



GUIDELINE FOR THE FORMULATION OF SCOPES OF ACCREDITATION FOR INSPECTION BODIES

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FURTHER INFORMATION

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0. PREAMBLE

0.1 Purpose

The purpose of this document is to assist Accreditation Bodies (ABs) in consistently meeting the requirements of ISO/IEC 17011:2017 associated with scopes and to encourage an effective and harmonised approach to scopes among Accreditation Bodies in relation to ISO/IEC 17020:2012.

0.2 Scope

0.2.1 This document is based upon the ILAC (International Laboratory Accreditation Cooperation) document ILAC G28 07-2018 *Guideline for the Formulation of Scopes of Accreditation for Inspection Bodies*. On the transfer of the role of ILAC to the Global Accreditation Cooperation Incorporated (Global ACI), the text has been reformatted to be a Global ACI document without any substantive change to the text.

0.2.2 Accreditation is third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. The scope of accreditation of an inspection body is the formal and precise statement of the extent and limitations of the specific conformity assessment tasks in which the inspection body has satisfactorily demonstrated competence to an accreditation body. The competencies required for inspection work vary with the type of item inspected, the purpose of the inspection, the stage of the item from creation to disposal and any stage in between. A scheme for defining the extent and limitations of competence of an inspection body must incorporate all the parameters required for any type of inspection. This guidance document attempts to identify the parameters required. The assessment (and reassessment) of the scope of accreditation represents the core of the accreditation process and may be defined as the set of operations carried out by the AB in order to ensure, with an adequate degree of confidence, that the inspection body has the competence to provide all the services defined by the scope reliably.

1. GENERAL

1.1 Scope of Accreditation

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

1.1.2 ISO/IEC 17011:2017 Clause 7.8.4 refers to flexible scopes. This document does not differentiate between flexible and fixed scopes. The guidance provides a great deal of inherent flexibility. The AB may decide to sub-divide a field of inspection to provide a very limited and specific scope or not sub-divide a field of inspection to provide a more flexible scope to reflect the extent and limitations of an individual inspection body.

1.1.3 ISO/IEC 17011:2017 Clause 3.14 defines that the granting of accreditation is for a defined scope.

1.1.4 ISO/IEC 17011:2017 Clause 3.15 defines that maintenance of accreditation is for a previously defined scope.

- 1.1.5 ISO/IEC 17011:2017 Clause 3.16 defines that the extending of accreditation involves adding conformity assessment activities to the scope of accreditation.
- 1.1.6 ISO/IEC 17011:2017 Clause 3.17 defines that reducing of accreditation involves cancelling part of a previously defined scope.
- 1.1.7 ISO/IEC 17011:2017 Clause 3.18 defines that the suspension of accreditation involves the placing of restriction on all or part of a previously defined scope.
- 1.1.8 ISO/IEC 17011:2017 Clause 3.19 defines that the withdrawal of accreditation involves the cancellation of the full scope of accreditation.
- 1.1.9 ISO/IEC 17011:2017 Clause 3.25 states that witnessing, as part of assessment shall be within the scope of accreditation. This implies that the scope of accreditation is sufficiently detailed to facilitate the planning of appropriate witnessing where relevant.
- 1.1.10 ISO/IEC 17011:2017 Clause 3.32 defines a technical expert as a person who provides specific knowledge or expertise related to the scope of accreditation. This implies that the scope must be sufficiently detailed to facilitate the selection of appropriate technical experts for an assessment when required.
- 1.1.11 ISO/IEC 17011:2017 clause 7.8.1 requires the accreditation body to provide information on the accreditation to the accredited conformity assessment body including the scope of accreditation. See also clause 8.2.2 publicly available information.
- 1.1.12 ISO/IEC 17011:2017 clause 7.8.3(b) requires that the scope of accreditation for inspection bodies shall identify, as a minimum
- the type of inspection body, e.g. as defined in 4.1.6 and Annex A: of ISO/IEC 17020:2012 (referred to as “level of independence” in this document for clarity.)
 - 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 regulations, inspection methods, standards and/or specifications containing the requirements against which the inspection is to be performed, as applicable.
- 1.1.13 ISO/IEC 17011:2017 Clause 8.2.2 requires that the accreditation body make publicly available scopes of accreditation, which should be updated regularly to reflect changes of scope for any reason, including suspension or withdrawal of accreditation.
- 1.1.14 ISO/IEC 17020:2012 Annex A refers to ‘items inspected’. This document does not explicitly use the term ‘item inspected’ as this term may include a combination of inspection category, inspection field, range of inspections and stage of inspection.
- 1.1.15 The formulation and assessment of the scope of accreditation represents the core of the accreditation process. The role of the Accreditation Body is to ensure (to an adequate degree of confidence) that the inspection body has the competence to offer all the services defined in the scope.

