



---

***Publication  
Reference***

**EA-2/17 M: 2020**

---

**EA Document on  
Accreditation  
for Notification Purposes**

***PURPOSE***

The document presents the policy agreed by EA Members for accreditation of Conformity Assessment Bodies for notification purposes.

### *Authorship*

This document has been written by the Horizontal Harmonization Committee.

### *Official language*

The publication may be translated into other languages as required. The English language version remains the definitive version.

### *Copyright*

The copyright of the publication is held by EA. The publication may not be copied for resale.

### *Further information*

For further information about this publication, contact your national member of EA or the EA secretariat: [secretariat@european-accreditation.org](mailto:secretariat@european-accreditation.org)

Please check our website for up-to-date information <http://www.european-accreditation.org/>

**Category:** Members Procedural document  
**EA-2/17 is a mandatory document.**

**Date of approval:** 14<sup>th</sup> April 2020

**Date of Implementation:** April 2021, **see transition period below**

Within one year from publication, all NABs shall have procedures in place to implement the requirements of this document. Within three years from publication, all CABs accredited for the purpose of notification shall comply with this document.

---

**CONTENTS**


---

<b>1 SCOPE .....</b>	<b>4</b>
<b>2 DEFINITIONS .....</b>	<b>4</b>
<b>2.1 DEFINITIONS .....</b>	<b>4</b>
<b>2.2 ACRONYMS.....</b>	<b>5</b>
<b>3 GENERAL POLICY.....</b>	<b>5</b>
<b>3.1 PURPOSE OF ACCREDITATION FOR NOTIFICATION .....</b>	<b>5</b>
<b>3.2 USE OF HARMONISED STANDARDS (HS) FOR ACCREDITATION.....</b>	<b>5</b>
<b>3.3 RESPONSIBILITIES.....</b>	<b>6</b>
<b>3.4 APPLICATION TO LEGISLATION .....</b>	<b>6</b>
<b>3.5 USE OF THE NOTIFIED BODIES COORDINATION GROUP DOCUMENTS .....</b>	<b>6</b>
<b>4 PREFERRED HARMONISED STANDARDS .....</b>	<b>7</b>
<b>4.1 DESCRIPTION OF THE PREFERRED HS APPROACH .....</b>	<b>7</b>
<b>4.2 IMPLEMENTATION.....</b>	<b>7</b>
<b>5 ACCREDITATION SCOPES.....</b>	<b>8</b>
<b>5.1 ASPECTS TO BE CONSIDERED.....</b>	<b>8</b>
<b>5.2 MAIN ELEMENTS TO BE INCLUDED IN THE SCOPE .....</b>	<b>8</b>
<b>5.3 EXAMPLES.....</b>	<b>9</b>
<b>ANNEX A - PREFERRED STANDARDS (HS) PER LEGISLATION (MANDATORY).....</b>	<b>11</b>
<b>ANNEX B - APPLICABILITY OF STANDARDS (HS) (MANDATORY).....</b>	<b>17</b>
<b>ANNEX C - CRITERIA FOR SELECTING WITNESSING (MANDATORY).....</b>	<b>21</b>
<b>ANNEX D - MAP OF HS REQUIREMENTS BASED ON DECISION 768/2008 (INFORMATIVE).....</b>	<b>25</b>
<b>ANNEX E - SPECIFIC ASPECTS OF THE CONSTRUCTION PRODUCTS REGULATION (INFORMATIVE).....</b>	<b>36</b>

## **1 SCOPE**

This document contains the policy agreed by EA for accreditation of Conformity Assessment Bodies by National Accreditation Bodies as a basis for notification by Notifying Authorities to become Notified Bodies to work within the scope of Union Harmonisation Legislation<sup>1</sup> and other related legislation that does not fully follow the New Legislative Framework in so far as this legislation provides for accreditation as sufficient means of demonstrating the technical competence of Notified Bodies. This document also applies to bodies performing assessment and verification of constancy of performance under the Construction Products Regulation. It identifies the requirements that shall be used by National Accreditation Bodies when assessing and accrediting Conformity Assessment Bodies seeking notification.

This document is a “Members’ procedural document” with a mandatory status. It is intended to apply to all National Accreditation Bodies (NABs) that assess and accredit Conformity Assessment Bodies (CABs) for notification purposes, unless the notifying and/or regulating authority - at its own discretion - has officially established and published different requirements, see section 4.2 for details.

