EA Accreditation for Notification (AfN) Project

Report – Updated
09 April 2020

EUROPEAN ACCREDITATION

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I - Project aims

According Regulation (EC) No 765/2008 accreditation is defined as “an attestation by a National Accreditation Body (NAB) that a Conformity Assessment Body meets the requirements set by harmonized standards and, where applicable, any additional requirements including those set out in relevant sectorial schemes, to carry out a specific conformity assessment activity”. Therefore, NABs have to use harmonized standards for the assessment when accreditation is used as the basis for notification.

The Union Harmonization Legislations do not stipulate which harmonized standard(s) have to be used. That means that Notifying Authorities and/or NABs may choose the appropriate harmonized standard for each of the Union Harmonization Legislations and the related modules. As a consequence, therefore the conformity assessment bodies in different member states have to meet different requirements with the significant effects - inter alia - that:

- accreditations may not be comparable;
- the competence of the accredited bodies may be compromised;
- diversity of expenditures and hence unfair competition for the conformity assessment bodies in Europe;
- this could cause confusion in the marketplace[1].

To ensure a coherent level of outcome provided by conformity assessment bodies being accredited and notified by the Member State the accreditation by NABs should be conducted in a harmonized way throughout Europe.

The aim of the project is the harmonization of the accreditation requirements used as basis for notification by defining the preferred harmonized standards for each Union Harmonization Legislation.

The outputs of the AfN project are also fed into the revision of EA-2/17 – *EA Document on Accreditation for Notification Purposes*. Revision 4 of this Mandatory Document includes the tables of preferred standards and provides for a deadline by when all notified bodies shall be using the preferred standard.

[1] In Commission staff working document (SDW(2014) 23 final) “Evaluation of the Internal Market Legislation for Industrial Products” is stated on p. 68: “However, there were also concerns raised by industry and national authorities regarding the consistency of accreditation across the Union, which was viewed as varying greatly. A number of conformity assessment bodies pointed out that there is a need to build on the progress already made through the NLF in strengthening common approaches to accreditation and developing practical tools, guidance documents and criteria for national Accreditation Bodies carrying out the accreditation of Notified Bodies”.

II - Project headlines

- The initial list of preferred standards has been completed covering 20 Directives and Regulations.
- The process has been undertaken for relevant legislations under the New Legislative Framework (NLF) as well as non-aligned New Approach legislation, for example the Construction Products Regulation.
- The term “aligned” is used in this document to identify legislation that uses the modules defined in decision (EC) 768/2008.
- The results for each legislation have been collated and where possible, in a large number of cases, a common position for each module has been identified.
- The methodology has drawn-in expertise from subject matter experts (from both conformity assessment and technical perspectives) from across the EA community.
- Surveys have taken place where EA members have been asked to comment on the results to date, the Project Team received a number of comments but with many following similar themes, the Project Team has carefully considered these and has offered responses through the Project Steering Group.
- Through the EA Executive Committee, the Project Team has contributed to comments regarding the next revision of the European Commission’s Blue Guide, including the inclusion of ISO/IEC 17065 Conformity assessment — Requirements for bodies certifying products, processes and services for more modules within the conformity assessment standards table.
- Recommendations are made in this report for the use of the list of preferred standards and for the re-issue of EA 2/17 as a Mandatory Document.
- The preferred standards are to be mandatory from a fixed date with no deviation permitted, unless the notifying authorities have published other requirements/standards
- The preferred standards listing is in line with the Blue Guide.
- The results of the AfN Project have as been submitted for inclusion in the Official Journal of the European Union (OJEU) identifying the Conformity Assessment Standards applicable to each module and legislation.
- Methodology needs to be agreed regarding how to deal with new and recast legislation with regard to identifying preferred standards.

III - Project Team

Project Manager: Kevin Belson – UKAS (UK)

Initial Team members: Franco Gattafoni – Accredia (Italy)

George Kallergis – ESYD (Greece)

Stina Nylen – SWEDAC (Sweden)

Gabriel Zrenner – DAkkS (Germany)

Vladimir Mucko – HAA (Croatia)

Experts in individual regulations / directives have been taken from a range or EA NABs including Turkey, Germany, Hungary, UK, Greece, Finland, France, Croatia, Italy, Romania, Sweden, Spain, Czech Republic, Belgium and others. To date a total number of 38 experts have been involved in the project.

IV - Overall Project Status

At the time of writing this report, the following directives/regulations have been subject to review:

- Directive 2014/30/EU – EMC
- Regulation 305/2011/EC – Construction Products
- Directive 2014/33/EC – lifts and safety components for lifts (now updated to include specific coverage of safety components)
- Directive 90/385/EEC – Active implantable medical devices (now replaced by Regulation (EU) 2017/745 on medical devices)
- Directive 92/42/EEC – Hot Water Boilers
- Directive 93/42/EEC – Medical Devices (now replaced by Regulation (EU) 2017/745)
- Directive 98/79/EC – In vitro diagnostic medical devices (now replaced by Regulation (EU) 2017/746)
- Directive 2000/14/EC – Noise emission in the environment by equipment for use outdoors
- Directive 2006/42/EC – Machinery
- Directive 2009/142/EC – Appliances Burning Gaseous Fuels
- Directive 2010/35/EU – Transportable Pressure Equipment

