

## 1. Parties

- 1.1 Irish National Accreditation Board (hereinafter referred to as “**INAB**”) of Health and Safety Authority, James Joyce Street, Dublin 1.
- 1.2 [INSERT NAME] (hereinafter referred to as the “**National Authority**”) of [INSERT ADDRESS]

## 2. Definitions

- **Accreditation** means a third-party attestation [by INAB] related to a CAB conveying formal demonstration of its competence to carry out specific conformity assessment tasks [in respect of which the National Authority has certain functions]
- **Applicant Body** means any organisation or body applying to INAB for the purposes of accreditation under (insert specific details);
- **Applicant Notified Body** means any individual, organisation or body corporate applying to INAB for the purposes of accreditation under [INSERT DETAIL AS PER CLAUSE 3.4];
- For the purposes of this agreement the term Applicant body is used and includes applicant notified bodies;
- **Data Protection Legislation** means all applicable data protection law, including the General Data Protection Regulation (Regulation (EU) 2016/679), the Data Protection Act 2018 and any legislation which amends, extends, consolidates, re-enacts or replaces same, including any statutory instruments and regulations that may be made pursuant thereto from time to time/ the General Data Protection Regulation (Regulation (EU) 2016/679) and any implementing legislation, including the Data Protection Act 2018 (as amended or replaced from time to time) and all Irish and European Union laws and regulations (with direct effect) relating to the processing of personal data and privacy and applicable to INAB and/or the Organisation
- **Notified Body** means any organisation or body corporate that has been accredited by INAB and has been designated to carry out conformity assessment according to a directive. Notification of Notified Bodies and their withdrawal are the responsibility of the notifying Member State /National Authority;
- **Approved body** as referred to in this agreement, is any organisation or body that has been accredited by INAB and has been designated to carry out a conformity assessment according to a predetermined standard /agreement;
- **CAB** is conformity assessment body and is a body that performs a conformity assessment service and that can be the object of accreditation;
- [INSERT OTHER RELEVANT DEFINITIONS, IF APPLICABLE]

## 3. Background & Scope

- 3.1 INAB is the national body with responsibility for the accreditation of laboratories, certification bodies and inspection bodies and provides accreditation in accordance with the relevant International Organisation of Standardisation.
- 3.2 From time to time, INAB is requested or seeks to have an agreement with a National Authority which *relies* on accreditation as the preferred means to demonstrate competence of CABs providing accredited services under Regulation (European or National). INAB is not undertaking assessment on behalf of the National Authorities nor assuming any regulatory role.
- 3.3 The purpose of this agreement is to set out the basis upon which INAB and the National Authority shall exchange certain information relating to applicant /accredited Organisations Notified Bodies/ Bodies under Regulation for the purposes of assisting the Parties in discharging their respective statutory and or regulatory functions. The information to be exchanged, without variation, is documented below in Sections 4 and 5.

- 3.4 INAB accreditation is not a substitute for nor does it extend to any enforcement action, under the auspices of the National Authority.
- 3.5 It is agreed that both bodies have separate decision making processes in terms of accreditation and appointment/approval respectively.
- 3.6 INAB shall complete the information in Appendix I.
- 3.7 The National Authority shall complete the information in Appendix II.
- 3.8 INAB shall publish a list of Authorities with which it has a signed agreement. This template agreement will also be published along with the information on mandatory requirements provided in Appendix II.
- 3.9 Mandatory requirements which are determined by the National Authority for the application and/or interpretation of the accreditation scheme and which are publicly available (see 3.8) may be assessed by INAB as part of their accreditation process. This shall be confirmed in Appendix II. Inspection/verification/regulatory/enforcement activities expected to be performed by the National Authority itself are not part of these requirements. Additional requirements over and above the accreditation requirements may necessitate additional time on site and the Authority is advised that this may incur an annual cost.
- 3.10 An agreed format for scopes of accreditation with the National Authority shall be put in place.
- 3.11 It is advisable to schedule regular meetings between INAB and the National Authority and the frequency can be agreed.
- 3.12 The National Authority acknowledges that any decisions in respect of the accreditation application or to a change in status to accreditation (including but not limited to suspension of revocation of accreditation, partial or otherwise,) are made at the discretion of INAB in accordance with the discharge of its statutory functions.
- 3.13 Information shall be exchanged only between the parties identified in Section 4 and 5 below.
- 3.14 This agreement does not preclude or supersede any other agreements or reporting arrangements between the National Authorities and CABS.

