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Guidance on Accreditation for Notification Purposes

TURKISH ACCREDITATION AGENCY

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0. INTRODUCTION

The new framework law (NLF) has been accepted by the EU on 09 July 2008 with respect to the modernization of the New Approach for the introduction of the products to the market and this framework has been published on the Official Gazette of the European Union (EU) on 13 August 2008. This broad package of precautions which aims to eliminate the obstacles for free movement of the products, represent an important support for the marketing of the goods between the member states of EU and is composed of the regulations no 764/2008, 765/2008 and the decree no 768/2008. By means of the legislation no 765/2008 and 768/2008 which are under the scope of the New Framework Law, the conditions required for the authorization of Conformity Assessment Bodies (CABs) (testing, inspection and certification bodies) in a manner to include the precautions which increase the utilization of accreditation and open rules have been put forward in this respect. As a result of this, it is aimed to increase the quality and safety of the conformity assessment of the products. The reinforced system shall force CABs to provide high quality services as needed by the producers, consumers and the public authorities.

In accordance with the aim mentioned above, accreditation certificate takes place among the documents which must be submitted by CABs to the authorized institutions as prescribed in Article - 22 of the Annex I of the European Union legislation no 768/2008/EC. In this context, the "accreditation" has become a pre-requirement in certification applications.

As a result, a new service has been defined by EA for the accreditation bodies which are members of the association with the support of European Commission. The name of this new service is the Accreditation for Authorization/Notification purposes. CABs may voluntarily apply for accreditation in order to be notified for the products within the scope of EU Regulations. However they will not use the scope of the related annex (see Annex B) of the certificate they have received at the end of the accreditation process for voluntary certification activities. **TÜRKAK accreditation mark must be used on the certificate/report defined in the legislation (e.g. EC Type Approval Certificate, Design Approval Certificate, etc.) resulting from conformity assessment activities. In cases where the TÜRKAK accreditation mark cannot be used, written reference specified in the R10.06 Guide can be made. If the relevant Competent Authority requests that the TÜRKAK accreditation mark not be used on this certificate/report, or if the use of the accreditation mark is prohibited in the normative references of the relevant legislation, the TÜRKAK accreditation mark shall not be used and no written reference shall be made.**

Finally, the newest revision of the EA 2/17 M:2020 "EA Document on Accreditation for Notification Purposes" was accepted on 14 April 2020 and introduced in April 2021.

1. SCOPE

This document defines, on the basis of "EA Document on Accreditation for Notification Purposes", the methods and rules for CABs which request accreditation for notification purposes in the processes of receiving, assessment and accreditation of accreditation applications for

notification in order to provide 3rd Party conformity assessment services as a notified body (NB) in the framework of the Directive/Regulation/Bylaw specified in Annex-C and in accordance with the adjustment laws of the European Union.

Accreditation processes shall be conducted in line with the P701 Procedure, by taking into account the matters set out in this Guide. Additional requirements included in TURKAK Guidelines (e.g., R50.01 for Testing, R50.04 for Product Certification, etc.) which are drawn up on the basis of harmonised standards and possible to use for accreditation shall also apply.

Further, additional requirements included in the relevant TURKAK Documents/Guidelines which are drawn up on the basis of applied Regulations/Bylaws (R50.08 Guidelines for Accreditation of Candidates for Notified Bodies under EU 305/2011 Construction Products Regulation; R50.09 Guidance on Accreditation of Candidates for Notified Bodies under 2006/42/EC Machinery Directive, etc.) shall also apply in addition to this Guide.

The requirements set out in "EA-2/17 M:2020 Document on Accreditation for Notification Purposes" must be taken into consideration in the assessment of the scopes within the framework of accreditation for notification purposes. CABs which apply for accreditation for notification purposes or CABs that are already accredited in this field must meet the requirements of "EA-2/17 M:2020 Document on Accreditation for Notification Purposes".

