SLOVENSKA AKREDITACIJA

D05-02d7

ASSESSMENT OF CABs FOR NOTIFICATION PURPOSES

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1 PURPOSE

The purpose of this Annex to D05-02 Assessment, and where relevant, also to D05-02d1, D05-02d4 and D05-02d3, is to set out the scope and methods of assessment of conformity assessment bodies (CABs) for the purpose of notification to different regulations or directives.

2 SCOPE

This document shall be used in accreditation procedures for the purpose of notification under the following normative documents:

– **Regulation (EU) No 305/2011** of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, with amendments available on http://eur-lex.europa.eu/eli/reg/2011/305 [1];

– **Directive 2010/35/EU** of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC [2];

– **Directive 2014/33/EU** of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts [3].

– **Directive 2014/31/EU** of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments [4];

– **Directive 2014/32/EU** of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments, with amendments available on https://eur-lex.europa.eu/eli/dir/2014/32 [5];

– **Directive 2014/53/EU** of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC, with amendments available on https://eur-lex.europa.eu/eli/dir/2014/53 [6];

– **Regulation (EU) 2016/425** of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC, with amendments available on https://eur-lex.europa.eu/legal-content/SL/TXT/?uri=CELEX%3A02016R0425-20160331&qid=1689668402788 [7].

3 GENERAL

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 provides the framework for market surveillance of products for the purpose of ensuring that these products meet the requirements for high level of protection of public

interest, such as the protection of health in general, safety and health at work, protection of consumers, the environment and safety. With Regulation (EC) No 765/2008, the requirements for accreditation are also extended to the regulated area.

Prior to placing a product on the EU market, the manufacturer shall carry out the conformity assessment procedure. Every New Approach Directive/Regulation describes the type and content of possible conformity assessment procedures – the modules (*Table 1*). The provisions of several Directives/Regulations at the same time shall be used for more complex products. The manufacturer himself may only carry out the procedures under modules A and C, whereas in modules B, D, E, F, G and H he shall cooperate with an independent institution (notified body) for the specific field of products or testing.

Table 1: Overview of modules ("Blue Guide" on the implementation of EU product rules 2022 [8])

MODULE	DESCRIPTION
A Internal production control	Covers both design and production. The manufacturer himself ensures the conformity of the products to the legislative requirements (no EU-type examination).
A1 Internal production control plus supervised product testing	Covers both design and production. A + tests on specific aspects of the product carried out by an **in-house accredited body** or under the **responsibility of a notified body** at the manufacturer's choice.
A2 Internal production control plus supervised product checks at random intervals	Covers both design and production. A + product checks at random intervals carried out by a **notified body** or **in-house accredited body**.
B EU-type examination	Covers design. It is always followed by other modules by which the conformity of the products to the approved EU-type is demonstrated. A **notified body** examines the technical design and/or the specimen of a type and verifies and attests that it meets the requirements of the legislative instrument that apply to it by issuing an EU-type examination certificate. There are 3 ways to carry out EU-type examination: 1) production type, 2) combination of production type and design type, and 3) design type.
C Conformity to EU-type based on internal production control	Covers production and follows Module B. Manufacturer must internally control its production in order to ensure product conformity against the EU-type approved under module B.
C1	Covers production and follows Module B. Manufacturer must internally control its production in order to ensure product conformity against the EU-type approved under module B.

MODULE	DESCRIPTION
Conformity to EU-type based on internal production control plus supervised product testing	C + tests on specific aspects of the products carried out by an **in-house accredited body** or under the responsibility of a notified body chosen by the manufacturer.
C2 Conformity to EU-type based on internal production control plus supervised product checks at random intervals	Covers production and follows Module B. Manufacturer must internally control its production in order to ensure product conformity against the EU-type approved under module B. C + product checks at random intervals tests on specific aspects of the products carried out by a **notified body** or **in-house accredited body**.
D Conformity to EU-type based on quality assurance of the production process	Covers production and follows Module B. The manufacturer operates a production (manufacturing part and inspection of final product) quality assurance system in order to ensure conformity to EU-type. The **notified body** assesses the quality system.
D1 Quality assurance of the production	Covers both design and production. The manufacturer operates a production (manufacturing part and inspection of final product) quality assurance system in order to ensure conformity to legislative requirements (no EU-type, used like module D without module B). The **notified body** assesses the production (manufacturing part and inspection of final product) quality system.
E Conformity to EU-type based on product quality assurance	Covers production and follows Module B. The manufacturer operates a product quality (production quality without the manufacturing part) assurance system for final product inspection and testing in order to ensure conformity to EU-type. A **notified body** assesses the quality system. The idea behind module E is similar to the one under module D: both are based on a quality system and follow module B. Their difference is that the quality system under module E aims to ensure the quality of the final product, while the quality system under module D (and D1 too) aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E is thus similar to module D without the provisions relating to the manufacturing process.
E1 Quality assurance of final product inspection and testing	Covers both design and production. The manufacturer operates a product quality (production quality without the manufacturing part) assurance system for final product inspection and testing in order to ensure conformity to the legislative requirements (no module B (EU-type), used like module E without module B). The **notified body** assesses the quality system. The idea behind module E1 is similar to the one under module D1: both are based on a quality system. Their difference is that the quality system under module E1 aims to ensure the quality of the final product, while

MODULE	DESCRIPTION
	the quality system under module D1 aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E1 is thus similar to module D1 without the provisions relating to the manufacturing process.
F Conformity to EU- type based on product verification	Covers production and follows Module B. The manufacturer ensures compliance of the manufactured products to approved EU-type. The **notified body** carries out product examinations (testing of every product or statistical checks) in order to control product conformity to EU-type. Module F is like C2 but the notified body carries out more systematic product checks.
F1 Conformity based on product verification	Covers both design and production. The manufacturer ensures compliance of the manufactured products to the legislative requirements. The **notified body** carries out product examinations (testing of every product or statistical checks) in order to control product conformity to the legislative requirements (no EU-type, used like module F without module B). Module F1 is like A2 but the notified body carries out more detailed product checks.
G Conformity based on unit verification	Covers both design and production. The manufacturer ensures compliance of the manufactured products to the legislative requirements. The **notified body** verifies every individual product in order to ensure conformity to legislative requirements (no EU-type).
H Conformity based on full quality assurance	Covers both design and production. The manufacturer operates a full quality assurance system in order to ensure conformity to legislative requirements (no EU-type). The **notified body** assesses the quality system.
H1 Conformity based on full quality assurance and design examination	Covers both design and production. The manufacturer operates a full quality assurance system in order to ensure conformity to legislative requirements (no EU-type). The **notified body** assesses the quality system and the product design and issues an EU design examination certificate. Module H1 in comparison to module H provides in addition that the notified body carries out a more detailed examination of the product design. The EU-design examination certificate must not be confused with the EU-type examination certificate of module B that attests the conformity of a specimen 'representative of the production envisaged', so that the conformity of the products may be checked against this specimen. Under EU design examination certificate of module H1, there is no such specimen. EU design examination certificate attests that the conformity of the design of the product has been checked and certified by a notified body.

