Submission of documentation in advance of an INAB assessment visit

PS10

1. Purpose

1.1. This statement sets out the Irish National Accreditation Board (INAB) policy on the submission of documents by a conformity assessment body (CAB – laboratory, certification body, validation/verification body, inspection body, or reference material producer) to INAB, prior to an assessment/surveillance/re-assessment visit or scheduled witnessed activity or as part of an extension to scope application. This documentation will enable assessors to prepare effectively for the visit and allow for better time management at the on-site visit thus ensuring an efficient assessment.

2. Statement

2.1. It is INAB policy that all CABs shall provide the information specified in sections 5-13 to INAB six weeks prior to a scheduled assessment visit, and six months prior to a to a scheduled extension to scope assessment (visit or by correspondence). Information specified in section 4 should be submitted in advance of initial and re-assessment visits to a CAB's head office. Late submission may result in cancellation of the visit due to inadequate preparation time available. A cancellation fee comprising the sum of expenses incurred for such a visit will be levied.

2.2. Please read all sections together, as multiple sections may apply depending on the nature of the assessment.

2.3. All documentation submitted to INAB must be uploaded to INAB CRM (please consult the user guides) via the INAB portal. A zipped folder with all documents for each team member; the folder shall be labelled as CABNAME_REGNO_DATEOFVISIT_ASSESSOR INITIALS.

2.4. The CAB is requested to advise INAB at time of submission of any requirements with respect to site health and safety and to inform INAB if any personal protective equipment (PPE) is required for the forthcoming visit.

2.5. INAB would appreciate the availability of a single meeting room and visitor Wi-Fi for the duration of the visit. If this cannot be provided please advise the assessment manager well in advance of the visit and as a note with PS10 documentation.

2.6. Please complete relevant section of PS10F1 form on the INAB website with all submissions for all assessors.

2.7. The CAB is reminded to immediately inform INAB of any changes to its operations which would impact on its ability to meet the applicable accreditation standard, INAB terms and conditions, regulations and other accreditation criteria.

2.8. In the case of initial assessments and extensions to scope, the purpose of the documentation requested in this policy statement is to enable a satisfactory document review to evaluate the CAB's system for conformity with the relevant standard(s) and other requirements for accreditation. For surveillance, the purpose is to help INAB assessment teams to prepare for assessments. In this case, the documentation to be submitted is mainly summary information.

2.9. During the performance of remote assessments or to clear nonconformities, some additional records may be requested which may contain personal information. The CAB is requested to redact details that will identify individuals. Should this redaction be unavoidable, INAB understands that the CAB has obtained consent from the individual(s) concerned. INAB record disposition information is found in the GDPR statement for clients on our website.

2.10. Summary table

PS10 Section		ISO 17025	ISO 15189	ISO 17034	ISO 20387	ISO 17020, ISO 17021-1, ISO 17024, ISO 17029, ISO 17065, ISO 14065
3	Documents to upload as a new applicant	All new applicants Please submit in advance of visit through INAB portal				
4	Documents required for each team member on the day of the visit	All CABs. Please submit in advance for initial assessment and reassessment (head office only; not required for witnessed activities conducted separately). For all other visits, please ensure these documents are available at the start of the visit.				
5	Documents for submission: ALL CABs	All CABs. Please submit in advance through INAB portal				
		ISO 17025	**ISO 15189**	**ISO 17034**	**ISO 20387**	**ISO 17020, ISO 17021-1, ISO 17024, ISO 17029, ISO 17065, ISO 14065**
6	Documents for submission: laboratories	Please submit in advance through INAB portal	Please submit in advance through INAB portal	X	X	X
7	Documents for submission: certification & inspection bodies, for head office visits	X	X	X	X	Please submit in advance through INAB portal
8	Documents for submission: reference material producers (RMPs)	X	X	Please submit in advance through INAB portal	X	X
9	Documents for submission: Biobanks (BB)	X	X	X	Please submit in advance through INAB portal	X
10	Documentation for submission: witnessed activities (certification and inspection)	X	X	X	X	Please submit in advance through INAB portal
11	Documentation for submission: notified bodies	X	X	X	X	Please submit in advance through INAB portal
12	Documentation for submission: new applicants and extensions to scope, all CABs	All CABs. Please submit with your application through the INAB portal For new applications and applications for extension to scope				
13	Documentation submitted for file review during Covid-19 and similar crises	X	X	X	X	Please submit in advance through INAB portal

3. Documents to upload as a new applicant

3.1. Quality manual/document demonstrating how the requirements of the relevant accreditation standard are met or cross reference document where policies and procedures are addressed;
3.2. For laboratories; the current validated procedures and validation/verification summary report.

