Accreditation

The accreditation process determines, in the public interest, the technical competence and integrity of organisations offering testing, examination, verification, inspection, calibration and certification (often known collectively as evaluation services or conformity assessment services). Accreditation, which operates across all market sectors, provides an impartial assessment against internationally recognised standards.

Legal Entity Applying for Accreditation

INAB awards accreditations to entities legally established in Ireland.

When making an application for accreditation, the applicant organisation will be required to input the Company Registration Office (CRO) number. This number is to be that of the organisation legally responsible for the scope of accredited activities and it must be established in Ireland. This name will be the body to which accreditation is awarded and will be displayed on the scope of accreditation.

It is INAB policy to also display *'Trading As'* names, if applicable after the legal entity organisation name.

For entities seeking accreditation as part of Government, the following is INAB policy:

- If the organisation is part of a Government department, this is the legally identifiable entity for the purposes of accreditation;
- If the organisation is legislatively established separate to a Government department, then this is the legally identifiable entity for the purposes of accreditation;
- If the organisation within the health sector is part of a HSE hospital, then HSE is the legally identifiable entity for the purposes of accreditation. The location/group to which the organisation belongs will also be clearly identified on the scope of accreditation.

Scopes of Accreditation

INAB Scopes of Accreditation are published for each accredited body and contain information relevant to the accreditation standard. The Scope is intended to provide as much useful information as possible to the end user of the accredited service.

This document is intended to provide guidance to applicants and end users on interpreting INAB Scopes of Accreditation.

A. Classification System

INAB has developed a classification system for each standard which is summarised in the table below; all classification systems are available as .xls documents on the website.

	STANDARD	CLASSIFICATION	DETAIL
1	ISO 17025 Test Labs	Class-Const	Construction materials testing
		Class-Elect	Electrical testing
		Class-Opt	Optical testing
		Class-Rad	Radiometry testing
		Class-HTH	Heat, temperature and humidity testing
		Class-NDT	Non-destructive testing
		Class-Chem	Chemical testing
		Class-BiolVet	Biological and veterinary testing
		Class-AcoVib	Acoustic and vibration testing
		Class-Mech	Mechanical testing
		Class-For	Forensic testing

		Class-LabNB	Laboratory testing for notification
2	ISO 17025 Calibration Labs	Class-Met	Metrology
3	ISO 15189	Class-Med	Medical pathology testing (8 sub scopes)
4	ISO 17034	Class-RMP	Reference material producers
5	*ISO 17043*	*Class-PTP*	*Proficiency test providers (inactive)*
6	ISO 17020	Class-IB	Inspection
		Class-IBNB	Inspection for notification
7	ISO 17065	Class-Prod	Product certification
		Class-ProdNB	Product certification for notification
8	ISO 17024	Class-Per	Personnel certification
9	ISO 14065	Class-VB	Verification (GHG)
10	ISO 17021-1	Class-MgtSysX	Management systems certification
		Class-MgtSysIAF	ISO 9001, ISO 14001, ISO 27001, ISO 45001, ISO 50000, SR OHSAS 18001, PEFC, CSP
		Class-MgtSysFSSC	FSSC
		Class-MgtSysISO22000	ISO 22000
		Class-MgtSysISO13485	ISO 13485
		Class-MgtCertNB	Management systems certification for notification
11	ISO 20387	Class-Biobank	Biobanking
12	ISO 17029	Class-VV	Validation and verification

Test Laboratories: each classification for ISO 17025 and ISO 15189 test laboratories are further classified by field of testing, appropriate to the main technical discipline.

Calibration Laboratories: the field of calibration/metrology is specified within this classification system.

Management Systems Certification Bodies: Scopes are classified according to IAF codes issued by the International Accreditation Forum and available in ID1 at www.iaf.nu. Further classification is by NACE code industry sector.

Inspection Bodies

Inspection Bodies are categorised into Type A, B, or C which reflects their degree of independence from the items inspected. Further information is available in the ISO 17020. Inspection bodies can be more than 1 type but not for the same scope.

Reference Material Producers

The CAB is required to identify if the RM is '*certified*' or '*not certified*' and type this into the scope template.

Biobanks: Biobanks are classified according to the type of biological material or data.

