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| Organisation Change Information Form AF-1-F  The following information is required by The Irish National Accreditation Board (INAB), a division of the Health and Safety Authority, in fulfilment of the Organisation’s obligations under Clause 3.11 of the INAB Terms and Conditions available at [www.inab.ie](http://www.inab.ie)  Instructions  The Organisation (Conformity Assessment Body, CAB) shall provide INAB with the following information in the event of:   * 1. any change of ownership or control of the Organisation or,   2. any sale by the Organisation of its business (including to not limited to name change, merger, acquisition) or,   3. any other event by which the control of the business run by the Organisation will be transferred or changed, in advance of the said change or,   Where a CAB moves premises, this shall be informed through the INAB CRM system and an assessment will occur.  Where a CAB is adding a new site/premises/branch office this shall be applied for as an extension to scope through the INAB CRM system.  All information requested in this form should be provided in full, as soon as it becomes available and in any event before the effective operational date of the change and returned to:  The INAB Executive, Metropolitan Building, James Joyce Street, Dublin 1, marked for the attention of the relevant assessment manager OR emailed directly to the relevant assessment manager (note wet signatures only and scanned is accepted if submitting by email).    Additional information may be provided by the CAB on supplementary sheets, which should be clearly cross-referenced with the question numbers to which they refer.  Additional advice or information may be obtained by contacting the Irish National Accreditation Board Executive at the above address or Tel: 01-6147182, e-mail: [inab@inab.ie](mailto:inab@inab.ie) |

| Section A: Change in Legal Entity/Ownership |  |
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| A.1 Information on Proposed Change |  |

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| **1.** | CAB Name |  |
| **2.** | INAB reference number |  |
| **Ownership. Note where the legal entity changes, this will result in resignation of the existing INAB registration number and award of a new registration no. following an assessment** | | |
| **3.** | Existing ownership |  |
|  | New ownership (if applicable) |  |
|  | Existing company registration no. (enter detail) |  |
|  | New company registration no. (if applicable)  *Attach* certificate of incorporation  *Attach* organisation chart |  |
| **CAB Name Change** | | |
| **4.** | Where a CAB changes its **name only** and there is no change in legal entity (3 above), then this is processed through the INAB CRM system. | |
|  | Existing CAB name |  |
|  | Proposed CAB name |  |

**A.2 CAB Analysis and Assessment**

The CAB shall comprehensively provide in one document all the following and attach

* A full description of the changes indicated in Section A.1.3;
* Effective operational date for the changes;
* CABs risk analysis on changes to include (but not limited to) impacts on impartiality/independence, customer service, ability to continue to provide accredited services;
* Key actions to be taken by the CAB to ensure effective implementation of the change.

**Section B: Changes to Key Personnel**

For changes to key personnel identified in Appendix I, the CAB shall:

* Confirm the competency assessment and authorisation of the person appointed is in place;
* Confirm the training plan for the role of the person appointed is in place and has been agreed;
* Provide the effective date of appointment
* Provide change to organisation chart, if applicable
* Update contact information in CRM, if needed

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| **5.** | **Change in Key Personnel** | |
|  | Describe |  |

**Section C: Changes to Equipment**

Testing laboratories should manage effective equipment change through the INAB flexible scope policy, PS11 and in accordance with PS32.

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| **Submitted by on behalf of CAB:** | |  |
| **Date:** | |  |
| **Section D: INAB Internal Review**  The information is reviewed by the INAB Officer responsible for the CAB, in consultation with assessors, as appropriate and presented to the INAB Manager for:   1. Assessment to be performed 2. Noting as part of decision making, OR 3. Award of new accreditation and registration number   Review, conclusions and recommendation of INAB Officer:   |  | | --- | |  |   Completed by INAB Manager (A.1.2 above only):   |  |  | | --- | --- | | |  | | --- | |  | | | | |

**Appendix I: Key Personnel**

Acronyms used:

* (D) TM: Technical Manager and deputy
* (D) QM: Quality Manager and deputy
* (D) SM: Scheme Manager and deputy
* (D) LD: Laboratory Director and deputy
* (D) CM: Clinical management (by discipline, subscope)
* Gov: Membership of the Governing Body/Impartiality Committee
* Rev&Dec: Reviewers and decision makers
* FS: Persons with responsibility for flexible scope
* O&I: Persons with responsibility for providing opinions and interpretations
* Top M – Top Management with responsibility for the biobank

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| **Standard** |  | | | | | |  |
| **ISO 17025** | TM | QM | Deputy (if applicable)   * TM * QM |  |  | FS | O&I |
| **ISO 15189** | LD | TM | QM | CM | Deputy   * TM * QM * CM * LD | FS |  |
| **ISO 20387** | LD | TM | QM | CM | Deputy   * TM * QM * CM * LD |  |  |
| **ISO 17020** | TM | QM | Deputy   * TM * QM |  |  |  |  |
| **ISO 17065** | SM | QM | Deputy   * SM * QM | Gov | Rev&Dec |  |  |
| **ISO 17021-1** | SM | QM | Deputy   * SM * QM | Gov | Rev&Dec |  |  |
| **ISO 17034** | TM | QM | Deputy   * TM * QM |  |  |  |  |
| **ISO 17024** | SM | QM | Deputy   * SM * QM | Gov | Rev&Dec |  |  |
| **ISO 17029** | SM | QM | Deputy   * SM * QM | Gov | Rev&Dec |  |  |
| **ISO 17043** | TM | QM | Deputy   * TM * QM |  |  |  |  |