*Note 1: Nothing in this document is intended to be binding to Notifying Authorities. In particular, it does not establish any requirements with regard to the procedures of Notifying Authorities as referred to by article R14.1 of the decision (EC) 768/2008.*

*Note 2: In the area of the Construction Products Regulation there are significant differences to other legislation forming part of the so called New Legislative Framework. In order to allow application of this document also in the area of the Construction Products Regulation, a specific Annex E was added to the document explaining specific aspects of this area. Reference is made in the text of the document to this annex wherever necessary.*

## **2 DEFINITIONS**

### **2.1 Definitions**

In the context of this document, the term “Notified Body” (NB) is used for all Conformity Assessment Bodies (CABs) which are seeking notification, or which are already notified.

The term “Notified Body” is also used for bodies performing third party Assessment and Verification of Constancy of Performance under the Construction Products Regulation.

The term “aligned” is used in this document to identify legislation that uses the modules defined in decision (EC) 768/2008.

---

<sup>1</sup>See: [https://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index\\_en.htm](https://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm)

## 2.2 Acronyms

In this document the following acronyms and abbreviations are used:

CAB	Conformity Assessment Body which either seeks notification or is already notified
NB	Notified Body
NAB	National Accreditation Body
NA	Notifying Authority
UHL	Union Harmonisation Legislation
HS	Harmonised Standard with requirements used for the accreditation of Conformity Assessment Bodies
NLF	New Legislative Framework
CPR	Construction Product Regulation
NANDO	New Approach Notified and Designated Organisations Information System
AVCP	Assessment and Verification of Constancy of Performance ( <i>see Annex E for details</i> )

## 3 GENERAL POLICY

### 3.1 Purpose of accreditation for notification

The main purpose of accreditation, when used as a tool to support notification of CABs in the framework of UHL elaborated according to the provisions of Decision (EC) 768/2008, is to give confidence to the NA on:

- 1) competence, impartiality, independence and consistent operation of the CAB to perform the tasks it is notified for;
- 2) the fulfillment by the CAB of the requirements established by each UHL within the scope of accreditation.

### 3.2 Use of Harmonised Standards (HS) for accreditation

Accreditation is defined in Regulation (EC) 765/2008 as “*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*”.

Therefore, NABs shall use Harmonised Standards (HS) in assessments for accreditation. However, the conformity assessment activities described in the modules defined in Decision (EC) 768/2008 or conformity assessment procedures defined in other UHL are not described

in a way which fits exactly with the description in the HS (i.e. testing, inspection and certification), and each module does not identify the HS to be used for its conformity assessment activities. This means that, for each module, different HS may be considered for accreditation of the NB, but they may have to be supplemented by the above mentioned “*additional requirements*”.

EA has developed a preferred HS approach in order to provide a consistent and comparable implementation of accreditation for notification purposes. The tables in annex A of this document identify the HS which is the preferred standard for each module and legislation, and, in addition, the table in annex B includes the additional requirements taken from other HS which are needed to underpin the standard for an appropriate assessment of the competence and performance under each module.

### **3.3 Responsibilities**

Accreditation and notification are two different activities which are performed by the NAB and the Notifying Authority respectively.

When the NAB is asked to perform accreditation in support of notification, it will be the NAB's responsibility to apply the most appropriate accreditation procedure, thus selecting the HS to be used with all the eventual additional requirements of the UHL that, together, need to be assessed to ensure fulfilment of all the corresponding requirements of the UHL.

### **3.4 Application to legislation**

The specific requirements to be fulfilled by NBs are established in each UHL.

To be accredited, NB shall be assessed by NABs using:

- 1) one HS and the additional requirements as described in section 3.2 in this document as applicable to the module, conformity assessment procedure or AVCP-system requested; and
- 2) the requirements for NBs included in the relevant UHL.

This document applies to EU directives and regulations which follow the New Legislative Framework which are aligned with Decision (EC) 768/2008. It shall also be applied to other Directives and Regulations (for example Assessment and Verification of Constancy of Performance under the Construction Products Regulation – see *Annex E for details* - or the modules for the Railways Interoperability Directive (EU) 2016/797) which are not aligned with Decision (EC) 768/2008. In these cases, further guidance to the use of the tables in annex A may be needed, similar to that given in annex B.

