014 Evropskega parlamenta in Sveta z dne 4. februarja 2014 o tahografih v cestnem prometu, Priloga I, poglavje III(f) in VI Pravilnik o odobritvi in nalogah delavnic za tahografe in naprave za omejevanje hitrosti (Ur. list RS, št. 24/19 in 184/20), čl. 5 do 16  Interno navodilo: Kontrola tahografov, izdaja 3	Kontrola z metodo: - na prosto vrtečih se valjih na lokaciji kontrolnega organa - na merilni stezi dolžine 20 m na lokaciji kontrolnega organa ali na terenu

\* In column 4 of the Table ("Methods and procedures") the editions of normative documents and internal procedures in force at the time of issuing this Annex are defined. The inspection body may introduce minor modifications to these procedures (e.g. adjustment to a new edition of normative/internal document). Information on the current status of editions is maintained by the inspection body and published on its website (state the link) / on the bulletin board on inspection body's premises / in the document (state the document identification number), which is available on request.



c) Scope for notification purposes

### Detailed description of scope of accreditation for notification purposes

Inspection – notified body, Mala ulica 3, 0000 Veliko mesto

Dodatne zahteve, opredeljene v shemi / <i>Additional requirements defined in the scheme</i> : <b>Smernice za določitev in prigrasitev organov za ugotavljanje skladnosti na podlagi Zakona o tehničnih zahtevah za proizvode in ugotavljanju skladnosti (ZTZPUS-1) in Pravilnika o varnosti dvigal (Direktiva 2014/33/EU) / Guidelines for the designation and notification of conformity assessment bodies based on the Act on Technical Requirements for Products and Conformity Assessment (ZTZPUS-1) and the Elevator Safety Regulation (Directive 2014/33/EU)</b>				
Tip obsega: <b>fiksni</b> / <i>Type of scope: fixed</i>				
št. No.	Predmet kontrole (proizvod, storitev, proces) <i>Item of inspection (product, service, process)</i>	Vrsta kontrole <i>Inspection type</i>	Metode in postopki (normativni dokumenti, interni postopki) <i>Methods and procedures (normative documents, internal procedures)</i>	Opombe <i>Notes</i>
3.	Dvigala / <i>Lifts</i>	- končni pregled	Direktiva 2014/33/EU in SIST EN 81-72:2020	Kontrola se izvaja v skladu z zahtevami, ki so navedene v Prilogi V Direktive 2014/33/EU.

## 7 CHANGES WITH REGARD TO PREVIOUS REVISION

In Chapter 5, under Methods and procedures, a more detailed explanation has been added how to mark cancelled normative document in the accreditation scope. In Chapter 6 examples of accreditation scope have been updated.

## 8 TRANSITORY AND FINAL PROVISIONS

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## 9 CONTROL OF THE DOCUMENT

The document is adopted by the SA Board after its content has been considered and adopted by the Accreditation Committee. If the SA Board disagrees with the proposal which was approved by the Accreditation Committee, it shall be referred back to the Accreditation Committee for consideration. Changes that do not affect the content can be adopted by the SA Board without the involvement of the Accreditation Committee.

A valid copy of this document shall be located in i4 (SA's information system). A clean copy shall be published on SA's website, and available in printed form at SA's head office.

Individual copies may be controlled in physical form. The recipients or places of storage shall be shown in records on issuance of the document.

Other printouts and copies hereof shall have informative nature and shall not be considered as controlled copies. The validity of these documents should be checked in i4 or on SA's website.