Publication Reference **EA-2/17 M: 2026**

EA Document on Accreditation for Notification Purposes

PURPOSE

The document presents the policy agreed by EA Members for accreditation of Conformity Assessment Bodies for notification purposes

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

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

Further information
For further information about this publication, contact your national member of EA or the EA secretariat: secretariat@european-accreditation.org

Please check our website for up-to-date information http://www.european-accreditation.org/

Category:	Members Procedural document **EA-2/17 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 contains the policy agreed by EA for accreditation of Conformity Assessment Bodies by National Accreditation Bodies as a basis for notification by Notifying Authorities to become Notified Bodies to work within the scope of Union Harmonisation Legislation[1] and other EU legislation that does not (fully) follow the reference provisions of Decision (EC) 768/2008 which is part of the New Legislative Framework in so far as this legislation provides for accreditation as sufficient means of demonstrating the technical competence of Notified Bodies.
This document also applies to bodies performing third-party assessment and verification of tasks under the Construction Products Regulation and the Recognized Third-party Organisations and user inspectorates under the Pressure Equipment Directive.
It identifies the requirements that shall be used by National Accreditation Bodies when assessing and accrediting Conformity Assessment Bodies for notification purposes.

This document is to be used in conjunction with its supplements:

- Supplement 1: Non-aligned legislation/modules/activities (Mandatory)
- Supplement 2: Examples of Scoping (Informative)
- Supplement 3: Specific aspects of the Construction Products Regulation (Informative)

Note: In the area of the Construction Products Regulation there are significant differences to other legislation forming part of the so called New Legislative Framework. In order to allow application of this document also in the area of the Construction Products Regulation, the specific Supplement S3 was added to the document explaining specific aspects of this area. Reference is made in the text of the document to this supplement wherever necessary.

This document is a “Members’ procedural document” with a mandatory status. It applies to all National Accreditation Bodies (NABs) that assess and accredit Conformity Assessment Bodies for notification purposes.

It should be noted that nothing in this document is intended to be binding to Notifying Authorities. In particular, it does not establish any requirements with regard to the procedures of Notifying Authorities as referred to by article R14.1 of the Decision (EC) 768/2008.

2 DEFINITIONS

2.1 Definitions

In this document, “aligned” refers to legislation that applies the conformity assessment modules as they are defined and with the names given to them in Decision No 768/2008/EC.

In this document, “non-aligned” refers to legislation that applies modules or activities which, according to expert opinion in the AfN report, differ by content or by name from the conformity assessment modules as described in Decision No 768/2008/EC.

[1]See: https://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

Note: The definitions of “aligned” and “non-aligned” in this document are different from the EU commission as presented in “New legislative framework - Internal Market, Industry, Entrepreneurship and SMEs”.

2.2 Acronyms

In this document the following acronyms and abbreviations are used:

CAB	Conformity Assessment Body
NB	Notified Body
NAB	National Accreditation Body
AfN	Accreditation for Notification
NA	Notifying Authority
UHL	Union Harmonisation Legislation
HS	Harmonised Standard with requirements used for the accreditation of Conformity Assessment Bodies under the EA MLA
NLF	New Legislative Framework
NANDO	New Approach Notified and Designated Organisations information system
AVCP	Assessment and Verification of Constancy of Performance (*see Supplement S3 for details*)
AVS	Assessment and Verification systems (*see Supplement S3 for details*)
GNB	Group of Notified Bodies set up by the European commission
AfN report	EA Accreditation for Notification (AfN) project, published on EA webpage

3 GENERAL POLICY

3.1 Purpose of accreditation for notification

The main purpose of accreditation, when used as a tool to support notification of CABs, is to give confidence to the NA on:

1) competence, impartiality, independence and consistent operation of the CAB to perform the tasks it is notified for;
2) the fulfillment by the CAB of the requirements established by each UHL or other applicable EU legislation within the scope of accreditation.

3.2 Use of Harmonised Standards (HS) for accreditation

Accreditation is defined in Regulation (EC) 765/2008 as "a*n attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity".*

Therefore, NABs shall use Harmonised Standards (HS) in assessments for accreditation. However, the conformity assessment activities described in the modules defined in Decision (EC) 768/2008 or conformity assessment procedures defined in other applicable EU legislation are not always described in a way which fits exactly with the description in the HS (i.e. testing, inspection and certification), and each module does not identify the HS to be used for its conformity assessment activities.

