Title	**ACCREDIA approach to accreditations for notifications regarding the CE marking and rules for CABs requesting this typology of accreditation**
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NOTE: The present document represents the English version of document under reference at the specified revision. In case of conflict, the Italian version will prevail. To identify the revised parts reference must be made to version in Italian language only.

Preparation	Approval	Authorization	Application date
Area Manager	The Director of Department	The General Director	19-11-2018

CONTENTS

1. INTRODUCTION

The scope of the document is to describe the motivations and implementation modalities for the accreditation of conformity assessment bodies (CABs), for the purposes of the issue of authorizations on the part of competent authorities, for the purposes of notifications to the European Commission and subsequent inclusion on the NANDO registrar of notified bodies.

The approach arises from the European Commission's Blue Guide on the implementation of EU product rules 2016 – Annex VI par. 4 establishing which standards are applicable for the assessment of notified bodies, taking into consideration all the standards used by NABs in the accreditation processes. A major contribution to the definition of the most appropriate standards of accreditation, according to the conformity assessment procedures (8 basic modules + 8 araints), was provided by a WG organized by EA and consisting of experts from European ABs, including ACCREDIA.

Acronyms:

- NAB - National Accredited Body;
- ON - Notified Body;
- CAB – Conformity Assessment Body;
- OONN – Notified Bodies;
- CSA AR – Sector Accreditation Committee for Regulated Activities.

2. REFERENCES

TABLE – Annex VI par. 4 "BLUE GUIDE" European Commission (2016)

MODULE	ISO 17000 APPLICABLE STANDARDS
A1, A2	ISO 17025 (+ ability decide on conformity), or ISO 17020 (ISO 17025 to be complied with for testing required), or ISO/IEC 17065 (ISO 17025 to be complied with for the requested tests),
B	ISO 17020 (ISO 17025 to be complied with for the requested tests), or ISO/IEC 17065 (ISO 17025 to be complied with for the requested tests),
C1, C2	ISO 17025 (+ ability to evaluate or decide on conformity), or ISO 17020 (ISO 17025 to be complied with for the requested tests), or ISO/IEC 17065 (ISO 17025 to be complied with for the requested tests),
D, D1	ISO17021 (+ product related knowledge) or ISO/IEC 17065

MODULE	ISO 17000 APPLICABLE STANDARDS
E, EE	ISO17021 (+ product related knowledge) or ISO/IEC 17065
F, F1	ISO 17025 (+ ability to evaluate and decide on conformity), or ISO 17020 (ISO 17025 to be complied with for testing required), or ISO/IEC 17065 (ISO 17025 to be complied with for the requested tests),
G	ISO 17020 (ISO 17025 to be complied with for the requested tests), or ISO/IEC 17065 (ISO 17025 to be complied with for the requested tests),
H	ISO17021 (+ product related knowledge)
H1	ISO 17021 + ISO 17020 or EN 45011 or ISO/IEC 17065 (ISO 17025 to be complied with for the requested tests),

EA has set up a TFG which, after in-depth discussion during meetings held amongst European NABs, issued a document which reformulated the previous approach with a version defined as "Approach 1+" whereby 1 is the standard for the granting of accreditation, and + is the requirements of additional standards for guaranteeing full conformity with the requirements of the directives.

The additional requirements are contained in EA Guide 2/17, with mandatory application for NABs since Jan. 1, 2010. This Guide is has been revised to better meet the needs concerning its application to the different typologies of accreditation with the CE marking, in force from 23.11.2017, published by EA on 23.11.2016. the table below summarizes the approach:

MODULE	OBJECT OF THE ASSESSMENT	CHOICE OF POSSIBLE STANDARDS FOR THE ACCREDITATION OF NBs			
		ISO/IEC 17065	ISO 17020	ISO 17021	ISO 17025
A	Internal production control	**Not applicable**			
A1	Internal production control together with one or more tests on one or more aspects of the finished product	1+P	1+P		1+CD
A2	Internal production control together with official controls made at odd intervals	1+P	1+P		1+CD
B	CE exam of the Type	1+P+RP	1+P		1+CD
C	Conformity to type based on internal production control	Non applicabile			
C1	Conformity to type based on internal production control together with one or more tests on one or more aspects of the finished product	1+P+RP	1+P		1+CD
C2	Conformity to type based on internal production control together with product testing under official controls made at odd intervals	1+P+RP	1+P		1+CD
D	Conformity based on quality guarantee in the production process	1+AQ	1+AQ	1+RP	
D1	Quality guarantee of the production process	1+AQ	1+AQ	1+RP	
E	Conformity to type based on guarantee of product quality	1+AQ	1+AQ	1+RP	
E1	Quality guarantee provided by inspection and testing of the final product	1+AQ	1+AQ	1+RP	
F	Conformity to type based on product audit	1+P+RP	1+P		1+CD
F1	Conformity based on product verificaton	1+P+RP	1+P		1+CD
G	Conformity based on unit verificaton	1+P+RP	1+P		1+CD
H	Conformity based on total quality guarantee	1+AQ	1+AQ	1+RP	
H1	Conformity based on total quality guarantee and project examination	1+AQ	1+AQ	1+RP	

NOTES

1 Indicate the possible standard to be used for accreditation (prevailing standard).

+ Indicate that the additional requirements of the extra standard need to be applied (such requirements may be deduced from an analysis of the differences which emerge in the Guide EA 2/17).

P Indicate the additional requirements of ISO 17025 if laboratory testing is required.

CD Indicate the procedures and judgment capacities and decide on the basis of testing results if the essential requirements are fulfilled and/or if the harmonized standards have been complied with. If so the additional requirements of ISO/IEC 17065 and ISO 17020 shall be applied.

RP Indicate the ability to formulate a professional judgment regarding the requirements of the product based on the additional requirements of ISO/IEC 17065 or ISO 17020.

AQ Indicate the ability to evaluate and approve the QMS of the producer on the basis of the additional requirements of ISO 17021.

3. INDICATIONS REGARDING THE APPLICABLE STANDARDS FOR THE VARIOUS DIRECTIVES

The New Legislative Framework (NLF) establishes, in its two main documents, outlined below, that the conformity assessments performed by CABs take into account the economic efficiency of the activities – see below.

Regulation 765

Accreditation provides an authorized attestation of the technical competence of the bodies which ensure conformity with the applicable standards (NBs) - § 9.

The regulation introduces a Community framework with regard to market surveillance, setting out the minimum rules in the light of the objectives which the member states must achieve - § 26.

The ABs shall verify that conformity assessments are carried out in an appropriate manner, meaning that unnecessary burdens are not imposed on undertakings and that due account is taken of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process – article 8, § 10.

Decision 768

In the interests of competitiveness, it is crucial that notified bodies apply the modules without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the modules must be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies - § 45.

Community legislation should take account of the specific situation of small and medium-sized enterprises as regards administrative burdens. Community legislation should provide for the situation of such enterprises to be taken into account in setting the rules for the selection and implementation of the most appropriate conformity assessment procedures and concerning the obligations placed on conformity assessment bodies to operate in a proportionate manner in relation to the size of undertakings and to the liited serial or non-serial nature of the production in question - § 50.

Finally, quoting the procedures for conformity assessment, the decision clarifies "the need to avoid imposing modules which would be too burdensome in relation to the risks covered by the legislation concerned" article 4 d).

ACCREDIA decided it was burdensome and unnecessary to ask CABs to apply all the requirements of all the standards referable to single modules of conformity assessment, especially for reasons of the management of assessments on the part of organizations, as well as the economic burdens of the procedures which would be passed on to producers (hereafter referred to as organizations). Therefore, ACCREDIA decided, in accordance with the interested parties, that the two most suitable standards for accreditation activities for "authorization" and "notification" should be as follows:

a) UNI CEI EN ISO/IEC 17065, in cases where it is provided for in the modules (annexes/articles) that laboratory tests should be conducted for the conformity assessment for product safety as defined in the directives or harmonized standards. In such cases it is also necessary to evaluate further requirements related to testing activities in accordance with ISO/IEC 17025;

b) UNI CEI EN ISO/IEC 17020, in cases where the conformity is assessed exclusively by means of inspection (dimensional, visual, functional, hydraulic, resistance tests etc.), without the need for testing labs or if indicated in the directive in question.

