

WASPLM-IFCC - Joint Policy Statement on "Principles of Clinical Laboratory Accreditation"

Die „Weltvereinigung der Gesellschaften für Pathologie und Laboratoriumsmedizin“ (WASPLM) und die „International Federation of Clinical Chemistry and Laboratory Medicine“ (IFCC) haben 1999 eine gemeinsame Erklärung zur Akkreditierung medizinischer Laboratorien verabschiedet.

Der Entwurf wurde von Dr. *Whitfield*, Australien, Secretary IFCC, und Dr. *Merten*, Deutschland, President-Elect WASPLM, vorbereitet und mit den Gremien der Gesellschaften zwischen 1997 und 1999 abgestimmt.

Abstimmungsbedarf bestand insbesondere in der festzulegenden Qualifikation eines „Direktors von Laboratorien“. Die in der Vereinbarung festgelegte Beschreibung würdigt die unterschiedlichen Entwicklungen in verschiedenen Ländern. In vielen Staaten gilt Medizin als Basisstudium, dem eine spezielle Weiterbildung über mehrere Jahre angeschlossen wird und die zur Qualifikation als „Laborarzt“, „Klinischer Pathologe“, „Molekularpathologe“, „Klinischer Chemiker“, „Klinischer Biochemiker“ bzw. „Klinischer Labordiagnostiker“ führt. Andere Länder folgen dem Vorgehen Frankreichs und führen nach einem Basis-

studium, z. B. in Medizin oder Pharmazie, eine mehrjährige Weiterbildung in „Biologie Clinique“ oder „Medical Biochemistry“ durch, die zu einer vergleichbaren Qualifikation führt.

Diese Gegebenheiten sind Grundlage der gemeinsamen Erklärung:

„Direktoren von Laboratorien müssen initial eine universitäre Qualifikation in Medizin oder Naturwissenschaft aufweisen, oder eine andere initiale Universitätsqualifikation, die durch nationale Vorschriften (Politik) als angemessen erachtet wird und sie müssen eine spezialisierte theoretische und praktische Fachweiterbildung in klinischer Laborarbeit nachweisen.“

Es ist nun Aufgabe der verantwortlichen Gremien die Anforderung an eine ausreichende Qualifikation und die Inhalte einer fachlichen Weiterbildung auszuarbeiten und sich auf gemeinsame Anforderung festzulegen.

Dr. med. *Utz P. Merten*

President World Association of Societies of Pathology and Laboratory Medicine

Principles of Clinical Laboratory Accreditation

A Joint 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 organizations, or governments who pay for testing expect the laboratory to provide 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 organization

2. Scope and Administration

- Inspection and accreditation processes should include all laboratories and in-vitro diagnostic activi-

ties, 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 organizations 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:

- Organization 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 qualifications in medicine or science or another initial university qualification deemed appropriate by national policy; but must have specialized 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 organizational conflicts of interest
- Non-discrimination against patients or staff based on race, gender, political or religious beliefs, or economic circumstances.

5. About IFCC and WASPaLM

The International Federation of Clinical Chemistry (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 laboratory science.
- promote international co-operation and co-ordination in the development of clinical laboratory science 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 laboratory scientists world wide.
- Sponsor and support International Congresses of Clinical Chemistry and International Congresses of Clinical Laboratory science; 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 laboratory science of international interest and concern.
- Provide consultation and advice on facets of clinical laboratory science 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 organization and establishment of new societies concerned with clinical laboratory science.
- Contribute in other ways wherever practical and feasible to the improvement of clinical laboratory science and its 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.

IFCC Technical Secretariat
Centre du Medicament
Universite de Nancy I
30, Rue Lionnois
F-54000 Nancy, France.

The World Association of Societies of Pathology and Laboratory Medicine (WASPaLM) was founded in 1947 as the International Society of Clinical Pathology; changed to the WASPaLM in 1972. At present, there are more than 55 Societies, Colleges or Associations in over 40 countries involved within WASPaLM, and over 40 corporate sponsors engaged in the in-vitro diagnostic industries.

The mission of WASPaLM is to improve health throughout the world by promoting the teaching and practice of all aspects of Pathology/ Laboratory Medicine.

Its goals are:

- to promote education, research and international quality standards, through the committees and secretariats of WASPaLM and the World Pathology Foundation,
- to promote high quality, cost-effective medical laboratory services,
- to promote the exchange of information between pathologists throughout the world,
- to encourage the formation of, and cooperation between, societies of pathology throughout the world,
- to foster cooperation between WASPaLM and other international health organizations.

In 1969 the World Pathology Foundation was established and the Gordon Signy Fellowship exists to enable young pathologists to visit other countries to learn special skills. There were 25 fellowships awarded since 1969.

The WASPaLM Administrative Office
c/o Japan Clinical Pathology Foundation for International Exchange, Sakura-Sugamo Building 7th Floor
Sugamo 2-1 1-1
Toshima-ku, Tokyo, 170, Japan

Information über die Neuerscheinung eines Normenentwurfs

E DIN EN ISO 15197

„Bestimmung von Leistungskriterien von In-Vitro-Blutzuckermesssystemen für das Management des Diabetes mellitus beim Menschen“

Als Entwurf erschienen im April 2000 (prEN ISO 15197 : 2000)

Die Hauptüberschriften des Entwurfs sind: Anwendungsbereich / Normative Verweisungen / Begriffe / Design / Produktinformation und -dokumentation / Design des Blutzuckermessgerätes und die Untersuchung möglicher Störungen / Bewertung der technischen Leistung – Bewertung der Leistung beim Betrieb durch den Anwender

Anhang: „Anforderungen an die analytische Leistung in der Selbstüberwachung des Blutzuckers zur Kontrolle des Diabetes mellitus“

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Prof. Dr. *Dieter Meißner*, Dresden
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