For each module, one HS is identified as the obligatory HS for accreditation of the CAB. Where an NAB uses an alternative HS, based on principle as described in 4.2, this does not remove the obligation to assess the relevant requirement elements of the obligatory HS. In all cases, the NAB shall assess the CAB against the set of "obligatory requirements" identified for each module.

To support consistent and comparable accreditation for notification purposes, EA has developed an approach which defines, for each module, both:

- the HS considered the obligatory HS, and
- the "obligatory requirements" that the NAB shall assess

The table in Annex A identifies the obligatory HS for each aligned module, as defined in Decision (EC) 768/2008, and lists the "obligatory requirements" for that module. These obligatory requirements comprise (i) specific requirement elements taken from the obligatory HS (to ensure they are always covered, including when an alternative HS is applied), and (ii) the "additional requirements" taken from other HS which are necessary to underpin an appropriate assessment of competence and performance under the module. Supplement S1 provides the same information for non-aligned legislation/modules/activities.

3.3 Responsibilities

Accreditation and notification are two different activities which are performed by the NAB and the NA respectively.

When the NAB is asked to perform accreditation in support of notification, it will be the NAB's responsibility to apply the most appropriate accreditation procedure, based on the HS to be used and the obligatory requirements that, together, needs to be assessed to ensure fulfilment of all the corresponding requirements of the UHL or other applicable EU legislation.

3.4 Application to legislation

The specific requirements to be fulfilled by a CAB to become a NB are established in each UHL or other applicable EU legislation.

To be accredited, CAB shall be assessed by NABs using:

1) the obligatory HS and the obligatory requirements as described in section 3.2 in this document as applicable to the module, conformity assessment procedure or AVCP/AVS-system requested; and
2) the requirements for NBs included in the relevant UHL or other applicable EU legislation and
3) the requirements included in the relevant harmonised technical standards or technical specifications. (See chapter 6 in case such harmonized technical standards are not available or not chosen by the manufacturer)

This document applies to EU directives and regulations which follow the New Legislative Framework which are aligned with Decision (EC) 768/2008. It shall also be applied to other Directives and Regulations (for example the Construction Products Regulation - or the Railways Interoperability Directive (EU) 2016/797) which are not aligned with Decision (EC) 768/2008. For non-aligned directives and regulations, see also Supplement S1.

3.5 Use of the Notified Bodies Coordination Group Documents

Article R17, paragraph 11 of Decision (EC) 768/2008 establishes the principle that NBs participate in or inform their assessment personnel of the activities of the corresponding Notified Body Coordination Group established under the corresponding UHL and apply their administrative decisions and documents as general guidance.
Therefore, assessors of NABs performing assessments of CAB as a basis for notification by NAs shall be well aware and informed of the corresponding decisions and documents of the Notified Body Coordination Groups as long as they are publicly available to the NAB. It is the responsibility of the corresponding NAB to assure the competence of their assessors including their knowledge of these documents.

In case the decisions and documents of the corresponding Notified Body Coordination Group are not easily available to the NAB's assessors, the NAB should inform the EA secretariat, who will try to provide support in this case.

4 OBLIGATORY HARMONISED STANDARDS

4.1 Description of the Obligatory HS approach

EA has identified an obligatory HS to be used for the accreditation of CABs for each module (identified in table in annex A) as described in Decision (EC) 768/2008. This listing has been developed based on the technical and process requirements of the module concerned with the obligatory HS being considered the best fit in each case.
The obligatory HS shall be used for accreditation in order to reflect the consensus approach when accrediting for notification.

The AfN report collects this information regarding the harmonised standards to be used for all the EU Directives/Regulations. The AfN Report is regularly updated, and as such, may contain information for recently published legislation that is still not covered by EA-2/17. Therefore,

NABs should not grant accreditation for legislation requiring accreditation for the purpose of notification that has not been included in the AfN Report.
In addition to this, the table in annex A identifies for each module the obligatory requirements and procedures needed to assess the competence of CABs.

In all cases, the HS has to be used in full i.e. CABs have to meet all of the requirements of the HS for the assessment of the CAB. Requirements cannot be subtracted from the prescribed standard; however, due to the nature of the conformity assessment activity, a requirement may be found as not applicable, provided that such an exclusion is allowed by the HS.

Where there is overlap between the HS and the provisions of the UHL or other applicable EU legislation, the most stringent provisions take precedence.

