

GUIDELINES FOR CROSS-BORDER ACCREDITATION



Code: LN-1.3-01 (Formerly ESP-1.3-01)
Version: 2

LEVEL 1:

1.3 Organizational Structuring and Assurance

PREPARED BY:

Date: 2019-02-16

Research and Development Professional

CHECKED BY:

Date: 2019-02-18

Legal Department
Research and Project Coordinator**APPROVED BY:**

Date: 2019-02-19

Director of Management Development and
Improvement

1. OBJECTIVE

Establish within the framework of the MLA/MRA agreements of the International Laboratory Accreditation Cooperation (ILAC), the International Accreditation Forum (IAF) and the InterAmerican Accreditation Cooperation (IAAC), the requirements to be fulfilled before the National Accreditation Body of Colombia (ONAC) for the national recognition of accreditations granted by Accreditation Bodies of different economies to Conformity Assessment Bodies (CABs) located in Colombia. It also establishes the conditions regarding the treatment to be given by ONAC to Accreditation Bodies from economies other than Colombia when these intend to grant accreditation to a CAB domiciled outside Colombia or to a CAB established in Colombia, but with headquarters or key activities in another economy (country).

2. SCOPE

These requirements apply to all cross-border accreditation carried out by ONAC and to all accreditation carried out directly in Colombia by a foreign Accreditation Body as a signatory of the MRA-ILAC, MLA-IAF and MLA-IAAC mutual recognition agreements.

3. DEFINITIONS AND REFERENCE DOCUMENTS

DEFINITION DOCUMENTS:

For the understanding of this document, the definitions of Decree 1595 of 2015 which is part of the Sole Regulatory Decree of the Commerce, Industry and Tourism Sector, Decree 1074 of 2015, ISO/IEC 17000 and ISO/IEC 17011 standards, IAF/ILAC A5, and documents used by ILAC MRA, IAF MLA and IAAC MLA, which correspond to the multilateral mutual recognition agreements that promote the equivalence of accreditation systems, are used.

REFERENCE DOCUMENTS:

For the following documents taken as reference, the current version applies for each of them.

- Decree 1595 of 2015; whereby rules related to the National Quality Subsystem are issued and Chapter 7 and Section 1 of Chapter 8 of Title 1 of Part 2 of Book 2 of the Sole Regulatory Decree of the Commerce, Industry and Tourism Sector, Decree 1074 of 2015, are amended, and other provisions are issued.
- IAAC MD001. IAAC Multilateral Recognition Agreement (MLA).
- IAAC MD002. Policy and procedures for the Multilateral Recognition Agreement for accreditation bodies.
- NTC-ISO/IEC17000; Conformity assessment. Vocabulary and general principles.
- ISO/IEC 17011; Conformity assessment. General requirements for accreditation bodies performing accreditation of conformity assessment bodies.
- ILAC G21 - Cross-border Accreditation - Principles of Cooperation.
- IAF MD12 - Evaluation of Certification Activities for Cross-Border Accreditation.
- ILAC P4; ILAC Mutual Recognition Agreement. Policy and Management.
- ILAC P5; ILAC Mutual Recognition Agreement. Scope and Obligations.
- IAF ML4; Policies and Procedures for an MLA at the level of Accreditation Bodies and Regional Accreditation Groups.
- IAF/ILAC A2; IAF/ILAC Multilateral Mutual Recognition Agreements. (Agreements). Requirements and Procedures for Accreditation Body Evaluation.
- IAF/ILAC A5; IAF/ILAC Multilateral Mutual Recognition Agreements. (Agreements). Application of ISO/IEC 17011.

4. LINKING THE DOCUMENT TO THE MANAGEMENT SYSTEM PROCESSES

Location within process management		Process owner
1 st Level	1.0 Management Process	Chief Executive Officer
2 nd Level	1.3 Organizational Structuring and Assurance	Director of Management, Development and Improvement
3 rd Level	Not Applicable	

See Process Map in the Management System Manual.

