

## Guide to INAB Assessment Procedures

P7

### TABLE OF CONTENTS

FOREWORD .....	2
1. INTRODUCTION .....	3
2. PREPARING FOR THE FIRST ASSESSMENT VISIT .....	5
3. OVERVIEW OF PRE-ASSESSMENT VISIT PROCEDURES .....	7
4. OVERVIEW OF ASSESSMENT VISIT PROCEDURES .....	7
5. THE INTRODUCTORY MEETING .....	8
6. EXAMINATION OF CAB OPERATIONS - laboratories .....	8
7. EXAMINATION OF CAB OPERATIONS - certification and inspection bodies .....	9
8. THE DETAIL REPORT FORM (AF117) .....	11
9. THE SUMMARY REPORT FORM (AF118) .....	12
10. FACTORS AFFECTING THE ASSESSMENT TEAM'S RECOMMENDATION .....	13
11. THE CLOSING MEETING .....	13
12. POST-ASSESSMENT PROCEDURES .....	14
13. SURVEILLANCE, EXTENSION and RE-ASSESSMENT .....	14
14. SPECIAL VISITS .....	15
15. ADDITIONAL VISITS .....	16
16. SUSPENSION/WITHDRAWAL OF ACCREDITATION .....	16
17. RESIGNING ACCREDITATION .....	16
18. ACCREDITATION SYMBOL .....	16
19. CERTIFICATE OF ACCREDITATION .....	17
20. DIRECTORY OF ACCREDITED BODIES .....	17
21. CROSS FRONTIER ACCREDITATION .....	17
22. MULTI-SITE ACCREDITATION .....	17
23. ACCREDITATION FOR THE PURPOSES OF NOTIFICATION .....	17

## 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 EN 45000 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/IEC 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, “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”
- EN 45011 (ISO/IEC Guide 65), “General requirements for bodies operating product certification systems”

The above standards are available from [www.standards.ie](http://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 documentation used during the accreditation process. See also publication DC1 (available at [www.inab.ie](http://www.inab.ie)) for an index of all INAB documentation.

INAB Executive  
July 2010

## 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 and re-assessment that the required standards are maintained. The purpose of this publication is to describe INAB procedures in carrying out pre-assessment, assessment, surveillance and extension to scope visits.

Assessment plays a central part in providing the evidence for which certificates and scopes of accreditation are awarded. When applying for accreditation each CAB gives basic information on its activities and staff in the application form and on its administrative and operating procedures in its quality manual 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, INAB accreditation requirements as detailed in INAB regulations and terms & conditions, and other relevant EA<sup>1</sup>/ILAC<sup>2</sup>/IAF<sup>3</sup> 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 Teams conducting assessments for INAB"*).
- 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 quality system 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 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. Assessment, surveillance and re-assessment 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 surveillance 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