4.2 Implementation

NABs shall use the obligatory HS for accreditation for notification. Any accreditation for notification not using the obligatory HS shall be justified by the existence of a published requirement of a notifying and/or regulatory authority (e.g. law, decree, ordinance, published procedural document of the NA), binding to the CAB, not to accept the obligatory HS but a different one. This justification has to be recorded by the NAB and made available upon request for EA and provided for the peer-evaluations.
For aligned directives/regulations the corresponding obligatory requirements included in annex A have to be fulfilled.
For non-aligned directives/regulations/activities and directives/regulations/activities where exceptions have been identified based on expert opinion that a particular module is slightly different from the modules presented in (EC) 768/2008 the obligatory requirements in Supplement S1 will apply.
If the NAB is imposed by the NA using an HS which is not acceptable for accreditation, as stated in Annex A and Supplement S1, the NAB shall inform the NA that it could not be used in accreditation for notification purpose.

5 ACCREDITATION SCOPES

Accreditation information issued by NABs for notification purposes shall comply with the requirements of EN ISO/IEC 17011 and make reference to the HS used as reference and granted for a given scope, make reference to the relevant UHL or other applicable EU legislation and comply with the following provisions.

5.1 Aspects to be considered

The following shall be considered when defining scopes of accreditation for notification purposes:

1) relevant requirements according to EN ISO/IEC 17011 and the applicable HS as well as other requirements for CABs seeking notification,
2) the type of data needed as input to the NANDO database,

3) the needs of the Notifying Authorities,
4) the needs of the persons using information (primarily the customers of the NBs).

5.2 Main elements to be included in the scope

The following shall be the main elements to be included in the scope of accreditation:

a) HS which is used as reference and applied in full for the accreditation of the CAB;
b) the identification of legislation (it may be complemented with a reference to the national regulations);
c) the conformity assessment procedure used (module, article or annexes, systems of a particular directive/regulation) or AVCP/AVS-system;
d) products/category – family – homogeneous groups of products (with reference to relevant decision for Construction Products Regulation) as presented in the NANDO classification;

In addition to the listed elements (a-d) the following elements are to be considered as supplementary elements that could be adding extra value to the scope based on the requests from notifying authority and applicable legislations that could provide a more complete and transparent presentation of the of the CAB´s competence.

e) product characteristics (as set out in the applicable legislation) or product specification such as harmonised product standard and/or harmonised technical specifications, according to NANDO classification;
f) other sectoral or technical documents according to the requirements of the directive/regulation concerned;
g) Limitations, if relevant, for e) to f)

Where possible, the accreditation scope should use the same wording as used by NANDO. If the NANDO wording is not adopted into the scope, correlation must be provided.

Additionally, the accreditation scope can also include other information if required by the NA, applicable legislation or mandatory documents if deemed necessary due to other circumstances.

Examples of scopes for different EU directives and regulations are presented in Supplement S2.

6 CASES WHERE HARMONISED TECHNICAL STANDARDS ARE NOT USED

The manufacturers can choose whether or not to apply and refer to harmonised technical standards. Reason for this can either be based on the own choice of the manufacturer or that there is no harmonised technical standard for the specific product yet available.

Note: This is not applicable in the case when the applicable legislation makes the harmonised technical standards or specifications mandatory (e.g. Regulation (EU) 305/2011 and (EU) 2024/3110)

However, if a manufacturer chooses not to apply a harmonised technical standard, it has the obligation to demonstrate that its products are in conformity with essential requirements by the use of other means of its own choice that provide for the level of safety or protection of other interests required by the applicable legislation. In these cases, the manufacturers do not benefit from the presumption of conformity. This implies that they demonstrate, in the technical file of a relevant product, in a more detailed manner how the standards or technical specifications they use provide conformity with the essential requirements, for instance by the justification of a particular technical solution applied, evaluation report of functional safety , a gap analysis, etc.

Consequently, in order to ensure a correct implementation of the internal market rules, Notified Bodies are required to be able to demonstrate that they have the competences to perform the required conformity assessment and to issue the required attestation to certify that the regulatory requirements have been fulfilled, also in the (complete) absence of harmonised technical standards. In order to do this the Notified body has to apply conformity assessment policies and procedures that are based on the applicable directive or regulation (in particular annexes regarding the modules), available harmonised technical standards, reliable methods developed by the Notified Bodies coordination groups or other reliable documents.

The NAB needs to - as a part of the accreditation process of the CAB - verify that the choice of policies and procedures by the CAB is appropriate to perform the required conformity assessment activities. As a part of this verification the NAB should request the CAB to provide evidence of this as a result of their own analysis, showing how they have secured that all relevant requirements are covered and motivate their choice of policy and procedures.

