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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.

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1. SCOPE, FIELD OF APPLICATION AND ACCREDIA POLICY

1.1. The scope of the present document is to describe the procedural modalities implemented by ACCREDIA regarding the acceptance of the application and the granting of accreditation/extension to conformity assessment bodies (CABs) which possess sites abroad:

- in particular, in the European Economic Area (EEA) countries, respecting the requirements of Regulation (EU) 765:2008, where a national accreditation Body (NAB) exists, signatory to the multilateral and bilateral agreements (EA MLA/BLA) as established by European Co-operation for Accreditation (EA) in accordance with EA-INF/03;
- in other countries where national NABs exist which are signatory to the multilateral IAF MLA (mutual agreements) and ILAC MRA (multilateral recognition arrangements);
- in countries where a NAB, signatory to the multilateral and bilateral agreements, does not exist.

1.2. It is ACCREDIA policy, in conformity with Regulation (EU) 765/2008, in particular, articles 6 (principles of competition) and 7 (Cross Frontier accreditation) and with the relative EA/IAF/ILAC Guidances, not to promote or market its accreditation services beyond the national market.

2. REFERENCE DOCUMENTS

2.1. NORMATIVE REQUIREMENTS AND DOCUMENTS = REGULATIONS

- UNI CEI EN ISO/IEC 17011:2018 Conformity assessment - requirements for accreditation bodies accrediting conformity assessment bodies;
- Regulation (EU) 765/2008 of the European Parliament and of the Council of July 9, 2008, setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (CEE) 339/93.

2.2. EA / IAF / ILAC DOCUMENTS

- EA-1-06-A-AB:2017 EA Multilateral Agreement Criteria for signing Policy and procedure for development;
- EA-INF/03:2018 Signatories to the EA Multilateral and Bilateral Agreements;
- EA 2/13 M: 2012 EA Cross Frontier accreditation policy;
- IAF ML1:2016 Guidance for the Exchange of Documentation among MLA Signatories for the Assessment of Conformity Assessment Bodies;
- ILAC G21:09/2012 Cross Frontier Accreditation – Principles for Cooperation.

2.3. INTERNAL REFERENCE DOCUMENTS

- ST - the ACCREDIA Statute;
- ST-01 - General Regulation enforcing Statutory Provisions;

- Accreditation regulations for the individual ACCREDIA Departments;
- CO – Contractual Accreditation Agreement between ACCREDIA and bodies providing conformity assessment activities (CABs);
- ACCREDIA Circular n. 3/2016 = Application of Regulation (EU) 765/2008, with specific reference to article 7 (Cross Frontier accreditation).

For every ACCREDIA document the applicable revision is the revision in force which can be downloaded from ACCREDIA's website.

3. TASKS AND RESPONSIBILITIES

The activities and roles described in the ACCREDIA internal documents are applicable.

4. PROCEDURE AND REQUIREMENTS FOR CROSS FRONTIER ACCREDITATION

4.1. PRELIMINARY EXAMINATION OF THE GEOGRAPHICAL AREA

During preliminary contacts and the examination of the application for accreditation in accordance with § 1.1, ACCREDIA shall perform and document an examination of the main aspects regarding the geographical area in which the applicant CAB operates, with regard to:

- the country where the CAB has its registered head office;
- the location of all the sites declared by the CAB in the application for accreditation;

The examination of the geographical areas is especially important if the CAB is located within the EEA or in a state whose NAB is signatory to the multilateral or bilateral agreements (EA, IAF, ILAC) to which ACCREDIA is also signatory. In this case the applicable documents are:

- article Art.7¹ of the EU Cross Frontier Regulation for accreditation, Regulation (EU) 765/2008;
- the criteria reported in the document EA-2/13 EA Cross Border accreditation policy.

