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EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members

PURPOSE

This document describes EA's policy and procedures for cooperation between national accreditation bodies when accreditation is provided by a national accreditation body (NAB), to a conformity assessment body (CAB) which has locations in another country in the EA region and/or conducts conformity assessment activities in another country in the EA region. This document describes the minimum level of cooperation between EA members and guidance on good practice. 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)

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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CONTENTS

1	DEFINITIONS	4
2	SCOPE	4
3	GENERAL POLICY	4
4	COOPERATION REQUIREMENTS FOR CROSS BORDER ACCREDITATION	5
5	REQUIREMENTS FOR ACCREDITATION FOR CONFORMITY ASSESSMENT BODIES WITH LOCATIONS IN MORE THAN ONE COUNTRY IN THE EA REGION	6
6	COOPERATION PROCEDURE BETWEEN EA MEMBERS ON CROSS BORDER ACCREDITATION OF MULTIPLE LOCATION CABS	8
	APPENDIX (MANDATORY).....	10
1.	BACKGROUND.....	10
2	KEY CONCEPTS.....	10
3	COMMON QUESTIONS	13

1 DEFINITIONS

For the purpose of this document the following definitions apply in addition to those provided in ISO/IEC 17000, ISO/IEC 17011 and Regulation (EC) 765/2008 of the European Parliament and Council.

1.1 EA region: The geographical region covered by countries of the EA members in accordance with EA's Articles of Association.

1.2 Foreign accreditation body (FAB): "Foreign accreditation body" refers to an accreditation body when it accredits a conformity assessment body which has a location(s) where conformity assessment activities take place 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 accreditation body of a country where there is a location(s) where conformity assessment activities take place that are included in an accreditation granted by an accreditation body in another 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 (NAB), to a conformity assessment body (CAB) which has locations in another country in the EA region and/or conducts conformity assessment activities in another country in the EA region. This document describes the minimum level of cooperation between EA members and guidance on good practice. 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, and to the accreditation of all types of CABs.

2.3 EA encourages its members to implement and respect, 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. Outside the EA region, each EA member may have its own policy concerning accreditation in other countries, taking into account ILAC and IAF policies as appropriate.

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 As required by Article 6.2 of Regulation (EC) No 765/2008, 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 in the EA region 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 If a FAB has granted accreditations in another country in the EA region due to the lack of available competence of the LAB to accredit the requested activity or due to the fact that the LAB is not a signatory of the relevant EA MLA/BLA, CABs shall be informed of the fact that they will have to transfer their accreditation to the LAB as soon as these conditions change. In these situations, the principles of this document apply. The FAB shall not initiate a new accreditation cycle or extend the accreditation after the LAB enters the MLA/BLA.

3.5 At each re-assessment the FAB 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.

3.6 When a NAB accredits a CAB established in its own country for a foreign national regulation, the accrediting NAB shall ensure, in cooperation with the NAB of the country issuing the regulation, that it has access to the necessary expertise and information concerning that regulation.

3.7 This policy is consistent with ISO/IEC 17011, with the European Regulation (EC) 765/2008 and takes into account the guidance published by the European Commission (e.g. CERTIF documents) and IAF and ILAC policies.

3.8 Recognising the public authority nature of accreditation in the EA region, it is the EA policy that, wherever possible, the FAB shall subcontract to the LAB the assessment of the CAB's activities conducted under the FAB's accreditation, including witnessed assessments, that are performed in the LAB's country, whenever the LAB is a signatory to the relevant EA MLA scope.

4 COOPERATION REQUIREMENTS FOR CROSS BORDER ACCREDITATION

4.1 Where it is permissible (see 3.3) and an EA member is going to accredit a CAB in another country in the EA region, it shall inform the LAB of its intentions and keep it informed of its actions. The FAB shall take all necessary steps to cooperate as much as possible with the LAB.

4.2 Before accepting an application from a CAB established in another country in the EA region, the FAB shall confirm that the requirements of Regulation (EC) 765/2008 (Article 6.3) are met and shall liaise with the LAB as necessary.

4.3 When an EA member provides accreditation services in another country in the EA region, it shall ensure it has the necessary competence to conduct the accreditation, taking into account factors such as language, local laws and regulations, culture, etc. in addition to the normal

technical competence requirements. The FAB shall seek the cooperation of the LAB for such information that may not be readily available for the FAB. The LAB shall facilitate the access of the FAB 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 LAB as much as possible. If the LAB is not taking part in the performance of the assessment, the FAB shall give the opportunity to the LAB to observe that assessment.

