Scope :
This procedure applies to the accreditation of conformity assessment bodies owners of several sites, they are managed by the same MS, these CABs are considered as multi-site bodies

Responsible for the application:
The HD are responsible for the application of this procedure.

Amendement
the modifications to the accreditation procedure for multi-site CABs Rev 02 relate to:

- The withdrawal of the document IAF/ILAC A5:11/2013 IAF/ILAC multi-lateral mutual Recognition Arrangements, See chapter “4. Reference documents”.

- The introduction of the definition of "head office" see chapter "2. Vocabulary and abbreviations".

- The introduction of PRO 31 see chapter 4. Reference documents.

- Deletion of two paragraphs "Intermediate closing meetings by site, ... the results of the evaluation." and “If not where, according to the evaluation plan, …, otherwise a replacement is mandated by management.” see Chapter 5.4.

- The withdrawal of sub-chapter “5.6.1 Sampling”.

Established on: 24/01/2023 By: Heads of Technical Departments Visa:	Checked on: 24/01/2023 By: Quality Manager Visa:	Approved on: 25/01/2023 By: General Director Visa:

1. Object :

The purpose of this procedure is to define specific aspects of the accreditation process for multi-site CABs. The steps in the accreditation process are conducted in accordance with the Accreditation Procedure (PRO 12).
This procedure clarifies the conditions under which sampling of sites for assessment during surveillance is possible.

2. Vocabulary and Abbreviations :

Site: the infrastructure or permanent facility where a CAB performs conformity assessment process activities.
Additional site: A site or group of sites to be added to the scope of an accreditation granted for a multi-site.
Multi-site CAB: An organization with an identified central function (head office), where certain conformity assessment activities are planned, controlled or managed, and a network of local or international locations, branches (sites), where these activities are wholly or partially performed.
The network must have the same system (the same quality manual and the same internal audit and the same management review).
central office: Site of the multi-site organization where the management of the conformity assessment body is located. This site is usually also the head office

CAB: Conformity Assessment Body
MS : Management System
GD: General Director
QM : Quality Manager
HD: Head of Department
AM: Accreditation Manager
LA: Lead Assessor

3. Review Procedure:

The Quality Manager will review this procedure whenever it is useful to improve the operation of the ALGERAC system.

4. Reference documents :

- ISO/IEC 17011:2017 "Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies".
- IAF/ILAC A5:11/2013IAF/ILAC multi-lateral recognition arrangements
- GEN 01: Quality Manual
- PRO 12: Procedure for Accreditation
- PRO 16: Procedure for Decisions on Accreditation
- PRO 23: Procedure for Suspension, Reduction or Withdrawal of Accreditation
- PRO 25: Procedure for Monitoring and Renewal
- PRO 13-1: Sampling procedure in the fields of laboratories and inspection
- PRO 31 Accreditation transfer procedure

5. Description of the Procedure:

5.1 The qualification criteria for a CAB multisites are:

- The sites must have a legal relationship;
- The head office of the organization has established a management system that complies with the relevant reference standard and that the organization as a whole meets the requirements of the standard and must take into account the applicable regulations;
- All sites are subject to the common management system, defined, implemented and continuously monitored by the head office. This means that the head office has the right to implement corrective actions at any site, if necessary.
- All such sites (including the central administrative function) are subject to the organization's internal audit program;
- The organization's management system is centrally managed according to a similarly controlled plan and will be subject to a management review initiated from the head office;
- The organization can demonstrate its ability to collect and analyze data (list not exhaustive below) from all sites, including the head office, and its authority and ability to initiate organizational changes, if required:

a) system documentation and changes;
b) Management review;
c) complaints;
d) evaluation of corrective actions;
e) planning an internal audit and evaluating the results.

5.2Application for Accreditation:

The CAB shall:

1. identify the legal entity candidate of accreditation;
2. Identify all sites and those for which accreditation is sought;
3. Provide information demonstrating satisfaction of the qualification criteria identified above (5.1).
4. Describe the area of expertise of each site.
5. Document the exchange of information, documents and resources between the various sites.

5.2.1 Application Review (Eligibility):

Prior to accepting the application for multi-site accreditation, the relevant HD/AM should ensure that all the required documentation to demonstrate satisfaction of the criteria are submitted and that all sites proposed for inclusion in the multi-site organization's accreditation meet the criteria.