### **3.5 Use of the Notified Bodies Coordination Group Documents**

Article R17 paragraph 11 of Decision (EC) 768/2008 establishes the principle that NBs participate in or inform their assessment personnel of the activities of the corresponding

Notified Body Coordination Group established under the corresponding UHL and to apply their administrative decisions and documents as general guidance.

Therefore, assessors of NABs performing assessments of conformity assessment bodies as a basis for notification by NAs should be well aware and informed of the corresponding decisions and documents of the Notified Body Coordination Groups. It is the responsibility of the corresponding NAB to assure the competence of their assessors including their knowledge of these documents.

In case the decisions and documents of the corresponding Notified Body Coordination Group are not easily available to the NAB's assessors, the NAB should inform the EA secretariat, who will try to provide support in this case.

## **4 PREFERRED HARMONISED STANDARDS**

### **4.1 Description of the Preferred HS approach**

EA has identified the preferred standards used for the accreditation of CABs for each module (identified in tables in annex A). This listing has been developed based on the technical and process requirements of the module concerned with the preferred standard being considered the best fit in each case.

The preferred standard shall be used as the basis of an accreditation and to reflect the consensus approach when accrediting for notification.

In addition to this, the table in annex B identifies for each HS the additional requirements and procedures needed to assess the competence of CABs.

*Note: to develop this table, EA has taken into account the recommendations from the European Commission such as the Blue Guide and SOGS document N612 EN as well as the comparison produced by CEN/CENELEC TC1 in N460 document.*

In all cases, the HS has to be used in full i.e. CABs have to meet all of the requirements of the HS as the basis for the assessment of the CAB. Requirements cannot be subtracted from the selected standard; however due to the nature of the conformity assessment activity, a requirement may be found as not applicable, provided that such an exclusion is allowed by the HS.

Where the application of a HS is required by the UHL, and there is overlap between the HS and the provisions of the UHL, the most stringent provisions take precedence.

### **4.2 Implementation**

NABs shall use the preferred standard as the basis for accreditation for notification. Any accreditation for notification not using the preferred standard shall be justified by the existence of a published requirement of a notifying and/or regulatory authority (e.g. law, decree, ordinance, published procedural document of the NA), binding to the CAB, not to accept the

preferred standard but a different one. This justification has to be recorded by the NAB and made available upon request for EA and provided for the peer-evaluations.

For aligned directives/regulations and the CPR (*AVCP-system, see Annex E for details*), the corresponding additional requirements included in annex B have to be fulfilled in any case, even if a different standard than the preferred standard is used. For non-aligned directives/regulations the additional requirements in annex B will apply in principle.

For the legislation using the modules presented in annex B, a combination of modules and HS not covered by annex B is considered to be not suitable for accreditation for notification.

## **5 ACCREDITATION SCOPES**

Accreditation information issued by NABs for notification purposes shall make reference to the HS used as reference and granted for a given scope, make reference to the relevant UHL and comply with the following provisions.

### **5.1 Aspects to be considered**

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

- 1) relevant requirements according to EN ISO/IEC 17011 and the applicable HS as well as other requirements for CABs seeking notification,
- 2) the type of data needed as input to the NANDO database,
- 3) the needs of the Notifying Authorities,
- 4) the needs of the persons using information (primarily the customers of the NBs).

### **5.2 Main elements to be included in the scope**

The following shall be the main elements to be included in the scope of accreditation:

- a) HS which is used as reference and applied in full for the accreditation of the CAB;
- b) the identification of legislation (it may be complemented with a reference to the national regulations);
- c) the conformity assessment procedure used (module, article or annexes, systems of a particular directive/regulation) or AVCP-system;
- d) products/category – family – homogeneous groups of products (according to NANDO classification where possible);
- e) product characteristics (as set out in relevant legislation) or product specification (harmonised product standard, harmonised technical specifications – *see Annex E for details* -, other sectoral or technical documents according to the requirements of the directive/regulation concerned).

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 NA, applicable legislation or mandatory documents if deemed necessary due to other circumstances.