In cases of completely new legislations (or new types of products), where no harmonised technical standards nor technical specifications are available, or the NB coordination group is not yet active in such way that they have agreed on any conformity assessment procedure of the requirements, it is recommended that the NAB is careful before accepting the CAB own choice of policy and procedures without sufficient evidences that they are suitable. It is in these cases also important that the CAB has done a more in-depth analysis of the conformity assessment procedure to demonstrate that it is appropriate for its purpose in order to evaluate the necessary requirements. The NAB must consider this policy and procedure, including the in-depth analysis, as part of its assessment activity. The NAB is encouraged to also, if relevant, discuss with other NABs and/or NA on how to proceed.

7 USE OF SUBCONTRACTORS/SUBSIDIARES BY NOTIFIED BODIES

CABs may subcontract (mentioned as outsourcing in the accreditation standards) specific conformity assessment tasks or rely on subsidiaries, provided that such arrangements do not compromise the confidentiality, impartiality or objectivity of their conformity assessment activities. When subcontracting, the CAB must ensure that the subcontractor or subsidiary meets the same requirements applicable to the CAB and if requested by the NA be able to provide information on such subcontracting arrangements.
The CAB remains fully responsible for all tasks performed by subcontractors or subsidiaries and must obtain the client’s agreement before any subcontracted activity takes place. The CAB must also maintain documentation concerning the assessment and monitoring of the

qualifications of the subcontractor or the subsidiary and the work they perform, and ensure this information is available to the NA and NAB if requested.

The NAB shall as a part of their assessment of the CAB verify that the CAB systematically assesses and monitors the competence of its subcontractors and subsidiaries, identifies and manages any risks of conflicts of interest, and can demonstrate their compliance with all relevant requirements of the UHL. Depending on the means the CAB uses to demonstrate the subcontractor or subsidiary´s compliance with all relevant requirements of the UHL the NAB may request, as a part of this verification, to perform assessment activities on the site of the subcontractor or subsidiary.

As part of its assessment of the CAB, the NAB shall verify whether a CAB that subcontracts conformity assessment activities can demonstrate that it maintains the required level of knowledge of the product and of the assessment methodologies, to ensure competent results, especially in the case of continuous subcontracting.

Use of contracted personnel by the CAB that act under its direct control shall not be seen as subcontracting but instead as internal personnel of the CAB. It is reminded that CAB´s personnel and operational sites in foreign countries, must also be covered as a part of the NAB's risk-based assessments of the CAB.

Subcontracting is permissible only where it preserves the integrity and impartiality of conformity assessment activities.

The European Commission has included requirements in some, but not all, UHL requiring that any subcontractor or subsidiaries engaged by a CAB must meet the same conditions as the CAB itself, including, in certain cases, the requirement to be "established under the national law of a Member State".

As these requirements differ across legislative frameworks, CABs must examine the specific provisions of the applicable legislation to ascertain whether subcontracting is limited to EU-based subcontractors/subsidiaries or whether the legislation itself, or an applicable agreement with the EU, allows the engagement of subcontractors/subsidiaries established in third countries.

ANNEX A – CONFORMITY ASSESSMENT STANDARDS FOR ACCREDITATION

The obligatory HS including obligatory requirements for all the modules of Decision (EC) 768/2008 are shown in table 1. Many of the directives and regulations that include notified body activities are based on these (EC) 768/2008 modules, but not in all cases.
Non-aligned directives and regulations including directives and regulations where exceptions have been identified based on expert opinion that the particular module is used in a slightly different way than the module presented in (EC) 768/2008 can be found in Supplement S1.

Table 1: Harmonised Conformity Assessment Standards (HS) for Accreditation for Notification purposes for directives/regulations with corresponding modules of Decision (EC) 768/2008

Module	Description	Obligatory HS	Obligatory requirements *	Not acceptable standard for the purpose of accreditation
A	**Internal production control**	**N/A**	**N/A**	**N/A**
A1	**Internal production control plus supervised product testing**	**ISO/IEC 17020**	**cd+pk+t**	**ISO/IEC 17021-1, 17024, 17029**
A2	**Internal production control plus supervised product checks at random intervals**	**ISO/IEC 17020**	**cd+pk+t**	**ISO/IEC 17021-1, 17024, 17029**
B	**EC type examination**	**ISO/IEC 17065**	**cd+pk+t**	**ISO/IEC 17021-1, 17024, 17025, 17029**
C	**Conformity to type based on internal production control**	**N/A**	**N/A**	**N/A**
C1	**Conformity to type based on internal production control plus supervised product testing**	**ISO/IEC 17065**	**cd+pk+t**	**ISO/IEC 17021-1, 17024, 17029**