2. REFERENCES

The documents stated below are of first degree importance for the implementation of this guidance;

- Law No. 7223 on Product Safety and Technical Regulations,
- Commission on the Common Regulatory Framework for the Marketing of the Products and Decree of the European Parliament no 768/2008/EC,
- Regulation (EC) No 765/2008 of the European Parliament and of the Council Setting Out the Requirements for Accreditation and Market Surveillance Relating to the Marketing of Products,
- EA-2/17, Guidance on Accreditation for Notification Purposes,
- EN ISO/IEC 17000, Conformity Assessment — Terms and general principles,
- EN ISO/IEC 17011, Conformity Assessment – General Conditions for the Accreditation Bodies Accrediting the Conformity Assessment Bodies (CABs),
- TS EN ISO/IEC 17020, General Criteria for the Operation of Various Types of Bodies Performing Inspection,
- TS EN ISO/IEC 17065, Conformity Assessment - Requirements for Bodies Certifying Products, Processes and Services,
- TS EN ISO/IEC 17021-1, Conformity Assessment - Requirements for Bodies Providing Audit and Certification Of Management Systems,
- TS EN ISO/IEC 17024, Conformity Assessment - General Conditions for the Certification Bodies Dealing with Personnel Certification,

- TS EN ISO/IEC 17025, General Conditions for the Competence of Test and Calibration Laboratories.

3. TERMS AND DEFINITIONS

3.1. Accreditation

It is the certification of the competence of CABs by a National Accreditation Body in order to deal with specific conformity assessment activities which are defined by the adjusted standards and the pre requirements which are stated in the related sector programmes if available.

3.2. Accreditation for Notification Purposes

It is the certification of the competence of CABs by a National Accreditation Body in order to deal with specific conformity assessment activities which are defined in the Regulations of the European Commission.

3.3. National Accreditation Body

The single notified authority within the member state which provides the accreditation service with the authority granted by the State (Turkish Accreditation Agency in Turkey which was founded with the Law no 4457).

3.4. Conformity Assessment

The process which demonstrates whether the conditions defined for a process, person, service or institution are fulfilled or not.

3.5. Conformity Assessment Body (CAB)

An organization that conducts conformity assessment activities and can be subject to accreditation.

3.6. Notified Body (NB)

A Conformity Assessment Body (CABs) which is authorized to provide third party conformity assessment services as a notified body (NB), and so notified by the member state to the European Commission and other member states for notification purposes in accordance with the harmonization legislation of the European Union.

3.7. Harmonized Standard

A standard that is adopted by one of the European Standardization Bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and

of rules of Information Society Services on the basis of a request made by the Commission in accordance with Article 6 of that Directive.

3.8. Community Harmonization Legislation

Community harmonization legislation of the European Union which harmonizes the conditions for the marketing of products.

4. ACCREDITATION PROCESS

4.1. Application

Applications for standards TS EN ISO/IEC 17025, TS EN ISO/IEC 17020, TS EN ISO/IEC 17065, TS EN ISO/IEC 17021-1 or TS EN ISO/IEC 17024 which form the basis for the conformity assessment procedures (module, system, etc.) of the Directive/Regulation (see Annex C) must be filled (by marking the accreditation for notification option) by the authorized representative of the CAB.

4.1.1. Conditions for candidate bodies

Only the applications of certification bodies (CBs), CABs providing testing services that solely operate as a 3rd party, and Type A inspection bodies shall be accepted. The conditions sought from CABs which are NB candidates are presented in Annex A.

4.1.2. Documents to be submitted during application

In applications for notification purposes, the documents set out in Annex D shall be uploaded to the TURKAK Corporate Service Portal during the application stage.

4.2. Assessment process

Where the harmonization of regulations is delayed, TURKAK may undertake accreditation processes in line with the original European Union legislation by considering the transition periods allowed in the original legislation and relying on the affirmative opinion of the T.R. Ministry of Trade and the relevant Ministry.

4.2.1. Office assessment

In initial accreditation assessments, office assessments shall be conducted for each European Commission Regulation or their transposed national counterpart.

In office assessments, CABs must have prepared their documentation (certification scheme, procedures and instructions, methods, checklists, sampling schemes (if applicable), testing processes (if any), etc.), by including the harmonized standards of the relevant legislation in the management system, for all relevant conformity assessment procedures (module, system, etc.) in each product group covered by the directive/regulation (legislation) subject to assessment. CABs

must also have adequate practical experience as well as competent personnel of adequate number and experience, and must have completed the competence criteria for such personnel. Otherwise, an accreditation scope shall be recommended only in the framework of the products/product groups and conformity assessment procedures (module, etc.) for which adequate documentation, practical experience and competent personnel are available.

