



## INAB Regulations

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# SECTION 1: General introduction

The Irish National Accreditation Board (hereinafter referred to as “INAB”), is the authority for the granting, maintenance, renewal, or withdrawal of accreditation under the relevant national, European and international standard(s), using applicable INAB, EA<sup>1</sup>, IAF<sup>2</sup>, and ILAC<sup>3</sup> guidelines and/or other publicly available criteria, covering testing, calibration, inspection, certification and verification hereinafter referred to as “the schemes.”

INAB is established as a committee of the Health and Safety Authority under the Safety Health and Welfare at Work Act 2005 as amended by the Industrial Development (Forfás Dissolution) Act 2014.

ISO/IEC 17011 is an international standard that sets out the general requirements for bodies operating accreditation systems for conformity assessment bodies (CABs) and forms the basis of mutual recognition arrangements between accreditation bodies. INAB implements ISO/IEC 17011 with supporting mandatory and guidance documents published by EA, IAF and ILAC.

Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products (hereinafter referred to as ‘the Regulation on accreditation’) enshrines the Community policy in the area of accreditation. It introduces a comprehensive legal framework for accreditation which lays down at Community level the principles for its operation and organisation. It imposes obligations on national accreditation bodies, Member States and the European Commission and sets out the respective responsibilities as well as the co-ordinating role of the European co-operation for Accreditation (EA).

It is INAB’s policy and in keeping with Regulation 765/2008, to offer accreditation only to those conformity assessment bodies (CABs) that have established a legal entity in Ireland. Established, in this sense and for the purposes of INAB accreditation requires, at a minimum, that the body is legally responsible in Ireland for the conformity assessment activities delivered under the scope of accreditation.

In exceptional circumstances, INAB may consider providing accreditation to a CAB operating in Ireland and that has not established a legal entity in Ireland or Europe where the CAB can justify to INAB that INAB accreditation is essential for its operations in Ireland.

This document sets out the INAB mandatory regulations including those governing payment of fees, use of the accreditation symbol and/or reference to accreditation, clearance of nonconformities, withdrawal of accreditation, complaints and appeals. It should be read and applied in conjunction with the requirements set out in INAB terms and conditions.

INAB will specify the procedures by which application for accreditation should be made, the conditions for granting, maintenance and renewal of accreditation, and the conditions under which accreditation may be withdrawn.

While accreditation will normally be a sound indicator of the quality of service offered by an organisation for those activities for which it is accredited, it cannot be taken to constitute a representation by INAB that the organisation always maintains a particular level of performance. Accreditation does not diminish and should not be regarded as in any way diminishing the obligations and duties of the organisation to its clients.

Award of accreditation implies that the conformity assessment body has been determined to meet the requirements of the appropriate accreditation standard and is a statement of the technical competence of the CAB for its scope of accreditation. No other implication can be drawn.

An accredited CAB is awarded accreditation for a defined scope of activities. An alternative service cannot be offered for activities defined in the INAB scope of accreditation; in other words, a CAB cannot offer a non-accredited service for accredited activities.

INAB policy PS23 refers. Management systems certification bodies refer to IAF resolution 2015-14 available on <https://www.iaf.nu/>.

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<sup>1</sup> European Co-operation for Accreditation

<sup>2</sup> International Accreditation Forum

<sup>3</sup> International Laboratory Accreditation Cooperation

The monitoring of conformity with these regulations and criteria is based on regular assessment/surveillance visits by trained assessors, acting on behalf of INAB, for the relevant scheme.

INAB, as a signatory to EA<sup>1</sup> ILAC and IAF multi-lateral agreements, is required to cooperate with other EA members and to share information on cross-frontier activities of its applicant and accredited CABs that provide accredited services outside Ireland, as detailed in applicable cross-frontier policies. INAB applicant and accredited CABs are expected to cooperate with local signatory accreditation bodies.

The frequency with which organisations are normally subject to surveillance, assessment and reassessment will be prescribed by INAB. This will be dependent, in any given case, on the types of activity for which a CAB has been accredited, but surveillance visits would normally take place at intervals of 12 months and reassessment every 5 years. Over and above this INAB reserves the right to carry out additional and unannounced visits and to require surveillance or reassessment visits at intervals other than those prescribed.

This document and other INAB publications are available from [www.inab.ie](http://www.inab.ie).

## SECTION 2: Payment of fees and charges

### General

This section sets out INAB regulations on payment of fees for INAB services and schemes. It should be read and applied in conjunction with INAB terms and conditions.

INAB will direct all communication on financial matters to the main contact; it is then the CAB's responsibility to re-direct those communications to the appropriate personnel within the organisation, as necessary. The CAB is required to maintain all contacts (including finance contacts) up to date in the CRM. Should the VAT exemption status of a CAB change at any time, please submit a change request through the CRM and also contact the HSA Finance Unit.

INAB activity is funded from the following sources:

- Accreditation: from fees charged for assessment activity from all applicant and accredited CABs (annual);
- GLP: from fees charged for evaluations of all applicant and approved facilities (biennial);
- Support functions (HR, ICT, Finance etc.): from central allocation to the HSA;
- Scheme development: charged to scheme owner (SO) as schemes arise.

### Regulations

#### **2.1 Payment of Fees**

INAB charges fees for the operation of all its schemes. Fees are set annually and are subject to, at minimum, a yearly review. They are published in the schedule of fees for the calendar year. VAT (Value added tax) is charged at the rate applicable at the time of invoice issued.

All payments must be received electronically; no cheques are accepted.

The banking details for the HSA/INAB are:

Bank Name:	Bank of Ireland
Address:	Lower Baggot Street, Dublin 2, Ireland
Account Name:	Health and Safety Authority
Sort Code:	90 14 90
Account No.:	57907703
IBAN:	IE72 BOFI 9014 9057 907703
BIC:	BOFIE2D
VAT:	6605325E
Email:	<a href="mailto:hsafinance@crowleysdfk.ie">hsafinance@crowleysdfk.ie</a>

The INAB client is required to quote the client number and invoice reference on all electronic fund transfers (EFTs). These references are found on the invoice issued from the Authority/INAB. Invoices and reminders are issued electronically to the finance contact details provided by the CAB.

If required and if requested from INAB administration, the HSA login details to obtain the current Tax Clearance Certificate (TCC) can be provided.

Charging arrangements between an organisation and its clients are in no way the responsibility of, and are not subject to the control of INAB.

Queries on INAB invoices can be raised directly with the INAB assessment manager or with the HSA Finance Unit.

Invoices are issued at the start of each calendar year to include the annual management fee, the planned surveillance/reassessment visit (onsite and off-site assessment) and the technical area fee.

Invoicing of witnessed audits/inspections, initial assessments and any additional assessments are invoiced after the event has occurred. Where witnessed inspections occur with the head office assessment, these shall be invoiced with the annual invoice at the start of the year.

## **2.2 Application Fee (for all organisations)**

An application fee is levied to offset costs involved in reviewing and processing the application documents; the fee is applicable at point of application and no onsite visit shall be undertaken until the application fee is paid.

The application fee is per organisation or group of organisations at a single location and listed at the time of application on the application form.

Subsequent applications for the accreditation of related organisations not included in the original application may be subject to a further application fee.

## **2.3 Technical Area Fee**

Technical areas may be defined as:

- ISO/IEC 17025 laboratories – each sub-scope (chemical, biological, metrology etc.)
- ISO 15189 laboratories – each sub-scope (clinical chemistry, haematology, histopathology etc.)
- Management systems certification bodies – each management system (ISO 9001, ISO 14001)
- Each scheme under product certification is considered a new technical area
- Each product directive (NBs) is considered a new technical area
- Flexible scope is considered a technical area

## **2.4 Pre-Assessment Fee (for all organisations)**

A pre-assessment fee is levied to offset the costs involved in the review of the implementation of the management system.

