CREATION OF JOINT COMMITTEE ON TRACEABILITY IN LABORATORY MEDICINE

At a meeting held at the BIPM from 9 – 11 June 2002, first steps were taken to create a Joint Committee on Traceability in Laboratory Medicine (JCTLM). The aim of the Joint Committee is to meet the need for a worldwide platform to promote and give guidance on internationally recognized and accepted equivalence of measurements in Laboratory Medicine and traceability to appropriate measurement standards.

In recent years, major driving forces in the rapidly growing need for comparability of measurements in Laboratory Medicine and traceability to measurement standards have been: the EC Directive on In-vitro Diagnostic Medical Devices (98/79/EC); the introduction of ISO 17025; and a general increasing awareness of the costs of diagnostic measurements and tests with the consequent need for reliability.

Internationally recognized and accepted equivalence of measurements in Laboratory Medicine and traceability to appropriate measurement standards will lead to:

• improvement in quality of health care for the patient;
• reduction of costs for governments and health-care insurers due to the reduction in the number of repeat tests and improvement in efficiency of health care
• reduction of costs for the IVD industry;
• removal of redundant written standards by unification of regional standards;
• removal of technical barriers to trade through global acceptability of measurements and tests

The sixty people present represented the major international and intergovernmental organizations concerned with measurements in laboratory medicine, metrology and health, the principal producers of IVD reference materials, the IVD industry associations from Europe, Japan and the USA, regulatory bodies from Europe, Japan and the USA, standards writing bodies, accreditation and quality assessment organizations.

It was agreed to create a Joint Committee for Traceability in Laboratory Medicine (JCTLM) comprising the international and intergovernmental organizations (CIPM/BIPM, IFCC, ILAC and WHO) as the four principal promoters, acting as the Executive, together with members drawn from the above-mentioned organizations in attendance at the meeting. Note that the world’s national metrology institutes are represented through CIPM/BIPM.

The JCTLM is thus a unique forum for collaboration among many diverse communities.

The JCTLM created two working groups, the first on reference materials and reference procedures, and the second on reference laboratories.

One of the first aims of the working groups is provide practical support to the IVD industry worldwide with respect to the traceability of values assigned to calibrators and/or control materials required by the forthcoming European Directive on in vitro diagnostics and by comparable regulations in other countries.

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