- Directive 2013/29/EU - Pyrotechnic articles
- Directive 2014/31/EU – Non-Automatic Weighing Instruments
- Directive 2014/32/EU – Measuring Instruments (MID)
- Directive 2013/53/EU – Recreational Craft
- Directive 2014/68/EU – Pressure Equipment
- Directive 2014/28/EU - Explosives for Civil Uses
- Directive 2014/29/EU – Simple Pressure Vessels (SPV)
- Directive 2014/34/EU – Equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)
- Directive 2014/53/EU - Radio Equipment
- Directive 2014/90/EU – Marine Equipment
- Regulation (EU) 2016/424 – Cableway Installations
- Regulation (EU)2016/425 – Personal Protective Equipment
- Regulation (EU) 2016/426 – Appliances burning gaseous fuels
- Regulation (EU) 2016/797 – Interoperability of the rail system
- Regulation (EU) 2017/745 – Medical devices*
- Regulation (EU) 2017/746 – In vitro diagnostic medical devices*

*Note: The Medial Devices Regulations have been included in this project and have been analysed using the agreed methodology, however it is recognised that these are treated differently to other regulations as they do not apply accreditation to demonstrate the competence of notified bodies.

For the following legislations there is little or no activity from an accreditation perspective and so these are not being progressed:

- Directive 2004/52/EC – Electronic Road Toll Systems
- Regulation EC No. 552/2004 – European Air Traffic Management

V - Feedback from Results

On an ongoing basis, results have been shared with EA members for comments, initially as part for the original project reporting and later in conjunction with the revision process for EA-2/17 and the draft OJEU listing. All comments received have been considered and incorporated where relevant.

Initial feedback highlighted a clear difference of approach within the EA NABs in certain cases, notably in the use of ISO/IEC 17065 or ISO/IEC 17020 in various modules, and between ISO/IEC 17065 and ISO/IEC 17021-1 for Factory Production Control related modules. However, through discussion and debate a consensus position was agreed regarding these areas.

Summarised below are the main, common issues highlighted:

ISO/IEC 17065 v ISO/IEC 17020

A number of comments were made regarding the many cases where ISO/IEC 17065 has been selected but where respondents believe that ISO/IEC 17020 Conformity assessment — Requirements for the operation of various types of bodies performing inspection would be suitable.

The Project Team agrees that in a number of cases ISO/IEC 17020 would be suitable to address the requirements of the Modules and directives concerned, however please note that the objective of this project is to identify a single preferred standard for each module, and in most cases the review process, using the expert reviewers, has identified ISO/IEC 17065 as the preferred standard.

However, the Project Team disagrees with the use of **ISO/IEC 17020 for Module B**. Module B is for EU Type Examination which covers aspects of inspection but also design review which the Project Team sees as a certification function, therefore ISO/IEC 17065, supported by ISO/IEC 17067 Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes, seems the most appropriate standard. The Blue Guide describes EU-Type Examination as “examination of conformity of the type/specimen against the relevant legal requirements” this is more than inspection. Of course, in accordance with the requirements of ISO/IEC 17065, any inspection activity would need to meet the relevant requirements of ISO/IEC 17020.

ISO/IEC 17065 v ISO/IEC 17021-1 for Factory Production Control (FPC) Related Modules

A number of comments were received stating a preference for ISO/IEC 17021-1 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements to be used for FPC and Production Quality Assurance related modules.

While it is noted that ISO/IEC 17021-1 could be used, this project is to achieve one preferred standard for each module, the majority of experts used selected ISO/IEC 17065. The Project Team concludes that FPC is not the same as a QMS audit as covered by ISO/IEC 17021-1, FPC is a more focussed evaluation of the production controls in place for a particular product type, and this fits better under ISO/IEC 17065.

ISO/IEC 17065 and Testing activities

Some comments were received stating that testing was not covered by ISO/IEC 17065.

The Project Team disagrees, because ISO/IEC 17065 does cover testing, in clauses 6.2.1 and 6.2.2, requiring compliance with the relevant requirements of ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.

ISO/IEC 17065 and Professional Judgement

A number of comments received highlighted a concern that professional judgement is often needed, especially regarding Module G, and that this is not covered by ISO/IEC 17065.

The Project Team concluded that while professional judgement is not specifically stated in ISO/IEC 17065, it would be covered under the overall competence requirements stated in clause 6.1.2.1 of the standard.

Application of ISO/IEC 17065 Requirements

Real harmonisation between the NABs also requires the harmonisation of the clauses in ISO/IEC 17021-1 that will be applicable when ISO/IEC 17065 is used for the modules D, E, H and H1.

VI - Recommendations for Next Steps

It is important that the lists of preferred standards are maintained in the case of revisions/recasts and for new legislation being published. This will fall under the responsibility of the EA Horizontal Harmonisation Committee (HHC), supported by the relevant EA Technical Committees. This will be triggered whenever there is a revision to an existing Regulation/Directive or whenever a new legislation is issued. Any changes will be implemented through the revision of EA-2/17 and, through the European Commission, updates to the OJEU, should the corresponding legislation require such a change. In all cases EA-1/14 *Control of documents* and other mandatory EA, IAF and ILAC documents shall be applied, unless there is a conflict with Regulation (EC) No 765/2008.

However, in carrying out this ongoing maintenance EA will stick to the general principle of using the preferred standard for each legislation and module. This maintenance process should also give due consideration to the Blue Guide on the implementation of EU products rules, published by the European Commission, so as to ensure that EA-2/17 and the Blue Guide remain harmonised.