1.2 Uses of Scopes According to ISO/IEC 17011:2017

- 1.2.1 The requirement to formulate a scope of accreditation and the mandatory elements are clear in ISO/IEC 17011:2017 as outlined above. Non-mandatory content and level of detail that should be included in scopes are implied in ISO/IEC 17011:2017 through references to scopes in other clauses.
- 1.2.2 Clause 3.22, the definition of **assessment**, states that the assessment of a conformity assessment body is for a defined scope. This implies the need for sufficient detail in an agreed scope statement to define the coverage of the assessment.
- 1.2.3 Clause 7.2.1(c) requires a clearly defined scope to be included in the application for accreditation. Clearly defined, implies sufficient detail to enable the AB to assemble an appropriate assessment team.
- 1.2.4 Several other clauses of ISO/IEC 17011:2017 refer to the scope in relation to selection of assessment teams, in particular:
- 1.2.5 Clause 3.32, the definition of a technical expert implies that scopes to be assessed and the definition of the competence of an assessment team should be related. As individuals have varying breadths and depths of expertise, effectively matching a team member to an assessment task implies a level of detail in the definition of the scope to be assessed.
- 1.2.6 Clause 7.4.1 states that, “The accreditation body shall appoint an assessment team consisting of a team leader and, where required, a suitable number of assessors and/or technical experts for the scope to be assessed. When selecting the assessment team, the accreditation body shall ensure that the expertise brought to each assignment is appropriate. In particular, the team as a whole:
- a) shall have appropriate knowledge of the specific scope of accreditation;
 - b) shall have understanding sufficient to make a reliable assessment of the competence of the conformity assessment body to operate within its scope of accreditation.”

If the scope of accreditation is not defined precisely enough it is difficult to demonstrate that clause 7.4.1 has been met.

1.3 Other Uses of Scopes

Scopes are also used for the following purposes by various parties and these uses should be considered where appropriate when compiling scope statements

- For clients of inspection bodies – to find an inspection body that is currently accredited for specific inspections
- For Accreditation Bodies – to define the extent and limits of accreditation granted
- For inspection bodies and other interested parties to define what the inspection body can and cannot claim accreditation for
- For regulators/specifiers and scheme owners to know that their requirements are covered by 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

Global ACI-TECH-2-001 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies

2. THE DEFINITION OF THE SCOPE OF ACCREDITATION

2.1 Scope Description

2.1.1 The scope of accreditation describes the extent and limitations of competence as determined through accreditation assessments.

2.1.2 The scope of accreditation should be defined in sufficient detail to accurately inform interested parties such as inspection bodies, accreditation bodies, regulators, scheme owners and clients of inspection bodies what areas of inspection are covered.

2.1.3 Definition of scope components used in this guidance document

These definitions are intended to clarify terms used in ISO/IEC 17020:2012, but which are not defined in the Standard. The term 'type of inspection' is not defined in this document because where it is used in clause 6.1.2 of the Standard it is understood to be a general term encompassing other characteristics of inspections. It is also not a preferred term because of the potential confusion with other uses of the word 'type'.

