A019
Legislation concerning notification of conformity assessment bodies

Modifications: p. 7

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1. Introduction

The purpose of this document is to present the “New Approach” directives and regulations for which OLAS accredits conformity assessment bodies (CAB) in the context of their notification to European Commission and EU Member States. In chapter 3 are introduced all european directives and national transpositions thereof that a nortification is possible and the requirements for the conformity assessment bodies.

Since 1 June 2008, accreditation is mandatory in Luxembourg for conformity assessment activities for which a CAB wants to be notified to the European Commission and the other Member States. The OLAS procedure *P008 – Designation of notified bodies within the framework of the “New Approach”* Directives lays down the principles for the notification by the Grand-Duchy of Luxembourg. The procedures describes in chapter 4 how OLAS accredits the different directives and modules.

The following chapter describes shortly the decision N°768/2008/CE.

2. Decision n° 768/2008/EC

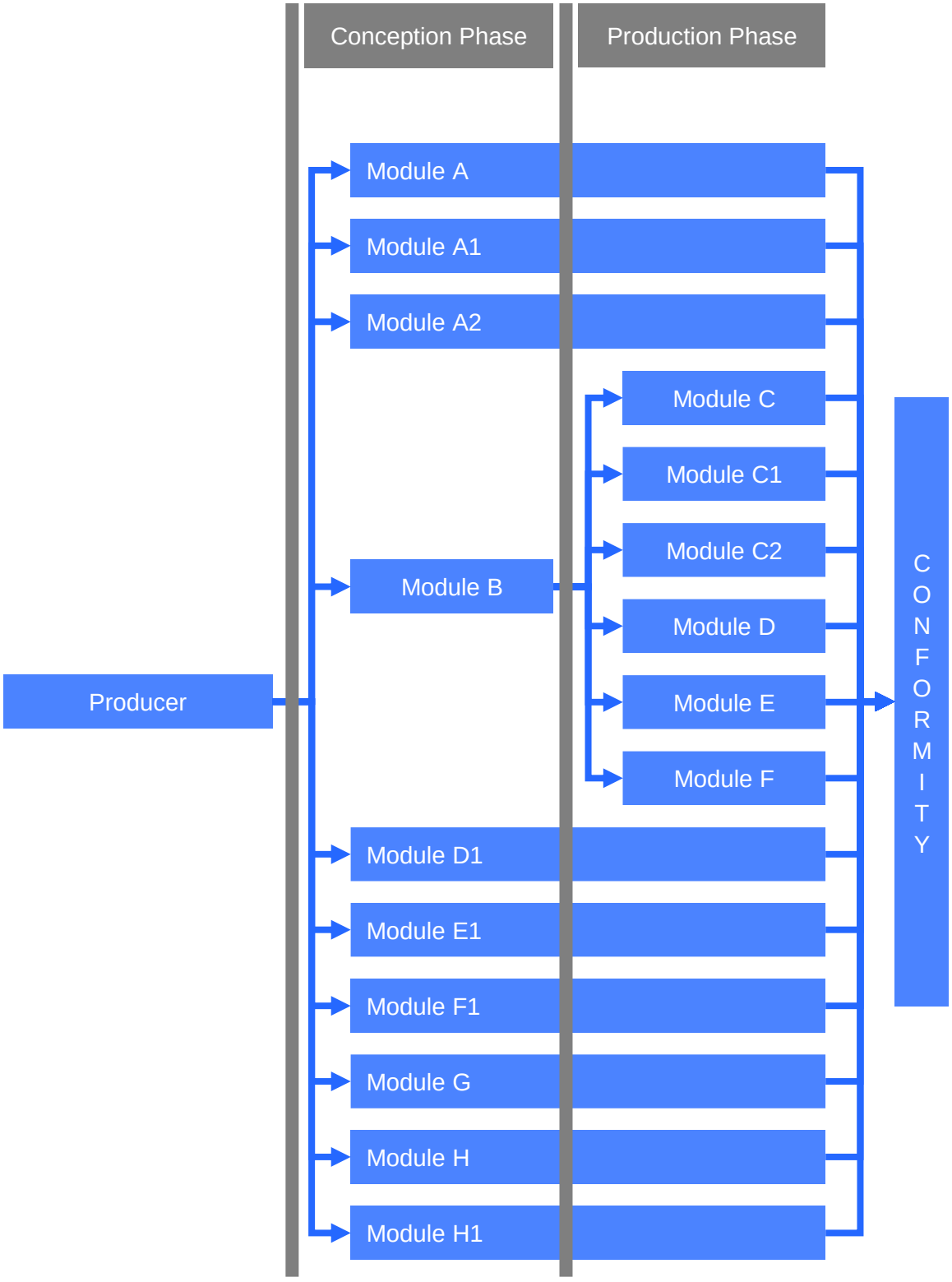
Decision n° 768/2008/EC includes reference provisions that have to be integrated into the legislation relating to products, but it has no direct legal effect. As “New Approach”, directives are aligned with this decision, and following transposing into national legislation, the new requirements become mandatory. In all directives, the applicable conformity assessment (modules) will be taken from the decision, while specifying that some differences might be kept because of the specificities of one sector or another.