4.4 EA member NABs are required to establish an effective cooperation, both the FAB and LAB shall ensure that they react and respond in accordance with the requests made by each party. In the exceptional case where the LAB and the FAB have not been able to establish cooperation according to EA procedures, they shall both keep records of the reason why they have not been able to cooperate. This information shall be documented, retained and provided on request.

4.5 An EA member shall ensure that the legally enforceable arrangements it has with its clients, include clauses that enable the relevant LABs to be used for assessments of conformity assessment activities performed in their countries without the need for prior approval or communication, if the LAB 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 FAB and the LAB can share information with each other concerning the CAB even if the LAB does not perform the assessment..

5 REQUIREMENTS FOR ACCREDITATION FOR CONFORMITY ASSESSMENT BODIES WITH LOCATIONS IN MORE THAN ONE COUNTRY IN THE EA REGION

5.1 Where a CAB legally established in one country of the EA region also operates in locations in other countries of the EA region, it may seek an accreditation to cover the activities for all of its locations, with the AB of the country where it is legally established. The following conditions shall be met and apply irrespective of the legal personality of the locations (further information is provided in the appendix to assist in the interpretation of the requirements).

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 (see also Appendix). 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.

5.1.2 The accreditation information issued to the CAB by the NAB, of the country where it is legally established shall name only the legal entity of that CAB which is responsible for the accredited conformity assessment activities conducted at all of its locations.

5.1.3 All of the locations to be included under the accreditation of the CAB shall operate under the same management and the same management system.

5.1.4 The registered legal entity (the CAB) shall demonstrate that it has control of and monitors the activities at its locations. The registered legal entity shall be able to demonstrate that such control and monitoring is in place and properly working.

5.1.5 Where the individual locations have a different legal entity to that of the accredited CAB they shall not offer accredited services to their local market under their local legal entity as this local legal entity is not within the scope of accreditation awarded by the FAB.

5.1.6 The legal entity of the accredited CAB, maintains the responsibility for the activities performed by its locations covered under the scope of its accreditation.

5.1.7 Individual locations of the CAB may offer conformity assessment activities to the local market only on behalf of the accredited CAB. The certificates and reports issued under the accreditation awarded by the FAB shall contain the name and address of the accredited legal entity without reference to the name or the logo of any local CAB. The quotations, contracts, certificates and reports issued shall not create any confusion as to the legal entity of the CAB which holds the accreditation.

5.2 The principles of multiple location cross border accreditation require the CAB and the locations included within the scope of accreditation to abide by the following.

1. The CAB shall fully cooperate with the NABs involved.
2. Individual locations cannot reject the participation of the LAB in the assessment, reassessment and monitoring processes.

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

5.3 If a location is removed from the list of locations held in the accreditation information, e.g. 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 CAB for controlling and monitoring activities (5.1.4) and for taking responsibility for performed activities (5.1.6).

5.4 It is the responsibility of the FAB to develop an assessment programme to cover the activities, locations and personnel to be assessed in accordance with its usual assessment procedures taking into account the risk associated with the activities and the market conditions in the locations. The review of the risk shall be undertaken with input from the LAB(s) utilising their knowledge and expertise of their respective markets and regulations. Specific considerations to take into account when establishing the approach and degree of sampling required include, but are not limited to:

- Different local regulations
- Knowledge of the local market
- Volume of work carried out by the CAB at different locations
- Impact of the CAB activities conducted under the FAB accreditation on the local market e.g. the proportion of the market share held by the CAB
- History of assessment results of the conformity assessment activity and/or location

- Level of control and monitoring demonstrated by the CAB for each given location
- Whether or not the local office holds accreditation from the LAB for the same of different scope and/or utilises the same or different conformity assessment processes and/or operated the same or different management system
- Where location holds accreditation by the LAB, the cycle/frequency of the LAB assessment shall be utilised as far as possible

6 COOPERATION PROCEDURE BETWEEN EA MEMBERS ON CROSS BORDER ACCREDITATION OF MULTIPLE LOCATION CABS

6.1 It is essential that the FAB has the cooperation of the LAB in order to determine the approach for the assessment of the CAB (see 5.4 above). Both parties shall be committed to make and respond to all requests and announce at an early stage any difficulties they foresee or encounter. For existing accredited activities the FAB shall provide sufficient information to the LAB concerning the anticipated assessment requirements over the accreditation cycle. The FAB shall also inform the LAB 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 the LAB to have input to the planning and for resource planning by the LAB. The scope of the assessment shall be reported to the LAB at the latest three months before the due date of the assessment. For additional requests e.g. ad-hoc assessments or extensions to scope, the FAB shall notify the LAB as soon as the request is known and the FAB and LAB shall work together to manage and, wherever possible, meet the CAB's expectations in a timely manner.