2.1.3.1 Type of inspection body

Each scope item should be classified with a level of independence in accordance with the Type A or B or C definitions in ISO/IEC 17020:2012 Annex A, in order to be accredited.

A specific scope item cannot have more than one independence type.

Note:

ISO/IEC 17020:2012 refers to inspection bodies being designated as type A, B or C based on their demonstrated level of independence. This document recognises that an inspection body may have different levels of independence for different scope items according to the criteria in ISO/IEC 17020:2012 Annex A. This guidance does not require individual scope items to be designated as Type A, B or C but accepts that this may be appropriate in some circumstances.

2.1.3.2 Inspection category

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.

Note:

The term “inspection category” is used in this document as a heading in the compilation of scopes only. The available categories are limited to those listed in the ISO/IEC 17020:2012: 3.1 definition of inspection. Understanding of these categories is further clarified by Note 1 following the definition of inspection, clauses 3.2, 3.3 and 3.4 of ISO/IEC 17020:2012 and clause 3.1n1 of Global ACI-TECH-2-001.

The use of the term “inspection category” does not add any requirements or complexity, it is simply a collective term representing the four words highlighted in the definition of inspection in ISO/IEC 17020:2012.

*The importance of these four “categories” is that examination of anything that cannot be “categorised” 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.*

2.1.3.3 Inspection field

A broad area of activity in which inspection is used. Inspection fields may be divided into sub-fields where appropriate. (See Table 1 for examples)

Note:

This guidance document does not limit the number of levels of subdivision of inspection fields. Generally, subdivision of fields represents a reduction of risk. 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.

2.1.3.4 Range of inspection

Limits on inspection work within an inspection field or sub-field delimited by appropriate textual or numeric parameters. (See Table 1 for examples.) If an inspection body has demonstrated competence, to inspect all items included in the fields and sub-fields listed, there is no need for a range to be quoted.

Note:

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

2.1.3.5 Stage of inspection

The point in the life cycle of a product, process, service or installation at which inspection takes place. (See Table 1 for examples)

Note:

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.

2.1.3.6 Inspection requirements

Criteria against which conformity is assessed by inspection. (See Table 1 for examples)

Note:

Inspection requirements are most commonly expressed in published standards, regulations, inspection scheme rules, inspection methods or contractual requirements but may also be general requirements such as safety or fitness for purpose, based on professional judgement.

2.2 Multi-Location Inspection Bodies

Some inspection bodies offer inspection services from multiple physical or virtual locations, but do not offer the same scope of accredited inspection services from all locations. It is important that ABs, inspection bodies and users of inspection services understand clearly which inspection activities are offered as accredited services from each location. ABs should ensure that their scopes clearly represent the extent and limits of the services that are subject to accreditation assessments.

2.3 In-House Calibration of Measuring Equipment

When an inspection body is permitted by an AB to calibrate measuring equipment, used during inspection, in-house, this activity should not be included in the scope of accreditation.

Note:

ISO/IEC 17020 accreditation is not appropriate for organisations providing instrument calibration as a service.

2.4 Measurements as an Integral Part of Inspections

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

2.4.2 If the inspection body performs the measurement activity in contexts other than as part of inspections covered by its scope of accreditation, it cannot claim accreditation for the measurement activity alone under ISO/IEC 17020:2012.

2.5 Limitation of Scope

- 2.5.1 Clause 3.1 of ISO/IEC 17011:2017, the definition of accreditation, is clear that accreditation is limited to those specific conformity assessment tasks which an organisation has demonstrated competence to perform. “It is therefore not appropriate to include a conformity assessment task in a scope of accreditation, where the conformity assessment body is unable to demonstrate the relevant competence.”. Based on Global ACI-TECH-2-001: Clause 6.3.1n1, it may be concluded that it is possible to include in the scope of accreditation the inspection or assessment of evidence, including results or reports provided by third parties, in order to make a conformity assessment decision. In this case the inspection of specified types of evidence, such as reports or records, is an inspection in its own right.
- 2.5.2 When deciding the level of detail to be included in scopes of accreditation an accreditation body should consider the needs of all stakeholders and both the value and risks associated with the level of detail provided.

