INAB Assessment Procedures P7

FOREWORD

The Irish National Accreditation Board (INAB) is the Irish national body, within a European network of accreditation bodies, with responsibility for accreditation in accordance with the relevant International Organisation for Standardisation (ISO) Standards and guides and the harmonised series of European standards. Bodies that demonstrate competence and conformity with the relevant criteria are awarded accreditation. Following award of accreditation, INAB monitors accredited bodies to ensure that conformity with criteria is maintained.

In keeping with the provisions and principles of EU Regulation 765/2008 (*"Setting out the requirements for accreditation and market surveillance relating to the marketing of products"),* it is INAB policy not to offer accreditation to conformity assessment bodies based outside Ireland.

In the INAB scheme for the accreditation of conformity assessment bodies (referred to hereafter as CABs), the relevant International Standards are as follows:

- ISO 15189, "Medical laboratories – particular requirements for quality and competence."
- ISO/IEC 17020, "General criteria for the operation of various types of bodies performing inspection"
- ISO/IEC 17021-1, "Conformity assessment - requirements for bodies providing audit and certification of management systems"
- ISO/IEC 17024, "Conformity assessment - general requirements for bodies operating certification of persons"
- ISO/IEC 17025, "General requirements for the competence of testing and calibration laboratories"
- ISO/IEC 17065 "Conformity Assessment – requirements for bodies certifying products, processes and services" ISO/IEC 14065, "Greenhouse gases – requirements for greenhouse gas validation and verification bodies"
- ISO/IEC 17034, "General requirements for the competence of reference material producers"
- ISO 20387 Biotechnology – Biobanking – General requirements for biobanking.
- ISO/IEC 17029, "Conformity assessment — General principles and requirements for validation and verification bodies"
- ISO 14065, "Greenhouse gases - Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition".

The above standards are available from www.standards.ie.

In the accreditation of CABs to these standards, on-site assessments play a key role. This publication has therefore been drawn up to provide CABs and assessors with guidance on preparing for the assessment visit, and on the procedures which will be followed during and after the visit.

See Appendix 1 at the end of this document for a list of forms used during the accreditation process.

See also publication *DC1 "INAB Mandatory and guidance documents – Policy & Index"* (available at www.inab.ie) for an index of all INAB documentation.

1. INTRODUCTION

1.1 The main function of INAB is to establish and attest the competence of CABs to carry out defined types of activities and subsequently to ensure by surveillance assessment and reassessment visits that the required standards are maintained. The purpose of this publication is to describe INAB procedures in carrying out preassessment, assessment, extension to scope and reassessment visits.

Assessment plays a central part in providing the evidence for which accreditation certificates and scopes of accreditation are awarded. When applying for accreditation each CAB gives basic information on its activities and staff in its application via the INAB CRM (Client Relationship Management) electronic system and on its administrative and operating procedures in its quality documentation which is submitted to INAB at the time of application.

It is essential, however, to check the work of the CAB by observation on-site. The purpose of this on-site assessment is to determine whether a CAB complies with the applicable accreditation standard and INAB accreditation requirements as detailed in INAB regulations and terms & conditions, and other relevant EA[1]/ILAC[2]/IAF[3] publications.

1.2 INAB uses technical assessors/experts on a contract basis to assist INAB in conducting assessments. All contracted personnel have appropriate training and experience in specialist fields and have been qualified by INAB against defined criteria. Assessment teams are required to operate a code of conduct when carrying out on-site visits (see INAB Policy Statement PS8, *"Code of Conduct for Assessment Visits"*).

1.3 The assessment procedures used by INAB must cater for all sizes of CABs carrying out a wide range of activities. Assessors will take this into account when judging whether the management systems of such CABs complies with the relevant accreditation standard and INAB requirements. References to "lead assessor" or "meeting of the assessors" may also be inappropriate to small CABs, where a single assessor, operating for one day, may be all that is required.

1.4 The CAB, if it is a laboratory (or, where applicable, an inspection body), may also be required to participate in proficiency testing, measurement audit or inter-laboratory comparisons as necessary (see INAB Policy Statement PS1, *"Policy on Proficiency Testing"*).

1.5 All information relating to the CAB during the application process is maintained confidential by INAB and its assessors, subject to Freedom of Information (FOI) requirements and General Data Protection Regulation (GDPR) requirements.

1.6 INAB has a suite of forms which the assessment team uses during the accreditation process (see Appendix 1).

1.7 Payment of Fees

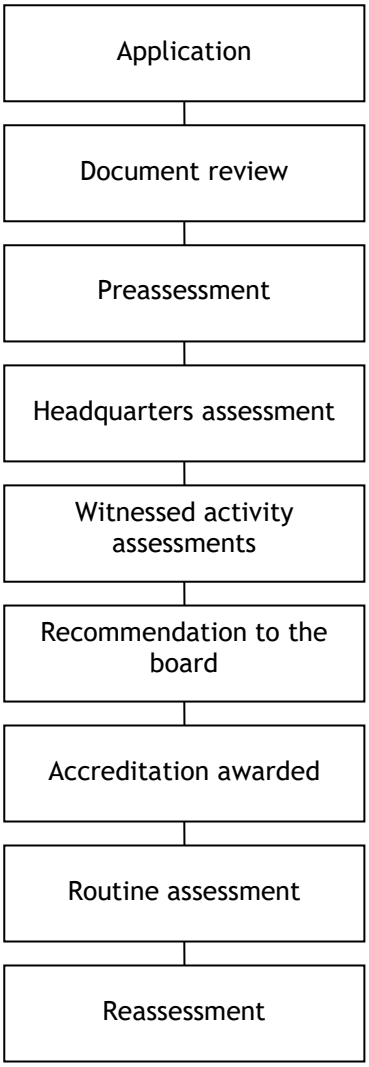
The cost of accreditation is outlined in the Schedule of Fees which is issued annually and is available on the INAB website. Initial assessment, surveillance assessment and reassessment fees depend directly on the amount of work required.

Accredited conformity assessment bodies are required to pay an annual membership fee and are invoiced at the beginning of each year. Depending on the type of body, fees for assessment visits, witnessed audits, and any other visits are invoiced during the year.

An application will be considered closed if the conformity/assessment body is inactive for a period of 180 days either in terms of payment of fees or responses to INAB. INAB will give 30 days notice of closure and once closed re-application and payment of fees will be necessary.

