

Submission of documentation in preparation for an INAB visit

PS10

1) Purpose

This statement sets out the Irish National Accreditation Board policy on the submission of documents by an Organisation to INAB, prior to an assessment/surveillance/re-assessment visit or scheduled witnessed activity.

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) Applicable CAB Sections

- 2.1) Section 4.1, all laboratories
- 2.2) Section 4.2, medical laboratories undergoing assessment for compliance with Articles 14 and 15 of the EU Directive 2002/98/EC (to also include section 4.1)
- 2.3) Section 4.3, calibration laboratories (to also include section 4.1)
- 2.4) Section 5 - certification bodies, head office visits
- 2.5) Section 6 - inspection bodies, head office visits
- 2.6) Section 7 - certification and inspection bodies, witnessed activity

3) Statement

- 3.1) It is the policy of the Irish National Accreditation Board (INAB) that all Organisations provide the information specified in clauses 4-7 to INAB six weeks prior to a scheduled witnessed activity or an assessment/surveillance/re-assessment visit, in the format outlined in clause 9 below.
- 3.2) The Organisation is reminded to immediately inform INAB of any changes to their operations which would impact on their ability to meet the applicable accreditation standard, INAB T&C, Regulations and other accreditation criteria.
- 3.3) Accredited CABs performing work in the regulated sector shall annually review relevant legislation and any other mandatory requirements to ensure continuing compliance. This review shall be available for INAB assessment teams.

3.4) Accredited certification and inspection bodies are requested to contact their INAB officer at the start of each year to provide proposed dates to meet (13.11 INAB publication P7 refers). The purpose of this meeting, among other things, is to allow adequate planning of witnessed audits/inspections for the coming year.

3.5) All CABs are required to review their compliance with mandatory documents (INAB DC1 refers) and submit a one page summary statement on compliance with each, cross referencing internal documents/procedures.

4) Documents For Submission: Laboratories

4.1) All Laboratories

4.1.1) Quality manual and record clearly identifying any amendments made to the quality manual since the last visit.

4.1.2) Schedule of all audits identifying planned and completed audits since last visit

4.1.3) Minutes of last Management Review meeting(s)

4.1.4) A Summary Report (no more than 1 page) of performance in Proficiency Testing schemes (PT) and Inter-Laboratory Comparisons (ILCs), where applicable. This summary report should comprise:

- ▶ The identity of the scheme
- ▶ The number of rounds completed and the parameters tested since the last visit
- ▶ The Organisation's performance in each round
- ▶ Out of specification results to be clearly identified.
- ▶ Brief summary of consequences and conclusions from investigations into any out of specification results

INAB does not require the Organisation to send the full data reports.

4.1.5) Where applicable, a list of amendments to any accredited test methods since the last visit to include the reason for the amendment along with confirmation that validation has been completed and the method remains fit for purpose. INAB does not require, at this stage, the amended test methods.

4.1.6) Where a laboratory makes a significant technical change or requests an amendment to an accredited test method, the laboratory must make a written application to INAB. Documentation and validation data as required on application forms AF-2-A and AF-2-D shall be submitted for consideration by INAB. The laboratory shall not make a claim for accreditation for the amended test method until approved by INAB.

4.1.7) A list detailing all instruments calibrated in-house which support measurements e.g. balance and temperature calibration. Information on activities that could be considered as performance checks is not required (see INAB Policy PS13).

- 4.1.8) A review of the relevant legislation affecting your scope of accreditation.
- 4.1.9) Records of the audit of the effectiveness of the corrective actions implemented in response to the nonconformities raised at the previous INAB assessment.
- 4.1.10) For laboratories operating a flexible scope of accreditation, the current version of the LAAT (refer to INAB policy document, PS11).
- 4.1.11) A copy of a recently issued test report.

4.2) **Medical Laboratories complying with Articles 14 and 15 of EU Directive 2002/98/EC** must provide the following in addition to documentation specified in section 4.1

- 4.2.1) Organisation chart outlining changes to the reporting relationships between Blood Bank and Haemovigilance and Traceability functions with the organisation;
- 4.2.2) Current list of liaison personnel for Haemovigilance and Traceability, identifying changes since the last INAB visit;
- 4.2.3) Identification of changes in relationship between the Blood Bank and recipient organisations;
- 4.2.4) Current schedule of Blood Transfusion Committee meetings;
- 4.2.5) List of notifications to the National Haemovigilance Office of SAE/R reports since the last INAB visit;
- 4.2.6) Summary report of blood usage since the last INAB visit;
- 4.2.7) Schedule of Blood Bank audits of Haemovigilance and Traceability functions;
- 4.2.8) Current list of SOPs specified in AML-BB;
- 4.2.9) Current process flow diagram for blood through and to/from the hospital;
- 4.2.10) Current list of blood fridges and identification of equipment changes since last INAB visit;

4.3) **Calibration Laboratories** must provide the following in addition to documentation specified in section 4.1

- 4.3.1) Matrix summary of inter-laboratory comparison (ILCs) participation for the period of the accreditation cycle (since assessment or re-assessment), to identify;
 - ▶ The Organisation's performance in each round
 - ▶ Out of specification results to be clearly identified.
 - ▶ Brief summary of consequences and conclusions from investigations into any out of specification results

INAB does not require the Organisation to send the full data reports.

4.3.2) A copy of a recently issued calibration certificate for each discipline accredited (e.g. temperature, mass, volume, etc).

4.3.3) Where a laboratory requests an amendment to an accredited calibration method (including measurement range or CMC, calibration and measurement capability), the laboratory must make a written application to INAB. Documentation and validation data as required on application forms AF-2-A and AF-2-D shall be submitted for consideration by INAB. The laboratory shall not make a claim for accreditation for the amended method until approved by INAB.