2.6 Consistency of Scopes

It is considered good practice for accreditation bodies to express scopes using standard words, phrases, concepts, definitions or other means, as far as is practicable. This practice encourages consistency and impartiality in the expression of scopes, for organisations offering equivalent services, and also improves search functions.

2.7 Components of an Inspection Scope

- 2.7.1 The scope of inspection accreditation is typically defined by parameters such as those described in Table 1.
- 2.7.2 Not every area of inspection will need all of these parameters and some areas of inspection may need additional parameters.
- 2.7.3 Where the expression of the scope of accredited activities is stipulated in a scheme document this should be followed.

Table 1: Typical parameters for describing the scope of accreditation for inspection (see also application note in Global ACI-TECH-2-001: 5.1.3n1.)

Parameter	Comment/explanation
a) Type (A, B, or C) <i>(as defined in ISO/IEC 17020:2012 Annex A)</i>	Each accredited inspection activity must meet the requirements of ISO/IEC 17020:2012: Annex A. It is possible for different inspection activities performed by the same inspection body to have different A, B or C types.
<u>b)</u> Inspection category i.e. product, process, service, or installation <i>(as listed in the ISO/IEC 17020:2012 definition of inspection)</i>	To be accredited to ISO/IEC 17020:2012 inspection activities must be attributable to one of these categories. See Notes on inspection categories and terminology following this table.
<u>c)</u> Inspection field e.g. Engineering, agriculture, cargo, commodities, manufactured products etc. Example subdivisions of the field of engineering: Mechanical Structural Electrical Chemical Example of subdivisions of Mechanical Engineering Pressure equipment Cranes and lifting gear Rotating machinery	The 'inspection field' is a broad area of inspection work and is required by ISO/IEC 17011:2017 clause 7.8.3(b). Accreditation bodies may choose to use as many levels of subdivision of fields as they consider appropriate for the areas of accreditation they offer. Accreditation bodies should be aware of the dangers of granting simple scopes of accreditation that cover wide fields of inspection. The implication is that the accreditation body has done sufficient assessment to justify their decision that the inspection body is competent to perform all inspections that could be covered by the inspection field descriptions in the published scope.

d) Range of inspection The range is generally the most detailed parameter defining the items that may be inspected under a specific accreditation scope item. Example of a range of inspection within the sub-field of Cranes and sub-field Gantry Cranes < 100T SWL	The 'range of inspection' defines limits of competence within a field or sub-field. Where no range is stated this implies that the inspection body is competent to inspect all objects of inspection that fall within the field or sub-field description.
e) Stage of the product at which inspection takes place. e.g. design stage, type examination, initial inspection, fabrication, installation, in-service inspection, repair or alteration, surveillance during manufacture, planting, harvest, storage, shipping (including container filling) etc.	Terms for stages at which inspection takes place may vary from industry to industry. In some cases there may be no stages. Stages are needed when different inspector competencies are required at different stages of a product.
f) Inspection requirements or criteria. Unambiguous reference to standards, specifications (including client or in-house specifications and, where necessary, to inspection methods), regulations, inspection schemes or other documents that contain requirements against which inspection is performed. Where there are no published standards or specific criteria against which compliance is judged the term "general requirements" may be used. Examples of general requirements include statements of safety or compliance with good engineering practice which are reliant purely on professional judgement rather than comparison with any published criteria.	Inclusion of inspection criteria is required by ISO/IEC 17011:2017: clause 7.8.3(b) Where necessary, to avoid ambiguity, scopes of accreditation should include the date, revision numbers or other unique identifiers of standards, parts of standards, regulations, contractual requirements, scheme rules etc. Where there are large numbers of similar standards or specifications that require the same competence, these may be grouped using appropriate summary text.