Depending on the exact subject matter, any questions arising with regard to the general principles of the AfN will be handled by the HHC, questions regarding the technical application/interpretation of a specific Conformity Assessment Scheme in its use in AfN will be considered by the relevant Technical Committee in coordination with the HHC as necessary.

VII - Annex A – Tables of Preferred Standards see EA-2/17)

Note: The column in table 1 entitled “other references equivalent to this module” covers non-aligned legislations where there is a corresponding module covering the same process as the NLF module (for example Annex IX of the Machinery Directive is a direct equivalent of NLF Module B). The table 2 covering non-aligned legislations covers legislations and modules where there are specific attestation modules that do not directly align with the standard NLF modules.

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

Table 1: Preferred Standards for aligned legislations and related conformity assessment activities

Module		Other references equivalent to this module	Preferred Standard	Exceptions
A1	Internal production control plus supervised product testing		ISO/IEC 17020	
A2	Internal production control plus supervised product checks at random intervals		ISO/IEC 17020	Measuring Instruments Directive No 2014/32/ EU: ISO/IEC 17065
B	EU Type Examination	Machinery Directive No 2006/42 EC- Annex IX; In vitro diagnostic medical devices (IVDMD) Directive No 98/79/EC Annex V; Active implantable medical devices (AIMD) Directive No 90/385/EEC Annex III;	ISO/IEC 17065	

Module		Other references equivalent to this module	Preferred Standard	Exceptions
C	Conformity to EU-type based on internal production control		ISO/IEC 17020 (SPV) ISO/IEC 17065 (HWB)	Module C does not require a NB with the exception of: Simple Pressure Vessels Directive No. 2014/29/EU (SPV) Hot-Water Boilers Directive No. 92/42/EEC (HWB)
C1	Conformity to EU-type based on internal production control plus supervised product testing		ISO/IEC 17065	Recreational craft and personal watercraft (RCD) Directive no 2013/53/EU: ISO/IEC 17020
C2	Conformity to EU-type based on internal production control plus supervised product checks at random intervals		ISO/IEC 17065	
D	Conformity to EU-type based on quality assurance of the production process		ISO/IEC 17065	
D1	Quality assurance of the production process		ISO/IEC 17065	
E	Conformity to EU-type based on product quality assurance		ISO/IEC 17065	
E1	Quality assurance of final product inspection and testing		ISO/IEC 17065	

Module		Other references equivalent to this module	Preferred Standard	Exceptions
F	Conformity to EU-type based on product verification	Lifts and safety components for lifts Directive No: 2014/33/EC Annex V Final Inspection	ISO/IEC 17065	Lifts and safety components for lifts Directive No: 2014/33/EC ISO/IEC 17020
F1	Conformity based on product verification		ISO/IEC 17065	
G	Conformity based on unit verification	Noise emission in the environment by equipment for use outdoors Directive No 2000/14/EC Annex VII	ISO/IEC 17065	
H	Conformity based on full quality assurance	Machinery Directive No 2006/42/EC Annex X; Noise emission in the environment by equipment for use outdoors Directive No 2000/14/EC Annex VIII; In vitro diagnostic medical devices (IVDMD) Directive No 98/79/EC Annex IV; Active implantable medical devices (AIMD) Directive No 90/385/EEC Annex II;	ISO/IEC 17021-1	
H1	Conformity based on full quality assurance plus design examination		ISO/IEC 17065	

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Table 2: Preferred Standards for non-aligned legislations and conformity assessment activities, where there is no direct equivalent in the NLF Modules

Legislation	Conformity assessment procedure	Preferred Standard
2014/68/EU Pressure equipment (PED)	Approval of NDT personnel	ISO/IEC 17024
	Approval of Permanent Joining Personnel	ISO/IEC 17024
	Approval of Permanent Joining Procedures	ISO/IEC 17020
	European Approval of Materials	ISO/IEC 17065
Construction Product Regulation (EU) No 305/2011 (CPR)	System 1	ISO/IEC 17065
	System 1+	ISO/IEC 17065
	System 2+	ISO/IEC 17065
	System 3	ISO/IEC 17025
98/79/EC In vitro diagnostic medical devices (IVDMD)	Annex III EC Declaration of Conformity	ISO/IEC 17065
	Annex VI EC Verification	ISO/IEC 17065
	Annex VII EC Declaration of Conformity (Production quality assurance)	ISO/IEC 17065
90/385/EEC Active implantable medical devices (AIMD) modified by Directive No 93/42/EEC, 93/68/EEC and 2007/47/EC	Annex IV EC Verification	ISO/IEC 17065
	Annex V EC Declaration of Conformity to Type (Assurance of production quality)	ISO/IEC 17065

Legislation	Conformity assessment procedure	Preferred Standard
93/42/EEC Medical Devices	Annex IV EC verification	ISO/IEC 17065
	Annex V EC Declaration of Conformity - Production Quality Assurance	ISO/IEC 17065
	Annex VI EC Declaration of Conformity – Product Quality Assurance	ISO/IEC 17065
2000/14/EC Noise emission in the environment by equipment for use outdoors	Type Approval	ISO/IEC 17020: 2012 (except clause 8.1.3)
	Supervision of manufacture and Initial Inspections and Tests	ISO/IEC 17020: 2012 (except clause 8.1.3)
	Periodic Inspections, Intermediate Inspections and Exceptional Inspection	ISO/IEC 17020: 2012 (except clause 8.1.3)
	Surveillance of the in-house inspection service	ISO/IEC 17020: 2012 (except clause 8.1.3)
	Reassessment of conformity	ISO/IEC 17020: 2012 (except clause 8.1.3)
2013/53/EU Recreational craft and personal watercraft (RCD)	PCA – Post construction assessment	ISO/IEC 17065
Railways Interoperability Directive (EU) 2016/797 (RID)	All modules in accordance with Decision 2010/713/EU in conjunction with the ERA Mandatory Technical Document 000MRA1044.	ISO/IEC 17065

VIII - Annex B – Template for consideration by Experts

The following template was used by the experts when considering the most relevant conformity assessment standard for each Legislation/Module/System. The use of the templates was intended to ensure a harmonise approach for the experts concerned and ensure that all relevant aspects were considered.