### 5.3 Examples

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
<b>Construction products according to Regulation (EU) No 305/2011</b>		
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)	<b>Regulation (EU) No 305/2011</b> System 1+	EN 413-1:2011
<b>Personal protective equipment according to Regulation (EU) 2016/425</b>		
- respiratory protective equipment - excluding self-rescue and escape equipment - excluding equipment with high-pressure air supply system	<b>Regulation (EU) 2016/425</b> Module B Module C2 Module D	Regulation (EU) 2016/425 Annex II
- equipment providing chest and groin protection		
- equipment providing eye protection		
<b>Interoperability of the rail system within the Community according to Directive (EU) 2016/797</b>		
1. Trans-European high-speed rail system - 1.1 Infrastructure	<b>Decision (EU) 2010/713/EU</b> Module CA1 Module CA2 Module CD Module CH1	Regulation (EU) 1299/2014; 1300/2014; 1303/2014; 2016/912

<b>Electromagnetic compatibility according to Directive 2014/30/EU</b>		
Electric and electronic appliances (apparatus with electrical and/or electronic parts liable to generate electromagnetic disturbances or liable to be affected by such disturbances)	<b>Directive 2014/30/EU</b> 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 NA.

**ANNEX A - PREFERRED STANDARDS (HS) 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 the NLF module. Table 2 covers non-aligned directives where there are specific attestation modules that do not directly align with the standard NLF modules.

Where exceptions are identified, these are based on the expert opinion that the particular module is used in a slightly different way to the other NLF directives.

**Table 1: Preferred Standards for Aligned Directives/Regulations and related Conformity Assessment 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)

Module		Other references equivalent to this module	Preferred Standard	Exceptions
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	
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	

Module		Other references equivalent to this module	Preferred Standard	Exceptions
H	Conformity based on full quality assurance	<p>Machinery Directive No 2006/42/EC Annex X;</p> <p>Noise emission in the environment by equipment for use outdoors Directive No 2000/14/EC Annex VIII</p> <p>In vitro diagnostic medical devices (IVDMD) Directive No 98/79/EC Annex IV;</p> <p>Active implantable medical devices (AIMD) Directive No 90/385/EEC Annex II;</p>	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 in the NLF Modules:**

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 STANDARDS (HS) (MANDATORY)****Table 3: Conformity Assessment Standards for Accreditation for Notification purposes incl. Applicable Additional Requirements:**

Module	Description	EN ISO/IEC 17065	EN ISO/IEC 17020	EN ISO/IEC 17021-1	EN 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	

Module	Description	EN ISO/IEC 17065	EN ISO/IEC 17020	EN ISO/IEC 17021-1	EN ISO/IEC 17025
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	

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

### Key

- \* Indicates for the corresponding module the preferred standard that shall be used whenever possible (refer to annex A for details of specific legislation).
- 1 The possible Harmonised Standards used for accreditation.
- + Additional applicable requirements of the other pertaining Harmonised Standards used for assessing the NB, as relevant to the situation.
- t Additional applicable requirements of EN ISO/IEC 17025 if testing is required. To this end fulfilment of the applicable requirements of clause 6 and 7 (except 7.9) in EN ISO/IEC 17025:2017 shall be demonstrated.
- cd Capability of and procedures for judging and deciding based on results of tests and/or inspections, if the essential requirements are fulfilled and/or the Harmonised 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 – based on product knowledge - 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 and 9.1 to 9.4 and 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. Specification of “t”, “cd”, “pk”, “qa” has been introduced to harmonise the understanding and clarify the content of the assessment in the particular context of accreditation for notification purposes, even if the concerned standard is already mentioned in the standard which is used in full. This applies even if the chosen standard is the preferred standard.

The option retained has been to specify for all modules the technical competencies to be checked in addition to the standard used in full, despite the fact that EN ISO /IEC 17065 makes reference respectively to EN ISO/IEC 17020, 17021-1 and 17025. This option gives the advantage to clarify which clauses of the additional standard have to be assessed during the assessment of the NB, in addition to the requirements mentioned in the accreditation standard, such as clause 6.2.1 of EN ISO/IEC 17065.

4. Any formal findings raised by the NAB shall be primarily referenced to the nearest relevant clause in the selected baseline (1) standard. Reference to the “+” standards can be made in the text.

5. 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).