2.8 Note on Inspection Categories

2.8.1 When considering a scope of inspection accreditation the definition of inspection in ISO/IEC 17020:2012 is intended to help focus on exactly what the inspection body inspects. The term inspection category is used in this guidance document as a collective term for the four “categories” included in the definition of inspection in ISO/IEC 17020:2012, which are **product**, **process**, **service** and **installation**.

2.8.2 An accreditation body should carefully consider which inspection **category** a specific inspection is in, as inspecting a product is very different from inspecting the process used to produce the product or the appropriateness of a product in a particular installation. Assigning the category correctly helps to ensure that appropriate expertise is used during assessments. Stating the category in published scopes also helps potential clients select an accredited inspection body with the specific competencies they require.

2.9 Note on Inspection Category Terminology

2.9.1 Alternative words may be used for these categories e.g. ‘commodity’, ‘report’ or any other word that describes the result of a process may be substituted for ‘product’. The concepts expressed in the definitions of **product**, **process**, **service** and **installation** are important, though different words may be used in different industries or sectors to describe them.

2.9.2 See Annex A for inspection category examples.

2.9.3 See Annex B for scope content examples.

3. AMENDMENT TABLE

Section	Previous Version	Summary Of Changes
All	-	New issue on the establishment of Global ACI

ANNEX A - INSPECTION CATEGORY EXAMPLES

Inspection category example from the engineering industry

- A pressure vessel may be inspected during fabrication as a **product** (the result of the process of fabrication) where the conformity assessment decision would be compliance with the approved design;
- The **process** of fabrication of a pressure vessel could be inspected, in which the accredited inspection body witnessed the implementation of a documented process, ensuring that appropriately qualified persons were involved and all records of materials, tests etc. were in place and recorded. This would be closer to a technical audit than a hands on inspection. The conformity assessment decision would be compliance with the approved process.
- A pressure vessel may be inspected as part of an **installation**, in which case the conformity assessment may relate to the safety or appropriateness of a vessel in a particular application, considering the associated equipment and process requirements.
- A pressure vessel may also be inspected as a **product** when in-service. In this case the product would be the result of the pressures, temperatures and materials in the vessel over time and the conformity assessment decision could be the estimated remaining life of the vessel or the current safety of the vessel.

In the four cases above, all of which could be related to the same pressure vessel, the competencies required are very different when inspecting the **product** of fabrication processes, a **process** itself or part of an **installation**. It is important that accreditation bodies differentiate these categories of inspection because, while one inspection body may have all the competencies required to justify a scope of “pressure vessel inspection” another inspection body may have competencies required for only one or two of these categories, in which case a scope of “pressure vessel inspection” would be misleading.

In the two **product** examples above the competencies involved are different because the **stage** at which inspection takes place is different.

Inspection category example from the agricultural industry

In the agricultural industry the following inspections could all relate to many growing crops.

- Seeds may be inspected before sowing. In this case seeds are the **product** of a natural process and the conformity assessment decision would relate to the correct variety of seed, freedom from contamination, disease, damage etc.
- The **process** of growing crops may be inspected in which case the conformity assessment decision could be to confirm that water management, fertiliser management, pest and disease management etc. were appropriate or were following defined criteria such as those for organic production.
- The **service** provided by a contractor transporting harvested product could be inspected. The conformity decision in this case might include the appropriateness of vehicles to prevent contamination, loss, spoilage etc. and the timeliness of transport in relation to contractual obligations.

- A food storage **installation** could be inspected to check it had appropriate facilities to prevent spoilage or loss, and to facilitate effective traceability and reconciliation of quantities in and out.

These four examples could all relate to the same crop, however; the competencies required of inspectors in each case would be different. In some cases the expertise required would be very specific to the crop in question, in others the competence required may apply to any crop or food product and in yet others the competence required may be related to vehicles, buildings, facilities or contract management and accounting which are not specific to any particular product or commodity.

It is for this reason that establishing which inspection category is appropriate is critically important in choosing an assessment team, and also for providing clear and unambiguous information to the inspection body and to clients of accredited inspection bodies, regulators etc.