EA Accreditation for Notification Project (AfN): Review of Best Fit Conformity Assessment Standards per Directive/Regulation and Module

You may be aware that EA has started a project aimed at building on the work already undertaken and further harmonise the approach by NABs to the assessment and accreditation of CABs for Notification purposes.

As part of the activity, we are undertaking a review of each directive/regulation and attestation module (or equivalent) to define which conformity assessment standard (accreditation standard) is the most suitable, preferred standard, for accrediting CABs for that activity.

As an expert in a specific direction/regulation, you are asked to review the directive and modules concerned, using this form, and taking consideration of the points listed, to state what you feel is the best fit or preferred standard. You are also asked to note any additional requirements of the directive/module that are not specifically covered by the conformity assessment standard.

Please note that the form can be expanded to allow more space as needed.

If you have any questions, please contact the EA Secretariat - secretariat@european-accreditation.org

EA Accreditation for Notification Project: Choice of Standards Questionnaire

Directive/Regulation:	Module/System/Attestation process:

1. Using your expertise in the above directive, consider the requirements for accrediting a Notified body for each module and suggest which should be the preferred conformity assessment standard to use, taking into account the following points, please justify your choice.	Suggested Preferred Standard:
	Justification:
• Is it specifically required by the regulation/directive?	
• Does the standard cover the conformity assessment activities (best fit)?	
• Does the chosen standard provide the necessary assurance?	

Directive/Regulation:	Module/System/Attestation process:

• How can the choice be justified to the marketplace (stakeholders)?	
• Could be applied to other modules of the same directive?	
• Does the standard cover additional requirements within the legislation (e.g. independence, liability assurance)?	
• What other standards could be used as alternatives?	
You may also consider the following related points:	
• The output to the conformity assessment activity (T/E certificate, lab test etc.).	
• The Blue Guide	
• EA 2/17	
• Industry practice (if there is a very well accepted approach)	
• (NB Guidelines for implementation)	
• (EC Guidelines for implementation)	
2. What should we consider regarding additional requirements?	Response
Are there any NB related requirements in the directive that would not be directly covered by the Conformity assessment standard? (for example specific competence requirements, third party requirements or risk methodology). Also please consider if there are requirements not covered by the best fit conformity assessment standard but that are covered in other conformity assessment standards. Please list these additional requirements and identify the relevant document and clause.	

Review carried out by	Name:	National Accreditation Body:	Date:

IX - Annex C – Directory of Preferred Conformity Assessment Standards per Directive/Regulation

The preferred standards listed below have been recommended following a thorough process of review by technical and accreditation experts taking consideration of a range of factors relating to the accreditation in support of Notified Body activity.
The tables only cover Modules that require input from a Notified Body or Equivalent.
Any specific additional elements to be covered in addition to the preferred conformity assessment standard are included in blue text, in all cases the specific requirements of the Directive or Regulation concerned, and of EA 2/17, must be included.

Directive / Regulation	Directive 2014/30/EU - EMC	
Attestation Module / System	**Preferred Standard**	**Justification**
Module B – EU Type Examination	ISO/IEC 17065	Both 17020 and 17065 were recommended by the experts, after discussion by the project team using the required criteria for the project, ISO/IEC 17065 was selected as it covers all aspects of Module B. It also links into ISO/IEC 17020 through clause 6.2.1 and 6.2.2. This review was carried out using the new version directive. However for EMC there is concentration on inspection of documentation and historically many NBs are accredited to ISO/IEC 17020.

Directive / Regulation	Regulation 305/2011/EC - Construction Products	
Attestation Module / System	**Preferred Standard**	**Justification**
System 1	ISO/IEC 17065	The System is clearly aimed at Product Certification and this is the clear choice of standard.
System 1+	ISO/IEC 17065	This system covers product certification with testing, ISO/IEC 17065 covers the testing requirements while focussing on product certification, it is a clear fit for this system.
System 2+	ISO/IEC 17065	This system is for factory production control and this is best assessed through ISO/IEC 17065.
System 3	ISO/IEC 17025	This system is aimed purely at testing and so ISO/IEC 17025 is clearly the correct standard.