## **2.5 Initial Assessment Fee (for all organisations)**

The initial assessment fee is levied to offset the costs involved at the first assessment of the implementation of the management system on site (headquarters assessment).

The initial assessment fee is dependent on the work to be undertaken by INAB and the number of assessors and assessor days required for the assessment of an organisation in any particular case as required by the scope of accreditation.

## **2.6 Witnessed Audit Fee (Certification Bodies/Verifiers/Inspection Bodies)**

The witnessed audit fee is levied to offset the costs involved in witnessing a verifier/auditor/inspector while completing an audit/verification/inspection at a third party site. The fee is dependent on the number of INAB assessors and assessor days required to complete this activity.

## **2.7 Fee for Review of Schemes submitted by Scheme Owners**

INAB policy PS18 refers. Fees levied to scheme owners are at the day rate set out in the current fee schedule.

## **2.8 Annual Management & Technical Area Fee**

Applicant and accredited CABs are subject to an annual management fee to offset the cost of administering the organisation's accreditation and a technical area fee reflective of the current applied for or accredited scope.

In certain circumstances where INAB incurs unexpected costs, INAB reserves the right to charge additional fees.

Full annual management fees are due for the year in which an organisation's accreditation is terminated, resigned or suspended, including voluntary suspension.

## **2.9 Assessment Time (all organisations)**

CABs are invoiced for the time spent performing the assessment per day per assessor and with a minimum of 0.5 days preparation and post assessment time, per assessor. In the event more preparation or follow up time is needed, this is invoiced as incurred.

## **2.10 Proficiency Testing / Inter-laboratory Comparison Testing Fees (for Laboratories/Inspection Bodies)**

Where a programme of proficiency testing and/or Inter-laboratory comparison testing is required, the organisation concerned will be responsible for the necessary arrangements and costs, independent of INAB.

## **2.11 Cancellation Fee (for all organisations)**

Where a confirmed visit has to be postponed by the organisation for any reason the organisation is liable for any expenses incurred by INAB. The same applies if INAB has to cancel a visit because of the action or inaction of the CAB; for example, failure to submit documentation listed in INAB publication PS10 in time. If a confirmed visit is cancelled within 6 weeks of the confirmed date, a cancellation fee comprising the sum of expenses incurred for such a visit plus 50% of the fee applicable for the visit will be levied in addition to the assessment or annual management fee.

## **2.12 Fees for Additional Visits (for all organisations)**

INAB reserves the right to levy fees if additional visits are found to be necessary, or if at any stage a failure to comply with INAB requirements imposes additional work on INAB or its assessors.

INAB carries out routine unannounced visits for which no fee will be charged.

A fee will be charged for an assessment arising from a change of premises.

## **2.13 Fees for Extensions to Scope of Accreditation (for all organisations)**

The fees for extension to scope applications are documented on the current fee schedule. The fee applied will depend on whether the application relates to an existing or new technical area and when the application is submitted. The fee applies whether the application is assessed on site or in exceptional circumstances by correspondence.

## **2.14 Order Numbers**

Any organisation that requires its order number to be quoted on invoices issued by INAB shall supply such order numbers when advised by INAB of the planned annual management fee invoice (and corresponding response dates) or when making an application for extension to scope or when any other assessment event occurs. It is the CABs responsibility to submit this information in a timely manner prior to any assessment event.

In the event that purchase order numbers are not received invoices will be issued without an order number and will not be reissued under any circumstances.

## SECTION 3: The use of the INAB logo, the INAB accreditation symbol and reference to accreditation

### General

This section sets out INAB regulations for the use of the INAB logo, the INAB accreditation symbol and reference to accreditation. It should be read and applied in conjunction with the INAB terms and conditions.

The objective of these regulations is to ensure that the use of the accreditation symbol and/or reference to accreditation is not used in such circumstances as may be considered misleading to clients or bring accreditation into disrepute. In particular, it shall not mislead as to what is accredited (scope) or who holds accreditation. INAB reserves the right to determine regulations to meet this objective and to assess their effective implementation. It is the accredited organisation's responsibility to ensure full conformity with these regulations.

An organisation may only display the accreditation symbol or make reference to accreditation relating to the organisation's accredited activities subject to the conditions laid out in these requirements, the attached appendices and in the applicable EA (EA-3/01), IAF and ILAC documents and the INAB terms and conditions.

### Regulations

- 3.1** A 'logo' is the symbol used by the Irish National Accreditation Board (Appendix I). This form of logo may only be used by the Irish National Accreditation Board. The copyright of this logo belongs to the Irish National Accreditation Board.
- 3.2** An 'accreditation symbol,' the ownership of which is vested in INAB, is a combination of the INAB logo in association with the registration number, accreditation standard and reference to the scope of accreditation (Appendix I).
- 3.3** The use of the accreditation symbol is restricted to accredited organisations; clients of INAB accredited organisations are not permitted to use the accreditation symbol, whether or not it is in combination with a conformity assessment mark.
- 3.4** INAB permanent staff may use the INAB logo when giving presentations. The logo is also incorporated into stationery for use by staff. Assessors who undertake work on behalf of INAB are not permitted to use either the logo or the accreditation symbol.
- 3.5** The accreditation symbol shall be displayed in a form identical to that provided in this document (Appendix I) and shall be uniformly enlarged or reduced as specified below.
- 3.6** Where an organisation wishes to make a text reference to its INAB accreditation, it shall without variation, use the phrase, "An INAB accredited [calibration laboratory] [testing laboratory] [certification body] [inspection body] [verification body] [reference material producer] [etc.] Reg. No. [0000]." Where the activity is covered by the EA MLA, the organisation may additionally include 'covered by the EA MLA.'
- 3.7** An organisation shall only use the accreditation symbol and make claims that it is accredited in respect of the specific activities and sites which are defined in the scope of accreditation.
- 3.8** It is INAB policy to require that accredited CABs use the accreditation symbol or reference to accreditation on reports and/or certificates. As required by European accreditation rules (EA-3/01 refers), when the accreditation symbol or prescribed text is not used on a report and/or certificate, conformity with the applicable accreditation standard cannot be presumed and the activity will not be recognised as an accredited activity. Therefore, in the exceptional cases where an accredited CAB chooses not to use the accreditation symbol or reference accreditation on test reports and/or certificates and where those reports/certificates contain both accredited and unaccredited activities, and subject to any requirement of law, the CAB shall identify on the test report/certificate those activities which are accredited by INAB. Reference to the current scope of accreditation

(alone) is not sufficient to fulfil this requirement. [This requirement ensures that the CAB is recognised for the scope of the accredited activity report and provides transparency to the recipient of the report and/or certificate.] It is the CAB's responsibility to ensure its clients and all end users are fully aware of the accredited status of test results/certifications/inspections issued from the accredited CAB.

