PRINCIPLES OF CLINICAL LABORATORY ACCREDITATION

A POLICY STATEMENT BY
THE INTERNATIONAL FEDERATION OF CLINICAL CHEMISTRY
AND LABORATORY MEDICINE
(IFCC)
and

THE WORLD ASSOCIATION OF SOCIETIES OF PATHOLOGY AND
LABORATORY MEDICINE
(WASPaLM)

1. THE PURPOSES AND NATURE OF LABORATORY ACCREDITATION

It is in the interests of patients, of society, and of governments that clinical laboratories operate at high standards of professional and technical competence, for the following reasons:

- Decisions about diagnosis, prognosis and treatment are frequently based on the results and interpretations of laboratory tests, and irreversible harm may be caused by erroneous results

- Users of clinical laboratory services (both patients and clinicians) may not have sufficient technical knowledge to allow them to determine whether a laboratory operates at a satisfactory level

- Patients, and to a lesser extent clinicians, may have no choice about the laboratory to be used

- Laboratory testing can be expensive and the patients, insurance organisations, or governments who pay for testing expect the laboratory to provides valid information

• It is in the interests of competent laboratories that their competence is verified through a process of inspection, comparison against appropriate standards, and public affirmation of their good standing.

Accreditation is an external audit of the ability of a laboratory to provide a high quality service. This requires a laboratory to submit information demonstrating:

• conformity with published accreditation standards,

• existence of a management system addressing internal and external measures of quality, outlined in a quality management manual,

and

• a qualified expert appraisal by an accreditation body.

2. SCOPE AND ADMINISTRATION

• Inspection and accreditation processes should include all laboratories and in-vitro diagnostic activities, including physician office laboratories and point-of-care testing.

• Accreditation should be based on inspection visits and peer review, in addition to provision of information to an inspection agency. The aims of the accreditation system should include improvement of standards of practice through dissemination of information and through continuing professional education.

• Standard-setting and the inspection process should be implemented by accreditation bodies in which medical and scientific professional societies are strongly represented. Government agencies or health insurance organisations should participate in these bodies to the extent necessary to ensure acceptance and public accountability of the accreditation system. The accreditation system should be revised regularly. The major responsibility for standard-setting remains with the medical and scientific professionals engaged in clinical laboratory work.

3. ASSESSMENT CRITERIA

Standards should be defined by the accreditation body and assessed by peer review. The standards should include:

• Organisation and administration

This includes the existence of an appropriate administrative and staffing structure, with documentation of accountability and responsibilities.

• Staff qualifications

There must be sufficient staff with appropriate education and training, with provision for continuing education and assurance of staff competencies.

Staff performing testing should have post-secondary education in appropriate scientific disciplines, and training in laboratory procedures.

Laboratory directors may have initial university qualifications in medicine or science, or another initial university qualification deemed appropriate by individual national policy; but must have specialised post-graduate professional education and training in clinical laboratory work.

- Facilities

The working environment must be safe for staff and patients, and sufficient and appropriate for the work. Equipment, materials and reagents must be of suitable quality and appropriate for the purposes for which they are used.

- Quality policy

There must be documentation of policies and procedures, and of laboratory methods. Internal and external quality assurance procedures, and systems evaluation, must cover the preanalytical, analytical and postanalytical phases of sample analysis or examination.

4. ETHICS

Patients are increasingly and appropriately aware of healthcare issues, and desire participation in decisions affecting their health. The ultimate responsibility of a clinical laboratory is to the patient.

Adherence to high standards, such as those related to timeliness of test results, laboratory accuracy and precision, clinical relevance of the tests performed, qualifications and training of personnel, and prevention of errors, is an ethical responsibility of all clinical laboratory staff.

Inspection and accreditation of clinical laboratories should also ensure that the owners, managers and staff comply with ethical standards, such as:

- Maintenance of confidentiality of patient information

- Adherence to appropriate technical and professional standards regardless of cost pressures

- Avoidance of personal, financial and organisational conflicts of interest

- Non-discrimination against patients or staff based on race, gender, political or religious beliefs, or economic circumstances.

5. ABOUT IFCC

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) was founded in 1952 in order to advance the science and practice of clinical chemistry throughout the world, in the interests of the peoples of the world. The purposes of the IFCC are now to:

- establish, encourage and foster high professional standards of clinical chemistry and laboratory medicine

- promote international co-operation and co-ordination in the development of clinical chemistry and laboratory medicine in matters of research, procedures, materials, regulations and practices, education and training, codes of ethics and related subjects

- provide a basis for closer liaison and the free exchange of professional information among clinical chemists and other experts in laboratory medicine world wide

- Sponsor and support International Congresses of Clinical Chemistry; sponsor and support regional congresses and meetings of international scope and interest

- Encourage, sponsor and/or conduct studies, and prepare recommendations, reviews and reports on facets of clinical chemistry and laboratory medicine of international interest and concern

- Provide consultation and advice on facets of clinical chemistry and laboratory medicine to all members of the IFCC, other international and regional societies, states, nations, industries and others concerned with the provision of health services and materials

- Encourage and assist in the organisation and establishment of new societies concerned with clinical chemistry and laboratory medicine

- Contribute in other ways wherever practical and feasible to the improvement of clinical chemistry and laboratory medicine and their services to humanity.

IFCC now has member societies representing clinical chemistry and laboratory medicine in 76 countries, and 41 Corporate Members engaged in the in-vitro diagnostics industries.

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