

Policy on legal entities

PS30

1) Purpose

This statement sets out the Irish National Accreditation Board (INAB) policy on recording legal entities in the Client Relationship Management System (CRM), scopes, and certificates of accreditation¹.

2) Policy

INAB awards accreditation to Conformity Assessment Bodies (CABs) that are legally responsible for the activities performed under accreditation. It is not the intention of this policy to prescribe legal requirements for establishment of entities in Ireland; that is the responsibility of the CAB in consultation with appropriate legal advice.

The CAB is reminded of the contractual requirement (INAB Terms and Conditions) to inform INAB of key changes to legal ownership and the necessity to complete the applicable form AF1F.

This statement sets out INAB's policy on documenting the legal entity in its publicly available information.

3) References

- 3.1) ISO 17011:2017: Conformity assessment - requirements for accreditation bodies accrediting conformity assessment bodies;
- 3.2) INAB guidance on establishment, GD03 (current version);
- 3.3) INAB policy on multi-site CABs, PS19 (current version);
- 3.4) Applicable criteria if any in relevant accreditation standards

4) Policy – Legal Entities

4.1) Legal entity established under the Companies legislation

The legal entity as documented on the Company Registration Office (CRO) will be recorded in INAB systems. The CAB will be required to enter the CRO number into the CRM but this is not made publicly available by INAB. For the purposes of accreditation, sole traders are not considered established legal entities.

4.2) Legal entity established under Statute or Ministerial Order

The legal entity as provided for under statute or Ministerial order or any other Government legal instrument will be recorded in INAB systems. The CAB will be required to reference the applicable legislation conferring their establishment into the CRM but this is not made publicly available by INAB. There may be instances where public bodies are establishment under the Companies legislation – please refer to 4.1.

4.3) Legally Established Group Structures

The legal entity, however established, that is responsible for the accredited activity will be recorded in INAB systems. The CAB will be required to document relevant related

¹ INAB systems = CRM, scope of accreditation, certificate of accreditation, website entry

bodies within the group structure, and the services, if any, that are relied upon within the group e.g. if they are wholly owned as a subsidiary.

4.4) Administrative Group Structures

Based on information currently available, there are a number of hospital groups established on a non-statutory administrative basis².

It is INAB policy that the INAB systems shall record only the legally identifiable and responsible entity (4.1 to 4.3) and not the hospital group. The CAB shall document within its own systems, the hospital group to which it is affiliated.

4.5) Trading Names

A CAB may include a 'trading name' in INAB systems. This can only be associated in all CAB documentation with the legal entity (4.1 - 4.4 above). This will be recorded on the INAB scope and certificate, on evidence of registration. The trading name shall be registered with the CRO.

4.6) Company Ownership

It is not policy to record shareholder/company owners in INAB systems; however, the CAB is required to document this fully in the management system in order to effectively evaluate impartiality requirements within the accreditation standards. These evaluations and supporting audits/risk assessments are assessed by INAB.

5) Policy – Addresses

The CAB is requested to enter into the CRM the company registered address and the locations where accredited activity is performed in permanent facilities.

INAB systems shall record the following address details:

- (i) Company registered address and business address(es) on the scope of accreditation and on the INAB website;
- (ii) Sites/locations where samples are received/processed are recorded in INAB systems.
- (iii) No address on the accreditation certificate;
- (iv) CAB offices performing administrative functions only, e.g. personal base, finance, HR functions etc are not recorded in INAB systems;

6) Policy – Sites

It is INAB policy that all sites where conformity assessment activity is performed under INAB accreditation are documented in INAB systems.

See PS19 for further detail.

7) Policy – Site Identifications

The following identifier system is used on scopes of accreditation:

- A. Laboratories
 - a. Category A, permanent facilities, all sites
 - b. Category B, activity performed away from the permanent facility
- B. Certification Bodies
 - a. All sites from where certification is deployed and under legal arrangement with the accredited Certification Body (CB)

² <https://health.gov.ie/future-health/reforming-our-hospitals/hospital-groups/>

- b. Countries where the CB issues certificates will be noted in CRM
- C. Inspection Bodies
 - a. All sites from where inspection is deployed and under legal arrangement with the accredited Inspection Body (IB)
 - b. Countries where the IB issues certificates will be noted in CRM

8) Policy – Reporting

It is INAB policy that all reports and certificates issued reference the legal entity as recorded in INAB systems.

Please note, reports and certificates cannot only reference trading names.

For further information on multi-site CABs, please see PS19.

For regulations on the use of the accreditation symbol, please see R1.

9) Implementation

6 months from initial issue date.

Immediate implementation for future revisions.

10) Contact

For further information, please contact your assigned Assessment Manager.

11) Information Sources

www.cro.ie

www.european-accreditation.org