- 3.9** Where an accredited CAB uses the accreditation symbol or makes reference to accreditation on test reports and/or certificates and where those reports/certificates contain both accredited and unaccredited activities, then the difference in accreditation status shall be positively and unambiguously identified.
- 3.10** Where an organisation wishes to use the accreditation symbol and make claims of accreditation status in communication media, or to make reference to other approvals, other symbols or marks in reports/certificates or in communication media, in order to avoid undue associations or misunderstandings regarding what or who is accredited and who provided the accreditation, it shall clearly and unambiguously describe the nature of the approval and from whom it is granted and shall ensure reference to other approvals is in no way misleading to INAB accreditation.
- 3.11** An organisation shall at no time and under no circumstances use the accreditation symbol without its associated registration number and reference to its scope of accreditation.
- 3.12** An organisation shall not use the accreditation symbol or make any reference to accreditation on test reports, or certificates, or quotations/contracts for work or brochures, which does not contain any accredited activity.  
Accreditation shall not be stated, implied or suggested for non-accredited activities delivered by the CAB.
- 3.13** Certificates issued by organisations accredited by INAB shall only refer to INAB accreditation and shall not include references to accreditations issued by other bodies or any other approvals (e.g. the UKCA mark or number).
- 3.14** Letterheads or other corporate stationery shall not bear the accreditation symbol if none of the conformity assessment activities mentioned in the document are within the CAB's scope of accreditation.
- 3.15** Site calibration and testing laboratories are permitted to use the INAB accreditation symbol under the same conditions as those applicable to the permanent laboratory. The location where the accredited activity is performed shall be included in the report/certificate (see PS19).
- 3.16** A calibration laboratory may issue calibration labels bearing the INAB accreditation symbol for equipment calibrated under its scope of accreditation. It is not permitted to issue labels for equipment tested under a laboratory's testing scope of accreditation.
- 3.17** A reference material producer may choose to include reference to their accreditation status on labels attached to the reference materials produced under their scope of accreditation. This may be either in the form of their INAB accreditation symbol or as a text reference (text in 3.6 shall be used).
- 3.18** Where an organisation wishes to use the accreditation symbol for purposes other than letterheads, publicity or promotional materials (including websites), quotations or proposals, reports or certificates (e.g. vehicles, company infrastructure), the organisation shall obtain INAB's written consent prior to any release and conform to the requirements set out in these Regulations. In all cases, the text provided for in 3.6 shall be used.
- 3.19** An accredited organisation shall not use a certification mark on a calibration certificate/test report. Accredited certification bodies shall ensure that their clients do not use the certification mark on a calibration certificate/test report. In the case of management systems certification bodies, the accredited organisation shall ensure that the certification mark does not appear on products.



- 3.20** An INAB accredited organisation shall not provide certification to any standard used as a basis for accrediting conformity assessment bodies (CABs) (e.g. ISO/IEC 17025, ISO 15189). INAB is required to initiate suspension of an organisation's accreditation that provides such certifications.
- 3.21** An organisation is not permitted to use the accreditation symbol or text reference to accreditation on business cards held by the organisation's staff.
- 3.22** INAB does not permit the end users of accredited services or any other body or entity that is not accredited to use its accreditation symbols or text reference to accreditation.
- 3.23** The accredited CAB shall inform its customers of any undue use or misuse of the accreditation symbol or other claim of accreditation status by its customers and shall take the necessary steps to ensure proper use. CABs shall inform INAB of any misuse or abuse of the accreditation symbol or logo that they encounter.
- 3.24** An organisation shall not affix the accreditation symbol on its own, or allow the fact of its accreditation to be used to imply that a product, process, system or person is approved by INAB.
- 3.25** CABs shall not refer to INAB in such a way as to state, imply or suggest that INAB accepts responsibility for the accuracy of test, calibration or inspection results or certification decisions covered by accreditation.
- 3.26** The CAB shall not imply that any recommendation to award accreditation (following an initial assessment or an extension to scope assessment) is confirmation of their future accredited status.
- 3.27 INAB MLA Signatory Status**
- INAB is signatory to the multi-lateral agreements of the European co-operation for Accreditation (EA) for testing and calibration (ISO/IEC 17025 and ISO 15189), inspection (ISO/IEC 17020), reference material production (ISO 17034) and certification (ISO 17021-1, ISO/IEC 17024 and ISO/IEC 17065) activities.
  - INAB is signatory to the multi-lateral recognition arrangement of the International Accreditation Forum (IAF) for certification (ISO 17021-1, ISO/IEC 17024 and ISO/IEC 17065) activities.
  - INAB is signatory to the mutual recognition arrangement of the International Laboratory Accreditation Co-operation (ILAC) for testing and calibration (ISO/IEC 17025 and ISO 15189) activities and reference material production (ISO 17034).
  - INAB permits reference to its multi-lateral agreement signatory status on reports and certificates by its accredited conformity assessment bodies (CABs), in the form of words expressed above. Reference to MLA signatory status by accredited CABs on their letterheads and stationery is not permitted.
  - INAB permits the use, under license, of the ILAC and IAF marks on reports and certificates. Please refer to [www.inab.ie](http://www.inab.ie) for further information.
- 3.28 INAB Accreditation Symbol – Technical Use Specifications**
- Where the accreditation symbol is displayed on an unfolded portion of stationery or area no greater than A4, the maximum width size of the symbol shall be 40mm and the minimum size 25mm. On larger or smaller portions of stationery the width/height size may be proportionately enlarged or reduced to an absolute minimum size of 12mm. Where the size of the accreditation symbol is 15mm or less, the symbol may only be used in black.
  - Accredited CABs shall ensure that they have, as far as is feasible, satisfied the requirements of these regulations when publishing the INAB accreditation symbol in electronic format. At a minimum, they should ensure that all of the wording on the INAB symbol is legible at a screen resolution of 1920 x 1080.
  - An accreditation symbol on an unfolded portion of stationery shall be displayed:
    - only if the logo or title of the organisation concerned is also shown;

- with no more prominence than the logo or title of the organisation concerned; and
  - no more than once for each INAB accreditation.
- d) The accreditation symbol shall only be printed in one of the following colours and no other versions of the symbol are permitted:
- A single colour which may be;
    - i. black or
    - ii. Green Pantone 5483 CVC;
  - Two colours which shall be the INAB colours;
    - i. Green Pantone 5483 CVC
    - ii. Yellow Pantone 7405
- e) Organisations may use embossed, relief or die-stamped versions or other graphical or digital versions of the accreditation symbol providing they comply with these requirements.
- f) Electronic versions of the accreditation symbol in the above colours are available from INAB in the following formats only:
- Windows Metafile for use on PC in, for example, Microsoft Word;
  - Mac EPS files for Mac use and for supplying to printers for lithographic printing; and
  - GIF for website use.
- g) An organisation must ensure that reproduction of the accreditation symbol is accurate and legible with no degradation and/or distortion.
- h) Where an organisation is accredited in more than one accreditation field, only the applicable accreditation symbols shall be used in one report or certificate.

### **3.29 INAB Accreditation Symbol – Accredited Scope**

- (a) An accredited CAB is awarded accreditation for a defined scope of activities. An alternative service cannot be offered for activities defined in the INAB scope of accreditation; in other words, a CAB cannot offer a non-accredited service for accredited activities.
- (b) ISO/IEC 17025 clause 7.1 requires test and calibration laboratories to implement a contract review process to provide testing and calibration activities that meet customer needs and is acceptable. It is INAB policy that if a CAB is accredited for a test/calibration/certification as defined in the scope of accreditation, then the CAB shall offer this test/calibration/certification as an accredited service at all times.
- (c) ISO 15189:2012 clause 4.1.2.2 (and clause 5.3.3 and 5.5 of ISO 15189:2022) requires that laboratory services, including appropriate advisory and interpretative services, meet the needs of patients and those using the laboratory services. Clause 4.4 of ISO 15189:2012 (and clause 7.2.3.1 of ISO 15189:2022) confirms that each request accepted by the laboratory is considered an agreement. In the case of medical laboratory accreditation to ISO 15189, INAB recognises and acknowledges that these laboratories may offer a reduced suite of tests (for example out of hours, on call or at weekends). However the laboratory shall provide the same level of accredited testing service for this reduced suite of tests. The INAB accreditation symbol shall be displayed on the test/calibration report or certificate, with unaccredited activity clearly identified.
- (d) IAF Resolution 2015–14 resolved that IAF accreditation body members shall have legally enforceable arrangements with their accredited CABs that prevents the CAB from issuing non-accredited management systems certificates in scopes for which they are accredited. Accredited management systems certification bodies shall not issue non-accredited certificates within their scope of accreditation.

