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|  OFFICE LUXEMBOURGEOIS<br>D'ACCREDITATION ET DE<br>SURVEILLANCE | <b>A019 – Legislation concerning<br/>notification of CABs</b> |            |              |  |
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# A019

## Legislation concerning notification of conformity assessment bodies

Modifications: complete revision of the document

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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 notification 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

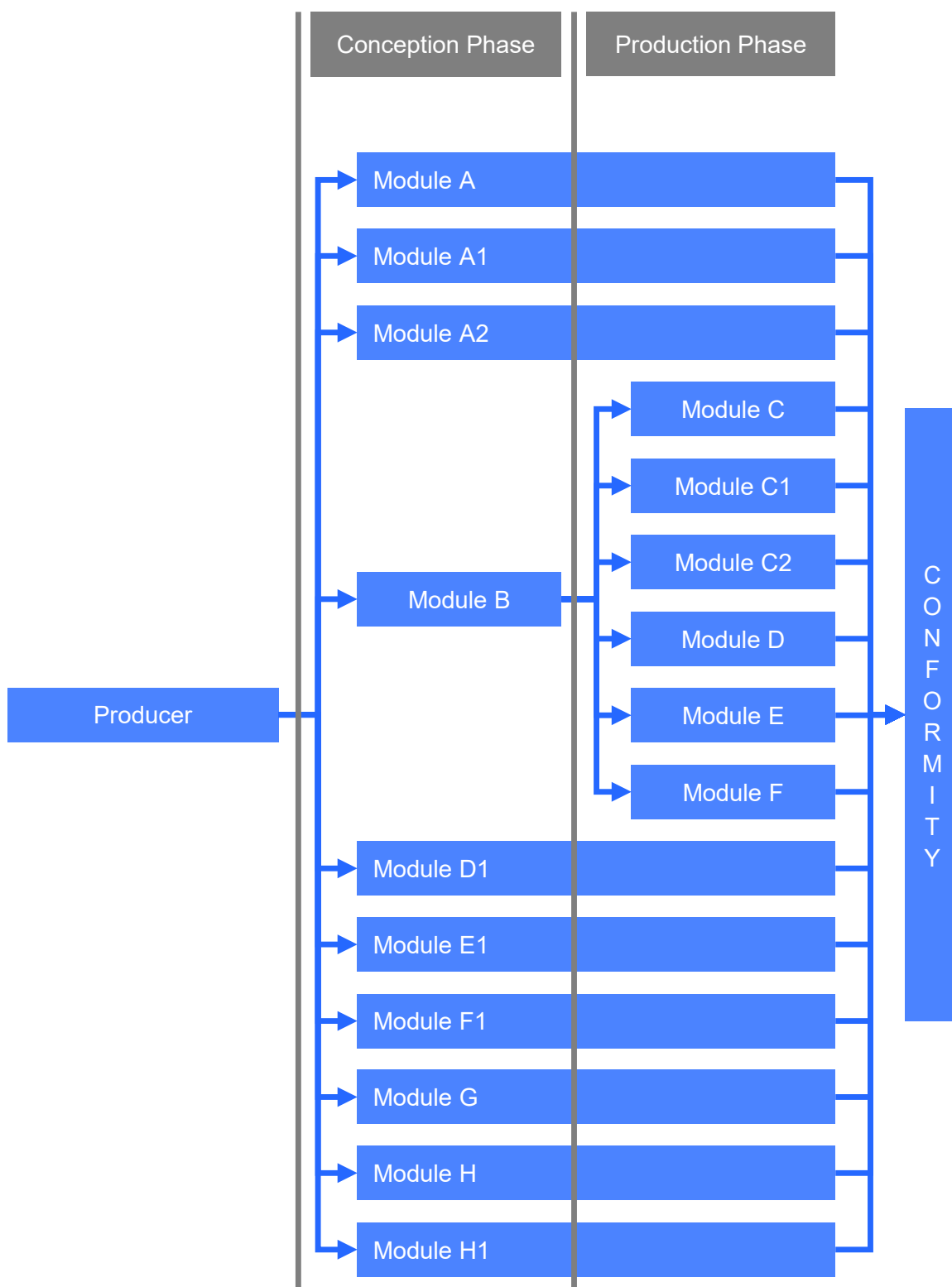
Decision n° 768/2008/EC includes reference provisions that have to be integrated into the legislation relating to products, but it has no direct legal effect. As “New Approach”, directives are aligned with this decision, and following transposing into national legislation, the new requirements become 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).