¹ Article 7 "Cross Frontier accreditation" (Regulation (EU) 765:2008)

1. Where a conformity assessment body requests accreditation it shall do so with the national accreditation body of the Member State in which it is established or with the national accreditation body to which that Member State has had recourse in accordance with Article 4(2). However, a conformity assessment body may request accreditation by a national accreditation body other than those referred to in the first subparagraph in any one of the following situations:

a) Where the Member State in which it is established has decided not to establish a national accreditation body and has not had recourse to the national accreditation body of another Member State in accordance with Article 4(2);

b) where the national accreditation bodies referred to in the first subparagraph do not perform accreditation in respect of the conformity assessment activities for which accreditation is sought;

c) where the national accreditation bodies referred to in the first subparagraph have not successfully undergone peer evaluation under Article 10 in respect of the conformity assessment activities for which accreditation is sought.

2. Where a national accreditation body receives a request pursuant to paragraph 1(b) or (c), it shall inform the national accreditation body of the Member State in which the requesting conformity assessment body is established. In such cases, the national accreditation body of the Member State in which the requesting conformity assessment body is established may participate as an observer.

3. A national accreditation body may request another national body to carry out part of the assessment activity. In such a case the accreditation certificate shall be issued by the requesting body.

It is emphasized that the term “established” given as used in par. 1 of art. 7 shall be understood to mean the head office of the CAB with legal responsibility for the activities and the certificates and reports issued, irrespective of the legal nature², on the basis of which the CAB is “legally established” in the Member State where this site is located.

With regard to this the following situations may arise:

- **CAB with head office, legally established outside Italy and with secondary sites, if such exist, in various geographical areas, amongst which in Italy;**
- **CAB with head office, legally established in Italy and with sites, if such exist, in various geographical areas;**
- **CAB already accredited by a different NAB in another country and with a secondary site in Italy.**

4.1.A – CAB WITH HEAD OFFICE, LEGALLY ESTABLISHED OUTSIDE ITALY WITH, IF SUCH EXIST, SITES IN VARIOUS GEOGRAPHICAL AREAS, AMONGST WHICH ITALY

ACCREDIA must firstly ascertain if there is a NAB in the country where the CAB is established and, if there is, if the NAB is signatory to the multilateral or bilateral agreements (EA, IAF, ILAC) to which ACCREDIA is also signatory.

If there is no NAB in that country ACCREDIA or the NAB.

- does not issue the type of accreditation requested;
- is not signatory to the multilateral agreements for the type of accreditation requested;

ACCREDIA is free to perform accreditation activities. It shall, however inform the local NAB (if one exists) of the activities it intends to perform.

In this situation, there are two cases, as follows:

1 – Countries within the EEA (European Economic Area)

In this case Regulation 765/2008 is applicable and a NAB exists.

ACCREDIA proceeds according to article 7 of the Regulation and according to the document EA 2/13³.

² See “**CERTIF 2009-06 REV6 - CROSS BORDER ACCREDITATION ACTIVITIES**”, SOGS N595 EN REV6 *The multi-site accreditation is however only permitted under the Regulation if the accredited CAB maintains the final responsibility for the activities performed by local sites covered by the scope of the multi-site accreditation. The accreditation certificate issued by the NAB where the head office is established names one legal entity - the head office - and it is this legal entity which holds the accreditation and which is responsible for the accredited activities of the CAB, including any activity performed by the local site that forms part of the scope of the accreditation. (...)The solution of the multi-site accreditation can be applied to all types of local entities (subsidiaries, branches, agencies, offices, etc.), regardless of their legal personality and is in principle valid for all types of CABs.*

³ See EA 2/13: 5.1.1 *The accreditation certificate issued by the National Accreditation Body, of the country where the head office is established shall name one legal entity, that of the head office, and it shall be this legal entity that holds the multisite accreditation and is responsible for the accredited activities of the conformity assessment body, including any activity performed by the local sites that forms part of the scope of accreditation.*

If the CAB has a number of sites in the EEA, it shall identify the site which is responsible for certification and reports (legally established – Headquarter – see EA 2/13: 5.1.1), and request accreditation.

A CAB which is established and operates within the EEA:

- if it is accredited for a certain scope (area or schemes/sectors) within the EEA, it may also possess other accreditations obtained outside the EEA, but only for activities:
 - undertaken outside the EEA;
 - which have no relations with European legislation;
- it may request first accreditation from an AB outside the EEA, but only for activities:
 - undertaken outside the EEA;
 - which have no relations with European legislation⁴.