6. Notified Bodies should 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.

7. CABs may have a separate accreditation in addition to the one covering the baseline (1) standard in order to further demonstrate its ability to perform certain (additional) activities under accreditation. In these cases the fulfillment of the requirements of the “+” standard can be sufficiently covered by the corresponding separate additional accreditation for the relevant scope (for example a CAB having accreditation under EN ISO/IEC 17065 for the performance of module B can also provide the proof of fulfillment of the requirements of the “t” element via a separate accreditation in accordance with EN ISO/IEC 17025).

## **ANNEX C - CRITERIA FOR SELECTING WITNESSING (MANDATORY)**

Clause 7.4.7 of ISO/IEC 17011:2017 establishes that the “*accreditation body shall develop an assessment plan to cover the activities to be assessed, the locations at which activities will be assessed, the personnel to be assessed where applicable and the assessment techniques to be utilized including witnessing where appropriate or applicable.*”

This annex describes how to use witnessing as one assessment technique in accreditation for notification purposes.

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

- 1) Witnessing shall normally be used as an assessment technique to determine the competent performance of all on-site conformity assessment activities of a CAB.
- 2) Other assessment techniques that can be used are file review and/or technical interviews (particularly preferred for the assessment of module B, but should also be used to complement the information gained through witnessing and increase the sampling).
- 3) The results of witnessing of one conformity assessment activity, or a combination of conformity assessment activities, may demonstrate and confirm the ability and effectiveness of the CABs processes for a competent evaluation for comparable conformity assessment activities.

When applying these principles to a complete assessment (e.g. an initial assessment or extension to scope in new areas), the NAB should ensure that it will cover all areas to be assessed, i.e. all directives or regulations, with the necessary witnessing (principle 1).

This normally results in witnessing or doing file reviews of all modules (*or AVCP-systems, see Annex E for details*) of all directives/regulations covered by the accreditation (principle 2) upon granting, extending and during an accreditation cycle. 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.

The same principle applies to modules/activities that require participation of the assessor on site (principle 3): If some modules of one directive/regulation are very similar (e.g. module D and E) the witnessing may be limited to one of them (i.e. grouping of modules, see table 5), in which case the more complex should be chosen.

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 NAB shall document the reasons and justification for taking such an approach.

Witnessing is normally to be performed in advance of granting, or extending, the accreditation for a new conformity assessment activity. Nevertheless, it is recognized that in the area of accreditation for notification purposes the possibilities of having clients available are very

limited as the performance of the corresponding conformity assessment activities will normally be restricted to notified bodies requiring accreditation in advance of receiving this notification.

It is therefore considered to be appropriate for the NAB, when accrediting a CAB / conformity assessment activity for the first time, to accept alternative ways of performing witnessing e.g. with comparable cases or simulated exercises sufficient to determine the competence of the CAB to perform the activities covered by its scope of accreditation.

When accrediting a CAB / conformity assessment activity for the first time, it is also acceptable to grant the accreditation under the condition that the CAB once notified informs the NAB as soon as it receives requests from its first clients. The CAB shall cooperate with the NAB during organization of the first activities for its clients to ensure that the witnessing of that activity takes place. The NAB shall have the necessary arrangements in place to ensure that no accredited certificates are issued until appropriate witnessing has been satisfactorily performed.

Where alternative ways of performing witnessing do not exist or are not sufficient to determine the competence of the CAB to perform the activities covered by its scope of accreditation, if the NA asks the NAB for information to consider a temporary notification, the NAB may provide the information on the CAB's competence gained already on the basis of the documents reviewed and (office) assessments done by the NAB. In such cases, unless the accreditation is confirmed within a given timeframe, the NAB should inform the NA to allow it to reconsider its notification and withdraw it.

Selection and 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 witnessing and file reviews during an accreditation cycle should enable the NAB to cover the different conformity assessment procedures (modules/AVCP-systems) for the related regulations/directives and the different categories of products/product areas included in the scope of accreditation.

