

METHODOLOGICAL GUIDELINE FOR ACCREDITATION

MSA – I/01

FIELD AND SCOPE OF ACCREDITATION OF INSPECTION BODIES

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1 INTRODUCTION

This MSA specifies the principles for defining the field and scope of accreditation, as well as the type of independence of an inspection body for the purposes of accreditation in accordance with ISO/IEC 17020. This Guideline is binding on SNAS, applicants for accreditation and accredited bodies.

2 RELATED DOCUMENTS

ISO/IEC 17000:2020 Conformity assessment. Vocabulary and general principles.

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

ISO/IEC 17011:2017 Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies.

ILAC G28: 2018 Guideline for the Formulation of Scopes of Accreditation for inspection Bodies.

MSA I/02 Guidance on the application of ISO/IEC 17020:2012 (ILAC-P15:05/2020), issue 3, version 2

3 TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in standards ISO/IEC 17000, ISO/IEC 17020 and the following:

3.1 FIELD OF ACCREDITATION

is a general definition of the scope of activities that accreditation is applied for or has been granted.

3.2 SCOPE OF ACCREDITATION

is a detailed description of the body's activities, for which accreditation is requested or has been granted.

3.3 ACTIVITY SPECIFICATION

is a range of activities which the body applies for and which is by form identical to the "Scope of Accreditation", but its content may be different.

4 TYPE OF INSPECTION BODIES

Type of an inspection body shows a level of its independence. The inspection body shall be independent to the extent that is required with regards to the conditions under which it performs its services. Depending on these conditions are introduced three types of inspection bodies A, B, C:

Type A – an inspection body providing third-party inspections (third-party inspection body).

Type B – an inspection body providing first party inspections, second party inspections, or both, which forms a separate and identifiable part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items of inspect and which supplies inspection services only to its parent organization (in-house inspection body).

Type C – an inspection body providing first party inspections, second party inspections, or both, which forms an identifiable but not necessarily a separate part of an organizations involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects and which supplies inspection services to its parent organization or to other parties, or to both.

4.1 INSPECTION BODY WORKING IN SEVERAL TYPES OF INDEPENDENCE

If an inspection body forms a part of a legally identifiable part of an organization and seeks to operate as an inspection body Type A in a certain scope and in other scope as an inspection body Type B or C it shall to fill the field and scope of accreditation of relevant type of inspection body (tables 1 – 4) for each type of inspection body separately. The tables are a part of Annex OA-5 to the Application for accreditation services.

Note: Templates of the Tables 1 – 4 are shown in the Annex.

5 FIELD AND SCOPE OF ACCREDITATION

5.1 FIELD OF ACCREDITATION

The field of accreditation is a general definition of the scope of inspection activities which are accredited or for which the inspection body seeks accreditation.

Note: The field of accreditation of an inspection body is stated in the Accreditation Certificate and provides brief information on the nature and the scope of inspection activity.

5.2 SCOPE OF ACCREDITATION

The scope of accreditation is a detailed description of activities for which accreditation is sought or has been granted.

The scope of accreditation defines all inspection activities of the inspection body covered by accreditation. The scope of accreditation shall be clearly defined with sufficient clarity to enable potential clients to identify unambiguously and precisely the item of inspection, the type and the scope of inspection and, where applicable, the regulations, standards or specifications containing the requirements against which the inspection is performed.

SNAS grants accreditation only with the fixed scope of accreditation. This means that, within the accredited activities, an inspection body may routinely apply standard, modified standard or non-standard inspection methods and, where applicable, sampling methods within the fixed scope, which are neither modified nor validated during the accreditation cycle.

For an inspection body with the fixed scope of accreditation, the scope of accreditation shall specify the inspection procedures under both the "Inspection methods and procedures" section and the "Inspection requirements or criteria" section. These procedures shall be uniquely identifiable and designated, for example, by their edition, revision, update or version/year of publication, in accordance with the inspection body's document management system.

Where an inspection body specifies standards designated as STN, EN, ISO, ISO/IEC, EPA or similar in the "Inspection methods and procedures" section and the "Inspection requirements or criteria" section of the scope of accreditation, such standards shall be cited together with their year of publication.

The fixed scope of accreditation does not allow additional or modified activities to be readily incorporated into the scope of accreditation without further assessment, even where competence in the relevant field has already been demonstrated. Accredited inspection bodies may apply for an extension of the scope of accreditation at any time during the accreditation cycle. Such applications shall be assessed within the applicable timeframe in accordance with Act No. 53/2023 Coll. on the Accreditation of Conformity Assessment Bodies and the relevant SNAS guidelines.

Scope of accreditation is defined by:

- a) type of an inspection body (type of an inspection)
- b) category of an inspection
- c) field (and sub-fields) of inspection
- d) range of inspection
- e) stage of inspection
- f) inspection requirements or criteria
- g) methods and procedures of inspection

***Note:** The scope of accreditation of an inspection body is stated in Annex to the Decision on Accreditation and to the Accreditation Certificate.*

Specification of the field and the scope of accreditation is stated in **Table 1** uniformly for all types of inspection bodies seeking accreditation, re-accreditation or accreditation

extension. The completed table forms Annex OA5 to the Applications for Accreditation Service” and is considered to be the proposed scope of accreditation. The content of the table may be amended during or following the assessment to reflect the assessment results and actual fulfilling of the requirements of the standard, in accordance with the accreditation decision.

5.2.1 Type of an inspection body (type of an inspection)

The type of inspection body refers to a level of its independence. The inspection body shall be independent to the extent that is required with regard to the conditions under which it performs its services. In order to be accredited each subject of the scope would be assessed according to the level of independence and in compliance with definitions of type A or B or C in the ISO/IEC 17020:2012 Annex A. Depending on these conditions there are three types A, B, C of inspection body established.

5.2.2 Inspection Category

The inspection category refers to the nature of the item inspected, as listed in the definition of inspection in ISO/IEC 17020:2012 i. e. **product, process, service or installation**. See note on inspection categories at the end of this guidance document for further clarification (in Annex No. 2 – ILAC G28, Chapter 2.7 and Table No. 1).