The Member State needs to decide whether or not it will use accreditation to attest CABs' competence for notification purposes.

In cases where Slovenia decides to use accreditation for attesting the competence of CABs, it shall define by a scheme, and taking into account EA-2/17 M – EA Document on Accreditation for Notification Purposes [9], the most appropriate accreditation standard for individual module under individual Directive/Regulation setting out the requirements for accreditation.

4 ASSESSMENT INSTRUCTIONS

4.1 Regulation (EU) No 305/2011 (CPR)

Construction product means any product or kit which is produced and placed on the market for incorporation in a permanent manner in construction works or parts thereof and the performance of which has an effect on the performance of the construction works with respect to the basic requirements for construction works.

Regulation (EC) No 305/2011 lays down conditions for the placing on the market of those construction products that are contained in harmonised technical specifications (harmonised standards or European Assessment Documents). The manufacturer of such "harmonised" construction product shall issue a Declaration of performance for it and affix the CE marking to it before placing it on the market.

Harmonised technical specifications mean harmonised standards and European Assessment Documents.

Harmonised standard means a standard as defined in Article 2 (1)(c) of Regulation (EC) No 1025/2012.

European Assessment Document means a document adopted by the organisation of TABs for the purposes of issuing European Technical Assessments.

Annex V to Regulation (EC) No 305/2011 sets out 5 conformity assessment systems, four of them involving third party.

The term "Conformity Assessment System" for construction products has been changed by Regulation (EC) No 305/2011, so that the term "Assessment and Verification of Constancy of Performance (AVCP) System" is now used for this activity. The AVCP System involving third party includes systems 1, 1^+, 2^+ and 3 (the latter is not the subject of this document; see *Table 2* for description of the first three systems).

In June 2022, the ministry responsible for economy issued the document "Guidelines on setting up and notification of bodies for the assessment and verification of constancy of performance of construction products" [10]. Accreditation requirements are set out in point 6 under "*Requirements for notified bodies for construction products*". Regulation (EC) No 305/2011 is considered to comprise the Regulation as well as all the documents issued on its basis (changes, delegated regulations), available on the EUR-Lex website: http://eur-lex.europa.eu/eli/reg/2011/305 and online: https://single-market-economy.ec.europa.eu/sectors/construction/construction-products-regulation-cpr_en.

This document addresses the assessment of the body for assessment and verification of constancy of performance of construction products (AVCP body), who carries out, in compliance with Regulation (EC) No 305/2011, assessment and verification of constancy of performance of construction products (Systems 1 and 1+), and certification of factory production control for construction products (System 2+) thereby meeting the requirements for competence laid down in the standard SIST EN ISO/IEC 17065 [11]. Also, the guides and positions adopted within the Group of Notified Body for Construction Product Regulation (GNB-CPR) shall be taken into account when assessing.

Table 2: Overview of Assessment and Verification of Constancy of Performance (AVCP) Systems

AVCP System	Task for manufacturer	Task for notified body
1+	The manufacturer shall carry out: (i) factory production control, (ii) further testing of samples taken at the factory in accordance with the prescribed test plan.	The notified body for certification of products shall decide on issuance, restriction, suspension or withdrawal of Certificate of Constancy of Performance of Construction Product on the basis of the following assessments and verifications carried out by the body: (i) assessment of the construction product's performance on the basis of testing (including sampling), calculation, tabulated values or descriptive documentation of the product, (ii) initial inspection of the manufacturing plant and of factory production control, (iii) continuous surveillance, assessment and evaluation of factory production control, (iv) audit – testing of samples taken by the notified body for certification of products at the factory or at the manufacturer's storage facilities.
1	The manufacturer shall carry out: (i) factory production control, (ii) further testing of samples taken at the factory in accordance with the prescribed test plan.	The notified body for certification of products shall decide on issuance, restriction, suspension or withdrawal of Certificate of Constancy of Performance of Construction Product on the basis of the following assessments and verifications carried out by the body: (i) assessment of the construction product's performance on the basis of testing (including sampling), calculation, tabulated values or descriptive documentation of the product, (ii) initial inspection of the manufacturing plant and of factory production control, (iii) continuous surveillance, assessment and evaluation of factory production control.
2+	The manufacturer shall carry out: (i) assessment of the construction product's performance on the basis of testing (including sampling), calculation, tabulated values or descriptive documentation of the product, (ii) factory production control, (iii) testing of samples taken by the manufacturer at the factory in accordance with the prescribed test plan.	The notified body for certification of products shall decide on issuance, restriction, suspension or withdrawal of Certificate of Constancy of Performance of Construction Product on the basis of the following assessments and verifications carried out by the body: (i) initial inspection of the manufacturing plant and of factory production control, (ii) continuous surveillance, assessment and evaluation of factory production control.

4.1.1 Assessment focuses

The assessment of AVCP bodies includes assessment of the main site of the AVCP body, or its dislocated sites at which the key activities and witnessing of the assessment and verification of constancy of performance at the manufacturers of construction products are performed.

4.1.1.1 Main site or dislocated sites

In the course of the assessment of the AVCP body's main site or its dislocated sites, the assessor team shall use, in addition to the general assessment techniques, primarily the following techniques: examination of records, system documents and interviews with the AVCP body's staff involved in the procedure of assessment and verification of constancy of performance. They shall focus on the elements set out in the document D05-02d4, 2.1 and 2.1.1, and in particular on:

4.1.1.1.1 Assessment of organisation (SIST EN ISO/IEC 17065(5), CPR, Art. 43)

The AVCP body shall be established under the national law of Slovenia and shall have legal personality (CPR Art. 43 (2)).

The AVCP body shall have taken out liability insurance (CPR, Art. 43 (9)).

