General requirements and guidelines for the accreditation of conformity assessment bodies with activities as notified bodies

This document may need to be complemented with a document of the BELAC 2-405 series for a specific Community Harmonization Legislation

The only valid versions of the documents of the BELAC management system are those available from the internet website (www.belac.be)
English translation for information only
French and Dutch version remain the authoritative documents

Date of implementation: 01.10.2020

Note : Accredited bodies with activities as notified body shall use the preferred standard by 01.04.2023 at the latest.

must use the most appropriate accreditation standard as the basis for the accreditation for the purpose of application by 01.04.2023

HISTORY OF THE DOCUMENT

Revision and date of approval	Reason for revision	Extent of revision
0 **CC 10.12.2009**	Integration of EA-2/17 in the BELAC documentation	
1 **Written procedure** **CC 19.04.2016**	Integration of annex B of EA-2/17 Revision May 2015 in the BELAC documentation	Full document
2 **CC 20.04.2017 +** **Written procedure** **12.06.2017**	Integration of EA- 2/17 (revision November 2016) in the BELAC documentation	Full document
3 **CC 29.06.2020**	Integration of the requirements of EA-2/17 revision April 2020 in the BELAC management system documentation	Full document

General requirements and guidelines for the accreditation of conformity assessment bodies with activities as notified bodies

1. AIM OF DOCUMENT AND REFERENCES

The present document aims to further specify the general requirements and guidelines relevant for the accreditation of conformity assessment bodies performing conformity assessment tasks as notified bodies within the framework of the Community Harmonization Legislation.

This document applies to the accreditation of bodies performing activities as notified bodies in the framework of European Directives and Regulations which follow the New Legislative Framework wich are aligned with Decision EC 768/2008. It shall also be applied to other Directives and Regulations (e.g Assessment and Verification of Constancy of Performance under the Construction Products Regulation – see annex F for details – or the modules for the Railways Interoperability Directive (EU) 2016/797 which are not aligned with Decision (EC) 768/2008[1]; in these cases further guidance may be needed .

This document applies only when accreditation is used by National Notifying Authorities to support its notification decision. The Accreditation Body does not assume the responsibility of the Notifying Authority. It is acknowledged that accreditation and notification are two different activities which are performed separately.

Decision EC 768/2008 defines the general framework for the notification of conformity assessment bodies according to the Community Harmonization Legislation. The specific requirements to be complied with by the notified bodies are defined in each Community Harmonization Legislation. The main purpose of accreditation when used as a tool to support notification is to give confidence to the national notifying authorities on :

1) the competence, impartiality and consistent performance of the Notified Body to perform the tasks it is notified for ;
2) the fulfillment by the notified body of the requirements established by each Community Harmonization Legislation..

Within the remit of this document, the wording « notified bodies » include all conformity assessment bodies having applied for notification or already notified for the performance of activities within the framework of the Community Harmonization Legislation.

The present document complies with and refers to :

- the European and national provisions with respect to the notification of conformity assessment bodies;
- the recommendations of the Blue Guide version 2016 issued by the European Commission;
- the provisions of the document EA-2/17 version April 2020 : “Accreditation for Notification Purposes”.

[1] https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

2. TERMS AND DEFINITIONS

2.1 Accreditation: *an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity [article 2 (10) Regulation EC 765/2008]*

2.2 National accreditation body: *the sole body in a Member State that performs accreditation with authority derived from the State [article 2 (11) Regulation EC 765/2008]*

2.3 Conformity assessment *: the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled [article 2 (12) Regulation EC 765/2008]*

2.4 Conformity assessment body*: a body that performs conformity assessment activities including calibration, testing, certification and inspection [article 2 (16) Regulation EC 765/2008]*

2.5 Notified body: *conformity assessment body notified by a member State to the Commission and to the other Member states as being authorized to perform conformity assessment tasks according to the Community harmonisation legislation* [Decision EC 768/2008].
In the context of this document, the term "notified body" is used for

- *all conformity assessment bodies which are seeking notification or which are already notified ;*
- *bodies performing third party Assessment and Verification of Constancy of Performance under the Construction Products Regulation.*

2.6 Harmonised standard*: a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services on the basis of a request made by the Commission in accordance with Article 6 of that Directive [article 2 (9) Regulation EC 765/2008]*
In the context of this document, the term "notified body" is used for

- *all conformity assessment bodies which are seeking notification or which are already notified ;*
- *bodies performing third party Assessment and Verification of Constancy of Performance under the Construction Products Regulation.*
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2.7 Community harmonisation legislation*: any Community legislation harmonising the conditions for the marketing of products [article 2 (21) Regulation EC 765/2008]*

2.8 Aligned:
The term aligned is used in this document to identify legislation that uses the modules defined in Decision (EC) 768/2008

3 RECIPIENTS

With follow-up of modifications:	Co-ordination Commission Accreditation Board Secretariat Assessors Accredited bodies
Without follow-up of modifications:	Experts Any external request

4. GENERAL REQUIREMENTS FOR THE ACCREDITATION OF CONFORMITY ASESSMENTS BODIES PERFORMING ACTIVITIES AS NOTIFIED BOIES

4.1 Principles

The specific requirements to be fulfilled by NBs are established in each Community harmonization Legislation.