If ACCREDIA grants accreditation in compliance with the laws of another EU nation, it shall perform assessment activities with the support of the NAB of the country in which the reference laws and standards for accreditation are currently in force.

2 – Non-EU countries

In cases where the CAB's registered office is in a non-EU country and its other EU sites do not issue certifications/reports, it is not mandatory to apply for accreditation from the AB, recognized according to Regulation 765/2008, of the Member State where there is the remote site. In such cases Regulation 765/2008 is not applicable.

ACCREDIA shall verify, or have verified, that:

- the CAB is not already accredited by another NAB;
- the CAB has not received any sanctions from other NABs;
- for multi-site CABs, identifying the geographical location of the head office and of secondary locations. In these cases the ACCREDIA regulations/procedures/instructions for multi-site CABs are applied.

ACCREDIA shall in all cases understand the justifications whereby the CAB has requested accreditation from ACCREDIA, and it shall present to the CAB, in exhaustive and positive manner, the various forms of collaboration, signaling any criticalities on the part of ACCREDIA and fulfilling the request (including the greater costs the CAB will face from ACCREDIA compared with the local NAB), in the spirit of the applicability of the IAF/ILAC Cross Frontier documents.

Following completion of the above activities, if there is an explicit request by the CAB to proceed with the application for accreditation, ACCREDIA can decide, informing the local NAB, if there is one, whether to proceed with the application or stating the reasons for rejecting it.

If the application is accepted, ACCREDIA shall invite the NAB to collaborate closely in the management of the accreditation file in question.

⁴ See **CERTIF 2013-02**– Requirement to seek accreditation in the Member State of establishment, § 4 – Conclusion. *This should apply for all conformity assessment activities that take place in Europe and concern products or services that are to be placed on the internal market.*

4.1.B - CAB WITH HEAD OFFICE LEGALLY ESTABLISHED IN ITALY AND WITH SITES IN VARIOUS GEOGRAPHICAL AREAS ABROAD

If the assessed site is abroad, ACCREDIA, where possible, shall demonstrate that the assessment team possesses the competence to operate in the geographical area in question (see § 4.2).

4.1.C – SECONDARY SITE IN ITALY OF A CAB ALREADY ACCREDITED BY A DIFFERENT NAB OF ANOTHER COUNTRY

ACCREDIA shall be available, compatibly with internal priorities, to collaborate with the various NABs who so request, in accordance with the applicable international standards.

4.2. COMPETENCE REQUIREMENTS OF THE ACCREDIA ASSESSMENT TEAM FOR THE FOREIGN GEOGRAPHICAL AREA

Generally, regarding assessment activities conducted abroad, if a specific competence is required by the local laws and voluntary standards (such as the EMS scheme), the ACCREDIA team shall be flanked by a member of the local NAB or by a local expert (provided by the local NAB or directly requested by ACCREDIA, for example, from among the local Italian representatives – ambassador, consul etc.) except in cases where ACCREDIA can justify and provide evidence of adequate competence in local legislation on the part of the ACCREDIA team.

If a local expert is used ACCREDIA shall require that such expert shall:

- prepare and have available in advance a summary of the main laws applicable to the scheme and sector of the conformity assessment. The TL shall attach this summary to the assessment report;
- sign the commitment to confidentiality and the absence of conflicts of interests with the CAB and the audited organization.

As the typology of experts used in such cases is not normally on ACCREDIA's list, evidence of the evaluation of their competence shall also be reported in the assessment report.

In the quotation presented to the CAB there shall be an additional item covering the expenses for the presence of the NAB's assessors and/or local experts used directly by ACCREDIA.

4.3. MANAGEMENT OF THE ACCREDITATION PROCESS

If ACCREDIA decides to proceed in collaboration with the local NAB, it shall provide documented evidence of the terms of the agreement reached.

If ACCREDIA decides to proceed with accreditation activities, where conditions exist to operate by itself, it shall apply the accreditation regulations and the applicable procedures of the individual departments.

4.4. RECORDS

The modalities for records, unless otherwise agreed with the NAB, are implemented in line with the ACCREDIA procedures and instructions.