Notified Bodies (NBs)

1. Construction Products Regulations (CPR): Name of the standard to be referenced with year, corrigenda, revision as detailed in the OJEI. See

https://ec.europa.eu/growth/sectors/construction/product-regulation/harmonised-standards_en

Mandatory International Documents: As signatory to international agreements, INAB is obliged to implement requirements on the content of scopes of accreditation. For example, these include:

- ISO 17011, the standard by which accreditation bodies are evaluated
- EA-3/11, scopes of accreditation for CBs certifying food safety management systems
- IAF MD8, scopes of accreditation for CBs certifying medical device management systems

B. Sites and Key Locations

Within laboratory testing and calibration accreditation to ISO 17025 and ISO 15189, INAB has two categories of laboratory environment:

- Category A: Laboratory premises at a fixed location – there may be multiple premises under an accredited scope performing similar or distinct testing/calibration. All premises are under the one legal responsibility and ownership of the accredited CAB. It is INAB policy to specify premises, addresses and contact details of all locations on the scope. Where a CAB has a number of site locations, these are identified separately in the template and will appear on the scope, with the associated conformity assessment activity. All **laboratory locations** where testing/calibrations are performed are clearly identified on the scope of accreditation, by address and testing at that site.
- Category B: Testing or calibration performed away from any laboratory premises but under the control of the laboratory; this may be at a customer site, or at a sampling site, or in hospital wards etc. (e.g. Point of Care Testing POCT). Customer sites and POCT locations are not identified on the scope of accreditation.

For *medical testing laboratories accredited to ISO 15189* providing testing at the point of patient care (POCT), this testing will be identified as Category B, defined above.

All category A sites shall be visited on initial and re-assessment visit and sampled throughout the accreditation cycle. Conformity assessment activities on customer or other sites remote from the laboratory shall be sampled throughout the accreditation cycle.

C. Laboratory Methods/Procedures

The scopes of accreditation for all CABs will include a record of the CAB's accredited internal procedure. These internal operating procedures are normally based on reference standards which may also be documented in the scope. The extent by which a CAB bases its accredited methodology on a standard reference will vary and users of accredited services need to ensure that they are fit for its intended purpose.

The standard method reference on the scope of accreditation is only that which details procedural requirements pertinent to the activity.

INAB does not include version numbers of procedures on scopes of accreditation but it is understood that the accredited CAB uses the current version within its quality management system.

D. Reference to Standards and Editions

It is INAB policy that the year of publication for international and reference standards are published on the scopes of accreditation e.g. ISO 9001:2015. This is included as a footnote for management systems CBs.

The edition of in-house SOPs is not included.

E. Flexible Scope

INAB offers flexible scopes of accreditation to laboratories accredited for testing activities to ISO 17025 and ISO 15189. For laboratories that have flexible scope, the tests will be identified on the scope of accreditation. The published INAB scope of accreditation is supplemented with a controlled template maintained by and available from the laboratory.

Flexible scope is not available for calibration laboratories, inspection or certification bodies.

Further information available in the INAB policy document, PS11, on the website.

The following categories of flexible scope may be awarded:

Note 1 - Range may be extended for the test
Note 2 – New parameters / tests may be added
Note 3 – New matrices may be added
Note 4 – Changes to equipment / kits where the underlying methodology does not change

F. Services

An accredited CAB may offer its services to the public or only to its internal organisation. This differentiation will be evident from the scope of accreditation through one of the following statements:

- Service available to the public
- Service not normally available to the public

G. Presentation

INAB scopes are printed in landscape format, if appropriate to do so.

H. Registration Numbers and Accreditation Symbol

Each accredited CAB has its own unique registration number which is assigned once accreditation is awarded. This number will appear on the scope of accreditation and is embedded into the CABs accreditation symbol (example below) which is used on certificates and reports. This allows end users to readily check the validity of the accredited services provided. The registration numbering system is summarised as.