5) Documents For Submission: Certification Bodies (CB) for Head Office visits

5.1) Quality manual and relevant operational procedures and list of amendments, clearly identifying the changes;

5.2) Schedule of internal audits, indicating planned and completed audits since last visit;

5.3) Minutes of last management review meeting(s);

5.4) Changes to the structure of the organisation, changes to involvement with related bodies;

5.5) Details of any changes to the impartiality committee, where applicable;

5.6) Details of new certificates issued since the last head office visit, with associated EA sector or technical area;

5.7) Details of changes to legislation that have an impact on the scope of accreditation;

5.8) For CBs who produce/manage the drafting and maintenance of technical standards, amendments to standards in response to required legislative updates, authorised through the mechanism of the appropriate forum/technical advisory committee, will be assessed by INAB prior to each headquarters visit. INAB must be satisfied that all amendments have been made following appropriate procedures and with proper implementation of the CB's management procedures. Details of these amendments must be submitted to INAB. If it is discovered that controls have not been effectively implemented, sanctions may be imposed as per INAB regulations. Any other amendments involving significant technical changes, not related to legislative updates, must be applied for as an extension/amendment to scope. This must be done prior to the introduction of the amendment to allow for assessment by the team and decision by the manager.

5.9) Details of all critical and foreign locations where audits are carried out or where offices are located;

5.10) Details of activity related to scope of accreditation; in particular, related to areas of the scope where there has been no activity, and details of how the certification body manages the maintenance of competence in these areas;

- 5.11) A list of relevant operational procedures (e.g. auditor monitoring, competence evaluation); and
- 5.12) Records of an audit of the effectiveness of corrective actions implemented in response to any nonconformities raised at the previous INAB assessment.

6) Documents For Submission: Inspection Bodies (IB) for Head Office visits

- 6.1) Quality manual and relevant operational procedures and list of amendments, clearly identifying the changes and confirming they are based on the most recent standard;
- 6.2) Schedule of internal audits, indicating planned and completed audits since last visit;
- 6.3) Minutes of last management review meeting(s);
- 6.4) Changes to the structure to the organisation and the documented impact analysis on impartiality and independence with confirmation of Inspection Body 'type' (ISO 17020 Clause 4 refers) to include confirmation with justification of inspection body type (ISO 17020 Clause 4 refers);
- 6.5) Identification of each business, informal or any other relationship with third party organisations with an interest in the area of inspection together with the documented impact/risk analysis on impartiality and independence. This requirement must also be performed for other functions performed by the inspection body (e.g. certification, training, consultancy, etc). This analysis shall also include identification of related bodies. Note for Governmental inspection bodies, its position within Government must be clearly identified and evaluated for independence and impartiality;
- 6.6) Documented procedure for management of conflicts of interest;
- 6.7) A list of relevant operational procedures;
- 6.8) Details of changes to legislation that have an impact on the scope of accreditation;
- 6.9) Details of all critical and foreign locations where audits are carried out or where offices are located;
- 6.10) Details of activity related to scope of accreditation; in particular, related to areas of the scope where there has been no activity, and details of how the inspection body manages the maintenance of competence in these areas;
- 6.11) Completion in full of RM-IB form available on the INAB website at www.inab.ie
- 6.12) A Summary Report (no more than 1 page) of performance in Proficiency Testing schemes (PT), where applicable.
- 6.13) For accredited inspection contractors (AICs) implementing European Council Directive 1999/13/EC (S.I. 543/2002 and S.I. 199/2007), a copy of the inspection procedure(s) and inspection checklists for each accredited sector; and
- 6.14) Records of an audit of the effectiveness of corrective actions implemented in response to any nonconformities raised at the previous INAB assessment.

7) Documents For Submission: Conformity Assessment Bodies for the purposes of notification, Head Office visits:

In addition to the information listed in Sections 4 - 6, the CAB is required to submit the following:

- 7.1) Identification of any changes impacting on impartiality and independence;
- 7.2) Procedure for management of impartiality;
- 7.3) Summary evidence of ongoing involvement in Notified Body groups on the European level;
- 7.4) List of approved sub-contractors with identified tasks;
- 7.5) Notified body (NB) identification number;
- 7.6) List of personnel authorised as competent in the conformity assessment activities;
- 7.7) Summary log of communications with the Notifying Authority;
- 7.8) Summary of activity levels of certificates issued/suspended/withdrawn;

8) Documentation for Submission: Witnessed activities (Certification and Inspection)

- 8.1) Copy of the audit plan, where applicable;
- 8.2) Previous client audit report completed by the CB/IB, as applicable;
- 8.3) Location of, and directions to, the witnessed activity, with contact details for on-site personnel;
- 8.4) Records clearly showing that the competence of all personnel involved in the activity has been assessed and demonstrated;
- 8.5) Records of technical review of the witnessed activity;
- 8.6) Details of audit/inspection duration determination/calculation;
- 8.7) A copy of the audit/inspection procedure.

9) Health and Safety

The organisation is requested to advise INAB at time of submission of the above documentation of their requirements with respect to site health and safety and to inform INAB if any Personal Protective Equipment (PPE) is required for the forthcoming visit.

10) Format of Document Submission

Please submit:

- ▶ One complete set of documents for the INAB officer;

- ▶ One complete set of documents for the lead assessor;
- ▶ One set of relevant technical and quality documents for each technical assessor;
- ▶ Each set should be clearly labelled and separately sorted/packaged e.g. separate envelope.

11) Contact

For further information about this statement please contact an INAB officer at The Irish National Accreditation Board.

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