Dutch Accreditation Council (RvA)

Accreditation of notified bodies on the basis of European directives/regulations

Document code:	**RvA-T043-UK**
	Version 3, 11-9-2018

An RvA-Explanatory note describes the policy and/or the procedures of the RvA concerning a specific field of accreditation. In case the policy and/or procedures for a specific field of accreditation as described in a RvA Explanatory note, is documented by EA, ILAC or IAF, the RvA will bring its policy and procedures in line with the EA, ILAC or IAF-document.
A current version of the Explanatory is available through the website of the RvA. (www.rva.nl).

Contents

1 Introduction

The RvA has accredited organisations to undertake conformity assessments within the framework of European product legislation. For a number of these accreditations it applies that on the basis of this accreditation a body can be notified by a Dutch notifying authority[1] for inclusion in the European database for notified bodies (NANDO). This explanatory note describes the basic principles for the RvA assessments within the framework of these accreditations. An explanation is also provided about the requirements used for these assessments, in particular as regards the relationship between the requirements from the harmonised standards used for accreditation and the requirements contained in the directives or regulations. Finally, an explanation is provided about the way in which the assessments are to be conducted.

An assessment of a (candidate) notified body (Nobo), whereby the explanations provided in this document are used, can result in the following text or a similar text being stated in the scope of the accreditation: “The accreditation for the activities below is suitable for notification”. On the basis of this notification the notifying authority can rely on the fact that the accreditation takes into account the specific requirements for Nobos in the relevant European legislation.

This explanatory document does not relate to accreditation of ‘accredited in-house bodies’, as referred to in Article R21 of Decision 768/2008/EC. Accredited in-house bodies are not notified to the Member States or to the Commission however on the request of a notifying authority the company they form part of or the national accreditation body provides information about their accreditation to the notifying authority. If a directive/regulation provides for an accredited in-house body then this is detailed in a specific accreditation protocol’ (SAP) for the relevant area of activity. A SAP provides details of the method of assessment by the RvA for accreditation.

2 Basic principles

An organisation applying for accreditation for an activity for which the organisation wishes to be registered in Brussels (NANDO) by a Dutch notifying authority shall have to notify this in its application for accreditation. The same applies if the application concerns an extension of an existing accreditation. It is only if this is stated on an application to the RvA that the RvA is able to take into account the specific requirements for Nobos during the assessment.

[1] The terms ‘notification’ and ‘designation’ are used interchangeablyin practice. Designation is undertaken at national level and can be a condition before notification as a notified body (Nobo) can take place. This document relates to notification as a Nobo.

The fact that the accreditation is intended for notification means that the RvA will define the scope of accreditations in a manner that corresponds with the intended scope of the notification. This also means that the RvA will make its choice of harmonised standard [2] for accreditation on the basis of the guidelines contained in the Blue Guide[3], unless the directive or regulation states otherwise, or unless the notifying authority deviates from this.

When selecting this standard, the RvA follows the policy that the European cooperation for Accreditation (EA) in EA-2/17; EA Document on Accreditation for Notification Purposes, has described in Tables 2 and 3 of that document (Table of Preferred Standards or Table of Preferred Standards for non-aligned directives/regulations and modules), unless there are reasons for deviating from that. The harmonised standard used by the RvA for the various modules is set out in RvA policy rule BR010 and, where necessary, further detailed in a SAP for a specific directive or regulation. Any deviations from Tables 2 and 3 of EA-2/17 are explained in that.

The fact that the accreditation is intended for notification means that in addition to the criteria used in the relevant harmonised standard for accreditation, additional criteria from the relevant directive or regulations will also be used. The rationale for the latter is that a (module from a) directive or regulation is regarded by the EA as a scheme[4], and that the stating of a scheme on the scope of accreditation means that the assessment has been undertaken against the requirements of the scheme relating to the conformity assessment body (CAB). However, the latter does not apply to the requirements of a scheme that is supervised differently, such as compliance with national legislation. The fact that in the Netherlands a Nobo has to comply with the Government Information (Public Access) Act (Wob) or the General Administrative Law Act (Awb) for example, does not mean that the RvA assesses against these requirements.