3.3. Documents in Section 4 - 13 as appropriate, clearly labelled;
3.4. For notified bodies (see section 11 also):

3.4.1. List of harmonised standards linked to applied or accredited scope elements;
3.4.2. List of applicable guidance including any issued from notified body groups;
3.4.3. Summary evaluation of requirements – linked to applied or accredited scope elements;
3.4.4. Mechanism for provision of information to national authorities;
3.4.5. Mechanism for management of product recalls/failures and subsequent action and communication; and
3.4.6. Information on facilities used for testing, within and external to the EU (Blue Guide 5.2.2 refers)

4. Documents required for each team member on the day of the visit

Note: Please submit in advance for initial assessment and reassessment.
For all other visits, please ensure these documents are readily available on the day of the visit.

4.1. Schedule of all internal audits identifying planned and completed audits since last visit;
4.2. A copy of a recently issued report/certificate for all accredited disciplines;
4.3. Register and summary of nonconforming work investigation for each applicant/accredited area;
4.4. Primary sample collection manual (ISO 15189 only);
4.5. A review of conformity with mandatory documents (INAB DC1 refers) cross referencing internal documents/procedures;
4.6. Identification of all relationships with related organisations/third party organisations with an interest in the accredited area/extension to scope area[1];
4.7. A documented impact/risk analysis on impartiality and independence of CAB activities

5. Documents for submission: ALL CABs

5.1. Quality manual/document demonstrating how the requirements of the relevant accreditation standard are met, with a record clearly identifying any amendments made since the last visit;
5.2. Records of the most recent management review;
5.3. Organisation chart, highlighting changes to the reporting relationships or the structure of the CAB and related business units;
5.4. Current list of key personnel and deputies and detail of changes since the last INAB assessment;
5.5. Details of activity related to scope of accreditation and how the CAB manages the maintenance of competence in areas where there has been no activity;
5.6. Details of all critical and foreign locations where conformity assessment activities[2] are carried out or where offices are located;
5.7. Document describing changes to legislation affecting your scope of accreditation.
5.8. Records and CAB conclusions of the audit of the effectiveness of the corrective actions implemented in response to the nonconformities raised at the previous INAB assessment.
5.9. List of all organisations to which accredited activity is outsourced/referred/subcontracted.

[1] May not be applicable for laboratory accreditation
[2] Conformity assessment activities: testing, calibration, inspection, certification, verification, production of reference materials

6. Documents for submission: laboratories

In addition to the information listed in sections 4 & 5, the laboratory is required to submit the following:

6.1. Proficiency testing 5 year plan and performance covering the full accreditation cycle;
6.2. The investigation reference number for any out of specification results with a brief summary of conclusions;
6.3. For laboratories operating a flexible scope of accreditation, the current version of the List of Flexible Scope Changes (refer to INAB policy document, PS11);
6.4. Process flow diagram from sample receipt to reporting (if changed since last assessment);
6.5. The current list of blood fridges, a summary report of blood usage and a list of notifications to the National Haemovigilance Office of SAE/R since the last INAB visit;[3]
6.6. For laboratories accredited for Point of Care Testing, submit the POCT system summary (Appendix 1 in PS31));
6.7. Where applicable, a summary of amendments to accredited test methods since the previous visit;[4]
6.8. If the laboratory is completing in house calibrations please provide the following information:
  6.8.1. List of equipment calibrated in-house
  6.8.2. For each piece of equipment please provide the calibration method (SOP) and the calibration and measurement capability of the method
  6.8.3. Proficiency testing 5 year plan covering all calibration methods
  6.8.4. The investigation reference number for any out of specification results with a brief summary of conclusions
6.9. A list of laboratory test procedures including (where applicable) the published standard (national or international, including version or date) on which each procedure is based. Any addition to or deviation from the published standard shall be noted in this summary (see PS34/PS35).

