

INAB Guidance on CAB Establishment in Ireland for the Purpose of Accreditation

The Irish National Accreditation Board (INAB) is the national body in Ireland with responsibility for the accreditation of laboratories, certification bodies and inspection bodies. Regulation (EC) No. 765/2008¹ provides a legal framework for the provision of accreditation services for conformity assessment activities across Europe. The objective of the Regulation is to ensure that, within the European Union (EU), one accreditation certificate is sufficient for the whole territory of the EU. In accordance with Regulation (EC) No. 765/2008, where a conformity assessment body (CAB) requests accreditation, it shall do so with the national accreditation body of the Member State in which it is “established.”²

Under the Regulation, INAB may only properly accredit bodies that are established in Ireland. INAB considers it useful to set out its thinking as to the elements of the CAB’s business it views as potentially relevant, in deciding whether a CAB is established in Ireland. INAB requires that CABs seeking to establish in Ireland are controlled by boards and management operating in Ireland and not run from elsewhere. INAB and the Irish Notifying Authorities must be capable of ensuring the monitoring of the total CAB as it has to take the responsibility for its operations.

In deciding whether a CAB seeking INAB accreditation is “established” in Ireland, INAB requires submission of a comprehensive analysis with the application for accreditation. INAB will review this submission prior to a commitment to any onsite assessment.

INAB shall judge whether the applicant/accredited body is sufficiently independent in order to demonstrate full legal responsibility for the accredited activities.

The submission shall address Parts A, B and C:

Part A: Organisational Matters

- Whether the body has a functional, staffed premises (business address, not just a registered office) in Ireland;
- The key activities of the body, and whether these key activities take place in Ireland and/or elsewhere;
- Contractual arrangements between the Irish entity and the entities outside Ireland, including contracts of employment;
- Insurances are held by the Irish entity;
- Whether the responsibility for conformity assessments lies with the Irish body;
- While subcontracting is accepted, the core activity and technical competence must be where the CAB is established. INAB expects that all decision-making will be conducted from the Irish body;
- Which parts of the CAB’s business are outsourced and how it is managed;
- What members of staff and/or senior management and/or top management are located (i.e. living) in Ireland; please note the ODCE requirement that at least one Director is resident in the European Economic Area (EEA) and other Irish Revenue requirements. If none of the directors meet this requirement the company must consider taking out a Non-EEA Resident Director Bond;
- Whether employees are seconded to Ireland and/or employed on a contract for services basis;
- Whether the body at present assesses in Ireland;
- The legal form of the body, e.g. incorporated in Ireland;
- An Irish contact address, website address and phone number;

¹ REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

² Established is not the same as registered for the purposes of INAB accreditation

- Whether Board or other key meetings take place in Ireland. The applicant is strongly advised to seek legal advice, where appropriate, on these matters in advance of application.

Although not the focus of an INAB assessment, the CAB is expected to comply with all applicable Irish legislation with respect to the establishment of a company in Ireland. The website of the Office of the Director of Corporate Enforcement, www.odce.ie, may be a useful reference. INAB does not provide any further advice on this matter.

Part B: Agreements

The CAB shall also clearly document what services/reporting arrangements/connections/financial dependence etc. exist between the legally responsible and independent applicant Irish notified body and a parent company.

Part C: Requirements of Union Legislation (Notified Bodies/Recognised Third Party Organisations (RTPOs))

The CAB shall submit an analysis documenting how the legally responsible Irish entity demonstrates that **all** the requirements on notified bodies specified in the particular Directive(s)/Regulation(s) are fulfilled. Each requirement to be clearly itemised.

INAB reserves the right to request updated information on Parts A, B and C prior to surveillance visits.

Other Information – Applicant Notified Bodies:

The applicant is advised to consult the Blue Guide³.

While INAB assesses establishment of a CAB for accreditation, please note that the Irish Notifying Authority and the European Commission will perform further assessments on this matter (establishment), prior to appointment as a NB or RTPO.

The applicant is advised to clarify this directly with the Notifying Authority prior to application for notified body status.

³ The 'Blue Guide' on the implementation of EU product rules 2022