

For the attention of

- Accredited Conformity Assessment Bodies and applicants
- ACCREDIA evaluators
- The Ministry of Economic Development

Our. ref.: DC2016SSV249

Milan, 27/07/2016

Re:: **ACCREDIA Circular n° 3/2016**
Application of Regulation (CE) 765/2008 with specific reference to article 7 – Cross Frontier Accreditation

The present communication is a reminder of the commitments undertaken by Conformity Assessment Bodies (**CAB**) established in the European Economic Area (**EEA**) in accordance with Regulation (CE) 765/2008, in the light of the further clarification provided by European Commission¹ and by the Italian Ministry of Economic Development, the contact point in Italy for accreditation activities.

1. Field of application of Regulation (CE) 765/2008

The application of Regulation (CE) 765/2008 refers to conformity assessment activities in both the voluntary and mandatory areas as set out in article 3 of the Regulation.

Article 3 states:

This section shall apply to accreditation, used on a mandatory or voluntary basis, relating to conformity assessment, independently of the legal status of the body performing the accreditation.

Regulation (CE) 765/2008 is applicable to all conformity assessment activities as stated in article 2, point 13, which states:

'Conformity Assessment Body' shall mean a body that performs conformity assessment activities including calibrations, testings, certifications and inspections;

2. Activities undertaken by Bodies established in the European Economic Area (EEA)

Paragraph 1 of Article 7 states:

Where a conformity assessment body (CAB) 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, paragraph 2².

¹¹ <http://ec.europa.eu/growth/single-market/goods/building-blocks/accreditation/>

² See also CERTIF 2013-02– Requirement to seek accreditation in the Member State of establishment, § 4 – Conclusion. *To avoid introducing competition between accreditation bodies and leaving a loophole for conformity assessment bodies to shop around for accreditation certificates, Art. 7(1) of the Regulation should be understood as it stands: 'Where a conformity assessment body seeks accreditation it shall do so with the national accreditation body of the Member State in which it is established [...]' (emphasis added by the Commission)*

The interpretation of the term “established” shall be understood to mean the Body’s registered office, having legal responsibility for activities and certificates/reports issued, irrespective of its juridical nature³.

It is a requirement that the CAB in question is “*legally established*” in the Member State⁴.

It follows that:

- A CAB with a number of locations in the EEA shall identify the European location which is responsible for issued certifications (headquarters - see EA 2/13: 5.1.1⁵) and shall apply for accreditation to the recognized National Accreditation Body⁶ in compliance with Regulation (CE) 765/2008, and competent in the Member State where the location is legally situated.
- If a CAB, which has its legal head office outside the EEA, opens an office in the EEA and this EEA office does not issue certificates/reports, it is not necessary to apply for accreditation through this office to the NAB with recognition against Regulation (CE) 765/2008, in the Member State where the location is situated.
- A CAB established (headquarters) and operating in the EEA and accredited for a certain area/sector in the EEA, can possess other accreditations outside the EEA but only for activities that:
 - a) are carried out outside EEA and
 - b) do not relate to the European legislation.
- A CAB established (headquarters) in the EEA can apply for the first accreditation from an AB outside the EEA, but only for activities that
 - a) are carried out outside EEA and
 - b) do not relate to the European legislation⁷

3. Declaration of equivalence, given from NAB, of certificates/reports issued by CABs accredited or not in the EEA

In the EEA it is the CAB's responsibility to seek accreditation from the NAB of the Member State it is established. NABs monitor accredited CABs in order to ensure they continue to fulfil the criteria for accreditation.

In accordance with the IAF MLA/ ILAC MRA agreements, certificates/reports issued by a CAB accredited by an Accreditation Body which is signatory to the IAF MLA/ ILAC MRA agreements, are equivalent to certificates/reports issued by all accredited bodies which are signatory to the IAF MLA/ ILAC MRA agreements⁸.