6.2 When an EA member performs assessments for another EA member, ISO/IEC 17011 clause 6.4.4 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 from the EA secretariat

6.3.1 The FAB shall specify the scope of the requested assessment in such detail that the risk for misunderstanding is minimised. The FAB shall provide the LAB with all information needed to ensure effective assessment within the agreed time frame according to the agreement signed. The FAB shall inform the LAB of the outcome of the accreditation decision when it is made.

6.3.2 When a LAB agrees to undertake assessments on behalf of a FAB, the LAB shall ensure that it follows the instructions of the FAB in relation to communications with the CAB and the scope of the requested assessment. The LAB 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 FAB. 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 FAB.

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

6.5 As indicated in 5.4 the FAB shall take into account whether the LAB has issued any accreditation at the location of the CAB and is conducting assessments at the location for its

own purposes. Where this is the case the cycle and frequency of the LAB shall be utilised, unless the FAB requires a more stringent requirement.

6.6 In advance of any assessment the FAB shall provide the LAB with at least the following:

- Report of the last assessment of the location identified as holding the management control; including the details of nonconformities and actions arising
- Up-to-date information about the CAB including details of how it is organised and managed and how the conformity assessment activities carried out at/from its locations are controlled
- Any specific additional requirements or activities to be particularly assessed by the LAB
- Any requirements from regulators which may have an impact on the activities of the location when accreditation is being granted for the purposes of notification
- Full scope of the activities which can be performed by the local location under the CAB's accreditation
- Detailed description of the scope to be assessed, including any sector schemes
- Assessment plan, including witnessing for the location over the full accreditation cycle
- Assessment programme for all of the CAB's activities, including witnessing, if necessary

6.7 The LAB shall provide the FAB with at least the following:

- Assessment results in accordance with the timescales specified in the agreement between the NABs
- Assessment report within the time frame stated in the agreement between the ABs
- Statement on recommendations regarding the closure of any findings if these are to be reviewed by the LAB according to the agreement. (Note that corrective actions may have been provided directly to the FAB e.g. where the location passed the responsibility to another location e.g. its main office.)

6.8 The FAB shall notify the LAB of any decision to suspend or terminate accreditation for an activity performed in the LAB's country. Equally the LAB shall notify the FAB of any decision to suspend or terminate accreditation for an activity that takes place at a location that holds local accreditation granted by the LAB. 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.

6.9 The FAB and the LAB shall exchange any valid and relevant information, such as outcomes of assessments, complaints, market feedback etc, concerning the individual locations where they are both involved.

6.10 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.

APPENDIX (MANDATORY)

1. BACKGROUND

This appendix is to assist in the interpretation of the requirements stipulated in section 5.1. In this document certain expressions are used which require further interpretation in order to achieve a harmonized implementation. In addition, a need was identified for advice on how the fulfilment of these requirements could be assessed. Thus, this appendix interprets, and gives advice on how to assess compliance to, the requirements stipulated in section 5.1 of the main document.

2 KEY CONCEPTS

Below are listed definitions of key concepts used in clause 5.1. Also, guidance is given on how to assess whether the specified requirements are fulfilled.

2.1 Same organisation (5.1.1)

Definition:

Group of legal entities, composed of multiple locations connected with the registered legal entity on the basis of contractual or equivalent legal relationships, operating under the same commercial name and logo.

Comments to definition:

The names of the individual legal entities may be slightly different but shall include the commercial name of the organisation. The names of the individual legal entities may e.g. include letter codes defining type of organisation (e.g. "Ltd" or "GmbH") or regional identifiers (e.g. "Svenska" or "Deutsche"). The commercial name may be translated, partially or in full, to accommodate the local market.

Assessment focus:

- Contractual agreements or documentation of other legal relationships between the registered legal entity and its locations
- Registration of the commercial name and logo
- Marketing material
- Issued reports and/or certificates

2.2 Same management (5.1.3)

Definition:

*Same set of persons or organisational entities (e.g. CEO, Board of Directors) of the **same organization** taking overall **responsibility for the accredited activities**.*

Assessment focus:

- Organisation charts linked to named individuals
- Reporting lines from locations to the registered legal entity
- Descriptions of authorities and responsibilities of persons:
 - approving policies and instructions for conformity assessment activities,
 - approving authorities and responsibilities of personnel involved in conformity assessment activities, and
 - authorising certificates and reports.
- Names of persons at the registered legal entity assigned authorities and responsibilities to control and monitor activities performed at locations, including decisions concerning resource management etc.
- Evidence of monitoring from the central controls within the CAB each location in every aspect (managerial, financial and operational). (Note that the sole performance of internal audits is not considered sufficient for taking responsibility for accredited activities.) Evidence of monitoring may be written instructions and records produced and maintained.
- Evidence of effective communication within the organisation. Special care should be taken where there is not a single language of communication within the organisation used by all members of the management in a position to influence the quality of the accredited services.
- Is transfer of overall managerial and operational responsibility for activities of each location to personnel employed by a foreign company (registered legal entity) possible according to the company legislation in the country where the location is established?