	STANDARD		REG. NO. SYSTEM
1	EN ISO/IEC 17025	Test	123**T**
2	EN ISO/IEC 17025	Calibration	123**C**
3	EN ISO 15189	Medical examination	123**MT**
4	EN ISO 17034	Reference material	123**RM**
5	ISO 17043	Proficiency test	123**PT**
6	EN ISO/IEC 17020	Inspection	**9**XXX
7	EN ISO/IEC 17065	Product certification	**6**XXX
8	EN ISC/IEC 17024	Personnel certification	**7**XXX
9	EN ISO 14065	Verification GHG	**85**XX
10	EN ISO/IEC 17021-1	Manager system certification	**5**XXX
11	ISO 20387	Biobanking	**XXXBB**

12	EN ISO/IEC 17029	Validation and verification	**8**XXX

I. Scope References/Footnotes

INAB will provide detail on scopes of accreditation through footnote references. The following explains the footnote references (without variation) displayed on INAB scopes:

- The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.
  Note 1 - Range may be extended for the test
  Note 2 – New parameters/tests may be added
  Note 3 – New matrices may be added
  Note 4 – Changes to equipment/kits where the underlying methodology does not change
  For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.

- For medical testing laboratories, the following footnotes apply:
  [a] The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006) OR (if applicable)
  The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006). It also provides Haemovigilance and Traceability services to another site, further details available in the SLA between the accredited medical testing laboratory and the relevant site.

  [b] The hospital pathology laboratory is accredited for the provision of Point of Care testing in accordance with ISO 15189:2012 and ISO 22870:2016, for the tests identified in category B. For further details please refer to the laboratory's list of equipment and delivery points.

  Or
  The hospital pathology laboratory is accredited for the provision of Point of Care testing in accordance with ISO 15189:2022 for the tests identified in category B. For further details please refer to the laboratory's list of equipment and delivery points.

- For CABs accredited for the purposes of notification (Notified bodies), the following footnote applies:
  [A] The CAB is accredited for the purposes of notification under [Directive/Regulation detail]. For further information on the notified body status refer to the EU NANDO database and contact the notifying authority [NA detail].

- For Opinions and Interpretations, ISO 17025, testing
  * The laboratory is accredited to provide opinions and interpretations for the tests identified

- For Calibration Laboratories, ISO 17025
  Calibration and Measurement Capability (CMC) is expressed in terms of the following parameters:
    - Measurand or reference material
    - Calibration or measurement method or procedure and type of instrument or material calibrated/measured
    - Measurement range and additional parameters where applicable
    - Expanded measurement uncertainty. Where provided as a percentage (%), the % relates to the applicable measured value.

  Measurement uncertainty shall be reported in compliance with EA 4/02 "*Evaluation of the Uncertainty of Measurement in Calibration*".
  In accordance with INAB policy, uncertainties are calculated for an estimated confidence level of not less than 95%.

- Specific application references for Management Systems Certification Bodies (CBs), ISO 17021-1:
  [I] The CAB has been assessed in accordance with the normative document ISO 22003-1:2022 to provide certification to ISO 22000: 2018 and the FSSC scheme
  [II] The CAB has been assessed in accordance with the normative document ISO/IEC 27006:AMD1:2020 to certify to ISO 27001: 2017
  [III] The CAB has been assessed in accordance with the normative document ISO 50003:2014 to certify to ISO 50001: 2018
  Include the management system and applicable year in the footnote at the end of the last page of the relevant scope page
  Include the issue year for Level 5 standards on scope footer in the following format:
  "Note that this schedule refers to ISO/IECxxx:YYYY"

- Management Systems Certification Bodies (CBs), ISO 17021-1
  For CBs accredited to ISO 45001 for the Safety Schemes in Procurement (SSIP), the following categories may be added to the scope, as appropriate:
    - SSIP Approved
    - SSIP Approved: Principal Contractor
    - SSIP Approved: Contractor
    - SSIP Approved: Principal Designer
    - SSIP Approved: Designer
    - SSIP Approved: Group
    - SSIP Approved: Non-Construction

- For Management Systems Certification Bodies (CBs), ISO 17021-1
  For CBs accredited to ISO 9001 for the UK National Highway Sector Scheme (NHSS), the following categories may be added to the scope, as appropriate:
    - National Highway Sector Scheme No 12A & 12B: Static Temporary Traffic Management on Motorways and High Speed Dual Carriageways Including On Line Widening Schemes
    - National Highway Sector Scheme No 12C: Mobile lane closure traffic management on motorways and other dual carriageways
    - National Highway Sector Scheme No 12D: Installing, Maintaining and Removing Temporary Traffic Management on Rural and Urban Roads

- National Highway Sector Scheme No 13: The supply and application of surface treatments to road surfaces -
- Highway Sector Scheme No 15: The Supply of Paving Grade Bitumen
- Highway Sector Scheme No 16: Laying of Asphalt mixes