See also PS22, *Policy on Witnessing Activities and Scope Management for Certification and Verification Bodies*.

- (e) IAF Resolution 2017–19 resolved that IAF accreditation body members shall have legally enforceable arrangements with their accredited CABs that prevents the CAB from issuing non-accredited personnel certificates in scopes for which they are accredited. Accredited personnel certification bodies shall not issue non-accredited certificates within their scope of accreditation.

See also PS22, *Policy on Witnessing Activities and Scope Management for Certification and Verification Bodies*.

- (f) IAF Resolution 2018–13 resolved that IAF accreditation body members shall have legally enforceable arrangements with their accredited CABs that prevents the CAB from issuing non-accredited product certificates in scopes for which they are accredited. Accredited product certification bodies shall not issue non-accredited certificates within their scope of accreditation.

See also PS22, *Policy on Witnessing Activities and Scope Management for Certification and Verification Bodies*.

## SECTION 4: Clearance of nonconformities

### General

This section sets out INAB regulations for the clearance of all nonconformities. The requirements in this section are given without prejudice to INAB's right in appropriate cases to withdraw an organisation's accreditation forthwith for failure to clear nonconformities.

It is the policy of INAB that all applicant/accredited organisations adhere to the following regulations for the clearance of nonconformities.

### Regulations

- 4.1** INAB requires organisations to implement corrective actions in response to nonconformities with accreditation criteria and to audit the effectiveness of their implementation in a timely and efficient manner.

Nonconformities are categorised at the assessment team private meeting as follows:

- i. A 'minor' nonconformity is the failure to comply with the scheme requirements.
- ii. A 'major' nonconformity is the failure to comply with the scheme requirements to the extent that would compromise the confidence that is placed in the accredited activity, or where quality arrangements are demonstrably inadequate or absent for a major aspect of a CAB's work. This includes misuse of the INAB accreditation symbol or reference to accreditation.

Note that where corrective actions for findings raised at a previous INAB assessment have not been implemented by the time of the next assessment, a major nonconformity will always ensue. A major nonconformity may also be raised should appropriate progress not have been made on corrective actions agreed to address a finding raised at a previous INAB assessment.

- 4.2** All communications shall be channelled through INAB, except where INAB expressly approves otherwise, in which case copies shall be sent to INAB.
- 4.3** Proposed actions will normally be agreed and accepted during the assessment visit. If agreement is not made at the visit, the timeframe for submission of details of corrective actions to address minor nonconformities shall not exceed 3 months from the visit date for initial assessments and/or extensions to scope and 1 month from the date of surveillance/additional/unannounced/re-assessment visits.
- 4.4** INAB's default position is that major nonconformities raised at INAB assessment visits will result in partial or full suspension of accreditation and/or additional assessment. Additional assessment time will be charged at standard INAB rates. The recommendation of the team and supporting justifications in these cases shall be documented on the AF118 form. In any case, INAB shall require corrective action evidence to be submitted and to include:
- Immediate correction of the issue giving rise to the major nonconformity. This may involve notifying customers and/or withdrawing test results and certificates,
  - Analysis of extent and cause
  - Planned corrective actions to prevent recurrence of the issue.

The timeframe for receipt of this evidence shall not exceed 2 weeks from the date of the visit. In exceptional circumstances, INAB may alter this timeframe.

Where suspension occurs, an onsite assessment will be required to reinstate accreditation and verify the effective implementation of corrective actions for all nonconformities; the appropriate assessment team will be decided by the assessment manager.

Where additional assessment is required, the date shall be set immediately and shall occur no later than 3 months from the date of the assessment visit where it was considered necessary. The purpose of the assessment is to verify effective implementation of corrective actions for all nonconformities. The appropriate assessment team will be decided by the assessment manager.

- 4.5** In the circumstance where an organisation fails to clear nonconformities in the first documentary attempt, the INAB assessment manager will determine the timeframe for submission of additional documentation, which shall not exceed 2 weeks.
- 4.6** INAB may in exceptional circumstances permit an extension to these timeframes where the organisation can establish that more time is justified. In such circumstances the extension to the timeframe will apply only to the clearance of the particular nonconformity(s) requiring the extension to the timeframe. All other nonconformities must be cleared within the normal timeframes.
- 4.7** INAB will review the organisation's accreditation status in the event that:
- (a)** Where relevant, the proposed corrective actions are not submitted to INAB or
  - (b)** Responses to nonconformities raised are not submitted to INAB within the agreed timeframe and/or
  - (c)** Incomplete or inadequate responses are submitted to INAB within the agreed timeframe.
- 4.8** This review may result in all or part of the organisation's scope of accreditation being terminated or, where appropriate, suspended until the outstanding nonconformity(ies) have been satisfactorily cleared.
- 4.9** Following the review described in section 4.8, INAB may decide to set a new timeframe for the satisfactory clearance of the outstanding nonconformity(s) and in such cases, shall inform the organisation in writing of the decision taken. The new timeframe shall not exceed one month except where the organisation is suspended in which case a timeframe of up to 3 months will apply. Where an organisation under suspension fails to clear all nonconformities within the agreed timeframe, that organisation's accreditation may be terminated.
- 4.10** INAB will suspend or terminate, as appropriate, all or part of the organisation's scope of accreditation if the organisation:
- (a)** consistently fails to clear minor nonconformities within agreed timeframes;
  - (b)** fails to clear a major nonconformity within the agreed timeframe.
- 4.11** In the event of a major nonconformity being raised, the INAB assessment manager (in consultation with the lead assessor, if different) shall:
- (a)** consider recommending suspension or termination, or, in the case of an initial application, refusal of accreditation for part or all of the scope of accreditation; or
  - (b)** decide if an additional and/or unannounced visit is required to witness the clearance of the nonconformity or to address any issues relating to its clearance.

In either case, the assessment manager shall ensure that the integrity of INAB accreditation is not compromised by any action or timeframe agreed to address the major nonconformities.

- 4.12** INAB awards accreditation for a 5 year period as specified on the accreditation certificate. INAB must arrange re-assessment visits at such dates to provide sufficient time to allow for clearance of all nonconformities raised and to ensure that accreditation is maintained into the next accreditation cycle before the certificate expires. Where, for whatever reason, a certificate does expire before award of maintenance of accreditation into the next accreditation cycle, the CAB no longer holds nor can claim to hold INAB accreditation. Any conformity assessment activity performed (testing, calibration, inspection, certification, etc.) cannot be performed as an accredited activity.

#### **4.13 Response to Nonconformities**

**a) Surveillance/Re-assessment/Unannounced Visits**

Minor nonconformity – CAB is required to submit to INAB:

- Analysis of extent and cause (mandatory)
- Description of corrective actions taken or planned (mandatory)
- Evidence of implementation of corrective action (if specified by assessor)

Major nonconformity – CAB is required to submit to INAB:

- Analysis of extent and cause (mandatory)
- Description of corrective actions taken (mandatory)
- Evidence of implementation of corrective action (mandatory)

**b) Initial Assessments/Extensions to Scope**

For all nonconformities

- Analysis of extent and cause (mandatory)
- Description of corrective actions taken (mandatory)
- Evidence of implementation of corrective action (mandatory)

## SECTION 5: Organisational information & changes to organisations

### General

This section sets out INAB regulations on the information gathered by INAB on organisations for the purposes of communication and on the requirements for organisations to inform INAB, without delay, of significant changes relevant to its accreditation.

