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# **EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation Between EA Members**

## ***PURPOSE***

This document states the policy and procedures agreed by EA members concerning accreditation of conformity assessment bodies with sites or key activities in other countries than that where the accredited conformity assessment body is established. This document also describes the procedures to be followed by EA members concerning accreditation in another country under the conditions of European Regulation (EC) 765/2008 article 6 part 3.

*Authorship*

This document has been prepared by the EA Horizontal Harmonization Committee.

*Official language*

The text may be translated into other languages as required. The English language version remains the definitive version.

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**Category:** Members' procedural document - Mandatory

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**Transition period:** The transition period of implementation for this document ends 31.12.2014 for all cross border activities that already exist. However, if an EA member receives a new application for multisite accreditation where the sites are in other European countries than the country of the EA member receiving the application, then this document shall be applied immediately for that accreditation.

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## 1. Definitions

For the purpose of this document the following definitions apply.

**1.1 EA region:** The geographical region covered by countries of the EA members, the countries which have been formally identified by the EU or EFTA as candidate countries for membership in the EU or EFTA and countries of accreditation bodies with which EA has signed a bilateral agreement is referred to as the “EA region”.

**1.2 Foreign accreditation body (FAB):** “Foreign Accreditation Body” refers to an Accreditation Body when it accredits a conformity assessment body which has sites with key activities in another country than the country of the accreditation body accrediting it.

**1.3 Local accreditation body (LAB):** The term “Local Accreditation Body” refers to the national accreditation body of the country where the accredited conformity assessment body is established. The term also refers to the accreditation body of a country where there is a site included in an accreditation granted by an accreditation body in another country.

**1.4 National accreditation body (NAB):** The term “National Accreditation Body” refers to the accreditation body in a country legally appointed by the government of that country.

## 2. Scope

**2.1** This document describes EA’s policy and procedures for cooperation between national accreditation bodies when accreditation is provided by a national accreditation body, to a conformity assessment body which has sites in another country (also called multisite accreditation) in the EA region or has key activities in another country in the EA region. This document also describes the procedures to be followed by EA members concerning accreditation in another country under the conditions of European Regulation (EC) 765/2008 article 6 part 3 (also called cross border accreditation).

**2.2** This policy and procedure on cross border cooperation applies to all EA members as defined in the Articles of Association, to all accreditation bodies with which EA has signed a bilateral agreement and to the accreditation of all types of conformity assessment bodies.

**2.3** EA encourages its members to implement and respect, as far as possible, the spirit and intent of the policy defined in this document also in relation to their accreditation activities in countries and economies outside the EA region.

**2.4** The intention of this document is to ensure cooperation between National Accreditation Bodies where a National Accreditation Body has to perform assessment of conformity assessment bodies or sites of conformity assessment bodies in another country in the EA region. This document describes the minimum level of cooperation between EA members

### **3. General Policy**

**3.1** It is EA Policy that an EA member shall not promote or market its accreditation services in the country of another accreditation body in the EA region.

**3.2** EA members shall not compete with other EA members in the EA region.

**3.3** EA members shall only consider providing accreditation services to conformity assessment bodies in countries or economies of other EA members in the cases defined in the European Regulation (EC) 765/2008 article 6 part 3. This shall also apply to countries of accreditation bodies with which EA has a bilateral agreement.

**3.4** This policy does not address conformity assessment body operations in foreign countries when the activity is not classified as a key activity. However, it is the responsibility of the AB providing the accreditation to ensure that accredited conformity assessment bodies operating in foreign countries have the necessary competence and when this involves witnessing activities of the conformity assessment body in the foreign country, a foreign accreditation body is encouraged to ask for the support of the local accreditation body.

**3.5** Furthermore, when a national accreditation body accredits a conformity assessment body in its own country for a foreign national regulation, the accrediting national accreditation body shall ask for assessment support from the national accreditation body of the country issuing the regulation in order to make sure that it has full information on the implementation of that regulation.

**3.6** This policy is consistent with ISO/IEC 17011, with the European Regulation (EC) 765/2008 and SOGS Certif. 2009/06 rev6 (also referred to as SOGS N595 rev6) and takes into account the IAF and ILAC cross frontier guidelines (References IAF GD 3 and ILAC-G21).