Directive / Regulation	Directive 2014/33/EC - lifts and safety components for lifts	
LIFTS		
Attestation Module / System	**Preferred Standard**	**Justification**
Module B Annex IV B	ISO/IEC 17065 Reference clause 6.2 for MS elements: a 2 stage initial audit is not necessary)	Although it is not uncommon for Lifts NBs to be accredited to ISO/IEC 17020, 17065 is seen as the most suitable standard for this activity as it covers all elements of the module.
Module D Annex XII	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Module E Annex X	ISO/IEC 17065	This module concerns Product Quality Assurance is a more focussed audit rather than a management systems assessment.
Module G Annex VIII	ISO/IEC 17065	As this module is carried out alongside Module B, ISO/IEC 17065 is seen as the best fit.
Module H1 Annex XI	ISO/IEC 17065 (reference clause 6.2: a 2 stage initial audit is not necessary)	This is a QA based module but with design examination, ISO/IEC 17065 covers both of these activities.
Annex VI Final Inspection Annex V	ISO/IEC 17020 Type A Inspection Body	This standard is the best fit for this module which is inspection based.
SAFETY COMPONENTS FOR LIFTS		
Attestation Module / System	**Preferred Standard**	**Justification**
Module B Annex IV A	ISO/IEC 17065 Reference clause 6.2 for MS elements: a 2 stage initial audit is not necessary)	ISO/IEC 17065 covers all aspects of Type Examination and links to other Conformity Assessment Standards through clause 6.2.
Module E Annex VI	ISO/IEC 17065	This module concerns Product Quality Assurance is a more focussed audit rather than a management systems assessment.
Module H Annex VII	ISO/IEC 17021-1 + Auditor competence must include specific product knowledge	This module is based on Quality Assurance auditing.
Module C2 Annex IX	ISO/IEC 17065	Production control elements are clearly covered by this standard and any product testing is provided for through clause 6.2.

Directive / Regulation	Directive 2014/34/EU - ATEX	
Attestation Module / System	**Preferred Standard**	**Justification**
Module B	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of Type Examination and links to other Conformity Assessment Standards through clause 6.2.
Module C1	ISO/IEC 17065	Production control elements are clearly covered by this standard and any product testing is provided for through clause 6.2.
Module D	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Module E	ISO/IEC 17065	This module concerns Product Quality Assurance is a more focussed audit rather than a management systems assessment.
Module F	ISO/IEC 17065	The required output for this module is a Certificate of Conformity and 17065 is the best standard to cover the activities required.
Module G	ISO/IEC 17065	As this module is carried out alongside Module B, ISO/IEC 17065 is seen as the best fit.

Directive / Regulation	Directive 2014/68/EU – Pressure Equipment	
Attestation Module / System	**Preferred Standard**	**Justification**
Approval of NDT Personnel	ISO/IEC 17024	This is an RTPO activity and is clearly personnel certification.
Approval of Permanent Joining Personnel	ISO/IEC 17024	This is an RTPO activity and is clearly personnel certification.
Approval of Permanent Joining Procedures	ISO/IEC 17020 Type A Inspection Body	This is an inspection activity, inspecting the permanent joining procedures.
European Approval of Materials	ISO/IEC 17065	The module requires determination of the appropriate inspections and tests; this is more than just an inspection, or just a testing activity. ISO/IEC 17065 incorporates all of these activities.

Directive / Regulation	Directive 2014/68/EU – Pressure Equipment	
Attestation Module / System	**Preferred Standard**	**Justification**
Module A2	ISO/IEC 17020 Type A Inspection Body	This module covers random product checks to verify ongoing conformity, it is an inspection activity.
Module B	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of Type Examination and links to other Conformity Assessment Standards through clause 6.2.
Module B1	ISO/IEC 17065	This module specifically includes conformity of design which would indicate a product certification approach.
Module C2	ISO/IEC 17065	Production control elements are clearly covered by this standard and any product testing is provided for through clause 6.2.
Module D	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Module D1	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Module E	ISO/IEC 17065	This module concerns Product Quality Assurance is a more focussed audit rather than a management systems assessment.
Module E1`	ISO/IEC 17065	This module concerns Product Quality Assurance is a more focussed audit rather than a management systems assessment.
Module F	ISO/IEC 17065	The required output for this module is a Certificate of Conformity and 17065 is the best standard to cover the activities required.
Module G	ISO/IEC 17065	As this module is carried out alongside Module B, ISO/IEC 17065 is seen as the best fit.
Module H	ISO/IEC 17021-1 + Auditor competence must include specific product knowledge	This module is based on Quality Assurance auditing.
Module H1	ISO/IEC 17065	This is a QA based module but with design examination, ISO/IEC 17065 covers both of these activities.

Directive / Regulation	Directive 2014/29/UE SPV	
Attestation Module / System	Preferred Standard	Justification
Module B	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of Type Examination and links to other Conformity Assessment Standards through clause 6.2.
Module C	ISO/IEC 17020 Type A Inspection Body	This is a special case, normally Module C does not require intervention by the Notified Body but for this directive there is a specific action for the NB to examine documents created by the manufacturer.
Module C1	ISO/IEC 17065	Production control elements are clearly covered by this standard and any product testing is provided for through clause 6.2.
Module C2	ISO/IEC 17065	Production control elements are clearly covered by this standard and any product testing is provided for through clause 6.2.

Directive / Regulation	Directive 2014/28/EU Explosives for Civil Uses	
Attestation Module / System	Preferred Standard	Justification
Module B	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of Type Examination and links to other Conformity Assessment Standards through clause 6.2.
Module C2	ISO/IEC 17065	Production control elements are clearly covered by this standard and any product testing is provided for through clause 6.2.
Module D	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Module E	ISO/IEC 17065	This module concerns Product Quality Assurance is a more focussed audit rather than a management systems assessment.
Module F	ISO/IEC 17065	The required output for this module is a Certificate of Conformity and 17065 is the best standard to cover the activities required.
Module G	ISO/IEC 17065	As this module is carried out alongside Module B, ISO/IEC 17065 is seen as the best fit.

