



EA Accreditation for Notification (AfN) Project

**Final Project Report
endorsed by the EA General Assembly in May 2016**

EA has completed its Accreditation for Notification (AfN) Project, aimed at increasing harmonisation between accreditation bodies when accrediting Conformity Assessment Bodies for the purposes of Notification against EU Directives. The project has called on expertise from across the EA and has resulted in the creation of a list of Preferred Conformity Assessment Standards for each Regulation/Directive and Module. It is expected that the list of preferred standards will be published in an updated version of publication EA-2/17 - *EA Document on Accreditation for Notification Purposes*.

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1. 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 thereof 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.

2. Project headlines

- The initial list of preferred standards has been completed covering 20 Directives and Regulations.
- The results for each directive have been collated and where possible a common position for each module has been identified.
- The methodology has drawn-in expertise from subject matter experts from across the EA community.

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”.

- 2 Surveys have taken place where EA members have been asked to comment on the results to date, the PT received a number of comments but with many following similar themes, the Project Team has carefully considered these and has offered responses through the PSG.
- Through the EA EX Committee, the PT has contributed to comments regarding the next revision of the EC Blue Guide, including the inclusion of ISO/IEC 17065 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 listing is in line with the draft Blue Guide.
- Methodology needs to be agreed regarding how to deal with new and recast legislation with regard to identifying preferred standards.

3. Project Team

Project Manager: Kevin Belson – UKAS (UK)

Team members: Franco Gattafoni – Accredia (Italy)
 George Kallergis – ESYD (Greece)
 Stina Nylen – SWEDAC (Sweden)
 Gabriel Zrenner – DAkkS (Germany)
 Vladimir Mucko – HAA (Croatia)

Project Steering Group (comprising members of the EA Executive Committee)

Vagn Anderson – DANAK (Denmark) - Convenor
 Leopoldo Cortex – IPAC (Portugal)
 Rózsa Ring – NAT (Hungary)
 Geir Samuelsen – NA (Norway)

Experts in individual regulations / directives have been taken from a range of EA NABs including Turkey, Germany, Hungary, UK, Greece, Finland, France, Croatia, Italy, Romania, Sweden, Spain, Belgium and others. To date a total number of 29 experts have been involved in the project.

4. Overall Project Status

The project has not considered those directives that will shortly be recast (for example PPE), it was agreed to defer these until the recast directive is made available.

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 2014/34/EU – equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)
- Directive 2014/68/EU – Pressure Equipment
- Directive 2014/29/EU – Simple Pressure Vessels (SPV)
- Directive 2014/28/EU - Explosives for Civil Uses
- Directive 2013/29/EU - Pyrotechnic articles
- Directive 2014/53/EU - Radio Equipment
- Directive 2006/42/EC – Machinery
- Directive 2014/90/EU – Marine Equipment
- Directive 2013/53/EU – Recreational Craft
- Directive 93/42/EEC – Medical Devices
- Directive 98/79/EC - In vitro diagnostic medical devices
- Directive 90/385/EEC- AIMD- Active implantable medical devices
- Directive 2000/14/EC - Noise emission in the environment by equipment for use outdoors
- Directive 2010/35/EU – Transportable Pressure Equipment
- Directive 2014/31/EU – Non Automatic Weighing Instruments: Awaiting results from one remaining expert
- Directive 2014/32/EU – Measuring Instruments (MID): Awaiting results from one remaining expert
- Directive 2009/142/EC Appliances Burning Gaseous Fuels

For the following directives there is little or no activity and so these are not being progressed at the moment: -

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

5. Feedback from Results

The AfN results to date have been collated into a table of preferred standards, versions of which have been circulated to EA NABs requesting comments. A number of constructive comments have been received and these are welcomed. Specific PT feedback is included in the comments listing, this includes some comments specific to the directive and module concerned and these have been carefully considered and taken into account by the PT.

Feedback highlights 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 for Factory Production Control related modules.

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 would be suitable.

