

TITLE APPLICATION PROCEDURE FOR CROSS FRONTIER ACCREDITATIONS

REFERENCE PG-12

REVISION 04

DATE 2022-10-31

NOTE *This document is the English version of the document under reference at the specified revision. In case of conflict, the Italian version will prevail. To identify the revised parts reference shall be made only to version in Italian*

PREPARATION

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AUTHORIZATION

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APPLICATION DATE

2022-12-01

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1. SCOPE, FIELD OF APPLICATION AND ACCREDIA POLICY

The purpose of this document is to describe the procedural modalities implemented by ACCREDIA regarding the acceptance of the application and the granting of accreditation/extension/renewal/transfer of accreditation to conformity assessment bodies (CABs) which possess sites or locations abroad:

- in particular, in countries in the European Economic Area (EEA), respecting the requirements of Regulation (EU) 765:2008, where a National Accreditation Body (NAB) exists, signatory to the multilateral and bilateral agreements (EA MLA) as established by European co-operation for Accreditation (EA) in accordance with the document EA-INF/03 in the current revision;
- in other countries where NABs exist which are signatory to the multilateral IAF MLA (Multilateral Agreements) and ILAC MRA (Multilateral Recognition Arrangements);
- in countries where a NAB, signatory to the Multilateral Agreements, does not exist.

The requirements of this document also apply to the performance of assessment activities performed in other countries in the EA Region (see the provisions of § 2.1 of the document EA 2/13 in the current revision).

It is ACCREDIA policy, in conformity with Regulation (CE) 765/2008, specifically in 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 boundaries of its national market.

2. REFERENCE DOCUMENTS AND DEFINITIONS

2.1. REGULATORY NORMATIVE DOCUMENTS

- 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 and subsequent amendments.

2.2. EA / IAF / ILAC DOCUMENTS

- EA-1-06-A-AB:2022 EA Multilateral Agreement Criteria for signing Policy and procedure for development;
- EA-INF/03:2022 Signatories to the EA Multilateral and Bilateral Agreements;
- EA 2/13 M:2019 EA Cross Frontier accreditation Policy and Procedure for Cross Frontier Cooperation between EA Members;
- 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 (*under revision*).

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 (EC) 765/2008, with specific reference to article 7 (Cross Frontier accreditation).

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

2.4. TERMS AND DEFINITIONS

The terms and definitions set out in the applicable ACCREDIA documents, in the standards and reference documents referred to by them (e.g. ISO/IEC 17000, ISO/IEC 17011, EA-2/13) are applied.

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 analysis of the application for accreditation in accordance with § 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 established its legal entity;
- 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 (depending upon the case in question):

- the requirements of Art.7¹ (Cross Frontier Accreditation) of Regulation (CE) 765/2008);

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

- the criteria reported in the document EA-2/13 "EA Cross Border accreditation policy" in the current revision, including the appendix, where applicable;
- the provisions of this procedure and the criteria of the document ILAC G21.

It is emphasized that the term "established" 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/reports/declarations issued, irrespective of the legal nature², on the basis of which the CAB is "legally established" in the Member State where this site is located³

With regard to this the following situations may arise:

- CAB with legal entity registered outside Italy and with secondary sites, if such exist, in various geographical areas, including Italy;
- CAB with legal entity registered 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 LEGAL ENTITY REGISTERED OUTSIDE ITALY WITH, IF SUCH EXIST, SITES IN VARIOUS GEOGRAPHICAL AREAS, INCLUDING 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, or the NAB

- does not issue the type of accreditation requested,

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.

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.

³The term "legally established" means that the legal entity that is accredited is the one held legally responsible for all the conformity assessment activities it carries out.

- 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.

The CABs in question must be informed that they will have to proceed with the transfer of accreditation to the local NAB as soon as the above conditions change. Furthermore, ACCREDIA will not be able to start a new accreditation cycle or extend accreditation if it has evidence of the fact that the NAB of the country concerned has become signatory to the MLA agreements.

In the context of the QMS-ASD (Aerospace, Security and Defense) scheme, in cases where ACCREDIA accredits (or has started the accreditation process) a legal entity located outside the national borders, ACCREDIA shall inform the local NAB recognized by ICOP (if there is one) sufficiently in time, and the relative RMS (or SMS if applicable) of the relevant international region.

In the light of the above contexts, there may be two cases, as follows:

1 – Countries within the EEA (European Economic Area)

In this case Regulation (EC) 765/2008 (with subsequent amendments) is applicable and a NAB exists.

ACCREDIA proceeds according to article 7 of this Regulation and according to the document EA 2/13.

If the CAB has a number of sites in the EEA, it shall identify the site which is responsible for certifications/reports/declarations (“*the responsibility of a single legal entity*” – see EA 2/13 requirement 5.1.1⁴) and apply for accreditation.

In accordance with Regulation (EC) 765/2008 it is forbidden for a CAB established in Italy to request from another Accreditation Body, whether it is established in Europe or outside Europe, accreditation in a scheme/sector, if the same accreditation can be provided by ACCREDIA. If, on the other hand, the CAB is already covered by ACCREDIA accreditation in this scheme/sector, it is possible to request further accreditation for this, provided that it is to a non-European Accreditation Body.

Furthermore, if ACCREDIA accredits according to foreign national regulations, it is mandatory to carry out the verification activity with the support of the Accreditation Body of the state in which the Regulation used as a reference for accreditation is in force.

