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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 (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.

The 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 the 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 refused or 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 alternate levels of service for accredited activities.

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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 the EA<sup>1</sup> ILAC and IAF multi-lateral agreement is required to co-operate with other EA members and 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 Policy document PS7 refers). INAB applicant and accredited CABs are expected to co-operate with local signatory accreditation body.

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 it has been accredited, but as a general guide surveillance visits would normally take place at intervals of 6 to 12 months and reassessment every 3 to 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 the website [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 the INAB 'Terms and Conditions'.

INAB will direct all communication on financial matters to the main contact; it is then the CABs responsibility to re-direct those communications to the appropriate personnel within the organisation, as necessary.

### **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 by scheme.

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:hsafinancehelpdesk@crowleysdfk.ie">hsafinancehelpdesk@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 provide 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 the INAB invoices can be raised directly with the INAB officer or with the Finance Unit at [hsafinancehelpdesk@crowleysdfk.ie](mailto:hsafinancehelpdesk@crowleysdfk.ie).

#### **2.2 Application Fee (For all Organisations)**

An application fee is levied to offset costs involved in processing the application documents and appointing the lead assessor.

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 Document Review Fee (For Certification Bodies/Verifiers)**

A document review fee is levied to offset costs incurred in carrying out an initial review of documentation by the lead assessor.

### **2.4 Pre-Assessment Fee (For all Organisations)**

A pre-assessment fee is levied to offset the costs involved in the onsite review of the implementation of the quality 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 quality 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 Certification body / verifier auditor / inspector while completing a certification 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 Annual Management Fee**

The annual management 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.

#### **(a) Laboratories/Inspection Bodies**

Accredited laboratories and inspection bodies are subject to an annual management fee to offset the cost of administering the organisation's accreditation including the annual assessment visit.

#### **(b) Certification Bodies/Verifiers**

These organisations are subject to an annual management fee to offset the cost of administering the organisation's accreditation which does not include the annual assessment fee as this is charged separately as per the Schedule of Fees.

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.

The first annual management fee is calculated and invoiced 6 months from the date of the award of accreditation. This fee charged will be proportionate to the remaining months of the year and subject to a minimum of half the annual fee. The full annual management fee thereafter becomes due in January each year.

## **2.8 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.

## **2.9 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. 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.

## **2.10 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.

## **2.11 Fees for Extensions to Scope of Accreditation (For all Organisations)**

Where an extension to scope application can be managed within the normal visit programme, no fee will apply.

A fee will be levied for an extension to scope of accreditation where such an extension requires a visit. A fee may be charged where an extension to scope requires additional assessor time at the routine annual assessment.

A fee will be charged when an accredited organisation applies for an extension to scope of accreditation that INAB could consider granting by correspondence. This fee will be levied at a minimum half assessor day fee rate or pro-rata depending on the amount of additional effort involved in reviewing the supporting documentation and application and any follow up documentation required to consider such applications for extension to scope of accreditation.

Applications for extensions to scope will not be processed without a purchase order number (PON).

## **2.12 Order Numbers**

Any organisation that requires its order number to be quoted on invoices issued by INAB shall supply such order numbers within 14 days of being requested by INAB to provide such order numbers.

