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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.

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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.

Further information
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CONTENTS

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 Harmonization Legislation.[1]

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 Authority has officially established and published different requirements.

It identifies the requirements that shall be used by National Accreditation Bodies when accrediting Conformity Assessment Bodies seeking notification.

Note 1 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.

Note 2 In this document the following abbreviations are used:

CAB Conformity Assessment Body.

NB Notified Body

NAB National Accreditation Body

NA Notifying Authority

UHL Union Harmonization Legislation

HS Harmonized Standard with requirements for the operations of Conformity Assessment Bodies

NLF New Legislative Framework

[1]See: http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

2. GENERAL PROVISIONS

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 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 Union Harmonization Legislation.

2.1 Competence, impartiality and consistent performance of the Notified Body

Accreditation is defined in Regulation (EC) 765/2008 as "a*n attestation by a National Accreditation Body that a Conformity Assessment Body meets the requirements set by Harmonized 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 have to use Harmonized Standards (HS) for assessment when accreditation is used as the basis for notification.
It is widely accepted, however, that the conformity assessment activities described in the modules defined in Decision (EC) 768/2008, do not restrict the use of Harmonized Standards to one for each module, as the conformity assessment activities are not described in a way which fits exactly with the descriptions in the HS.

This means that, for each module, different standards could be used for accreditation of the NB, but some of them have to be supplemented by "*additional requirements*". In this respect, NABs, as the bodies responsible for declaring fulfillment of the requirements for the NB, are responsible for identifying those standards that are suitable to be used for accreditation, considering the conformity assessment activities for which the CAB is seeking accreditation. It is the responsibility of the national authorities to judge whether accreditation granted by the NAB is suitable for notification purposes.

EA has developed a table (see Table 1 in section 3.1 of this document) which identifies those Harmonized Standards that NABs may use to assess Conformity Assessment Bodies and their competence for each module, and among these Harmonized standards, the one which is the preferred standard (as identified by EA – see Table 2 in section 3.1). Table 1 includes the additional requirements (taken also from other Harmonized Standards) which are needed to underpin the standard for an appropriate assessment of the competence and performance of the NBs operating under each module.

2.2 The fulfilment by the Notified Body of the requirements established by each Union Harmonization Legislation

The specific requirements to be fulfilled by NBs are established in each Union Harmonization Legislation.

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

1) one Harmonized Standard as described in section 3.1 in this document as applicable to the module requested; and

2) the requirements for Notified Bodies included in the relevant Union Harmonization Legislation.

The accreditation certificate shall make reference only to the Harmonized Standard used as reference and granted for a given scope (see annex A for informative reference of expression of scope).

This document applies only to the accreditation activities 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.

3. HARMONIZED STANDARDS TO BE USED BY NABs TO ASSESS COMPETENCE FOR EACH MODULE INCLUDING THE ADDITIONAL REQUIREMENTS

The tables in section 3.1 identify those Harmonized Standards technically valid to assess the competence of NBs for a given module.

EA has identified also the preferred conformity assessment standards for each module (identified in tables 2 and 3 in 3.1); the 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 intention is that the preferred standard should be used as a guide for legislators when developing new legislation, and to reflect the consensus approach when accrediting for notification.

The use of the preferred standard must be encouraged and, wherever possible, ABs should use the preferred standard as the basis for accreditation for notification. Any accreditation for notification not using the preferred standard shall be justified.

The table 1 in section 3.1 hereafter is based to some extent on the current practice in several EU Member States. The table elaborates on the activities in brackets in the table of the Annex named “Using Harmonized standards to assess the competence of Conformity Assessment bodies” of the *Blue Guide* in details, identifying for each HS the additional requirements and procedures needed to assess the competence of CABs.
This table may be interpreted or modified by EA if individual Union Harmonisation Legislations differ in the Conformity Assessment activities from the identified modules (as defined in Decision (EC)768/2008).

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

It is for the national Notifying Authorities, preferably in close cooperation with its NAB, to allow accreditation of a NB against any of the suitable HS or to limit accreditation to some or one of them.

In the accreditation process, the assessment of competence always includes a technical assessment of the capacity of the NB to perform in a technically competent manner the conformity assessment activities described in the module.