The AVCP body shall be a third-party body independent from the organisation or the construction product it assesses (CPR, Art. 43 (3), sent. 1). The AVCP body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of construction products which it assesses, can on condition that its independence and the absence of any conflict of interest are demonstrated, be considered to be such a body (CPR, Art. 43 (3), sent. 2; Art. 43 (4)). Evidence of independence as well as evidence of absence of conflict of interest may be provided by the certification body through analysis of related bodies. In its analysis, the AVCP body must include the top management and the personnel (under permanent or temporary employment contracts) and members of committees, who shall not be involved in or directly participate in the design, manufacture or construction, marketing, installation, use or maintenance of the construction products they assess, nor be authorised representatives of any of those parties. The personnel of the AVCP body shall not engage in any activity that may conflict with their independence of carrying out the activities that are subject to assessment/accreditation. This shall, in particular, apply to consultancy service. The analysis shall also include the body's subsidiaries and subcontractors.

The assessor shall make sure that the AVCP body understands harmonised standards, as to when they become harmonised, how they are controlled by the AVCP body's management system, the control of GNB-CPR documents, the procedure of controlling those documents (also the delegated regulations) and their implementation in the AVCP body's management system. In the AVCP body, the understanding of the use of simplified procedures by manufacturers shall be checked, e.g. in the case of European Assessment Documents for micro-enterprises (CPR, Arts. 36 – 38).

4.1.1.1.2 Testing as part of product certification in Systems 1+ and 1 (SIST EN ISO/IEC 17065(6.2))

When the AVCP body for products/processes has internal resources for laboratory testing, it may demonstrate the competence of the testing laboratory by accreditation to SIST EN ISO/IEC 17025. If not so, the fulfilment of the requirements of SIST EN ISO/IEC 17025 is checked during the assessment. When the AVCP body uses outsourcing for testing, the provisions under 4.1.1.1.3 below shall apply.

4.1.1.1.3 Subcontractors (in addition to SIST EN ISO/IEC 17065 (6.2.2, CPR, Art. 45)

The AVCP body shall be responsible for all the activities within the framework of the applicable system of assessment and verification of constancy of performance, also for the performance of tasks by the subcontractor. The AVCP body shall ensure that the subcontractor meets the requirements of CPR, Art. 45(1); also, the subcontractor shall be an independent third party, independent from the organisation or the construction product it assesses.

When the AVCP body subcontracts certain activities within the scope of assessment and verification of constancy of performance, it shall obtain the client's agreement with the proposed subcontractor (CPR, Art. 45(3)). When the AVCP body entrusts testing activities to a subcontractor, it shall ensure that the requirements of SIST EN ISO/IEC 17025 are met. The AVCP body shall keep a list of subcontractors.

The AVCP body shall not subcontract its decision on certificates.

4.1.1.1.4 Use of external testing facilities (CPR, Art. 46)

On request of the manufacturer and where justified by technical, economic or logistic reasons, the AVCP body may decide to carry out tests for Systems 1+, 1 of assessment and verification of constancy of performance either in the manufacturing plants using the test equipment of the internal laboratory of the manufacturer or in an external laboratory, using the test equipment of that laboratory. In both cases the AVCP body shall obtain prior consent of the manufacturer of the construction product, and the tests shall be carried out under the AVCP body's supervision. Pursuant to CPR, Art. 46(1) para. (2), the AVCP body using such external testing facilities shall be specifically designated as competent to work away from its own accredited testing laboratories. This information shall be accessible in the NANDO base.

The AVCP body shall ensure that, in testing using external laboratories, the requirements of CPR, Article 46, or the relevant requirements of SIST EN ISO/IEC 17025(6) are met, that it possesses the necessary knowledge and experience for carrying out the tests and for assessing the testing capacity. The AVCP body shall be responsible for the tests carried out in external testing laboratories.

In the case that the AVCP body carries out tests in the manufacturing plants using the test equipment of the internal laboratory of the manufacturer, or in an external laboratory, using the test equipment of that laboratory, in accordance with CPR, Article 46, this shall be noted in the checklist and in the assessment report.

4.1.1.1.5 Personnel (in addition to SIST EN ISO/IEC 17065 (6.1, CPR, Art. 43)

The personnel shall have the following:
- appropriate technical and professional training depending on the scope of the activity,
- appropriate knowledge, experience and understanding of CPR, the assessment procedures,
- appropriate knowledge, experience and understanding of the applicable harmonised technical specifications and other relevant standards and regulations.

The personnel responsible for the activities of assessment and verification of constancy of performance shall have:
- appropriate training (completed appropriate higher education or comparable education),

- proven several years of experience in the activity (with respect to individual construction product); this includes in particular appropriate knowledge of the production process and the impact of change/difference on construction products' performance.

The AVCP body shall keep evidence of technical competence, training and maintenance of competence.

The personnel of the AVCP body shall participate in the relevant standardisation committees (CPR, Art. 43(11)) and in the activities of the Notified Body Coordination Group established under the Regulation (EC) No 305/2011 (CPR, Art. 55), or be informed of the activities of these groups. The participation can be either direct or through a national mirror group set up for this purpose in the Republic of Slovenia. The personnel shall apply as general guidance in their work the administrative decisions and documents produced by the Notified Body Coordination Group (CPR, Art. 43(11)).

Note: Notified bodies undertaking tasks under Systems 1+ and 1 as well as manufacturers undertaking tasks under Systems 2+ may, in assessing and verifying constancy of performance of construction products, consider the European Technical Assessment issued for the construction product in question as the assessment of the performance of that product. Notified bodies and manufacturers shall therefore not undertake the tasks referred to in points 1.1(b)(i), 1.2(b)(i), 1.3(a)(i), 1.4(b) and 1.5(a)(i) respectively, from the applicable Annex V.

4.1.1.1.6 Certification documentation (SIST EN ISO/IEC 17065 (7.7))

In addition to the requirements of the standard SIST EN ISO/IEC 17065, the certification documentation shall contain all the information required by the harmonised technical specification or other harmonisation documents. The decisions of the Notified Body Coordination Group shall apply as guidance (CPR, Art. 43(11)).

4.1.1.1.7 Exchange of information (CPR, Art. 53(2))

The AVCP body shall inform the notifying authority of any refusal, restriction, suspension or withdrawal of accreditation; any circumstances affecting the scope of and conditions for, notification; any request for information on assessment and/or verification of constancy of performance activities which they have received from market surveillance authorities; on request, third party tasks in accordance with the systems of assessment and verification of constancy of performance carried out within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

The AVCP body shall provide the other bodies notified under this Regulation and carrying out similar third-party tasks in accordance with the systems of assessment and verification of constancy of performance for construction products covered by the same harmonised technical specifications, with relevant information on issues relating to negative and, on request, positive results from these assessments and/or verifications.

4.1.1.1.8 CE marking (CPR, Arts. 8 and 9, SIST EN ISO/IEC 17065 (4.1.3.1))

The AVCP body shall require the manufacturer/importer to affix the CE marking before the construction product is placed on the market, and that the CE marking is followed by the identification number of the notified body, when such body takes part in the factory production control.