The PT 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 PT 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 PT sees as a certification function, therefore ISO/IEC 17065, supported by ISO/IEC 17067, 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 for FPC Related Modules

A number of comments were received stating a preference for ISO/IEC 17021 to be used for FPC and Production Quality Assurance related modules.

While it is noted that ISO/IEC 17021 could be used, this project is to achieve one preferred standard for each module, the majority of experts used selected ISO/IEC 17065. The PT concludes that FPC is not the same as a QMS audit as covered by ISO/IEC 17021, 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 for Testing

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

The PT disagrees; 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

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 PT concluded that while professional judgement is not specifically stated in ISO/IEC 17065 it would be covered under the overall competence requirements stated in 6.1.2.1.

Application of 17065 Requirements

Real harmonisation between the AB's also requires the harmonisation of the clauses in 17021 that will be applicable when 17065 is used for the modules D, E, H and H1. The same applies to the question whether or not IAF-MD's will need to be applied (such as MD5).

Agreed, it is therefore recommended that the Project Team in the final report include a part listing issues for further consideration.

Based on this comment the following issues could be mentioned:

- How to assure a common NAB approach to assessment of external resources cf. 6.2.2 in ISO/IEC 17065?
- How to use ILAC and IAF mandatory documents when assessing NBs?
- Are NABs obliged to provide accreditation based on all HS listed in the Blue Guide for all EU legislation?

6. Revision of the Blue Guide

The European Commission Blue Guide is under revision, through the EA Executive Committee a change was proposed regarding the inclusion of ISO/IEC 17065 in Annex 6, and specifically in the table of applicable Conformity Assessment Standards for Modules D, D1, E, E1 and (H1), and clarification of the descriptive text regarding use of CASs. To date it appears that the suggested changes will be adopted but we will continue to monitor the situation.

7. Recommendations for Next Steps

The AfN Project Team, supported by the AfN Project Steering Group, proposes a resolution that the EA General Assembly endorses the AfN listing of Preferred Harmonised Standards, for use by the EA and its members, as the EA recommendation for the accreditation in support of Notified Body accreditation.

This listing is to be used as the EA recommendation for future accreditations in support of Notification. It is also proposed that the GA recommends EA to apply a model of involving experts (the AfN expert process) for reviewing future new and/or changed EU legislation when preparing recommendations for accreditations based on such legislation.

It is recommended that, as discussed by the EA Executive Committee, EA 2/17 be amended to reflect the preferred standards listing and, supported by the preferred standards listing, that EA 2/17 should be re-issued as a mandatory document. The preferred standards listing should be included in the document with a clear statement as to its use and its relationship with the Alternative Approach to allocation of Conformity Assessment standards.

The following wording is to be included in EA 2/17:

EA has identified also the preferred conformity assessment standards for each module (identified in the table in 3.1); the listing has been developed based on the technical and process requirements of the module concerned with the preferred standard being considered the best fit in each case. The intention is that the preferred standard should be used as a guide for legislators when developing new legislation, and to reflect the consensus approach when accrediting for notification. The listing should be used when accrediting CABs for notification purposes.

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

ANNEX

EA Accreditation for Notification (AfN) Project

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 CAS 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	<p>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.</p> <p>However for EMC there is concentration on inspection of documentation and historically many NBs are accredited to ISO/IEC 17020.</p>

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 + 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.
Module A2	ISO/IEC 17020	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 + 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	Possible Alternative
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 + 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 + 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 + 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	<p>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.</p> <p>Beside this the experts analysing this directive also unanimously recommended ISO/IEC 17065 as being the standard most suitable for this module.</p>
Module D	ISO/IEC 17065	<p>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.</p> <p>Beside this the experts analysing this directive also unanimously recommended ISO/IEC 17065 as being the standard most suitable for this module.</p>
Module E	ISO/IEC 17065	<p>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.</p>

		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 this 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 this 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 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 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 + 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	This is a true Full QA based module and so ISO/IEC 17021 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	This is a true Full QA based module and so ISO/IEC 17021 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	This is equivalent to Module H for which ISO/IEC 17021 is seen as the best fit as this is a QMS approach.
Unit verification annex VII	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 + 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.