

## Laboratory Accreditation

### IS-7

INAB offers laboratories accreditation to the international standard ISO/IEC 17025:2017, “*General requirements for the competence of testing and calibration laboratories*” and ISO 15189:2012, “*Medical laboratories -- Requirements for quality and competence*”.

The standards contain requirements for the competence of medical testing, testing and calibration laboratories and detail the requirements to be met by laboratories in developing a management system for quality, administrative and technical operations. The standards are applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. They require laboratories to establish and maintain a quality system to manage aspects such as document control, complaint handling, contract review, purchasing, audits and investigation into non-conforming testing/calibrations. In addition, the laboratory is required to have policies and procedures to describe training, test/calibration methods, quality assurance, reporting and measurement traceability.

ISO 17025 laboratories accredited by INAB cover testing in areas such as: chemical, biological, mechanical, heat and temperature, metrology, electrical, and construction materials. INAB has accredited laboratories from the private and public sectors. Private laboratories are sometimes stand-alone operations that are actively seeking work and service Irish industry and the public through the provision of accredited testing and calibration operations. Accreditation gives users of laboratories confidence in the quality of the service provided. Other laboratories in the private sector are part of bigger organisations such as larger pharmaceutical corporations which can require accreditation in order to ensure the quality of results reported when complying with environmental legislation or for other corporate reasons. In the public sector there is sometimes a requirement for organisations to gain accreditation for the specific field in which they operate such as public health laboratories which test food & water samples collected by environmental health officers for various pathogens. Accreditation of calibration laboratories underpins the national measurement system by ensuring the competence of these providers. Traceability to national and ultimately to international standards is a vital cog of any economy operating in the international sphere. An accredited calibration laboratory has demonstrated competence for the calibration of instruments/equipment within a specific range of measurement and to a precise uncertainty.

Medical laboratories accredited by INAB cover testing in areas such as: clinical chemistry, haematology, histopathology, immunology and microbiology. Medical testing laboratories may also be accredited for point-of-care, a service in which testing is performed near or at the site of the patient, but under the control of the accredited laboratory. Accreditation is to ISO 15189 and also to the requirements of ISO 22870, “*Point-of-care testing (POCT) - requirements for quality and competence*”.

In recent years there has been growth in laboratory accreditation in response to requirements imposed by third parties, e.g. requirements for laboratories that undertake testing of the materials used in the construction of roads to be accredited for these tests. Health and safety concerns have seen growth in areas such as asbestos testing, food safety and water quality. INAB accreditation under ISO 15189 directly supports legislative implementation in the area of blood transfusion testing and haemovigilance & traceability of blood and blood products (S.I. 360/2005 and S.I. 547/2006). While not directed by legislation, accreditation to ISO 15189 is also a requirement for laboratories providing testing services in support of the national cancer screening programmes.

INAB applicant and accredited laboratories are required to implement in full the requirements of the applicable standard and associated EA, ILAC<sup>1</sup> and INAB mandatory documents, which can be accessed from the INAB website at [www.inab.ie](http://www.inab.ie).

Laboratories are accredited for a defined range of activities and these are detailed in a scope of accreditation which is annexed to the organisation's accreditation certificate. A directory of these scopes of accreditation is maintained by INAB and is available from the INAB website.

Once the laboratory has all of the organisational and technical measures in place, and has been operating a laboratory service for a period of time sufficient to have historical records built up, and is able to demonstrate that the operation is stable (typically three months minimum), it can apply to INAB for accreditation.

The process for the accreditation of laboratories is fully described in INAB Publication P7, also available from the INAB website.

For further information please contact INAB at:

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<sup>1</sup> EA is the European Co-operation for Accreditation  
ILAC is the International Laboratory Accreditation Co-operation