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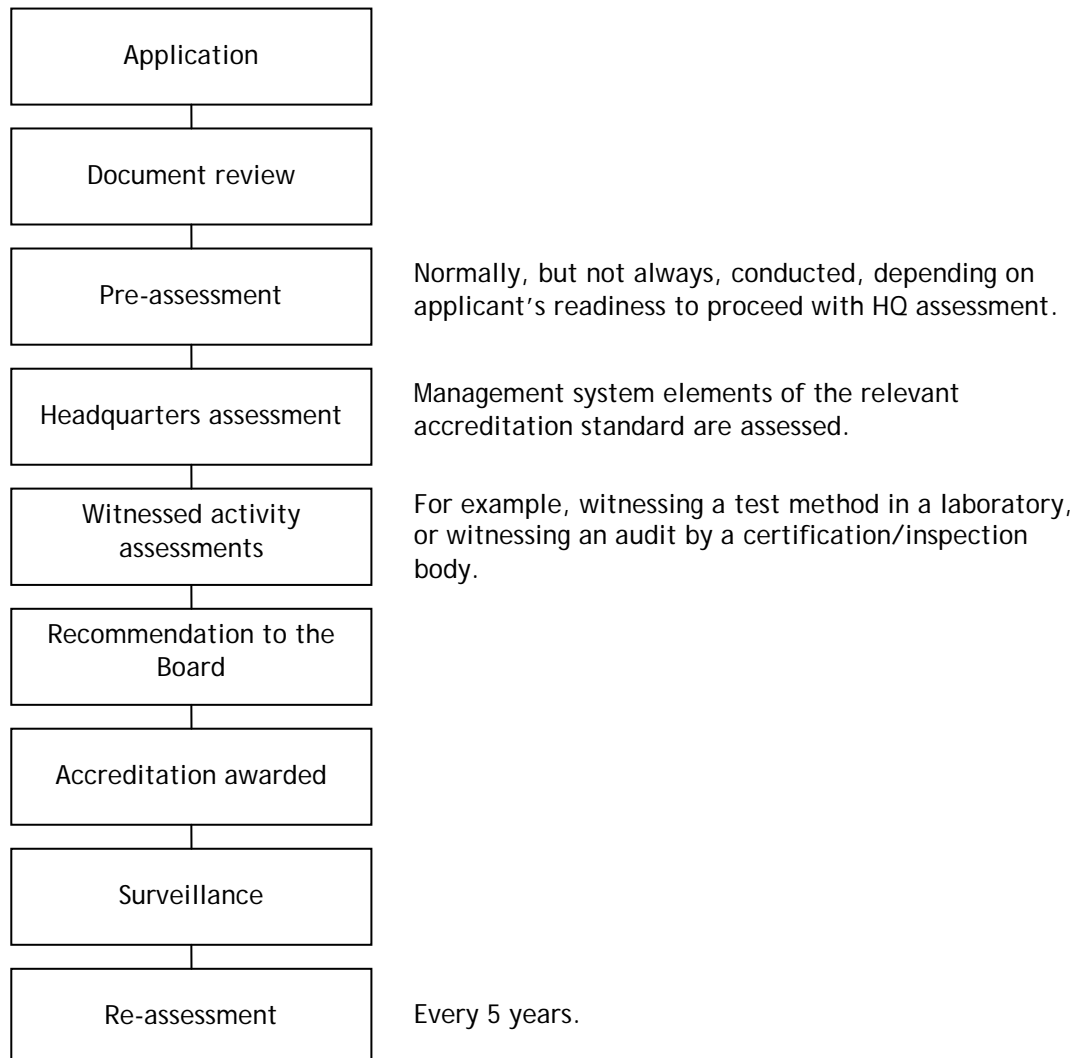
<sup>1</sup> European Co-operation for Accreditation

<sup>2</sup> International Laboratory Accreditation Co-operation

<sup>3</sup> International Accreditation Forum

to INAB. INAB will give 30 days notice of closure and once closed re-application and payment of fees will be necessary.

## THE ASSESSMENT PROCESS



See also <http://www.inab.ie/aboutaccreditation/theaccreditationprocess/> 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 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.
- 2.3 The CAB should complete an application form providing information on its staff and facilities, and specifying as precisely as possible the types of activities for which accreditation is sought. It is important that these forms are completed in detail with comprehensive cross-referencing to relevant documentation where applicable, to ensure clarity and to prevent any delays in processing the application. These must be submitted to the manager of INAB together with two copies of the CAB's quality manual. Copies of application forms and other INAB publications can be obtained from the INAB website at [www.inab.ie](http://www.inab.ie).
- 2.4 Independence, impartiality and integrity of inspection bodies:
  - 2.4.1 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 EA/IAF/ILAC A4 for all inspection bodies.
  - 2.4.2 **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).
  - 2.4.3 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.
  - 2.4.4 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 C of ISO 17020) within the organisation to ensure adequate segregation of responsibilities and accountabilities through appropriate structures.
- 2.5 Categories of testing and calibration laboratories:
  - 2.5.1 Category A  
Permanent laboratory calibration and testing where the laboratory is erected on a fixed location for a period expected to be greater than three years.

### 2.5.2 Category B

Site calibration and testing that is performed by staff sent out on site by a permanent laboratory that is accredited by the Irish National Accreditation Board.

### 2.5.3 Category C

Site calibration and testing that is performed in a site/mobile laboratory or by staff sent out by such a laboratory, the operation of which is the responsibility of a permanent laboratory accredited by the Irish National Accreditation Board.