[1] European Co-operation for Accreditation
[2] International Laboratory Accreditation Co-operation
[3] International Accreditation Forum

THE ASSESSMENT PROCESS



Frequently (but not always) conducted, depending on applicant's readiness to proceed with HQ assessment.

Management system elements of the relevant accreditation standard are assessed.

For example, witnessing a test method in a laboratory, or witnessing an audit by a certification/inspection body.

Every 5 years.

See also INAB website for a detailed description of the accreditation process.

2. PREPARING FOR THE FIRST ASSESSMENT VISIT

2.1 Having decided to seek accreditation by INAB, a CAB is strongly recommended to review its current procedures and documentation against the requirements of the applicable accreditation standard, INAB regulations and INAB terms & conditions. During this internal review, the CAB should pay particular attention to its quality system and documentation and, if appropriate, to equipment calibration arrangements. If the review indicates a need for any modifications to existing procedures or documentation, then the CAB should arrange to have these carried out and be in operation prior to the assessment visit.

2.2 INAB will normally only accept applications from conformity assessment bodies that are established as a legal entity in Ireland, or where the assessment process is managed and controlled in Ireland. The terms & conditions and regulations documents are available on the INAB website and must be read by the applicant at the time of preparing an application. INAB Publication GD03, *"Guidance on the establishment of CABs in Ireland for the purposes of accreditation"* provides more information on this.

2.3 To initiate an application, the CAB should make either a telephone enquiry or an email enquiry through the Contact Us section of the INAB website.

2.4 INAB Administration will direct the CAB to the Accreditation Process section on the INAB website, https://www.inab.ie/about-us/about-accreditation/accreditation-process/.

2.5 This provides information from pre-application stage through to accreditation stage. All links to relevant documents, forms and standards are available under this section on the website. INAB Administration will provide a secure link to the CRM portal to facilitate CAB preparation and submission of the application.

2.6 The prospective applicant CAB is advised of the applicable EA, ILAC and IAF guidelines for the relevant field of accreditation and the web address/location, if appropriate at this stage also.

2.7 The CAB will be asked to complete the application through the INAB CRM. The necessary type of information required will relate to the information on the CAB's organisation structure, its staff and facilities.

2.8 Information on the types of conformity assessment activities for which accreditation is sought will also be requested as part of the initial application. It is important that this information is completed in detail to ensure clarity and to prevent any delays in processing the application. When the application is completed on the CAB portal with relevant documentation uploaded here also, the CAB submits the application to the manager of INAB. Copies of application forms and other INAB publications can be obtained from the INAB website at www.inab.ie. CRM CAB user manuals and CRM factsheets to assist in using the client CRM portal are listed in INAB Publication DC 1 and are available from the CAB portal library.

2.9 Independence, impartiality and integrity of inspection bodies:

2.9.1 Inspection Bodies may be Type A, B or C as defined in ISO 17020. Guidance on the definitions of Type A, B or C are given in ILAC P15 for all inspection bodies.

2.9.2 Type A inspection bodies shall be independent third parties engaged in inspection only. Bodies also involved in consultancy are unlikely to meet all the independence criteria in A.1 of annex A of ISO 17020. The IB, and its staff responsible for carrying out the inspection, shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user of maintainer of the items which they inspect, nor the authorized representative of any of these parties (Annex A.1 of ISO 17020 refers).

2.9.3 The inspection body which forms a separate and identifiable part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the

items it inspects and has been established to supply inspection services to its parent organization ONLY shall meet the criteria of a Type B Inspection Body. The parent company may be involved in other activities.

2.9.4 A Type C inspection body is involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects or similar comparative items and may supply inspection services to other parties not part of the parent organisation. It is required to have 'safeguards' (see Annex A of ISO 17020) within the organisation to ensure adequate segregation of responsibilities and accountabilities through appropriate structures.

2.10 Categories of testing and calibration laboratories:

2.10.1 Category A

Permanent calibration or testing laboratory where the laboratory is erected on a fixed location for a period expected to be greater than three years.

2.10.2 Category B

Site calibration and testing that is performed by staff sent out to a site by a permanent laboratory that is accredited by the Irish National Accreditation Board. This may include a site/mobile laboratory, testing or calibration at a customer premises, or medical point of care testing (ISO 15189).

2.11 It is INAB policy to define the scope of accreditation in terms as precise as possible. This is so that clients will know accurately and unambiguously the range of activities covered by a CAB's accreditation. Applicant CABs will therefore be required to specify, as precisely as possible, the types of activities for which accreditation is sought. The scope can be extended after initial accreditation when more resources become available to the applicant body. An applicant must be able to demonstrate competence in a given activity through work with a client in that scope area.

2.12 INAB CRM scope classification templates (STXCRM) provide assistance in the classification systems for conformity assessment activities. These are listed on INAB publication DC1 and are available on the INAB website.

2.13 On receipt of the application via CRM, an INAB staff member is appointed by the manager of INAB as the INAB assessment manager to the CAB. S/he will arrange for the services of an assessment team, bearing in mind the range, type of activity and other factors involved. The assessment team comprises a lead assessor (and an assessment manager where an external lead assessor is used), and a technical assessor and may include additional technical assessors as required for the requested scope of accreditation.

2.14 The assessment manager will inform the CAB of the proposed assessment team to ensure no potential conflicts of interest exist. The CAB may object to the appointment of any particular team members as long as such objection, on the grounds of a potential conflict of interest, is justified.

2.15 As part of its application, the CAB is asked to complete the CAB self-assessment (AF108) form and to submit documentation outlined in PS10. The lead assessor reviews the applicant's completed AF108 form and documentation (quality manual, relevant procedures, description of competence of personnel), to establish whether the applicant organisation has the necessary resources and capability to meet accreditation requirements.

The documentation review consists of a desktop study, set up as a 'Preliminary Review of Application' event on the CRM, and will review in particular:

- The scope of accreditation sought;
- The scheme applied for;
- That all checklist items have been completed by the CAB;

- The organisational structure of the applicant;
- The structure of the quality system; and
- The necessity for additional technical expertise.

2.16 Following the documentation review, the lead assessor records findings in the AF108 form, and uploads it to the CRM for access by the applicant so that any issues identified may be addressed and, if feasible, corrective actions implemented, before an on-site assessment is carried out. The lead assessor will consult with a technical assessor if necessary, and will comment on:

- Identified gaps where CAB has not implemented requirements;
- Whether the scope is correctly completed (if not, assign it back to the CAB via the CRM);
- Areas to follow up, prior to onsite assessment, if necessary; and
- Other matters of relevance.