In the event that purchase order numbers are not received within 14 working days of request by INAB, 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. INAB reserves the right to determine regulations to meet this objective and to assess their effective implementation. It is the accredited Organisations 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.
- 3.3 The use of the accreditation symbol is restricted to accredited organisations.
- 3.4 INAB permanent and contract staff may use the INAB accreditation logo when giving presentations and the logo is also incorporated into stationery for use by staff. Assessors who undertake work on behalf of INAB are not permitted to use the accreditation logo.
- 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 reference to its INAB accreditation rather than using the accreditation symbol, 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'.
- 3.7 An organisation shall only claim that it is accredited in respect of the 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 CABs responsibility to ensure their 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 be positively and unambiguously identified.
- 3.10** Where an organisation wishes to make reference to other approvals, 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.
- 3.13** Letters printed on letterheads bearing the accreditation symbol and accompanying test reports, certificates or quotations/contracts for work containing no accredited results shall include a disclaimer stating that the attached results are not covered by the scope of accreditation.
- 3.14** Documentation issued by a laboratory bearing the INAB accreditation symbol and/or reference to accreditation which include opinions and/or interpretations on test results must include a disclaimer (close to the symbol or the opinion/interpretation) stating that the opinions and/or interpretations are not covered by the 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.
- 3.16** A calibration laboratory may issue calibration labels bearing the INAB accreditation symbol for equipment calibrated under its scope of accreditation.
- 3.17** Where an organisation wishes to use the accreditation symbol for purposes other than letterheads, publicity or promotional materials (including web-sites), quotations or proposals, reports or certificates the organisation shall obtain INAB's written consent prior to any release and conform to the requirements set out in these Regulations.
- 3.18** 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.
- 3.19** An INAB accredited organisation shall not provide certification to any standard used as a basis for accrediting Conformity Assessment Bodies (CABs) (e.g. ISO 17025, ISO 15189). INAB is required to initiate suspension of an Organisation's accreditation that provides such certifications.
- 3.20** An organisation is not permitted to use the accreditation symbol or text reference to accreditation on business cards held by the organisation's staff.
- 3.21** INAB does not permit the end users of accredited services to use its accreditation symbols or text reference to accreditation.
- 3.22** An organisation shall not allow the fact of its accreditation to be used to imply that a product, process, system or person is approved by INAB.



**3.23** 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.

**3.24 INAB MLA Signatory Status**

- (a) INAB is signatory to the multi-lateral agreements of the European Co-operation for Accreditation (EA) for testing and calibration (ISO 17025 and ISO 15189), inspection (ISO 17020) and certification (ISO 17021 and ISO 17065) activities.
- (b) INAB is signatory to the multi-lateral agreement of the International Accreditation Forum (IAF) for certification (ISO 17021 and ISO 17065) activities.
- (c) INAB is signatory to the multi-lateral agreement of the International Laboratory Accreditation Co-operation (ILAC) for testing and calibration (ISO 17025 and ISO 15189) activities.
- (d) 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.
- (e) 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.

**3.25 INAB Accreditation Symbol – Technical Use Specifications**

- (a) 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 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.
- (b) 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.
- (c) 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
- (f) Organisations may use electronic versions of the accreditation symbol providing they comply with these requirements.
- (g) 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 supplying to printers for lithic printing; and
  - GIF file for website use.

- (h) An organisation must ensure that reproduction of the accreditation symbol is accurate and legible with no degradation and/or distortion.

## SECTION 4: CLEARANCE OF NONCONFORMITIES

### General

This section sets out INAB regulations for the clearance of all nonconformities.

### Regulations

- 4.1** It is without prejudice to INAB's right in appropriate cases to withdraw an organisation's accreditation forthwith for failure to clear nonconformities.
- 4.2** INAB will require organisations to implement corrective actions in response to nonconformities with the accreditation criteria and to audit the effectiveness of their implementation, in a timely and efficient manner.

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

**(a)** Nonconformities are categorised at the assessment team private meeting as follows:

- i.** A 'minor non- conformity' is the failure to comply with the scheme requirements.
- ii.** A 'major non- conformity' is the failure to comply with the scheme requirements to the extent that could compromise the confidence that is placed in the accredited activity.
- iii.** Observations: Findings raised during the course of an assessment which may not be classified as a nonconformity to accreditation requirements. It is important that assessors/experts only raise findings where they have a real concern that the finding is in breach of accreditation requirements. Where such a finding is raised and subsequently not categorised as a major or minor non-conformity, the assessor/expert shall remove it from the nonconformity report and include it in the XX116 audit trail report with a more detailed explanation on the issue.

**4.3** All communications shall be channelled through INAB, except where INAB expressly approves otherwise, in which case copies shall be sent to INAB.

**4.4** Organisations shall adhere to the following timeframes for the clearance of nonconformities and submission of corrective actions to INAB:

- (a)** Proposed corrective actions will normally be agreed and accepted during the assessment visit. If agreement is not made at the visit, timeframes listed in (b) below shall not be exceeded.
- (b)** The timeframe for the clearance of all 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.