#### **4. Information Obligations - INAB**

- 4.1 INAB shall advise the National Authority of any changes to the accreditation status of the applicant/accredited CAB. The detail can be requested directly from the CAB;
- 4.2 INAB does not provide any assessment reports, and these may be requested directly from the CAB.
- 4.3 Where applications are made to INAB, which are under this agreement, INAB will advise the applicant to contact the National Authority. INAB will not provide personal information on applicant CABS.
- 4.4 INAB shall advise the National Authority of any changes to accreditation standards or mandatory accreditation requirements.
- 4.5 INAB has included in its terms and conditions with CABS that *“where a regulatory / national / competent authority requests information from the Organisation on major nonconformities raised in INAB assessments or complaints / negative feedback received on accredited activity, INAB expects this to be provided in a timely manner.”* INAB strongly

encourages the National Authority to request this information from CABs on a routine basis.

**5. Information Obligations – National Authority**

- 5.1 The National Authority shall advise INAB if Regulations (European or national) have changed, or mandatory requirements have been added / amended.
- 5.2 The National Authority shall communicate any issues or problems encountered as part of national surveillance/enforcement/monitoring to the CAB directly, informing INAB of such issues. INAB will investigate the closure of such issues / problems with the CAB at the next available on site visit, unless agreed otherwise. The National Authority shall satisfy itself that such issues have been resolved to their satisfaction.
- 5.3 In circumstances where the National Authority is exercising its right to revoke approval of the CAB, it shall immediately inform INAB of its intention.

**6. Information Agreement between INAB and the National Authority**

- 6.1 Each party (the “**PROVIDING PARTY**”) is responsible for ensuring that the provision of information by it to the other party (the “**RECEIVING PARTY**”) in the context of this Agreement, and its use by the Receiving Party in compliance with the restrictions set out in this Agreement, shall not breach any obligations owed to third parties including, without limitation, any confidentiality obligations or obligations under the Data Protection Acts.
- 6.2 This Agreement does not require the provision of any personal data.

**7. Review**

This agreement shall be reviewed annually with each Authority by the INAB Programme Manager and updated as needed.

## 8. Signatures

<b>Signed on Behalf of INAB</b>	
Name	Rosemary Hayden
Position	Programme Manager INAB
Email	rosemary.hayden@inab.ie
Telephone	01-6147182
Date	
Signature	
Agreement reference	INAB-

<b>Signed on Behalf of the National Authority</b>	
Name	
Position	
Email	
Telephone	
Date	
Signature	

## APPENDIX I: FOR OFFICE USE - INAB

The Organisations (CABs) affected by this Agreement shall be accredited to (tick):

- ☐ **ISO 17025:** *General requirements for the competency of testing and calibration laboratories, TESTING.*
- ☐ **ISO 17025:** *General requirements for the competency of testing and calibration laboratories, CALIBRATION.*
- ☐ **ISO 15189:** *Medical laboratories – requirements for quality and competence.*
- ☐ **ISO 20387:** *Biotechnology — Biobanking — General requirements for biobanking.*
- ☐ **ISO 17034:** *General requirements for the competence of reference material producers.*
- ☐ **ISO 17021-1:** *Conformity assessment – requirements for bodies providing audit and certification of management systems.*
- ☐ **ISO 17020:** *Conformity assessment – requirements for operation for various types of bodies performing inspections.*
- ☐ **ISO 17065:** *General requirements for bodies operating product certification systems.*
- ☐ **ISO 17024:** *General requirements for bodies operating certification of persons.*
- ☐ **ISO 14065:** *Greenhouse gases – requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition.*
- ☐ **ISO 17029:** *Conformity assessment — General principles and requirements for validation and verification bodies.*

### INAB REFERENCE DOCUMENTS

- (i) Commission Blue Guide (current version) – for Notified Bodies
- (ii) EA publication 2/17 – for Notified Bodies
- (iii) Applicable EA/ILAC/IAF<sup>1</sup> mandatory documents

[www.european-accreditation.org](http://www.european-accreditation.org)  
[www.ilac.org](http://www.ilac.org)  
[www.iaf.nu](http://www.iaf.nu)

---

<sup>1</sup> EA is European Co-operation for Accreditation; ILAC is the International Laboratory Accreditation Co-operation; IAF is the International Accreditation Forum

## SCOPE

The scope will follow the template in the CRM. However additional text may be added as notes, by agreement. Once agreed, this text will apply to scopes for all CABs accredited within the Regulation/Scheme.

Additional scope text:

--

## APPENDIX II: FOR OFFICE USE – INFORMATION PROVIDED BY THE NATIONAL AUTHORITY

The National Authority is requested to set out a brief description of its function and how accreditation is to support this function.

--

The National Authority is requested to specify all mandatory requirements applicable and provide a link to their website. This link will be added to the INAB website (see 3.8, 3.9 above). Confirmation that the Authority requires the mandatory documents assessed as part of the accreditation process.

--

The National Authority is requested to specify if the accredited CAB is to be noted on an approval list/EU NANDO database for notified bodies.