The requirements for notified conformity assessment bodies are specified in detail in Article R17 of paragraphs 2 to 11 of Decision 768/2008/EC. The various "new approach" directives may set more requirements for CABs.

As products are subjected to conformity assessment both during the design and production phase, a conformity assessment procedure covers both design and production phases.

A module may cover:

- either one of these two phases (in this case a conformity assessment procedure is composed of two modules);
- or both phases (in this case a conformity assessment procedure is composed of one module).


Conception Phase
Production Phase
Module A
Module A1
Module A2
Module B
Module C
Module C1
Module C2
Module D
Module E
Module F
Module D1
Module E1
Module F1
Module G
Module H
Module H1
Producer
CONFORMITY

Summary of the modules according to the decision n° 768/2008/EC:

	Module A : Internal production control	Module A1 : Internal production control plus supervised product testing	Module A2 : Internal production control plus supervised product checks at random intervals	Module D1 : Quality assurance of the production process	Module E1 : Quality assurance of final product inspection and testing	Module F1 : Conformity based on product verification	Module G : Conformity based on unit verification	Module H : Conformity based on full quality assurance (EN ISO 9001:2015[1])	Module H1 : Conformity based on full quality assurance plus design examination
Design + Production	The manufacturer himself ensures the conformity of the products to the legislative requirements	Module A + tests on specific aspects of the product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer.	Module A	The manufacturer operates a production quality assurance system in order to ensure conformity to legislative requirements.	The manufacturer operates a product quality assurance system for final product inspection and testing in order to ensure conformity to the legislative requirements	The manufacturer ensures compliance of the manufactured products to the legislative requirements	The manufacturer ensures compliance of the manufactured products to the legislative requirements.	The manufacturer operates a full quality assurance system in order to ensure conformity to legislative requirements.	The manufacturer operates a full quality assurance system in order to ensure conformity to legislative requirements.
	/		Product checks at random intervals carried out by a notified body or inhouse accredited body.	The notified body assesses the production quality system.	The notified body assesses the quality system.	The notified body carries out product examinations (testing of every product or statistical checks) in order to control product conformity to the legislative requirements.	The notified body verifies every individual product in order to ensure conformity to legislative requirements.	The notified body assesses the quality system.	The notified body assesses the quality system and the product design and issues an EU design examination certificate[2].

	Module B : EU-type examination		
Design		A notified body examines the technical design and or the specimen of a type and verifies and attests that it meets the requirements of the legislative instrument that apply to it by issuing an EU-type examination certificate. There are 3 ways to carry out EU-type examination: 1) production type, 2) combination of production type and design type and 3) design type.	

	Module C : Conformity to EU-type based on internal production control	Module C1 : Conformity to EU-type based on internal production control plus supervised product testing	Module C2 : Conformity to EU-type based on internal production control plus supervised product checks at random intervals	Module D : Conformity to EU-type based on quality assurance of the production process (EN ISO 9001:2015[3])	Module E : Conformity to EU-type based on product quality assurance (EN ISO 9001:2015[4])	Module F : Conformity to EU-type based on product verification
Production	Manufacturer must internally control its production in order to ensure product conformity against the EU-type approved under module B.	Manufacturer must internally control its production in order to ensure product conformity against the EU-type approved under module B.	Manufacturer must internally control its production in order to ensure product conformity against the EU-type approved under module B.	The manufacturer operates a production (manufacturing part and inspection of final product) quality assurance system in order to ensure conformity to EUtype.	The manufacturer operates a product quality (= production quality without the manufacturing part) assurance system for final product inspection and testing in order to ensure conformity to EU-type	The manufacturer ensures compliance of the manufactured products to approved EU-type.
		Module C + tests on specific aspects of the product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer.	Module C + product checks at random intervals tests on specific aspects of the product carried out by a notified body or in-house accredited body.	The notified body assesses the quality system.	The notified body assesses the quality system.	The notified body carries out product examinations (testing of every product or statistical checks) in order to control product conformity to EU-type.

