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| CAB self-assessment & INAB document review | AF108 |
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| **Conformity assessment body (CAB) name:** |       |
| **INAB reference number (from CRM):** |       |
| **Standard:***[Select from ISO17025 (test), ISO 17025 (calibration), ISO 15189, ISO 17034, ISO 17020, ISO 17021-1, ISO 17065, ISO 17024, ISO 17043, ISO 14065, ISO 17029, ISO 20387]* |       |
| **CAB person completing self-assessment:** |       |
| **Completion date:** |       |

**PART A: CAB Self-Assessment**

For the applicable standard, please provide a brief description of the CAB’s implemented system cross referencing internal documentation. Section 1 is mandatory for all CABs; subsequent parts are dependent on the application.

**Please note any gaps may result in a delay in processing the application**.

This form is provided with **all applications** (initial and extension to scope) to assist the INAB team’s preparation.

Refer to INAB publication DC1 for all mandatory documents with which the CAB must comply.

Refer to INAB PS10 for the supporting documentation to submit with applications.

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| **1.** | **All CABs, all standards** | **Briefly describe where the CAB complies, cross-referencing procedures, manuals etc.** |
|  | Organisation & business activity |       |
| Management system |       |
| Document control |       |
| Corrective action |       |
| Control of records |       |
| Internal audit |       |
| Management review |       |
| CAB IT systems description  |       |
| INAB policies |       |
|  | Information on activities conducted at all locations (including virtual site(s)) |       |
|  | Specify all legislation (European and national) relevant to the scope applied for. If none, leave this section blank |       |
|  | If there is a regulatory deadline by which accreditation must be achieved, please specify. Please note that applications must be received no later than 6 months in advance of any regulatory deadline. |       |
|  | Is the CAB certified to ISO 9001? |       |

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| **2** | **ISO 17025 Test and Calibration Labs** | **Briefly describe where the CAB complies, cross-referencing procedures, manuals etc.** |
|  | Control of nonconforming work |       |
| Accommodation and environmental conditions |       |
| Method validation |       |
| Test and calibration methods |       |
| Equipment |       |
| Measurement traceability |       |
| In-house calibrations |       |
| Reporting of results |       |
| Participation in proficiency testing/inter-laboratory comparisons |       |
| EA and ILAC mandatory documents |       |
| **In submitting this application for accreditation or extension for scope of accreditation, the CAB is confirming its view that:** |
|  | The laboratory complies with ISO 17025 | Yes [ ]   | No [ ]   |
|  | The laboratory complies with INAB mandatory policies, regulations and terms & conditions | Yes [ ]   | No [ ]   |
|  | The laboratory is aware of and has reviewed all international mandatory documents relevant to laboratory accreditation | Yes [ ]   | No [ ]   |
|  | The laboratory has completed validation on all tests applied for | Yes [ ]   | No [ ]   |
|  | The laboratory is participating in a proficiency testing or inter-laboratory programme for all tests applied for | Yes [ ]   | No [ ]   |
|  | The laboratory has completed an internal audit against all requirements relevant to the application | Yes [ ]   | No [ ]   |

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| **3** | **ISO 15189 Medical Test Labs** | **Briefly describe where the CAB complies, cross-referencing procedures, manuals etc.** |
|  | Control of nonconforming work |       |
| Facilities and environmental conditions |       |
| Method validation/verification |       |
| Test and calibration methods |       |
| Equipment |       |
| Metrological traceability |       |
| In-house calibrations |       |
| On-call services and processes |       |
| Advisory services |       |
| Risk management processes |       |
| Reporting of results |       |
| Communication with service users |       |
| Point of care testing (POCT), if applicable |       |
| Participation in proficiency testing/inter-laboratory comparisons |       |
| EA and ILAC mandatory documents |       |
| **In submitting this application for accreditation or extension for scope of accreditation, the CAB is confirming its view that:** |
|  | The laboratory complies with ISO 15189 | Yes [ ]   | No [ ]   |
|  | The laboratory complies with INAB mandatory policies, regulations and terms & conditions | Yes [ ]   | No [ ]   |
|  | The laboratory is aware of and has reviewed all international mandatory documents relevant to laboratory accreditation | Yes [ ]   | No [ ]   |
|  | The laboratory has completed validation/verificationon all tests applied for | Yes [ ]   | No [ ]   |
|  | The laboratory is participating in a proficiency testing or inter-laboratory programme for all tests applied for | Yes [ ]   | No [ ]   |
|  | The laboratory has completed an internal audit against all requirements relevant to the application | Yes [ ]   | No [ ]   |