### **4. Cooperation requirements for Cross Border Accreditation**

**4.1** Where it is permissible and an EA member is going to accredit a conformity assessment body in a foreign country for whatever reason, whether this is in or outside the EA region, it shall inform the Local Accreditation Body of its intentions and keep it informed of its actions. The Foreign Accreditation Body shall take all necessary steps to cooperate as much as possible with the Local Accreditation Body.

**4.2.** An EA member National Accreditation Body is permitted to provide accreditation to conformity assessment bodies in the EA region, outside its own country, only in the following situations:

- (a) where the country in which the conformity assessment body is established has decided not to establish a national accreditation body and has not had recourse to the national accreditation body of another country;
- (b) where the national accreditation body in the country where the conformity assessment body is established does not perform accreditation in respect of the conformity assessment activities for which accreditation is sought;
- (c) where the national accreditation body in the country where the conformity assessment body is established has not successfully undergone peer evaluation in respect of the conformity assessment activities for which accreditation is sought.

**4.3** When an EA member accredits a conformity assessment body in its own country and the conformity assessment body has foreign sites performing key activities, these foreign sites can be covered under the accreditation granted to the conformity assessment body, under the conditions given in Chapter 3 of this document. For the purposes of this document this is called multisite accreditation. The procedure for multisite accreditation is given in Chapter 5 of this document.

**4.4** Outside the EA region, each EA member may have its own policy concerning accreditation in other countries.

**4.5** Before accepting an application within the conditions described in 4.2 (b) and (c), the Foreign AB shall confirm with the Local AB that one of these conditions apply.

**4.6** When an EA member, in the situations described in 4.2 and 4.3, is requested to provide accreditation services in another country in the EA region, it should pay utmost attention to using the specific competence needed, taking into account factors such as language, local laws and regulations, culture, etc. in addition to the normal technical competence requirements. The Foreign AB shall seek the cooperation of the Local AB for such information that may not be readily available for the Foreign AB. The Local AB shall facilitate the access of the Foreign AB to this information and to competence resources if and when available. The preferred EA approach to ensure access to relevant competence is to use resources of the Local AB as much as possible.

**4.7** When the conditions under 4.2 or 4.3 have changed and at each re-assessment the Foreign AB shall confirm that previously accepted justifications and conditions for providing cross border accreditation still apply. The records of these justifications shall be retained and be subject to evaluation during EA Peer Evaluations.

**4.8** In the exceptional case where the Local AB and the Foreign AB have not been able to establish cooperation according to EA procedures, they will both keep records of the reason why they have not been able to cooperate. This information shall be documented, retained and provided on request.

**4.9** An EA member shall ensure that the contracts with its clients, include clauses that enable the Local ABs to be used for assessments of conformity assessment activities performed in other countries without the need for prior approval or communication, if the Local AB is a signatory of the relevant EA MLA and provides accreditation for the relevant conformity assessment activity. Such a clause shall also make sure that the Foreign AB and the Local AB can share information with each other concerning the conformity assessment body.

## **5. Cooperation requirements for multisite accreditation for conformity assessment bodies with sites in more than one country in the EA region**

**5.1** Where a conformity assessment body with a Head Office established in one country also has local sites situated in other countries of the EA region, it may seek an accreditation to cover the activities for all of its sites(also called multisite accreditation in this document), with the AB of

the country where its head office is established. For multisite accreditation the following conditions shall be met and apply irrespective of the legal personality of the local sites.

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.

5.1.2 The head office and all of the sites to be included under the accreditation shall operate under the same management and the same global quality management system.

5.1.3 The head office shall have the means to substantially influence and control the activities of the sites. The head office shall be able to demonstrate that such influence and control is in place and properly working.

5.1.4 The local sites shall not offer accredited services to the local market under their own name and logo within the multisite accreditation.

5.1.5 The accredited conformity assessment body, i.e. the head office maintains the final responsibility for the activities performed by the local sites covered under the scope of the multisite accreditation of the head office.

5.1.6 Where these local sites carry out key activities as defined in EN ISO/IEC 17011 (see also IAF/ILAC A5), then the accreditation certificate shall in its annexes clearly identify the address of these sites.