Sampling of the client and personnel records to be reviewed in an office assessment shall be conducted to also cover all conformity assessment procedures (module, system, etc.).

Processes related to the transnational operations of CABs shall be executed in line with the R10.10 guidance document.

In accreditation assessments for notification purposes, compliance with relevant IAF MD documents shall be sought in the assessment of the quality management system-based modules (modules D, E, H and their variations).

Any nonconformity identified by TURKAK in an assessment shall be entered into records in line with the relevant article of the preferred standard, with reference to the standard that sets out additional requirements.

4.2.2. Assessments to be witnessed (witness assessments)

In initial accreditation assessments, witness assessments shall be undertaken in accordance with the grouping shown in the table below, representing to an adequate extent all conformity assessment procedures (module, system, etc.) applied for each European Commission Regulation or their transposed national counterparts.

Module	Module Description	Required Witness Assessment
A1	Internal production control plus supervised product checks	A1 or A2 or C1 or C2 or B or F or G
A2	Internal production control plus supervised product checks at certain intervals	
B	EC-type examination	B
C	EC-type conformity 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	EC-type conformity based on internal production control plus supervised product testing	C1 or C2 or A1 or A2 or B or F or G
C2	EC-type conformity based on internal production control plus supervised product checks at random intervals	
D	Conformity of production processes to quality assurance based on EC-type	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 EC-type based on product quality assurance system	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 EC-type based on product verification	F or F1 or G
F1	Conformity based on product verification	F1 or G or B
G	Conformity based on unit verification	G or F1 or B
H	Conformity based on full quality assurance	H or H1
H1	Conformity based on full quality assurance plus design examination	H1

Assessment and Verification of Constancy of Performance	**Required Witness Assessment System**
1+	1+
1	1 or 1+
2+	2+ or 1 or 1+
3	As this system is under ISO/IEC 17025, witness assessment or case examination is included in office assessment.

The following, in addition to many different factors, shall be taken into consideration in the selecting and determining the number of the activities to be witnessed in the accreditation cycle:

- Number of technical personnel
- Personnel turnovers
- Scope extension
- Changes in equipment, testing methods or harmonized standards (particularly cases related to accreditation in line with ISO/IEC 17025)
- Competence in product types and similar legislation as previously demonstrated.

4.2.2.1. Documents and records that must be communicated to the assessment team before witness assessment

1. Records of the application review of the CAB client, regarding that the documents and records set out in the legislation were submitted to it in full and that necessary examinations have been made

2. Records showing that product technical file has been examined:

- Checking of design calculations

- Checking of all drawings related to design (sub-assembly drawings, connection elements, etc).

- Records of the checking of the testing and inspection reports by the producer

- Records related to the examination of the list of harmonized standards that must be included in the technical file

3. Records related to the activities and examinations regarding the conformity assessment processes specified in the relevant legislation, that must be undertaken by the candidate NB (Example 1: Module B; Records of examinations such as assessment of materials, approval of procedures, etc. Example 2: Module A; Records of final assessment)

4. Where applicable, checking of the ability of the samples communicated by the producer to represent production (Example: Module B PED)

5. Assessment plan, drafted by the candidate NB, regarding the relevant product (sampling, testing, measurement and inspection plan, audit, etc.)

6. Records and rationale related to the designation of the duration of the audit to be undertaken by the candidate NB

7. Records of the assessment of the competence of the audit team of the candidate NB and that they are able to fully examine the scope related to the product

8. Detailed (document examination, inspection and testing, notifications, meetings, interviews, etc.) hourly assessment plan for the examinations to be conducted on-site (producer's premises or where measurement, testing and inspection will take place as agreed upon with the producer)

The full and complete documents and records listed above must be submitted to the accreditation assessment team no later than 15 days before witness assessment; otherwise, no witness assessment shall be conducted.