To be accredited, Notified Bodies shall be assessed by BELAC using:

1) one harmonized standard appropriate for the concerned conformity assessment

It is widely accepted that the conformity assessment activities described in the Community harmonization Legislation (and in particular modules defined in Decision (EC) 768/2008), are not described in a way which fits exactly with the descriptions in the accreditation standards.
This means that some of these standards have to be supplemented by "additional requirements".

Tables in annex A identify the most appropriate accreditation standard per module and legislation. The first table covers aligned legislations but also non-aligned legislations which include a module corresponding to a module of Decision (EC) 768/2008. The second table covers non-aligned legislations including a specific attestation module not directly corresponding to a standard module.
Tables in annex B identify the complementary requirements of other accreditation standards which shall be taken into account to support the requirements of the main standard and shall allow, per module, an appropriate assessment of the competence and level of performance of the notified body.

2) The requirements for Notified Bodies included in the relevant Harmonization legislation, i.e. :

- the general requirements of Decision EU 768.2008: see annex A for more details ;
- the specific requirements of the concerned Directive or Regulation (lifts, construction products …)
- the harmonized technical standards applicable for the concerned Directive or Regulation.

4.2 Selection of the accreditation standard(s) to be used for the assessment of a notified body

4.2.1 The tables in annexes A and B identify the most appropriate accreditation standard (as well as the relevant additional requirements) to assess the competence of a notified body in function of the concerned type of conformity assessment.

4.2.2 BELAC uses the most appropriate accreditation standard as the basis for accreditation for notification. Any accreditation not using this preferred standard is an exception that can only be justified by the existence of a binding requirement for the notified body, published by the notifying authority; the selected accreditation standard shall comply with one of the possibilities documented in annex B. BELAC maintain records with justification of these exceptions.

For aligned Directives and Regulations and as well as for the CPR Regulation, the corresponding additional requirements included in annex B have to be fulfilled in any case even if another accreditation standard is used.
For non-aligned Directives and Regulations, the additional requirements in annex B are considered on a case-by-case basis.

4.2.3 Whenever felt necessary, BELAC further specifies the provisions for accreditation in view of notification in a document of the 2-405-xxx series for the concerned Community harmonization Legislation. The document 2-405-xxx includes, whenever relevant, the specific requirements derived from the transposition of the European Legislation into a national legislation.

4.3 Use of the Notified Bodies Coordination Group Documents

Article R17 § 11 of Decision (EC) 768/2008 establishes the principle that notified bodies shall

- participate in or inform their assessment personnel of the activities of the corresponding Notified Body Coordination Group established for the legislation they are concerned with;
- apply their administrative decisions and documents as general guidance .

Therefore, BELAC assessors performing assessments of conformity assessment bodies as a basis for notification shall be well aware and informed of the decisions and documents of the Notified Coordination Group documents.

5. DESCRIPTION OF THE ACCREDITATION SCOPE OF NOTIFIED BODIES.

5.1 General principles

The following should be considered when defining scopes of accreditation for notification purposes:

1) the needs of the persons using information (primarily the customers of the NBs)
2) the needs of the notifying authorities
3) the type of data needed as input to the NANDO database
4) the conformity to EN ISO/IEC 17011 and the relevant Harmonized Standards for Conformity Assessment Bodies as well as the other applicable requirements for bodies seeking for a notification.

5.2 Main elements to be included in the scope

a) Harmonized Standard which is used as reference and applied in full for the accreditation of the CAB;
b) the identification of the directive or regulation (complemented, if requested by a Notifying Authority, with a reference to the national regulations);
c) the conformity assessment procedure used (module, article or annexes, and systems of a particular directive/regulation);
d) products/category – family – homogeneous groups of products – categories of products ;
e) product specification (harmonized product standard, other standard or technical documents) as appropriate or product characteristics as set out in relevant legislation.

Where possible, the accreditation scope should use the same wording as used by NANDO. Additionally, the accreditation scope can also include other information if required by the notifying authority , the relevant legislation or mandatory documents if deemed necessary due to other circumstances.

5.3 These general provisions may need to be complemented with provisions described in a document of the BELAC 2-405 xxx series for a specific Community harmonization Legislation.

5.4 Examples: see under annex F

ANNEX A: PREFERRED STANDARD PER LEGISLATION (mandatory)

Note: The column in table 1 entitled "other references equivalent to this module" covers non-aligned directives where there is a corresponding module covering the same process as described in Decision (EC) 768/2008. Table 2 covers non-aligned where there are specific attestation modules that do not directly align with the modules described in decision (EC) 768/2008.