### Regulations – Organisational Information

**5.1** The organisation is required to provide and keep up to date the following information on the INAB CRM system:

- CAB (legal entity established in Ireland) name and address,
- CAB contact details,
- Finance contact details for the purposes of electronic invoicing

### Regulations – Changes to Organisations

**5.2** Significant changes that shall be notified to INAB relate to:

- (a) CAB name
- (b) its legal, commercial, ownership or organisational status,
- (c) the organisation, top management and key personnel,
- (d) main policies,
- (e) resources and premises
- (f) scope of accreditation, and
- (g) other such matters that may affect the ability of the organisation to fulfil requirements for accreditation

**5.3** Where any changes occur to the structural operation or trading conditions (including name changes) of an organisation, the appropriate INAB form for this purpose shall be completed and forwarded to INAB. An organisation must inform INAB of its intention to relocate, and of its effective voluntary suspension date while the relocation is taking place. INAB will consider suspension of any CAB that fails to inform INAB in advance.

**5.4** Where an organisation is acquired by a new legal entity, and the original legal entity ceases to exist, the organisation shall resign its scope of accreditation in full. The new legal entity may apply for accreditation through the CRM and the normal process and procedures shall apply. It is the responsibility of the accredited organisation to provide INAB with adequate notice of impending changes (no less than 3 months) and effective operational dates to ensure minimal break in their accreditation status. Accredited organisations cannot 'transfer' their accreditation to a new legal entity. If an organisation is acquired by another legal entity and the same personnel from the original legal entity continue to operate the accredited activity, INAB will review the changes to ensure that the requisite competence and management are in place. In all cases INAB will determine whether an assessment (with associated fees) will take place.

**5.5** Where an organisation changes trading name, the organisation shall confirm that there has been no change in the legal entity by submitting a change request through the CRM.

**5.6** Where an organisation opens a branch office either within Ireland or outside the country, this shall be applied for as an extension to scope through the INAB CRM system. INAB will determine if an assessment visit to the new office is necessary and how this shall be reflected on the scope.

**5.7** INAB form AF1F available on the website applies.

**5.8** Where a CAB fails to notify INAB in a timely manner, a nonconformity shall be raised by the INAB team at the next assessment.

## **Regulations – Transfer of Accredited Certification**

**5.9** In accordance with IAF MD 2:2017 on the Transfer of Accredited Certification of Management Systems, INAB expects its accredited certification bodies (CBs) to co-operate fully with the requested transfer. Where the issuing certification body does not cooperate with the accepting certification body or suspends or withdraws the transferring client's certification without cause, this will result in a review of the CB's accreditation, which may include the suspension or withdrawal of accreditation.



## SECTION 6: Withdrawal of accreditation

### General

INAB's policy in relation to the withdrawal of accreditation involves a range of measures, which are designed to protect the integrity of the accreditation system and to ensure that organisations respect the requirements of accreditation. These measures are; voluntary suspension, suspension, resignation and termination of all or of part of the organisation's scope of accreditation. This section of the regulations should be read in conjunction with INAB terms and conditions.

### Regulations

#### **6.1 Definitions**

- (a) *Voluntary Suspension:*  
A request by an organisation holding INAB accreditation, to temporarily withdraw all or part of its scope of accreditation;
- (b) *Suspension:*  
A temporary withdrawal by INAB of all or part of an organisation's scope of accreditation;
- (c) *Resignation:*  
A request by an organisation holding INAB accreditation to permanently withdraw all or part of its scope of accreditation;
- (d) *Termination:*  
A permanent withdrawal by INAB of all or part of an organisation's scope of accreditation;
- (e) *Accreditation Certificate Expiry Date:*  
Date after which the organisation's scope of accreditation has expired.

**6.2** Should the lead assessor or the INAB assessment manager responsible for the accredited organisation recommend suspension, such recommendation for suspension shall be presented to the manager of INAB.

**6.3** The manager of INAB, or in her absence the deputy manager, may authorise suspension.

**6.4** There is no time limit for how long a CAB can have its accreditation (full or part) in voluntary suspension. However, if nonconformities raised in relation to involuntary suspension have not been cleared within 12 months, accreditation (full or part) will be terminated. In either case, INAB will perform an onsite assessment to reinstate accreditation, to confirm that any nonconformities raised in relation to the suspension are cleared. The information obligations on INAB in 6.11 will apply.

**6.5** Only the INAB Board may authorise termination of an organisation's accreditation.

**6.6** Accreditation may be resigned by an organisation upon giving not less than 5 days' notice in writing to that effect to INAB.

**6.7** At any point in the application or assessment process, if there is evidence of fraudulent behaviour, if the CAB intentionally provides false information or if the CAB conceals information, INAB shall reject the application or terminate the assessment process.

**6.8** In the case of withdrawal (involuntary suspension, expired accreditation, resignation or termination) INAB shall send a letter to the organisation confirming the withdrawal of accreditation. It shall detail the actions required by the organisation arising from the withdrawal and shall include, in the case of voluntary or involuntary suspension, the procedure for re-instatement of accreditation.

- 6.9** Certificates issued by certification bodies under INAB accreditation will be valid for a maximum period of three months from the date that the certification body resigns or INAB terminates its accreditation. The organisation is referred to the INAB terms and conditions for obligations in this regard.
- 6.10** In the event that a CAB resigns or INAB withdraws (suspends, reduces or terminates) its accreditation, the CAB shall notify its clients in writing without undue delay of the withdrawal of INAB accreditation and inform them of the associated consequences.
- 6.11** INAB shall publish on the website [www.inab.ie](http://www.inab.ie), the effective date, name and contact details of CABs:
- That have had accreditation suspended, including voluntary suspension (full scope);
  - That have had accreditation suspended, including voluntary suspension (for partial scope by technical area);
  - That have resigned accreditation;
  - That have had accreditation terminated by INAB;

### **Expiry of Certificates**

- 6.12** It is the responsibility of the CAB to ensure timely acceptance of visit dates and to ensure that corrective actions are responded to in a timely manner in order to mitigate against certificates expiring. INAB makes every effort to schedule assessment dates six months in advance in a re-assessment year, but in certain cases due to restricted technical assessor availability, few/no options of assessment date may be offered, or assessment dates may only be available within six months of certificate expiry. The CAB is requested to cooperate with INAB in these situations. In any event, it is the responsibility of the accredited organisation to accept and undergo a re-assessment visit on a date not later than three months prior to the expiry date of its accreditation certificate. CABs are reminded that if a certificate of accreditation expires, the CAB will no longer be accredited and the directory entry on the INAB website will be amended to reflect this.
- 6.13** It is INAB's responsibility to ensure recommendations are processed, and INAB assessment teams address corrective actions in a timely manner.
- 6.14** In the event that a certificate expires, the CAB is not permitted to issue accredited results/certificates and must desist from using the INAB accreditation symbol.
- 6.15** Accreditation may be reinstated within six months of expiry, by decision of the INAB manager but without an additional visit, only if the reassessment has been completed and the nonconformities are closed. INAB reserves the right to raise additional charges in these cases for off-site work.

# SECTION 7: Resolution of complaints

## **Part 1: General**

This section sets out the regulations for handling complaints submitted to INAB.

Complaints may be made against INAB and/or its activities or against the activities of an INAB accredited organisation. Because INAB accredited organisations are ultimately responsible for the correctness and validity of the accredited service provided, INAB requests that in the first instance, complaints are addressed with the organisation. INAB expects that the organisation will handle the matter through its own complaint handling procedure. If the accredited organisation does not investigate the matter and respond to the complainant, then INAB will be in a position to conduct its own investigation.