4.2.3. Transition period regarding the accreditation standards applicable in accreditation scope for notification purposes after revision of EA-2/17 documentation

Transition requirements with regard to European Union Legislation (regulations, etc.) are designated for bodies which applied or will apply for accreditation for notification purposes and bodies which are currently accredited; the list of accreditation standards applicable in cases where no different accreditation standard is designated by the relevant Ministry in the accreditation of NBs in accordance with the relevant EU Legislation (regulations, etc.) is presented in Annex C. In this direction, applications shall be accepted according to the accreditation standards only prescribed in the Annex (List of Applicable Accreditation Standards According to Directives/Modules) on the basis of each Directive/Module.

5. ACCREDITATION CERTIFICATE AND SCOPE

5.1. Certificate

An accreditation certificate shall be issued based on the CAB standard which forms the basis for the module/system applied for. This certificate is not different from the current certificate in use for the voluntary field.

5.2. Scope

The scope of a CAB which was accredited for notification purposes shall be described in a separate annex to the certificate, in the context of which the EA-2/17 document shall be referred to.

Examples of scopes are presented in Annex B.

6. PROFESSIONAL LIABILITY INSURANCE

Liability cover prices for professional liability insurance shall be determined through a financial analysis. The financial analysis shall be examined by the TURKAK assessment team. The minimum liability cover prices that are or will be designated by Ministries shall not prevent the execution of this analysis.

The activities conducted as part of professional liability insurance must be clearly expressed in terms of regulation(s). If the insurance also covers activities other than NB's activities, liability cover prices shall not be less than the figures determined by the Ministry and the situation must be demonstrated in the financial analysis (EA 2/17 Table 6 R17.9).

The exceptional provisions of insurance must not include NB's activities and responsibilities.

7. EA 2/17 1+ APPROACH

The requirements for the regulation specified in the scope of accreditation and for each module/system assessed for conformity, presented in the table in Annex B to EA 2/17 and Annex C to this guidance, must be included in certification schemes and sub-documentation. In this context, the NB must document which additional accreditation standard it employs for each module/system in which it operates, and which articles of the standard it deals with.

8. COMPETENCE

NBs must establish competence criteria for each function they specify in their organization charts. Competence is the ability to implement knowledge and skills to achieve the desired outcomes. While the training, education and experience requirements set out in Ministerial legislations are the minimum conditions for qualification, the knowledge and skill requirements to fulfil the tasks specified in the job description of functions must be

documented. These designated competence criteria shall be employed in the selection and training, pre-authorization activities, authorization, and performance monitoring of personnel.

These technical competencies must be established to include normative references, harmonized standards, and regulation guidance requirements particularly for the personnel who manages and executes technical activities. They may include, for example, knowing relevant GNB position papers, knowing the required ambient conditions for measurements, ability to perform dimensional measurements, ability to implement decision rules, ability to perform load tests, ability to implement low-tension tests, etc. (EA 2/17 Table 6 R17.7).

The TURKAK assessment team may implement certain methods to comprehend the competence of the personnel of the CB during assessments. These may include such methods as interviews, checking of records, on-site monitoring, etc.

During witness and/or office assessments, if required, the TURKAK assessment team may conduct, in compliance with confidentiality rules, interviews which will not have negative impacts on the assessment scheme, in order to better understand the competencies of the CAB assessment team members.

9. CERTIFICATION SCHEMES

NBs shall establish their own certification schemes under the regulations for which they are accredited. These schemes may include one or more regulations. The content of certification schemes must meet the requirements of normative documents, etc., such as R50.04 Article 4, TS EN ISO/IEC 17067.

Annex-A. CONDITIONS FOR CABS WHICH ARE CANDIDATE NOTIFIED BODIES

1. CAB must be founded under national law and vested with legal personality.

2. CAB must be a 3rd party institution independent from the organization or product it assesses (In order to meet this requirement, the areas of activity described in the articles of association of the body may only be 3rd party conformity assessment activities.

   A CAB belonging to a professional union or association that interferes with the design, production, procurement, assembly, utilization or maintenance of the product it assesses may be regarded as a 3rd party organization, provided that it can prove its independency and there is no conflict of interests.