Table 1: Preferred standards for Aligned Directives/Regulations and related Conformity Assessments Activities:

Module		Other references equivalent to this module	Preferred Standard	Exceptions
A1	Internal production control plus supervised product testing		ISO/IEC 17020	
A2	Internal production control plus supervised product checks at random intervals		ISO/IEC 17020	Measuring Instruments Directive No 2014/32/EU: ISO/IEC 17065
B	EU Type Examination	Machinery Directive No 2006/42 EC- Annex IX; In vitro diagnostic medical devices (IVDMD) Directive No 98/79/EC Annex V; Active implantable medical devices (AIMD) Directive No 90/385/EEC Annex III;	ISO/IEC 17065	
C	Conformity to EU-type based on internal production control		ISO/IEC 17020 (SPV) ISO/IEC 17065 (HWB)	Module C does not require a NB with the exception of: Simple Pressure Vessels Directive No. 2014/29/EU (SPV) Hot-Water Boilers Directive No. 92/42/EEC (HWB)
C1	Conformity to EU-type based on internal production control plus supervised product testing		ISO/IEC 17065	Recreational craft and personal watercraft (RCD) Directive no 2013/53/EU: ISO/IEC 17020
C2	Conformity to EU-type based on internal production control plus supervised product checks at random intervals		ISO/IEC 17065	
D	Conformity to EU-type based on quality assurance of the production process		ISO/IEC 17065	
D1	Quality assurance of the production process		ISO/IEC 17065	

Module		Other references equivalent to this module	Preferred Standard	Exceptions
E	Conformity to EU-type based on product quality assurance		ISO/IEC 17065	
E1	Quality assurance of final product inspection and testing		ISO/IEC 17065	
F	Conformity to EU-type based on product verification	Lifts and safety components for lifts Directive No: 2014/33/EC Annex V Final Inspection	ISO/IEC 17065	Lifts and safety components for lifts Directive No: 2014/33/EC ISO/IEC 17020
F1	Conformity based on product verification		ISO/IEC 17065	
G	Conformity based on unit verification	Noise emission in the environment by equipment for use outdoors Directive No 2000/14/EC Annex VII	ISO/IEC 17065	
H	Conformity based on full quality assurance	Machinery Directive No 2006/42/EC Annex X; Noise emission in the environment by equipment for use outdoors Directive No 2000/14/EC Annex VIII In vitro diagnostic medical devices (IVDMD) Directive No 98/79/EC Annex IV; Active implantable medical devices (AIMD) Directive No 90/385/EEC Annex II;	ISO/IEC 17021-1	
H1	Conformity based on full quality assurance plus design examination		ISO/IEC 17065	

Table 2: Preferred Standards for Non-Aligned Directives/Regulations and Conformity Assessment Activities, where there is no direct equivalent with the modules described in decision (EC) 768/2008:

Directive	Conformity assessment procedure	Preferred Standard
2014/68/EU Pressure equipment (PED)	Approval of NDT personnel	ISO/IEC 17024
	Approval of Permanent Joining Personnel	ISO/IEC 17024
	Approval of Permanent Joining Procedures	ISO/IEC 17020
	European Approval of Materials	ISO/IEC 17065
Construction Product Regulation (EU) No 305/2011 (CPR) (*see Annex E for details*)	System 1	ISO/IEC 17065
	System 1+	ISO/IEC 17065
	System 2+	ISO/IEC 17065
	System 3	ISO/IEC 17025
98/79/EC In vitro diagnostic medical devices (IVDMD)	Annex III EC Declaration of Conformity	ISO/IEC 17065
	Annex VI EC Verification	ISO/IEC 17065
	Annex VII EC Declaration of Conformity (Production quality assurance)	ISO/IEC 17065
90/385/EEC Active implantable medical devices (AIMD) modified by Directive No 93/42/EEC, 93/68/EEC and 2007/47/EC	Annex IV EC Verification	ISO/IEC 17065
	Annex V EC Declaration of Conformity to Type (Assurance of production quality)	ISO/IEC 17065
93/42/EEC Medical Devices	Annex IV EC verification	ISO/IEC 17065
	Annex V EC Declaration of Conformity - Production Quality Assurance	ISO/IEC 17065

	Annex VI EC Declaration of Conformity – Product Quality Assurance	ISO/IEC 17065
2000/14/EC Noise emission in the environment by equipment for use outdoors	Annex VI Internal control of production with assessment of technical documentation and periodical checking	ISO/IEC 17065
2010/35/EU Transportable pressure equipment (TPED)	Type Approval	ISO/IEC 17020:2012 (except clause 8.1.3)
	Supervision of manufacture and Initial Inspection and Tests	ISO/IEC 17020:2012 (except clause 8.1.3)
	Periodic Inspections, Intermediate Inspections and Exceptional Inspection	ISO/IEC 17020:2012 (except clause 8.1.3)
	Surveillance of the inhouse inspection service	ISO/IEC 17020:2012 (except clause 8.1.3)
	Reassessment of conformity	ISO/IEC 17020:2012 (except clause 8.1.3)
2013/53/EU Recreational craft and personal watercraft (RCD)	PCA – Post construction assessment	ISO/IEC 17065
Railways Interoperability Directive (EU) 2016/797 (IOD)	All modules in accordance with Decision 2010/713/EU in conjunction with the ERA Mandatory Technical Document 000MRA1044.	ISO/IEC 17065