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| **4** | **ISO 17020 Inspection Bodies** | **Briefly describe where the CAB complies, cross-referencing procedures, manuals etc.** |
|  | Management of independence and impartiality |       |
|  | Inspector competence |       |
|  | Risk management |       |
|  | Liabilities |       |
|  | Subcontractors |       |
|  | Measurement traceability |       |
|  | Locations where inspection services are provided |       |
|  | Reporting |       |
|  | EA and ILAC mandatory documents |       |
| **In submitting this application for accreditation or extension for scope of accreditation, the CAB is confirming its view that:** |
|  | The inspection body complies with ISO 17020 | Yes [ ]   | No [ ]   |
|  | The inspection body complies with INAB mandatory policies, regulations and terms & conditions | Yes [ ]   | No [ ]   |
|  | The inspection body is aware of and has reviewed all international mandatory documents relevant to inspection body accreditation | Yes [ ]   | No [ ]   |
|  | The inspection body has completed the risk management form (RM-IB) for the inspections applied for | Yes [ ]   | No [ ]   |
|  | The inspection body has completed an internal audit against all requirements relevant to the application | Yes [ ]   | No [ ]   |
|  | The inspection body has documented all activities and performed an analysis of impartiality and independence in relation to the application | Yes [ ]   | No [ ]   |
|  | The inspection body complies with ISO 17020 | Yes [ ]   | No [ ]   |

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| **5** | **ISO 17034 Reference Material Producers** | **Briefly describe where the CAB complies, cross-referencing procedures, manuals etc.** |
|  | Measurement traceability |       |
|  | Collaborators/subcontractors |       |
|  | Distribution |       |
|  | Reporting |       |
|  | EA and ILAC mandatory documents |       |
| **In submitting this application for accreditation or extension for scope of accreditation, the CAB is confirming its view that:** |
|  | The RMP complies with ISO 17034 | Yes [ ]   | No [ ]   |
|  | The RMP complies with INAB mandatory policies, regulations and terms & conditions | Yes [ ]   | No [ ]   |
|  | The RMP is aware of and has reviewed all international mandatory documents relevant to RMP accreditation | Yes [ ]   | No [ ]   |
|  | The RMP has completed validation on all tests/calibrations applied for | Yes [ ]   | No [ ]   |
|  | The RMP is participating in a proficiency testing or inter-laboratory programme for all tests/calibrations applied for | Yes [ ]   | No [ ]   |
|  | Characterisation testing is performed in a ISO 17025 accreditation laboratory | Yes [ ]   | No [ ]   |
|  | The RMP has completed an internal audit against all requirements relevant to the application | Yes [ ]   | No [ ]   |

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| **6** | **ISO 20387 Biobanking**  | **Briefly describe where the CAB complies, cross-referencing procedures, manuals etc.** |
|  | Governance structure, governance body / advisory board |       |
| Resource management, financial and personnel.  |  |
| Facilities / environmental conditions |       |
| Externally provided services  |  |
| Equipment  |  |
| Acquisition of BMaD  |  |
| Storage and disposal of BMaD  |  |
| Transport / Distribution (if applicable)  |  |
| Preparation / testing (if applicable)  |  |
| Traceability of BMaD  |  |
| Quality control of BMaD  |  |
| Method validation |  |
| In-house calibrations |  |
| Report requirements  |  |
| EA and ILAC mandatory documents |       |
| **In submitting this application for accreditation or extension for scope of accreditation, the CAB is confirming its view that:** |
|  | The biobank complies with ISO 20387 | Yes [ ]   | No [ ]   |
|  | The biobank complies with INAB mandatory policies, regulations and terms & conditions | Yes [ ]   | No [ ]   |
|  | The biobank is aware of and has reviewed all international mandatory documents relevant to biobank accreditation | Yes [ ]   | No [ ]   |
|  | The biobank has completed validation on all testing applied for | Yes [ ]   | No [ ]   |
|  | The laboratory has completed an internal audit against all requirements relevant to the application | Yes [ ]   | No [ ]   |