In cases where ACCREDIA accredits a CAB whose legal entity is located within the EA Region or where ACCREDIA conducts assessment activities within the EA Region, it is mandatory to subcontract the conduct of this activity to the local Accreditation Body if it is a signatory of the relevant MLA.

This requirement is binding whether it concerns on-site or witness assessments, regardless of whether they are performed remotely, mixed (blended) or on-site.

⁴ See EA 2/13: 5.1.1 Accreditation covering multiple locations is only possible where all the activities can fall under the responsibility of a single legal entity. Where individual locations covered by the accreditation also hold a different legal personality, it is expected that those legal entities will be related and form part of the same organisation. The responsibility shall be demonstrated on the basis of contractual or other legal arrangements between the accredited legal entity and its locations and internal regulations in the locations that further specify these relationships in terms of management and responsibilities.

If the local Accreditation Body cannot, for various reasons, perform the assessment, ACCREDIA must in any case ensure the possibility that it participates as an observer and this will also include the possible need for ACCREDIA and the NAB to share information regarding the CAB under assessment.

In the subsequent development of the relative surveillance program in the accreditation cycle, ACCREDIA will conduct a risk analysis which will take into account various factors as required by § 5.3 of the document EA 2/13. In this process ACCREDIA and the local NAB will be able to exchange any valid and relevant information, such as the results of the assessments, complaints, market feedback, etc., which concern the single locations where they are both involved in the assessment activities.

In cases of multi-site CABs, the accreditation certificate issued by ACCREDIA will report only the legal entity responsible for all the conformity assessment activities conducted by all its sites. Where secondary sites have a different legal entity, they cannot offer accredited services on the market, as they do not fall within the scope of the accreditation of the legal entity holder of the accreditation.

The provisions of § 5.1 of the document EA 2/13 are applied.

2 – Non-EU countries

In cases where the CAB is a legal entity registered in a non-EU country Regulation (EC) 765/2008 cannot be applied.

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;
- the CAB is multi-site, identifying the geographical location of its legal entity and of other secondary locations operating under its responsibility. In such cases the ACCREDIA regulations/procedures/operative instructions for multi-site CABs are applied.

ACCREDIA must, however, understand the motivations whereby the CAB has requested accreditation from ACCREDIA, and it shall present to the applicant CAB, in exhaustive and positive manner, the various forms of collaboration, signaling any criticalities on the part of ACCREDIA in accepting the application (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 it exists, whether to proceed with the application or state 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, which will also include the possibility that ACCREDIA subcontracts to it the conduct of all, or part, of the assessment activities.

In cases of multi-site CABs, the accreditation certificate issued by ACCREDIA will report only the legal entity that is responsible for all the conformity assessment activities conducted by all its sites. Also in this type of case it is confirmed that, where the offices have a different legal entity, they cannot offer accredited services on the market on behalf of their own legal entity because the latter is not covered by the scope of accreditation.

4.1.B - CAB WITH LEGAL ENTITY REGISTERED IN ITALY AND WITH SITES IN VARIOUS GEOGRAPHICAL AREAS ABROAD

If the site subject to assessment is located abroad, ACCREDIA, where possible, will subcontract to the local NAB the assessment of the CAB's activities, including the witness assessments, which are carried out in the country of the local NAB, if the NAB is signatory to the relevant EA/IAF MLA scope⁵.

In cases where the local NAB is not a signatory to the relevant EA/IAF MLA scope or in case of unavailability of the NAB to perform the assessment, the activity will be carried out directly by ACCREDIA which will appoint an assessment team with the competences indicated in § 4.2 of this procedure.

For the assessment of sites located within the EA Region, in accordance with the provisions of EA 2/13 in the current revision, additional provisions will be applied in accordance with § 4.1.A - Case 1 Countries of the European Economic Area EEA.

4.1.C - SECONDARY SITE IN ITALY OF A CAB ALREADY ACCREDITED BY A DIFFERENT ACCREDITATION BODY IN ANOTHER COUNTRY

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

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

If ACCREDIA has to carry out the assessment directly for the reasons referred to in point 4.1.B and if specific competence is required by the local laws and voluntary standards (such as, for example, 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 – embassy, consulate etc.) except in cases where ACCREDIA can justify and provide evidence of adequate competence in local legislation on the part of the ACCREDIA team (e.g. number of assessment activities carried out for the scheme being assessed in the State concerned).

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.

Since this type of experts used in such events are not normally included on ACCREDIA's list of experts, the evidence of the evaluation of their competence shall be obtained before the assessment and attached to the assessment report. As regards the Technical Experts provided by the local NAB, competence in the area is ensured by the appointment provided by the NAB.

⁵ In the context of the EA Region, the provisions of § 3.8 of document EA 2/13 and of § 4.1.A of this procedure apply, for which the subcontracting is mandatory.

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

It should be noted that the individual sites as well as the legal entity cannot refuse the participation of the local NAB in the assessment activities that ACCREDIA will have to carry out.

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.

ACCREDIA shall inform the local NAB of its subcontracting needs for the following year, where possible within the first three (3) months before the new year or in any case at least three (3) months before the period in which the relevant assessment activities must be carried out.

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

For the application of the requirements of this procedure and of the document EA-2/13, all the points specified in the **appendix of the document EA-2/13** must be observed, which has an obligatory nature for ACCREDIA and for the CABs, providing evidence of it in the assessment report.

4.4. RECORDS

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