The following tables shall be used as guidance for grouping of modules, and deviations are expected to be justified by the NAB:

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

<b>Module to be included in the scope</b>	<b>Description of the module</b>	<b>Witnessing required</b>
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 Regulation (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 - MAP OF HS REQUIREMENTS BASED ON DECISION 768/2008 (INFORMATIVE)**

### **CRITERIA LAID DOWN IN THE HARMONISED STANDARDS USED AS A BASIS FOR ACCREDITATION THAT DEAL WITH THE RESPECTIVE PROVISIONS LAID DOWN IN DECISION (EC) 768/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON A COMMON FRAMEWORK FOR THE MARKETING OF PRODUCTS**

#### Preamble

Decision (EC) 768/2008 of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (*The Decision*) sets out the following principle in Article R18:

*Where a Conformity Assessment Body demonstrates its conformity with the criteria laid down in the **relevant Harmonised Standards or parts thereof** the references of which have been published in the Official Journal of the European Union it shall be presumed to comply with the requirements [for Notified Bodies] **in so far as the applicable harmonised standards cover those requirements.***

The specific requirements applicable to the CAB are those of the directives and regulations for which they are notified, or want to be notified.

The following table document identifies which requirements laid down in the Harmonised Standards used as a basis for accreditation deal with the principles set out in Decision (EC) 768/2008 and adopted by relevant UHL.

In some cases, the specific principle is already covered by the accreditation standard, in other cases the specific provision is not covered or is only partially covered by the paragraph quoted in correspondence.

It should be noted that the fact that a particular standard clause or section deals with a specific provision of Decision (EC) 768/2008 does not necessarily mean that the referenced standard clause or section covers all of it. When accrediting for notification purposes, both the requirement of the particular standard and the requirement set out in each UHL, implementing the principles of the Decision (EC) 768/2008 (directive or regulation), shall be fulfilled and shall be verified by the NAB.

For example (and there are other examples) the criteria in EN ISO/IEC 17025 relating to impartiality and independence are insufficient for allowing 'presumption of conformity' with the principles set out in R17.3 and R17.4. The assessment should therefore focus on the UHL requirements regarding clause R17.3 and R17.4.

Any formal findings raised by the NAB shall be primarily referenced to the relevant clause in the harmonisation accreditation standard (see mapping). Reference to the UHL should be made in the text.

Note that other requirements apply as well. Requirements related to specific modules, articles and annexes based on the Decision (EC) 768/2008 are specified in the relevant UHL. If the UHL (directive or regulation) does not implement the principles of Decision (EC) 768/2008, the corresponding directive/regulation shall be used.

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)
<b>GENERAL REQUIREMENTS</b>					
<b>Legal and contractual matters</b>					
<b>R17.2:</b> <i>A notified body shall be established under national law and have legal personality.</i>	4.1.1	5.1	5.1.1	5.1.1	4.1
<b>Management of impartiality</b>					
<b>R17.3:</b> <i>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.</i>	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

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)
<p><b>R17.4:</b> <i>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.</i></p> <p><i>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.</i></p>	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

<b>Provisions laid down in Decision (EC) 768/2008</b>	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1 : 2015	EN ISO/IEC 17024:201 2
(1)	(2)	(3)	(4)	(5)	(6)
<b>R17.4:</b> <i>Notified bodies shall ensure that activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of its conformity assessment activities.</i>	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
<b>R17.5:</b> <i>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.</i>	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
<b>R17.8:</b> <i>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.</i>	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

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 17024:201 2
(1)	(2)	(3)	(4)	(5)	(6)
<b>Liability and financing</b>					
<b>R17.9:</b> <i>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.</i>	4.3	This standard does not require liability assurance	5.1.4	5.3.1	4.4
<b>Identification number of notified bodies</b>					
<b>R12.3:</b> <i>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 instructions, by the manufacturer or his authorized representative.</i>	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 requirements in the specific legislation for which the Conformity Assessment Body wishes to be notified				

STRUCTURAL REQUIREMENTS					
Role as notified body					
<p><b>R17.6(b):</b> <i>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.</i></p>	<p>4.6a) 5.1.2 6.2.1 7.1.1 7.1.2 7.1.3</p>	<p>7.2</p>	<p>5.2.4 7.1.1 7.1.2 7.1.3 7.1.4</p>	<p>8.1.1 8.5.1</p>	<p>8.2 8.3 9.2.1 9.2.2 9.2.3</p>
Cooperation with other bodies					
<p><b>R17.11:</b> <i>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.</i></p>	<p>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.</p>				

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 17024:201 2
<b>RESOURCE REQUIREMENTS</b>					
<b>Personnel</b>					
<b>R17.6(a):</b> <i>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.</i>	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
<b>R17.7:</b> <i>The personnel responsible for carrying out the conformity assessment activities shall have the following:</i> <i>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;</i> <i>b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out such operations;</i> <i>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;</i> <i>d) the ability required to draw up the certificates, records and reports to demonstrate that the assessments have been carried out.</i>	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