ANNEX B: APPLICABILITY OF ACCREDITATION STANDARDS (mandatory)

Table 3: Conformity Assessment Standards for Accreditation for Notification Purposes including Applicable Additional requirements:

Module	Description	ISO/IEC 17065	ISO/IEC 17020	ISO/IEC 17021-1	ISO/IEC 17025
A	Internal production control	n.a	n.a	n.a	n.a
A1	Internal production control plus supervised product testing	1 + t	***1+ t + cd**		1 + cd
A2	Internal production control plus supervised product checks at random intervals	1 + t	***1 + t + cd**		1 + cd
B	EC type examination	***1 + t + pk**	1 + t + cd		
C	Conformity to type based on internal production control	n.a	n.a	n.a	n.a
C1	Conformity to type based on internal production control plus supervised product testing	***1 + t + pk**	1 + t + cd		1 + cd + pk
C2	Conformity to type based on internal production control plus supervised product checks at random intervals	***1 + t + pk**	1 + t + cd		1 + cd + pk
D	Conformity to type based on quality assurance of the production process	***1 + qa**	1 + qa	1 + pk	
D1	Quality assurance of the production process	***1 + qa**	1 + qa	1 + pk	
E	Conformity to type based on product quality assurance	***1 + qa**	1 + qa	1 + pk	
E1	Quality assurance of final product inspection and testing	***1 + qa**	1 + qa	1 + pk	
F	Conformity with type based on product verification	***1 + t + pk**	1 + t + cd		
F1	Conformity based on product verification	***1 + t + pk**	1 + t + cd		
G	Conformity based on unit verification	***1 + t + pk**	1 + t + cd		
H	Conformity based on full quality assurance	1 + qa	1+ qa	***1 + pk**	
H1	Conformity based on full quality assurance plus design examination	***1 + qa**	1 + qa	1 + pk	

Table 4: Conformity Assessment Standards for Accreditation for Notification purposes incl. Applicable Additional Requirements in the Area of the Construction Products Regulation:

AVCP-System (see Annex E)	Description	EN ISO/IEC 17065	EN ISO/ IEC 17025
1+	determination of the product-type, initial inspection of factory production control, continuous surveillance of factory production control, audit-testing of samples	* 1 + t + pk	
1	determination of the product-type, initial inspection of factory production control, continuous surveillance of factory production control	* 1 + t + pk	
2+	initial inspection of factory production control, continuous surveillance of factory production control	* 1 + pk	
3	determination of the product-type		1

Key for reading:

***** The most appropriate accreditation standard to be used

1 The accreditation standard that can be used for accreditation.

+ Additional applicable requirements of the other pertaining accreditation standards used for assessing the notified body:

t Additional applicable requirements of EN ISO/IEC 17025:217 if testing is required. To this end fulfilment of the applicable requirements of clauses 6 and 7 (with the exception of 7.9) shall be demonstrated.

cd **C**apability of and procedures for judging and **d**eciding based on results of tests and/or inspections, if the essential requirements are fulfilled and / or the Harmonized Standards have been applied when required. To this end, fulfillment of clauses 4.1.2, 4.1.3, 7.5 and 7.6 in EN ISO/IEC 17065:2012 shall be demonstrated.

pk Ability to make professional judgments related to product requirements where required. To this end fulfilment of clauses 6.1.2, 6.1.3 and 6.1.6 to 6.1.10 in EN ISO/IEC 17020:2012 shall be demonstrated.

qa Ability to assess and approve manufacturer's quality systems where required. To this end, fulfillment of clauses 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10, 9.1, 9.2, 9.4, 9.6 in EN ISO/IEC 17021-1 :2015 shall be demonstrated.

Notes :

1. It is noted that the detailed requirements taken from the "+" standards will vary according to the level of coverage of that requirement within the baseline standard being used. In cases where the requirements of the baseline standard go beyond the requirements taken from the "+" standard the requirements of the baseline standard will always prevail.

2. For EN ISO/IEC 17020, only Type A inspection bodies are valid for a Notified Body activity, unless otherwise stated in the Legislation (for example user inspectorate under PED). For EN ISO/IEC 17025, the requirements to be an independent third-party with absence of conflict of

interest as laid down in the corresponding legislation must be fulfilled. For EN ISO/IEC 17020 and EN ISO/IEC 17025 the requirements for follow up and surveillance as laid down in the corresponding legislation must also be fulfilled.

3. It should be noted that in addition to the above table, EN ISO/IEC 17024 shall be used in certain specific cases (for example PED Approval of Permanent Joining Personnel).

4. Notified Bodies shall take into account the relevant IAF MD documents while assessing quality management system-based modules e.g. Modules D, E and their derivatives as long as there are no other specific requirements of the corresponding notified body coordination group in this regard. For module H and its derivatives Notified Bodies shall comply with the relevant IAF MD documents.