**4.5** All major nonconformities raised at INAB assessment visits may result in suspension of accreditation and/or an additional visit. 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,
- Root cause analysis and investigation,
- Corrective action.

The timeframe for receipt of this evidence shall not exceed 2 weeks from the date of the visit.

In exceptional circumstance, INAB may alter this timeframe.

In the event that an additional visit 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.

- 4.6** In the exceptional circumstance where an organisation fails to clear non-conformities in the first documentary attempt, the INAB officer will determine the timeframe for submission of additional documentation, which shall not exceed 2 weeks.
- 4.7** 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 non-conformity(s) requiring the extension to the timeframe. All other non-conformities must be cleared within the normal timeframes.
- 4.8** 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 non-conformities 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.
- 4.9** 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(s) have been satisfactorily cleared.
- 4.10** Following a review as contemplated by section 4.8, INAB may decide to set a new timeframe for the satisfactory clearance of the outstanding non-conformity(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.
- 4.11** 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.
- 4.12** In the case of an initial application where the organisation fails to clear the nonconformities within the agreed timeframes a re-assessment will be required.
- 4.13** In the event of a major nonconformity being raised, the lead assessor in consultation with the INAB officer 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;
  - (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;
  - (c)** review the reports from previous surveillance/other visits to the organisation to ascertain if the history of the organisation, when taken together with the major nonconformity indicates an underlying problem with the maintenance of accreditation;
  - (d)** ensure that the integrity of INAB accreditation is not compromised by any action or timeframe agreed to address the major non- conformities.
- 4.14** 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 Conformity Assessment Body (CAB) no longer holds nor can claim to hold INAB accreditation. Any conformity assessment activity performed (testing, calibration, inspection, certification) cannot be performed as an accredited activity.

#### **4.15 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 (specified by assessor)

Major 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 (mandatory)

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

For all nonconformities

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

Where corrective actions have not been implemented prior to the subsequent INAB assessment, a major nonconformity will always ensue.

## **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:

- (a) CAB (legal entity established in Ireland) name and address,
- (b) CAB contact details,
- (c) 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.

**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 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 and effective operational dates to ensure minimal break in their accreditation status.

**5.5** Where an organisation changes trading name, the organisation shall confirm that there has been no change in the legal entity by utilising the appropriate INAB form, completing the relevant sections and forwarding to INAB.

**5.6** Where an organisation opens a branch office either within Ireland or outside the country, the relevant parts of the appropriate INAB form shall be completed. INAB will determine if an assessment visit to the new office is necessary.

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

**5.7** In accordance with *IAF MD2:2017 on the Transfer of Accredited Certification of Management Systems*, INAB expects its accredited Certification Bodies (CBs) to co-operate fully with the requested transfer. Failure to do so may result in a review of the CB 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;

**6.2** Should the lead assessor or the INAB officer 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** An organisation shall only be in suspension or voluntary suspension for a period not exceeding 3 months. In exceptional circumstances INAB may permit an extension of this timeframe to a maximum of 6 months.

**6.5** Failure to clear non-conformities, if any, following suspension or voluntary suspension within the agreed time frame may result in termination of accreditation

**6.6** The INAB officer responsible for an organisation shall recommend termination to the Manager of INAB.

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

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

**6.9** In the case of withdrawal (voluntary or involuntary suspension, 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.

**6.10** 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 regards.

**6.11** In the event that the certification body resigns or INAB terminates its accreditation the certification body shall notify its clients in writing without delay of its withdrawal of INAB accreditation and inform them that the certificates issued under INAB accreditation will no longer be valid after 3 months from the date of resignation or termination.



## **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 organization.

#### **Regulations**

- 7.1** Complaints shall be submitted in writing to the Manager of INAB clearly stating the nature and justification.
- 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 an INAB officer to deal with the complaint, who is in no way connected to the complaint.
- 7.7** The designated officer shall acknowledge the complaint in writing to the Complainant.
- 7.8** It will be normal practice to provide full disclosure of the details of the complaint to all parties concerned, while taking all necessary measures to preserve the confidentiality of information obtained during the investigation of the complaint.
- 7.9** INAB expects its applicant and accredited 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 officer 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 the Manager of INAB.
- 7.16** The organisation may send their 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 Manager of INAB will consider all submissions prior to making his decision.
- 7.18** The INAB officer will then formally reply to the organisation detailing the decision and actions to be taken by INAB where applicable.
- 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 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.

