Requirements for Accreditation of multi-site conformity assessment bodies

Document No.

R-GEN-03
1. **Scope:**

This document sets out AAA policy on:

- The accreditation and assessment of multi-site conformity assessment bodies (CABs);
- Co-operation with national accreditation bodies for cross border accreditation

2. **Assessment and Accreditation of Multi-Site CABs (General Information)**

2.1 An applicant organization that manages and operates conformity assessment activity from a central office through a number of sites can seek a single accreditation conditional on the requirements specified by AAA being fulfilled.

2.2 These sites can be based in USA or overseas.

2.3 An applicant CAB must identify all relevant sites for consideration in the scope of accreditation under the centrally controlled management system along with the scope of activity for each.

2.4 Accredited CABs are required to identify all sites where conformity assessment activities and processes supporting conformity assessment are conducted or controlled that determine the effectiveness of the CAB’s performance of the accredited activity. The application for an additional site shall be made through the CRM only.

2.5 AAA accredited CABs are required to apply for an extension to scope, following the normal process, prior to conformity assessment activities at other (new) locations/sites being accredited. The application shall provide AAA with documented procedures that demonstrate that the new location/site is established in such a way as to meet accreditation requirements.

2.6 Each AAA accredited CAB shall confirm annually the list of all sites, the legal
relationships in place and a description of activities performed on behalf of the CAB.

2.7 It is not possible to add additional sites/locations under the flexible scope policy.

2.8 AAA will seek to establish through objective evidence and by using various techniques that the quality system is effectively and fully implemented at all sites.

2.9 Reports and certificates issued shall document the location from where the conformity assessment activity is performed.

2.10 Temporary locations work to the same requirements and may be subject to assessment on a sampling basis as part of the accreditation process to provide evidence of the operation and effectiveness of the system. These sites are specified on the scope of accreditation and application is through the routine extension to scope process.

2.11 If AAA observes non-conformities at the central office or at any one of the sites of an organization with multiple sites, the corrective action procedure shall apply to all applicable sites. In the event that the results of any of the assessments of ‘sample sites’ reveal that there is a significant weakness or inconsistency in the application of the quality system, AAA will review the assessment program and may increase the number of sites to be assessed.

2.12 Failure by one site to comply with AAA requirements may lead to removal of the site from the schedule of accreditation. If the cause of nonconformity is the lack of central control then accreditation will be subject to review by AAA and may lead to suspension or withdrawal of accreditation from all sites.

2.13 All sites shall be under agreement to the CAB.

2.14 An AAA accreditation certificate issues to one legal entity.
3. On-Site Assessment of Multi-Site CABs

3.1 For multi-site CABs the central quality system and technical control will be subject to surveillance each year. It is anticipated that, in addition to the central office, at least one site will be visited each year, with a visit to each site generally taking place over the accreditation cycle.

3.2 The following shall apply (note AAA reserves the right to increase the frequency of site visits):

3.2.1 Head office managing and controlling all conformity assessment activity: annual assessment

3.2.2 Laboratories and inspection bodies – client premises: This category is where the accredited laboratory performs testing/calibration/sampling/inspection on client premises. The frequency of on-site assessments at client premises will be determined by AAA but shall occur at initial assessment, re-assessment and at least once during the accreditation cycle;

3.2.3 Certification bodies, witnessing of client audits is governed by IAF MD 12

4. CABs Affiliated to Parent Organizations

4.1 Such organizations established as a separate legal entity but retain close association with a parent organization/headquarters organization in another jurisdiction.

4.2 The CAB under assessment must demonstrate that it has sole responsibility and control of its operations, however the CAB may still rely on the provision of certain services from the parent organization/headquarters organization, the scope of which might reasonably be documented in a service level agreement, for example.

4.3 The quality system documentation of the CAB must clearly describe the level
of services provided by the parent organization/headquarters organization, the controls in place for the CAB to manage the services provided, how conflicting/additional requirements are managed and how the AAA CAB audits and reviews such arrangements.

4.4 AAA requires that all relevant personnel, documentation and systems are readily available for each AAA assessment visit.

5. References:

- ISO/IEC 17025:2005/2017 General requirements for the competence of testing and calibration laboratories
- ISO 15189:2012 Medical laboratories - Particular requirements for quality and competence
- ISO/IEC 17020:2012 Conformity assessment - Requirement’s for the operation of various types of bodies performing inspection
- ISO/IEC 17011:2017 Requirements for bodies providing assessment and accreditation of conformity assessment bodies
- IAF MD12 Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries, available from www.iaf.nu