2.17 By completing the AF108 form, the assessment manager makes a recommendation on how to proceed. A preassessment visit may be recommended in order to provide the assessor and the CAB with a better understanding of what the assessment visit will involve. If the lead assessor, having reviewed the application to determine the state of readiness of the CAB to proceed with its application, finds that the CAB falls substantially short of meeting the criteria for accreditation, s/he shall make a recommendation that the application be rejected. If the application is rejected, the CAB shall be informed, in writing, of the grounds for the decision.

2.18 Assuming all is in order, the assessment manager will arrange suitable dates with the CAB and the assessment team.

2.19 Applications from conformity assessment bodies operating from more than one location are processed depending on the activities taking place at each location. Of primary consideration is the extent of management control from a central office. INAB establishes the structures of the applicant body and its locations at the time of application and ensures that the applicant is aware of any consequences on an overall accreditation in the event of one or more locations failing to comply with the accreditation criteria.

2.20 During the setting up of assessment arrangements, INAB provides relevant documentation, records etc. to the assessment team via access to the applicant's uploaded documentation and information.

2.21 INAB uses a number of standard forms to reduce the administrative effort. They are self-explanatory, and reflect the sequence of actions during the preparation for an assessment visit.

2.22 When finalising the arrangements for the assessment visit, the CAB is asked to ensure that:

- Key members of the CAB's staff will be available on the date(s) of the visit
- These staff members are aware of the procedures which will be followed during the assessment process, particularly those described in sections 5, 6 and 7 below and
- A suitable room is made available for the assessors to meet from time to time, in order to discuss the progress of the assessment, to evaluate the observations made and to complete their paperwork.

3 OVERVIEW OF PREASSESSMENT VISIT PROCEDURES

3.1 The preassessment visit is normally carried out by the lead assessor (and the assessment manager, if an external lead assessor is used), and generally takes one day. The main purpose of the preassessment is to review the CAB's quality systems and procedures in a general way with the CAB management, and to review the facilities and any equipment, if

applicable to the activity being assessed. The assessment team will identify gaps in the CAB's quality system, in preparation for the initial assessment. This visit provides an opportunity for the CAB to discuss its application more thoroughly with the team and for the team to discuss the format of the assessment visit with the CAB. However, it is important that the INAB team should never stray into giving prescriptive advice; the team must exercise due care to avoid consultancy.

3.2 The lead assessor will complete a summary report and assessment trail report for the preassessment visit and will advise INAB if the CAB should progress to an assessment visit. The reports are uploaded to the CRM for access by INAB and the CAB.

3.3 The assessment manager, on being informed by the CAB of its decision to progress to assessment, will finalise the assessment team and arrange suitable dates for the assessment visit.

4. OVERVIEW OF ASSESSMENT VISIT PROCEDURES

4.1 Two weeks prior to the assessment visit, the assessment manager will make available, via the CRM, a completed visit plan to the CAB. The purpose of this visit plan is to detail what areas/activities will be assessed by each member of the assessment team and what specific activities will be witnessed during the assessment.

4.2 The assessment visit begins with an introductory meeting between the INAB assessment team and representatives of the CAB. This is followed by detailed discussions and observations of the CAB's system at work, to determine whether or not it meets the requirements of the relevant accreditation standard, the INAB regulations and INAB terms & conditions. During this stage each assessor will expect to be accompanied by a member of the CAB's staff nominated by the management and having responsibility for the particular section of work being assessed. Therefore a particular assessor may be accompanied by several different members of staff in the course of a visit. The visit ends with a closing meeting between the assessors and CAB's representatives at which each assessor presents his/her observations and the lead assessor sums up the findings of the team as a whole. The team will wish to meet in private to prepare for this closing meeting. For assessments lasting longer than one day, the assessors may also hold a brief review meeting at the end of each day to compare notes and discuss any changes in timetable which may have become necessary. An interim meeting may also be held with the CAB management if, for example, a member of the assessment team has completed his/her work.

5. THE INTRODUCTORY MEETING

5.1 The assessment starts with an introductory meeting at which the assessors and the CAB's representatives become acquainted, and the purpose of the assessment and what is expected of the CAB during the visit is clarified. The CAB representatives should include the quality manager and relevant technical management.

5.2 The meeting is normally chaired by the lead assessor, and covers the following points:

a) Introductions;
b) An explanation of the purpose of the assessment and the functions of the assessors, a description of how the assessment will be conducted and what forms will be used, and confirmation that the CAB staff understand the assessment procedure;
c) Discussion of the significance of the quality documentation;
d) Discussion of the scope of activities covered by the CAB's application and the terms in which the scope of accreditation should be defined;
e) A review of the assessment schedule and confirmation that a representative of the CAB has been assigned to accompany each assessor;

f) An explanation of the role of the CAB's representatives in the assessment, particularly in agreeing statements of fact concerning observations made by assessors which might indicate a nonconformity with the relevant accreditation standard, and/or INAB regulations and INAB terms & conditions;
g) An explanation that where possible and appropriate the accompanying CAB representative may propose corrective actions to observations raised;
h) Findings and non-conformities (NCs) and types (major/minor) and providing proposed corrective actions/plans;
i) Timeframes for clearance;
j) Reports (assessment reports , summary report);
k) CRM system, client portal, assessor portal;
l) Decision process (board/manager);
m) Scope of accreditation –CRM (content, classification, matrix type);
n) Assessment programme (content);
o) An explanation of what will happen at the closing meeting and confirmation of the time and venue;
p) An assurance that all findings will be treated in confidence subject to FOI (freedom of information) requirements;
q) Arrangements for providing an office and any administrative services needed by the assessors;
r) Confirmation of work hours, lunch break, etc.; and
s) An opportunity for the CAB's representatives to ask relevant questions.

6. EXAMINATION OF CAB OPERATIONS – Laboratories/Reference Material Producers / Biobanks

6.1 The most important part of the assessment consists of on-site observations of the laboratory/RMP/biobank going about its normal business. Assessors need to form a general impression of the organisation's capability, and in particular the suitability of the equipment / facilities for the work for which accreditation is sought. Equally, they need to assess the competence of the staff and the effectiveness of the management system in ensuring that errors are avoided. The assessment therefore proceeds by the assessors examining the operation of the general systems for ensuring the validity of test results / materials and then selecting particular areas of work for more detailed study.