3. CAB, its senior management and personnel who executes conformity assessment duties shall not directly interfere with the design, production, marketing, assembly, utilization or maintenance of the products assessed by the CAB or represent any party that engages in these activities. Additionally, it shall not engage in any activity that may violate the independency, objectivity and integrity of its decisions concerning the conformity assessment activities to be authorized by CAB. This means, in particular, that they cannot provide consultancy services.
   CAB must ensure that the activities of its branches and sub-contractors do not affect the impartiality, objectivity and confidentiality of conformity assessment activities.

4. CAB and its personnel must perform conformity assessment activities with the technical competence required in that field and with professional integrity at the highest level. In, particular, it must be free from financial pressure and provocation that could affect the results or decisions of conformity assessment activities from persons or groups that may have an interest in the results of the activities.

5. CAB must be competent to practise all conformity assessment tasks, performed either by itself or by other parties under its responsibility, which are assigned to it by the relevant section of the law and for which it will be authorized. It must fulfil the conditions described below at all times, for all conformity assessment procedures and all variety or category of products for which it was authorized.

   (a) Have personnel with the technical know-how as well as sufficient and appropriate experience to fulfil conformity assessment tasks.

(b) Describe the conformity assessment activities executed in a way that enables the transparency and reproduction of applicable procedures. Have suitable policies and procedures that distinguish between the tasks executed in the scope of the NB and other activities.
(c) In order for the implementation of the activities, have procedures that take into account the scale and structure of the sector of operation, complexity level of the product technology in question, and the structure of the production process (serial or batch).

Furthermore, CAB must have the tools available and be able to access all facilities and equipment required to properly fulfil the technical and administrative tasks related to conformity assessment activities.

6. The personnel in charge of executing conformity assessment activities must:

(a) Have the relevant applicable technical and professional training relating to all conformity assessment activities for which CAB is authorized,
(b) Sufficient knowledge of the conditions of and authorization for the assessments they execute,
(c) Sufficient knowledge and understanding of the implementation of applicable harmonized standards, main requirements, relevant EU harmonization legal terms and regulations,
(d) Ability to draft certificates, records and reports demonstrating the execution of the assessments.

7. CAB must guarantee the impartiality of its senior management and personnel.

Remuneration of the senior management and assessment personnel shall not depend on the number and results of the inspections executed.

8. Unless undertaken by the government according to national legislation or unless the member state is directly responsible for conformity assessment, CAB must take out **professional liability** insurance.

9. CAB personnel must consider professional confidentiality concerning all information obtained while executing their tasks under the relevant section of the law or any other national legal provision implementing the law. Property rights must be reserved.

10. CAB must participate in the relevant standardization activities and NB coordination group activities structured under EU harmonization laws, or ensure that the assessment personnel

is informed of the results of these efforts. It must refer to the documents and administrative decisions produced as a result of the works of these groups as general guidance.

11. **If there is no legal barrier, the NB must use the TURKAK mark on the certificates which it issues, in the framework of the rules designated in R10.06.**

12. **The NB cannot use the CE mark on the certificates which it issues.**

Annex-B: EXAMPLES OF SCOPES

1) Where the conformity assessment standard TS EN ISO/IEC 17065 is employed:

Accreditation Mark	**Name of Body** **Accreditation No:** **Revision No: .. Date: …….**	
	TYPE OF CONFORMITY ASSESSMENT BODY	
	ADDRESS	PHONE FAX E-MAIL WEB

Additional assessment document for this scope: EA 2/17
Accreditation for Notification Purposes, Name of Relevant Regulation

Product Group, Product / Intended Use	Regulation Annex/Module

Note: This scope only applies to the NB activities in the obligatory field.

2) Where the conformity assessment standard TS EN ISO/IEC 17021-1 is employed:

Accreditation Mark	**Name of Body** **Accreditation No:** **Revision No: .. Date: ……**	
	TYPE OF CONFORMITY ASSESSMENT BODY	
	ADDRESS	TEL FAX E-MAIL WEB

Additional assessment document for this scope: EA 2/17
Accreditation for Notification Purposes, Name of Relevant Regulation

Product Group, Product/Intended Use/Product Range	Annexes or Relevant Articles of Procedure/Modules/Regulation

Note: This scope only applies to the NB activities in the obligatory field.