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 <sup>1</sup> )                               | 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.   |

| 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. |   |  |   |  |  |
| Production                     | 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 <sup>3</sup> )  | Module E : Conformity to EU-type based on product quality assurance (EN ISO 9001:2015 <sup>4</sup> )   | Module F : Conformity to EU-type based on product verification   |
|                                | 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

<sup>1</sup> Except for requirements relating to customer satisfaction and continual improvement.

<sup>2</sup> Supplementary requirements which may be used in sectoral legislation.

<sup>3</sup> Except for subclause 7.3 and requirements relating to customer satisfaction and continual improvement.

<sup>4</sup> 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. Pyrotechnic articles

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|--|--|
| <b>Directive :</b>                                 | <a href="#"><u>Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles</u></a> |
| <b>Conformity assessment procedures:</b>           | Annex II   |
| <b>Requirements relating to notified bodies:</b>   | Article 25   |
| <b>Operational obligations of notified bodies:</b> | Article 33   |
| <b>Information obligation of notified bodies :</b> | Article 35   |
| <b>Nationale transposition:</b>                    | <a href="#"><u>Loi modifiée du 27 mai 2016 concernant la mise à disposition sur le marché d'articles pyrotechniques</u></a>  |
| <b>Notified Body in Luxembourg:</b>                | SNCH (Modules : B, D)  |

#### 3.2. Recreational crafts

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| <b>Directive :</b>                                 | <a href="#"><u>Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC</u></a>   |
| <b>Conformity assessment procedures:</b>           | Article 19   |
| <b>Requirements relating to notified bodies:</b>   | Article 30   |
| <b>Operational obligations of notified bodies:</b> | Article 38   |
| <b>Information obligation of notified bodies :</b> | Article 40   |
| <b>Nationale transposition:</b>                    | <a href="#"><u>Loi du 23 décembre 2016 relative aux bateaux de plaisance et aux véhicules nautiques</u></a><br><br><a href="#"><u>Règlement grand-ducal du 23 décembre 2016 portant abrogation du règlement grand-ducal modifié du 8 septembre 1997 portant application de la directive 94/25/CE du Parlement européen et du Conseil du 16 juin 1994 concernant le rapprochement des dispositions législatives, réglementaires et administratives des Etats membres relatives aux bateaux de plaisance</u></a> |
| <b>Notified Body in Luxembourg:</b>                | SNCH (Article 21: Modules : B, D; Article 22: Modules : A1)  |

### 3.3. Simple pressure vessels

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| <b>Directive :</b>                                 | <a href="#">Directive 2014/29/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 simple pressure vessels</a>  |
| <b>Conformity assessment procedures:</b>           | Annex II  |
| <b>Requirements relating to notified bodies:</b>   | Article 21  |
| <b>Operational obligations of notified bodies:</b> | Article 39  |
| <b>Information obligation of notified bodies :</b> | Article 31  |
| <b>Nationale transposition:</b>                    | <a href="#">Loi du 27 juin 2016 concernant la mise à disposition sur le marché des récipients à pression simples</a><br><a href="#">Règlement grand-ducal du 27 juin 2016 portant abrogation du règlement grand-ducal modifié du 2 juillet 1992 relatif aux récipients à pression simples</a> |
| <b>Notified Body in Luxembourg:</b>                | LC Luxcontrol ASBL (Modules : B, C, C1, C2)   |

### 3.4. Non-automatic weighing instruments

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| <b>Directive :</b>                                 | <a href="#">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</a> |
| <b>Conformity assessment procedures:</b>           | Article 13, Annex II  |
| <b>Requirements relating to notified bodies:</b>   | Article 23  |
| <b>Operational obligations of notified bodies:</b> | Article 31  |
| <b>Information obligation of notified bodies :</b> | Article 33  |
| <b>Nationale transposition:</b>                    | <a href="#">Règlement grand-ducal du 26 janvier 2016 concernant les instruments de pesage à fonctionnement non automatique</a>  |
| <b>Notified Body in Luxembourg:</b>                | Service de métrologie (Module : F)  |

### 3.5. Lifts

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| <b>Directive :</b>                       | <a href="#">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</a> |
| <b>Conformity assessment procedures:</b> | Article 16 (Lifts)   |

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| <b>Requirements relating to notified bodies:</b>   | Article 24  |
| <b>Operational obligations of notified bodies:</b> | Article 32  |
| <b>Information obligation of notified bodies :</b> | Article 34  |
| <b>Nationale transposition:</b>                    | <a href="#">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</a> |
| <b>Notified Body in Luxembourg:</b>                | LC Luxcontrol ASBL (Annex V, VIII)<br>Vinçotte Luxembourg ASBL (Annex V)  |