6.2 In the case of laboratories, normally each assessor investigates the ability to perform one or more types of test or, in the case of a large laboratory, may concentrate on particular aspects of the laboratory's activities. S/he may select a specific test, whether it is currently being performed or not, and ask to see the apparatus involved (and the manufacturer's manuals) and enquire into its state of calibration. S/he may select items of work in progress and witness measurements and examine documentation concerning test items. S/he may trace back results from previously issued test reports to the original entries in the laboratory's notebooks.

6.3 The object of assessment is to establish by observation whether the work of the laboratory / biobank or RMP is conducted in accordance with the relevant accreditation standard and INAB regulations. To secure the greatest possible measure of agreement on the facts, and to avoid subsequent dispute, assessors are provided with nonconformity spreadsheets, for making an agreed record of any observation which may indicate a failure to comply with requirements. Use of these spreadsheets is described in section 8 below.

6.4 The majority of the technical requirements relating to the day-to-day operations of INAB accredited laboratories are covered by ISO 17025 or ISO 15189, for RMPs by ISO 17034 and ISO20387 for Biobanks, rather than the INAB regulations. Assessors are therefore mostly concerned with checking for conformity with the former. However the INAB regulations impose certain requirements which are not specifically covered by the above

mentioned standards. For example if the assessors find, during a reassessment or surveillance assessment visit, that since the last visit there have been significant changes in staff, equipment or range of services available they may wish to be assured that the changes have been properly notified to INAB as required by INAB regulations.

7. EXAMINATION OF CAB OPERATIONS – Certification, Verification and Inspection bodies

Witnessed activity

7.1 The purpose of a witnessed activity is to observe the audit/inspection/assessment procedures in practice and to ensure that the level of competence displayed by the audit/inspection/assessment personnel is such that credible certification/verification/inspection results.

7.2 The number of witnessed activities will depend on the nature and breadth of the scope of accreditation applied for, but is unlikely to be less than two in most circumstances. Other factors considered include the element of risk in a given industry, the country of operation and the processes involved. For management systems, at least one stage 1 audit (see ISO 17021-1) will be witnessed during an initial assessment.

7.3 When deciding on the number of on-site assessments needed, the following aspects will be considered:

- The fields and types of inspection/certification on the accreditation schedule;
- The certification/inspection body's procedures for selecting, training, authorising and monitoring auditors/inspectors, having regard to the qualifications and experience required for different fields and types of inspection;
- The results of internal audits from central office and locations;
- The locations from which auditors/inspectors operate;
- Any statutory requirements;
- The extent to which auditors/inspectors are required to exercise professional judgement; and
- Assessment of multiple locations (where applicable).

7.4 When deciding on the activities to be witnessed, account will be taken of the following:

- The variety of products, services, processes and plants covered by the activities;
- Skills needed by auditor/inspector;
- Statutory requirements; and
- The extent to which auditors/inspectors are required to exercise professional judgement.

7.5 When deciding on which auditors/inspectors will be assessed, account will be taken of:

- New recruits or new authorisations;
- Qualifications and experience;
- Location;
- Statutory requirements; and
- The extent to which auditors/inspectors are required to exercise professional judgement.

If no individual person can cover the entire scope of a specific field then more than one person will be assessed for that field. Where there is any evidence which casts doubt on the competence of staff, the sample size of auditors/inspectors assessed on site may be increased.

7.6 During the witnessed activity, the INAB team will need to see that as a minimum:

- The auditor/inspector has the competence for the activity performed;
- The auditor/inspector's competence is consistent with records;
- The auditor/inspector has access to all necessary documented procedures;
- The procedures are up-to-date;

- The auditor/inspector implements the procedures fully and correctly, i.e. no short-cuts, no personalised application where it is not permissible to do so;
- Records of all observations are made while on site as required by procedure;
- For inspection bodies, records clearly identify what has been inspected, using what method/procedure, and when;
- All findings that indicate immediate or urgent action are reported as required to the client whilst on site;
- Reports comply with the CAB requirements, to the relevant accreditation standard, to EA/IAF/ILAC guidance as appropriate and to relevant statutory requirements; and
- Facilities and equipment as appropriate are fit for purpose.

7.7 Where a witnessed activity is not conducted in English, the CAB may be required to pay the costs of an independent interpreter.

7.8 Where applicable at the opening meeting the CAB representative will be asked to allow the INAB lead assessor a chance to explain INAB's role and purpose to the organisation/person being audited/assessed.

7.9 The INAB assessor(s) will not participate in or otherwise influence the outcome of the witnessed activity, but will provide feedback to the auditor/verifier/inspector after his/her closing meeting.

7.10 The number of INAB representatives at on-site assessments will normally be two persons, one of whom will normally be a permanent INAB staff member.

7.11 For inspection bodies, it may be necessary to examine equipment and documentation, such as procedures and instructions, records, reports and planning arrangements. If an inspector operates from home, this examination will be arranged at a mutually acceptable location.

7.12 A report of the witnessed activity is produced and submitted to the applicant. This report also forms part of the eventual recommendation to the board of INAB.

8. NONCONFORMITIES

8.1 Nonconformities, recording possible failures of the CAB's conformity with the relevant accreditation standard or with INAB regulation, provide part of the objective evidence on which the team's recommendation to INAB will be based. A spreadsheet comprising the list of findings raised by each assessor must be completed by an assessor on the day of the visit while the situation is still clear in the minds of the assessor and the CAB's representative. This not only ensures that the report is accurate but it also enables the CAB's representative to signify his/her acknowledgement of the recorded facts at the end of the visit by signing the AF119 signature log sheet form. Apparent nonconformities will be discussed with the CAB's representative who may be able to point to an acceptable explanation. The CAB's staff will always be allowed to see what is being recorded.

8.2 Where several observations within the same section of the CAB's operation indicate repeated occurrences of a particular feature which might indicate a nonconformity, this collective deficiency may be recorded on a single nonconformity on the CRM NC spreadsheet avoiding the necessity of recording each occurrence individually.

8.3 For each finding the following information is recorded on the form:

- Details that allow the observation to be traceable
- The observed feature which does not comply with the relevant accreditation scheme or INAB regulations/terms & conditions
- Any documents involved
- The relevant clause(s) in the accreditation standard or INAB regulations

8.4 It is important to recognise that the NC spreadsheet is intended solely for recording **factual** observations, such as "Three samples being prepared for test X had no labels or

other form of identification" or "No calibration certificate could be provided for equipment Y". No attempt should be made at the time of recording an observation to classify its significance. Interpretation of all the recorded facts, in the context of INAB requirements, is carried out by the assessment team in conjunction with the lead assessor, in a private meeting prior to the closing meeting with the CAB's representatives.