The importance of these four “categories” is that examination of anything that cannot be “categorized” as **a product, process, service or installation** is outside the definition of inspection and therefore cannot be accredited as inspection in accordance with ISO/IEC 17020: 2012.

5.2.3 Inspection field (and sub-field)

A broad area of activity in which inspection is used. Inspection field may be divided into sub-fields where appropriate.

The number of levels of subdivision of inspection fields is not limited. Generally, subdivision of fields represents a reduction of risk of incorrect definition of inspection activities. Subdivisions may be used to systematically refine the definition of the products, processes, services or installations covered by the scope of accreditation. Subdivisions of inspection fields may be used to define different inspection activities on a particular product, process, service or installation. Subdivisions of inspection fields should not be used to define different stages or categories of inspection as these are distinct concepts in this document.

5.2.4 Inspection Range

Limits on inspection work within an inspection field or sub-field delimited by appropriate textual or numeric parameters. The range of inspection is used to place limits on the items inspected within those represented by an inspection field and sub-fields. The range is generally the most detailed parameter defining the items that may be inspected under a specific accreditation scope item.

If an inspection body has demonstrated competence to inspect all items included in the defined fields and subfields listed, the range does not need to be specified. Otherwise, its specification is required.

5.2.5 Stages of inspection

The point in the life cycle of a product, process, service or installation at which inspection takes place. Stages of inspection are relevant when different inspection competencies (knowledge, skills and experience) are required for inspections of the same inspected item at different times.

Stages of inspection should be used only when relevant

5.2.6 Inspection requirements and criteria

Inspection requirements and criteria against which the inspection body assesses compliance most often occur in relevant laws, regulations, standards, decrees, etc., where individual requirements and criteria are described. Inspection requirements or criteria against which conformity is assessed by inspection body.

The inspection requirements or criteria must state a specific law, regulation, standard, decree or other document that specifies specific requirements or criteria for the inspection activity performed the so-called standard inspection methods.

Considering that SNAS does not accredit inspection bodies for a flexible scope of accreditation, it is not allowed to state general wording of criteria, such as "according to customer requirements", "according to technical specifications" or "according to technical standards" without stating in which standards the inspection requirements and criteria are stated, or the document/procedure must be stated where the inspection requirements and criteria are located, according to which conformity is assessed.

If the inspection body uses a non-standard inspection method developed by the inspection body or the client, these methods must be appropriate and fully documented in the form of an internal document. The documented inspection procedure must contain the exact scope of the inspection activity, a detailed description of the activities performed, the criteria for evaluating the subject of the inspection and a sample output document.

This internal document cannot be changed by the inspection body in the part describing the performance of the inspection activity - i.e. the scope of the inspection, the inspection procedure, the evaluation criteria (together with a list of precisely specified standards/documents, or with precisely defined technical specifications) and the sample output document cannot be modified. If the inspection body considers it necessary to modify the work procedure for performing the inspection, it must apply to SNAS for an extension of accreditation, where this procedure will be assessed by SNAS with the inclusion of new standards or new technical specifications.

Formal changes to work procedures (such as those where the scope of the inspection, the inspection procedure, the evaluation criteria (with a list of standards/documents, with technical specifications) and the sample output document do not change) can be carried out by inspection bodies without the assessment of SNAS.

5.2.7 Inspection methods and procedures

Inspection methods and procedures represent a sequence of steps or modes applied for performance of a particular inspection activity. They are defined, as a rule, in requirements for conformity assessment. These requirements are delineated in relevant Acts, regulations, Standards, resolutions, public notices, prescripts and specifications and generally are incorporated into own inspection procedures. The inspection body has to prepare and document its own methods and procedures.

Where justified, an inspection body may have sampling accredited to ISO/IEC 17020:2012 as a separate activity. Resolution EA 2022 (52) 11 states that the preferred standard for sampling is ISO/IEC 17025, but where appropriate, ISO/IEC 17020 – Conformity assessment – Requirements for the operation of various types of inspection bodies may also be used for the accreditation of bodies carrying out sampling as a separate activity, provided that all the relevant requirements of the preferred standard are applied as additional requirements within the accreditation process.

If the inspection body wants to carry out a measurement on another occasion than as part of an inspection specified in the accreditation certificate, it cannot declare such measurement itself to be accredited according to ISO/IEC 17020 in accordance with MSA I/02 (ILAC-G27: 07/2019) Appendix 1 Chapter 2.1.

5.3 SITES OF AN INSPECTION BODY

If an inspection body has sites in several locations it is obliged, in **Table 2**, to mention their all addresses, included virtual places and to identify items of inspection scope which are inspected in those locations (ISO/IEC 17011:2017, art. 7.2.1b).

Note: For the case of more sites and / or branches of the inspection body, the note states at which site/branch inspections are carried out for individual items of the scope of accreditation.

5.4 FUNCTIONAL AND/OR LABORATORY TESTING

If an inspection body performs or requires for inspection purpose also functional testing or measurement and/or laboratory testing, the **Table 3** shall be completed and annexed to the Application. In the Table the inspection body shall state a list of “F” functional tests, measurement “M” and/or “L” laboratory tests performed together with a list of related technical equipment used for. It shall be also stated whether the test is performed by the inspection body personnel “V” or by subcontracting “D”.

5.5 SCOPE OF ACCREDITATION OF AN INSPECTION BODY FOR NOTIFICATION PURPOSES

The scope of accreditation of an inspection body shall be defined as follows:

Inspection body Type A

Inspection category: Product

Inspection field (subfield): The general designation of the product covered by the applicable Directive/Regulation and the applicable conformity assessment procedures (module, Article, Annex or systems specified in the relevant Directive/Regulation) shall be stated.

Inspection range: The products/category – group – homogeneous product families (according to the NANDO classification, where applicable) for which the inspection body seeks accreditation for notification purposes shall be specified. This parameter is mandatory.

Stage of inspection: The stage in the life cycle of a product, process, service or installation at which the inspection is performed, where applicable.