### 2.5.4 Category D

Site calibration and testing that is performed on site by individuals and organisations that do not have a permanent calibration/testing laboratory. Testing may be performed using

- portable test equipment;
- a site laboratory;
- a mobile laboratory or
- equipment from a mobile or site laboratory

- 2.6 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.
- 2.7 INAB publication P9, "Classification System for Testing and Calibration" provides assistance in the classification of testing/calibration methods.
- 2.8 Publication P10, "Classification System for Inspections" does likewise for inspection bodies.
- 2.9 For management system certification bodies, EA/IAF and NACE codes are used to classify areas of competence depending on industry sector.
- 2.10 On receipt of the application form and quality manual, an INAB staff member is appointed as the INAB officer 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 an INAB officer, a lead/technical assessor and may include additional technical assessors as required for the requested scope of accreditation.
- 2.11 The INAB officer will discuss the proposed team with the CAB to obtain agreement and ensure no potential conflicts of interest exist.
- 2.12 In most cases a pre-assessment visit by the lead assessor will be recommended in order to provide the assessor and the CAB with a better understanding of what the assessment visit will involve.
- 2.13 In all cases the assessors will consider and discuss with the CAB the precise terms in which its accreditation is to be defined. This should be done as part of the pre-assessment visit, if carried out, otherwise at the introductory meeting of the main assessment visit.
- 2.14 The lead assessor reviews the quality manual and application. S/he advises INAB on the suitability of the CAB for pre-assessment and submits a preliminary

report. In exceptional circumstances an application may progress directly to an assessment.

- 2.15 The INAB officer will arrange suitable dates with the CAB and the assessment team.
- 2.16 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.
- 2.17 During the setting up of assessment arrangements, INAB provides relevant documentation, records etc. to the assessment team and 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.
- 2.18 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 and 6/7 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 PRE-ASSESSMENT VISIT PROCEDURES**

- 3.1 The pre-assessment visit is normally carried out by the lead assessor and the INAB officer and generally takes one day. The main purpose of the pre-assessment 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 can then establish what areas need to be addressed by the CAB in order to prepare for the formal 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.
- 3.2 The lead assessor will complete a Pre-Assessment Visit Report and advise INAB if the CAB should progress to an assessment visit. This report is copied to the CAB.
- 3.3 The INAB officer, 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. If more than 12 months have passed since the pre-assessment visit the CAB will be informed that another pre-assessment may be necessary.

### **4. OVERVIEW OF ASSESSMENT VISIT PROCEDURES**

- 4.1 One week prior to the assessment visit the INAB officer will forward 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. necessary
- 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 manual;
  - 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 non-compliance 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) An explanation of what will happen at the closing meeting and confirmation of the time and venue;
  - i) An assurance that all findings will be treated in confidence subject to Freedom of Information requirements;
  - j) Arrangements for providing an office and any clerical services needed by the assessors;
  - k) Confirmation of work hours, lunch break, etc; and
  - l) An opportunity for the CAB's representatives to ask relevant questions.

## **6. EXAMINATION OF CAB OPERATIONS - laboratories**

- 6.1 The most important part of the assessment consists of on-site observations of the laboratory going about its normal business. Assessors need to form a general impression of the laboratory's capability, and in particular the suitability of the equipment for the work for which accreditation is sought and its state and maintenance and calibration. Equally, they need to assess the competence of the staff and the effectiveness of the management system in ensuring that errors are avoided in recording, analysing and reporting results. The assessment

therefore proceeds by the assessors examining the operation of the general systems for ensuring the validity of test results and then selecting particular areas of work for more detailed study. Many testing procedures bear a strong family resemblance to one another, and it may therefore be possible to judge the quality of the work from a relatively small number of observations, provided, of course, that there are effective systems for identifying specimens, specifying test procedures and avoiding confusion in recording results.

- 6.2 Normally each assessor investigates the laboratory's 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 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 detail report forms, for making an agreed record of any observation which may indicate a failure to comply with requirements. Use of these forms 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, rather than the INAB regulations. Assessors are therefore mostly concerned with checking for compliance with the former. However the INAB regulations impose certain requirements which are not specifically covered by ISO 17025 or ISO 15189, for example if the assessors find, during a re-assessment or surveillance 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 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 clause 9.2.3.1 of ISO 17021) 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 plant 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 been supplied with all necessary documented inspection methods and procedures;
  - The procedures are up-to-date;
  - The auditor/inspector implements the procedure 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 records are signed/initialled, as applicable;
  - 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. THE DETAIL REPORT FORM (AF117)**

