EUROPEAN ACCREDITATION

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Supplement 1 to EA-2/17 EA Document on Accreditation for Notification purposes

Non-aligned legislations/modules/activities

PURPOSE

This document is a supplement to the main text of EA-2/17 and describes the specific approaches taken when accrediting for the purpose of notification for non-aligned legislation and/or modules.

Authorship
This document has been prepared by the Horizontal Harmonization Committee.

Official language
The text may be translated into other languages as required. The English language version remains the definitive version.

Further information
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Category:	Members Procedural document **EA-2/17 S1 is a mandatory document**
Date of approval:	21st June 2026
Date of Implementation:	June 2027, see transition period below Within one year from publication, all NABs shall have procedures in place to implement the requirements of this document. The transition period applies only to new or revised requirements introduced in this version of the document.

CONTENTS

1 SCOPE

This document applies for modules/activities within EU Directives/Regulations that are defined as "non-aligned" in accordance with the definition as presented in EA 2/17, clause 2. This means that in some cases that only one or some of the modules/activities of a EU Directive/Regulation are identified as "non-aligned" which are shown in this Supplement.

For all modules/activities of EU Directives/Regulations that are not presented in this Supplement and are presented in the AfN report the Annex A of EA-2/17 applies in full.

2 CONFORMITY ASSESSMENT STANDARDS FOR ACCREDITATION

Table 1: Harmonised Conformity Assessment Standards (HS) for Accreditation for Notification purposes where there is NB activity with no direct equivalent in the corresponding modules of Decision (EC) 768/2008

Directive/ regulations	Description of activity	Obligatory HS	Obligatory requirements*	Not acceptable standard for the purpose of accreditation
92/42/EEC (HWB)	Module C	ISO/IEC 17065	cd+pk	ISO/IEC 17021-1, 17024, 17025, 17029
2000/14/EC (Noise)	Annex VI - Internal control of production with assessment of technical documentation and periodical checking	ISO/IEC 17065	cd+pk+t	ISO/IEC 17021-1, 17024, 17029
2000/14/EC (Noise)	Annex VII – Unit verification	ISO/IEC 17065	cd+pk+t	ISO/IEC 17021-1, 17024, 17029
2000/14/EC (Noise)	Annex VIII – Full quality assurance	ISO/IEC 17021-1	qa+pk	ISO/IEC 17024, 17025, 17029
2006/42/EC (Machinery)	Annex IX – EC Type Examination	ISO/IEC 17065	cd+pk+t	ISO/IEC 17021-1, 17024, 17025, 17029
2006/42/EC (Machinery)	Annex X – Full Quality Assurance	ISO/IEC 17021-1	pk+qa	ISO/IEC 17024, 17025, 17029
2010/35/EU (TPED)	Type Examination according to point 1.8.7.2 of ADR	ISO/IEC 17020:2012 (except clause 8.1.3)	pk	ISO/IEC 17021-1, 17024, 17025, 17029 17065
2010/35/EU (TPED)	Supervision of manufacture and Initial Inspection and Tests according to points 1.8.7.3 and 1.8.7.4 of ADR	ISO/IEC 17020:2012 (except clause 8.1.3)	pk	ISO/IEC 17021-1, 17024, 17025, 17029 17065

Directive/ regulations	Description of activity	Obligatory HS	Obligatory requirements*	Not acceptable standard for the purpose of accreditation
2010/35/EU (TPED)	Periodic Inspections, Intermediate Inspections and Exceptional Inspection according to point 1.8.7.6 of ADR	ISO/IEC 17020:2012 (except clause 8.1.3)	pk	ISO/IEC 17021-1, 17024, 17025, 17029 17065
2010/35/EU (TPED)	Reassessment of conformity	ISO/IEC 17020:2012 (except clause 8.1.3)	pk	ISO/IEC 17021-1, 17024, 17025, 17029 17065
2013/53/EU (RCD)	MODULE C1: Conformity to EU-type based on internal production control plus supervised product testing	ISO/IEC 17020	cd+pk+t	ISO/IEC 17021-1, 17024, 17029
2013/53/EU (RCD)	PCA – Post construction assessment	ISO/IEC 17065	cd+pk+t	ISO/IEC 17021-1, 17024, 17029
2014/32/EU (MID)	MODULE A2: nternal production control plus supervised instrument checks at random intervals	ISO/IEC 17065	cd+pk+t	ISO/IEC 17021-1, 17024, 17029
2014/33/EU (Lifts)	Annex V: Final Inspection	ISO/IEC 17020	cd+pk+t	ISO/IEC 17021-1, 17024, 17029
2014/34/EU (ATEX)	Module A : Internal production control (retaining of technical documentation)	ISO/IEC 17065	cd	ISO/IEC 17024, 17029
2014/68/EU (PED)	Approval of NDT personnel	ISO/IEC 17024	ap	ISO/IEC 17021-1, 17025, 17029
2014/68/EU (PED)	Approval of Permanent Joining Personnel	ISO/IEC 17024	ap	ISO/IEC 17021-1, 17025, 17029
2014/68/EU (PED)	Approval of Permanent Joining Procedures	ISO/IEC 17020	pk+t	ISO/IEC 17021-1, 17024, 17029
2014/68/EU (PED)	European Approval of Materials	ISO/IEC 17065	cd+pk+t	ISO/IEC 17021-1, 17024, 17025, 17029
2014/68/EU (PED)	User inspectorates	ISO/IEC 17020	pk	ISO/IEC 17021-1, 17024, 17025, 17029, 17065
2014/29/EU (SPVD)	Module C	ISO/IEC 17020	pk	ISO/IEC 17021-1, 17024, 17025, 17029

