



Policy on the accreditation and assessment of multi-site and cross-border conformity assessment bodies

PS19

1) Purpose

- 1.1) This document sets out the Irish National Accreditation Board's (INAB) policy on:
 - A. The accreditation and assessment of multi-site conformity assessment bodies (CABs);
 - B. Co-operation with national accreditation bodies for cross border accreditation
- 1.2) The Irish National Accreditation Board (INAB) is the national body responsible for assessing the competence of conformity assessment bodies (CABs) to the relevant ISO (International Organisation for Standardisation) standards.
- 1.3) Accreditation is the process whereby an independent body (INAB) examines and assesses a conformity assessment body (CAB) to ensure it is competent and operates a system that complies with international standards.
- 1.4) Following the award of accreditation INAB monitors accredited bodies to ensure maintenance of conformity with the criteria continues.

2) Contact

For further information please contact your assigned assessment manager at **The Irish National Accreditation Board**.

3) Implementation

From date of publication.

4) References

- 4.1) ISO 17011, *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies*.
- 4.2) EA-2/13, *EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members* (current version) and associated supplement(s) available from www.european-accreditation.org
- 4.3) ILAC G21, *Cross-Frontier Accreditation - Principles for Cooperation* (current version), available from www.ilac.org
- 4.4) Regulation 765/2008 *setting out the requirements for accreditation and market surveillance for the marketing of products and repealing regulation (EEC) No. 339/93*, available from www.inab.ie.
- 4.5) IAF MD12 *Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries*, available from www.iaf.nu
- 4.6) European Commission Certification document 2009-06 on cross border accreditation activities
- 4.7) INAB scope interpretation document CRM FS-14

PART A: Multi-Site Conformity Assessment Bodies

5) Definitions

- 5.1) *Site* - Any site where conformity assessment activity is being undertaken on a temporary or permanent basis, or sites that belong to the CAB with an involvement in conformity assessment activities. Such sites may be owned, rented or leased (or by any other legally enforceable arrangement) by the CAB. (The terms site, location, and branch office are interchangeable).
- 5.2) *Multi-site organisation* - An organisation with a central office in which certain activities are performed or managed within a network of sites at which such activities are fully or partially carried out. All sites have a direct legal or contractual link with the central office of the organisation and are subject to a common quality system. *Note: accommodating the accreditation of multi-site organisations does not imply that INAB provides group accreditation to multiple legal entities.*

6) Policy: Assessment and Accreditation of Multi-Site CABs (General Information)

- 6.1) An applicant organisation that manages and operates conformity assessment activity from a central office (established and based in Ireland) through a number of sites can seek a single accreditation conditional on the requirements specified by INAB being fulfilled. The central office must maintain responsibility for the activities performed by any locations covered by the scope of accreditation.
- 6.2) These sites can be based in Ireland or overseas.
- 6.3) An applicant CAB must identify all relevant sites for consideration in the scope of accreditation under the same management and under a centrally controlled management system along with the scope of activity for each.
- 6.4) 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
- 6.5) INAB 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 INAB with documented procedures that demonstrate that the new location/site is established in such a way as to meet accreditation requirements.
- 6.6) Each INAB 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. The report is compiled as part of the PS10 document submission prior to each assessment visit.
- 6.7) It is not possible to add additional sites/locations under the flexible scope policy.
- 6.8) INAB will seek to establish through objective evidence and by using various techniques that the quality system is effectively and fully implemented at all sites.
- 6.9) In addition to 6.2 to 6.5 above, INAB reserves the right to amend its policy in consideration of performance over a 5 year period, the extent of any changes which have taken place and the level of confidence which can be placed in the performance measures and control systems of the CAB.
- 6.10) Reports and certificates issued shall document the location from where the conformity assessment activity is performed.
- 6.11) 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.

- 6.12) If INAB observes non-conformities at the central office or at any one of the sites of an organisation 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, INAB will review the assessment programme and may increase the number of sites to be assessed.
- 6.13) Failure by one site to comply with INAB requirements may lead to removal of the site from the schedule of accreditation. As the CAB must demonstrate that it has control of, and monitors the activities at its locations, if the cause of nonconformity is the lack of central control then accreditation will be subject to review by INAB and may lead to suspension or withdrawal of accreditation from all sites.
- 6.14) The CAB shall determine if, based on its own legal advice and Irish employment law, employee contracts shall specify the location of all employees. In any event, this shall be available in the quality management system.
- 6.15) All sites shall be under agreement to the CAB.
- 6.16) An INAB accreditation certificate issues to one legal entity. Where individual locations have a different legal entity, they shall not offer accredited services under that legal entity; they may only offer such services on behalf of the accredited CAB. Any certificates or reports issued must be from the accredited CAB, without reference to the name/logo of the individual location. Quotations, contracts, etc. must not create any confusion as to the legal entity of the CAB which holds INAB accreditation.
- 6.17) For information on the same/common management system and organisation, please see EA-2/13 Appendix A, which is mandatory for cross-border multi-site CABs.