Inspection requirements or criteria: The applicable conformity assessment Directive/Regulation shall be specified (this may be supplemented by references to national legislation).

Inspection methods and procedures: The specific inspection procedures according to which the inspection is carried out for notification purposes for the individual conformity assessment procedures (module, Article, Annex or systems specified in the relevant Directive/Regulation) shall be specified.

6 ANNEXES

Annex 1: Templates of Tables

Annex 2: ILAC-G28:07/2018 - informative

6.1 ANNEX 1: TEMPLATES OF COMPLETED TABLES

Field and scope of accreditation

Field of accreditation:

(text in Slovak and in English which will be quoted in the Accreditation Certificate)

Inšpekcia tlakových, zdvíhacích, elektrických, plynových zariadení a ich častí, inšpekcia technických podmienok pre prevádzkovanie liehovarníckych závodov.

Inspection of pressure, lifting, electric, gas equipment and their parts. Inspection of technical specifications for operating of distiller plants.

Scope of accreditation:

Template of Table 1

(Text which will be mentioned in the Annex to the Accreditation Certificate)

Example No 1 (for illustrative purposes only)

Inspection Body C Type						
Ord. No	Category of inspection	Field of inspection (and sub-fields)	Range of inspection	Stage of inspection	Inspection requirements and criteria	Methods and procedures of inspection
1	Installation	Food industry and Agriculture Sub-field a) Livestock retention installation		before export	Law on animal products 1999	IP 1/2017
2	Product	Food industry and Agriculture Sub-field a) Livestock medical investigation	cattle poultry	before slaughter	Law on animal products 1999	IP 2/2017 Procedure on sampling OP 3/2018 STN EN...

Example No 2 (for illustrative purposes only)

Inspection Body A Type

Ord. No	Category of inspection	Field of inspection (and sub-fields)	Range of inspection	Stage of inspection	Inspection requirements and criteria	Methods and procedures of inspection
1	Product	Engineering Mechanical devices				
1a)		Sub-field a) Cranes and lifting devices Mobile cranes	< 100 T	Production In-service	EN XXXXX Regulation Y	OS 1/2018/ZZ
1b)		Sub-field b) Free lifting devices		In-service	Safety assessment	OS 2/2018/ZZ

Example No 3 (for illustrative purposes only)

Inspection Body A Type						
Ord. No	Category of inspection	Field of inspection (and subfields)	Range of inspection	Stage of inspection	Inspection requirements and criteria	Methods and procedures of inspection
1	Process	Manufactured Items Building products Factory inspection	Building glass Fire products	Production Production	EN XXXXX EN YYYYY	OD-11/14 OD-21/14 OD-22/14

Example 4 - Accreditation of an Inspection Body for Notification Purposes (for illustrative purposes only)

Inspection body A type						
Item No.	Inspection category	Field of inspection (subfields)	Inspection range	Stages of inspection	Inspection requirements or criteria	Inspection methods and procedures
1	Product	Inspection of pressure equipment, assemblies and their components (PED) for			Directive 2014/68/EU (PED) Government Regulation of the	

Inspection body A type						
Item No.	Inspection category	Field of inspection (subfields)	Inspection range	Stages of inspection	Inspection requirements or criteria	Inspection methods and procedures
		conformity assessment purposes)	All products		Slovak Republic No. 1/2016 Coll.	
		Approval of welding procedures for permanent joining		Before the start of production or during production	Annex I clause 3.1.2	IP 01 version X
		- Module A2		During production	Annex III clause 2	IP 02 version Y
		- Module C2		During production	Annex III clause 4	IP 02 version Y
		- Module F		During production	Annex III clause 9	IP 03 version Z
		- Module G		Before the start of production or during production	Annex III clause 10	IP 03 version Z
2	Product	Transportable Pressure Equipment (TPED) – Inspection for conformity assessment purposes			Directive 2010/35/EU (TPED) Act No. 254/2011 Coll.	
		- periodic inspection	- Tanks, battery-vehicles/battery-wagons, multiple-element gas containers (MEGCs), and their valves and other accessories, where applicable - Pressure receptacles, including refillable and non-refillable pressure receptacles, including cartridges, their valves and other accessories, where applicable	Before launching the equipment and during operation	Article 12 of Directive 2010/35/EU and Section I.1 of Annex I and Section II.1 of Annex II to Directive 2008/68/EC	PP-105 version X N – 105 version X
		- intermediate inspection			Article 12 of Directive 2010/35/EU and Section I.1 of Annex I and Section II.1 of Annex II to Directive 2008/68/EC	
		- exceptional check			Article 12 of Directive	

Inspection body A type						
Item No.	Inspection category	Field of inspection (subfields)	Inspection range	Stages of inspection	Inspection requirements or criteria	Inspection methods and procedures
					2010/35/EU and Section I.1 of Annex I and Section II.1 of Annex II to Directive 2008/68/EC	
		- reassessment of conformity			Article 13 of Directive 2010/35/EU and Annex III to Directive 2010/35/EU	
		- Conformity assessment of new equipment			Article 12 of Directive 2010/35/EU and Section I.1 of Annex I and Section II.1 of Annex II to Directive 2008/68/EC	
3	Product	Inspection of lifts and safety components for lifts for conformity assessment purposes			Directive 2014/33/EU and Government Regulation of the Slovak Republic No. 235/2015 Coll.	
		-Final inspection inšpekcia	lifts	Before launching the equipment and during operation	Annex V	PP -01 version Y
		-Module G	lifts		Annex VIII	PP – 02 version Z
		-Module C2	Lift safety components		Annex IX	PP-03 version X
4	Product	Inspection of cableway installations designed to carry persons as conformity assessment		Before launching the equipment and during operation	Regulation (EU) 2016/424	
		Module F	Cableway installations designed to carry persons: - Safety components - Subsystems		Annex V	IP-001 version Z IPQ-003 version X
		Module G			Annex VI	IP 001 version - Z IPQ – 004 version Y

Instruction for completing the table 1:

Type of inspection body: A, B, C or a combination thereof

Scope of accreditation:

Column 1 – Item No.:

Enter the serial numbers of the inspection items according to the classification proposed by the applicant for accreditation.