3 The requirements

The general requirements specified for Nobos are included in the relevant directive or regulation. In part of the directives/regulations, these requirements are aligned with Decision 768/2008/EC, which means that the requirements from 768/2008/EC are included in the directives/regulations; we call these the NLF[5] directives/regulations.

[2] A harmonised standard means a standard as referred to in Regulation (EC) 765/2008 Article 2 paragraph 9. The standards for accrediting Nobos are EN-ISO/IEC 17020, EN-ISO/IEC 17021-1, EN-ISO/IEC 17024, EN-ISO/IEC 17025 and/or EN-ISO/IEC 17065. Products can be tested for compliance against the essential requirements using harmonised technical standards. The list of harmonised standards is published in the Official Journal van de EU (https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en).

[3] The 'Blue Guide' on the implementation of EU product rules – 2016. Published by the European Commission (http://ec.europa.eu/DocsRoom/documents/16210/).

[4] See description of the EA-MLA structure in EA-1/06 (www.european-accreditation.org/publications)

[5] NLF: New Legislative Framework

However, this is not (yet) the case for the other directives/regulations and the texts in the directive or regulation deviate from the texts in the NLF directives/regulations with regard to the requirements for the Nobos. This section therefore makes a distinction between the NLF directives/regulations and the other directives/regulations.

The following explanation concerns the general requirements for Nobos. This does not mean the specific requirements specified for the activities of the Nobos in the directives/regulations, under the section Conformity Assessment and/or in the description of the modules.

3.1 Assessments within the framework of the NLF directives/regulations

In addition to the requirements contained in Article R17 of 768/2008/EC, other articles from 768/2008/EC also contain requirements that Nobos are deemed to comply with. Because these are requirements concerning the conformity assessment activities that are carried out under accreditation then compliance with these requirements is also evaluated by the RvA during the assessments.

With due regard for Article R18 of 768/2008/EC it is necessary to consider what requirements are covered by the requirements contained in the harmonised standards that are used for accreditation. R18 specifically states: "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 set out in Article [R17] in so far as the applicable harmonised standards cover those requirements".

The relationship between the requirements from the relevant harmonised standards for accreditations and the requirements contained in 768/2008/EC are shown in Annex 1. The table in the Annex 1 is based on document EA-2/17. Footnotes are used to show where the harmonised standard does not (adequately) cover the requirement. The extra requirements from 768/2008/EC shall be used additionally by the RvA for the accreditation of (candidate) Nobos.

We regard the following as NLF directives/regulations:

A. The directives that form part of the 'European Alignment Package' (a group of directives that were amended almost simultaneously to 768/2008/EC), namely:

Non-automatic weighing instruments (NAWI)	2014/31/EU
Measuring instruments (MID)	2014/32/EU
Electromagnetic compatibility (EMC)	2014/30/EU
Explosives for civil uses (EXPLO)	2014/28/EU
Equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)	2014/34/EU
Lifts (LIFTS)	2014/33/EU
Simple pressure vessels (SPV)	2014/29/EU
Pyrotechnic articles (PYRO)	2013/29/EU

The Low Voltage Directive 2014/35/EU (LVD) also forms part of the aforementioned alignment package. However, this directive no longer includes a role for Nobos. Organisations are not accredited for activities based on LVD 2014/35/EU.

B. The directives/regulations that were not part of the alignment package but which were harmonised with 768/2008/EC during the last revision are:

Pressure equipment (PED)	2014/68/EU
Recreational craft and personal watercraft (RCD)	2013/53/EU
Radio equipment (RED)	2014/53/EU
Toys	2009/48/EC
Transportable pressure equipment (TPED)	2010/35/EU
Personal protective equipment	(EU) 2016/425
Appliances burning gaseous fuels	(EU) 2016/426
Interoperability of the rail system	(EU) 2016/797

These directives/regulations use the same requirements for Nobos as used in the directives in the alignment package.

In addition to notified bodies, the Pressure equipment directive (PED) also has what are known as 'recognised third-party organisations'. These undertake activities in accordance with Annex I, 3.1.2 and/or 3.1.3 of the PED. These organisations are evaluated against the same requirements as the notified bodies.