ANNEX B – EXAMPLES OF INSPECTION SCOPE CONTENTS

Examples in this annex have been annotated to indicate different scope components as described in this document.

Text in *italics* does not form part of the scope statement – it is for annotation and explanatory purposes only.

These examples are **not** intended to provide any guidance on the layout of a scope statement or schedule.

These examples are intended to show how scopes may be formulated using the components detailed in this guidance document.

Many ABs issue separate certificates of accreditation and schedules of accreditation which may be many pages long. Technically a certificate and a schedule to the certificate are one document; however, for clarity this guidance does not imply or suggest that the detailed scope should be presented in a single page document.

Scope example 1

Name and logo of Accreditation Body]					
NAME of Inspection Body					
Accreditation No 1234					
Inspection Body Addresses and contact details					
Head Office or primary location		Additional Locations (If different from Head Office)			
		1 2 3			
Type (A,B,C)	Inspection category	Inspection Field (and sub-fields)	Range of inspections	Stage of inspection	Inspection requirements or criteria
A	Product	Engineering Mechanical Cranes and lifting gear Mobile Cranes Loose lifting gear	<100T	Fabrication In-service In-service	EN XXXXX Regulation Y Safety assessment

Field *Sub-field* *Sub-sub-fields* *Range* *Stages* *Inspection requirements*

This inspection body is accredited for inspecting specified cranes within the mechanical engineering field for conformity with specific requirements, during fabrication and in service, and for inspecting loose lifting gear for conformance with general safety requirements.

Two stages have been identified for cranes because the competencies involved in inspection during fabrication of a crane and of a crane when in-service are significantly different. This does not preclude an inspector from performing both types of inspection.

Scope example 2

Name and logo of Accreditation Body]					
NAME of Inspection Body					
Accreditation No 1234					
Inspection Body Addresses and contact details					
Head Office or primary location		Additional Locations (If different from Head Office)			
		1 2 3			
Type (A,B,C)	Inspection category	Inspection Field (and sub-fields)	Range of inspections	Stage of inspection	Inspection requirements or criteria
C	Installation	Food and Agriculture Containment facilities for live animals		Pre-export	Animal Products Act 1999
C	Product	Food and Agriculture Examination of live animals	Cattle Poultry*	Ante-mortem	Animal Products Act 1999

Field

Sub-field

Range

Stages

Inspection requirements

This inspection body is accredited for inspecting buildings and facilities for the containment of live animals prior to export and for the inspection of specific types of animal, before slaughter.

Both scope sections have been classified under the **field** of Food and Agriculture, but the competencies required of the inspectors are completely different and this is reflected in the different inspection **categories**.

In the first instance it has been established that the competencies of inspectors of installations are not dependent on the type of animal the facility is used for and therefore no **range** has been specified.

In the second instance there are different competencies for different types of 'product' (animals) and therefore the **range** has been used to specify the most detailed divisions considered necessary.

*In this case the range is defined in the inspection requirements document, in other circumstances the types of animal could have been used as a subdivision of the field.

Scope example 3

Name and logo of Accreditation Body]					
NAME of Inspection Body					
Accreditation No 1234					
Inspection Body Addresses and contact details					
Head Office or primary location		Additional Locations (If different from Head Office)			
		1 2 3			
Type (A,B,C)	Inspection category	Inspection Field (and sub-fields)	Range of inspections	Stage of inspection	Inspection requirements or criteria
A	Process	Manufactured Products Construction Products Factory production control	Glass for construction Fire-protective products	Fabrication	EN XXXXX EN YYYYYY

Field *Sub-field* *Sub-sub-field* *Range* *Stage* *Compliance criteria*

This inspection body is accredited for inspecting the factory production control system implemented by the manufacturer to ensure the quality of the production of construction products. The conformity assessment decision is whether or not the **process** of factory production control, defined in the compliance criteria document is being followed.