Column 2 – Inspection category:

Indicate, in accordance with the definition of inspection given in ISO/IEC 17020:2012, whether the item of inspection is a product, process, service or installation.

Column 3 – Inspection field (and subfields):

Specification of the general field of activities for which the inspection is performed. Where appropriate, the inspection field may be divided into subfields.

Column 4– Inspection range:

Specification of the limits of the inspection activities within an inspection field or subfield, defined by appropriate textual or numerical parameters or by inspection items.

Column 5 – Stage of inspection:

The stage in the life cycle of a product, process, service or installation at which the inspection is performed.

Column 6 – Inspection requirements or criteria:

Inspection requirements and criteria against which conformity is assessed by inspection body. As a rule, the relevant law, regulation, standard, decree, etc., where the individual requirements and criteria are described, is cited.

The Inspection Requirements or Criteria must state a specific law, regulation, standard, decree or other document that states specific requirements or criteria for the performed inspection activity, the so-called standard inspection methods.

Considering that SNAS does not accredit inspection bodies for a flexible scope of accreditation, it is not allowed to state general wording of criteria, such as "according to customer requirements", "according to technical specifications" or "according to technical standards" without stating in which standards the inspection requirements and criteria are stated, or the document/procedure must be stated where the inspection requirements and criteria are located, according to which conformity is assessed.

Column 7 – Methods and procedures:

When specifying inspection methods and procedures, the provisions of Clause 5.2.7 shall generally apply.

The inspection procedure shall state the inspection procedure itself and, if necessary, another general regulation (e.g. methodological instructions) on which the inspection procedure is based. If tests are performed during the inspection and they need to be specified, these test standards shall also be included (e.g. AMS, EMS, etc.).

In the Inspection Methods and Procedures, the inspection procedures shall always be listed first, followed by the testing standards/procedures, procedures of measurement and sampling that are part of the inspection activities.

Table 2 - Template

Sites of the inspection body

No.	Address of the inspection body's site	Item of the site inspection
1.	Záhumenská 48, 011 68 Žilina	1, 2
2.	Lietavská 28/B, 040 17 Košice	1

Instruction for completing the table 2:

Column 3 – Item of the site inspection:

The inspected items at individual inspection sites shall be identified by serial numbers of the inspection items listed in the table 1 (column 1).

Table 3 - Template

Scope of tests during inspection

No.	Tested characteristic / measured quantity	Type of test	Testing instrument / sampling method	Type of provider
1.	pressure	M	manometer	V

Instruction for completing the table 3:

Column 1 – Serial number:

The serial number of the relevant inspection shall be entered in this column.

Column 2 – Tested characteristic/measured quantity:

This column shall describe (identify) the characteristic to be tested or the quantity to be measured.

Column 3 – Type of test:

This column shall indicate the type of test. Functional tests shall be designated by the letter "F", laboratory tests by the letter "L", and measurements by the letter "M".

Column 4 – Testing instrument / sampling method:

For a functional test ("F"), the name and, where applicable, the characteristics of the equipment required to perform the test shall be specified. For a laboratory test ("L"), the sampling method for the sample(s) shall be specified.

Column 5 – Type of test provider / measurement provider:

This column shall indicate the type of test provider. If the test is performed by the inspection body, the letter "V" shall be entered. If the test is subcontracted, the letter "D" shall be entered.

*Table 4 - Template***"in-house" calibration**

(calibration, metrological activities conducted its own inspection body)

„in-house“ calibration Yes ☐ No ☐

List of calibrations performed "in-house" (only if the answer to the previous question is "Yes")

Instructions for completing the table 4:**Line - "in-house" calibration :**

The inspection body marks the relevant field with a cross according to whether it does or does not conduct or undertake calibration or metrology tasks alone.

In the case the inspection body conducts the calibration or metrology tasks by itself, it completes the relevant table.

6.2 ANNEX 2: ILAC-G28: 07/2018 – INFORMATIVE**ILAC-G28:07/2018 - Guideline for the Formulation of Scopes of
Accreditation for Inspection Bodies****CONTENT****PREAMBLE****PURPOSE****AUTORSHIP****1. GENERAL**

- 1.1 Scope of Accreditation
- 1.2 Use of Scopes in Accordance with ISO/IEC 17011:2017
- 1.3 Further Use of Scopes
- 1.4 References

2. DEFINITION OF THE SCOPE OF ACCREDITATION

- 2.1 Scope of Accreditation
- 2.2 Inspection Bodies with Multiple locations
- 2.3 „In house“ Calibration of Measuring Equipment
- 2.4 Measurement as an Integral Part of Inspection
- 2.5 Limitations of Scopes
- 2.6 Consistency of Scopes
- 2.7 Components of the Inspection Scope

Annex A – EXAMPLES OF INSPECTION CATEGORIES**Annex B – EXAMPLES OF THE CONTENT OF THE INSPECTION SCOPES**

PREAMBLE

Accreditation is a third-party attestation relating to a conformity assessment body that serves as formal evidence of its competence to carry out specific conformity assessment activities. The scope of accreditation of an inspection body is an official and precise statement of the scope and limitations of the specific conformity assessment activities for which the inspection body has satisfactorily demonstrated its competence to the accreditation body. The competencies required for inspection activities vary according to the type of items subject to inspection, the purpose of the inspection, the stage in the life cycle of those items from their creation to their disposal, and any stage in between. A scheme for defining the scope and limitations of an inspection body's competence shall encompass all the parameters required for any type of inspection. This guidance document seeks to identify those required parameters. The assessment (and reassessment) of the scope of accreditation constitutes a key part of the accreditation process and may be defined as the set of activities carried out by the accreditation body (AO) to provide an appropriate level of confidence that the inspection body is competent to reliably perform all services included within its scope of accreditation.

PURPOSE

The purpose of this publication is to assist accreditation bodies in consistent implementation of the requirements of ISO/IEC 17011:2017 relating to scopes of accreditation and to promote an effective and harmonized approach to the scopes of accreditation for inspection bodies in accordance with ISO/IEC 17020:2012.

