

1) Purpose

- 1.1) This document sets out the Irish National Accreditation Board's (INAB) policy on the assessment and accreditation of multi site Conformity Assessment Bodies (CABs).
- 1.2) The Irish National Accreditation Board (INAB) is the national body responsible for assessing the competence of Conformity Assessment Bodies (CABs) to the relevant ISO (International Organisation for Standardisation) standards and guides and the EN 45000 series of European standards.
- 1.3) Accreditation is the process whereby an independent body (INAB) examines and assesses a Conformity Assessment Body (CAB) to ensure it is competent and operates a system that complies with international standards.
- 1.4) Following the award of accreditation INAB monitors accredited bodies to ensure conformity with the criteria is maintained.
- 1.5) Conformity Assessment Bodies with affiliated sites in other countries shall also comply with INAB Policy PS7 - *Policy on Cross Frontier Accreditation*.

2) Definitions

- 2.1) *Premises* - Sites that belong to the CAB with an involvement in conformity assessment activities. Such sites may be owned, rented or leased (or by any other legally enforceable arrangement) by the CAB.
- 2.2) *Site* - Any site where conformity assessment activity is being undertaken on a temporary or permanent basis.
- 2.3) *Multi-site organisation* - An organisation with a central office in which certain activities are performed or managed within a network of sites at which such activities are fully or partially carried out. All sites have a direct legal or contractual link with the central office of the organisation and are subject to a common quality system. *Note: accommodating the accreditation of multi site organisations does not imply that INAB provides group accreditation to multiple legal entities.*
- 2.4) *Critical Location* - where one or more key activities are performed according to ISO 17011 clause 7.5.7 (to include policy formulation, planning conformity assessment, contract review, review, approval and decision on the results of conformity assessment).

3) References

- 3.1) ISO 17011 *Conformity assessment - General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.*

4) Policy - Information

- 4.1) An applicant organisation that operates from a central office through a number of sites can seek a single accreditation provided that the conditions as specified by the accreditation body are fulfilled. For sites that are located in another country, refer also to INAB Policy PS7 (*INAB Policy on cross frontier accreditation and certificates issued outside Ireland*).
- 4.2) On application, the CAB must indicate the number of sites being operated under the centrally controlled management system along with the scope of activity for each.
- 4.3) INAB applicant and accredited CABs are required to identify all sites (known as **critical locations**) where activities are conducted or controlled that determine the effectiveness of the CAB's performance of the accredited activity. Such key activities are noted in ISO 17011 (7.5.7) and include policy formulation, process and/or procedure development and, as appropriate, contract review, planning conformity assessments, review, approval and decision on the results of conformity assessments.
- 4.4) It is INAB policy to list all critical locations on the CAB scope of accreditation.
- 4.5) INAB accredited CABS are required to notify INAB, at a minimum, three months in advance of a critical location becoming operational.
- 4.6) Each INAB accredited CAB shall confirm annually the list of all sites, the legal relationships in place and a description of activities performed on behalf of the CAB. The report is compiled on form PS19F1 available from the INAB website www.inab.ie
- 4.7) In providing the information in 4.4 above, the CAB must stipulate which activities are performed in each location and, if applicable, provide a written justification as to why it is not considered a critical location.
- 4.8) Where sub-contract arrangements exist with another legal entity, the precise nature of the relationship must be specified along with details of the sub-contractors accreditation status.
- 4.9) The purpose of this report is to allow INAB to plan an assessment programme for each of its accredited and applicant CABs with up to date knowledge of the full geographical scope of the CAB's activities.
- 4.10) An applicant CAB must complete this form in full, if relevant, with their initial application for accreditation or extension to scope of accreditation.