The NAB has to assure that the outcome of this assessment (in terms of "technical competence" level) is the same irrespective of the standard used as reference, as the competence of the CAB to perform the activities described in a given module should not depend on the HS chosen for the assessment; only the way the NB demonstrates such competence is different depending on the standard (see Annex B).

This document applies to EU directives and regulations which follow the standard New Approach Model which are aligned with Decision (EC) 768/2008.

The document shall also be used for UHL that does not follow the standard New Approach Model (for example, the systems covered by the Construction Products Regulation or the modules for the Rail interoperability Directive (EC) 713/2010), or which are not aligned with Decision (EC) 768/2008. In these cases, further guidance to the use of this table 3 may be needed.

3.1. Harmonized Standards suitable for the accreditation Notified Bodies

In all cases, the Harmonised Standards have to be used in full i.e. CABs have to meet all of the requirements of the Harmonised Standard as the basis for the assessment of the CAB. Requirements cannot be subtracted from the selected standard; however a requirement may be declared not applicable, if objectively demonstrated.

Table 1 – Conformity Assessment Standards Suitable for Accreditation for Notification purposes

Module	Description	EN/ISO/IEC 17065	EN/ISO/ IEC 17020	EN/ISO/IEC 17021	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		1 + cd
A2	**Internal production control plus supervised product checks at random intervals**	1 +t	1 +t		1 + cd
B	**EC type examination**	1+ t + pk	1+ t		1 + cd
C	**Conformity to type based on internal production control**	N/A	N/A	N/A	N/A

Module	Description	EN/ISO/IEC 17065	EN/ISO/ IEC 17020	EN/ISO/IEC 17021	EN/ISO /IEC 17025
C1	**Conformity to type based on internal production control plus supervised product testing**	1+ t + pk	1+ t		1 + cd
C2	**Conformity to type based on internal production control plus supervised product checks at random intervals**	1+ t + pk	1+ t		1 + cd
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		1+ cd
F1	**Conformity based on product verification**	1 + t + pk	1 + t		1+ cd
G	**Conformity based on unit verification**	1 + t + pk	1 + t		1 + 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	

Key

1 The possible Harmonized Standards used for accreditation.

\+ Additional applicable requirements of the other pertaining Harmonized 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 5 in EN ISO/IEC 17025:2005 shall be demonstrated.

cd Capability of and procedures for judging and deciding based on results of tests, if the essential requirements are fulfilled and / or the Harmonized Standards have been applied when required. To this end, fulfillment of clauses 4.1, 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 clause 9 in EN ISO/IEC 17021:2011 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.

2. For EN ISO/IEC 17020, only Type A inspection bodies are valid for a Notified Body activity, unless otherwise stated in the Legislation.

3. Specification of "t", "cd", "pk", "qa" has been introduced to harmonize 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.
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 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. For accreditation using EN ISO/IEC 17065 and EN ISO/IEC 17020, there is no additional requirement (as those requirements come from a standard which is already prescribed); it is only a clarification of the requirements to be fulfilled in the context of accreditation for the purpose of notification.

4. Any formal findings raised by the NAB using the flexible approach 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.

Table 2: Table of Preferred Standards

Module		**Other references**	**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	
B	EU Type Examination	Machinery Directive No 2006/42 EC- Annex IX; Marine Equipment (MED) Directive No 96/98/EC Annex III; 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; Appliances burning gaseous fuels (GAD) Directive No 2009/142/EC (ex-90/396/EEC) Annex II;	ISO/IEC 17065	
C	Conformity to EU-type based on internal production control		ISO/IEC 17020	
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

Module		**Other references**	**Preferred Standard**	**Exceptions**
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	Marine Equipment (MED) Directive No 96/98/EC Annex V	ISO/IEC 17065	
D1	Quality assurance of the production process		ISO/IEC 17065	
E	Conformity to EU-type based on product quality assurance	Marine Equipment (MED) Directive No 96/98/EC Annex VI	ISO/IEC 17065	
E1	Quality assurance of final product inspection and testing		ISO/IEC 17065	
F	Conformity to EU-type based on product verification	Marine Equipment (MED) Directive No 96/98/EC Annex IV	ISO/IEC 17065	
F1	Conformity based on product verification		ISO/IEC 17065	
G	Conformity based on unit verification		ISO/IEC 17065	