### 3.6. Pressure equipment

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| <b>Directive :</b>                                 | <a href="#">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</a>   |
| <b>Conformity assessment procedures:</b>           | Article 14, Article 15, Article 16, Annex I points 3.1.2 et 3.1.3  |
| <b>Requirements relating to notified bodies:</b>   | Article 24   |
| <b>Operational obligations of notified bodies:</b> | Article 34   |
| <b>Information obligation of notified bodies :</b> | Article 36   |
| <b>Nationale transposition:</b>                    | <a href="#">Loi du 27 juin 2016 concernant la mise à disposition sur le marché des équipements sous pression</a><br><a href="#">Règlement grand-ducal du 27 juin 2016 abrogeant le règlement grand-ducal du 21 janvier 2000 concernant les équipements sous pression</a> |
| <b>Notified Body in Luxembourg:</b>                | LC Luxcontrol ASBL (Module: A2, B, C2, D, D1, E, E1, F, G, H, H1; Article 15, Annex I §3.1.2)  |

### 3.7. Noise emission in the environment by equipment for use outdoors

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| <b>Directive :</b>                                 | <a href="#">Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors</a> |
| <b>Conformity assessment procedures:</b>           | Annex V, Annex VI, Annex VII, Annex VIII (≡ Module H)  |
| <b>Requirements relating to notified bodies:</b>   | Annex IX   |
| <b>Operational obligations of notified bodies:</b> | /  |
| <b>Information obligation of notified bodies :</b> | /  |



|                                     |  |
|-------------------------------------|--|
| <b>Nationale transposition:</b>     | <a href="#"><u>Règlement grand-ducal modifié du 21 décembre 2001 portant application de la directive 2000/14/CE du Parlement Européen et du Conseil du 8 mai 2000 concernant le rapprochement des législations des Etats membres relatives aux émissions sonores dans l'environnement des matériels destinés à être utilisés à l'extérieur des bâtiments</u></a> |
| <b>Notified Body in Luxembourg:</b> | SNCH (Annexes: VI, VII, VIII)  |

### 3.8. Construction products

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| <b>Directive :</b>                                 | <a href="#"><u>Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC</u></a> |
| <b>Conformity assessment procedures:</b>           | Annex V  |
| <b>Requirements relating to notified bodies:</b>   | Article 43   |
| <b>Operational obligations of notified bodies:</b> | Article 52   |
| <b>Information obligation of notified bodies :</b> | Article 53   |
| <b>Nationale transposition:</b>                    | /  |
| <b>Notified Body in Luxembourg:</b>                | LQMS (Système 2+)  |

#### Assessment and verification of the constancy of performance of construction products

Regulation (EU) n° 305/2011 concerning construction products is a special case. While reference provisions of the decision n° 768/2008/EC have been included in the regulation, it does not use the conformity assessment modules, but it describes 5 systems of assessment and verification of constancy of performances:

- systems 1+/1 : certification of the constancy of performances by a notified body;
- system 2+ : certification of factory production control by a notified body;
- system 3 : determination of the product-type by a notified laboratory;
- system 4 : declaration by the manufacturer.

The following table shows the different tasks for the manufacturer and the notified body under each of the systems for assessing and verifying the constancy of performance of construction products.

| Responsibility | Activity   | certificate of constancy of performance of the product |          | certificate of conformity of the factory production control | No certification |          |
|----------------|--|--|----------|---|------------------|----------|
|                |  | System 1+  | System 1 | System 2+   | System 3         | System 4 |
| Manufacturer   | Sampling for determination of the product-type   |  |          |   | M                |          |
|                | Determination of the product-type on the basis of type-testing, type calculation, tabulated values or descriptive documentation of the product |  |          | M   |                  | M        |
|                | Factory production control   | M  | M        | M   | M                | M        |
|                | Further testing of samples taken at the factory according to the prescribed test plan  | M  | M        | M   |                  |          |
| Notified Body  | Sampling for determination of the product-type   | PCB  | PCB      |   |                  |          |
|                | Determination of the product-type on the basis of type-testing, type calculation, tabulated values or descriptive documentation of the product | TCB  | TCB      |   | L                |          |
|                | Initial inspection of factory and of factory production control  | IB   | IB       | IB  |                  |          |
|                | Continuous surveillance, assessment and evaluation of factory production control   | IB   | IB       | IB  |                  |          |
|                | Audit-testing of samples taken before placing the product on the market  | IB   | TCB      |   |                  |          |

M: Manufacturer  
 PCB: notified product certification body  
 IB: Inspection body under the responsibility of a notified product certification body  
 TCB: Testing laboratory under the responsibility of a notified product certification body  
 L: Testing laboratory