8.5 Thus, while the CAB could disagree with the assessment team's recommendations to INAB, there should be no doubt concerning the observations on which these are based.

8.6 At the private meeting of the assessment team, findings must be carefully considered to determine whether or not nonconformities against the relevant accreditation standard or regulations are involved. Each is then classified as either a major or minor nonconformity. Findings that are considered as opportunities for improvement only are recorded in the assessment reports, not on the NC spreadsheet. Specific solutions shall not be recommended.

8.7 A minor nonconformity is allocated for a minor failure to comply with requirements, for example, for not providing an up-to-date specification for one particular test activity or for not providing adequate operating instructions for the staff using a particular piece of equipment (such incidents might be indicative of a more widespread lack of control, and they should prompt the assessor to probe more deeply).

8.8 A major nonconformity is allocated when the quality arrangements are demonstrably inadequate, or totally absent for a major aspect of the CAB's work. An example of this would be the complete absence throughout a CAB, or in several parts of a CAB, of a system for competence records for staff.

8.9 A major nonconformity may also be allocated when a number of similar minor nonconformities have been raised and where this indicates a possible weakness in a particular area of the quality or technical systems.

8.10 In the event that an INAB nonconformity from the previous year has not been effectively, or fully resolved at the subsequent INAB assessment, this shall be raised as a minor nonconformity requiring further work. The nonconformity should be raised again as a nonconformity linked to the current event, but the text should refer to the previous nonconformity reference.

8.11 If the CAB has made no attempt to resolve an INAB nonconformity from the previous year, this shall result in a major nonconformity.

8.12 The spreadsheet is then uploaded to the CRM, where each individual NC can be accessed and dealt with by the CAB via its portal to the CRM.

9. THE SUMMARY REPORT FORM (AF118)

9.1 After the assessors have completed their individual assignments, they hold a private meeting at which each can summarise his/her own findings and contribute to a co-ordinated view of the CAB's work. At this stage the lead assessor completes the summary report form, taking into account his/her own findings and those of the other assessors involved.

9.2 The summary report form summarises the assessors' findings, highlights matters needing corrective actions/plans and records the assessment team's agreed recommendations to INAB concerning the award of accreditation. This recommendation may be to award accreditation unconditionally, to award accreditation conditional on the satisfactory clearance of all nonconformities as raised during the assessment within the agreed timeframe, or to refuse accreditation. In exceptional circumstances where the assessment team cannot agree on the recommendation, the CAB will be advised that the recommendation is being postponed until the matter has been discussed with the manager of INAB.

9.3 The completion of the summary report form is one of the most important duties of the lead assessor. This document is a formal record of the team's observations and conclusions, and as such it must be factual and complete. It must always contain a concise judgment on the extent to which the CAB complies with the relevant requirements and a statement on the CAB's competence to carry out the types of activities for which accreditation has been sought. Because it summarises the observed failures to comply with requirements and is essentially a critical record, it must be carefully prepared to accurately reflect the actual findings.

9.4 The summary report form should not be simply a compendium of nonconformities. It should correlate deficiencies which indicate a general weakness in the system, e.g. "Three departures from the CAB's written procedures were observed (referring to relevant NCs), indicating a lack of management control and/or ineffective review procedures" or "The absence of written instructions in four important sections (reference) provides evidence of inadequate arrangements for ensuring conformity with clause X of relevant standard." Only deviations from the relevant accreditation standard or INAB regulations/terms & conditions should be cited, because these requirements are the formal basis of the assessment of the CAB's arrangements. The AF119 form is signed by all members of the INAB team to confirm accuracy of this report and other reports provided at the visit, and to confirm that confidentiality and conflict of interest requirements have been met.

9.5 If, in the opinion of an assessor with specialised experience, there is any reason to doubt the CAB's competence to perform any of the types of activity for which accreditation is sought, for example, through lack of experienced staff or, in the case of a laboratory or inspection body, faulty apparatus, this should be noted in the summary report.

9.6 The summary report form (AF118) should be completed at the private meeting and uploaded to the CRM at the end of the visit or as soon as possible after the visit. This form should not be used to express appreciation of facilities or hospitality provided by the CAB, which can be done verbally or by email.

9.7 In addition to the summary report and the nonconformities given in the CRM portal, further reports in the X116 series (plus their annexes if applicable) are completed, which summarise the areas reviewed, the personnel interviewed, and contain cross-references to the completed nonconformities. Different reports are generated depending on the type of CAB and the relevant accreditation scheme; see Appendix 1 for details. In cases where an assessment involves more than one accreditation standard, separate reports must be used for each standard. These reports may not be provided on the day of the assessment, but will be provided as soon as possible afterwards. If, in exceptional circumstances, the report differs from the outcome given at the close of the assessment visit, an explanation for this will be given in writing to the CAB. However, the recommendation given by the assessment team on the day of the assessment should not change.

10. FACTORS AFFECTING THE ASSESSMENT TEAM'S RECOMMENDATION

10.1 In agreeing on its recommendations the assessment team will take into account the number and importance of the individual nonconformities brought to light during the assessment, as well as the general performance of the CAB. If, for example, a major nonconformity was discovered during the assessment, this would provide grounds for not recommending accreditation.

10.2 Where there are relatively few minor nonconformities, the assessment team may under certain circumstances recommend award of accreditation. However, all recommendations for accreditation which involve outstanding nonconformities should be conditional upon them being corrected within a specified time (normally not exceeding 3 months). For surveillance assessments, recommendations for maintenance of accreditation are conditional on minor NCs being corrected within 1 month, and major

NCs within two weeks). This information is included, where appropriate, in the summary report. The representative of the CAB will be asked to countersign the AF119 report, to emphasise the conditional nature of the agreement and recommendation.

10.3 The assessment team should take into account the number and importance of the individual nonconformities found during the assessment, together with other factors, particularly the general attitude and ability of the management to correct them, in deciding whether or not to recommend conditional accreditation. In the case of an initial assessment, the assessment manager will then prepare a report containing the recommendation for consideration by the board of INAB, who make the decision on accreditation. In the case of surveillance, unannounced visits, extension to scope or reassessment visits, the assessment manager presents the report and assessment team's recommendation to the manager of INAB who makes the decision on maintenance of accreditation and extensions to scope for routine extensions. For significant extensions to scope, decisions are made by the board of INAB (see section 13).