- 8.1 The detail report form, recording possible failures of the CAB's compliance with the relevant accreditation standard or INAB regulations, provides the objective evidence on which the team's recommendation to INAB will be based. A form must be completed by an assessor immediately after any incident or observation which might indicate non-compliance or as soon as possible afterwards 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 immediately by signing the detail report form. Apparent non-compliances 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 non-compliance, this collective deficiency may be recorded on a single detail report form, avoiding the necessity of recording each occurrence individually.
- 8.3 On each detail report form the following information is recorded:
- Where the observation was made;
  - The system/test/calibration under discussion;
  - The observed feature which may not comply with the relevant accreditation standard or INAB regulations/terms & conditions;
  - Any documents involved;
  - The relevant clauses in the relevant accreditation standard or INAB regulations;
  - The name(s) of the person(s) with whom the matter was discussed; and
  - The signatures of the assessor and the representative of the CAB accompanying him/her.
- 8.4 It is important to recognise that a detail report form 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, 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 the observations will be classified as either major or minor non-compliances or remain as observations.

8.7 In addition to the detail report forms, further reports are completed, which summarise the areas reviewed and contain cross-references to the completed detail report forms. Different reports are generated from the xx116 series depending on type of CAB; see Appendix 1 section 2 (b) for details. Forms CF108 and AF109 are also used for witnessed activities.

## 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 During this meeting the detail report forms must be carefully considered to determine whether or not non-compliances against the relevant accreditation standard or regulations are involved. Each is then classified as either a major or minor non-compliance.

9.3 A minor non-compliance 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).

9.4 A major non-compliance 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.

9.5 A major non-compliance may also be allocated when a number of similar minor non-compliances have been raised and where this indicates a possible weakness in a particular area of the quality or technical systems.

9.6 The summary report form summarises the assessors' findings, highlights matters needing corrective action 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 non-compliances 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.

9.7 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.

9.8 The summary report form should not be simply a compendium of detail report forms. It should correlate deficiencies which indicate a general weakness in the system, e.g. "Three departures from the CAB's written procedures were observed (detail form 5, 10 and 14), indicating a lack of management control and/or ineffective review procedures" or "The absence of written instructions in

four important sections (detail forms 1, 4, 7 and 9) provides evidence of inadequate arrangements for ensuring compliance 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. This form is signed by all members of the INAB team to confirm accuracy of reports, and to confirm confidentiality and conflict of interest requirements have been met.

9.9 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 with a recommendation for remedial action.

9.10 The summary report form should be completed in legible handwriting, or typed. This form should not be used to express appreciation of facilities or hospitality provided by the CAB, which should be done verbally or by letter.

## **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 non-compliances brought to light during the assessment, as well as the general performance of the CAB. If, for example, a major non-compliance was discovered during the assessment, this would provide grounds for not recommending accreditation.

10.2 Where there are relatively few minor non-compliances the assessment team may under certain circumstances recommend accreditation. However, all recommendations for accreditation which involve outstanding non-compliances should be conditional upon them being corrected within a specified time (normally not exceeding 3 months for an assessment visit and 1 month for subsequent surveillance visits). This type of information must be included, where appropriate, in the summary report, which the representative of the CAB will be asked to countersign, 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 non-compliances 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 INAB officer 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, surprise or reassessment visits, the INAB officer presents the report and assessment team's recommendation to the manager of INAB who makes the decision on maintenance of accreditation.

## **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 read and sign the summary report, and provide him/her with a copy if facilities are available (alternatively a copy will be forwarded by the INAB Executive as soon as possible after receipt of the assessment team's report).

11.2 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 compliance with the relevant accreditation standard and INAB regulations/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 non-compliances, 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 them to take up the matter with the INAB Executive so that their 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 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 by post to INAB (e.g. revised procedure documents, up-to-date competence records, etc.). Sometimes, however, an additional visit to the CAB may be necessary (e.g. to verify the satisfactory implementation of the corrective actions), 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 two copies of evidence of corrective actions. One complete copy is placed on the INAB file and one copy (clearly identifying the corrective actions with the relevant non-compliance and relevant assessor) is forwarded to the relevant assessor, for review and clearance using the AF121 form.

12.3 When the assessment team is satisfied that all non-compliances have been cleared, the INAB officer 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, EXTENSION and RE-ASSESSMENT

13.1 Following the granting of INAB accreditation the CAB will receive regular surveillance and re-assessment 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.