Module		**Other references**	**Preferred Standard**	**Exceptions**
H	Conformity based on full quality assurance	Machinery Directive No 2006/42/EC Annex X; Marine Equipment (MED) No 96/98/EC Annex II; In vitro diagnostic medical devices (IVDMD) Directive No 98/79/EC Annex IV; Active implantable medical devices (AIMD) Directive No 93/42/EEC Annex II; Noise emission in the environment by equipment for use outdoors Directive No 2000/14/EC Annex VIII	ISO/IEC 17021	
H1	Conformity based on full quality assurance plus design examination		ISO/IEC 17065	

Table 3 – Table of Preferred Standards for non-aligned Directives/Regulations and modules

Directive	**Conformity assessment procedure**	**Preferred Standard**
97/23/EC 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) and Directive 89/106/EEC	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	ISO/IEC 17065

Directive	**Conformity assessment procedure**	**Preferred Standard**
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	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
	Supervision of manufacture	ISO/IEC 17020
	Periodic Inspections, Intermediate Inspections and Exceptional Checks	ISO/IEC 17020
	Initial Inspections and Tests	ISO/IEC 17020
2009/142/EC (ex-90/396/EEC) Appliances burning gaseous fuels (GAD)	EC Declaration of Conformity	ISO/IEC 17065
	EC Verification	ISO/IEC 17065
	EC Unit Verification	ISO/IEC 17065
	EC Declaration of conformity to type (guarantee of production quality	ISO/IEC 17065

ANNEX A (INFORMATIVE)

DESCRIPTION OF THE ACCREDITATION SCOPE OF NOTIFIED BODIES

This document (Annex A) sets out guidelines which should be used by all EA member Accreditation Bodies for the description of scopes when granting accreditation to Conformity Assessment Bodies wishing to become notified to a New Approach Directive or Regulation.

A1 Considerations

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.

A2 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;

e) product specification (harmonized product standard, other standard or technical documents) as appropriate or product characteristics (such as mechanical properties, electrical properties, etc.);

f) as an option, the assessment procedure/method used, only if this is required in the directive or by the national authorities.

Elements a-b-c-d should be explicitly mentioned in the publicly available accreditation documents.
The detailed information related to elements d) and e) should always be available on request, but may be presented in a separate document in order to allow easier update.

A3 Examples of presentation

Directive	Conformity Assessment procedure/ Module/article	Category of products or individual products	Essential requirements: Product specification / Properties/Standards
89/686/EEC Personal protective equipment	B, C2, D/ Articles 10, 11A, 11B	Hearing protectors	Mechanical and acoustical properties
		Personal eye-protection	Mechanical and optical properties
2003/44/EC Recreational Craft Directive	Aa, B, D, E, F , G tai/or H/ Annex I, A	Personal watercraft	Small craft - Hull identification – Coding system Small craft - Man overboard prevention and recovery

The first three columns include the information which is to be published in the NANDO database. The fourth column and any other supplementary information should only be for use by the NAB and the CAB.
Exceptions and limitations should also be communicated to the market and to the Notifying Authority.

In cases when NANDO does not have a harmonized approach, EA together with the Notifying Authorities may wish to discuss a harmonization of the nomenclature.

ANNEX B (INFORMATIVE)

CRITERIA LAID DOWN IN THE HARMONIZED STANDARDS USED AS A BASIS FOR ACCREDITATION THAT DEAL WITH THE REQUIREMENTS FOR NOTIFIED BODIES LAID DOWN IN DECISION (EC) 768/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON A COMMON FRAMEWORK FOR THE MARKETING OF PRODUCTS

B1 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*) reads in Article R18:

Where a Conformity Assessment Body demonstrates its conformity with the criteria laid down in the ***relevant Harmonized 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 harmonized standards cover those requirements.***

The following table document identifies which requirements laid down in the Harmonized Standards used as a basis for accreditation deal with those for Notified Bodies set out in Decision (EC) 768/2008. The numbering in the table follows the new structure of ISO/IEC standards for CABs and therefore starts with Chapter 5.
It should be noted that the fact that a particular standard clause or section deals with a requirement of Decision (EC) 768/2008 does not necessarily mean that the referenced standard clause or section covers all aspects required by the Decision. When accrediting for notification purposes, both the requirement of the particular standard and the requirement of Decision (EC) 768/2008 shall be fulfilled.