The standard UNI CEI ISO/IEC 17024 is applicable only for directives which envisage the qualification and/or certification of persons such as welders, non-destructive test personnel, as indicated in Directive 2014/68/UE PED.

The standard ISO/IEC 17065 (or ISO/IEC 17020, if the request is only for inspection activities and not tests is better suited for single rather than serial products), together with the applicable requirements of ISO/IEC 17025 which provide for lab tests, in compliance with the modules A1, A2, B, C1, C2, F, F1 and G. Accreditation against ISO/IEC 17021, as well as the preceding ones, also covers the activities contained in the modules D, D1, E, E1, H and H1.

After describing the standards used for accreditation in accordance with the various directives, it is necessary to specify that also the IAF/ILAC/EA Guides for the interpretation/application of the standard (if they exist) are applicable, as indicated in the list of documents LS-02 (ISO/IEC 17021 e ISO/IEC 17065), LS-03 (ISO/IEC 17020) and LS-04 (ISO/IEC 17025).

For definition of the term "competence" reference should be made to UNI EN ISO 19011 (capacity to apply knowledge and ability to obtain results) or to ISO/IEC 17021 (proven capacity to apply knowledge and ability).

4. OPERATIVE MODALITIES AND ASSESSMENT ACTIVITIES CONDUCTED BY ACCREDIA

In accordance with the general procedure set out in RG-01, "Regulation for the Accreditation of Certification and Inspection Bodies – general requirements", and with RG-01-03 "Regulation for the accreditation of Product Certification Bodies", RG-01-04 "Regulation for the Accreditation of Inspection Bodies", and with the decision of the Sector Accreditation Committee regarding accreditation for the purose of achieving authorization and notification from the competent authorities, ACCREDIA's assessment activities are undertaken as follows:

- presentation by the CAB of the application for accreditation or extension;
- verification that the application is properly completed and subsequent issue of the cost quotation. The quotation contains the program and the number of work days involved, for the witness assessments, calculated on the basis of the directives, modules and criticalities of the assessments and the homogeneous groupings of products required as the scope of accreditation;
- acceptance (if given) of the quotation by the body which gives formal consent to start conformity assessment activities;
- performance of the document review for accreditation or extension;
- performance of the initial or extension accreditation assessment at the location of the body. If the body is already authorized and notified, the ACCREDIA team conducts a full assessment (on the basis of the application documents received, through to the issue of the declaration of accreditation) of the certification files for the purposes of the CE marking managed by the body. Care shall be taken to sample the more critical files (such as the module and product family) regarding those which are available;
- if both assessment phases are concluded successfully (document review and on-site visit) the accreditation or extension file is submitted to the CSA AR for decision;
- performance of witness assessments (as applicable under the requirements of the accreditation directive) with the assessors of the accredited and notified bodies. The sampling criteria for these assessments are based on the decision to carry out witness assessments in the more critical modules/articles/annexes in each family of products.

The conduct of some witness assessments enables the validation of the work of the accredited and notified bodies on similar modules as required by the same directive, without necessarily doing witness assessments for each module/article/annex. This choice may not be made in advance, therefore it is recalled that in the quotations issued, only the regularity of the witness assessments is specified - frequency and number of days – without stating the modules/articles/annexes.

In cases where the CB or IB apply for accreditation for first authorization and notification (as a first step in order to operate as NBs) ACCREDIA will perform at least one witness visit of those planned (where possible), on the occasion of the first assessment activity carried out by the body as a notified body.

If the CAB does not permit ACCREDIA to carry out witness assessments within 24 months of the date of accreditation or extension, the relative files may be submitted to the CSA for an evaluation of the case.