2.3 Same management system (5.1.3)

Definition:

*Set of linked rules and procedures defined by **same management** to allow it to take **responsibility for accredited activities**.*

In order for the management system to be considered as the same it shall be designed to provide the same outcome of accredited activities regardless of where the activities are carried out or by whom. The policies governing conformity assessment activities shall be the same throughout the organisation. To provide consistency of results:

- The *same management* is to define in the *same management system* any sub-sets of alternative rules and procedures, used e.g. by different locations or throughout different geographical regions.
- All activities defined by the *same management system* are covered by an internal audit program managed and approved by the *same management*, and the outcome of individual audits, including decisions on corrective actions, is channelled through affected management at all levels as the situation warrants.
- All activities of the *same management system* are subject to a management review by the *same management*. The outcome of the management review, including any decisions, is channelled through affected management at all levels as the situation

warrants. The *same management* has the authority and legal means to enforce corrective and preventive actions.

Assessment focus:

- Management system structure.
- Rules for approval of policies and instructions.
- Implementation of policies.
- Application of requirements for competence, procedures for qualification and monitoring of personnel involved in conformity assessment activities.
- Internal audit program. Documentation of internal audits. Communication of corrective actions. Lack of same or similar nonconformities recurring throughout the organization.
- Procedure for management review. Documentation of management reviews. Communication and implementation of decisions. Lack of similar problems recurring throughout the organization.

2.4 Responsibility for accredited activities (5.1.1, 5.1.2 and 5.1.6)

Definition:

Responsibility for the performance and outcome of accredited activities.

Comments to definition:

In order to take responsibility for accredited activities the registered legal entity shall have full operational control over these activities. To this end, the registered legal entity shall have appropriate technical competence and the resources to assure control over the full scope of accreditation. To take responsibility for the outcome of accredited activities is to take responsibility for:

- the competence and resources used,
- the rules and procedures applied,
- the consistency obtained, and quality achieved through the application of these rules and procedures,
- the impartiality displayed applying these rules and procedures, and
- the contents of issued reports and/or certificates.

The responsibility is to be upheld:

- towards the customer,
- towards authorities,
- towards the public, and
- in court.

Assessment focus:

- harmonising conformity assessment outcomes through:
 - common or equivalent procedures
 - common or equivalent competence, training, qualification and monitoring requirements
- supervising conformity assessment activities, e.g. by means of:
 - internal audits
 - participation in proficiency testing schemes

- monitoring activities
- the checking of data, calculations, analyses and reports or certificates
- documentation of communication with authorities
- handling of complaints and appeals, both at the level of the registered legal entity and at the level of its locations
- handling of impartiality issues, both at the level of the registered legal entity and at the level its locations
- handling of media coverage, both at the level of the registered legal entity and at the level of its locations
- handling of legal cases, both at the level of the registered legal entity and at the level its locations

3 COMMON QUESTIONS

How do we deal with a scenario where the local legal entity of the location is also an independently accredited by the LAB?

Prior to establishing an agreement, it shall be made clear which legal entity will take responsibility for the contract with the client and under which identity the accredited work will be performed. The entire process then has to be performed following the quality management system of the accredited body contracted for the work. Any reports or certificates issued shall identify the accreditation under which the work is performed.

Who takes responsibility for the contract review if it is done locally?

Answer: This is up to the CAB to decide. If the responsibility is put locally, the registered legal entity shall take appropriate measures to implement needed policies, harmonise the procedures and supervise the activities. See interpretation of “responsibility for accredited activities”.

Are local office personnel able to authorise contracts on behalf of the registered legal entity?

The contract signature is a fundamental indicator of responsibility. Two basic cases exist:

- Unique contracts are signed with individual customers. In this case the contracts shall be signed by registered legal entity personnel.
- A standardised contract is signed or otherwise agreed with individual customers. In this case the standardised contract, e.g. in the form of a template, specifying requirements, prices and contents of assessment shall be approved by registered legal entity personnel. The acceptance of assignments related to such a contract may be signed by local personnel authorised to represent the registered legal entity.