5.1.7 The local sites may offer conformity assessment activities under the multisite accreditation to the local market only on behalf of the accredited conformity assessment body, i.e. the head office. The certificates and reports issued under the multisite accreditation shall contain the name and address of the accredited legal entity i.e. the head office without the logo of the local site. However, these certificates may make reference to the contact details of the local site issuing the certificate or report in question. The certificates issued shall not create any confusion as to the conformity assessment body which holds the accreditation.

5.1.8 The multisite accreditation is meant only for use by companies within the same organisation and where the head office maintains the responsibility for the activities performed and certificates/reports issued by the local sites. The responsibility shall be demonstrated on the basis of contractual or equivalent legal relationships between the head office and the local sites and internal regulations in the organisations that further specify these relationships in terms of management and responsibilities.

5.1.9 Multisite accreditation can be applied to all types of local sites such as subsidiaries, branches, agencies, offices, etc. regardless of their legal personality and is in principle valid for all types of conformity assessment bodies, as long as they carry out clearly defined and relevant activities within the scope of the multisite accreditation.

When these conditions are not met in all aspects, multisite accreditation cannot be and shall not be granted.

**5.2** The principles of multisite cross border accreditation require the conformity assessment body and the sites included in the multisite accreditation to abide by the following.

1. The multisite conformity assessment body shall fully cooperate with the NABs involved.
2. Local sites cannot reject the participation of the Local AB in the assessment, reassessment and surveillance processes.

When accepting applications EA members shall make sure that the applicant is made aware of and accepts these conditions.

**5.3** Holding the final responsibility, as mentioned in 5.1.5, for activities performed by the local site implies that the head office takes the operational, financial and legal responsibility for activities performed by the local site, and this responsibility shall be confirmed in the conditions set by the NAB for its multisite accreditation of the head office. The NAB shall require that the conformity assessment body shall state that the head office takes full operational, financial and legal responsibility for activities performed by the local site, in its contracts with its customers.

**5.4** If a local site, as referred to in 5.1.6 is removed from the list of local sites on the accreditation certificate, for lack of fulfilment of requirements, the impact on the status of the full scope of accreditation shall be determined. In this regard particular consideration shall be given to the requirements on the head office for controlling activities (5.1.3) and for taking responsibility for performed activities (5.1.5).

**5.5** A site where key activities are performed shall during initial assessment be visited and assessed, before it can be covered under the multisite accreditation .

**5.6** The programme for follow-up assessment (surveillance and reassessment) of sites where key activities are performed shall normally take place at the same frequency as at an equivalent single site conformity assessment body. The frequency of surveillance visits may be reduced or increased based upon a risk assessment undertaken by the accrediting EA member. Justifications for a reduction or increase in frequency shall be recorded for each case by the EA members and be subject to evaluation during EA Peer Evaluations.

## **6. Cooperation procedure between EA members on cross border, multisite accreditation**

In all circumstances where a Foreign AB knows that it will need the cooperation of a Local AB for performing assessments, it shall report this as soon as possible. The Foreign AB shall inform the Local AB of its needs in the coming calendar year at the latest three months before the beginning of the calendar year. At this stage, the exact scope of the assessment may not be clear but such early information is essential to allow for resource planning by the Local AB. The scope of the assessment will have to be reported to the Local AB at the latest three months before the due date of the assessment. If these general rules are followed regularly, any exceptions will be easier for the Local AB to handle.

**6.1** Cooperation between Local and Foreign AB can only function efficiently if both parties are committed to responding to all requests in a timely manner and announce at an early stage any difficulties they may encounter.



**6.2** When an EA member performs assessments for another EA member, ISO/IEC 17011 clause 7.4.1 applies. An example of an Agreement between ABs for the purpose of the provision of services in accordance with the EA, ILAC and IAF Cross Frontier Policies is available on the EA intranet. This example is provided so that EA members may use this as a framework and amend it by mutual agreement to satisfy their particular needs. If EA members follow this template, they are presumed to meet EA's requirements on such an agreement.

**6.3** When a Local Accreditation Body agrees to undertake assessments on behalf of a Foreign Accreditation Body, the Local Accreditation Body may use its own accreditation assessment procedures, systems and reports and shall not be required to use the assessment procedures, systems or reports of the Foreign Accreditation Body. The report shall, in any case, contain sufficient information about the findings and supporting evidence to ensure that a sound decision can be taken by the Foreign Accreditation Body. The Foreign Accreditation Body shall specify the scope of the requested assessment in such detail that the risk for misunderstanding is minimised. The Local Accreditation Body shall ensure that it follows the instructions of the Foreign Accreditation Body in such matters. The Foreign Accreditation Body shall provide the Local Accreditation Body with all information needed to ensure effective assessment within the agreed time frame according to the agreement signed.