Directive / Regulation	Directive 2013/29/EU Pyrotechnic articles	
Attestation Module / System	**Preferred Standard**	**Justification**
Module B	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of Type Examination and links to other Conformity Assessment Standards through clause 6.2.
Module C2	ISO/IEC 17065	Production control elements are clearly covered by this standard and any product testing is provided for through clause 6.2.
Module D	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Module E	ISO/IEC 17065	This module concerns Product Quality Assurance is a more focussed audit rather than a management systems assessment.
Module G	ISO/IEC 17065	As this module is carried out alongside Module B, ISO/IEC 17065 is seen as the best fit.
Module H	ISO/IEC 17021-1 + Auditor competence must include specific product knowledge	This module is based on Quality Assurance auditing.

Directive / Regulation	Directive 2014/53/EU Radio Equipment	
Attestation Module / System	**Preferred Standard**	**Justification**
Module B	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of Type Examination and links to other Conformity Assessment Standards through clause 6.2.
Module H	ISO/IEC 17021-1 + Auditor competence must include specific product knowledge	This module is based on Quality Assurance auditing.

Directive / Regulation	Directive 2006/42/EC Machinery	
Attestation Module / System	**Preferred Standard**	**Justification**
Annex IX EC Type Examination	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of Type Examination and links to other Conformity Assessment Standards through clause 6.2.
Annex X Full Quality Assurance	ISO/IEC 17021-1 + Auditor competence must include specific product knowledge	This module is based on Quality Assurance auditing.

Directive / Regulation	Directive 2014/90/EU Marine Equipment	
Attestation Module / System	**Preferred Standard**	**Justification**
Module B	ISO/IEC 17065	The usage of ISO/IEC 17065 is explicitly required by the Marine Equipment Directive, see annex III point 18. This requires all conformity assessment bodies to comply with this standard in order to be notified. Beside this the experts analysing this directive also unanimously recommended ISO/IEC 17065 as being the standard most suitable for this module.
Module D	ISO/IEC 17065	The usage of ISO/IEC 17065 is explicitly required by the Marine Equipment Directive, see annex III point 18. This requires all conformity assessment bodies to comply with this standard in order to be notified. Beside this the experts analysing this directive also unanimously recommended ISO/IEC 17065 as being the standard most suitable for this module.
Module E	ISO/IEC 17065	The usage of ISO/IEC 17065 is explicitly required by the Marine Equipment Directive, see annex III point 18. This requires all conformity assessment bodies to comply with this standard in order to be notified. Beside this the experts analysing this directive also unanimously recommended ISO/IEC 17065 as being the standard most suitable for this module.
Module F	ISO/IEC 17065	The usage of ISO/IEC 17065 is explicitly required by the Marine Equipment Directive, see annex III point 18. This requires all conformity assessment bodies to comply with this standard in order to be notified. Beside these two of the three experts analysing this directive also recommended ISO/IEC 17065 as being the standard most suitable for this module.
Module G	ISO/IEC 17065	The usage of ISO/IEC 17065 is explicitly required by the Marine Equipment Directive, see annex III point 18. This requires all conformity assessment bodies to comply with this standard in order to be notified. Beside these two of the three experts analysing this directive also recommended ISO/IEC 17065 as being the standard most suitable for this module.

Directive / Regulation	Directive 2013/53/EU Recreational Craft	
Attestation Module / System	**Preferred Standard**	**Justification**
Module A1	ISO/IEC 17020	This standard covers all aspects of activity required by this Module for the RCD.
Module B	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of Type Examination and links to other Conformity Assessment Standards through clause 6.2.
Module C1	ISO/IEC 17020	Standard ISO/IEC 17020 was unanimously chosen by all experts. In the specific case of the RCD, the product conformity aspects are carried out by the manufacturer, the activities carried by the notified body are very much inspection based (exhaust emissions).
Module D	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Module E	ISO/IEC 17065	The choice of the standard only had to decide between ISO/IEC 17021-1 and ISO/IEC 17065. The standard ISO/IEC 17065 was chosen as being most suitable, as according to the results of the experts the choice of ISO/IEC 17021-1 would have required additional product knowledge in the area of RCD.
Module F	ISO/IEC 17065	The required output for this module is a Certificate of Conformity and 17065 is the best standard to cover the activities required.
Module G	ISO/IEC 17065	The choice of the standard only had to decide between ISO/IEC 17020 and ISO/IEC 17065. The standard ISO/IEC 17065 was chosen as being most suitable, as the module requires issuance of a certificate and because it seemed to be an additional alternative for all experts.
Module H	ISO/IEC 17021-1 + Auditor competence must include specific product knowledge	This module is based on Quality Assurance auditing.
PCA – Post construction assessment	ISO/IEC 17065	ISO/IEC 17065 was chosen as it fits the module and seems to be an alternative for all experts.

Directive / Regulation	Directive 93/42/EEC Medical Devices	
Attestation Module / System	**Preferred Standard**	**Justification**
Annex II EC DECLARATION OF CONFORMITY (full quality assurance)	ISO/IEC 17065	This standard covers all aspects of activity required by this Module for this specific directive.
Annex III EC type examination	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of Type Examination and links to other Conformity Assessment Standards through clause 6.2.
Annex IV EC verification	ISO/IEC 17065	The annex IV is comparable to module C and is described as product certification and contains steps that are covered by ISO/IEC 17065.
Annex V EC DECLARATION OF CONFORMITY - Production quality assurance	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Annex VI EC DECLARATION OF CONFORMITY (Product quality assurance)	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.