- 13.2 The first surveillance visit is normally carried out 6 months after the date of accreditation and annually thereafter with a re-assessment visit normally taking place every 5 years. It is INAB policy, to change, where possible, assessors at re-assessment 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 form and submits this, with the relevant procedures and data, to their INAB officer at least 3 months prior to the next scheduled surveillance visit, to ensure that the extension can be accommodated at that visit if possible. 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 visit or re-assessment.
- 13.5 Decisions on maintenance of accreditation, where no extension to scope is processed, are made by the INAB line manager.
- 13.6 Decisions on re-assessment 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 INAB officer.
- 13.7 Decisions on extension to scope in a different field are made by the Board of INAB.
- 13.8 The INAB officer is responsible for notifying the CAB of the decision on accreditation.
- 13.9 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 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.
- 13.10 Other witnessed audits arising from concern over the performance of an accredited CB shall be determined as needed.
- 13.11 INAB also requires that a minimum number of witnessed inspections are completed annually; the information supplied as part of the inspection body risk analysis (RM-IB) will determine the level of witnessing undertaken.
- 13.12 At the start of each year, INAB meets with each accredited certification and inspection body to plan the work programme for the coming year. At this meeting, approximate dates for the head office visits and INAB's witnessed audit/witnessed inspection requirements are agreed. An estimate of costs for the coming year is provided by the INAB officer. This is also an opportunity for the CB/IB to discuss any queries/concerns with INAB outside the normal assessment process.

A mid year progress review is also held between INAB and CBs/IBs 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 surprise 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/re-assessment/witnessed audit visits and to assess compliance to the relevant standard and accreditation criteria.
- 15.2 The assessment team for additional visits will always include the INAB officer and/or lead assessor and/or additional technical expertise as considered appropriate.
- 15.3 During the assessment at the additional visit and in exceptional circumstances, minor non-compliances may be identified and the relevant AF117 forms completed accordingly. A maximum of 2 weeks from the date of the additional visit is allowed to clear these minor non-compliances.
- 15.4 Failure by the Organisation to clear the non-compliances within the specified timeframe will result in a recommendation for refusal/suspension of accreditation.
- 15.5 Where major non-compliances 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 non-compliance 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 non-compliances 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.

## **17. RESIGNING ACCREDITATION**

- 17.1 For varying reasons a conformity assessment body may wish to resign its accreditation. Written notice 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](http://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. INAB's policy statement PS7 ("INAB policy on issuing accredited certificates outside Ireland") details requirements for applicant and accredited organisations with regard to cross frontier accreditation.

## 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* available at [www.inab.ie](http://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 re-assessments.

(see *INAB Policy Statement PS7* available at [www.inab.ie](http://www.inab.ie), and *EA-2/13*, available from [www.european-accreditation.org](http://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 four years. However, the level of sampling of locations and auditors/inspectors/activities will depend on performance over the four 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 non-compliances 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 non-compliance 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 EC 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 on the 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: LIST OF INAB FORMS

### (1) Application Forms

AF-1-A	Laboratory accreditation application - laboratory
AF-1-B	Certification body and verifier application
AF-1-C	Inspection body application
AF-1-D	Laboratory accreditation application - medical laboratory
AF-1-D-BB	Annex to the above application form for blood banks
AF-1-E	Registration as an EMAS site
AF-2-A	Extension to scope of accreditation - laboratory
AF-2-B	Extension to scope of accreditation - certification bodies
AF-2-C	Extension to scope of accreditation - inspection bodies
AF-2-D	Extension to scope of accreditation - medical laboratory
AF-3-B	Application for review of conformity assessment schemes
AF-1-CAB	Application for assessment of bodies for approval/notification in relation to EC provisions

### (2) Report Forms

#### (a) Pre-Assessment

AF106	Preliminary report on CAB
F108	Pre-assessment visit report - laboratory
MF108	Pre-assessment report - medical laboratory
IF108	Pre-assessment report - inspection bodies
Other	CB head office forms as below
CAB116-IB	Assessment for the purposes of notification (inspection)

#### (b) Assessment

AF111	Visit Plan
F116	Assessment trail - laboratory
MF116	Assessment trail - medical laboratory
HQ116	Assessment trail - certification bodies (management systems and product)
HQP116	Assessment trail - certification bodies (personnel)
IF116	Assessment trail - inspection bodies
AF117	Detail report
AF118	Summary report
CF108	Witnessed audit report on CAB audit performance
AF109	Witnessed activity report
CAB116-IB	Assessment for the purposes of notification (inspection)

#### (c) Post-Assessment

AF121	Clearance of Non-Compliances
AF121A	Recommendation of approval of extension to scope by post

Other INAB data collections forms, returned on an annual basis  
(e.g. PS7F1, PS19F1 and RM-IB)

