

PROPOSED "JOINT COMMITTEE ON TRACEABILITY IN LABORATORY MEDICINE"

GENERAL INTRODUCTION

Aim of the Joint Committee

The JCTLM is being created to meet the need for a worldwide platform to promote and give guidance on internationally recognised and accepted equivalence of measurements in Laboratory Medicine and traceability to appropriate measurement standards.

Who will benefit?

In recent years, major drivers behind 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 and the consequent need for reliability.

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

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

New regulatory and voluntary standards

There has, in recent years, been considerable activity both within ISO and the EU related to new written standards and regulations for clinical chemistry and laboratory medicine.

To support the EC Directive on In-vitro Diagnostic Medical Devices to come into effect in December 2003, the European Commission mandated 20 written Standards (Norms) to be made by CEN Technical Committee 140; these written standards pertain to specific clauses in the Annex 1 of the IVD Directive (Essential Requirements).

With respect to reference measurement systems in the field of Laboratory Medicine, four such written Standards have been mandated:

- a) Presentation of Reference Measurement Procedures (EN 12286);
- b) Description of Reference Materials (EN 12287);
- c) Metrological traceability of values assigned to calibrators and control materials (EN/ISO 17511);
- d) Metrological traceability of catalytic concentration of enzymes assigned to calibrators and control materials (prEN/ISO 18153).

ISO established in 1998 its Technical Committee 212, and the four topics mentioned above were simultaneously handled by CEN and ISO working groups. Additionally, a working group of TC212 developed an International Standard on Requirements for Reference Measurement Laboratories (ISO/FDIS 15195).

With respect to the two traceability documents this resulted in prEN/ISO 17511 and prEN/ISO 18153, showing the importance of establishing global/worldwide written standards rather than regional ones.

In standard prEN/ISO 17511 is the basic document on the issue of traceability requirements. In this document the issues and problems on the traceability of value assignment to calibrators and control materials, to be demonstrated by the manufacturers of in-vitro diagnostic products, are explained and solutions given.

Responsibility for worldwide traceability in laboratory medicine

The full-scale - ideal - demonstration of the traceability chain is given in prEN/ISO 17511. In this document are mentioned the organisations expected to be responsible for establishing the tools to obtain proper and appropriate traceability chains.

These organisations include: the inter-governmental metrology organisation (BIPM), international professional scientific and medical organisations viz. IFCC and WHO, as well as the IVD Industry, Certified Reference Material (CRM) producers and the network(s) of Reference Measurement Laboratories.

In the field of laboratory medicine, it is now evident that these bodies should collaborate very closely to provide an appropriate structure within which the requirements for measurement standards outlined above can be met. This is the purpose of this initiative.

Action so far:

In May 2001 a preparatory working group, composed of representatives of the IFCC, the BIPM, NMI-VSL, NIST and the EC IRMM met to explore the possibility of creating a joint committee of the principal international organizations working in the field to coordinate and initiate common actions aimed at establishing global traceability in laboratory medicine.

In November 2001 a further meeting took place of a somewhat enlarged group to take the matter forward. Included were representatives of the US IVD industry ADVAMED, the European IVD industry EDMA and the US FDA. The conclusion of discussions was that a workshop should be arranged in June 2002 with the title "Traceability in Laboratory Medicine", that would bring together representatives of a wide range of interested parties from around the world. At this workshop, it is hoped to put the future activities of a Joint Committee on a more formal basis and adopt an outline of a work programme.

Promotors of the JCTLM and partners in future actions

It is planned that the principal promotors of the JCTLM shall be the international organisations dealing with metrological, scientific, health and accreditation aspects namely, IFCC, BIPM, WHO (**to be confirmed**) and ILAC. Many other stakeholders take part or are invited to take part in the activities of the JCTLM, e.g. regional organisations in the field of regulatory affairs (FDA, USA; European Commission, Europe), CRM producers (notably IRMM, Europe; NIST, USA), networks of reference measurement laboratories (DGKC, Germany; CDC, USA), EQA/PT organisers (CAP, USA; EQALM, Europe), written Standards (horizontal or vertical) setting bodies (ISO, CEN and NCCLS, USA, JCCLS, Japan) and last - but not least - the IVD industry from USA (AdvaMed), Europe (EDMA) and Japan

(JACR). The international organizations IFCC, BIPM, WHO and ILAC represent the national member-institutes, which in their respective countries are responsible for establishing systems of internationally recognised metrology (traceability), laboratory medicine and accreditation.

It is intended that the activities of the JCTLM should reflect a truly global partnership of the players/stakeholders in the field of Laboratory Medicine. Inevitably, this will become a large group, and it is likely that at regular intervals, perhaps every two years, a General Assembly will be convened to which all participants in the JCTLM activities will be invited.