3) Where the conformity assessment standard TS EN ISO/IEC 17020 is employed:

Accreditation Mark	**Name of Body** **Accreditation No:** **Revision No: .. Date: ……**	
	TYPE OF CONFORMITY ASSESSMENT BODY	
	ADDRESS	TEL FAX E-MAIL WEB

Additional assessment document for this scope: EA 2/17
Accreditation for Notification Purposes, Name of Relevant Regulation

Product Group, Product / Intended Use	Type of Inspection/Modules	Standard/Specification/Remarks

Note: This scope only applies to the NB activities in the obligatory field.

4) Where the conformity assessment standard TS EN ISO/IEC 17024 is employed:

Accreditation Mark	**Name of Body** **Accreditation No:** **Revision No: .. Date: ……**	
	TYPE OF CONFORMITY ASSESSMENT BODY	
	ADDRESS	TEL FAX E-MAIL WEB

Additional assessment document for this scope: EA 2/17
Accreditation for Notification Purposes, Name of Relevant Regulation

Product Group, Product/Intended Use/Product Range	Procedure/Modules	**Regulation** Article/ Annex

Note: This scope only applies to the NB activities in the obligatory field.

5) Where the conformity assessment standard TS EN ISO/IEC 17025 is employed, the suitable one of the following examples shall be used:

a)

Accreditation Mark	**Name of Body** **Accreditation No:** **Revision No: .. Date: ……**	
	TYPE OF CONFORMITY ASSESSMENT BODY	
	ADDRESS	TEL FAX E-MAIL WEB

Additional assessment document for this scope: EA 2/17
Accreditation for Notification Purposes, Name of Relevant Regulation

Commission Decision	Product Family, Product / Intended Use	Technical Specification, Standards / Founding Function

Note: This scope only applies to the NB activities in the obligatory field.

NOTE: In cases where Horizontal notification is employed in addition to the conformity assessment standard TS EN ISO/IEC 17025, the suitable one of the following examples shall be used:

Horizontal Notification (Regulation on Construction Products Annex-5 Article 3)

Key Characteristics	Specification, Standards	Founding Function

Note: This scope only applies to the Horizontal Notification activities in the obligatory field.

b)

Accreditation Mark	**Name of Body** **Accreditation No:** **Revision No: .. Date: …….**	
	TYPE OF CONFORMITY ASSESSMENT BODY	
	ADDRESS	TEL FAX E-MAIL WEB

Additional assessment document for this scope: EA 2/17
Accreditation for Notification Purposes, Name of Relevant Regulation

Product Family, Product / Intended Use/Product Range	Procedure/Modules	Articles or Annexes of Directive

Note: This scope only applies to the NB activities in the obligatory field.

Annex-C: LIST OF ACCREDITATION STANDARDS BY DIRECTIVES/MODULES

Regulation/Directive:
*Regulation on Lifts (2014/33/EU)
*Regulation on Pressure Equipment (2014/68/EU)
*Regulation on Simple Pressure Vessels (2014/29/EU)
*Regulation on Appliances Burning Gaseous Fuels (2016/426/EU)
*Regulation on Recreational Craft and Personal Watercraft (2013/53/EU)
*Regulation on Electromagnetic Compatibility (2014/30/EU)
*Regulation on Personal Protective Equipment (2016/425/EU)
*Regulation on Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (2014/34/EU)
*Regulation on Safety of Toys (2009/48/EC)
*Regulation on Non-Automatic Weighing Instruments (2014/31/EU)
*Measuring Instruments Directive (2014/32/EU)
*Directive on Efficiency Requirements for New Hot-Water Boilers Fired with Liquid or Gaseous Fuels (92/42/EC)