7) Policy: On-Site Assessment of Multi-Site CABs

- 7.1) 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.
- 7.2) The following shall apply (note INAB reserves the right to increase the frequency of site visits):
 1. Head office managing and controlling all conformity assessment activity: annual assessment
 2. Certification bodies – witnessing of client audits is governed by PS22;
 3. Medical testing laboratories (blood transfusion services) – in the event that an accredited laboratory provides haemovigilance and traceability services to other locations, on-site assessments shall occur at initial assessment, re-assessment and at least once during the accreditation cycle. The medical testing laboratory shall ensure that these sites do not refer to accreditation in any way.

8) Policy: On-Site Assessment of CABs performing accredited activity at client premises

- 8.1) 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 INAB but shall occur at initial assessment, re-assessment and at least once during the accreditation cycle;

9) Policy: CABs Affiliated to Parent Organisations

- 9.1) Such organisations are established in Ireland as a separate legal entity but retain close association with a parent organisation/headquarters organisation in another jurisdiction.

- 9.2) 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 organisation/headquarters organisation, the scope of which might reasonably be documented in a service level agreement, for example.
- 9.3) The quality system documentation of the CAB must clearly describe the level of services provided by the parent organisation/headquarters organisation, the controls in place for the CAB to manage the services provided, how conflicting/additional requirements are managed and how the INAB CAB audits and reviews such arrangements.
- 9.4) INAB requires that all relevant personnel, documentation and systems are readily available for each INAB assessment visit.

10) Policy: CABs & Sub-Contracting Arrangements

- 10.1) Where sub-contract arrangements exist with another legal entity, the precise nature of the relationship shall be specified along with details of the sub-contractor's accreditation status.

11) Policy: Multi-Site CABs and Scopes/Certificates of Accreditation

- 11.1) It is INAB policy to list all sites/locations on the CAB scope of accreditation where conformity assessment activity occurs or is deployed and under ownership/lease to the accredited entity.
- 11.2) In the following scenarios, sites are not listed on the scopes of accreditation. However this information shall be readily identifiable and documented in the CAB's quality system. The CAB shall keep INAB informed as this information changes and it will be recorded in the INAB CRM. These additional sites will be included in the CAB risk-based assessment plan, and will be visited as part of INAB surveillance assessments:
 - Offices where administrative functions only are performed (excluding head office);
 - CAB customer locations;
 - Sites where accredited medical testing laboratories provide haemovigilance services;
 - Distinct buildings within a campus location, sharing the same address;
 - Locations where activity is performed which directly influences the conformity assessment activity e.g. sample reception, pre-analytical activity
 - Locations where point of care testing (POCT) is provided within the primary facility.

PART B: Cross Border Co-Operation and Procedure

12) Cross Frontier Policy

- 12.1) In accordance with the EU regulation 765/2008 (Article 6), it is INAB's policy not to compete with other national accreditation bodies (NABs).
- 12.2) It is INAB's policy to offer accreditation only to CABs that are legally established in Ireland.
- 12.3) In addition, INAB accredited CABs may wish to issue reports or certificates under INAB accreditation to entities in countries outside Ireland including:
 1. Countries into which accredited certificates/reports are issued directly from the CAB's head or any other office and;
 2. Countries in which the CAB operates from locations/sites from which conformity assessment activities are performed, whatever the legal relationship of such offices with the parent CAB.
- 12.4) Where a CAB establishes a site/location/branch office in another country, it shall demonstrate its knowledge and competence on:
 1. Local regulations;
 2. Knowledge of the local market.

INAB's assessment programme will take these into account, as well as other factors such as:

- Volume of work
- Impact of CAB activities, for example proportion of market share
- History of assessment results
- Level of control and monitoring by the CAB of the location
- Whether or not the location holds local accreditation for the same scope, and local AB assessment frequency.

INAB may consult with the local national accreditation body (LAB) on these matters, as necessary.

- 12.5) In implementing this policy and undertaking the on site assessment of critical locations and branch offices, INAB shall follow the applicable international guidance (EA-2/13, IAF MD12 and ILAC-G21) and complete such work by subcontracting the assessment to the local accreditation body where this is possible.
- 12.6) INAB will perform the initial assessment of the CAB or an extension into a new scope area, in all cases. However, the local AB will be invited to observe the assessment. The location involved cannot reject such participation.
- 12.7) INAB will inform the local accreditation body of witnessed activity performed in its country and may subcontract the witnessed activity.
- 12.8) The CAB shall co-operate with the local national accreditation body, for any assessment activity subcontracted by INAB.
- 12.9) INAB shall have a contractual arrangement, compliant with the requirements of GDPR, with any NAB to which it subcontracts work.
- 12.10) INAB and the local accreditation body (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. INAB shall notify the LAB of any decision to suspend or terminate accreditation for an activity performed in the LAB's country. Equally, the LAB is expected to notify INAB of any decision to suspend or terminate accreditation for an activity covered by accreditation granted by the LAB. INAB will consider if such suspension/termination affects any accreditation it provides.

- 12.11) All INAB subcontracted assessment activity is managed through the INAB CRM.
- 12.12) CABs with sites/locations/branch offices outside Ireland are required to provide the information requested in PS19 annually when submitting PS10 documentation prior to assessments.