11 THE CLOSING MEETING

11.1 The closing meeting between the assessment team and the CAB's representatives is held after the lead assessor has completed the summary report, incorporating the assessment team's agreed recommendations which s/he will present to INAB. At this meeting the lead assessor will cover the following matters:

- Thank the CAB for their assistance and co-operation and refer to individuals as appropriate;
- Give, with the assistance of other assessment team members, a brief verbal presentation on the findings of the assessment of the CAB. Questions should be deferred until after the findings have been presented;
- Emphasise that because the assessment did not cover every aspect of the CAB's activities it cannot be guaranteed that no deficiencies exist in areas where none have been reported;
- Discuss and record the statement of scope of accreditation being recommended in the light of the assessment findings;
- Inform the CAB of the assessment team's intended recommendations to INAB;
- Point out any corrective action that may be called for as a condition of recommendation of accreditation, and try to reach agreement on a timetable for its implementation and on the method of verification to be used; and
- Ask the representative from the CAB to sign the AF119 report in acceptance of the recommendation and findings.

11.2 Upload the NC reports and the AF118 report to the CRM if possible or else provide the CAB with a copy if facilities are available and upload reports to the CRM event as soon as possible following the visit. The lead assessor will then close the meeting.

11.3 The closing meeting must be conducted with impartiality and with an objective, professional approach by the assessment team. The lead assessor will make it clear in his/her opening remarks that the objective of the assessment is to assess the CAB's conformity with the relevant accreditation scheme requirements, INAB regulations and terms & conditions.

11.4 In presenting the summary report, the team must not be drawn into debating the validity of their conclusions or the recommendations. If these are questioned, the lead assessor may, however, enumerate the individual nonconformities, which justify the recommendations in question and point out the combined effect of the observations of his assessment. If the CAB is still unwilling to accept the recommendations, or implement corrective actions, or contests the overall assessment, the lead assessor will advise it to capture this in the AF119 from and to take up the matter with the INAB Executive so that its input will be taken into account when the decision is being made.

12. POST-ASSESSMENT PROCEDURES

12.1 In cases where accreditation is conditional on specific corrective actions/plans being implemented by the CAB, INAB will require evidence that the required measures have been taken before issuing the certificate of accreditation. In many cases it will be possible to provide the evidence to INAB (e.g. revised procedure documents, up-to-date competence records, etc.) electronically using CRM. Refer to CRM 2, "*INAB CAB Portal User Guide.*" Sometimes, however, an additional visit to the CAB may be necessary (e.g. to verify the satisfactory implementation of the corrective actions/plans), and the cost of such additional visits will be charged to the CAB. See clause 15 below for further details.

12.2 The CAB is required to submit to INAB a complete set of responses to all nonconformities raised.

12.3 The relevant assessors review the submission for clearance via the INAB CRM system. Refer to CRM 1, "*INAB Assessor Portal User Guide.*" When the assessment team is satisfied that all nonconformities have been closed, the assessment manager then prepares a report presenting the recommendation to the board of INAB for decision. The board may award accreditation either conditionally or unconditionally or may refuse accreditation. The secretary to the board of INAB will then formally notify the CAB of the board's decision.

13. SURVEILLANCE ASSESSMENTS, EXTENSION and REASSESSMENT

13.1 Following the granting of INAB accreditation the CAB will receive regular surveillance assessment and reassessment visits. Their purpose is to determine whether a CAB is continuing to comply with the relevant accreditation standard and INAB regulations. Similar procedures to those described in the previous sections will be followed for the conduct of these visits. In addition the assessment team will verify the effective implementation of corrective actions from the previous visit. An assessment programme (in the RMxxx series; see Appendix 1) for the full accreditation cycle is developed for each CAB, to ensure that that the conformity assessment activities representative of the scope of accreditation at the relevant locations are assessed during the accreditation cycle.

13.2 The first surveillance assessment visit is normally carried out 6 months after the date of accreditation and annually thereafter with a reassessment visit normally taking place every 5 years. Where possible, it is INAB policy, to change assessors at reassessment in order to maintain impartiality.

13.3 INAB also carries out visits at shorter intervals than usual both with and without prior warning as a tool to monitor the continued implementation of the relevant accreditation standard and INAB regulations.

13.4 A CAB may apply for an extension to its scope of accreditation by completing the relevant application for extension to scope via the CRM, with the relevant procedures and data, at least 6 months prior to the next scheduled surveillance assessment visit, to ensure that the extension can be accommodated at that visit if possible.

13.5 The application is reviewed to determine whether additional INAB assessment work is required. Where feasible, the additional assessment work will be carried out in conjunction with a surveillance assessment visit or reassessment.

13.6 Extensions to scope may, in some circumstances, be processed by correspondence.

For laboratories and reference materials producers (as applicable), changes like the following would not normally require an on-site visit by INAB, and can be considered for extension to scope by correspondence (please note this list is not intended to contradict existing INAB policies):

- If additional, replacement or upgraded analyser/equipment of the same type from the same manufacturer is used, using the same measurement principle;
- Changed or expanded panels are used (e.g. for organism identification/susceptibility testing, genetic mutations/gene sequences, autoantibodies/specific IgE);
- If a new or changed test kit is used, that is not significantly different from the existing one;
- New sample types that are not significantly different from existing;
- New analytes, targets, staining methods, probes, antibodies or measurement principles used with existing analysers/equipment;
- If there is a change of reference/validated method range
- (RMPs only) If there is a change to characterisation range and associated uncertainty.

For certification and inspection bodies, the following factors are taken into consideration:

- If existing auditor/inspector staff are used
- If the risk associated with the new activity is no greater than the current activity
- If the CB/IB documentation demonstrates that competence criteria for the extended activity have been developed, and that the competence of auditor/inspector staff has been assessed against those criteria (if allowed by INAB PS22).

13.7 Decisions on maintenance of accreditation, where no extension to scope is processed, are made by the INAB manager.

13.8 Decisions on reassessment or extension to scope in the same field are made by the manager of INAB following his/her review of the report and recommendation, completed by the assessment manager.