### **Regulations**

- 7.1** Complaints shall be submitted in writing to the manager of INAB clearly stating the nature of, and justification for, the complaint.
- 7.2** Authentication of a complaint would normally involve the receipt of a letter and/or other documentary evidence clearly indicating that a complaint has been made. Such documentary evidence must include the name and address of the complainant.
- 7.3** Complaints may be received from many varied sources including private individuals.
- 7.4** No investigation of complaints shall be pursued on the basis of hearsay.
- 7.5** From time to time, INAB may receive well authenticated information which raises questions requiring actions similar to those required for a formal complaint e.g. arising from publicity material. In such cases the regulations set out in this Section 7 will be followed as far as is reasonable and practicable.
- 7.6** The manager of INAB shall designate the quality team to deal with the complaint.
- 7.7** The quality manager shall acknowledge the complaint in writing to the complainant.
- 7.8** Information about the CAB obtained from sources other than the CAB (e.g. complainant, regulators) shall be confidential between the CAB and INAB. The provider (source) of this information shall be confidential to INAB and shall not be shared with the CAB, unless agreed by the source. It will be normal practice to otherwise provide full disclosure of the details of the complaint to all parties concerned, while taking all necessary measures to preserve the confidentiality of CAB information obtained during the investigation of the complaint.
- 7.9** INAB expects its applicant and accredited bodies to co-operate promptly for information requested as part of complaint investigations and in any event not later than 3 weeks from request.
- 7.10** INAB reserves the right to carry out additional visits if considered necessary as part of the investigation.
- 7.11** When the investigation has been completed the designated INAB assessment manager shall submit a written report on the complaint to the manager of INAB.
- 7.12** The manager of INAB will then formally reply to the complainant detailing the results of the investigation and actions to be taken by INAB where applicable.

## **Part 2: General**

This section sets out the regulations for organisations that disagree with recommendations on accreditation status made by INAB assessment teams.

### **Regulations**

- 7.13** Recommendations on accreditation status are made by INAB assessment teams at visits (assessment, surveillance, additional or unscheduled) to organisations or at any other time.
- 7.14** In the case of a recommendation to maintain accreditation, suspend accreditation or extend the scope of accreditation within the same field, these recommendations are presented to the manager of INAB for decision.
- 7.15** Organisations may not agree with the recommendation proposed by the assessment team and have the right to reply to INAB.
- 7.16** The organisation may send its submission, in writing, to the manager of INAB within 3 working days of notification of the recommendation. In exceptional circumstances (subject to regulatory requirements) INAB reserves the right to make a decision in advance of such submission.
- 7.17** The assessment manager will seek a wider opinion and consider all submissions.
- 7.18** The assessment manager will then formally reply to the organisation detailing the outcome and actions to be taken by INAB or the CAB where applicable. Timescales (regarding clearance of nonconformities, for example) remain unchanged and the normal assessment process is followed, and the file will be presented to the INAB decision maker(s) in due course for decision.
- 7.19** The organisation has the right to appeal this decision by the process documented in Section 8.

## SECTION 8: Appeals against decisions of INAB

### General

This section sets out INAB regulations on the resolution of appeals against decisions taken by INAB. An appeal shall be lodged within 30 days of the date of notification of the decision against which the appeal is lodged. Appeals can be taken against:

- a) A decision of the Accreditation Board and/or manager in respect of accreditation in relation of a body, or;
- b) A failure by the Accreditation Board and/or manager to make a decision in respect of accreditation in relation to the body.

Further detail may be found in the Industrial Development (Dissolution of Forfás) Act 2014.

For appeals against GLP outcomes refer to the INAB GLP Compliance Monitoring Programme publication.

### Regulations

- 8.1** Decisions on the award and termination of accreditation are made by the INAB Board. Decisions on the maintenance of accreditation, suspension of accreditation and on the award of extensions to the scope of accreditation (within the same field) are made by the manager of INAB.
- 8.2** The INAB Appeals Board will hear appeals against accreditation decisions taken by both the INAB Board and manager.
- 8.3** The INAB Appeals Board is appointed by the Board of the Health and Safety Authority for a term not exceeding five years.
- 8.4** The appellant shall be the applicant/accredited organisation lodging the appeal.
- 8.5** Appeals shall be submitted in writing to the manager of INAB. On receipt of the appeal, the appellant shall be provided with a copy of the internal appeals procedure.
- 8.6** The appellant shall have the right to appear in person during consideration of their appeal to present their case, provide relevant documentary evidence and call witnesses.
- 8.7** Should the appellant wish to be present during the consideration of the appeal then written notification to this effect shall be submitted together with the appeal and INAB will give the appellant at least two weeks prior written notice of the date on which the appeal will be considered.
- 8.8** The costs of the appeal shall be borne by the appellant unless the appeal is successful.
- 8.9** The decision of the INAB Appeals Board shall be final as to the merits of the appeal and shall bind both appellant and INAB.
- 8.10** The manager of INAB will then formally reply to the appellant detailing the outcome of the appeal and actions to be taken.

## SECTION 9: On-site logistics

### General

This section sets out INAB regulations on the requirements for on-site logistics, including health and safety provisions.

### Regulations

- 9.1** When making assessment visit arrangements, it is the CAB's responsibility to communicate to INAB, in advance, any risks associated with the site visit.
- 9.2** INAB assessment teams will adhere to any site specific health and safety policies.
- 9.3** INAB staff are furnished with selected personal protective equipment (PPE). However, INAB expects its customers to provide INAB assessment teams with the items that are required to reduce potential site risks to an acceptable level and to meet all legal requirements. These will generally be items that are:
- Used by several individuals; or
  - Are disposable (e.g. face masks and gloves); or
  - Are specially decontaminated/cleaned after use (e.g. laboratory coats); or
  - Are very specific in nature (e.g. breathing apparatus or safety harnesses)
- 9.4** INAB requests that a dedicated meeting room be provided for assessment team private meetings and interviews with staff during the assessment.
- 9.5** INAB requests that, where possible, WiFi access be provided during the assessment in order to enable effective use of the INAB IT system.

# SECTION 10: Applications for accreditation, extensions to scope and witnessing

## General

This section sets out INAB regulations on the requirements for new applications for accreditation and applications for extensions to scope.

All applications (new and extension to scope) must be submitted with the fully completed checklist available on the CRM portal, applicable to the accreditation standard and a purchase order (PO) number.

### **Part 1 Regulations: – Applications for Accreditation and Reinstatement**

- 10.1** Applications to INAB for accreditation are made by contacting the INAB Administration Unit who provide a secure login for access to the INAB CRM client portal (see Section 11).
- 10.2** Full details of the accreditation standard and scope of application is made online through the portal and submitted to INAB.
- 10.3** Applications are assigned to an INAB staff member who will be the point of contact throughout the accreditation process.
- 10.4** A guide to INAB assessment processes is available in publication P7, available on the website.
- 10.5** Normally a pre-assessment is arranged, which determines the CAB readiness to proceed to full assessment. Should the assessment not take place within 1 year of the pre-assessment visit, then the CAB file is rendered *inactive* within the INAB system and the application must be made again in full.
- 10.6** Applicants shall have performed a management review and a complete audit of the full system prior to initial assessment.
- 10.7** Where there has been no activity or contact from an applicant for more than 12 months, INAB shall reject/deactivate the application in the CRM; the CAB must submit a new application should they wish to proceed with accreditation.

