

**JOINT COMMITTEE on
TRACEABILITY
in LABORATORY MEDICINE
(JCTLM)**

Discussions/Developments so far

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Actions so far

- **2000** Informal discussions
- **2001 05** Geel IRMM
 - ◆ BIPM, IFCC, NIST, NMI-VSL
 - ◆ Explore the possibility of establishing global traceability in Laboratory Medicine
- **2001 11** Paris BIPM
 - ◆ + AdvaMed, EDMA, FDA
 - ◆ Mission Statement
 - ◆ Organisation of Workshop
- **2002 06** Paris BIPM
 - ◆ Workshop to establish JCTLM

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A JOINT VENTURE OF PROFESSIONALS

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Diagnostic Laboratories (IFCC)

Diagnostic Industry (AdvaMed, EDMA, JACR)

Metrology Institutes (BIPM)

Standards Organisations (ISO, CEN)

Regulatory Bodies (FDA, EC)

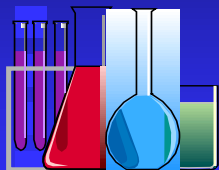
CRM Producers (IRMM, NIST)

Health Authorities (WHO)

Accreditation Bodies (ILAC)

EQAS Organisations (CAP, EQALM)

Network of Reference Measurement Laboratories



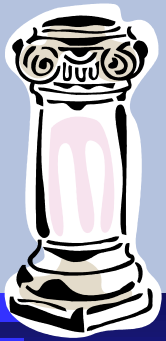
AIM

- Promotion of the traceability concept
- Promotion of link between Reference Laboratories and Metrology Institutes
- Co-ordination/guidance in the establishment of Reference Measurement Systems
- Identification of clinically relevant projects conducted by appropriate professional organisations – encourage collaborations
- Dissemination of information
- **Encourage application of Reference Measurement Systems by the IVD industry**



WHY?

- Implementation of
 - ◆ EC-IVD Directive (98/79/EC)
 - ◆ prEN ISO 17511
(Metrological traceability of values assigned to calibrators and control materials)



MEMBERS

- **Worldwide International Organizations**
(to provide the essential formal international references):
 - ◆ **BIPM, IFCC, ILAC, WHO**
these act as the principal promoters and stakeholders
- **Other Key Stakeholders**
 - ◆ **CRM-producers (notably IRMM and NIST)**
 - ◆ **IVD Industry (AdvaMed, EDMA, JACR)**
 - ◆ **EQA/Proficiency Organizations, Regulatory bodies,**
 - ◆ **WASPaLM, ISTH**
 - ◆ **EC-DG Enterprise**
 - ◆ **ISO**

ORGANISATION Structure

■ JCTLM

- ◆ Stakeholders as on previous slide:
- ◆ Priority setting
- ◆ Decision on projects
- ◆ Identification of appropriate organisation

■ Working Groups: Task oriented

■ Workshops and Symposia



Working Groups

- **WG 1: Reference Materials and Reference Procedures**
 - ◆ Availability of
 - ◆ Reference Materials
 - ◆ Reference Measurement Procedures
- **WG 2: Reference Measurement Laboratories**
 - ◆ Compliance with ISO regulations
 - ◆ Accreditation
 - ◆ Link to appropriate organisations (CCQM, IFCC, IRMM, NIST, CDC,)
 - ◆ Key comparisons through CCQM (CIPM MRA), or int. comparisons or collaborative studies through other bodies.

JCTLM

CONSENSUS POLICY

**For Establishing
Traceability in
Laboratory Medicine**