ANNEX C : CRITERIA FOR SELECTING WITNESSING (mandatory)

When planning and deciding on the required witnessing for an assessment the following principles shall be taken into consideration:

1. When applying to a complete assessment (e.g. an initial assessment or extension to scope in new areas), or during the accreditation cycle, the assessment shall cover all sectors (i.e all concerned legislations).

2. The assessment shall include file review and witnessing of activities (where relevant) for all concerned modules and types of products.

3. If some modules of one regulation/directive are very similar, the assessment might be limited to one or some of them (principle 3, see tables 5 and 6 below), in which case the more complex should be chosen.

4. It is considered highly unlikely that witnessing of the activities under different directives/regulations can be effectively combined in a single witness. When this is considered, the reasons and justification for taking such an approach shall be documented.

5. Witnessing is normally to be performed in advance of granting, or extending, the accreditation for a new conformity assessment activity. The accreditation may however be granted under conditions (see BELAC 3-11 point 2.10.3)

The selection and the number of witnessing activities during an accreditation cycle depends on various other parameters including:

- Number of technical staff involved in a specific conformity assessment activity,
- Changes to staff,
- Extensions to scope,
- Changes to relevant equipment, test methods or harmonised product standard (especially in relation to EN ISO/IEC 17025 accreditation) used for the conformity assessment,
- Existing demonstrated competence in the type of products and similar legislation

The following tables shall be used as guidance for grouping of modules, and deviations shall be justified:

Table 5: Modules of Decision 768/2008/EC that when witnessed, can provide assurance of competence to other modules where accreditation is sought:

Module to be included in the scope	Description of the module	Witnessing required
A1	Internal production control and supervised product testing	A1 or A2 or C1 or C2 or B or F or G
A2	Internal control of production and supervised product controls at random intervals	
B	Type examination	B
C	Conformity with type based on internal production control	C or D or E or H or A1 or A2 or C1 or C2 or D1 or E1 or H1
C1	Conformity to type based on internal production control and supervised product testing	C1 or C2 or A1 or A2 or B or F or G
C2	Conformity with type based on internal production control and supervised product controls at random intervals	
D	Conformity to type based on quality assurance of the production process	D or D1 or H or H1 or E or E1
D1	Quality assurance of the production process	D1 or H1 or E1
E	Conformity to type based on product quality assurance	E or E1 or D or D1 or H or H1
E1	Quality Assurance of Final Product Inspection and Testing	E1 or D1 or H1
F	Conformity to type based on product verification	F or F1 or G
F1	Conformity based on product verification	F1 or G or B
G	Conformity based on unit verification	G or F1 or B
H	Conformity based on full quality assurance	H or H1
H1	Conformity based on full quality assurance and design control	H1

Table 6: Systems of AVCP of Reulation (EU) 305/2011 that when witnessed, can provide assurance of competence to other AVCP-systems where accreditation is sought:

AVCP-System (*see Annex E*) to be included in the scope	Witnessing required
1+	1+
1	1 or 1+
2+	2+ or 1 or 1+
3	This is under ISO/IEC 17025 / testing, so witnessing or file review is included in the office assessment

ANNEX D:

CROSS REFERENCE BETWEEN THE SPECIFIC REQUIREMENTS OF DECISION EC 768/2008 FOR NOTIFIED BODIES AND THE CLAUSES OF THE ACCREDITATION STANDARDS (informative).

Preamble :

The reference to the clauses of the accreditation standards indicated in this part of the document are only intended to provide a link with the accreditation standards. The following principles have been used:

- Repetition of the criteria mentioned in Decision EC 768/2008 that are already included in all accreditation standards has been avoided ;
- The document includes those criteria not included in all accreditation standards. It therefore includes criteria not covered by any of the accreditation standards or only by some of them.

The evaluation of the competence of a body with the view to grant an accreditation as support for a notification process will include all criteria mentioned in this document and relevant for the concerned modules .

Table 6: Map of HS Requirements

Provisions laid down in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025: 2017	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1: 2015	EN ISO/IEC 17024: 2012
(1)	(2)	(3)	(4)	(5)	(6)
GENERAL REQUIREMENTS					
Legal and contractual matters					
R17.2 : *A notified body shall be established under national law and have legal personality.*	4.1.1	5.1	5.1.1	5.1.1	4.1
Management of impartiality					

Provisions laid down in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025: 2017	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1: 2015	EN ISO/IEC 17024: 2012
(1)	(2)	(3)	(4)	(5)	(6)
R17.3 : *A notified body shall be a third-party body independent from the organization or the product it assesses.* *A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of 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.*	4.2	4.1	4.1.1 4.1.2 4.1.3 4.1.4 4.1.5 4.1.6a) 5.2.1 6.1.12	5.2 6.2 4.2.4	4.3.2 4.3.5 4.3.6 4.3.7 4.3.8 5.2.3
R17.4 : *A notified body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the authorized representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the Conformity Assessment Body or the use of the products for personal purposes.* *A notified body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, nor represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgment or integrity in relation to conformity assessment activities for which they are notified. This applies in particular to consultancy services.*	4.2	4.1.1 to 4.1.4	4.1.1 4.1.2 4.1.3 4.1.4 4.1.5 4.1.6a) 5.2.1 6.1.12	5.2 4.2.4	4.3.2 4.3.5 4.3.6 5.2.1 5.2.3 6.2.1