The Foreign Accreditation Body shall inform the Local Accreditation Body of the outcome of the accreditation decision when it is made.

**6.4** The language to be used during the assessment and in reports shall be agreed between the accreditation bodies involved and the conformity assessment body in advance of the assessment. The default language shall be English.

**6.5** The approach to the cooperation between the Local Accreditation Body and the Foreign Accreditation Body will differ depending on the specific circumstances of the conformity assessment body. For cross border multisite accreditation, there are 3 possible cases:

- 1- The accredited conformity assessment body has a site with key activities in a country where the site is itself a CAB accredited by the Local AB for an identical scope
- 2- The accredited conformity assessment body has a site with key activities in a country where the site is itself a CAB accredited by the Local AB for a different scope
- 3- The accredited conformity assessment body has a site with key activities in a country where the site is not at all accredited as a CAB by the Local AB

The following table defines the principles of the cooperation between the accreditation body which has accredited the multisite conformity assessment body, so called "Foreign AB" in the table, and the accreditation body which will deliver assessment services, so called "Local AB" in the table. This table applies only if the Local Accreditation Body has the appropriate competence for the work it is being asked to deliver.

Conditions to be defined	Type of site with key activity to be assessed		
	<p><b>1. The site with key activity = a CAB accredited by the Local AB for an identical scope</b></p>	<p><b>2. The site with key activity = a CAB accredited by the Local AB for a different scope</b></p>	<p><b>3. The site with key activity = not accredited by the Local AB</b></p>
<p><b>Assessment cycle</b></p>	<p>Cycle of the Local AB (the assessment is part of the Local AB assessment) If the Foreign AB under whose accreditation the site is being assessed uses a more stringent requirement, the more stringent requirement applies, unless otherwise agreed with the local AB.</p>	<p>Cycle of the Local AB (the assessment is performed during the assessment of the Local AB) If the Foreign AB under whose accreditation the site is being assessed uses a more stringent requirement, the more stringent requirement applies, unless otherwise agreed with the local AB.</p>	<p>Cycle of the Foreign AB (assessment by the Local AB dedicated solely to the foreign accreditation scope)</p>
<p><b>Assessment content of the site on behalf of the Foreign AB</b></p>	<ul style="list-style-type: none"> <li>- Files and records under FAB accreditation</li> <li>- Witnessing as defined by the FAB for the activities under the foreign accreditation</li> <li>- Any additional requirements of the Foreign AB</li> </ul>	<ul style="list-style-type: none"> <li>- Key activities as defined by the Foreign AB in line with IAF/ILAC A5</li> <li>- Files records under FAB accreditation</li> <li>- Witnessing as defined by the FAB for the activities under the foreign accreditation</li> <li>- Any additional requirements of the Foreign AB</li> </ul>	
<p><b>Output of the assessment to be provided to the Foreign AB</b></p>	<ul style="list-style-type: none"> <li>- Assessment results to be reported immediately when a major noncompliance has been detected, which may influence the scope of accreditation</li> <li>- assessment report to be provided within the time frame stated in the agreement between the ABs</li> <li>- statement on how</li> </ul>	<ul style="list-style-type: none"> <li>- Assessment results as soon as possible, or as stated in the agreement between the ABs</li> <li>- Assessment report within the time frame stated in the agreement between the ABs</li> <li>- statement on how findings have been closed, if these are closed by the Local AB according to the agreement</li> <li>- statement on how findings have been closed, if these are closed by the Local AB according to the agreement</li> </ul>	