Directive / Regulation	98/79/EC IVDMD- in vitro diagnostic medical devices	
Attestation Module / System	**Preferred Standard**	**Justification**
Annex III EC declaration of conformity	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of this module.
Annex IV EC DECLARATION OF CONFORMITY (Full quality assurance system)	ISO/IEC 17021-1	This is a true Full QA based module and so ISO/IEC 17021-1 is intended for these activities.
Annex V EC TYPE-EXAMINATION	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of Type Examination and links to other Conformity Assessment Standards through clause 6.2.
Annex VI EC VERIFICATION	ISO/IEC 17065	The annex IV is comparable to module C and is described as product certification and contains steps that are covered by ISO/IEC 17065.
Annex VII EC DECLARATION OF CONFORMITY (Production quality assurance)	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.

Directive / Regulation	90/385/EEC- AIMD - active implantable medical devices	
Attestation Module / System	**Preferred Standard**	**Justification**
Annex 2 EC declaration of conformity (complete quality assurance system)	ISO/IEC 17021-1	This is a true Full QA based module and so ISO/IEC 17021-1 is intended for these activities.
Annex 3 EC TYPE-EXAMINATION	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of Type Examination and links to other Conformity Assessment Standards through clause 6.2.
Annex 4 EC VERIFICATION	ISO/IEC 17065	The annex IV is comparable to module C and is described as product certification and contains steps that are covered by ISO/IEC 17065.
Annex 5 EC DECLARATION OF CONFORMITY TO TYPE (Assurance of production quality)	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.

Directive / Regulation	Directive 2000/14/EC Noise emission in the environment by equipment for use outdoors	
Attestation Module / System	**Preferred Standard**	**Justification**
Annex VI Internal control of production with assessment of technical documentation and periodical checking	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Annex VIII Full quality assurance,	ISO/IEC 17021-1	This is equivalent to Module H for which ISO/IEC 17021-1 is seen as the best fit as this is a QMS approach.
Annex VII Unit verification	ISO/IEC 17065	All activities required by this Annex are covered by ISO/IEC 17065.

Directive / Regulation	Directive 2010/35/EU TPED	
Attestation Module / System	**Preferred Standard**	**Justification**
Type Approval	ISO/IEC 17020	Specifically required by the Directive.
Supervision of the Manufacture	ISO/IEC 17020	Specifically required by the Directive.
Periodic Inspections, Intermediate Inspections and Exceptional Checks	ISO/IEC 17020	Specifically required by the Directive.
Initial Inspections and Tests	ISO/IEC 17020	Specifically required by the Directive.

Directive / Regulation	Directive 2009/142/EC Appliances Burning Gaseous Fuels	
Attestation Module / System	**Preferred Standard**	**Justification**
Annex II EC Type Examination	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of Type Examination and links to other Conformity Assessment Standards through clause 6.2.
Annex II EC Declaration of Conformity	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of this activity and links to other Conformity Assessment Standards through clause 6.2.
Annex II EC Verification	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of this activity and links to other Conformity Assessment Standards through clause 6.2, a certificate of conformity is issued.
Annex II EC Unit Verification	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of this activity and links to other Conformity Assessment Standards through clause 6.2, a certificate of conformity is issued.
Annex II EC Declaration of Conformity to Type (guarantee of production quality)	ISO/IEC 17065	This is a product conformity module and ISO/IEC 17065 is the best fit standard for this activity.

Directive / Regulation	Directive 2014/32/EU Measuring Instruments Directive	
Attestation Module / System	**Preferred Standard**	**Justification**
Module A2	ISO/IEC 17065	This standard covers all aspects of activity required by this Module.
Module B	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of this activity and links to other Conformity Assessment Standards through clause 6.2.
Module C	ISO/IEC 17065	Production control elements are clearly covered by this standard and any product testing is provided for through clause 6.2.
Module C2	ISO/IEC 17065	Production control elements are clearly covered by this standard and any product testing is provided for through clause 6.2.
Module D	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Module D1	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Module E	ISO/IEC 17065	This module concerns Product Quality Assurance is a more focussed audit rather than a management systems assessment.
Module E1	ISO/IEC 17065	This module concerns Product Quality Assurance is a more focussed audit rather than a management systems assessment.
Module F	ISO/IEC 17065	The required output for this module is a Certificate of Conformity and 17065 is the best standard to cover the activities required.
Module F1	ISO/IEC 17065	The required output for this module is a Certificate of Conformity and 17065 is the best standard to cover the activities required.
Module G	ISO/IEC 17065	The choice of the standard only had to decide between ISO/IEC 17020 and ISO/IEC 17065. The standard ISO/IEC 17065 was chosen as being most suitable, as the module requires issuance of a certificate and because it seemed to be an additional alternative for all experts.
Module H	ISO/IEC 17021-1 + Auditor competence must include specific product knowledge	This module is based on Quality Assurance auditing.
Module H1	ISO/IEC 17065	This is a QA based module but with design examination, ISO/IEC 17065 covers both of these activities.