AUTHORSHIP

ILAC G28:07/2018 was prepared by the ILAC Inspection Committee Working Group and approved for publication by the ILAC General Assembly in 2018.

1 GENERAL

1.1 Scope of Accreditation

ISO/IEC 17011:2017, Clause 3.6, defines the scope of accreditation as the specific conformity assessment services for which accreditation is sought or has been granted. This definition does not specify the level of detail to be included in the scope statement.

ISO/IEC 17011:2017, Clause 7.8.4, addresses flexible scopes. This document does not distinguish between fixed and flexible scopes. Rather, it allows a considerable degree of flexibility. AOs may decide either to subdivide the field of inspection so as to establish a well-defined and specific scope of accreditation, or not to subdivide the field of

inspection, thereby allowing a more flexible scope that reflects the inspection activities and their limitations within the individual inspection body.

ISO/IEC 17011:2017, Clause 3.14, states that accreditation shall be granted for a clearly defined scope.

ISO/IEC 17011:2017, Clause 3.15, states that accreditation shall be maintained for a previously clearly defined scope.

ISO/IEC 17011:2017, Clause 3.16, states that extension of accreditation requires the addition of further conformity assessment activities to the scope of accreditation.

ISO/IEC 17011:2017, Clause 3.17, states that reduction of accreditation requires the removal of part of the previously clearly defined scope.

ISO/IEC 17011:2017, Clause 3.18, states that suspension of accreditation requires the prohibition of performing all or part of the previously defined scope of accreditation.

ISO/IEC 17011:2017, Clause 3.19, states that withdrawal of accreditation results in the cancellation of the entire scope of accreditation.

ISO/IEC 17011:2017, Clause 3.25, states that witness assessment, as part of the assessment cycle, shall be carried out on activities within the scope of accreditation. This means that the scope of accreditation shall be sufficiently detailed to facilitate the planning of appropriate witness assessments, where relevant.

ISO/IEC 17011:2017, Clause 3.32, defines a technical expert as a person providing specific knowledge or expertise with respect to the scope of accreditation. This means that, where necessary, the scope of accreditation shall be sufficiently detailed to facilitate the selection of an appropriate technical expert for the assessment.

ISO/IEC 17011:2017, Clause 7.8.1, requires the accreditation body to provide the accredited conformity assessment body with information on the accreditation, including the scope of accreditation. See also Clause 8.2.2 on publicly available information.

ISO/IEC 17011:2017, Clause 7.8.3 b) requires that the scope of accreditation of inspection bodies shall, as a minimum, identify:

- the type of inspection body, e.g. as defined in Clause 4.1.6 and Annex A of ISO/IEC 17020:2012 (referred to in this document, for clarity, as the level of independence);
- the inspection scheme, where relevant;
- the field of inspection for which accreditation has been granted;
- the range of inspection for which accreditation has been granted;

- the legislation, inspection methods, standards and/or specifications containing the requirements against which the inspection is performed, where applicable.

ISO/IEC 17011:2017, Clause 8.8.2, requires the accreditation body to make the scopes of accreditation publicly available and to keep them up to date so that they reflect any changes to the scope, including those resulting from suspension or withdrawal of accreditation.

ISO/IEC 17020:2012, Annex A, refers to "items subject to inspection". This document does not explicitly use that term because it may encompass a combination of the inspection category, field of inspection, range of inspection and stage of inspection.

The formulation and assessment of the scope of accreditation constitute a key part of the accreditation process. It is the responsibility of the accreditation body to provide an appropriate level of confidence that the inspection body is competent to perform all services covered by the scope of accreditation.

1.2 Use of Scopes in Accordance with ISO/IEC 17011:2017

The requirements for the formulation of the scope of accreditation and its mandatory elements are clearly specified in ISO/IEC 17011:2017, as described above. The non-mandatory content and the level of detail to be included in scopes are indicated in other clauses of ISO/IEC 17011:2017 that refer to scopes.

Clause 3.22, defining **assessment**, states that the accreditation assessment of a conformity assessment body shall be based on a clearly defined scope of activities. This implies that the agreed scope statement needs to contain sufficient detail to establish the focus of the accreditation assessment.

Clause 7.2.1 c) requires that an application for accreditation include a clearly defined scope of activities. "Clearly defined" means sufficiently detailed to enable the accreditation body (AB) to appoint an appropriate Assessment Group.

Several other clauses of ISO/IEC 17011:2017 relate to the scope in connection with the selection of the Assessment Group, in particular:

Clause 3.32, defining a technical expert, implies that the scope to be assessed and the competence of the Assessment Group shall be related. Since individuals possess varying breadth and depth of expertise, the effective selection of an appropriately qualified team member for assessment activities requires the scope to be defined in sufficient detail.

Clause 7.4.1 states that the accreditation body shall appoint an Assessment Team consisting of a Lead Assessor/Team Leader and, where required, an appropriate number of assessors and/or technical experts for the scope to be assessed. When forming the

Assessment Group, the accreditation body shall ensure that the Group as a whole has the competence necessary to perform the assessment. In particular, the Group as a whole:

- a) shall have appropriate knowledge of the specific scope of accreditation;
- b) shall have sufficient knowledge and experience to assess reliably the competence of the conformity assessment body to operate within the scope of accreditation."

If the scope of accreditation is not defined with sufficient precision, it is difficult to demonstrate that the requirements of Clause 7.4.1 have been fulfilled.

1.3 Further Use of Scopes

Scopes are also used by various interested parties for the following purposes. Where appropriate, these uses should be taken into account when preparing the scope statement:

- by clients of inspection bodies, to identify an inspection body that is currently accredited for specific inspection activities;
- by accreditation bodies, to define the scope and limitations of the accreditation granted;
- by inspection bodies and other interested parties, to determine which activities the inspection body may and may not claim as being accredited;
- by regulators, specifiers and scheme owners, to determine whether their requirements are covered by the accreditation.

1.4 References

ISO/IEC 17011:2017, *Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies*

ISO/IEC 17020:2012, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

ILAC P15:07/2016, *Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies*

2 DEFINITION OF THE SCOPE OF ACCREDITATION

2.1 Description of the Scope

The scope of accreditation describes the limits of competence established through the accreditation assessment.