Module	Applicable Accreditation Standard	Additional requirements to be assessed, with which CABs must comply, in addition to the standard applicable in assessments	Exceptions
A1	TS EN ISO/IEC 17020	Article 6 and 7 of TS EN ISO/IEC 17025:2017 (excluding 7.9) Articles 4.1.2, 4.1.3, 7.5 and 7.6 of TS EN ISO/IEC 17065:2012	
A2	TS EN ISO/IEC 17020	Articles 6 and 7 of TS EN ISO/IEC 17025:2017 (excluding 7.9) Articles 4.1.2, 4.1.3, 7.5 and 7.6 of TS EN ISO/IEC 17065:2012	Measuring Instruments Directive (2014/32EU) TS EN ISO/IEC 17065
B	TS EN ISO/IEC 17065	Articles 6 and 7 of TS EN ISO/IEC 17025:2017 (excluding 7.9) and Articles 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012	
C	TS EN ISO/IEC 17020 (Regulation on Simple Pressure Vessels) TS EN ISO/IEC 17065 (Hot-Water Boilers)	**Not applicable**	Module C requires no NBs except for: (2014/29/EU) Hot-Water Boilers (92/42/EC)
C1	TS EN ISO/IEC 17065	Articles 6 and 7 of TS EN ISO/IEC 17025:2017 (excluding 7.9) and Articles 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012	Regulation on Recreational Craft and Personal Watercraft (2013/53/EU): TS EN ISO/IEC 17020
C2	TS EN ISO/IEC 17065	Articles 6 and 7 of TS EN ISO/IEC 17025:2017 (excluding 7.9) and Articles 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012	

D	TS EN ISO/IEC 17065	Articles 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10, 9.1, 9.2, 9.3, 9.4 and 9.6 of TS EN ISO/IEC 17021-1:2015	
D1	TS EN ISO/IEC 17065	Articles 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10, 9.1, 9.2, 9.3, 9.4 and 9.6 of TS EN ISO/IEC 17021-1:2015	
E	TS EN ISO/IEC 17065	Articles 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10, 9.1, 9.2, 9.3, 9.4 and 9.6 of TS EN ISO/IEC 17021-1:2015	
E1	TS EN ISO/IEC 17065	Articles 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10, 9.1, 9.2, 9.3, 9.4 and 9.6 of TS EN ISO/IEC 17021-1:2015	
F	TS EN ISO/IEC 17065	Articles 6 and 7 of TS EN ISO/IEC 17025:2017 (excluding 7.9) and Articles 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012	Regulation on Lifts (2014/33/EU): TS EN ISO/IEC 17020
F1	TS EN ISO/IEC 17065	Articles 6 and 7 of TS EN ISO/IEC 17025:2017 (excluding 7.9) and Articles 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012	
G	TS EN ISO/IEC 17065	Articles 6 and 7 of TS EN ISO/IEC 17025:2017 (excluding 7.9) and Articles 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012	
H	TS EN ISO/IEC 17021-1	Articles 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012	
H1	TS EN ISO/IEC 17065	Articles 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10, 9.1, 9.2, 9.3, 9.4 and 9.6 of TS EN ISO/IEC 17021-1:2015	

Non-aligned Regulations and accreditation standards to be applied in Conformity Assessment Activities

Directive / Regulation: Regulation on Pressure Equipment (2014/68/EU)		
Conformity Assessment Procedure / Module	**Applicable Accreditation Standard**	**Requirements to be complied with and assessed by CABs during assessments in addition to the preferred standard**
Notification of personnel performing non-destructive inspection testing	TS EN ISO/IEC 17024	-

Approval of personnel performing fixed connection	TS EN ISO/IEC 17024	-
Approval of Fixed connection Procedures	TS EN ISO/IEC 17020	-
European Approval for Materials	TS EN ISO/IEC 17065	-

Regulation / Directive: Directive 2000/14/EC Relating to the Noise Emission in the Environment by Equipment for Use Outdoors		
Conformity Assessment Procedure / Module	**Applicable Accreditation Standard**	**Requirements to be complied with and assessed by CABs during assessments in addition to the preferred standard**
Assessment of Technical Documentation and Periodic Checks plus Internal Production Control (Annex-VI)	TS EN ISO/IEC 17065	TS EN ISO/IEC Art. 6 and 7 of 17025:2017 (excl. 7.9) and Art. 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012
Unit Verification (Annex-VII)	TS EN ISO/IEC 17065	TS EN ISO/IEC Art. 6 and 7 of 17025:2017 (excl. 7.9) and Art. 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012
Full Quality Assurance (Annex-VIII)	TS EN ISO/IEC 17021-1	Art. 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012