³ 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.*

⁴ See the interpretation given dated April 27 of the European Commission DG Internal Market, Industry, Entrepreneurship and SMEs: *Activities of ABs and CABs are regulated by Reg. 765/2008. The latter clearly states that CAB must seek accreditation in the Member State it is (legally) established (or with the national accreditation body to which that Member State has had recourse in accordance with Article 4.2), in order to (among other things) avoid multiple accreditation. Certif-2013-02 goes exactly in the same direction.*

⁴ 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.*

⁵ NAB: National Accreditation Body, is an Accreditation Body recognized by its member state according to regulation 765/2008

⁷ 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*

⁸ IAF members promote the acceptance of the certificates of conformity that bear a participating Accreditation Body's symbol (preferably in association with the IAF MLA Mark) and are within the scope of the MLA, as being on an equal basis with those of its own ac-

However, also in accordance with the IAF MLA/ ILAC MRA agreements, CABs shall not operate in violation of the applicable laws⁹.

It therefore follows that in accordance to EA / IAF/ILAC MLA and MRA agreements:

- A NAB, recognized according to Regulation (CE) 765/2008, if required, shall confirm the equivalence of certificates issued under the accreditation of another NAB recognized according to Regulation (CE) 765/2008 (see also the last point regarding MRA agreements).
- A NAB, recognized according to Regulation (CE) 765/2008, shall confirm
 - the equivalence of certificates/reports issued under non-EEA accreditation by CABs not established in the EEA (headquarters out of the EEA), if issued under IAF MLA/ ILAC MRA agreements.
 - but it request the interested party to control with the competent authorities and with the reference market the acceptance of the certificate/reports¹⁰ for activities that are related to the European legislation.
- A NAB, recognized according to Regulation (CE) 765/2008, shall
 - confirm the equivalence of certificates issued under non-EEA accreditation by a CAB established in the EEA if issued in accordance with the IAF MLA/ ILAC MRA agreements,
 - but it shall request the interested party to control with the competent authorities and with the reference market the acceptance of the certificate¹¹.
- If a specific agreement is in place (Mutual Recognition Agreements – MRAs¹²), between the European Commission and another State, a NAB, recognized according Regulation (CE) 765/2008, shall be able to confirm the equivalence of certificates/reports issued under non-EEA accreditation by a Notified Body not established in the EEA (headquarters out of the EEA), if issued under the recognition of the Notifying Authority of that State.

4. The Recognition of equivalence, issued by the national authority, of services rendered by accreditation bodies and the acceptance of the relative accreditation certificates and attestations issued by CABs under their accreditation

As mentioned above, an AB recognized according to Regulation (CE) 765/2008, in base agli accordi EA / IAF/ILAC MLA e MRA, shall confirm the equivalence of certificates/reports also if the certificates/reports issued under non-EEA accreditation by a CAB established in the EEA, if issued under the IAF MLA/ ILAC MRA agreements; but mostly in these cases it shall request that the interested parties control with the

credited bodies (IAF ML4:2014 4.4b). See also EA-INF/04:2016 del 26 Maggio 2016: *For CABs not established in EU: Under the Agreement certificates/reports issued by <CAB name8> accredited by <foreign NAB> which is also a signatory to the <ILAC MRA; IAF MLA> are accepted by <local NAB> as being as reliable as any comparable certificates/reports that have been issued by <laboratories / certification- / verification- / inspection bodies> accredited by <Local NAB>.*

8 See for information:

- **Code of Conduct for IAF Members, Issue 2, Version 2** "IAF member shall comply with applicable laws and regulations both domestic and international... Acceptance of this Code of Conduct is compulsory for IAF members as a condition of membership of IAF. Failure to abide by the Code of Conduct will serve as a basis for disciplinary action, at the discretion of the IAF Board, up to and including suspension or termination of IAF membership."
- ILAC P4 (Oct2013) - **ILAC Mutual Recognition Arrangement (Arrangement): Policy Statement**, section 5.2, last paragraph: "No accreditation body shall be required to have a policy or practice that is in violation of any existing laws of its economy, provided such laws are not in conflict with the requirements of ISO/IEC 17011."