	<p>findings have been closed, if these are closed by the Local AB according to the agreement</p> <ul style="list-style-type: none"> <li>- Decision or confirmation of decision of the local AB on its local accreditation of the site (granting, surveillance, renewal)</li> </ul>	
<p><b>Information to be provided to the Local AB by the foreign AB</b></p>	<ul style="list-style-type: none"> <li>- Report of the last head office assessment</li> <li>- Any specific additional requirements or activities to be particularly assessed by the Local AB</li> <li>- Any requirements from regulators which may have an impact on the activities of the foreign site when accreditation is being granted for the purposes of notification</li> <li>- Full scope of the activities which can be performed by the local site under the multisite accreditation</li> <li>- Detailed description of the scope to be assessed, including any sector schemes</li> <li>- Surveillance plan for the site over the full accreditation cycle</li> <li>- Global surveillance plan, if necessary</li> <li>- Global witnessing plan, if necessary</li> </ul>	
<p><b>Planning to be elaborated by the Foreign AB</b></p>	<ul style="list-style-type: none"> <li>- Global planning for all assessments to be done during the accreditation cycle so that the Local AB can plan its resources. For that purpose the FAB will have to have some type of global planning of its sampling process so that the Local AB has an approximate understanding of what will be expected of it concerning resources. There will always be last minute changes but on an overall basis it is important that the LAB has an understanding of what it is expected to deliver.</li> <li>- At least 3 months before the start of the calendar year the FAB shall confirm the plan for the coming year.</li> </ul>	

*Note to the planning: It is acknowledged that the activities of a conformity assessment body may change and the assessment plan may have to be changed at a later stage.*

**6.6** The Foreign Accreditation Body shall notify the Local Accreditation Body of its decision to suspend or terminate an accredited activity performed in the foreign site.

Equally the Local Accreditation Body shall notify the Foreign Accreditation Body of its decision to suspend or terminate an accredited activity of a site if that site holds an independent local accreditation through the Local Accreditation Body.

It is important that this information is communicated immediately after the decision has been taken and that each EA member considers if the suspension/termination affects any accreditations it provides.

**6.7** The Foreign Accreditation Body and the Local Accreditation Body shall exchange any valid and relevant information, such as outcomes of assessments, complaints, market feedback, etc, concerning conformity assessment bodies where they are both involved.

**6.8** EA member accreditation bodies shall appoint at least one contact point for communications concerning cross border activities. This contact shall be fed into the EA members' intranet in the dedicated area. Communication between EA members on cross border activities shall take place through the appointed contact point(s) in the planning phase. EA members shall make sure that communications are efficient and that timely responses are given.

## **7. Transfer to the local accreditation body**

**7.1** Article 39 of the European Regulation (EC) 765/2008 gives a maximum validity date for existing cross border accreditation certificates as 31 December 2014, but this does not apply when there is an extension to the expiry date or scope of the accreditation or a renewal. National Accreditation Bodies shall inform their conformity assessment bodies of the impact of the Regulation on the validity of their accreditations. Involved EA members shall facilitate the change of Accreditation Body for their customers and make the process as efficient as possible. Examples to facilitate this are:

- implementing the policy and procedures described in this document as soon as possible,
- making joint assessments with the Local AB,
- involving the Local AB in planning assessments.

**7.2** The accredited conformity assessment body should not be disadvantaged by having to suffer a gap in its accreditation. It is however the responsibility of the conformity assessment body to apply for accreditation with the Local Accreditation Body in time, to enable the Local Accreditation Body to make the assessment and take the accreditation decision. The Local Accreditation Body shall follow clause 7.11.1 of ISO/IEC 17011, which means that it will take account of the history of accreditation of the conformity assessment body. In all cases, the Foreign Accreditation Body will submit information to the Local Accreditation Body and as a minimum the scope of the accreditation held by the conformity assessment body through the Foreign Accreditation Body (through the latest accreditation certificate and related underlying schedules, etc), the last assessment report and a report on complaints, if any.

Transfer to local accreditation body during the accreditation cycle may take place prior to the reassessment at the request of the conformity assessment body. The conformity assessment body, the Local Accreditation Body and the Foreign Accreditation Body are encouraged to discuss and agree on the plan for the change to minimise costs for the conformity assessment body.

**7.3** If a Foreign Accreditation Body has granted accreditations in another country in the EA region due to the lack of competence of the Local Accreditation Body or due to the fact that the Local Accreditation Body is not a signatory of the relevant MLA agreement, conformity assessment bodies will be informed of the fact that they shall have to change to the Local Accreditation Body as soon as these conditions change. In these situations the principles of this document apply. The Foreign Accreditation Body shall not renew such an accreditation or extend the accreditation after the Local Accreditation Body enters the MLA.