The scope of accreditation shall be defined in sufficient detail to provide appropriate information to interested parties, such as inspection bodies, accreditation bodies, regulatory authorities, scheme owners and clients of inspection bodies, regarding the areas of inspection that benefit from independent assurance of competence.

Definitions of Scope Component Used in this Guideline

These definitions are intended to clarify the terms that are used but not defined in ISO/IEC 17020:2012. The term *inspection type* is not defined in this Guideline because, as used in Clause 6.1.2 of the standard, it is understood to be a general term encompassing other characteristics of inspection. Nor is it the preferred term for it may give rise to confusion through its association with other meanings of the word *type*.

Type of Inspection Body

Each scope item shall be assessed against the level of independence corresponding to the definitions of Type A, Type B or Type C given in Annex A of ISO/IEC 17020:2012 in order to be accredited. A particular scope item shall not belong to more than one type of independence.

Note:

ISO/IEC 17020:2012 refers to inspection bodies designated as Type A, Type B or Type C according to their demonstrated level of independence. This document recognizes that an inspection body may have different levels of independence for different scope items in accordance with the criteria specified in Annex A of ISO/IEC 17020:2012. This Guideline does not require separate scope statements for Type A, Type B or Type C activities, but recognizes that such an approach may be appropriate under certain circumstances.

Inspection Category

The inspection category relates to the nature of the item subject to inspection, as referred to in the definition of inspection in ISO/IEC 17020:2012, i.e. a product, process, service or installation. For further clarification, see the note on inspection categories at the end of this Guideline.

Note:

The term inspection category is used in this document solely as a heading for the preparation of scopes. The available categories are limited to those listed in the definition of inspection in Clause 3.1 of ISO/IEC 17020:2012. Further explanation of these categories is provided in Note 1 to the definition of inspection, Clauses 3.2, 3.3 and 3.4 of ISO/IEC 17020:2012, and Clause 3.1(a) of ILAC P15.

The use of the term *inspection category* introduces neither additional requirements nor unnecessary complexity; it is merely a collective term representing the four words referred to in the definition of inspection in ISO/IEC 17020:2012.

The significance of these four categories is that the assessment of anything that cannot be categorized as a **product, process, service** or **installation** falls outside the definition of inspection and therefore cannot be accredited as an inspection activity in accordance with ISO/IEC 17020:2012.

Field of Inspection

The general area of activities for which inspection is performed. Where appropriate, the field of inspection may be divided into subfields (see Table 1 for examples).

Note:

This Guideline does not limit the number of levels into which a field of inspection may be subdivided. In general, subdivision of the field reduces risk. Subdivision into subfields may be used to refine systematically the definition of the products, processes, services or installations covered by the scope of accreditation. It may also be used to distinguish different inspection activities relating to particular products, processes, services or installations. However, subdivision of fields of inspection should not be used to distinguish different stages or categories of inspection, as these represent separate concepts within this Guideline.

Range of Inspection

The limits of the inspection activities within a field or subfield of inspection, defined by appropriate textual or numerical parameters (see Table 1 for examples). Where an inspection body has demonstrated competence to perform inspections of all items within a particular field or subfield of inspection, it is not necessary to specify a range of inspection.

Note:

The range of inspection is used to define the limits of the items subject to inspection within a field or subfield of inspection. It is generally the most detailed parameter used to identify the items subject to inspection within a particular scope of accreditation.

Stage of Inspection

The stage in the life cycle of a product, process, service or installation at which the inspection is performed (see Table 1 for examples).

Note:

Stages of inspection are important where different competencies (knowledge, skills and experience) are required to inspect the same item at different stages of its life cycle. Stages of inspection should be used only where relevant.

Inspection Requirements

The criteria against which the inspection body assesses conformity (see Table 1 for examples).

Note:

Inspection requirements are most commonly specified in published standards, regulations, inspection scheme rules, inspection methods or contractual requirements, but may also consist of general requirements, such as safety or suitability for the intended purpose, based on the professional judgement.

2.2 Inspection Bodies with Multiple Locations

Some inspection bodies provide inspection services from several physical or virtual locations but do not offer the same scope of accredited inspection services from all of those locations. It is important that accreditation bodies, inspection bodies and users of inspection services clearly understand which accredited inspection activities are offered from each location. Accreditation bodies should ensure that their scopes clearly represent the coverage and limitations of the services subject to accreditation.

2.3 In-house Calibration of Measuring Equipment

Where an inspection body has the approval of the accreditation body to perform in-house calibration of measuring equipment used in inspection activities, this activity shall not be included in the scope of accreditation.

Note:

Accreditation according to ISO/IEC 17020 is not suitable for organizations providing equipment calibration as a service.

2.4 Measurement as an Integral Part of Inspection*¹

Some inspections include measurements, such as hydrostatic pressure or temperature measurements. An inspection body may perform such measurements provided that they form a documented part of the accredited inspection activity and that the inspection body has demonstrated the competence and capability to perform such measurements. As an integral part of an accredited inspection activity, such measurements should not be explicitly included in the scope of accreditation under ISO/IEC 17020:2012.

Where an inspection body performs measurements other than as part of inspection activities covered by its scope of accreditation, it shall not claim such measurements to be accredited under ISO/IEC 17020:2012.

¹ Translator's note: Unfortunately, this Guideline does not address the issue of sampling. However, it could be argued that the provisions of Clause 2.4 may also be applicable to sampling as a precedent.

2.5 Limitations of the Scope

Clause 3.1 of ISO/IEC 17011:2017, defining accreditation, makes it clear that accreditation is limited to those specific conformity assessment activities for which the organization has demonstrated competence. "It is therefore inappropriate to include any conformity assessment activity within the scope of accreditation where the conformity assessment body is unable to demonstrate the relevant competence."

However, ILAC P15, Clause 6.3.1 b), recognizes that the scope of accreditation may include the inspection or evaluation of evidence, including results or reports provided by third parties, for the purpose of making a conformity assessment decision. In such cases, the assessment of specified types of evidence, such as reports or records, constitutes the inspection activity itself.