7. Documents for submission: certification, inspection and validation/verification bodies for head office visits

In addition to the information listed in Sections 4 & 5, the CB/IB is required to submit the following:

7.1. Changes to the mechanism for safeguarding impartiality or involvement with related bodies;
7.2. Numbers of new certificates issued since the last head office visit, with associated IAF sector or technical area (CB);
7.3. Number of inspection certificates/reports issued since the last visit, identifying numbers issued outside Ireland;
7.4. Details of amendments to technical standards in response to required legislative updates;[5]
7.5. List of approved subcontractors with identified tasks; and
7.6. List of personnel authorised as competent in the conformity assessment activities.

8. Documents for submission: reference material producers (RMPs)

In addition to the information listed in Sections 4 & 5, the RMP is required to submit the following:

8.1. Changes to key authorized competent personnel that perform particular activities relating to RM production (personnel, including subcontractors, personnel of external bodies, or other individuals acting on the RMP's behalf);
8.2. Where an RMP uses subcontractors to undertake part of the production, include any changes to sampling, processing, handling, homogeneity and stability testing, characterization, storage or distribution of an RM,
8.3. RMP shall submit any changes to the planning stage or deviations from the production plan or the metrological traceability of the certified values or characterization study.

3 Blood bank laboratories

4 Where a laboratory makes a significant technical change or amendment to an accredited test method, the laboratory must make a written application to INAB. The laboratory shall not make a claim for accreditation for the amended test method until approved by INAB.

5 Other amendments involving significant technical changes, not related to legislative updates, must be applied for as an extension/amendment to scope prior to the introduction of the amendment.

9. Documents for submission: Biobanks (BB)

In addition to the information listed in Sections 4 & 5, the biobank is required to submit the following:

9.1. Changes to key authorized personnel that perform particular activities relating to the biobanking facility.
9.2. List of BMaD in the facility and any changes to the activities of the biobank since the last INAB assessment.
9.3. Summary EQA results, where applicable to the activity in the biobank.

10. Documentation for submission: witnessed activities (certification, validation/verification and inspection)

10.1. Copy of the audit/inspection plan, where applicable;
10.2. Previous client audit/inspection report completed by the CB/IB and certificate issued to the client, if applicable;
10.3. Location of, and directions to, the witnessed activity, with contact details for on-site personnel;
10.4. Records clearly showing that the competence of all personnel involved in the activity has been assessed and demonstrated;
10.5. Details of audit/inspection duration determination/calculation, where appropriate;
10.6. A copy of the audit/inspection procedure and the working documents used by the auditor/inspector.

11. Documentation for submission: notified bodies

11.1. Update on all information requested in section 3.3;
11.2. If applicable, list of certificates transferred from another notified body; and

12. Documentation for submission: new applicants and applications for extensions to scope, all CABs.

Please note timelines for submission of extension to scope applications (INAB R1). These documents are to be submitted with the application whether the application is to be assessed as part of the surveillance/re-assessment visit or as a standalone assessment event.

12.1. All: Scope elements to be entered on CRM including locations, if applicable; please note no claim of accreditation can be made until the assessment and decision are processed in INAB and communicated;
12.2. All: Completed AF108 form
12.3. Labs: validation/verification report and sign-off;
12.4. Labs: summary of proficiency testing/inter-laboratory comparison data;
12.5. Labs: test/calibration procedures;
12.6. CBs/IBs/VVBs: competence criteria matrix for authorised auditors/inspectors, reviewers and decision makers, as appropriate;
12.7. CBs/VVBs: scheme review, form AF3B (if applicable);
12.8. CBs/IBs/VVBs: audit/inspection checklists;
12.9. All: copy of proposed report/certificate for all elements of the application;
12.10. All: summary of outcomes of impartiality and risk analysis for the new activity;
12.11. All: Summary of training provided to all staff involved.
12.12. All: Internal audit of extension to scope

13. Documentation for submission: certification, validation/verification bodies and inspection bodies, submitting documentation for file reviews:

13.1. Number of certificates/reports issued against accredited scope
13.2. Client file to include:
13.2.1. Audit/inspection/examination report
13.2.2. Names of personnel involved in all aspects of the conformity assessment activity (auditor/inspector/examiner, reviewer, decision maker(if applicable))
13.2.3. Competence records for these personnel
13.2.4. Details of audit/inspection/validation/verification duration determination/calculation, where appropriate