Where an initial assessment for a new applicant CAB has occurred, the following shall apply:

- Evidence to of corrective actions to address all nonconformities shall be submitted within 3 months, and closed within 6 months of the initial assessment. Where this does not occur, INAB will review the file and if closure of the nonconformities is not possible at that time, the application is closed and a full initial assessment will be rescheduled;
- If an additional visit is needed to assess clearance of major non-conformities, this shall be completed within 6 months of the initial assessment;
- If there are significant changes within the organisation from the time of the initial assessment to the decision on accreditation, INAB reserves the right to undertake a follow-up full and/or partial assessment, prior to presenting the recommendation to the INAB Accreditation Board for decision. If major or minor non-conformities are identified at this follow-up assessment, they shall be addressed through the normal process.
- At that stage and following the points above, the application assessment process is concluded; the team will either recommend award or refusal of accreditation. This recommendation is presented to the Accreditation Board for decision.

### **Part 2 Regulations: – Extensions to Scope**

- 10.8** INAB normally organises assessments of minor extensions to scope at the scheduled annual surveillance visit. Where the request is in the same discipline and is such that it can be incorporated in the allocated timeframe without impacting the planned surveillance visit, minimal additional costs may be incurred. If the team judges that significant additional assessment time will be required, the extension to scope assessment will be scheduled for a separate day close to the scheduled surveillance visit date. INAB is prepared to organise an additional visit outside of the normal surveillance cycle at the request of the CAB where there is an urgent need to process the extension. The policy for charging fees for extensions to scope and associated additional assessment effort is outlined in Section 2 above.
- 10.9** INAB shall make every effort to include assessment of the application at the next scheduled visit however in exceptional circumstances and where the requested amendment/extension is very similar to current accredited activities, INAB may process the application by correspondence.
- 10.10** The policy for charging fees for these applications by correspondence is outlined in Section 2 above.
- 10.11** Advance planning is required where an application for extension/amendment to scope is to be assessed at the next scheduled INAB visit and the assessment may involve additional assessor(s) time and costs. INAB will advise the applicant on receipt if additional costs/time/assessors are required.
- 10.12** All applications for extension to scope for assessment at the next scheduled surveillance visit must be submitted to INAB at least **6 months** in advance of the visit and shall normally be accompanied by the required documentation and validation data specified in the relevant application form (see INAB PS10).
- 10.13** Where an application is received when the time on site and assessment team has been agreed and in the event that the application cannot be processed without additional time or assessor competence, INAB will make every effort to incorporate into the agreed scheduled visit but where this is not possible, an additional visit may be required.
- 10.14** For certification and inspection bodies, it may be necessary to schedule additional witnessing as part of the applications for extensions to scope assessment.
- 10.15** The CAB shall not make a claim for accreditation for the scope amendment/extension until assessed and awarded by INAB.
- 10.16** Applications for extensions/amendments to scope are made through the INAB CRM client portal.
- 10.17** Applicants (for extension to scope) shall have performed a thorough audit of the application prior to its assessment and this shall be submitted with the application.
- 10.18** Extensions to scope should only be submitted when the applied for test/inspection/calibration/certification is suitable for witnessing and full assessment by INAB. In the event that this is not the case, then INAB will be unable to make a recommendation to award accreditation and the application shall be made inactive in the CRM following a negative decision. A new application shall be made and associated costs and assessment time apply, should the CAB wish to proceed at a later date.
- 10.19** A decision on award of accreditation for an extension to scope shall not be made until such time as all nonconformities are closed to the satisfaction of the assessment team. This includes nonconformities raised as part of surveillance/re-assessment assessments.

### **Part 3 Regulations: – Witnessed Audits (Certification Bodies, CB). IAF MD17 refers**

- 10.20** As part of its assessment, INAB shall witness audits onsite at CAB client premises. Onsite witnessing is an important tool for INAB to satisfy itself of the competence of certification bodies (CBs) for their applied-for or accredited scope. It is therefore INAB's responsibility to select the witnessing (including but not limited to scope category, auditor, inspector) necessary to fully assess the entire scope over the accreditation cycle. Clause 3 of the terms and conditions, PS7 and PS22 refer. The



assessment manager with responsibility for the CAB will determine and track the annual witnessing events and present reports to the INAB decision makers in order to award or maintain accreditation. For management systems CBs, all accredited sub-scopes shall be witnessed annually.

- 10.21** In the event that a CB refuses a witnessing selected by INAB (including reasons presented by the CB client) the CB shall provide justification which will be considered by INAB. Should the justification not be accepted by INAB and/or there is a potential compromise to the assessment coverage of the scope, INAB may impose sanctions that could include:
- Additional fee to cover the INAB administrative costs;
  - Withdrawal of the accredited scope;
  - The CB shall be requested to withdraw the accredited certificate;
- In the event of certificate withdrawal, the CB shall inform other relevant Accreditation Bodies and scheme owners (if known) and shall copy INAB.
- 10.22** The CB shall have documented terms and conditions with its clients taking into account the above and further requirements in clause 2.4.3 of IAF MD17.
- 10.23** Scheduling witnessed activity can be challenging for INAB and the CB. In order to ensure efficient use of all resources concerned, the following INAB regulations shall apply:
- i. At the start of each calendar year and on a monthly basis, the CAB shall send the forthcoming schedule of confirmed audits to the INAB assessment manager, for witnessed audit selection. The CB shall have been informed of the witnessing activity selected by INAB following the annual meeting and no later than end January.
  - ii. Documentation specified in PS10 for witnessed audits must be received 1 week in advance of the audit, or INAB reserves the right to cancel the planned witnessing, at no cost to INAB..
  - iii. Witnessed audits cancelled by the CAB **OR** not confirmed by the CAB to INAB within 6 weeks of the planned audit date will incur an additional administrative cost and cancellation cost.
  - iv. Communications between INAB and the CAB on scheduling witnessing activity and subsequent logistics shall only be between the CAB primary/deputy contact and not assigned lead auditors/audit team members (even if employees of the CAB).
  - v. All INAB witnessing for surveillance purposes shall be complete by end September each year.
  - vi. In the event that witnessing does not occur (as per above) for 2 consecutive years within the same sub-scope, the INAB assessment manager shall review the accreditation status of the CAB for that sub-scope activity.

# SECTION 11: Customer relationship management system (CRM)

## General

This section sets out INAB regulations on the CAB responsibilities and obligations in relation to the CRM system.

The INAB CRM is only enabled for use with Microsoft Office versions 2010 and later.

### **Part 1 Regulations:**

- 11.1 CAB profile** is managed through the client portal. Details to be kept up to date include address(es), contact name, contact number and contact email. INAB does not collect information on fax or websites. This information is published on certificates, scopes and the INAB website. Please note INAB does not accept any email changes updating this information.
- 11.2 Changes to primary, deputy and financial contact** is the responsibility of the CAB, i.e. change request must be made with INAB to ensure correct person receives alerts and notifications for visits, updates, etc. from INAB. This is particularly important if the contact is absent for a period of time. Please note INAB does not accept any email changes updating this information.
- 11.3 Accreditation process** through the CRM is described in the user manual (CRM2). In particular, the CAB is required to:
- Accept and acknowledge the assessment team and visit date via the portal;
  - Submit all documentation related to your visit via the portal;
  - Manage nonconformities through the portal;
  - Manage scope i.e. request amendment, edits, withdrawals, extensions to scope via the portal, for INAB approval;
  - The CAB is reminded that minor scope edits may be submitted to correct typographical changes to scope only. Any change to reference methods/ measurement ranges, matrices, equipment, locations/sites must be processed through the extension to scope methodologies, without exception.
  - Change requests should be submitted with all the necessary information to make that change via the portal i.e. change financial contact, new contact name, email, etc.;
  - The CAB will need to take care when submitting documentation as INAB has to engage the IT helpdesk to remove an erroneous submission. This can cause significant time delay which may impact on the process.
- 11.4 Cautions on use** - The system is live, therefore it should at all times be used in accordance with the guidelines. No testing, no trial runs, no upload of irrelevant materials should be conducted within the live system.
- 11.5** The CAB is responsible to ensure and restrict access to the portal to the relevant persons within their organisation.