¹⁰ See EA-INF/04:2016 dated 26 May 2016: *Important notice: EU Regulation (EC) 765/2008 requires that, 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 it had recourse under the conditions of Article 7(1)). If that is not the case, we recommend to check acceptance of the certificate by authorities or the marketplace.*

¹¹ See EA-INF/04:2016 dated 26 May 2016: *Important notice: EU Regulation (EC) 765/2008 requires that, 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 it had recourse under the conditions of Article 7(1)). If that is not the case, we recommend to check acceptance of the certificate by authorities or the marketplace.*

¹² See <http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=mra.main>

competent authorities and with the reference market the acceptance of the certificate/reports (EA-INF/04:2016 dated 26 May 2016).

On the basis of Regulation (CE) 765/2008, article 11, paragraph 2, the national authority shall:

- a) recognize the equivalence of services rendered by ABs which have successfully undergone the peer evaluation in accordance with article 10;
- b) accept the accreditation certificates issued by ABs as above;
- c) accept the attestations issued by accredited CABs in accordance with Regulation (CE) 765/2008.

Article 11 – Presumption of conformity of NABs

1. the conditions set by article 8 are deemed satisfied by National Accreditation Bodies which, having successfully undergone the peer evaluation in accordance with article 10, demonstrate their conformity with the criteria set out in the relative harmonized standard, the reference for which is published in the official Gazette of the EU.
2. the national authorities recognize the equivalence of the services rendered by ABs which have successfully undergone the peer evaluation in accordance with article 10 and they accept, on the basis of the presumption as per paragraph 1 of the present article, the accreditation certificates of such bodies and the attestations issued by CABs holding their accreditation.

Consequently, in the light of the above:

- An EEA national authority, shall recognize certificates/reports issued under the accreditation of a NAB recognized under Reg. (CE) 765/2008 or if issued under the MRA agreements¹³, unless there are reasons (case by case basis) justifying the contrary.
- An EEA national authority shall not recognize certificates/reports issued in sectors falling into the scope of Reg 765/2008 by bodies (established or not the EEA), which are not notified under Reg. (CE) 765/2008 because such certificates are issued in violation of the Regulation.

The EEA national authority should accept certificates/reports issued by bodies not established in EEA in two cases as follows:

- Firstly, if the EEA sectorial rules and standards expressly specify so;
- Secondly, if there is a specific agreement (Mutual Recognition Agreements – MRAs¹⁴) between the European Commission and a Member State for the recognition of certificates/reports issued by a Notified Body which is not accredited in accordance with Reg. (CE) 765/2008 and not established in the EEA, if the certificates/reports are issued with the recognition of a Notifying Authority of the State which signed the agreement with the Commission.

5. Sanctions and communications to third parties

In cases where ACCREDIA, finds that a CAB it accredited does not fulfill its obligations, it shall take corrective measures. EA rules and guides will be followed.

If the NAB, with recognition in accordance with Reg. (CE) 765/2008, considers that there has been a violation of Reg. (CE) 765/2008, it shall inform EA and its authorities, including if relevant the Notification authorities. Notification authorities shall decide whether to inform the Directorate-General for the Internal Market, Industry, Entrepreneurship and SMEs of the European Commission.

¹³ See <http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=mra.main>

¹⁴ See <http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=mra.main>

National authorities shall decide, for their part, on possible sanctions.

In cases where ACCREDIA, in accordance with Reg. (CE) 765/2008, finds a violation of that Regulation on the part of a CAB, if the CAB is accredited for some schemes, ACCREDIA shall issue a Nonconformity against the body operating in violation of Reg. (CE) 765/2008 for improper use of accreditation (ISO 17011, § 7). With regard to the modalities for the closure of a NC, it is deemed acceptable to agree with the body on a program of not more than four years to restore accreditation by the competent AB in accordance with (ISO 17011, § 7) with regard to the activities performed in violation of the Regulation, if not differently stated by competent Authorities, case by case.

Please contact us for any clarifications.

Sincerely,


Dr. Filippo Trifiletti
General Director