<b>Provisions laid down in Decision (EC) 768/2008</b>	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1 : 2015	EN ISO/IEC 17024:201 2
(1)	(2)	(3)	(4)	(5)	(6)
<b>Equipment</b>					
<b>R17.6:</b> <i>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.</i>	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
<b>Outsourcing (subcontracting)</b>					
<b>R20.1:</b> <i>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.</i>	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
<b>R20.2:</b> <i>Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.</i>	6.2.2.4a)	7.8.2.1p 7.8.2.2	6.3.3	7.5.3a)	6.3.1 6.3.2
<b>R20.3:</b> <i>Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.</i>	6.2.2.4f)	7.1.1.c)	6.3.2	7.5.1	This standard does not require agreement of the client.
<b>R20.4:</b> <i>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.</i>	6.2.2.1 6.2.2.4c) d)	5.4 6.6.2	6.3.4	7.5.4	6.3.2

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 17024:201 2
(1)	(2)	(3)	(4)	(5)	(6)
<b>INFORMATION REQUIREMENTS AND CONFIDENTIALITY</b>					
<b>Information requirements</b>					
<p><b>R28.1:</b> <i>Notified bodies shall inform the notifying authority of the following:</i></p> <ol style="list-style-type: none"> <li>1. <i>any refusal, restriction, suspension or withdrawal of certificates;</i></li> <li>2. <i>any circumstances affecting the scope of and conditions for notification;</i></li> <li>3. <i>any request for information on conformity assessment activities performed which they have received from market surveillance authorities;</i></li> <li>4. <i>on request, conformity assessment activities performed within the scope of their notification and, any other activity performed, including, cross-border activities and subcontracting.</i></li> </ol>	<p>In general standards on Conformity Assessment Body Competence Criteria do not “require” information requirements with notifying authority or other bodies.</p> <p>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.</p> <p>When standard includes the following requirement  <i>"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"</i></p> <p>The requirement must be assessed in relation with information requirements of directives and regulations.</p>				
<p><b>R28.2:</b> <i>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</i></p>					
<b>Confidentiality</b>					
<p><b>R17.10:</b> <i>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.</i></p>	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

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 17024:201 2
(1)	(2)	(3)	(4)	(5)	(6)
<b>PROCESS REQUIREMENTS</b>					
<b>General requirements</b>					
<b>R17.6:</b> <i>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.</i>	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
<b>R17.6 c):</b> <i>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.</i>	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
<b>Operational obligations for notified bodies</b>					
<b>R27.1:</b> <i>Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in the relevant community harmonisation legislation.</i>	7.1.2 7.4.3 7.4.4	5.3	7.1.	9.1.3 9.2	9.2.1
<b>R27.2:</b> <i>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 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.</i>	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 17024:201 2
(1)	(2)	(3)	(4)	(5)	(6)
<b>R27.3:</b> <i>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.</i>	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
<b>R27.4:</b> <i>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.</i>	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	
<b>R27.5:</b> <i>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.</i>	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 NLF are not applicable. In some cases these differences are obvious and the text of this document already makes reference to them (like the used AVCP-systems), in other cases the differences are not that obvious but nevertheless need to be taken into account carefully. 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. The main text of the document makes reference to this annex whenever considered necessary.

### **1. Common Technical Language Approach**

The expression “constancy of performance” used in the CPR has a different meaning from conformity and it shall be understood as following: Under the CPR specific/defined performance of the product is evaluated. In some cases only part of the requirements of the standard are applied while conformity to the standard means compliance with the complete standard.

Under the CPR, the constancy of performance is evaluated on the basis of harmonised technical specifications. These are harmonised standards or 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.

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

### **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 NB to work on the basis of essential requirements only (as possible in other UHL). The HTS become applicable by NBs 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 summarised as follow:

- AVCP 1+: Product certification with regular additional audit testing (including testing see AVCP3) based on requirements in HTS
- AVCP 1: Product certification without audit testing (Including testing see AVCP3) based on requirements in HTS
- AVCP 2+: Certification of the factory production control based on requirements in HTS
- AVCP 3: Product evaluation according the HTS (and test standard referenced in HTS)

### **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 HTS.

### **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.