4.1.1.2 Scope of assessment (with regard to the overall scope of the AVCP bodies' accreditation)

4.1.1.2.1 Vertical audits

At the initial assessment and re-assessment in individual scheme, the assessors shall assess through vertical audits a representative part of certification procedures of those products, services, processes, which are more critical in terms of protecting the health of humans, animals and nature as well as insuring property, for each AVCP system. The selection shall also include cases of multi-site organisations, cases of cross border certification activities, as well as initial and surveillance inspections.

Within the framework of one accreditation cycle, the procedures for all groups of products from the scope of accreditation shall be looked at through vertical audit.

4.1.1.2.2 Witnessing audits

Within the framework of initial assessment of the AVCP body, a representative part of audits of those products, services, processes shall be witnessed which are more critical in terms of protecting the health of humans, animals and nature as well as insuring property, or at least one audit from each AVCP system. Within the framework of one accreditation cycle (three surveillances and one re-assessment), at least one audit from each product group (12) from the scope of accreditation shall be witnessed, System 1+ (*Table 3*) being the priority. At least one of the planned audits to be witnessed within the context of an assessment period should be (if possible) the initial audit.

When selecting the organisation in which the witnessing of audit/inspection is to be performed, the rule that not the same auditors should be witnessed or that the witnessing should not be performed in the same organisation (if possible) shall be followed.

Table 3: Classification of construction products into groups of products to be selected for witnessing

Commission Decision	Construction products	AVCP System	Group
1996/577*	Fire detection and fire alarm systems-kits and system components Fire suppression and extinguishing systems-kits and system components Explosion suppression systems-kits and system components Fire and smoke control installations-kits and installation components Point smoke detectors/alarms	1	1
2015/1958	Geosynthetics and related products	2+	2
1998/601*	Road construction products	1, 2+	2
1999/90*	Membranes	1, 2+	2
2003/655	Watertight covering kits for wetroom floors and walls	1, 2+	2
2011/19	Sealants for non-structural use in joints in buildings and pedestrian walkways	1	2
1999/453	Circulation fixtures Flooring	1	2
2001/19	Expansion joints for road bridges	1	2
1998/436*	Roof coverings Rooflights Roof windows and ancillary products	1	3
1999/455	Timber frame Log prefabricated building kits	1	3
1999/93*	Doors Windows Shutters Blinds Gates Building hardware	1	3
2000/245*	Flat glass, profiled glass and glass-block products	1	3

Commission Decision	Construction products	AVCP System	Group
2003/728	Metal frame building kits Concrete frame building kits Prefabricated building units Cold storage room kits Rock-fall protection kits	1	3
1995/467*	Chimneys, flues and specific products Gypsum products Structural bearings	1, 2+	4
1996/580*	Curtain wallings	1	4
1997/555	Cements Building limes Other hydraulic binders	1, 2+	4
1997/740*	Masonry and related products	1, 2+	4
1997/808*	Floorings	1	4
1998/279*	Non load-bearing permanent shuttering kits/systems based on hollow blocks or panels of insulating materials and, sometimes, concrete	1, 2+	4
1998/437*	Internal and external wall and ceiling finishes	1	4
1998/598*	Aggregates	2+	4
1999/469*	Concrete Mortar Grout	1+, 1, 2+	4
1999/470*	Construction adhesives	2+	4
1999/94*	Precast normal/lightweight/autoclaved aerated concrete products	1, 2+	4
1999/89*	Prefabricated stair kits	1, 2+	4
2002/592	Gypsum products Fixed fire-fighting systems Sanitary appliances Aggregates	1, 2+	4
1996/582	Structural sealant glazing Metal anchors	1, 2+	5
1997/161	Metal anchors for use in concrete for fixing lightweight systems	2+	5
1997/177	Metal injection anchors for use in masonry	1	5
1997/463	Plastic anchors for use in concrete and masonry	2+	5
1998/143	Systems of mechanically fastened flexible roof waterproofing membranes	2+	5
1997/597	Reinforcing and prestressing steel for concrete	1+	5
1998/213*	Internal partition kits	1	5
1998/456	Post-tensioning kits for the prestressing of structures	1+	5
1998/599*	Liquid applied roof waterproofing kits	1	5
1998/600*	Translucent roof kits (except glass-based kits)	1	5
2000/606	Internal covering system of gypsum fibre boards Prefabricated cavity trays Couplings and sleeves for standardised reinforcing bars Corrugated steel reinforcement sheets (for composite structural floor systems) Pile joint (connection device for load-bearing pre-cast concrete piles) Rock shoe (anchoring device for load-bearing pre-cast concrete piles)	1, 1+, 2+	5
1997/176*	Structural timber products	1, 2+	6
1997/462*	Wood-based panels	1, 2+	6
1997/638	Fasteners for structural timber products	2+	6
1999/454*	Fire stopping, fire sealing and fire protective products	1	6
1999/92	Light composite wood-based beams and columns	1	6
2000/447*	Prefabricated wood-based load-bearing stressed skin panels and self-supporting composite lightweight panels	1	6
1997/556*	External thermal insulation composite systems/kits with rendering	1, 2+	7
1999/91*	Thermal insulating products	1	7
2001/308	Vetures	1	7
1998/214*	Structural metallic products and ancillaries	1, 2+	8
1996/579*	Circulation fixtures	1	9
2015/1959	Wastewater engineering products	1	10
2000/273*	Vibration and impact noise isolation kit for floating floors Vibration and noise isolation kit for walls Wall plates made of stainless steel Wastewater trap kits	1	11

Commission Decision	Construction products	AVCP System	Group
	Channel bars Chemical anchoring kits Epoxy concrete/glass-reinforced polyester/epoxy mortar anchoring kits		
1999/471*	Heating appliances	1	12
1999/472*	Pipes, tanks and ancillaries not in contact with water intended for human consumption	1	12

* Consolidated text with amendments of informative nature. The original act and its amendments are available at the same link.

The procedure for witnessing audits and the assessment focuses is set out in the document D05-02d4, 2.2. In addition to those focuses, the assessors witnessing the audit need to focus on whether the AVCP body carrying out the audit examines the documentation, including the Declaration of Performance (DoP), as part of the certification procedure.