Provisions laid down in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1 : 2015	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)
R17.4 : *Notified bodies shall ensure that activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of its conformity assessment activities.*	4.2.3 4.2.6 4.2.7 4.2.8 6.2.2	6.6.2	6.3.1 6.1.12 6.1.13	4.6 5.2.3 5.2.5 5.2.6 ? 5.2.7 ? 5.2.11 5.2.12 7.5.1 7.5.3b),c) 8.4	4.3.6 4.3.7 5.1.1 5.2.3 6.3 7.3.5
R17.5 : *Notified bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of their conformity assessment activities, especially from persons or groups of persons with an interest in the results of those activities.*	4.2.2 4.2.3 4.2.5 4.2.12 6.1.1.2 6.1.2 6.1.3	4.1.1 4.1.2 4.1.3 4.1.4	4.1.2 4.1.3 4.1.6 a) 6.1.1 6.1.2 6.1.3 6.1.11	5.2.2 7.1 7.2	4.3.5 6.1.3 6.1.6 6.1.7 6.2.1 6.2.2
R17.8 : *The impartiality of the notified body, its top level management and assessment personnel shall be guaranteed. The remuneration of the notified body's top level management and assessment personnel shall not depend on the number of assessments carried out or on the results of such assessments.*	4.2.3 4.2.4 5.2	4.1.3	4.1.2 4.1.5 4.1.6 a) 6.1.11	5.2.1 5.2.2 5.2.12	4.3.1 4.3.6
Liability and financing					
R17.9 : *Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.*	4.3	This standard does not require liability assurance	5.1.4	5.3.1	4.4
Identification number of notified bodies					
R12.3 : *The CE marking shall be followed by the identification number of the notified body where such body is involved in the production control phase.* *The identification number of the notified body shall be affixed by the body itself or under its*	This chapter reflects specific requirements on CE marking for notified bodies according to the requirements of the relevant community harmonisation legislations. Therefore, these will have to be implemented based on the				

Provisions laid down in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1 : 2015	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)
instructions, by the manufacturer or his authorized representative.	requirements in the specific legislation for which the Conformity Assessment Body wishes to be notified				
STRUCTURAL REQUIREMENTS					
Role as notified body					
R17.6(b) : *At all times and for each conformity assessment procedure and for each kind or category of products in relation to which it has been notified, a Conformity Assessment Body shall have at its disposal the necessary descriptions of procedures according to which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of these procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities.*	4.6a) 5.1.2 6.2.1 7.1.1 7.1.2 7.1.3	7.2	5.2.4 7.1.1 7.1.2 7.1.3 7.1.4	8.1.1 8.5.1	8.2 8.3 9.2.1 9.2.2 9.2.3
Cooperation with other bodies					
R17.11 : *Notified bodies shall participate in, or ensure that their assessment personnel is informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Community harmonisation legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.*	In general standards on Conformity Assessment Body Competence Criteria do not “require” cooperation with other bodies. This requirement is specific for notified bodies and is to be assessed based on the requirements of the harmonised community legislation to the degree required by such legislation.				

Provisions laid down in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1 : 2015	EN ISO/IEC 17024:2012
RESOURCE REQUIREMENTS					
Personnel					
R17.6(a) : *At all times and for each conformity assessment procedure and for each kind or category of products in relation to which it has been notified, the Conformity Assessment Body shall have at its disposal the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks.*	6.1.1.1 6.1.1.2 6.2.1	6.2.2 6.2.3	6.1.2 6.1.3	7.1 7.2	6.1.2
R17.7 : *The personnel responsible for carrying out the conformity assessment activities shall have the following:* *a) sound technical and vocational training covering all the conformity assessment activities of the relevant scope for which the Conformity Assessment Body has been notified;* *b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out such operations;* *c)appropriate knowledge and understanding of the essential requirements, of the applicable Harmonised Standards and of the relevant provisions of the relevant Community harmonisation legislation and relevant implementing regulations;* *d) the ability required to draw up the certificates, records and reports to demonstrate that the assessments have been carried out.*	6.1.1.2 6.1.2 6.2.1	6.2.2 6.2.3 6.2.6	6.1.1 6.1.2 6.1.3 6.1.8 6.1.9	7.1 7.2	6.1.3 6.2.2.1