Directive/ regulations	Description of activity	Obligatory HS	Obligatory requirements*	Not acceptable standard for the purpose of accreditation
(EU) 2016/797 (IOD)	All modules in accordance with Decision 2010/713/EU	ISO/IEC 17065	ERA Mandatory Technical Document 000MRA1044	ISO/IEC 17020, 17021-1, 17024, 17025, 17029
2023/1542/EU (Batteries)	Annex VIII, Module D1 for Article 7 and article 8 only	ISO/IEC 17065	cd+pk+qa+v	ISO/IEC 17024, 17025
2023/1542/EU (Batteries)	Annex VIII, Module D1 for Article 6 to 10, 12, 13 and 14	ISO/IEC 17065	cd+pk+qa+v	ISO/IEC 17024, 17025
2023/1542/EU (Batteries)	Annex VIII, Module G for Article 7 and 8 only	ISO/IEC 17065	cd+pk+t+v	ISO/IEC 17021-1, 17024, 17025
2023/1542/EU (Batteries)	Annex VIII, Module G for Article 6 to 10, 12, 13 and 14	ISO/IEC 17065	cd+pk+t+v	ISO/IEC 17021-1, 17024, 17025
2023/1542/EU (Batteries)	Article 51 – Third party verification of battery due diligence policies	Depends on the scheme recognized according to article 53 of the regulation	Depends on the scheme recognized according to article 53 of the regulation	Depends on the scheme recognized according to article 53 of the regulation
(EU) 2024/370 (DWD)	Module B+D	ISO/IEC 17065	cd+qa	ISO/IEC 17021-1, 17024, 17025, 17029
(EU) 2024/1689 (AI)	Annex VII Conformity based on assessment of quality management system and assessment of technical documentation	ISO/IEC 17065	cd+qa	ISO/IEC 17024, 17025, 17029
(EU) 2024/2847 (CRA)	Annex VIII, Part II EU-type examination	ISO/IEC 17065	cd+pk+t	ISO/IEC 17021-1, 17024, 17025, 17029
(EU) 2024/2847 (CRA)	Annex VIII, Part IV Conformity based on full quality assurance	ISO/IEC 17021-1	pk+qa	ISO/IEC 17024, 17025, 17029

Table 2: **Conformity Assessment Standards for Accreditation for Notification purposes including Additional Requirements in the Area of the Construction Products Regulation 2011/305 and 2024/3110 (new CPR)**

System	Description	Obligatory HS	Obligatory requirement *	Not acceptable standard for the purpose of accreditation
1 (AVCP)	Assessment of the performance of the construction product carried out on the basis of testing initial inspection of factory production control, continuous surveillance of factory production control	ISO/IEC 17065	cd+pk+t	ISO/IEC 17021-1, 17024, 17025, 17029
1 (AVS)	Full notified body control without audit sample testing	ISO/IEC 17065	cd+pk+t	ISO/IEC 17021-1, 17024, 17025, 17029
1+ (AVCP)	Assessment of the performance of the construction product carried out on the basis of testing , initial inspection of factory production control, continuous surveillance of factory production control, audit-testing of samples	ISO/IEC 17065	cd+pk+t	ISO/IEC 17021-1, 17024, 17025, 17029
1+ (AVS)	Full notified body control including audit sample testing	ISO/IEC 17065	cd+pk+t	ISO/IEC 17021-1, 17024, 17025, 17029
2+ (AVCP)	Initial inspection of factory production control, continuous surveillance of factory production control	ISO/IEC 17065	cd+pk	ISO/IEC 17024, 17025, 17029
2+ (AVS)	Factory Production control	ISO/IEC 17065	cd+pk	ISO/IEC 17024, 17025, 17029
3 (AVCP)	Assessment of the performance of the construction product	ISO/IEC 17025	t	ISO/IEC 17020, 17021-1, 17024, 17029
3 (AVS)	Determination of the product type	ISO/IEC 17025	t+cd	ISO/IEC 17020, 17021-1, 17024, 17029
3+ (AVCP)	Control of environmental sustainability assessment	ISO/IEC 17029	v	ISO/IEC 17020, 17021-1, 17024, 17025