## SECTION 12: Cross-frontier activity

### General

It is INAB's policy and in keeping with Regulation 765/2008, to offer accreditation only to those conformity assessment bodies (CABs) that have established a legal entity in Ireland. Established, in this sense and for the purposes of INAB accreditation requires, at a minimum, that the body is legally responsible in Ireland for the conformity assessment activities delivered under the scope of accreditation.

In exceptional circumstances, INAB may consider providing accreditation to a CAB operating in Ireland and that has not established a legal entity in Ireland or Europe where the CAB can justify to INAB that INAB accreditation is essential for its operations in Ireland.

It is INAB policy to co-operate with local accreditation bodies that are signatory to multilateral agreements; INAB accredited CABs shall co-operate in such cases where INAB considers it necessary.

### Regulations

- 12.1** In cases where INAB conducts assessment activity outside Ireland the EA/ILAC and IAF cross-frontier and co-operation policies shall apply.
- 12.2** INAB will cooperate with the local accreditation body (INAB policy PS19 refers). This may include using the local accreditation body for assessment of conformity assessment activities performed in their countries without the need for prior approval or communication with the CAB, if the local AB is a signatory of the relevant EA MLA and provides accreditation for the relevant conformity assessment activity.  
INAB and the local accreditation body may share information, even if the local AB does not perform the assessment.
- 12.3** The INAB CAB is informed at each stage and the details of the local accreditation body provided.
- 12.4** INAB shall have signed agreements with any local accreditation body with which it cooperates.
- 12.5** All assessment activity and reporting is conducted in English.
- 12.6** INAB shall make every effort to keep costs for overseas assessments to a minimum; however any costs incurred by INAB in outsourcing its assessments to the local AB shall be fully recovered at the rates outlined in the current fee schedule.
- 12.7** Where witnessed activity is performed in the local language, the CAB shall provide the services of an independent translator(s) to accompany the INAB assessor(s); the costs of this service shall be borne by the CAB.
- 12.8** Where a CAB performs audits in other countries and the files are in the local language, these shall be translated to English for the INAB assessors, when selected during the course of the assessments.

## SECTION 13: Agreements with national authorities

### General

From time to time, INAB enters agreements with national authorities relying on accreditation. These are to facilitate and share information. Applicant CABs will be advised of these agreements, if they exist at time of application. Where information confidential to INAB is requested by the national authority, the CAB shall be required to permit sharing of this information.

See details at the link below:

<https://www.inab.ie/about-us/agreements-with-national-authorities/>

## SECTION 14: Sub-contracting and reference to accreditation

### General

The following section details INAB regulations in relation to CAB subcontracting, outsourcing, and referral, with regard to references to INAB accreditation.

It does not add to or repeat requirements in the accreditation standards, which remain fully applicable.

When a CAB is accredited by INAB for its scope of accreditation, it is accepted that the organisation provides an accredited service [PS23 refers]. However, it is acknowledged that in certain defined circumstances that:

- A CAB may subcontract<sup>4</sup> activity to support its accredited scope e.g. testing as part of accredited inspection;
- A CAB may outsource auditing services as part of its certification/inspection process;
- A CAB may refer specialised testing to another laboratory;
- A test laboratory may subcontract or refer testing which is not part of its accredited scope;
- A test laboratory may temporarily subcontract or refer testing which is part of its accredited scope, but the laboratory is unable to provide the accredited testing for a short and defined period of time.

### Regulations

In all scenarios, the following are INAB requirements:

- 14.1** INAB shall not grant accreditation to organisations for the scope for which it does not have the capability, competence or resources to undertake.
- 14.2** The CAB is responsible for all subcontracting/outsourcing/referrals and for ensuring that the selected organisation(s) are suitable and competent to undertake the activity. Accreditation is the preferred mechanism for ensuring competence.
- 14.3** The CAB shall ensure that the subcontractor complies with the required standard for the work performed.
- 14.4** The CAB shall not claim accreditation for the subcontracted work.
- 14.5** Where a report/certificate includes results of subcontracted testing these results shall be identified on the report. The CAB shall not use the accreditation symbol or make any reference to accreditation on test reports or certificates, which include only results from an external organisation and which does not contain any work completed by the accredited CAB.

In the event that a laboratory needs to subcontract accredited activity for a temporary, unforeseen reason, the following shall apply:

- 14.6** The lab shall perform risk assessments considering whether voluntary suspension of INAB accreditation is necessary;
- 14.7** INAB shall be informed in the event that temporary subcontracting extends beyond 3 months;
- 14.8** In the event that subcontracting is likely to extend beyond 6 months, the lab shall go into voluntary suspension due to inability to provide the accredited service;
- 14.9** The laboratory shall not claim accreditation for the subcontracted work;
- 14.10** Where a report/certificate includes subcontracted test results, these results shall be identified on the report.

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<sup>4</sup> When reference for subcontracting is made for ISO 15189 laboratories, it can be understood to apply to referral laboratories

## APPENDIX I – INAB LOGO AND ACCREDITATION SYMBOL

[The Irish National Accreditation Board Logo](#) (Trade Mark No. 231 365)



[INAB Accreditation Symbol](#) (Trade Mark No. 246 998)



**NOT FOR REPRODUCTION: REFERENCE ONLY**

## APPENDIX II – RELEVANT STANDARDS AND DOCUMENTS

INDEX OF ISO/IEC STANDARDS ASSOCIATED WITH INAB ACCREDITATION, AVAILABLE [WWW.STANDARDS.IE](http://WWW.STANDARDS.IE)

ISO/IEC Standard	Description	
ISO 14065	Greenhouse Gas Verification	Greenhouse Gas - Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition
ISO 15189	Medical Testing	Medical laboratories — Requirements for quality and competence
ISO/IEC 17020	Inspection	Conformity assessment — Requirements for the operation of various types of bodies performing inspection
ISO/IEC 17021-1	Certification (Management Systems)	Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements
ISO/IEC 17024	Certification (Persons)	Conformity assessment — General requirements for bodies operating certification of persons
ISO/IEC 17025	Testing and Calibration	General requirements for the competence of testing and calibration laboratories
ISO/IEC 17029	Verification/validation	Conformity assessment — General principles and requirements for validation and verification bodies
ISO 17034	Reference Material Production	General requirements for the competence of reference material producers
ISO/IEC 17065	Certification (Product)	Conformity assessment — Requirements for bodies certifying products, processes and services
ISO 20387	Biobank	Biotechnology – Biobank – general requirements for biobanking

GLP	EU/OECD GLP Principles	The enforcement of national legislation S.I. 18 of 2020 giving effect to Commission Directives 2004/09/EC and 2004/10/EC, which require certain testing on chemicals to be carried out in accordance with the annexed OECD Principles of Good Laboratory Practice
EMAS Verifier	ISO/IEC 17021-1 and Regulation 1221/2009	On the voluntary participation by organisations in a Community eco-audit and management scheme (EMAS), repealing Regulation (EC) 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC

Where can I access mandatory, guidance, and policy documents relevant to accreditation?

Name of Document	Description	URL
DC1	INAB Mandatory and Guidance Documents – Policy and Index	<a href="https://www.inab.ie/inab-documents/">https://www.inab.ie/inab-documents/</a>

The **DC1** document specifies which mandatory, guidance and policy documents are relevant to various organisations for each accreditation standard and provide an index, contact points, URLs to access the relevant information, documents and sites.