Provisions laid down in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1 : 2015	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)
Equipment					
R17.6 : *The notified body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.*	4.3.2 6.2 7.3.1	6.3.1 à 4 6.4.1. and 6.4.2.	6.2.1 6.2.2	6.1.3 7.1.1 7.1.4 9.1.2	6.4
Outsourcing (subcontracting)					
R20.1 : *Where the notified body subcontracts specific tasks connected with the assessment of conformity or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article R17* (of the Decision (EC) 768/2008) *and inform the notifying authority.*	6.2.2.1 6.2.2.2 6.2.2.3	6.6.2.c) and d)	6.3.1	7.5.1 7.5.3 b) 7.5.4	6.3.1 6.3.2
R20.2 : *Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.*	6.2.2.4a)	7.8.2.1p 7.8.2.2	6.3.3	7.5.3a)	6.3.1 6.3.2
R20.3 : *Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.*	6.2.2.4f)	7.1.1.c)	6.3.2	7.5.1	This standard does not require agreement of the client.
R20.4 : *Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or subsidiary and the work carried out by them.*	6.2.2.1 6.2.2.4c) d)	5.4 6.6.2	6.3.4	7.5.4	6.3.2
INFORMATION REQUIREMENTS AND CONFIDENTIALITY					
Information requirements					
R28.1 : *Notified bodies shall inform the notifying authority of the following:* *1. any refusal, restriction, suspension or withdrawal of certificates;* *2. any circumstances affecting the scope of and conditions for notification;* *3. any request for information on conformity assessment activities performed which they have received from market surveillance authorities;* *4. on request, conformity assessment activities performed within the scope of their notification and, any other activity performed, including, cross-border activities and subcontracting.*	In general standards on Conformity Assessment Body Competence Criteria do not “require” information requirements with notifying authority or other bodies.er bodies. This requirement is specific for notified bodies and is to be assessed based on the requirements of the harmonised community legislation to the degree required by such legislation. When standard includes the following requirement				

Provisions laid down in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1 : 2015	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)
R28.2 : *Notified bodies shall provide the other bodies notified under the same community harmonisation legislation carrying out similar conformity assessment activities and covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results*	*"When the conformity assessment body is required by law or authorized by contractual arrangements to release confidential information, the client or person concerned shall, unless prohibited by law, be notified of the information provided"* The requirement must be assessed in relation with information requirements of directives and regulations.				
Confidentiality					
R17.10 : *The personnel of the notified body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks under the relevant community harmonisation legislation or any provision of national law giving effect to it, except in relation to the competent administrative authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.*	4.5 6.1.1.3	4.2	4.2 6.1.13	8.4	6.1.6 6.1.7 7.3.3 7.3.4
PROCESS REQUIREMENTS					
General requirements					
R17.6 : *The Conformity Assessment Body shall be capable of carrying out all the conformity assessment tasks assigned to such a body by the provisions of the relevant community harmonisation legislation and for which it has been notified, whether those tasks are carried out by the Conformity Assessment Body itself or on its behalf and under its responsibility.*	6.1.2 6.2.2 7.1.1 7.3.2 7.4.4	7.2.1.1	5.1.3 5.2.2 6.1.3 6.3 7.1.	6.2 7.1.1 7.1.2 7.2.1 7.2.2	9.2.1
R17.6 c) : *At all times and for each conformity assessment procedure and for each kind or category of products for which it is notified, the Conformity Assessment Body shall have at its disposal the necessary procedures to perform their activities taking into consideration the size, the sector, the structure of the undertakings, the degree of complexity of the product technology in question and the mass or serial nature of the production process.*	4.4 7.1.1 7.3 7.4.4 7.10.1 7.10.2	7.2.1.1	7.1.	9.1.1 9.1.2 9.1.3 9.1.4	Not applicable
Operational obligations for notified bodies					
R27.1 : *Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in the relevant community harmonisation legislation.*	7.1.2 7.4.3 7.4.4	5.3	7.1.	9.1.3 9.2	9.2.1
R27.2 : *Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. The Conformity Assessment Bodies shall perform their activities taking into consideration the size, the sector, the structure of the undertakings*	4.4 7.1. 7.4.4	7.1.1 7.1.2	7.1.	9.1.3 9.1.4 9.2	9.2.1

Provisions laid down in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1 : 2015	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)
involved, the relative complexity of the technology used by the products and the serial character of production. *In so doing they shall nevertheless respect the degree of rigor and the level of protection required for the compliance of the product by the provisions of the relevant community harmonisation legislation.*					

Provisions laid down in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1 : 2015	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)
R27.3 : *Where a notified body finds that requirements laid down in of the relevant community harmonisation legislation or corresponding Harmonised Standards or technical specifications have not been met by the manufacturer, it shall require the manufacturer to take appropriate corrective measures and it shall not deliver any conformity certificate.*	7.4.6 7.4.7 7.11.1	7.8.6	This is not part of the work of an inspection body. It can be done if requested in the specific directive	9.4.9 9.4.10 9.5 9.6.5	9.4.6
R27.4 : *Where, in the course of the monitoring of conformity following the delivery of certificate, a Notified Body finds that a product does not comply any more, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw its certificate if necessary.*	7.4.6 7.4.7 7.6.6 7.11	Monitoring of conformity after the testing or inspection has been performed and report issued, is not part of the work of a laboratory or an inspection body. This can be done if requested in the specific directive.		9.4.9- 9.4.10 9.6	8.3 9.5
R27.5 : *Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.*	7.11			9.6.5	9.5.2

ANNEX E – SPECIFIC ASPECTS OF THE CONSTRUCTION PRODUCTS REGULATION (informative)

In the area of the construction products regulation (CPR) - Regulation (EU) No 305/2011 – several aspects of the New Approach (NLF) are not applicable. As this document is also applicable for the area of the CPR, this annex E explains differences between the NLF and the CPR and tries to clarify how the document shall be used in the specific environment of the CPR.