If the CAB does not meet any of the qualification criteria defined in this document (5.1) the application for Multi-site accreditation will not be accepted or will be accepted with a reduction of sites. The accreditation agreement is signed with the head office.

5.3.1 Evaluation Team:

The HD/AM designates a lead assessor (LA) who will be responsible for the evaluation and several assessors and technical experts to cover all technical areas to be evaluated

If more than one team is involved in the evaluation/monitoring of the network, a single LA is designated to coordinate the evaluation and consolidate all the results from the different teams into the evaluation report. The LA is maintained, if possible, for the entire accreditation cycle.

5.3.2 Document/Record Review:

The team shall:

1. identify the functions of the head office of the organization candidate of accreditation;
2. Assess the arrangements for meeting the requirements of the referenced standard;
3. Evaluate the management system operating records.

a) Assessment Plan:

At initial accreditation all sites are assessed to ensure that the network is working under the same management system wiche is functional
The plan should consider the time required to move from one site to another.
All conformity assessment activities subject to accreditation shall be assessed. The plan shall identify the activities to be assessed for each site as well as the head office.

b) Duration of the evaluation:

The amount of time spent on the evaluation at the head office depends on the number of sites.

5.4 Evaluation:

The opening meeting should be held at the head office , if possible with the participation of the managers of the sites under evaluation.

Opening meetings may be held at each site, avoiding any reference to findings already made during the evaluation of the head office and/or other sites .

Closing meetings can take place at each site at the end of the assessment, and if necessary, they can be held at the head office.

The LA analyzes the findings identified by the team during the evaluation and summarizes the results during the final discussion. The team formulates any requirements for accreditation.

Corrective actions for deviations must be executed on time according to the accreditation procedure (PRO 12) and the monitoring, renewal and extension procedure (PRO 25) or in common agreement with the team.

The HD/AM must monitor the treatment of deviations to ensure that deadlines are met.

a) Deviations:

1. When critical deviations are found at the head office or an individual site during the assessment or surviellence, the team should check to see if the other sites involved in the sampling are affected.

2. The team will analyze the deviations to determine whether or not the CAB is experiencing a generalized MS deficiency involving all sites;

3. If so, both the head office and individual sites must take corrective action;

4. Evidence of actions taken must be submitted for critical deviations;

5. In the case of systemic deviations, the HD may decide to conduct an additional assessment covering all sites, to ensure that the deviation has been resolved.

b) Report:
Upon completion of the assessment, the CAB shall receive a list of deviations.
Details on the handling of deviations should be provided in the assessment report.

5.5 Accreditation Decision :

The decision-making process follows the current procedure (PRO 16).

b) Accreditation certificates

1. A single certificate (FOR 16-1, FOR 16-3) is issued, containing the name and address of the organization's head office, the field of activity, as well as the list of all the accredited sites, those will be detailed in the technical annex;

2. Accreditation must be withdrawn in its entirety if the head office does not meet the criteria for continued accreditation;

3. The list of sites under accreditation is kept up to date by ALGERAC;

4. The CAB is obliged to inform of the closure of a site. If the CAB fails to do so, ALGERAC will consider this as an improper use of the accreditation and will act accordingly to its procedures.

5.6 Survillence:

The Survillences are conducted in accordance with PRO13-1 (Sampling Procedures for Inspection and Laboratory field).

6. Records:

- Application for accreditation (DOC 01)
- Application for medical biology laboratory accreditation (DOC 01-1)
- Evaluation plan (FOR 32)
- Evaluation team composition sheet (FOR 26)
- Evaluation report for inspection bodies (FOR 08)
- Evaluation report for test laboratories (FOR 09)
- Evaluation report for biomedical laboratories (FOR 09-1)
- Evaluation report for certification bodies (FOR 10)
- Deviation sheet (FOR 02)
- Invitation (FOR 58)
- Specialized accreditation committee meeting minutes (FOR 42)
- Opinion of the members of the specialized accreditation committee (FOR 14)
- opinion of the specialized accreditation committee and accreditation decision (FOR 15)
- Accreditation certificate (FOR 16)
- Monitoring plan (FOR 66)
- Multi-site accreditation certificate for EA-recognized scopes (FOR 16-1)
- Multi-site accreditation certificate for scopes not recognized by EA (FOR 16-3)