5) Policy - Site Assessment

- 5.1) For multi-site organisations the central quality system and technical control will be subject to surveillance each year. It is anticipated that, in addition to the central office, at least one site will be visited each year, with a visit to each site generally taking place over the four year period.
- 5.2) All CAB premises located within Ireland where one of key activities are performed (Critical locations located in Ireland) will be subject to the following:
- a) At the initial assessment stage INAB shall assess each critical location;
 - b) Once accredited, these CAB's premises as defined above will be assessed throughout the assessment period ensuring that all activities are examined at least once during the assessment cycle.
- 5.3) All CAB premises located outside of Ireland where one or more key activities are performed (Critical Locations) will be subject, at a minimum, to the following assessments (INAB Policy PS7 also refers):
- a) At the initial and re-assessment stage INAB shall assess (directly and with the support of the local AB) each critical location.
 - b) In planning the surveillance assessment programme for each critical location, INAB, in co-operation with the local AB shall assess each critical location during the accreditation cycle. In certain circumstances, more frequent surveillance may be necessary. The following conditions, at a minimum, will be taken into consideration when deciding the surveillance programme:
 - ▶ Levels of work being undertaken;
 - ▶ Risk factors of the work being undertaken in the critical location;
 - ▶ Justifiable confidence, based on access to information demonstrating the work undertaken, in the management control over the operations of the critical location by the head office of the CAB;
 - ▶ Access, secured by formal agreement, to the assessment results relative to the activities carried out at the critical location by other EA, IAF and ILAC Multilateral Agreement signatory Accreditation Bodies;
 - ▶ Training activity and supervision of the auditors carried out by the CAB's head office;
 - ▶ Positive result of the internal audit carried out by the CAB's head office in the critical location.
- 5.4) A critical location will be subject to an initial assessment prior to any key activity under the scope of INAB accreditation being undertaken. Where an accredited CAB

intends to utilize a new premises where key activities are performed, and which have not been previously reported to INAB, the CAB shall:

- a) apply to INAB via the extension to scope procedure;
 - b) provide INAB with documented procedures that demonstrate that the new premises, active in the provision of its accredited service is established in such a way as to meet accreditation requirements before INAB authorizes the issue of its accredited reports / certificates, either directly from the critical location itself or resulting from accredited work performed under the control of the critical location.
 - c) INAB accreditation may not be claimed for any activity performed at critical locations not on the scope of accreditation.
- 5.5) All CAB premises where no key activities are performed (NON Critical Locations) will be subject to an assessment at least once during the accreditation cycle.
 - 5.6) INAB will seek to establish through objective evidence and by using various techniques that the quality system is effectively and fully implemented at all sites.
 - 5.7) In addition to 5.2 to 5.5 above, INAB reserves the right to amend its policy in consideration of performance over the 4 year period, 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.
 - 5.8) For Category B and C laboratory testing, each site must be working to the same requirements and will be the subject of annual assessments to verify the operation and effectiveness of the system.
 - 5.9) For Category D laboratory testing, on site witnessing at CAB client premises will take place at an appropriate frequency.
 - 5.10) 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.
 - 5.11) If INAB observes non-compliances at the central office or at any one of the sites of an organisation with multiple sites, the corrective action procedure shall apply to all applicable sites. In the event that the results of any of the assessments of 'sample sites' 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 sites to be assessed.
 - 5.12) Failure by one site to comply with INAB requirements may lead to removal of the site from the schedule of accreditation. If the cause of non-compliance is the lack of central control then accreditation will be the subject of review by INAB and may lead to suspension or withdrawal of accreditation from all sites.
 - 5.13) An INAB accreditation certificate will be issued for one legal entity; it is INAB policy to document critical location details in the scope of accreditation.

6) Policy - CABs Affiliated to Parent Organisations

- 6.1) Such organisations are established in Ireland as a separate legal entity but retain close association with a parent/headquarter organisation in another jurisdiction.
- 6.2) The CAB under assessment must demonstrate that it has sole responsibility and control of its operations, however the CAB may still rely on the provision of certain services from the parent/headquarter organisation, the scope of which might reasonably be documented in a service level agreement, for example.
- 6.3) The quality system documentation of the CAB must clearly describe the level of services provided by the parent/headquarter organisation, the controls in place for the CAB to manage the services provided, how conflicting/additional requirements are managed and how the INAB CAB audits and reviews such arrangements.
- 6.4) INAB require that all relevant personnel, documentation and systems are readily available for each INAB assessment visit.

7) Contact

For further information please contact an accreditation officer at **The Irish National Accreditation Board**.