5. GENERAL CONSIDERATIONS

The International Laboratory Accreditation Cooperation (ILAC) at its 2001 assembly, established the "Cross Border Accreditation - Principles for Cooperation" guidance document as a code of good practice among ILAC Accreditation Bodies. The purpose of ILAC's Mutual Recognition Arrangements is to ensure that a test or calibration report issued by an accredited laboratory is accepted in the countries belonging to the multilateral agreement, the main objective being to avoid duplication of accreditation.

Additionally, the purpose of the IAF Multilateral Recognition Arrangement is to strengthen the network between Accreditation Bodies and Certification Bodies seeking equivalence of accreditation services; for this purpose, IAF establishes IAF MD12 - Evaluation of certification activities for cross-border accreditation, as a document that all signatories of multilateral recognition agreements must follow.

Within the framework of the MLA/MRAs, it should be understood that the cross-border accreditation activity is an activity of cooperation between the accreditation bodies signatory to these agreements and in no way of commercial competition.

5.1 Although International Cooperation strongly suggests obtaining accreditation through local accreditation bodies, there are situations in which it is possible for a conformity assessment body (CAB) to require the accreditation of a foreign Accreditation Body, due to the following situations:

- There is no local Accreditation Body.
- The local Accreditation Body does not offer the accreditation activity in the required scheme.
- The local Accreditation Body is not a signatory member of the recognition agreements with International Cooperation schemes.
- The end clients of the CABs request accreditation activity from a specific Accreditation Body and are not persuaded to accept accreditation by an equivalent local Accreditation Body.
- The CABs belong to an organization or group that has unification policies and require all its CABs to be accredited with the same Accreditation Body.

5.2 In addition to the above, it is important to take into account that in section 8 of Chapter 7 of Decree 1595 of 2015 regarding Conformity Assessment Bodies, within the national quality subsystem, the regulator established that:

"Article 2.2.1.7.8.1: Performance of conformity assessment bodies. The conformity assessment bodies located in the country shall be accredited by the National Accreditation Body with respect to a normative document to perform conformity assessment activities against a technical regulation, such as certification, inspection, performance of test/testing and calibration, or the provision of proficiency testing and other accredited activities. When the national accreditation body does not have the technical competence to accredit a body in a required scope, it may resort to the scheme defined for cross-border accreditation in order to provide the service in the country..."

6. REQUIREMENTS

6.1. GENERAL REQUIREMENTS

6.1.1 In the event that ONAC receives a request to provide accreditation services to a CAB in an economy other than Colombia and, considering that said CAB has a local Accreditation Body, ONAC, according to the requirements promoted by the recognition agreements with the MLA/MRA International Cooperation schemes (established in IAF/ILAC A2), shall take into account the

following requirements before formally accepting the accreditation request from the CAB, requirements of which shall be recorded in writing:

- Inquires the CAB if it is aware of the third-party conformity assessment services offered by the local Accreditation Body, considering that the latter exists in the local economy.
- Suggests to the CAB that the accreditation be granted by the local Accreditation Body, detailing precisely the advantages in terms of local factors and conditions, mainly in economic and cultural terms.
- Indicates to the CAB the equivalence between the accreditation granted by the local Accreditation Body and ONAC, specifying the basis of the multilateral recognition agreements.
- Informs the CAB that, according to the principles established in numeral 3 of the ILAC G21 Guide and when ONAC formally accepts the application requested by the CAB, the local Accreditation Body could participate as an observer and be present during the CAB accreditation process carried out by ONAC.
- Asks and records the reasons that motivate the CAB to request ONAC to carry out an accreditation activity outside its economy, despite the existence of a local Accreditation Body.
- ONAC must investigate all complaints and open processes related to the CAB applying for accreditation, which are addressed to the Colombian authorities and complaints that are being processed before the local Accreditation Body.
- Once the accreditation application has been accepted, ONAC shall communicate with the local Accreditation Body to inform them that it will carry out an accreditation service in their country, always safeguarding the principle of confidentiality.

6.1.2. In the event of a change in the situations described in section 6.1. above, ONAC shall confirm at each new evaluation that the justifications and conditions previously accepted for granting cross-border accreditation are still valid.