Module	Description	Obligatory HS	Obligatory requirements *	Not acceptable standard for the purpose of accreditation
C2	**Conformity to type based on internal production control plus supervised product checks at random intervals**	**ISO/IEC 17065**	**cd+pk+t**	**ISO/IEC 17021-1, 17024, 17029**
D	**Conformity to type based on quality assurance of the production process**	**ISO/IEC 17065**	**cd+qa**	**ISO/IEC 17024, 17025, 17029**
D1	**Quality assurance of the production process**	**ISO/IEC 17065**	**cd+qa**	**ISO/IEC 17024, 17025, 17029**
E	**Conformity to type based on product quality assurance**	**ISO/IEC 17065**	**cd+qa**	**ISO/IEC 17024, 17025, 17029**
E1	**Quality assurance of final product inspection and testing**	**ISO/IEC 17065**	**cd+qa**	**ISO/IEC 17024, 17025, 17029**
F	**Conformity with type based on product verification**	**ISO/IEC 17065**	**cd+pk+t**	**ISO/IEC 17021-1, 17024, 17025, 17029**
F1	**Conformity based on product verification**	**ISO/IEC 17065**	**cd+pk+t**	**ISO/IEC 17021-1, 17024, 17025, 17029**
G	**Conformity based on unit verification**	**ISO/IEC 17065**	**cd+pk+t**	**ISO/IEC 17021-1, 17024, 17025, 17029**
H	**Conformity based on full quality assurance**	**ISO/IEC 17021-1**	**qa+cd+pk**	**ISO/IEC 17024, 17025, 17029**
H1	**Conformity based on full quality assurance plus design examination**	**ISO/IEC 17065**	**cd+qa+pk**	**ISO/IEC 17024, 17025, 17029**

Key:

* Obligatory 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.

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, 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" 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 CAB, 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 “obligatory 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 apply 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 <u>not acceptable</u> 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.

ANNEX B – CRITERIA FOR SELECTING WITNESSING

Clause 7.4.7 of ISO/IEC 17011:2017 establishes that the "*accreditation body shall develop an assessment plan to cover the activities to be assessed, the locations at which activities will be assessed, the personnel to be assessed where applicable and the assessment techniques to be utilized including witnessing where appropriate or applicable.*"

This annex describes how to use witnessing in accreditation for notification purposes. This annex applies to both aligned UHL (Annex A) and non-aligned UHL (Supplement S1).

When planning and deciding on the required witnessing for an assessment the following principles shall be taken into consideration:

1) Witnessing shall normally be used as an assessment technique to determine the competent performance of all on-site conformity assessment activities of a CAB.
2) Other assessment techniques that can be used are file review and/or technical interviews (particularly preferred for the assessment of module B design, but should also be used to complement the information gained through witnessing and increase the sampling).
3) The results of witnessing of one conformity assessment activity, or a combination of conformity assessment activities, may demonstrate and confirm the ability and effectiveness of the CABs processes for a competent evaluation for comparable conformity assessment activities.

When applying these principles to an initial assessment or extension to scope in new areas, the NAB should ensure that it will cover all areas to be assessed, i.e. all directives or regulations, with the necessary witnessing (principle 1).

This results in witnessing as described in table 2 and 3, supplemented by file reviews of not witnessed modules (*or AVCP/AVS-systems, see Supplement S3 for details*) of all directives/regulations covered by the accreditation (principle 2) upon granting, extending and during an accreditation cycle.

The same principle applies to modules/activities that require participation of the assessor on site (principle 3): If some modules of one directive/regulation are very similar (e.g. module D and E) the witnessing may be limited to one of them (i.e. grouping of modules, see table 2), in which case the more complex should be chosen.

It is considered highly unlikely that witnessing of the activities under different directives/regulations can be effectively combined in a single witness. When this is considered, the NAB shall document the reasons and justification for taking such an approach.