The PED also has 'User inspectorates (UI)', which are subjected to specific requirements. The requirements that a UI has to comply with are set out in Article 25 of the PED and in paragraphs 3, 4, 8 and 9 they deviate from the requirements for the notified bodies as set out in Article 24 of the PED. The Transportable Pressure Equipment Directive (TPED) 2010/35/EU is, as regards structure and nature of the conformity provisions, different from the other directives. However, the requirements for the Nobo are the same.

C. Building products regulation, (EU) 305/2011 (CPR)

Regulation 305/2011 stipulates the same requirements for notified bodies as the NLF directives. Article R17 from 768/2008/EC is referred to in Article 43. R20 is can be found in Article 45, R27 in Article 52 and R28 in Article 53. The assessment can therefore be undertaken in a comparable way using the table in Annex 1. As additional requirements, the requirements contained in Article 46 concerning the use of facilities outside of the notified body's test laboratory have to be taken into account.

D. Marine equipment directive, 2014/90/EU (MED)

Appendix III of this directive contains the same requirements as the NLF directives, with the addition of two requirements (the numbering is changed with regard to R17):

(18) Conformity Assessment Bodies meet the requirements of standard EN ISO/IEC 17065:2012.

(19) Conformity Assessment Bodies ensure that test laboratories used for conformity assessments meet the requirements of standard EN ISO/IEC 17025:2005.

When assessing the Nobos for the MED the RvA will therefore use ISO/IEC 17065. The requirements under R20, R27 and R28 from 768/2008/EC are therefore included in the MED (in Articles 20, 23 and 24 respectively). The assessment can therefore be undertaken in a comparable way using the table in Annex 1.

3.2 Other directives/regulations

For the other directives/regulations the requirements for Nobos deviate from the requirements contained in 768/2008/EC and they are presented in different ways in the directives/regulations. A Nobo will therefore have to deduce from the directive/regulation the requirements that are applicable. The RvA assessors shall maintain the principle of 'presumption of conformity' insofar as the harmonised standards cover the requirements and as explained below. It applies for all directives/regulations that, with due regard for any transition periods, the latest 'consolidated version' will always be used.

3.2.1 Medical devices directive, 93/42/EEC (MDD)*

Annex XI of this directive gives the requirements for Nobos. Article 16 contains additional requirements for Nobos. Article 20 contains requirements for confidentiality. The principle of 'presumption of conformity' is also used in this directive (Article 16, paragraph 2) if the Nobo complies with a harmonised standard used for accreditation. The requirements contained in Articles 16 and 20 are not (completely) covered by the harmonised standards. The requirement for liability insurance in Annex XI of the directive is also not covered by the harmonised standards.

The requirements in Annex XI of the directive are further explained (interpreted) in Annex I of the Implementing Regulation (EU) 920/2013 concerning the designation and supervision of notified bodies in accordance with Directive 90/385/EEC and Directive 93/42/EEC. Because the texts in this Annex I deviate from the texts contained in 768/2008/EC and from the texts contained in the harmonised standards, the RvA will, in practice, use the texts contained in this Annex I of the regulation for the requirements, and will not apply the principle of 'presumption of conformity'.

For Directive 93/42/EEC the organisation can only be notified after what is known as a 'joint assessment' has been undertaken by the European Food and Veterinary Office (FVO) in collaboration with the competent authorities, as set out in the Implementing Regulation (EU) 920/2013. In the Dutch Medical devices decree (Besluit medische hulpmiddelen) accreditation is not mentioned at all as a condition. Although the experience is not that the Dutch notifying authority maintains accreditation as a condition, the RvA will assess against the aforementioned requirements for an accreditation application within the framework of this directive.

* N.B. Regulation (EU) 2017/745) replaces Directive 90/385/EEC and Directive 93/42/EEC.

3.2.2 Active implantable medical devices, 90/385/EEC (AIMD)*

The RvA currently has no parties accredited for the AIMD; this section of this explanatory note will be supplemented if there is an application for accreditation.

* N.B. Regulation (EU) 2017/745) replaces Directive 90/385/EEC and Directive 93/42/EEC.