Manufacturer Notified Body

[1] Except for requirements relating to customer satisfaction and continual improvement.
[2] Supplementary requirements which may be used in sectoral legislation.
[3] Except for subclause 7.3 and requirements relating to customer satisfaction and continual improvement.
[4] Except for subclauses 7.1, 7.2.3, 7.3, 7.4, 7.5.1, 7.5.2, 7.5.3 and requirements relating to customer satisfaction and continual improvement.

3. Presentation of "New approach" directives and regulations for which OLAS accredits conformity assessment bodies.

3.1. Non-automatic weighing instruments

Directive :	Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments
Conformity assessment procedures:	Article 13, Annex II
Requirements relating to notified bodies:	Article 23
Operational obligations of notified bodies:	Article 31
Information obligation of notified bodies :	Article 33
Nationale transposition:	Règlement grand-ducal du 26 janvier 2016 concernant les instruments de pesage à fonctionnement non automatique
Notified Body in Luxembourg:	Service de métrologie (Module : F)

3.2. Lifts

Directive :	Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts
Conformity assessment procedures:	Article 16 (Lifts)
Requirements relating to notified bodies:	Article 24
Operational obligations of notified bodies:	Article 32
Information obligation of notified bodies :	Article 34
Nationale transposition:	Loi du 27 mai 2016 concernant les ascenseurs et les composants de sécurité pour ascenseurs et modifiant la loi modifiée du 15 décembre 2010 relative à la sécurité des jouets
Notified Body in Luxembourg:	LC Luxcontroll ASBL (Annex V, VIII) Vinçotte Luxembourg ASBL (Annex V)

3.3. Pressure equipment

Directive :	Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment
Conformity assessment procedures:	Article 14, Article 15, Article 16, Annex I points 3.1.2 et 3.1.3

Requirements relating to notified bodies:	Article 24
Operational obligations of notified bodies:	Article 34
Information obligation of notified bodies :	Article 36
Nationale transposition:	Loi du 27 juin 2016 concernant la mise à disposition sur le marché des équipements sous pression Règlement grand-ducal du 27 juin 2016 abrogeant le règlement grand-ducal du 21 janvier 2000 concernant les équipements sous pression
Notified Body in Luxembourg:	LC Luxcontrol ASBL (Module: A2, Annexe I §3.1.2)

4. Accreditation for notification purposes

Document EA-2/17 - EA Document on Accreditation for Notification Purposes links the requirements for the assessment of notified bodies to the accreditation standards. Thus, when a CAB demonstrates its compliance with the requirements set out in the relevant harmonised standards (or parts thereof), it is presumed to meet the requirements set out for the notified bodies, to the extent that the applicable harmonised standards cover these requirements.

The following table explains OLAS' approach to the accreditation of CABs for the purpose of notification for the specific directives and modules.

Technical Domain	Module	Standard used by OLAS	Standard given by EA-2/17	Justification
Directive 2014/33/EU : Lifts				
PRO1.1	Final inspection (Annex V)	ISO/IEC 17065	ISO/IEC 17065	/
INS7		ISO/IEC 17020	ISO/IEC 17065 or ISO/IEC 17020	Exception in the EA-2/17
PRO1.1	G (Annex VIII : Unit Verification)	ISO/IEC 17065	ISO/IEC 17065	/
Directive 2014/31/EU : Non-automatic weighing instruments				
INS9.1	F	ISO/IEC 17020	ISO/IEC 17065	ISO/IEC 17020 + §4.1.2, 4.1.3, 7.5 et 7.6 - standard ISO/IEC 17065
Directive 2014/68/EU : Pressure equipment				
PRO1.4.1	A2	ISO/IEC 17065	ISO/IEC 17065	/
PRO1.4.1	G	ISO/IEC 17065	ISO/IEC 17065	/
INS4.3	Annexe I §3.1.2 – Approval of permanent joining personnel	ISO/IEC 17020	ISO/IEC 17024	Cf. annex A029
INS4.4	Annexe I §3.1.2 – Approval of permanent joining procedures	ISO/IEC 17020	ISO/IEC 17020	/