Witnessing is normally to be performed in advance of granting, or extending, the accreditation for a new conformity assessment activity. Nevertheless, it is recognized that in the area of accreditation for notification purposes the possibilities of having clients available are very limited as the performance of the corresponding conformity assessment activities will normally be restricted to notified bodies requiring accreditation in advance of receiving this notification.
It is therefore considered to be appropriate for the NAB, when accrediting a CAB / conformity assessment activity for the first time, to accept alternative ways of performing witnessing e.g. with

comparable cases or simulated exercises sufficient to determine the competence of the CAB to perform the activities covered by its scope of accreditation.

When accrediting a CAB / conformity assessment activity for the first time, it is also acceptable to grant the accreditation under the condition that the CAB once notified informs the NAB as soon as it receives requests from its first clients. The CAB shall cooperate with the NAB during organization of the first activities for its clients to ensure that the witnessing of that activity takes place. The NAB shall have the necessary arrangements in place to ensure that no accredited certificates are issued until appropriate witnessing has been satisfactorily performed.

If an accreditation is granted under the condition that the witnessing has been postponed, the following also applies:

1. The witnessing shall be carried out within a maximum of 18 months after receiving the accreditation – if, during this period, the witnessing has not been carried out, then the accreditation for that conformity assessment activity will be withdrawn, since the NAB is not able to fully assess the continuing competence of the CAB for all the applicable requirements;
2. Once the accreditation is withdrawn, the CAB may apply again, but the option of being accredited with postponing of the witnessing for after the first clients' requests have been received, will not be available for a period of time of two years. The CAB can, however, apply again under the normal regime of accreditation after witnessing.

Where alternative ways of performing witnessing do not exist or are not sufficient to determine the competence of the CAB to perform the activities covered by its scope of accreditation, if the NA asks the NAB for information to consider a temporary notification, the NAB may provide the information on the CAB's competence gained already on the basis of the documents reviewed and (office) assessments done by the NAB. In such cases, unless the accreditation is confirmed within a given timeframe, the NAB should inform the NA to allow it to reconsider its notification and withdraw it.

Selection and number of witnessing activities during an accreditation cycle depends on various other parameters including:

- Number of technical staff involved in a specific conformity assessment activity,
- Changes to staff,
- Countries where the activities are performed
- Extensions to scope,
- Changes to relevant equipment, test methods or harmonised product standard (especially in relation to EN ISO/IEC 17025 accreditation) used for the conformity assessment,
- Existing demonstrated competence in the type of products and similar legislation

The witnessing and file reviews during an accreditation cycle should enable the NAB to cover the different conformity assessment procedures (modules/ systems) for the related regulations / directives and the different categories of products/product areas included in the scope of accreditation.

The following tables 2 and 3 shall be used as guidance for grouping of modules, and deviations are expected to be justified by the NAB. However, it should be considered that in case of significantly different categories of products under one legislation, additional witnessing might be needed in order to assure sufficient coverage of all competences of the CAB.

Table 2: Modules of Decision 768/2008/EC that when witnessed, can provide assurance of competence to other modules where accreditation is sought

Module covered by the scope	Module description	Possible witnessing arrangement
A1	Internal production control and supervised product testing	A1 or A2 or C1 or C2 or B* or F or G
A2	Internal control of production and supervised product controls at random intervals	
B	Type examination	B* or G or H1
C	Conformity with type based on internal production control	C or D or E or H or A1 or A2 or C1 or C2 or D1 or E1 or H1
C1	Conformity to type based on internal production control and supervised product testing	C1 or C2 or A1 or A2 or B* or F or G
C2	Conformity with type based on internal production control and supervised product controls at random intervals	
D	Conformity to type based on quality assurance of the production process	D or D1 or H or H1 or E or E1
D1	Quality assurance of the production process	D1 or H1 or E1
E	Conformity to type based on product quality assurance	E or E1 or D or D1 or H or H1
E1	Quality Assurance of Final Product Inspection and Testing	E1 or D1 or H1
F	Conformity to type based on product verification	F or F1 or G
F1	Conformity based on product verification	F1 or G
G	Conformity based on unit verification	G or (B*+F1) or (B*+F)
H	Conformity based on full quality assurance	H or H1
H1	Conformity based on full quality assurance and design control	H1 or (B*+H)

B* EU-Type examination/production type (as specified in specific EU legislations e.g PED).

Table 3: Systems of AVCP/AVS of Regulation (EU) 305/2011 and (EU) 2024/3110 that when witnessed, can provide assurance of competence to other AVCP/AVS-systems where accreditation is sought

AVCP/AVS-System (see supplement S3) covered by the scope	Possible witnessing arrangements
1+	1+
1	1 or 1+
2+	2+ or 1 or 1+
3	3
3+	3+