

Medical Laboratory Accreditation

IS-1

INAB provides laboratory accreditation for medical laboratories to **ISO 15189** “*Medical Laboratories - Requirements for quality and competence*”. The standard is closely based on the general laboratory accreditation standard ISO 17025, but incorporates essential elements for medical laboratories.

In particular, the standard emphasizes patient needs and focuses on clinical personnel roles, responsibilities and needs. It addresses issues particular to a medical laboratory which include the provision of advisory services to clinicians, collection of patient samples, provision of testing in a medical emergency and the contribution of medical laboratory service to patient care.

The standard is applicable to private laboratories, and those laboratories based in both public and private hospitals.

For the medical laboratory programme INAB uses a combination of technical experts and medically qualified assessors from EA Accreditation Bodies who have significant experience in medical laboratory accreditation. INAB has also trained a number of Irish technical experts in ISO 15189.

To assist in the delivery of the medical laboratory accreditation programme, INAB has established a medical advisory committee comprising membership representative of and with an interest in the outcome of INAB accreditation.

Blood Transfusion

Irish Legislation (SI No 360 of 2005 and SI 547 of 2006) published on foot of European Directives on the quality and safety of blood and blood products, requires blood bank laboratories to operate to ISO 15189. These laboratories must also comply with additional requirements relating to blood traceability and haemovigilance (notification of serious adverse reactions and events).

A guidance document outlining minimum requirements for blood bank compliance was produced and published in 2006 by an INAB working group co-chaired by INAB and The Irish Medicines Board. INAB assessment teams use this publication (AML-BB) in conjunction with ISO 15189 to determine blood banks compliance.

INAB applicant and accredited Laboratories are required to implement in full the requirements of ISO 15189 and associated EA, ILAC¹ and INAB mandatory documents, which can be accessed from the INAB website at www.inab.ie

¹ EA is the European Co-operation for Accreditation
ILAC is the International Laboratory Accreditation Co-operation

Laboratories are accredited in compliance with ISO 15189 for a defined range of activities and these are detailed in a scope of accreditation which is annexed to the organisation's accreditation certificate. Laboratories accredited by INAB cover testing in areas such as: blood transfusion, clinical chemistry; haematology; microbiology; immunology; and histopathology.

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 to be able to demonstrate that the operation is stable, it can apply to INAB for accreditation.

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

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