When deciding on the level of detail to be included in the scope of accreditation, the accreditation body should consider the needs of all interested parties, together with the significance and risk associated with the level of detail provided.

2.6 Consistency of Scopes

It is considered good practice for accreditation bodies to express scopes using standardized words, phrases, terminology, definitions or other means, wherever possible. Such practice promotes consistency and impartiality in the expression of scopes for organizations providing equivalent services and facilitates their identification and comparison.

2.7 Components of an Inspection Scope

The scope of accredited inspection is normally defined by parameters such as those described in the table 1.

Not every field of inspection requires all of these parameters, and some fields of inspection may require additional parameters.

Where the expression of the scope of accredited activities is prescribed in a scheme document, that expression shall be respected.

Table 1: Typical Parameters Used to Describe the Scope of Accreditation for Inspection *(see also the application note in ILAC P15, Clause 5.1.3 a)*

Parameter	Comment / Explanation
a) Typ (A, B, or C) (as defined in <i>ISO/IEC 17020:2012 Annex A</i>)	Each accredited inspection activity shall comply with the requirements of Annex A of ISO/IEC 17020:2012. Different inspection activities performed by the same inspection body may be classified as Type A, Type B or Type C.
b) Inspection category i. e. product, process, service or installation (as stated in the definition of inspection in ISO/IEC 17020:2012)	To be eligible for accreditation in accordance with ISO/IEC 17020:2012, inspection activities shall fall within one of these inspection categories. See the Note on Inspection Categories and Terminology following this table.
c) Inspection field e.g. engineering, agriculture, freight transport, commodities, manufactured products, etc. Examples of engineering subfields: - mechanical engineering - civil engineering - electrical engineering - chemical engineering Examples of mechanical engineering subfields: - pressure equipment - cranes and lifting equipment - rotating machinery	The field of inspection is the general area of inspection activities, as required by ISO/IEC 17011:2017, Clause 7.8.3 b). Accreditation bodies may choose as many levels of subdivision of fields of inspection as they consider appropriate for the accreditation services they provide. Accreditation bodies should be aware of the risk of granting broad scopes of accreditation that encompass wide fields of inspection. Consequently, the accreditation body shall carry out an assessment sufficient to justify its decision that the inspection body is competent to perform all inspection activities that may be covered by the description of the field of inspection in the published scope of accreditation.
d) Inspection range In general, the range of inspection is the most detailed parameter defining the items that may be subject to inspection within a particular scope of accreditation. Example of a range of inspection within the subfield of cranes and the subfield of gantry cranes: < 100 t	The range of inspection defines the limits of competence within a field or subfield of inspection. Where no range of inspection is specified, the inspection body is deemed competent to perform inspections of all items falling within the defined field or subfield of inspection.
e) The stage in the life cycle of the product at which the inspection is performed. Examples: design, type testing, initial inspection, manufacturing, installation, in-service inspection,	The terminology used to describe the stages at which inspections are performed may vary from one industry to another. In some cases, no stage needs to

repair or modification, production surveillance, planting, harvesting, storage, maritime transport (including container stuffing), etc.	be specified. Where different stages of a product require different inspector competencies, the relevant stages shall be identified.
f) Inspection Requirements or Criteria Unambiguous references to standards, specifications (including client specifications or in-house specifications and, where necessary, inspection methods), legislation, inspection schemes or other documents containing the requirements against which the inspection is performed. Where no published standards or specific criteria exist against which conformity is assessed, the term "general requirements" may be used. Examples of general requirements include assessments of safety or conformity with good engineering practice, where the assessment is based primarily on professional judgement rather than comparison with specific criteria.	The inclusion of inspection requirements or criteria is required by ISO/IEC 17011:2017, Clause 7.8.3 b). Where necessary to avoid ambiguity, scopes of accreditation should include the publication dates, revision numbers or other specific identifiers of standards, legislation, contractual requirements, scheme rules and similar documents. Where a large number of similar standards or specifications require the same competence, they may be grouped together using an appropriate collective description.

Note on Inspection Categories

When defining the scope of accreditation for inspection, the definition of *inspection* in ISO/IEC 17020:2012 is intended to help identify precisely what the inspection body is inspecting. The term *inspection category*, as used in this Guideline, is a collective term for the four categories included in the definition of *inspection* in ISO/IEC 17020:2012, namely **product, process, service and installation**.

The accreditation body should carefully consider which category applies to a particular inspection activity, since the inspection of a product differs significantly from the inspection of the process used to manufacture that product or from the inspection of the suitability of a product within a particular installation. Correct categorization helps ensure that the appropriate expertise is applied during assessments. Identifying the inspection category in published scopes also assists clients in selecting an accredited inspection body with the competence they require.

Note on the Terminology of Inspection Categories

Alternative terms may be used for these categories. For example, *commodity, report*, or any other term describing the output of a process may be used instead of *product*. What

is important is that the concepts expressed by the definitions of **product**, **process**, **service** and **installation** are preserved, even though different industries and sectors may use different terminology to describe them.

See **Annex A** for examples of Inspection Categories.

See **Annex B** for examples of the Content of the Scopes of Accreditation.

Annex A – Examples of Inspection Categories

Examples of Inspection Categories in the Engineering Industry

- **Pressure vessels** may be inspected during manufacture as a **product** (the output of the manufacturing process). In this case, the conformity assessment decision relates to compliance with the approved design.
- The **manufacturing process** for a pressure vessel may be inspected. In this case, the accredited inspection body shall verify that the documented process has been established, confirm that appropriately qualified personnel have been involved, and verify that records relating to materials, testing, etc., are available and maintained. Such an inspection is closer to the technical audit than to traditional the inspection practice. The conformity assessment decision relates to compliance with the approved process.
- A **pressure vessel** may be inspected as part of an **installation**. In this case, the inspection may address the safety or suitability of the vessel for a particular installation, taking into account the associated equipment and process requirements.
- A **pressure vessel** may also be inspected as a **product in service**. In this case, the product has been subjected over time to the effects of pressure, temperature and the materials contained within it. The conformity assessment decision relates to the estimate of the remaining service life or the current safety of the vessel.