3.2.3 Medical devices for in-vitro diagnostics, 98/79/EEC (IVD)$

The RvA currently has no parties accredited for the IVD; this section of this explanatory note will be supplemented if there is an application for accreditation.

$ N.B. Regulation (EU) 2017/746 replaces Directive 98/79/EEC.

3.2.4 Yield requirements for new oil- and gas-powered central heating boilers, 92/42/EEC

Annex V of this directive contains requirements for Nobos. The principle of 'presumption of conformity' is also used in this directive (Article 8, paragraph 2) provided the Nobo complies with a harmonised standard used for accreditation. The requirement for liability insurance, in Annex V of the directive, is not covered by the harmonised standards.

3.2.5 Machinery directive, 2006/42/EC

Annex XI of the directive contains the requirements for Nobos. In addition to the requirements in this Annex, Article 14, paragraph 6 contains requirements for the suspension of declarations and informing the notifying authority (NA) about such suspensions. The principle of 'presumption of conformity' is also used in this directive (Article 14, paragraph 5) provided the Nobo complies with a harmonised standard used for accreditation. The requirements for liability insurance (point 6) and participation in coordinating activities (point 8) in Annex XI of the directive are not (completely) covered by the harmonised standards and are additional assessments.

In 2016 the Dutch machines (commodity act) decree was amended, as a result of which nationally, for a notified body for the Machinery directive (trade phase), the same requirements apply as for a notified body for the Lifts directive. They have therefore been brought in line with the requirements for a notified body as set out in Decision 768/2008/EC. The requirements for notified bodies for the Machinery directive are therefore the same as the requirements contained in Annex I of this document. The requirements set for a notified body for the Machinery directive on the basis of national legislation are therefore more stringent than the European directive.

3.2.6 Noise emission, 2000/14/EC

Annex IX of the directive contains the requirements for Nobos. The requirement for liability insurance (point 6) is not covered completely by the harmonised standards and is an additional assessment.

3.2.7 Gas appliances regulation,(EU) 2016/426

Articles 23, 31 and 33 contain the requirements for Nobos. The principle of 'presumption of conformity' is also used in this regulation (Article 24) provided the Nobo complies with a harmonised standard used for accreditation. The requirement for liability insurance (article 24, point 9) is not fully covered by the harmonised standards and is an additional assessment subject.

3.2.8 Personal protective equipment, (EU) 2016/425[$]

Articles 24, 32 and 34 contain the requirements for Nobos. The principle of 'presumption of conformity' is also used in this regulation (Article 25) provided the Nobo complies with a harmonised standard used for accreditation. The requirement for liability insurance (article 24, point 9) is not fully covered by the harmonised standards and is an additional assessment subject.

[$] N.B. The directive 89/686/EEC has been replaced by Regulation (EU) 2016/425 on 18 April 2018 but a transitional arrangement applies till 20 April 2019.

3.2.9 Interoperability of the rail system, 2008/57/EC[&]

Annex VIII of Directive 2008/57/EC contains the requirements for Nobos. The principle of 'presumption of conformity' is also used in this directive (Article. 28) provided the Nobo complies with a harmonised standard used for accreditation. The requirement for liability insurance (point 6) is not covered completely by the harmonised standards and is an additional assessment. It is the same case for the requirement for government agency independence (Annex VIII, point 2).

[&] N.B. This directive will be replaced on 16 June 2019 by Directive (EU) 2016/797. See paragraph 3.1 of this T043.

3.3 Application and interpretation documents

When assessing, the RvA uses application and interpretation documents that are published by the RvA, EA, ILAC the IAF or other authoritative organisations. The same applies for the application and interpretation documents (guidelines) which are published by the European Commission in the various directives/regulations (ec.europa.eu/growth/sectors/<relevant sector>), insofar as these do not conflict with the applicable harmonised standard(s) from the 17000 series.

Notified bodies participate in the notified body dialogue for the relevant directive/regulation. These Nobo groups also publish guidance documents. The RvA only uses the guidance documents that are endorsed by the relevant Commission Working Group and which do not conflict with the applicable harmonised standard(s) from the 17000 -series.