4.2 Directive 2010/35/EU on transportable pressure equipment (TPED)

The accreditation procedure for the purpose of notification under the Directive on transportable pressure equipment shall be performed for the following two groups of transportable pressure equipment:

a) all pressure receptacles, their valves and other accessories when appropriate, as defined in **Chapter 6.2 of Annexes** to Directive 2008/68/EC on the inland transport of dangerous goods [12], such as liquefied petroleum gas cylinders, technical gas cylinders, pressure drums, cryo vessels, cylinder packages,
b) tanks, battery vehicles/wagons, multiple-element gas containers (MEGC), their valves and other accessories, as covered **in Chapter 6.8 of the Annexes I and II** to Directive 2008/68/EC on the inland transport of dangerous goods,

when the equipment under (a) or (b) is used in accordance with those Annexes **for the transport of Class 2 gases**, excluding gases or articles with figures 6 and 7 in the classification code, and for the transport of the dangerous substances of other classes specified in Annex I to this Directive.

4.2.1 Accreditation standard

Annexes of the Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (Annex I, Transport by Road, Section I.1 ADR; Annex II, Transport by Rail, Section II.1 RID) provide that the accreditation standard used in accreditation procedure for the purpose of notification shall be the standard laying down the requirements for inspection bodies, namely SIST EN ISO/IEC 17020 [13].

Also, the required type of inspection body's independence is defined depending on the type of inspection performed by the notified body:

Type of transportable pressure equipment	Type of inspection	Required type of independence
pressure receptacles (Chapter 6.2*…)	periodic inspection	Type A or Type B
tanks (Chapter 6.8*…)	initial inspection periodic inspection interim inspection exceptional check	Type A

* Annexes I and II to Directive 2008/68/EC on the inland transport of dangerous goods (ADR, RID).

4.2.2 Conformity assessment procedures

Conformity assessment procedures for transportable pressure equipment are laid down in Annexes of the Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (Annex I, Transport by Road, Section I.1 ADR, Annex II, Transport by Rail, Section II.1 RID).

4.2.3 Requirements to be checked in the assessment

All the relevant requirements of the accreditation standard for the scope of activity of the notified body shall be checked for compliance in the assessment. In addition, compliance to the following requirements set out in the Directive on transportable pressure equipment (Directive 2010/35/EU) shall be checked:

– PI-marking of the transportable pressure equipment in accordance with Article 15 of the Directive,
– in accordance with Article 20(4) of the Directive, the notified body shall participate in, or ensure that its assessment personnel are informed of, the relevant standardisation activities and the activities of the Notified Body Coordination Group established pursuant to Article 29 of the Directive 2010/35/EU and apply as general guidance the administrative decisions and documents produced as a result of the work of that group,
– in accordance with the provisions of Article 27(1) of the Directive, the notified body shall inform the notifying authority (the ministry responsible for economy) of any refusal, restriction, suspension or withdrawal of a certificate; any circumstances affecting the scope of validity and the conditions for notification; any request for information on the activities performed, which they have received from market surveillance authorities; and, on request, the activities performed within the scope of their notification, as well as any other activities performed, including cross-border activities and subcontracting;
– in accordance with Article 27(2), the notified body shall provide the other bodies notified under this Directive carrying out similar conformity assessment procedures covering the same transportable pressure equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.

4.3 Directive 2014/33/EU on lifts and safety components for lifts

In March 2021, the ministry responsible for economy issued "Guidelines on setting up and notification of bodies for the assessment of conformity" based on the Technical Requirements for Products and Conformity Assessment Act (ZTZPUS-1) and on the ˝Rules on lift safety˝ (Directive 2014/33/EU), Ministry of the Economy, Tourism and Sport, March 2021 [14].

4.3.1 Accreditation standard

For accreditation for the purpose of notification in the field of lifts for:

– **final inspection**, as set out in Annex V of the Directive 2014/33/EU, the standard laying down the requirements for the operation of inspection bodies, i.e. SIST EN ISO/IEC 17020, shall be used, and
– **conformity assessment based on unit verification** (module G) in accordance with Annex VIII of the Directive 2014/33/EU, the standard laying down the requirements for certification bodies for products, processes and services, i.e. SIST EN ISO/IEC 17065, shall be used.

The inspection bodies performing conformity assessment of lifts shall carry out independent third party inspections. They shall meet type A independence requirements as laid down in SIST EN ISO/IEC 17020.

4.3.2 Use of harmonised standards and presumption of conformity

The lifts being the object of inspection shall meet the essential health and safety requirements set out in Annex I of the Directive.

The lifts which are in conformity with the harmonised standards or part thereof (a list is published online at: https://www.gov.si/teme/varnost-dvigal/ and https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/lifts_en), are presumed to be in conformity with the essential safety requirements set out in Annex I of the Directive.

4.3.3 Requirements to be checked in the assessment

All the relevant requirements of the accreditation standard for the scope of activity of the notified body shall be checked for compliance in the assessment, all by taking into account the provisions of the Directive 2014/33/EU, Art. 24. In addition, compliance to the following requirements set out in the Directive 2014/33/EU on lifts and safety components for lifts shall be checked:

– affixing of CE marking and other markings in accordance with the requirements of Article 19 of the Directive;
– participating in or ensuring that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities, as well as the activities of the Coordination Group of Notified Bodies for Lifts. The notified bodies shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group (Article 24(11) of the Directive 2014/33/EU);
– informing the notifying authority (the ministry responsible for economy) of any refusal, restriction, suspension or withdrawal of a certificate or approval decision; any circumstances affecting the scope of or the conditions for notification; any request for information on conformity assessment activities, which they have received from market surveillance authorities; and, on request, any conformity assessment activities performed within the scope of their notification, as well as any other activities performed, including cross-border activities and subcontracting; in accordance with Article 34 of the Directive 2014/33/EU, and in the case where certain tasks related to conformity assessment are subcontracted, in accordance with Article 26 of the Directive 2014/33/EU;
– in accordance with the provisions of Article 34(2) of the Directive, the notified body shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same type of lifts or the same safety components for lifts with relevant information on issues relating to negative and, on request, positive conformity assessment results.

4.3.4 Vertical audits

At the initial assessment in individual scheme, the assessors shall assess through vertical audits at least one procedure for individual conformity assessment module. The selection shall also include cases of multi-site organisations, cases of cross border certification activities, as well as initial and surveillance inspections/audits. Within the framework of one accreditation cycle, the procedures for a

representative part of products for individual accreditation standard from the scope of accreditation shall be looked at through vertical audit.

4.3.5 Witnessing of conformity assessment procedures

At least one conformity assessment procedure for individual standard shall be witnessed on-site within the framework of initial assessment of the CAB. Within the framework of one accreditation cycle (three surveillances and one re-assessment) the witnessing shall be carried out as planned in the Witnessing Plan, which is drawn up after the grant of accreditation. When selecting the certification procedure to be witnessed, the rule that not the same auditors should be witnessed or that the witnessing should not be performed in the same organisation shall be followed (if possible).