13.9 Decisions on extension to scope in a different field are made by the board of INAB. Examples include (please confirm with the assigned assessment manager):

- For testing, extending to a new scope classification in the STxxCRM series of documents (e.g. extending scope to include chemistry when existing scope is for biological testing);
- For calibration, extending to a new sub-scope classification within ST8CRM (e.g. extending scope to include volume when existing scope is for mass);
- For management systems certification, extending to include a new sub-scope (e.g. extending scope to include ISO 14001 when existing scope is for ISO 9001);
- For product certification, extending to include a new product/process/service (level 2 description as per ST12CRM);
- For certification of persons, extending to include a new competence specification (level 1 heading as per ST13CRM);
- For inspection bodies extending to include a new inspection field (level 1 description as per ST9CRM);
- For biobanks – extending to include a new category of biological material as per ST25CRM
- For validation and verification, extending to include validation/verification/new area of activity (level 2 description in ST26CRM).
- For reference materials producers, extending to include a new reference material category (level 1 description as per ST15CRM); and
- All cases where extension to scope involves accreditation for the purpose of notification.

13.10 The assessment manager is responsible for notifying the CAB of the decision on accreditation.

13.11 For certification bodies, INAB also requires a minimum number of witnessed audits to be completed each year for any accredited organisation as part of surveillance assessment activities. The number and applicable sectors of witnessed audits is normally established with each accredited organisation at the start of each year. At a minimum, 2 successful witnessed audits per organisation per accreditation standard are required to be completed annually. Failure to complete the required schedule of witnessed audits in the year may result in suspension of accreditation.

13.12 Other witnessed audits arising from concern over the performance of an accredited CB shall be determined as needed.

13.13 For inspection bodies, INAB also requires that a minimum number of witnessed inspections are completed annually; information supplied as part of the inspection body risk analysis (RMIB) will determine the level of witnessing undertaken.

13.14 At the start of each year, INAB may meet with CABs with large or complex scopes to plan the work programme for the coming year. At this meeting, approximate dates for the head office visits and INAB's witnessed activity requirements are agreed. An estimate of costs for the coming year is provided by the assessment manager. This is also an opportunity for the CAB to discuss any queries/concerns with INAB outside the normal assessment process.

A mid-year progress review may be held between INAB and CAB to discuss scheduling of visits and any other issues.

14. SPECIAL VISITS

14.1 Should information come to the attention of INAB, either through its own activities or from other sources, that casts doubt on an accredited body's continued conformity with accreditation criteria, a special visit may be conducted. The conduct of a special visit will depend on circumstances, but where applicable and to the extent possible the process follows that described in this document.

14.2 INAB also operates a policy of conducting unannounced visits on a randomly selected number of accredited organisations every year. See policy statement PS6 ("INAB policy on unannounced visits to INAB accredited organisations") for further details.

15. ADDITIONAL VISITS

15.1 The purpose of an INAB additional visit is to verify the effective implementation of the corrective actions raised at assessment/surveillance assessment/reassessment/ witnessed audit visits and to assess conformity to the relevant standard and accreditation criteria.

15.2 The assessment team for additional visits may include the assessment manager, a lead assessor and/or additional technical expertise as considered appropriate.

15.3 During the assessment at the additional visit and in exceptional circumstances, minor nonconformities may be identified. A maximum of 2 weeks from the date of the additional visit is allowed to clear these minor nonconformities.

15.4 Failure by the organisation to clear the nonconformities within the specified timeframe will result in a recommendation for refusal/suspension of accreditation.

15.5 Where major nonconformities are raised during an additional visit, the recommendation by the assessment team will normally be for refusal/suspension of accreditation. Failure to effectively implement corrective actions from the previous assessment visit will normally result in a major nonconformity being raised.

15.6 Prior to an additional visit, the organisation will be required to submit an audit of the effectiveness of the corrective actions implemented arising from nonconformities generated during the previous assessment visit.

16. SUSPENSION/WITHDRAWAL OF ACCREDITATION

16.1 Accreditation may be suspended or withdrawn if the conformity assessment body fails to meet INAB's requirements. In such instances INAB may decide on partial or complete suspension or withdrawal, citing its reasons. A decision can be implemented with immediate effect. Appeals against the decision of INAB will be referred to the INAB appeals committee whose decisions are final and binding on both INAB and the appellant.

16.2 INAB shall publish the name, contact details, scopes of accreditation and effective dates of the change in accreditation status of CABs on its website.

17. RESIGNING ACCREDITATION

17.1 For varying reasons a conformity assessment body may wish to resign its accreditation. Written notice via a CRM change request is required by INAB on the decision to withdraw.

18. ACCREDITATION SYMBOL

18.1 Only accredited conformity assessment bodies are authorised to use the INAB accreditation symbol. The regulations concerning the use of the symbol are detailed in the INAB regulations. Clients of the CAB are not permitted to use the INAB symbol.

19. CERTIFICATE OF ACCREDITATION

19.1 Conformity assessment bodies are issued with a certificate of accreditation. This details the scheme/standard, the activity and a unique accreditation number.

20. DIRECTORY OF ACCREDITED BODIES

20.1 INAB keeps a directory of accredited bodies, detailing the name and address, the responsible person(s), the accredited activity and accreditation number. See the INAB website at www.inab.ie.

21. CROSS-FRONTIER ACCREDITATION

21.1 Conformity assessment bodies providing INAB accredited services outside of Ireland are required to notify INAB of the countries concerned. Where certification business is conducted using overseas partners, agencies, joint ventures etc., these must also be notified to INAB.

22. MULTI-SITE ACCREDITATION

22.1 An applicant that operates from a central office through a number of locations may seek a single accreditation provided that conditions, as specified by INAB, are fulfilled (see INAB Policy Statement PS19 *"Policy on the accreditation and assessment of multi-site and cross-border conformity assessment bodies" available at www.inab.ie*).

22.2 On application, the CAB must indicate the number and range of locations being operated.

22.3 Selected locations will be visited, taking into account:

- The effectiveness of the management control by the central office of the inspection body of the activities of its network of locations;
- The results of internal audits from central office and locations;
- The results of management reviews;
- Variations in the size of locations;
- Complexity of the quality system;
- Complexity of the locations;
- Variations in working practices including, where applicable, equipment used; and

- Variations in activities undertaken e.g. fields/types of inspection/ calibration/testing/certification.

22.4 If the CAB operates in other countries from premises from which one or more key activities are performed, then all such premises will be subject to the same assessment as the head office at the initial assessment stage. Once accredited, these CAB premises will be assessed on a sample basis throughout the assessment period, ensuring that all are examined at least once between reassessments.