Directive / Regulation	Directive 2014/31/EU Non-Automatic Weighing Instruments	
Attestation Module / System	**Preferred Standard**	**Justification**
Module B	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of this activity and links to other Conformity Assessment Standards through clause 6.2.
Module D	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Module D1	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Module F	ISO/IEC 17065	The required output for this module is a Certificate of Conformity and 17065 is the best standard to cover the activities required.
Module F1	ISO/IEC 17065	The required output for this module is a Certificate of Conformity and 17065 is the best standard to cover the activities required.
Module G	ISO/IEC 17065	The choice of the standard only had to decide between ISO/IEC 17020 and ISO/IEC 17065. The standard ISO/IEC 17065 was chosen as being most suitable, as the module requires issuance of a certificate and because it seemed to be an additional alternative for all experts.

Directive / Regulation	Directive 92/42/EC Hot Water Boilers	
Attestation Module / System	**Preferred Standard**	**Justification**
Module B	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of this activity and links to other Conformity Assessment Standards through clause 6.2.
Module C	ISO/IEC 17065	Production control elements are clearly covered by this standard and any product testing is provided for through clause 6.2.
Module D	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Module E	ISO/IEC 17065	This module concerns Product Quality Assurance is a more focussed audit rather than a management systems assessment.

Directive / Regulation	Regulation (EU) 2016/424 Cableway Installations	
Attestation Module / System	Preferred Standard	Justification
Module B	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of this activity and links to other Conformity Assessment Standards through clause 6.2.
Module D	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Module F	ISO/IEC 17065	The required output for this module is a Certificate of Conformity and 17065 is the best standard to cover the activities required.
Module G	ISO/IEC 17065	The choice of the standard only had to decide between ISO/IEC 17020 and ISO/IEC 17065. The standard ISO/IEC 17065 was chosen as being most suitable, as the module requires issuance of a certificate and because it seemed to be an additional alternative for all experts.
Module H1	ISO/IEC 17065	This is a QA based module but with design examination, ISO/IEC 17065 covers both of these activities.

Directive / Regulation	Regulation (EU) 2016/425 PPE	
Attestation Module / System	Preferred Standard	Justification
Module B	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of this activity and links to other Conformity Assessment Standards through clause 6.2.
Module C	ISO/IEC 17065	Production control elements are clearly covered by this standard and any product testing is provided for through clause 6.2.
Module C2	ISO/IEC 17065	Production control elements are clearly covered by this standard and any product testing is provided for through clause 6.2.
Module D	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.

Directive / Regulation	Regulation (EU) 2016/426 Appliances Burning Gaseous Fuels	
Attestation Module / System	**Preferred Standard**	**Justification**
Module B	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of this activity and links to other Conformity Assessment Standards through clause 6.2.
Module C2	ISO/IEC 17065	Production control elements are clearly covered by this standard and any product testing is provided for through clause 6.2.
Module D	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Module E	ISO/IEC 17065	This module concerns Product Quality Assurance is a more focussed audit rather than a management systems assessment.
Module F	ISO/IEC 17065	The required output for this module is a Certificate of Conformity and 17065 is the best standard to cover the activities required.
Module G	ISO/IEC 17065	The choice of the standard only had to decide between ISO/IEC 17020 and ISO/IEC 17065. The standard ISO/IEC 17065 was chosen as being most suitable, as the module requires issuance of a certificate and because it seemed to be an additional alternative for all experts.

Directive / Regulation	Directive (EU) 2016/797 Interoperability of the Rail System	
Attestation Module / System	**Preferred Standard**	**Justification**
Module A1	ISO/IEC 17020	This standard covers all aspects of activity required by this Module.
Module A2	ISO/IEC 17020	This standard covers all aspects of activity required by this Module.
Module C1	ISO/IEC 17065	Production control elements are clearly covered by this standard and any product testing is provided for through clause 6.2.
Module C2	ISO/IEC 17065	Production control elements are clearly covered by this standard and any product testing is provided for through clause 6.2.
Module B	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of this activity and links to other Conformity Assessment Standards through clause 6.2.
Module D	ISO/IEC 17065	As this module is aimed at Production Quality Assurance it is more focussed than a full MS assessment, therefore 17065 is the best standard. The audit will focus closely on the design and production controls in place to assure continuous compliance to type as covered by the CE certification.
Module F	ISO/IEC 17065	The required output for this module is a Certificate of Conformity and 17065 is the best standard to cover the activities required.
Modules in accordance with Decision 2010/713/EU in conjunction with the ERA Mandatory Technical Document 000MRA1044.	ISO/IEC 17065	ISO/IEC 17065 covers all aspects of this activity as defined in the Directive and Decision.

Directive / Regulation	Regulation (UE) 2017/745 Medical Devices	
Attestation Module / System	**Preferred Standard**	**Justification**
Annex IX Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation	ISO/IEC 17065	ISOIEC 17065 is considered to be the best fit as this Annex is based on more than just a QMS audit, it includes assessment of technical documentation which falls under product certification.
Annex X Conformity Assessment based on Type-Examination	ISO/IEC 17065	This is directly a product certification activity.
Annex XI Conformity Assessment based on Product Conformity Verification	ISO/IEC 17065	This is directly a product certification activity.

Directive / Regulation	Regulation (EU) 2017/746 In vitro diagnostic medical devices	
Attestation Module / System	**Preferred Standard**	**Justification**
Annex IX Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation	ISO/IEC 17020	ISOIEC 17065 is considered to be the best fit as this Annex is based on more than just a QMS audit, it includes assessment of technical documentation which falls under product certification.
Annex X Conformity Assessment based on Type-Examination	ISO/IEC 17065	This is directly a product certification activity.
Annex XI Conformity Assessment based on Production Quality Assurance	ISO/IEC 17065	This is directly a product certification activity.