4.4 Directive 2014/31/EU on making available on the market of non-automatic weighing instruments (NAWI)

The ministry responsible for economy issued "Guidelines on setting up and notification of conformity assessment bodies based on the Act Regulating Technical Requirements for Products and Conformity Assessment (ZTPUS-1) and Rules concerning metrological requirements for non-automatic weighing instruments (Directive (EU) 2014/31)", January 2023 [15].

4.4.1 Accreditation standards

In the field of non-automatic weighing instruments, the accreditation standards and WELMEC Guides shall be used for accreditation for notification purposes of individual modules, in the manner as laid down in the Guidelines [15]:

Modules	Standard, Guide
EU-type examination (B)	EN ISO/IEC 17065 and WELMEC Guide 8.5
Conformity to EU-type based on quality assurance of the production process (D) Quality assurance of the production (D1)	EN ISO/IEC 17065 and WELMEC Guide 8.5
Conformity to EU- type based on product verification (F) Conformity based on product verification (F1)	EN/ISO/IEC 17020 and WELMEC Guide 8.7
Conformity based on unit verification (G)	EN ISO/IEC 17065 and WELMEC Guide 8.5

4.4.2 Use of harmonised standards and presumption of conformity

Non-automatic weighing instruments that are addressed by the Directive shall comply with the essential requirements laid down in Annex I of the Directive. The non-automatic weighing instruments that are in conformity with harmonised standards or a part thereof, whose references were published in the Official Journal of the EU, are presumed to conform to the essential requirements from Annex I of the Directive.

4.4.3 Requirements to be checked in the assessment

In the assessment, all the relevant requirements of the accreditation standard and of WELMEC Guides 8.5 and 8.7, respectively, for the scope of activity of the notified body shall be checked for compliance, taking into account the provisions of Directive 2014/31/EU, Article 23. In addition, compliance to the following requirements set out in Directive 2014/31/EU shall be checked:

- affixing of CE marking and other markings in accordance with the requirements of Article 18 and item 3 of Annex III of the Directive;
- participating in the relevant standardisation activities, as well as the activities of the Coordination Group of Notified Bodies NoBoMet, or ensuring that the notified bodies' personnel competent for carrying out conformity assessment tasks are informed of these activities. The notified bodies shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group (Article 23(11) of the Directive 2014/31/EU);
- informing the notifying authority (the ministry responsible for economy) of any refusals, restrictions, suspensions or withdrawals of a certificate or approval decisions; any circumstances affecting the scope of or the conditions for notification; any request for information on conformity assessment activities, which they have received from market surveillance authorities; and, on request, any conformity assessment activities performed within the scope of their notification, as well as any other activities performed, including cross-border activities and subcontracting; in accordance with Article 33 of the Directive 2014/31/EU, and in the case where certain tasks related to conformity assessment are subcontracted, in accordance with Article 25 of the Directive 2014/31/EU;
- in accordance with the provisions of Article 33(2) of the Directive, the notified body shall provide the other notified bodies carrying out similar conformity assessment activities covering the same type of weighing instruments, with relevant information on issues relating to negative and, on request, positive conformity assessment results.

4.4.4 Vertical audits

At the initial assessment in individual scheme, the assessors shall assess through vertical audits at least one procedure for individual conformity assessment module. The selection shall also include cases of multi-site organisations, cases of cross border certification/inspection activities, as well as initial and surveillance inspections/audits. Within the framework of one accreditation cycle, the procedures for all groups of products for individual accreditation standard from the scope of accreditation shall be looked at through vertical audit.

4.4.5 Witnessing of conformity assessment procedures

At least one conformity assessment procedure for individual accreditation standard shall be witnessed on-site within the framework of initial assessment of the CAB. Within the framework of one accreditation cycle (three surveillances and one re-assessment) the witnessing shall be carried out as planned in the Witnessing Plan, which is drawn up after the grant of accreditation. When selecting the certification procedure to be witnessed, the rule that not the same auditors should be witnessed or that the witnessing should not be performed in the same organisation shall be followed (if possible).

4.5 Directive 2014/32/EU on making available on the market of measuring instruments (MID)

The ministry responsible for economy issued "Guidelines on setting up and notification of conformity assessment bodies based on the Act Regulating Technical Requirements for Products and Conformity Assessment (ZTPUS-1) and Rules concerning measuring instruments (Directive (EU) 2014/32)", January 2023 [16].

4.5.1 Accreditation standards

In the field of measuring instruments, the accreditation standards and WELMEC Guides shall be used for accreditation for notification purposes of individual modules, in the manner as laid down in the Guidelines [16]:

Modules	Standard, Guide
Internal production control plus supervised product checks at random intervals (A2)	EN ISO/IEC 17065
EU-type examination (B)	EN ISO/IEC 17065 and WELMEC Guide 8.5
Conformity to EU-type based on internal production control plus supervised product checks at random intervals (C2)	EN ISO/IEC 17065
Conformity to EU-type based on quality assurance of the production process (D) Quality assurance of the production (D1)	EN ISO/IEC 17065 and WELMEC Guide 8.5
Conformity to EU-type based on product quality assurance (E) Quality assurance of final product inspection and testing (E1)	EN ISO/IEC 17065
Conformity to EU- type based on product verification (F) Conformity based on product verification (F1)	EN ISO/IEC 17020 and WELMEC Guide 8.7
Conformity based on unit verification (G)	EN ISO/IEC 17065 and WELMEC Guide 8.5
Conformity based on full quality assurance (H)	EN ISO/IEC 17021
Conformity based on full quality assurance and design examination (H1)	EN ISO/IEC 17065 and WELMEC Guide 8.5

4.5.2 Use of harmonised standards and presumption of conformity

Measuring instruments that are addressed by the Directive shall comply with the essential requirements laid down in Annex I of the Directive. The measuring instruments that are in conformity with harmonised standards or a part thereof, whose references were published in the Official Journal of the EU, are presumed to conform to the essential requirements from Annex I of the Directive.