4 Assessment process

4.1 The standards used for accreditation

The principle of 'presumption of conformity'[6] means that the RvA does not undertake any explicit assessment against the general requirements contained in the directives/regulations, but that these requirements are covered by the assessment against the harmonised standards from the 17000 series insofar as it is evident that these requirements are indeed covered from the aforementioned and in Annex 1.

[6] The principle of 'presumption of conformity' applies at two levels, namely for the requirements set for the Nobo against which the RvA evaluates via the standards used for accreditation (see 4.1) and for product compliance with the essential requirements against which the Nobo evaluates (see 4.2).

For the requirements that are adequately covered by the requirements contained in the harmonised standard, the RvA will not therefore undertake a separate assessment and will also not report separately. For the requirements for which this is not the case, the RvA will undertake the assessment explicitly against the additional requirements and, as a rule, will report explicitly on these. For this purpose, the assessment element H will be used in the report. The RvA uses no separate checklists for these requirements. The topics assessed have to be evident from the text in the report.

The initial assessment of a (candidate) Nobo shall be undertaken against all of the requirements. The basic principle for the frequency of assessing these requirements during the surveillances and re-assessments is provided in policy rule BR005. The specific requirements that are not (fully) covered in the harmonised standards will be dealt with at least once during an accreditation cycle.

Any non-conformity against an additional requirement will be written against the requirement from the relevant directive/regulation and reported under the most logical assessment element, such as (reference is made between brackets to the footnotes contained in Annex 1):

- A.1 or A.2 if it concerns the requirements relating to legal personality or insurance (footnotes A or C and D);
- H.7 for the requirement about being aware of standardisation and the Nobo dialogue (footnote E);
- F.6 for the requirements concerning sub-contracting (footnotes F and G);
- H.8 for the requirement about the provision of information to the notifying authority and colleague Nobos (footnote H);
- G.9 if it concerns the issuing of certificates by Nobos, demanding measures if the product is non-compliant and the suspension or withdrawal of certificates (footnotes I, J, K and L).

The assessment against the general requirements (harmonised standard plus additional requirements as explained in Annex 1) is the task of the assessor(s) in the team that are qualified for the relevant harmonised standards. These assessors will also assess the implementation of the module structure and the processes for a directive. The assessment of the specific product or technical requirements, which are described in the modules or the harmonised product standards for example, will be undertaken by the technical expert(s) in the assessment team.

The assessments by the RvA consist of a documentation and dossier assessment at the office of the CAB, and the witnessing of activities of the designated organisation. If dossier assessment and witnessing of activities is not yet possible, because the CAB does not yet have any notification, then a temporary accreditation with restrictive conditions can be granted in accordance with the rules contained in RvA-BR002.

4.2 Assessing against essential requirements

The directives and regulations use the principle of ‘presumption of conformity’ with the essential requirements provided the product complies with a harmonised (product) standard that is published by

the European Commission in its Official Journal. However, the manufacturer is not obliged[7] to use harmonised standards. The Nobo must assess whether the manufacturer's product complies with the essential requirements.

Because the use of the harmonised standards is not mandatory, the Nobo must also be able to assess the product if no or only part of the harmonised standards are used which give a 'presumption of conformity'.

4.3 Scope of accreditation

The configuration of the scopes of accredited bodies is the same for each directive/regulations for all harmonised standards used for accreditation and therefore deviates from that which is prescribed for each harmonised standard in document RvA BR003. The scopes are built up from the following elements (radio equipment for example):

Directive 2014/53/EU

Radio equipment

The accreditation for the activities below is suitable for notification

Product/product group	**Module/article**	**Conformity assessment procedure**
Radio equipment	EC type examination (module B)	Annex III, module B
Radio equipment	Conformity based on complete quality assurance (module H)	Annex IV

The modules the body is accredited for and the activities this covers are given for each directive/regulation in the scope. The scope descriptions for each directive/regulation are detailed further in various SAPs. The harmonised standards are not stated on the accreditation scope, with the exception of the CPR, where the use of harmonised standards is mandatory.

[7] The Construction products regulation (CPR) does make the use of harmonised standards mandatory.