Note that other requirements apply as well. Requirements related to specific modules, articles and annexes are specified in Decision (EC) 768/2008 and UHL.

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Requirements on Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025: 2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021: 2011	EN ISO/IEC 17024: 2012
(1)	(2)	(3)	(4)	(5)	(6)
5 GENERAL REQUIREMENTS					
5.1 Legal and contractual matters					
5.1.1 *A notified body shall be established under national law and have legal personality* (Decision (EC) 768/2008 Article R17,2)	4.1.1	4.1.1	5.1.1	5.1.1	4.1
5.2 Management of impartiality					
5.2.1 *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.* (Decision (EC) 768/2008 Article R17, 3)	4.2	4.1.4 + Note 1 and 2 4.1.5(b), (d)	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

Requirements on Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025: 2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021: 2011	EN ISO/IEC 17024: 2012
(1)	(2)	(3)	(4)	(5)	(6)
5.2.2 *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.* (Decision (EC) 768/2008 Article R17, 4)	4.2.1 4.2.2 4.2.5 4.2.6 4.2.7 4.2.8 4.2.9 4.2.10 4.2.11 4.2.12	4.1.4 + Note 2 4.1.5 (b), (d)	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 7.2.3	4.3.2 4.3.5 4.3.6 5.2.1 6.2.1

Requirements on Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021:2011	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)
5.2.4 *Notified bodies shall ensure that activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of its conformity assessment activities.* (Decision Article R17, 4)	4.2.3 4.2.6 4.2.7 4.2.8 6.2.2	4.5	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) 8.5	4.3.6 4.3.7 5.1.1 5.2.3 6.3
5.2.5 *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.(Decision (EC)* 768/2008 *Article R17, 5)*	4.2.2 4.2.3 4.2.5 4.2.12 6.1.1.2 6.1.2 6.1.3	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	6.1.3 6.1.6 6.1.7 6.2.1 6.2.2
5.2.8 *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.* (Decision (EC) 768/2008 Article R17, 8)	4.2.3 4.2.4 4.4.4 5.2	4.1.5 (b)	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
5.3 Liability and financing					

Requirements on Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021:2011	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)
5.4 Identification number of notified bodies					
5.4.1 *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.* (Decision (EC) 768/2008 Article R12, 3)	This chapter reflects specific requirements on CE marking for notified bodies according to the requirements of the relevant community harmonization 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				
6 STRUCTURAL REQUIREMENTS					
6.1 Role as notified body					
6.1.1 *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* (Decision (EC) 768/2008 Article R17, 6(b))	4.6a) 5.1.2 6.2.1 7.1.1 7.1.2 7.1.3	5.4	5.2.4 7.1.1 7.1.2 7.1.3 7.1.4	8.1.1 8.6.1	8.2 8.3 9.2.1 9.2.2 9.2.3
6.2 Cooperation with other bodies					
6.2.1 *Notified bodies shall participate in, or ensure that their assessment personnel is informed of, the relevant standardization activities and the activities of the notified body coordination group established under the relevant Community harmonization legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.* (Decision (EC) 768/2008 Article R17, 11)	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 harmonized community legislation to the degree required by such legislation.				

Requirements on Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021:2011	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)
7 RESOURCE REQUIREMENTS					
7.1 Personnel					
7.1.1 *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;* (Decision (EC) 768/2008 Article R17, 6(a))	6.1.1.1 6.1.1.2 6.2.1	5.2.1	6.1.2 6.1.3	7.1 7.2	6.1.2
7.1.2 *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 Harmonized Standards and of the relevant provisions of the relevant Community harmonization 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.* (Decision (EC) 768/2008 Article R17, 7.)	6.1.1.2 6.1.2 6.2.1	5.2.1 + Note 2	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