Regulation / Directive: Machinery Directive (2006/42/EC)		
Conformity Assessment Procedure / Module	**Applicable Accreditation Standard**	**Requirements to be complied with and assessed by CABs during assessments in addition to the preferred standard**
EC-type Examination (Annex-IX)	TS EN ISO/IEC 17065	TS EN ISO/IEC Art. 6 and 7 of 17025:2017 (excl. 7.9) and Art. 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012
Full Quality Assurance (Annex-X)	TS EN ISO/IEC 17021-1	Art. 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012

Regulation / Directive: Regulation on Construction Products (305/2011/EU)		
Assessment and Verification of Constancy of Performance	**Applicable Accreditation Standard**	**Requirements to be complied with and assessed by CABs during assessments in addition to the preferred standard**
System 1	TS EN ISO/IEC 17065	TS EN ISO/IEC Art. 6 and 7 of 17025:2017 (excl. 7.9) and Art. 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012
System 1+	TS EN ISO/IEC 17065	TS EN ISO/IEC Art. 6 and 7 of 17025:2017 (excl. 7.9) and Art. 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012
System 2+	TS EN ISO/IEC 17065	Art. 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012
System 3	TS EN ISO/IEC 17025	-

Regulation / Directive: Regulation on Recreational Craft and Personal Watercraft (2013/53/EU)		
Post-production assessment	TS EN ISO/IEC 17065	TS EN ISO/IEC Art. 6 and 7 of 17025:2017 (excl. 7.9) and Art. 6.1.2, 6.1.3, 6.1.6-6.1.10 of TS EN ISO/IEC 17020:2012

Regulation / Directive: Directive 2014/35/EU Relating to Electrical Equipment Designed for Use within Certain Voltage Limits
This Regulation makes no mention of the concept of NB. Therefore, no accreditation shall be granted by TURKAK in line with this Regulation.

Annex-D: DOCUMENTS AND RECORDS TO BE UPLOADED TO THE PORTAL AND KEPT UP-TO-DATE DURING AND AFTER ACCREDITATION APPLICATION FOR NOTIFICATION PURPOSES

1. Records of the fact that CAB is a legal person (if CAB is a business enterprise, the activity scope section of the Trade Registry Gazette where information on the organization is provided must indicate that only 3rd party conformity assessment services would be provided),

2. Fully completed Application Form,

3. Procedures for determining, reviewing and resolving the identified, perceived, or provable potential issues of conflict of interest of CAB,

4. Service fee policies and regulations,

5. Liability insurance and/or professional liability insurance policy (covering EU geography),

6. Procedures on the use of CB identification number,

7. Records of participation in the Group of Notified Bodies (GNB) meetings (membership) or records relating to the mechanism that makes the personnel involved in the conformity assessment process aware of the results of these group meetings,

8. Records and a list of the competencies of the technical manager and his/her representative for each area for which CAB requests notification) (e.g., A technical manager cannot be authorized for construction products and medical equipment both. Technical manager is the personnel who monitors/controls the personnel and process directly involved in CAB's conformity assessment activity, on the basis of a specific sector)

9. A list of the personnel employed and contracted for each area for which CAB seeks notification, along with evidence (records of experience and proficiency) related to the authorization of the personnel in the relevant area,

10. Commitment by CAB that no personnel shall not stray from impartiality, principle of independency, and ethical values in performing services (can be a part of the service contract). Additionally, commitments that information shall be kept confidential,

11. Checklists formulated based on the module(s) contained in the European Union legislation in question (Regulation, etc.)

12. A list of harmonized standards along with the relevant products for which CAB has the capability to conduct conformity assessment,

13. Checklists formulated for each product type or category for which CAB is competent for certification and/or inspection/testing,

14. A list of devices used in conformity assessment process,

15. A list of testing conducted as part of conformity assessment,

16. In the case of utilization of sub-contracting and/or a client's laboratory, evidence relating to **list of sub-contractors and competence** and relevant contracts,

17. **Regulations relating to the fact that the competent authority shall be provided with the information set out relevant legislation**,

18. Records of internal audit conducted to form as basis for the Conformity Assessment Standard(s) required for the module(s) of the European Union legislation in question and for the EA-2/17 document.

19. A list of domestic and transnational clients (Client names shall not be coded but indicate full name and address)