5 Changes with regard to the previous version

Compared to version 2 of December 2017 the following significant changes have been made with :

- replacement of the gas appliance directive and the personal protective equipment directive by regulations has been incorporated;
- column for ISO/IEC 17025:2017 added to annex 1;
- in annex 1 at R17.7 added that competences must secure the ability to provide a professional judgement regarding meeting the product requirements;
- in annex 1 at R17.6 added that ability and procedures must be included for judging and deciding about compliance with essential requirements and the application of harmonised standards, where required.

Annex 1

List of requirements which the RvA regards are 'covering' (presumption of conformity) for the requirements contained in the NLF directives and regulations. Where the requirements contained in the standards are not (fully) covering then this explained with a footnote. This table is based on EA-2/17 and generally follows the same layout.

Requirements in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1:2015	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)	(7)
GENERAL REQUIREMENTS						
Legal and contractual matters						
R17.2 *A notified body shall be established under national law and have legal personality*[A]	4.1.1	5.1	4.1.1	5.1.1	5.1.1	4.1
Management of impartiality						
R17.3 *A notified body shall be a third-party body independent from the organization or the product it assesses.* *A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, can, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered to be such a body.*	4.2	4.1 [B]	4.1.4 + Note 1 and 2 4.1.5(b), (d) [B]	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 6.1.2 6.2.1	4.3.2 4.3.5 4.3.6 4.3.7 4.3.8 5.2.3

[A] To be designated and notified within the framework of directives/regulations an organisation must have a legal personality. According to the Netherlands Civil Code, Book 2, Article 3, the following parties have a legal personality: associations, cooperatives, mutual benefit organisations, public limited companies, private companies with limited liability and foundations. The following organisation forms do not have a legal personality: commercial partnership, sole trader, limited partnership and a partnership established under Dutch law.

[B] The criteria in ISO/IEC 17025 relating to impartiality and independence are insufficient for allowing 'presumption of conformity' with the requirements contained in R17.3 and R17.4, even when notes 1 and 2 are applied. Evaluation should therefore be against the requirements contained in R17.3 and R17.4.

Requirements in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1:2015	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)	(7)
R17.4 *A notified body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the authorized representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the Conformity Assessment Body or the use of the products for personal purposes.* *A notified body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, nor represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgment or integrity in relation to conformity assessment activities for which they are notified. This applies in particular to consultancy services.*	4.2.1 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 6.2.1 **B**	4.1.4 + Note 2 4.1.5 (b), (d) **B**	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 6.2.1	4.3.2 4.3.5 4.3.6 5.2.1 6.2.1
R17.4 *Notified bodies shall ensure that activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of its conformity assessment activities.*	4.2.3 4.2.6 4.2.7 4.2.8 6.2.2	6.6 **B**	4.5 **B**	6.3.1 6.1.12 6.1.13	5.2.3 5.2.5 5.2.6 5.2.7 5.2.11 5.2.12 6.1.2 7.5.1 7.5.3b),c) 8.4	4.3.6 4.3.7 5.1.1 5.2.3 6.3

Requirements in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1:2015	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)	(7)
R17.5 *Notified bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of their conformity assessment activities, especially from persons or groups of persons with an interest in the results of those activities.*	4.2.2 4.2.3 4.2.5 4.2.12 6.1.1.2 6.1.2 6.1.3	4.1 6.2.1	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	5.2.3 7.1 7.2	6.1.3 6.1.6 6.1.7 6.2.1 6.2.2
R17.8 *The impartiality of the notified body, its top level management and assessment personnel shall be guaranteed. The remuneration of the notified body's top level management and assessment personnel shall not depend on the number of assessments carried out or on the results of such assessments.*	4.2.3 4.2.4 4.4.4 5.2	4.1 6.2.1	4.1.5 (b)	4.1.2 4.1.5 4.1.6 a) 6.1.11	5.2.2 5.2.3 5.2.12	4.3.1
Liability and financing						
R17.9 *Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.* [C]	4.3.1	[D]	[D]	5.1.4	5.3.1	4.4
Identification number of notified bodies						
R12.3*The CE marking shall be followed by the identification number of the notified body where such body is involved in the production control phase.* *The identification number of the notified body shall be affixed by the body itself or under its instructions, by the manufacturer or his authorized representative.*	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					

[C] The requirement contained in the Directive is stricter because insurance is mandatory. Another provision that the standards do provide as a potential option is not sufficient here.