Requirements on Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021:2011	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)
7.1.6 Monitoring					
7.2 Equipment					
7.2.1 *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.* (Decision (EC) 768/2008 Article R17, 6.)	4.3.2 6.2 7.3.1	5.3.1 5.5.1	6.2.1 6.2.2	4.3 6.1.3 7.1.1 7.1.4	6.4
7.3 Outsourcing (subcontracting)					
7.3.1 *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.* (Decision (EC) 768/2008 Article R20, 1.)	6.2.2.1 6.2.2.2 6.2.2.3	4.5.1	6.3.1	7.5.1 7.5.3 b) 7.5.4	6.3.1 6.3.2
7.3.2 *Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.* (Decision (EC) 768/2008 Article R20, 2.)	6.2.2.4a)	4.5.3	6.3.3	7.5.3a)	6.3.1 6.3.2
7.3.3 *Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.* (Decision (EC) 768/2008 Article R20, 3.)	6.2.2.4f)	4.5.2	6.3.2	7.5.1	This standard does not require agreement of the client.
7.3.4 *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.* (Decision (EC)	6.2.2.1 6.2.2.4c) d)	4.1.2 4.5.4	6.3.4	7.5.4	6.3.2

Requirements on Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021:2011	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)
768/2008 Article R20, 4.)					
8 INFORMATION REQUIREMENTS AND CONFIDENTIALITY					
8.1 Information requirements					
8.1.1 *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.* (Decision (EC) 768/2008 Article R28, 1.)	See comments to 8.1	See comments to 8.1	See comments to 8.1	See comments to 8.1	See comments to 8.1
8.1.2 *Notified bodies shall provide the other bodies notified under the same community harmonization 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.* (Decision (EC) 768/2008 Article R28, 2.)	See comments to 8.1	See comments to 8.1	See comments to 8.1	See comments to 8.1	See comments to 8.1

Requirements on Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021:2011	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)
8.2 Confidentiality					
8.2.1 *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 harmonization 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.* (Decision (EC) 768/2008 Article R17, 10.)	4.5 6.1.1.3	4.1.5(c)	4.2 6.1.13	8.5	6.1.6 6.1.7 7.3.3 7.3.4
9 PROCESS REQUIREMENTS					
9.1 General requirements					
9.1.1 *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 harmonization 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.* (Decision (EC) 768/2008 Article R17, 6.)	6.1.2 6.2.2 7.1.1 7.4.4 7.6.6	5.4	5.1.3 5.2.2 6.1.3 6.3 7.1.	7.1.1 7.1.2 7.2.1 7.2.2	9.2.1
9.1.2 *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.* (Decision (EC) 768/2008 Article R17, 6.)	4.4 7.1.1 7.3.2 7.4.4 7.10.1 7.10.2	5.4	7.1.	9.1.1 9.1.2 9.1.3 9.1.4	8.1 8.2
9.2 Scope of activities					

Requirements on Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021:2011	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)
9.3 Operational obligations for notified bodies					
9.3.1. *Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in the relevant community harmonization legislation.* (Decision (EC) 768/2008 Article R27, 1)	7.1.2 7.4.3 7.4.4	5.4	7.1.	9.1.1.1 9.2	9.2.1
9.3.2. *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 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 harmonization legislation.* (Decision (EC) 768/2008 Article R27, 2)	4.4 7.1. 7.4.4	5.4	7.1.	9.1.1 9.1.4 9.1.2.2	9.2.1

Requirements on Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021:2011	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)
9.3.3 *Where a notified body finds that requirements laid down in of the relevant community harmonization legislation or corresponding Harmonized 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.* (Decision (EC) 768/2008 Article R27, 3)	7.4.6 7.4.7 7.11.1	5.8.3	This is not part of the work of an inspection body. It can be done if requested in the specific directive	9.1.11 9.1.12 9.1.15 9.6	9.4.6
9.3.4 *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.* (Decision (EC) 768/2008 Article R27, 4)	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.		9.1.11 9.3.3 9.6	8.3 9.5

Requirements on Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021:2011	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)
9.3.5. *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.*(Decision (EC) 768/2008 Article R27, 5)	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.		9.6.1 9.6.2	9.5.2
9.4 Conformity assessment criteria					
9.5 Preparation for assessment and contract review					
9.6 Assessment					