(See EA-2/13, available from www.european-accreditation.org)

22.5 It will normally not be necessary to witness the full range of scopes for each selected location, but where a conformity assessment body manages its operations through a number of locations, the assessment of these will be on a sample basis, ensuring that each is assessed at least once every five years. However, the level of sampling of locations and auditors/inspectors/activities will depend on performance over the five year cycle, the extent of any changes which have taken place and the level of confidence which can be placed in the performance measures and control systems of the CAB.

22.6 INAB will seek to establish through objective evidence and by using various techniques that:

- The same quality system in operation for all locations is appropriate and effective to the CAB's needs, arrangements and methods of operation, including multiple location operations and number of staff
- All of the requirements of the relevant accreditation standard have been satisfactorily addressed and
- All locations are included in the internal audit programme and central review process.

22.7 Temporary locations must be working to the same requirements and may be subject to assessment on a sampling basis as part of the accreditation process to provide evidence of the operation and effectiveness of the system.

22.8 During the central office assessment, INAB may need to see records of certain activities which are being carried out at different locations.

22.9 If INAB observes nonconformities at the central office or at any one of the locations of an organisation with multiple locations, the corrective action procedure shall apply to all applicable locations. In the event that the results of any of the assessments of sample locations reveal that there is a significant weakness or inconsistency in the application of the quality system, INAB will review the assessment programme and may increase the number of locations to be assessed.

22.10 Failure by one location to comply with INAB requirements may lead to removal of the location from the schedule of accreditation. If the cause of nonconformity is the lack of central control then the corporate accreditation will be the subject of review by INAB and this may lead to suspension or withdrawal of accreditation from all locations.

23. ACCREDITATION FOR THE PURPOSES OF NOTIFICATION

23.1 INAB will accredit CABs for the purposes of notification in relation to EU legal provisions.

23.2 Applicants shall be required to have engaged with the relevant Irish notifying authority in advance of submitting an application and have obtained approval for the conformity assessment standard applied for.

23.3 Applicants will be required to demonstrate their active participation in notified body groups at European level.

23.4 INAB shall communicate decisions and other issues to the relevant Irish notifying authority on an ongoing basis and as necessary.

APPENDIX 1: INAB Assessment Form Matrix

For assessor use[4]; For CAB use; INAB CRM

INAB Process	Laboratory ISO 17025	Laboratory ISO 15189	Cert Body ISO 17065	Cert Body ISO 17021	Certification Body ISO 17024	Inspection Body ISO 17020	Biobank ISO 20387	Reference Material Producer ISO 17034	Validation and verification ISO 17029
Application	CRM	CRM	CRM	CRM	CRM	CRM	CRM	CRM	CRM
Applications - accreditation checklists	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
CAB self-assessment and INAB document review[5]	AF108	AF108	AF108	AF108	AF108	AF108	AF 108	AF108	AF108
Preassessment onsite	AF118/F116	AF118/MF116	AF118/Prod116	AF118/MSC116	AF118/F116	AF118/IF116	AF118/BB116	AF118/RM116	AF118/VVF116
Head office summary	AF118	AF118	AF118	AF118	AF118	AF118	AF118	AF118	AF118
Head office assessment trail	F116	MF116	Prod116	MSC-F116	PerCB-F116	IF116	BB116	RM116	VVF116
Flexible scope	AI-FS	AI-FS							
AML-BB annex (AII)		AII-HV&T							
POCT		MF116							
Witnessed activity			F-WA	F-WA	F-WA	F-WA			F-WA
ISMS annex				A-III ISMS					
EnMS annex				A-IV EnMS					
FSMS annex				A-V FSMS					
CB file review annex			Annex XVIII-FR	Annex XVIII-FR	Annex XVIII-FR	Annex XX-IBFR			Annex XVIII-FR

[4] The lead assessor completes the AF118 and the flexible scope annex in all cases; technical assessors each complete an X116 form, plus associated annex, depending on the discipline being assessed. Technical experts may complete their own x116 form and annex if familiar with the assessment standard; otherwise, they contribute to the lead assessor's report; in this scenario the individual assessor/expert contributions shall be clearly identified.

[5] To record the results of the document review completed during preliminary review of the application, the lead assessor/assessment manager complete parts B & C of the AF108 form after part A is completed by the CAB.

INAB Process	Laboratory ISO 17025	Laboratory ISO 15189	Cert Body ISO 17065	Cert Body ISO 17021	Certification Body ISO 17024	Inspection Body ISO 17020	Biobank ISO 20387	Reference Material Producer ISO 17034	Validation and verification ISO 17029
Scheme evaluation annex			AF3B	AF3B	AF3B	AF3B			AF3B
Nonconformities	CRM	CRM	CRM	CRM	CRM	CRM	CRM	CRM	CRM
Visit plan	CRM	CRM	CRM	CRM	CRM	CRM	CRM	CRM	CRM
Signature sheet	AF119	AF119	AF119	AF119	AF119	AF119	AF119	AF119	AF119
Assessment programme	RMLAB	RMLAB	RMCB/CWM	RMCB/CWM/AP-CB-CAB	RMCB/CWM	RMIB	RMBB	RMRMP	RMVV/CVM
	NOTIFIED BODIES *(the above forms, plus the following)*								
CPR Regulation Annex	A-VI CPR		A-VI CPR						
Machinery Directive Annex			A-VII MD A-VIIa						
Transportable Pressure Equipment Annex						A-VIII TPED			
Pressure Equipment Directive			A-IX PED	A-IX PED	A-IX PED	A-IX PED			
Marine Equipment Directive			A-X-MED	A-X-MED					
Electromagnetic Compatibility Directive			A-XI-EMC			A-XI-EMC[5]			
Radio Equipment Directive			A-XII-RED			A-XII-RED[6]			
Recreational Craft Directive			A-XIII-RCD			A-XIII-RCD			
Personal Protective Equipment Regulation			A-XIV-PPE						
Non-automatic Weighing Instruments Directive			A-XV-NAWI						

[6] For a transitional period, ending 14th April 2023 (see EA-2/17:2020)

INAB Process	Laboratory ISO 17025	Laboratory ISO 15189	Cert Body ISO 17065	Cert Body ISO 17021	Certification Body ISO 17024	Inspection Body ISO 17020	Biobank ISO 20387	Reference Material Producer ISO 17034	Validation and verification ISO 17029
Measuring Instruments Directive			A-XVI-MID	A-XVI-MID		A-XVI-MID			