1. Common Technical Language Approach

The expression “constancy of performance” used in the CPR has a different meaning from conformity:
Under the CPR, the constancy of performance is evaluated on the basis of harmonised technical specifications or according to European assessment documents (EAD). The EAD are technical specifications issued on the request of a manufacturer when its product is not covered or not fully covered by a harmonized standard. In some cases, only part of the requirements of the harmonized standard is used to demonstrate constancy of performance.

Under the CPR the documents issued/approved by the Group of Notified Bodies (position papers) need to be taken into account by the notified bodies.

2. Mandatory Use of Harmonized Technical Specifications

The CPR makes application of harmonised technical specification (HTS) mandatory to evaluate the constancy of performance of a product, see chapter IV of the CPR. It is not possible for a Notified Body to work on the basis of essential requirements only (as possible in other harmonized legislations). The HTS become applicable by Notified Bodies only when they have been published in the official journal of the EU.

3. Systems of Assessment and Verification of Constancy of Performance

The CPR uses AVCP systems instead of modules. For accreditation purposes only 4 of the AVCP systems are applicable and are summarized as follow:

AVCP 1+: Product certification based on initial and regular verification of the Factory Production Control (FPC) and on initial and regular additional testing performed by the Notified Body according to the requirements in harmonized technical standards and the referred test methods. Tests are also performed by the manufacturer on a regular basis as part of its FPC system.

AVCP 1: Product certification based on initial verification of the Factory Production Control (FPC) and on initial additional testing performed by the Notified Body according to the requirements in harmonized technical standards and the referred test methods. Tests are also performed by the manufacturer on a regular basis as part of its FPC system

AVCP 2+: Certification of the factory production control based on an initial and regular verification of the FPC system of the Notified Body, according to the requirements of the harmonized technical standards. Initial and regular tests are also performed by the manufacturer as part of its FPC system

AVCP 3: Product evaluation based on initial and regular tests performed by the Notified Body according to the requirements in harmonized technical standards and the referred test methods . The FPC system of the manufacturer is not verified by the Notified Body . Tests are also performed by the manufacturer on a regular basis as part of its FPC system

4. Declaration of Performance

The declaration of performance, issued by the manufacturer, states only the performance for which the product has been evaluated and that the manufacturer declares to remain the same. Therefore only parts of the requirements of HTS may be concerned which makes the difference with declaration of conformity to a harmonized technical standard.

5. CE Marking of Construction Products

The CE marking is a declaration, for a product type, of certain performances of the product and the sign that the manufacturer ensures the constancy of the declared performance. It is a summary of the information contained in the declaration of performance. Beside this, article 9.2 of the CPR requires some additional information to be affixed to the CE marking.

ANNEX F : PRESENTATION OF THE ACCREDITATION SCOPE (informative)

The following examples provide guidance on how scopes of accreditation may be defined.

Category of products or individual products	**Conformity Assessment procedure or AVCP-System**	**Essential requirements or harmonised technical specification:Product specification / Properties / Standards**
Construction products according to Regulation (EU) No 305/2011		
Cement, building limes and other hydraulic binders		
- masonry cements: preparation of concrete, mortar, grout and other mixes for construction and for the manufacture of construction products (Decision (EU) 97/555/EC Annex 3, as amended by Decision 2010/683/EU)	**Regulation (EU) No 305/2011** System 1+	EN 413-1:2011
Personal protective equipment according to Regulation (EU) 2016/425		
- respiratory protective equipment - excluding self-rescue and escape equipment - excluding equipment with high-pressure air supply system	**Regulation (EU) 2016/425** Module B Module C2 Module D	Regulation (EU) 2016/425 Annex II
- equipment providing chest and groin protection		
- equipment providing eye protection		
Interoperability of the rail system within the Community according to Directive (EU) 2016/797		
1. Trans-European high-speed rail system - 1.1 Infrastructure	**Decision (EU) 2010/713/EU** Module CA1 Module CA2 Module CD Module CH1	Regulation (EU) 1299/2014; 1300/2014; 1303/2014; 2016/912
Electromagnetic compatibility according to Directive 2014/30/EU		
Electric and electronic appliances (apparatus with electrical and/or electronic parts liable to generate electromagnetic disturbances or liable to be affected by such disturbances)	**Directive 2014/30/EU** Module B	Regulation (EU) Annex III

The three columns in the table include information which is to be published in the NANDO database. Other supplementary information can be added, especially if it is required by the Notifying Authority.