4.5.3 Requirements to be checked in the assessment

In the assessment, all the relevant requirements of the accreditation standard and, where relevant, of WELMEC Guides 8.5 and 8.7, respectively, for the scope of activity of the notified body shall be checked for compliance, taking into account the provisions of Directive 2014/32/EU, Article 27. In addition, compliance to the following requirements set out in Directive 2014/32/EU shall be checked:

– affixing of CE marking and other metrology markings according to the requirements of the Directive (Article 21);
– including subcontractors;
– including an accredited in-house body – impartiality, separation, supplying services (Article 30);
– participating in the relevant standardisation activities, as well as the activities of the Coordination Group of Notified Bodies NoBoMet, or ensuring that the notified bodies' personnel competent for carrying out conformity assessment tasks are informed of these activities. The notified bodies shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group (Article 40 of the Directive 2014/32/EU);
– informing the notifying authority (the ministry responsible for economy) of any refusals, restrictions, suspensions or withdrawals of a certificate or approval decisions; any circumstances

affecting the scope of or the conditions for notification; any request for information on conformity assessment activities, which they have received from market surveillance authorities; and, on request, any conformity assessment activities performed within the scope of their notification, as well as any other activities performed, including cross-border activities and subcontracting; in accordance with Article 38 of the Directive 2014/32/EU, and in the case where certain tasks related to conformity assessment are subcontracted, in accordance with Article 29 of the Directive 2014/32/EU, and when an accredited in-house body is included in the conformity assessment activities as per Article 30 of the Directive;

– in accordance with the provisions of Article 38(2) of the Directive, the notified body shall provide the other notified bodies carrying out similar conformity assessment activities covering the same type measuring instruments, with relevant information on issues relating to negative and, on request, positive conformity assessment results.

4.5.4 Vertical audits

At the initial assessment in individual scheme, the assessors shall assess through vertical audits at least one procedure for individual conformity assessment module. The selection shall also include cases of multi-site organisations, cases of cross border certification activities, as well as initial and surveillance inspections/audits. Within the framework of one accreditation cycle, the procedures for all groups of products for individual accreditation standard from the scope of accreditation shall be looked at through vertical audit.

4.5.5 Witnessing of conformity assessment procedures

At least one conformity assessment procedure for individual accreditation standard shall be witnessed on-site within the framework of initial assessment of the CAB. Within the framework of one accreditation cycle (three surveillances and one re-assessment) the witnessing shall be carried out as planned in the Witnessing Plan, which is drawn up after the grant of accreditation. When selecting the certification procedure to be witnessed, the rule that not the same auditors should be witnessed or that the witnessing should not be performed in the same organisation shall be followed (if possible).

4.6 Regulation (EU) 2016/425 on personal protective equipment (PPE)

The ministry responsible for economy issued "Guidelines on setting up and notification of conformity assessment bodies in the field of personal protective equipment", April 2023 [17].

4.6.1 Accreditation standard

In the field of personal protection equipment, the accreditation standard EN ISO/IEC 17065 shall be used for individual modules:

Moduli	Standard
EU-type examination (B)	EN ISO/IEC 17065
Conformity to EU-type based on internal production control plus supervised product checks at random intervals (C2)	EN ISO/IEC 17065
Conformity to EU-type based on quality assurance of the production process (D)	EN ISO/IEC 17065

4.6.2 Use of harmonised standards and presumption of conformity

Personal protection equipment that is addressed by the Regulation shall comply with the essential health and safety requirements laid down in Annex II of the Regulation. The personal protection equipment that is in conformity with harmonised standards or a part thereof (their list is available at https://www.gov.si/teme/osebna-varovalna-oprema), whose references were published in the Official Journal of the EU, are presumed to conform to the essential safety requirements from Annex II of the Regulation, comprised in standards or parts thereof.

4.6.3 Requirements to be checked in the assessment

In the assessment, all the relevant requirements of the accreditation standard for the scope of activity of the notified body shall be checked for compliance, taking into account the provisions of Regulation (EU) 2016/425, Articles 24, 26, 32 and 34. In addition, compliance to the following requirements set out in Regulation (EU) 2016/425 shall be checked:

– affixing of CE marking and other markings according to the requirements of Regulation (EU) 2016/425 (Article 17);
– including subcontractors (Article 26);
– participating in the relevant standardisation activities, as well as the activities of the Coordination Group of Notified Bodies NoBoMet, or ensuring that the notified bodies' personnel competent for carrying out conformity assessment tasks are informed of these activities. The notified bodies shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group (Article 36 of Regulation (EU) 2016/425);
– informing the notifying authority (the ministry responsible for economy) of any refusals, restrictions, suspensions, withdrawals of a certificate; any circumstances affecting the scope of or the conditions for notification; any request for information on conformity assessment activities, which they have received from market surveillance authorities; and, on request, any conformity assessment activities performed within the scope of their notification, as well as any other activities performed, including cross-border activities and subcontracting, in accordance with the provisions of Article 34 of Regulation (EU) 2016/425, and when certain tasks related to conformity assessment are subcontracted, in accordance with Article 26 of Regulation (EU) 2016/425.

4.6.4 Vertical audits

At the initial assessment in individual scheme, the assessors shall assess through vertical audits at least one procedure for individual conformity assessment module. The selection shall also take into account cases of multi-site organisations, cases of cross border certification activities, as well as initial and surveillance inspections/audits. Within the framework of one accreditation cycle, the procedures for all groups of products from the scope of accreditation shall be looked at through vertical audit.

4.6.5 Witnessing of conformity assessment procedures

At least one conformity assessment procedure shall be witnessed on-site within the framework of initial assessment of the CAB. Within the framework of one accreditation cycle (three surveillances and one re-assessment), the witnessing shall be carried out as planned in the Witnessing Plan, which is drawn up after the grant of accreditation. When selecting the certification procedure to be witnessed, the rule

that not the same auditors should be witnessed or that the witnessing should not be performed in the same organisation shall be followed (if possible).

4.7 Directive 2014/53/EU on making available on the market of radio equipment (RED)

The ministry responsible for economy issued "Guidelines setting up and notification of conformity assessment bodies based on the Act Regulating Technical Requirements for Products and Conformity Assessment (ZTPUS-1) and Rules on radio equipment (Directive (EU) 2014/53)", April 2023 [18].

4.7.1 Accreditation standards

In the field of radio equipment, the following accreditation standards shall be used for individual modules:

Modules	Standard
EU-type examination (module B)	EN ISO/IEC 17065
Conformity based on full quality assurance (module H)	EN ISO/IEC 17021-1

4.7.2 Use of harmonised standards and presumption of conformity

Radio equipment that is addressed by the Directive shall comply with the essential requirements laid down in Article 3 of the Directive. The radio equipment that is in conformity with harmonised standards or a part thereof (available at https://www.gov.si/teme/radijska-oprema), whose references were published in the Official Journal of the EU, are presumed to conform to the essential safety requirements from Article 3 of the Directive.