[D] Because this requirement concerning liability insurance is not stated in ISO/IEC 17025 then this requirement must be used in addition to ISO/IEC 17025 for laboratories.

Requirements in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1:2015	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)	(7)
STRUCTURAL REQUIREMENTS						
Role as notified body						
R17.6(b) *At all times and for each conformity assessment procedure and for each kind or category of products in relation to which it has been notified, a Conformity Assessment Body shall have at its disposal the necessary descriptions of procedures according to which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of these procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;*	4.6a) 5.1.2 6.2.1 7.1.1 7.1.2 7.1.3	7.2	5.4	5.2.4 7.1.1 7.1.2 7.1.3 7.1.4	8.1.1 8.1.2 8.5.1	8.2 8.3 9.2.1 9.2.2 9.2.3
Cooperation with other bodies						
R17.11 *Notified bodies shall participate in, or ensure that their assessment personnel is informed of, the relevant 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.*	**E**					
RESOURCE REQUIREMENTS						
Personnel						
R17.6(a) *At all times and for each conformity assessment procedure and for each kind or category of products in relation to which it has been notified, the Conformity Assessment Body shall have at its disposal the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;*	6.1.1.1 6.1.1.2 6.2.1	6.1	5.2.1	6.1.2 6.1.3	7.1 7.2	6.1.2

E The requirement for participation in or awareness of standardisation activities does not appear in any harmonised standard at all and is therefore an additional assessment.

Requirements in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1:2015	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)	(7)
R17.7 *The personnel responsible for carrying out the conformity assessment activities shall have the following:* *a) sound technical and vocational training covering all the conformity assessment activities of the relevant scope for which the Conformity Assessment Body has been notified;* *b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out such operations;* *c)appropriate knowledge and understanding of the essential requirements, of the applicable 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.*	6.1.1.2 6.1.2 6.2.1 [F]	6.1 6.2	5.2.1 + Note 2	6.1.1 6.1.2 6.1.3 6.1.8 6.1.9	7.1 7.2 [F]	6.1.3 6.2.2.1
R17.6 *The notified body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.*	4.3.2 6.2 7.3.1	6.3.1 6.3.5	5.3.1 5.5.1	6.2.1 6.2.2	6.1.4 7.1.1 7.1.4	6.4
Outsourcing (subcontracting)						
R20.1 *Where the notified body subcontracts specific tasks connected with the assessment of conformity or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article R17* (of the Decision 768/2008/EC) *and inform the Notifying Authority*[G]*.*	6.2.2.1 6.2.2.2 6.2.2.3	6.6.1 7.1.1	4.5.1	6.3.1	7.5.1 7.5.3 b) 7.5.4	6.3.1 6.3.2
R20.2 *Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.*	6.2.2.4a)	7.8.2.2	4.5.3	6.3.3	6.2.1 7.5.3a)	6.3.1 6.3.2

[F] Competences must secure the ability to make professional judgments related to product requirements where required.

[G] This requirement is stricter than the harmonised standard; informing the Notifying Authority is not a requirement in the harmonised standards. This point therefore has to be assessed in addition to the harmonised standards.

Requirements in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1:2015	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)	(7)
R20.3 *Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.*	6.2.2.4f)	7.1.1c)	4.5.2	6.3.2	7.5.1	[H]
R20.4 *Notified bodies shall keep at the disposal of the Notifying Authority the relevant documents concerning the assessment of the qualifications of the subcontractor or subsidiary and the work carried out by them.*	6.2.2.1 6.2.2.4c) d)	6.6.2	4.1.2 4.5.4	6.3.4	7.5.4	6.3.2
INFORMATION REQUIREMENTS AND CONFIDENTIALITY						
R28.1 *Notified bodies shall inform the Notifying Authority of the following:* *1. any refusal, restriction, suspension or withdrawal of certificates;* *2. any circumstances affecting the scope of and conditions for notification;* *3. any request for information on conformity assessment activities performed which they have received from market surveillance authorities;* *4. on request, conformity assessment activities performed within the scope of their notification and, any other activity performed, including, cross-border activities and subcontracting.*	[I]					
R28.2 *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.*						
Confidentiality						

[H] This requirement is stricter than the requirement in ISO/IEC 17024, which requires no agreement from the client; it therefore has to be used in addition to ISO/IEC 17024.