#### 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              |
|---|------------------------------------|-----------------------|---------------------------|----------------------------|
| <b>Directive 2000/14/EC : Noise emission in the environment by equipment for use outdoors</b> |                                    |                       |                           |                            |
| PRO1.9  | Annex VI                           | ISO/IEC 17065         | ISO/IEC 17065             | /                          |
| PRO1.9  | Annex VII                          | ISO/IEC 17065         | /                         | /                          |
| SMQ7.1  | H (Annex VIII)                     | ISO/IEC 17021         | ISO/IEC 17021             | /                          |
| <b>Regulation (EU) n°305/2011 : Construction products</b>                                     |                                    |                       |                           |                            |
| PRO1.3  | Système 2+                         | ISO/IEC 17065         | ISO/IEC 17065             | /                          |
| <b>Directive 2013/53/EU : Recreational craft and personal watercraft</b>                      |                                    |                       |                           |                            |
| PRO1.8  | A1 (sound emissions)               | ISO/IEC 17065         | ISO/IEC 17020             | Historically ISO/IEC 17065 |
| PRO1.8  | B (gaseous emissions)              | ISO/IEC 17065         | ISO/IEC 17065             | /                          |
| SMQ7.2  | D (gaseous emissions)              | ISO/IEC 17021         | ISO/IEC 17065             | System module              |
| <b>Directive 2014/33/EU : Lifts</b>   |                                    |                       |                           |                            |
| PRO1.1  | Final inspection (Annex V)         | ISO/IEC 17065         | /                         | /                          |
| INS7  |                                    | ISO/IEC 17020         | /                         | /                          |
| PRO1.1  | G (Annex VIII : Unit Verification) | ISO/IEC 17065         | ISO/IEC 17065             | /                          |
| <b>Directive 2013/29/EU : Pyrotechnic articles</b>  |                                    |                       |                           |                            |
| PRO1.10   | B                                  | ISO/IEC 17065         | ISO/IEC 17065             | /                          |
| SMQ7.3  | D                                  | ISO/IEC 17021         | ISO/IEC 17065             | System module              |
| <b>Directive 2014/31/EU : Non-automatic weighing instruments</b>                              |                                    |                       |                           |                            |
| INS9.1  | F                                  | ISO/IEC 17020         | ISO/IEC 17065             | Historically ISO/IEC 17020 |
| <b>Directive 2014/29/EU : Simple pressure vessels</b>   |                                    |                       |                           |                            |
| PRO1.4.2  | B                                  | ISO/IEC 17065         | ISO/IEC 17065             | /                          |
| PRO1.4.2  | C                                  | ISO/IEC 17065         | ISO/IEC 17020             | Historically ISO/IEC 17065 |
| PRO1.4.2  | C1                                 | ISO/IEC 17065         | ISO/IEC 17065             | /                          |
| PRO1.4.2  | C2                                 | ISO/IEC 17065         | ISO/IEC 17065             | /                          |
| <b>Directive 2014/68/EU : Pressure equipment</b>  |                                    |                       |                           |                            |
| PRO1.4.1  | A2                                 | ISO/IEC 17065         | ISO/IEC 17020             | Historically ISO/IEC 17065 |
| PRO1.4.1  | B                                  | ISO/IEC 17065         | ISO/IEC 17065             | /                          |
| PRO1.4.1  | C2                                 | ISO/IEC 17065         | ISO/IEC 17065             | /                          |
| PRO1.4.1  | D                                  | ISO/IEC 17065         | ISO/IEC 17065             | /                          |
| PRO1.4.1  | D1                                 | ISO/IEC 17065         | ISO/IEC 17065             | /                          |
| PRO1.4.1  | E                                  | ISO/IEC 17065         | ISO/IEC 17065             | /                          |
| PRO1.4.1  | E1                                 | ISO/IEC 17065         | ISO/IEC 17065             | /                          |
| PRO1.4.1  | F                                  | ISO/IEC 17065         | ISO/IEC 17065             | /                          |
| PRO1.4.1  | G                                  | ISO/IEC 17065         | ISO/IEC 17065             | /                          |

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| Technical Domain | Module | Standard used by OLAS | Standard given by EA-2/17 | Justification              |
|------------------|--------|-----------------------|---------------------------|----------------------------|
| PRO1.4.1         | H      | ISO/IEC 17065         | ISO/IEC 17021             | Historically ISO/IEC 17065 |
| PRO1.4.1         | H1     | ISO/IEC 17065         | ISO/IEC 17065             | /                          |