4.7.3 Requirements to be checked in the assessment

In the assessment, all the relevant requirements of the accreditation standard for the scope of activity of the notified body shall be checked for compliance, taking into account the provisions of Directive 2014/53/EU, Articles 26, 28, 34 and 37. In addition, compliance to the following requirements set out in Directive 2014/53/EU on availability of radio equipment shall be checked:

– affixing of CE marking and other metrology markings according to the requirements of the Directive (Article 20);
– including subcontractors;
– participating in the relevant standardisation activities, as well as the activities of the Coordination Group of Notified Bodies NoBoMet, or ensuring that the notified bodies' personnel competent for carrying out conformity assessment tasks are informed of these activities. The notified bodies shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group (Article 26 of the Directive);
– informing the notifying authority (the ministry responsible for economy) of any refusals, restrictions, suspensions, withdrawals of a certificate or approval decisions; any circumstances affecting the scope of or the conditions for notification; any request for information on conformity assessment activities, which they have received from market surveillance authorities; and, on request, any conformity assessment activities performed within the scope of their notification, as well as any other activities performed, including cross-border activities and subcontracting, in accordance with

the provisions of Article 36 of Directive 2014/53/EU, and when certain tasks related to conformity assessment are subcontracted, in accordance with Article 28 of Directive 2014/53/EU;

– in accordance with the provisions of Article 36(2) of the Directive, the notified body shall provide the other notified bodies carrying out similar conformity assessment activities covering the same categories of measuring instruments, with relevant information on issues relating to negative and, on request, positive conformity assessment results.

4.7.4 Vertical audits

At the initial assessment in individual scheme, the assessors shall assess through vertical audits at least one procedure for individual conformity assessment module. The selection shall also take into account cases of multi-site organisations, cases of cross border certification activities, as well as initial and surveillance inspections/audits. Within the framework of one accreditation cycle, the procedures for all groups of products for individual accreditation standard from the scope of accreditation shall be looked at through vertical audit.

4.7.5 Witnessing of conformity assessment procedures

At least one conformity assessment procedure shall be witnessed on-site within the framework of initial assessment of the CAB. Within the framework of one accreditation cycle (three surveillances and one re-assessment), the witnessing shall be carried out as planned in the Witnessing Plan, which is drawn up after the grant of accreditation. When selecting the certification procedure to be witnessed, the rule that not the same auditors should be witnessed or that the witnessing should not be performed in the same organisation shall be followed (if possible).

5 RECORDS

Each assessor shall make records of the assessment carried out into an appropriate checklist, specifying the scope and the assessment method of individual system elements against the requirements of the relevant standard, scheme and any guides, as well as any general findings and special comments, and references to the nonconformities found. The precise specification of the field (e.g. system, product, harmonised technical specification, object of inspection) shall be of particular importance for the vertical audits carried out.

The assessors of certification bodies shall also draw up a Witness Audit Report (OB05-43). The report shall be prepared separately for each witnessed procedure.

6 CHANGES WITH REGARD TO PREVIOUS REVISION

In Chapter 2, new normative documents have been added to be used in accreditation procedures for notification purposes.

The name of the notification authority has been generalised in several cases.

In Chapter 4.3, rules on implementation of vertical audit have been added.

Chapters 4.4 to 4.7 have been added to define the rules for assessing the CABs wishing to obtain accreditation / being accredited for notification purposes under MID, NAWI, RED Directives and PPE Regulation.

In Chapter 9, reference documents have been updated.

7 TRANSITORY PROVISIONS

N/A

8 CONTROL OF THE DOCUMENT

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

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

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

9 REFERENCE DOCUMENTS

[1] Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC with amendments, available at: http://eur-ex.europa.eu/eli/reg/2011/305

[2] Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC

[3] Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts

[4] Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments

[5] Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments, with amendments available on https://eur-lex.europa.eu/eli/dir/2014/32

[6] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC, with amendments available on https://eur-lex.europa.eu/eli/dir/2014/53

[7] Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC, with amendments

available on https://eur-lex.europa.eu/legal-content/SL/TXT/?uri=CELEX%3A02016R0425-20160331&qid=1689668402788

[8] Official Journal of the European Union, C 247, 29 June 2022 – “Blue Guide” on the implementation of EU product rules 2022

[9] EA-2/17 M:2020 – EA Document on Accreditation for Notification Purposes

[10] Guidelines on setting up and notification of bodies for the assessment and verification of constancy of performance of construction products, Ministry of the Economy, Tourism and Sport, June 2022 (https://www.gov.si/assets/ministrstva/MGRT/Dokumenti/DNT/Proizvodi-na-notranjem-trgu/Gradbeni-proizvodi/Smernice-za-priglasitev-organov.pdf)

[11] SIST EN ISO/IEC 17065:2012, Conformity assessment – Requirements for bodies certifying products, processes and services (ISO/IEC 17065:2012)

[12] Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 oninland transport of dangerous goods: Annex I, Transport by Road, I.1 ADR; Annex II, Transport by Rail, II.1 RID with amendments, accessible on https://eur-lex.europa.eu/eli/dir/2008/68

[13] SIST EN ISO/IEC 17020:2012, Conformity assessment – Requirements for the operation of various types of bodies performing inspection (ISO/IEC 17020:2012)

[14] Guidelines on setting up and notification of bodies for the assessment of conformity based on the Technical Requirements for Products and Conformity Assessment Act (ZTZPUS-1) and the Rules on lift safety (Directive 2014/33/EU), Ministry of the Economy, Tourism and Sport, March 2021 (https://www.gov.si/teme/varnost-dvigal/)

[15] Guidelines on setting up and notification of bodies for the assessment of conformity based on the Technical Requirements for Products and Conformity Assessment Act (ZTZPUS-1) and the Rules on metrological requirements for non-automatic weighing instruments (Directive (EU) 2014/31), Ministry of the Economy, Tourism and Sport, January 2023 (https://www.gov.si/teme/harmonizirano-podrocje-proizvodov/)

[16] Guidelines on setting up and notification of bodies for the assessment of conformity based on the Technical Requirements for Products and Conformity Assessment Act (ZTZPUS-1) and the Rules on measuring instruments (Directive (EU) 2014/32), Ministry of the Economy, Tourism and Sport, January 2023 (https://www.gov.si/teme/harmonizirano-podrocje-proizvodov/)

[17] Guidelines on setting up and notification of bodies for the assessment of conformity in the field of personal protection equipment, Ministry of the Economy, Tourism and Sport, February 2023 (https://www.gov.si/teme/osebna-varovalna-oprema/)

[18] Guidelines on setting up and notification of bodies for the assessment of conformity based on the Technical Requirements for Products and Conformity Assessment Act (ZTZPUS-1) and the Rules on radio equipment (Directive (EU) 2014/53), Ministry of the Economy, Tourism and Sport, April 2023 (https://www.gov.si/teme/radijska-oprema/)