

## **IFCC Statement on the use of ISO 15189 in the accreditation of medical laboratories**

In 1999, IFCC and WASP published a common 'policy statement' entitled 'Principles of Clinical Laboratory Accreditation' which detailed :

- the purposes and nature of (medical) laboratory accreditation,
- its scope and administration
- the assessment criteria and
- ethical standards

Since this policy statement an International Standard, ISO 15189:2003 (with minor revisions in 2007), has been published, that details the requirements for quality and competence in the medical laboratory. IFCC recognises that this Standard encompasses all the assessment criteria specified in the policy statement and as such should form the basis for the accreditation of laboratories.

Accreditation is done in several countries by independent National Accreditation Bodies (NAB), according to ISO 17011 and 'Mutual Lateral Agreements' between these bodies mean that accreditation in one country is accepted in other countries.

To comply with the IFCC-WASP policy statement, the accreditation of medical laboratories by these Accreditation Bodies have to follow some key principles, mentioned below:

1. The scope of accreditation should normally cover the substantial majority of the overall service provided by the laboratory within a medical field.
2. It is recognized that some Accreditation Bodies cannot enforce this. Nevertheless these NAB's should encourage medical laboratories to cover the majority of their examinations within each medical field in their scope.
3. The 'flexible' scope of accreditation is preferred. The laboratory shall maintain a list of all individual examinations for which it is accredited.
4. At the first level the scope of accreditation shall be defined as a medical field or discipline, such as for example Clinical Chemistry, Haematology, Immunology, Microbiology etc. It is accepted that on national level there may be differences in the way NAB's and the corresponding medical professions define the disciplines.
5. For each medical field, mentioned in the scope, it is expected that the laboratory provides a full service, which includes all pre-examination, examination and post-examination aspects that are essential to provide an effective and efficient laboratory service to the patients. Within this, it is expected that a medical laboratory is able to demonstrate its competence in interpreting the results of the examinations performed.

When accrediting medical laboratories according to ISO 15189, it has to be ensured that all aspects, important for the quality of service by medical laboratories, and mentioned in the policy statement, are duly covered.