System	Description	Obligatory HS	Obligatory requirement *	Not acceptable standard for the purpose of accreditation
3+ (AVS)	Control of environmental sustainability assessment	ISO/IEC 17029	v	ISO/IEC 17020, 17021-1, 17024, 17025

Key

***** Obligatory minimum requirements for performing the conformity assessment activities that have to be fulfilled by the CAB no matter which conformity assessment standard is used regarding accreditation.

t Applicable requirements of EN ISO/IEC 17025 if **t**esting is required. To this end fulfilment of the applicable requirements of clause 6 and 7 (except 7.9) in EN ISO/IEC 17025:2017 shall be demonstrated.

cd **C**apability of and procedures for judging and **d**eciding based on results of evaluation activities, if the essential requirements are fulfilled and/or the Harmonised Standards have been applied when required. To this end, fulfillment of clauses 4.1.2, 4.1.3, 7.5 and 7.6 in EN ISO/IEC 17065:2012 shall be demonstrated.

pk Ability – based on **p**roduct **k**nowledge - to make professional judgments related to product requirements where required. To this end fulfilment of clauses 6.1.2, 6.1.3 and 6.1.6 to 6.1.10 in EN ISO/IEC 17020:2012 shall be demonstrated.

qa Ability to assess and approve manufacturer's **q**u**a**lity systems where required. To this end, fulfillment of clauses 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10 and 9.1 to 9.4 and 9.6 in EN ISO/IEC 17021-1:2015 shall be demonstrated.

v Ability to **v**erify statement from economic operators in accordance with applicable legislations. To this end fulfilment of clauses 7.3, 8, 9.2, 9.3, 9.4, 9.5, 9.6, 9.7, 9.8 and 9.11 in EN ISO/IEC 17029:2019 shall be demonstrated.

ap Ability to **a**pprove **p**ersonnel in accordance with applicable legislations. To this end fulfilment of clauses 5.2, 6.1, 6.2, 6.4, 8 and 9.1 to 9.6 in EN ISO/IEC 17024:2012 shall be demonstrated.

Notes

1. For EN ISO/IEC 17020, only Type A inspection bodies are valid for a Notified Body activity, unless otherwise stated in the EU Legislation (for example User inspectorate under PED). For EN ISO/IEC 17025 and for EN ISO/IEC 17029, the requirements to be an independent third-party with absence of conflict of interest as laid down in the corresponding legislation must be fulfilled.

2. Specification of “t”, “cd”, “pk”, “qa”, “ap”, “v” has been introduced to harmonise the understanding and clarify the content of the assessment in the particular context of accreditation for notification purposes, even if parts of the concerned obligatory requirements are already mentioned in the standard which is used in full. This applies even if the chosen standard is the obligatory HS.
   The option retained has been to specify for all modules the technical competencies to be checked in addition to the standard used in full, despite the fact that EN ISO /IEC 17065 makes reference respectively to EN ISO/IEC 17020, 17021-1 and 17025. This option gives the advantage to clarify which clauses of the additional standard have to be assessed during the assessment of the NB, in addition to the requirements mentioned in the accreditation standard, such as clause 6.2.1 of EN ISO/IEC 17065.

3. Any formal findings raised by the NAB shall be primarily referenced to the nearest relevant clause in the standard being used for accreditation. Reference to the “additional requirement” from other standards can be made in the text.

4. Notified Bodies should take into account the relevant IAF MD documents while assessing quality management system-based modules e.g. Modules D, E and their derivatives. For module H under accreditation against EN ISO/IEC 17021-1, then the Notified Bodies shall comply with the relevant IAF MD documents in full. In both cases if there are contradictions with requirements of the corresponding notified body coordination group in this regard this take precedence over IAF.

5. In cases where an “obligatory requirement” is to be found in contradiction with requirement of the directive/regulation or of the documents of the GNB, these requirements of the directive/regulation or of the GNB document are understood to be part of the “scheme” and do always applies as long as this is not in contradiction to the selected standard. E.g. if a module D is accredited under ISO/IEC 17065 and the GNB documents ask for an audit-interval different to the requirement of ISO/IEC 17021-1 paragraph 9.1.3.2, the scheme-specific requirements of the GNB-document will prevail. But if this module D is accredited under ISO/IEC 17021-1 the full requirements of ISO/IEC 17021-1 have to be fulfilled.

6. Harmonised standard (HS) in assessments for accreditation regarding Medical Testing (EN ISO/IEC 15189), Proficiency Testing Providers (EN ISO/IEC 17043), Reference Material Producers (EN ISO/IEC 17034) and Biobanking (EN ISO 20387) is considered as not acceptable regarding accreditation for Notification purpose.

7. Additional normative documents may apply depending on the scope of accreditation and the relevant MLA, e.g. EN ISO 14065 shall be applied in combination with EN ISO/IEC 17029 if the validation/verification programme concerns environmental information.