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| **7** | **ISO 17021-1, ISO 17065, ISO 17024 Certification Bodies** | **Briefly describe where the CAB complies, cross-referencing procedures, manuals etc.** |
|  | Management of independence and impartiality |       |
|  | Competence management |       |
|  | Review and decision making |       |
|  | Countries where certificate are issued |       |
|  | Subcontractors |       |
| **In submitting this application for accreditation or extension for scope of accreditation, the CAB is confirming its view that:** |
|  | The certification body complies with ISO 17065, ISO 17021-1, ISO 17024 | Yes [ ]   | No [ ]   |
|  | The certification body complies with INAB mandatory policies, regulations and terms & conditions | Yes [ ]   | No [ ]   |
|  | The certification body is aware of and has reviewed all international mandatory documents relevant to certification body accreditation | Yes [ ]   | No [ ]   |
|  | The certification body has completed the CB metric (PS7F1) for the scope applied for | Yes [ ]   | No [ ]   |
|  | The certification body has prepared the scheme in accordance with EA-1/22If N/A leave blank | Yes [ ]   | No [ ]   |
|  | The certification body has validated the scheme | Yes [ ]   | No [ ]   |
|  | The certification body has completed an internal audit against all requirements relevant to the application | Yes [ ]   | No [ ]   |
|  | The certification body has documented all activities and performed an analysis of impartiality and independence in relation to the application | Yes [ ]   | No [ ]   |
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| **8** | **Notified Bodies** | **Briefly describe where the CAB complies, cross-referencing procedures, manuals etc.** |
|  | Participation in (or information on) relevant standardisation activities and the activities of the notified body coordination group |       |

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| **9** | **ISO 17029, ISO 14065 Validation/Verification Bodies** | **Briefly describe where the CAB complies, cross-referencing procedures, manuals etc.** |
|  | Management of independence and impartiality |       |
|  | Competence management |       |
|  | Review and decision making |       |
|  | Countries where certificate are issued |       |
|  | Outsourcing |       |
| **In submitting this application for accreditation or extension for scope of accreditation, the CAB is confirming its view that:** |
|  | The certification body complies with ISO 17029, ISO 14065 | Yes [ ]   | No [ ]   |
|  | The certification body complies with INAB mandatory policies, regulations and terms & conditions | Yes [ ]   | No [ ]   |
|  | The certification body is aware of and has reviewed all international mandatory documents relevant to certification body accreditation | Yes [ ]   | No [ ]   |
|  | The certification body has completed the metric form (PS7F1) for the scope applied for  | Yes [ ]   | No [ ]   |
|  | The certification body has prepared the scheme in accordance with EA-1/22If N/A leave blank | Yes [ ]   | No [ ]   |
|  | The certification body has validated the scheme | Yes [ ]   | No [ ]   |
|  | The certification body has completed an internal audit against all requirements relevant to the application | Yes [ ]   | No [ ]   |
|  | The certification body has documented all activities and performed an analysis of impartiality and independence in relation to the application | Yes [ ]   | No [ ]   |

**PART B: INAB Document Review (New CAB Applicants Only)**

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| **Review of Documentation Submitted with the Application** |
| **INAB Review** *(include justification, if the application is for an extension to scope by correspondence)* | **For Follow Up and Discussion** |
|       |       |

**PART C: INAB Assessment Manager Review**

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| Recommendation, with justification, based on document review | [ ]  a preassessment visit is recommended[ ]  plans for the initial assessment can proceed[ ]  plans for an initial or preassessment cannot proceed[ ]  plans for an extension to scope assessment can proceed |
| Justification:       |
| CAB agrees to preassessment? Y/N |       |
| If needed:Complete IP53F1Complete AF3B (CAB and assessment manager)  |       |
| INAB assessment team selected. Inform CAB  |       |
| New assessors/experts needed. Inform CAB |       |
| Time-period for assessment/pre-assessment. Inform CAB |       |

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| Date of INAB review |       |
| Review completed by |       |