6.2. COOPERATION BETWEEN ONAC AND THE LOCAL ACCREDITATION BODY

6.2.1. ONAC must have the acceptance of the CAB seeking accreditation before consulting with the local Accreditation Body.

6.2.2 If the CAB refuses to allow ONAC to consult with the local Accreditation Body, ONAC shall record the reasons presented by the applicant and shall inform the local Accreditation Body (without disclosing the identity of the CAB applying for accreditation). Indicating that ONAC will accredit a CAB, which does not wish its identity to be disclosed.

6.2.3. In the event that ONAC, being a signatory member of the recognition agreements with ILAC and IAF, decides to provide accreditation services outside its economy, it shall ensure the development of appropriate assessments taking into account relevant factors such as language, local rules and regulations, culture, among others. ONAC is also committed to consider and ensure compliance with technical competence requirements. Likewise, ONAC is committed to consult and consider with the local Accreditation Body in relation to the requirements it considers relevant according to local conditions. ONAC shall verify the status of the local accreditation of the CAB, whether it is suspended or withdrawn, or whether it is in the process of suspension or withdrawal, and shall take this into account when deciding on the acceptance of the application for accreditation.

6.2.4. Whenever possible, ONAC shall take into account the approach suggested by ILAC whereby cooperation with the local National Accreditation Body through the support of its staff and, where necessary, the assessment team, is essential to ensure access to relevant competence.

6.2.5. In case it is not possible to involve the local Accreditation Body staff in the assessment team, cooperation should be such that the local Accreditation Body is allowed to participate as an observer during the assessment, subject to the acceptance of the applicant CAB. If the applicant CAB does not accept the participation of the local Accreditation Body in any form, ONAC shall inquire the reasons supporting the CAB's position which shall be reported to the local Accreditation Body.

6.2.6. When the local Accreditation Body is not a signatory member of the MLA/MRA recognition agreements, or in case the scope of accreditation offered by the local Accreditation Body does not allow covering the accreditation activity requested by the CAB, ONAC commits to cooperate with the local Accreditation Body so that it may acquire experience in the development of opportunities for application to the recognition agreements.

6.3. MULTI-SITE ACCREDITATION IN THE FRAMEWORK OF CROSS-BORDER ACCREDITATION

6.3.1 As established in IAF MD 12: "Evaluation for the accreditation of conformity assessment bodies with activities in several economies", for situations in which a CAB has its main office established in Colombia, and also has sites located in other economies, the CAB may seek accreditation from ONAC to cover the activities of all the sites in which it operates.

For this, ONAC must request its accredited CABs to identify in writing:

- The economies in which accredited certificates are issued and the number of certificates in each economy.
- The economies in which the CAB operates from a fixed office where some critical activity is performed.
- The economies in which the CAB has remote staff performing some certification activity.
- Which fixed offices are responsible for performing and/or managing critical activities as defined in IAF/ILAC A5, or from where remote staff manage critical activities.
- The CAB's arrangements for managing all activities that are performed from foreign fixed offices or by remote personnel.

6.3.2. Assessment program

ONAC has an evaluation program that covers the current accreditation period and allows confirmation of the CABs compliance with the requirements of the respective conformity assessment standard(s), within the scope of the CAB's accreditation, regardless of where the certification activities are performed. The program shall be developed to identify the activities and critical activities to be evaluated, and the economies where these are performed and/or managed, taking into consideration the following:

- The relationship between the CAB and its foreign headquarters, agencies and/or branches and subsidiaries,
- The CAB's arrangements for managing its foreign certification activities,
- Whether the CAB maintains an accreditation from the local Accreditation Body,
- The number of fixed offices, which carry out certification activities in each economy,
- The number of remote staff carrying out certification activities in each economy,
- Where critical activities are performed and managed, or from where remote personnel manage and perform critical activities,
- The range of certification activities performed, where they are performed and from where they are managed by remote personnel,
- The effectiveness of the CAB's management controls for its certification activities,
- The accessibility of the CAB's records,
- The availability of CAB staff (internal and external) for interviews,
- The number of certificates issued through a particular fixed office,
- The schemes for which certification is granted through a particular fixed office, where a fixed office manages other fixed offices or remote staff outside its national borders,
- The number of different economies covered by remote staff and how they are managed,
- The risks presented by the activities performed and/or managed and where they are performed and/or managed,
- The capacity of the Accreditation Body to conduct remote assessments,
- The social and cultural aspects of each economy,
- The number and type of complaints received by the CAB in the past year.
- The effectiveness of the CAB's supervision in the control of its foreign certification activities, including the internal audits it carries out in the fixed offices and in the foreign offices.

6.3.3. Initial evaluation

The initial evaluation of the CAB should include the evaluation of all fixed offices, whatever the relationship to the CAB, where critical activities are performed and/or managed, or from which remote personnel performing critical activities are managed, and/or records are maintained. Where appropriate, the initial assessment should also include the assessment of selected fixed offices, whatever the relationship to the CAB, where other activities covered by the requirements of the relevant conformity assessment standard(s) are performed, or from which personnel performing these activities are managed.

For scope extensions, ONAC shall determine an evaluation program considering the factors indicated in 6.3.2 and whether the extension corresponds to a new main scope, a new sub-scope or is within an already accredited sub-scope. The evaluation program need not necessarily include visits to each fixed office.

6.3.4. Follow-up and Renewal

For monitoring and reassessment each fixed office, whatever the relationship with the CAB, in which critical activities are performed and/or managed or from which remote personnel performing critical activities are managed and/or records are maintained, must be assessed at least once in each accreditation cycle and in accordance with ONAC's assessment program.

ONAC shall have the procedure to sample fixed offices, including remote personnel, where other activities are performed or from which personnel performing these activities are managed. The procedure should ensure that a representative number of offices are assessed within a defined time frame.

6.4 ACCREDITATION IN COLOMBIA BY A FOREIGN ACCREDITATION BODY

6.4.1. In the event that accreditation is granted to a CAB in Colombia by an Accreditation Body from another economy, IAAC or IAF/ILAC signatory member, ONAC acquires the role of local Accreditation Body and the foreign accreditation body is expected to comply with the provisions of this document.

6.4.2 ONAC does not give an opinion regarding the decision of a CAB based in the national territory, which requests accreditation by an accreditation body from another economy. It is the responsibility of each organization to define, understand and comply with Colombian regulations, including those indicated in Decree 1595 of 2015, which establishes rules related to the National Quality Subsystem and modifies chapter 7 and section 1 of chapter 8 of title 1 of part 2 of part 2 of book 2 of the Single Regulatory Decree of the Commerce, Industry and Tourism Sector, Decree 1074 of 2015, and establishes other provisions or those that modify or replace it.

6.4.3 ONAC accepts without restrictions the conformity assessment results from signatories of international recognition agreements MRA/MLA of IAAC, IAF and ILAC, and evaluates that the CABs accredited by ONAC use in their activities conformity assessment services that comply with Decree 1074 of 2015 or what is defined by each responsible for the definition of the Technical Regulation in Colombia.

7. RECORDS

Code	Name	Physical Storage	Digital Storage
Does not apply	-	-	-

8. CHANGE CONTROL

Version	Approval date	Summary of Changes
1	2015-01-15	Initial preparation of the document
2	2019-02-19	<p>The document is updated to ONAC's new process structure and the document type is changed from "Specification" to "Guideline".</p> <p>The guidelines are updated according to the provisions of:</p> <ul style="list-style-type: none"> - Decree 1595 of 2015; whereby rules related to the National Quality Subsystem are issued and Chapter 7 and Section 1 of Chapter 8 of Title 1 of Part 2 of Part 2 of Book 2 of the Sole Regulatory Decree of the Commerce, Industry and Tourism Sector, Decree 1074 of 2015, are amended, and other provisions are issued. - ILAC G21 - Cross Border Accreditation - Principles of Cooperation. - IAF MD12 - Evaluation of Certification Activities for Cross-Border Accreditation.