[I] These requirements relating to informing the notifying authority do not appear in any harmonised standards at all and must be used in addition to the harmonised standards.

Requirements in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1:2015	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)	(7)
R17.10 *The personnel of the notified body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks under the relevant community 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.*	4.5 6.1.1.3	4.2.4	4.1.5(c)	4.2 6.1.13	8.4	6.1.6 6.1.7 7.3.3 7.3.4
PROCESS REQUIREMENTS						
General requirements						
R17.6 *The Conformity Assessment Body shall be capable of carrying out all the conformity assessment tasks assigned to such a body by the provisions of the relevant community 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.*	6.1.2 6.2.2 7.1.1 7.4.4 7.6.6	5.4 **J**	4.1.2 5.4 **J**	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
R17.6 *At all times and for each conformity assessment procedure and for each kind or category of products for which it is notified, the Conformity Assessment Body shall have at its disposal the necessary procedures to perform their activities taking into consideration the size, the sector, the structure of the undertakings, the degree of complexity of the product technology in question and the mass or serial nature of the production process.*	4.4 7.1.1 7.3.2 7.4.4 7.10.1 7.10.2	5.4 7.2	5.4	7.1	9.1.3 9.1.4 9.2	8.1 8.2
Operational obligations for notified bodies						

J This shall include capability 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.

Requirements in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1:2015	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)	(7)
R27.1 *Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in the relevant community harmonization legislation.*	7.1.2 7.4.3 7.4.4	5.4	4.1.2 5.4	7.1.	8.5.1b,d,e 8.5.2 9.1.1 9.1.2 9.1.3.1 9.3.1 9.5.3	9.2.1
R27.2 *Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. The Conformity Assessment Bodies shall perform their activities taking into consideration the size, the sector, the structure of the undertakings 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.*	4.4 7.1. 7.4.4	5.5	4.1.2	7.1.	9.1.3 9.1.4 9.2.1	9.2.1
R27.3 *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* [K]*.*	7.4.6 7.4.7 7.11.1	[L]	[L]		9.4.9 9.4.10 9.5.2 9.6.5	9.4.6

[K] Maintaining a category or classification of non-conformities that do not have to be closed before a certificate is issued is not possible for such non-conformities.

[L] For laboratories and inspection bodies this is not part of the normal tasks and this requirement is not provided for in ISO/IEC 17025 and ISO/IEC 17020. It therefore has to be evaluated separately to ISO/IEC 17020 and ISO/IEC 17025.

Requirements in Decision (EC) 768/2008	EN ISO/IEC 17065:2012	EN ISO/IEC 17025:2017	EN ISO/IEC 17025:2005	EN ISO/IEC 17020:2012	EN ISO/IEC 17021-1:2015	EN ISO/IEC 17024:2012
(1)	(2)	(3)	(4)	(5)	(6)	(7)
R27.4 *Where, in the course of the monitoring of conformity following the delivery of certificate, a Notified Body finds that a product does not comply any more, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw its certificate if necessary.*	7.4.6 7.4.7 7.6.6 7.11	[M]	[M]		9.4.9 9.6.1 9.6.5	8.3 9.5
R27.5 *Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.*	7.11	[N]	[N]		9.6.5.1 9.6.5.2	9.5.2

[M] For laboratories and inspection bodies this is not part of the normal tasks and this requirement is not provided for in ISO/IEC 17025 and ISO/IEC 17020. It therefore has to be evaluated separately to ISO/IEC 17020 and ISO/IEC 17025.

[N] For laboratories and inspection bodies this is not part of the normal tasks and this requirement is not provided for in ISO/IEC 17025 and ISO/IEC 17020. It therefore has to be evaluated separately to ISO/IEC 17020 and ISO/IEC 17025.