The four examples above may all relate to the same pressure vessel; however, the competencies required differ significantly depending on whether the inspection concerns the manufactured product, the manufacturing process, or the product as part of an installation. It is important that accreditation bodies distinguish between these inspection categories, since one inspection body may possess all the competencies required to offer a scope described as *inspection of pressure vessels*, whereas another inspection body may be competent in only one or two of these categories. In such a case, the scope *inspection of pressure vessels* would be misleading.

In the two product inspection examples above, different competencies are required because the inspections are performed at different stages of the product life cycle.

Examples of Inspection Categories in Agriculture

The following agricultural inspections may all relate to the same crop.

- **Seeds** may be inspected before sowing. In this case, the seeds are the **product** of a natural process, and the conformity assessment decision relates to varietal purity and the absence of contamination, disease, damage, etc.
- The **crop production process** may be inspected. In this case, the conformity assessment decision may confirm that water management, fertilizer management, pesticide management, disease control and similar activities have been adequate, or comply with specified requirements, such as those applicable to organic production.
- The **service** provided by a contractor transporting harvested crops may be inspected. The conformity assessment decision in this case may include the suitability of the transport vehicles to prevent contamination, loss or spoilage, and the timeliness of transport in accordance with contractual requirements.
- A **food storage facility** may be inspected as an **installation** to verify that it provides adequate facilities for preventing spoilage and losses and for ensuring effective traceability and reconciliation of incoming and outgoing stored quantities.

These four examples may all relate to the same crop; however, the competencies required of inspectors in each case are different. In some cases, highly specific expertise relating to the particular crop may be required. In others, the required competence may apply equally to any crop or food product. In still other cases, the required competence may relate to vehicles, buildings, equipment, contractual management or accounting, none of which is specific to any particular product or commodity.

For these reasons, determining the appropriate inspection category is of critical importance both for selecting a suitable Assessment Group and for providing clear and unambiguous information to inspection bodies, clients of accredited inspection bodies, regulators and other interested parties.

Annex B – Examples of the Content of Inspection Scopes

The examples in this Annex are accompanied by explanatory notes to illustrate the different components of the scope statements described in this Guideline.

Text in *italics* does not form part of the scope statement; it is included solely for explanatory and commentary purposes.

These examples are **not** intended to provide guidance on the format or scope entry of the statements.

Rather, they are intended to demonstrate how scopes of accreditation may be developed using the components described in this Guideline.

Many accreditation bodies issue a separate accreditation certificate together with annexes to the certificate, which may extend over several pages. From a formal perspective, the certificate and its annex(es) constitute a single document. However, for

the avoidance of doubt, this Guideline neither requires nor suggests that the detailed scope of accreditation should be presented in a single-page document.

Example - Scope 1

Name and Logo of the Accreditation Body Name of the Inspection Body Accreditation No. 1234					
Address(es) and Contact Details of the Inspection Body					
Head Office or Main Workplace		Other sites (if different from the Head Office)			
		1 2 3			
Type (A, B, C)	Inspection category	Inspection field (subfields)	Range of inspection	Inspection stage	Inspection requirements or criteria
A	Product	Engineering Machinery Cranes and Lifting Equipment Mobile Cranes Lifting Equipment	< 100 T	During manufacture In service In operation	EN XXXXX Regulation Y Safety Assessment

field *subfield* *subfield* *range* *stages* *insp. requirements*

This inspection body is accredited to perform inspection of specified cranes within the field of mechanical engineering against specified requirements, both during manufacture and while in service, and to inspect separate lifting equipment for conformity with general safety requirements.

For cranes, two stages of inspection have been identified because the competencies required to inspect cranes during manufacture and cranes in service differ significantly. This does not preclude the same inspector from being competent to perform inspections at both stages.

Example - Scope 2

Name and Logo of the Accreditation Body Name of the Inspection Body Accreditation No. 1234					
Address(es) and Contact Details of the Inspection Body					
Head Office or Main Workplace		Other sites (if different from the Head Office)			
		1 2 3			
Type (A, B, C)	Inspection category	Inspection field (subfields)	Range of inspection	Inspection stage	Inspection requirements or criteria
C	Installation	Food and Agriculture Livestock Containment Facilities		Before export	Animal Products Act 1999
C	Product	Food and Agriculture Examination of Live Animals	Livestock Poultry*	Before slaughter	Animal Products Act 1999

field *subfield* *range* *stages* *insp.requirements*

This inspection body is accredited to inspect facilities and equipment used for the containment of live animals prior to export, and to inspect specified species of live animals before slaughter.

Both scopes have been classified within the field of **Food and Agriculture**; however, the competencies required of inspectors are entirely different, as reflected by the different inspection categories.

In the first case, it has been demonstrated that the competencies required to inspect the installation do not depend on the species of animals for which the facility is used. Consequently, no **range of inspection** has been specified.

In the second case, different competencies are required for different types of **products** (animals). It was therefore considered necessary to use a **range of inspection** to define the most detailed level of classification.

In this case, the range of inspection is specified in the document containing the inspection requirements. Under other circumstances, the animal species may be used as inspection subfields.

Example - Scope 3

Name and Logo of the Accreditation Body Name of the Inspection Body Accreditation No. 1234					
Address(es) and Contact Details of the Inspection Body					
Head Office or Main Workplace		Other sites (if different from the Head Office)			
		1 2 3			
Type (A, B, C)	Inspection category	Inspection field (subfields)	Range of inspection	Inspection stage	Inspection requirements or criteria
A	Process	Manufactured Products Construction Products Factory Production Control (FPC)	Building Glass Fire Protection Products	Production	EN XXXXX EN YYYYY

field *subfield* *range* *stage* *conf. criteria*

This inspection body is accredited to inspect the factory production control (FPC) system implemented by the manufacturer to ensure the quality of the production of construction products. The conformity assessment decision determines whether the factory production control process complies with the conformity criteria specified in the applicable document.