The Appeals Board shall also hear appeals in relation to decisions taken by the Manager on:

- a) EMAS (eco Audit and Management System) registrations as required for Competent Bodies under Article 12 of regulation 1221/2009.

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 decisions made 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 INAB Appeals Board consists of three members with appropriate expertise, knowledge and understanding of the functions of INAB.
- 8.5** The Appellant shall be the applicant/accredited organisation lodging the appeal.
- 8.6** 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.
- 8.7** 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.
- 8.8** 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.
- 8.9** The costs of the appeal shall be borne by the Appellant unless the appeal is successful.
- 8.10** The decision of the INAB Appeals Board shall be final as to the merits of the appeal and shall bind both Appellant and INAB.
- 8.11** 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 INAB will confirm with clients, when making assessment visit arrangements that any risks associated with the site visit are communicated to INAB in advance.
- 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 which 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 AND EXTENSIONS TO SCOPE

### 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 number (PON). Applications will not be processed in the absence of a PON.

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

- 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 programme of the full system prior to the initial assessment.

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

- 10.7** INAB normally organises assessments of amendments or extensions to scope at the annual surveillance visit, unless an additional visit is specifically requested by the Conformity Assessment Body (CAB). INAB is prepared to organise an additional visit where there is an urgent need to process the extension. Where the request is in the same discipline and is such that it can be incorporated in the allocated timeframe for the surveillance visit minimal additional costs may be incurred.
- 10.8** 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.
- 10.9** The policy for charging fees for these applications by correspondence is outlined in Section 2 above.
- 10.10** 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.
- 10.11** 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.

- 10.12** 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.
- 10.13** For certification and inspection bodies, it may be necessary to schedule additional witnessing as part of the applications for extensions to scope assessment.
- 10.14** The CAB shall not make a claim for accreditation for the scope amendment/extension until assessed and awarded by INAB.
- 10.15** Applications for extensions/amendments to scope are made through the INAB CRM client portal.
- 10.16** 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.
- 10.17** 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**

- 10.18** As part of its assessment, INAB shall witness audits onsite at CAB client premises. Onsite witnessing is an important tool for Accreditation Bodies to satisfy itself of the competence of the Certification Bodies (CBs) for the applied or accredited scope. It is therefore the responsibility of the AB 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 refers.
- 10.19** 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.

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.

## SECTION 11: CLIENT 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 versions 2010 and later.

### **Part 1 Regulations:**

- 11.1 CAB profile** is now managed through the client portal. Details to be kept up to date include address, 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 CRM is described in the user manual. 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. amendment, edits, withdrawals requested *via* the portal, for INAB approval;
  - 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.

## APPENDIX I

[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 17024	Certification (Persons)	General requirements for bodies operating <b>certification schemes for persons</b>
ISO 17065	Certification (Product)	General guidelines for bodies operating <b>product certification systems</b>
ISO 17020	Inspection	General Criteria for the operation of various types of bodies performing <b>inspection</b>
ISO 17021-1	Certification (Management Systems)	Conformity Assessment – Requirements for bodies providing audit and certification of <b>management systems</b>
ISO 15189	Medical Testing	<b>Medical laboratories</b> – Particular requirements for quality and competence
ISO 17025	Testing and Calibration	General Requirements for the competence of <b>Testing and calibration laboratories</b>
ISO 14065	Greenhouse Gas Verification	<b>Greenhouse Gas</b> - Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition
ISO Guide 17034	Reference Material Producer	<b>Reference Material Producers</b> - General Requirements for the competence of Reference Material Producers

GLP	EU/OECD GLP Principles	The enforcement of national legislation S.I. No 4 of 1991 as amended by S.I. No. 294 of 1999 to give effect to Commission Directives 87/18/EEC, 88/320/EEC, 90/18/EEC, and Commission Directives 1999/11/EC and 1999/12/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 17021 and Regulation 1221/2009	On the voluntary participation 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="http://www.inab.ie/media/DC1.pdf">http://www.inab.ie/media/DC1.pdf</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.