THE NEED FOR TRACEABILITY IN LABORATORY MEDICINE

Mathias M. Müller
Institute of Laboratory Diagnostics
Vienna - Austria

LABORATORY MEDICINE

... an integrated discipline in health care:
risk assessment
diagnosis of health and disease,
follow-up and monitoring of patients.

... using physical, chemical, biochemical, immunological, molecular biological techniques for measurements of
body fluids, tissues, and cells

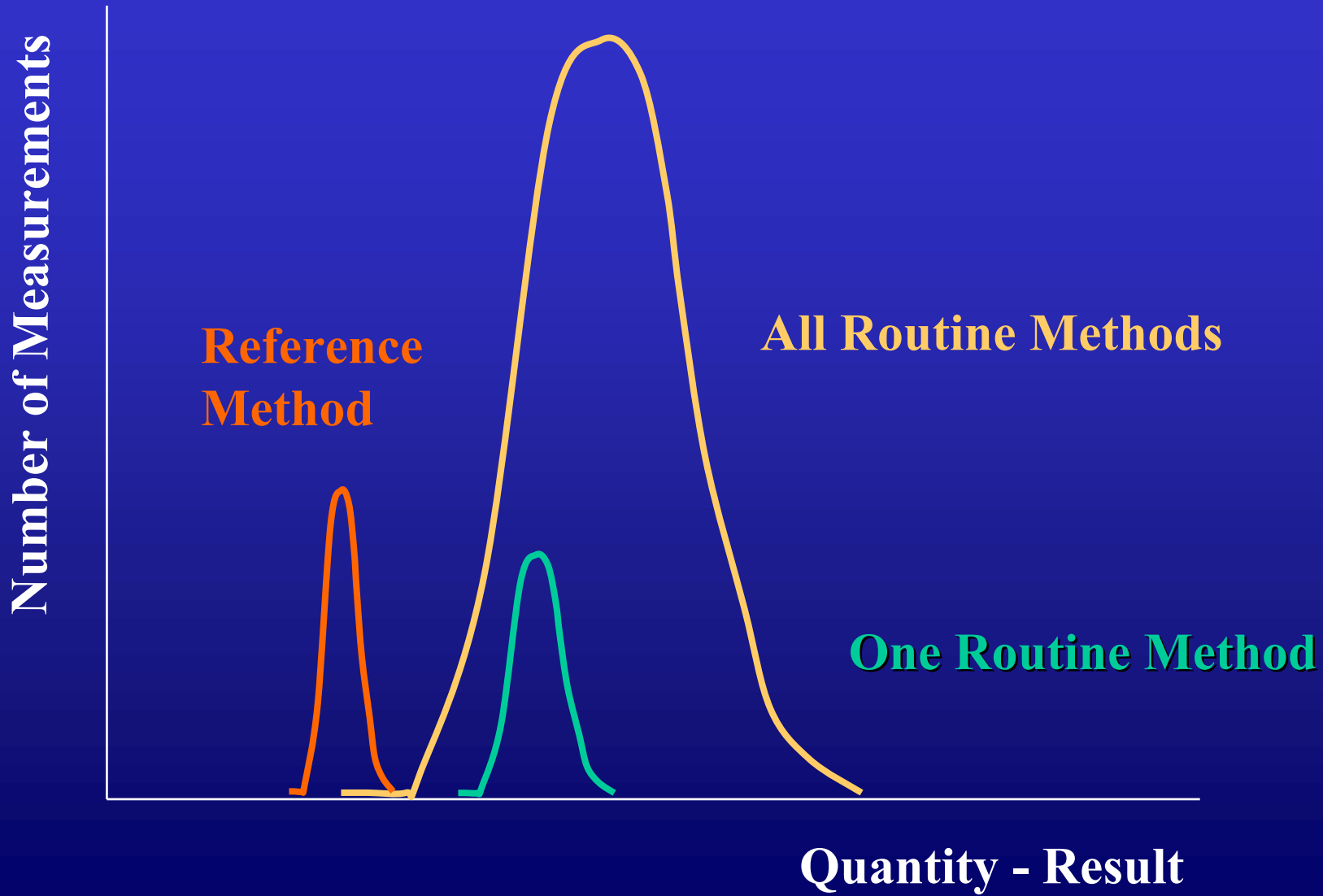
Inadequate or incorrect analytical performance has consequences for practical medicine and the health care system:

- incorrect interpretation of results by the physician
  - wrong diagnosis and treatment
  - additional diagnostic procedures
  - impairment of the patient's situation and behavior
- increase in health care expenses
  - wrong political decisions

AQAS - Method Target Values in 2 Control Samples

Analyte	LIA	EIA	MEIA	RIA
AFP (ng/ml)	39 79	32 93	35 99	26 72
CEA (ng/ml)	4 28	5 31	4 25	4 28
CA 19-9 (U/ml)	12 63	21 84	26 87	15 52
PSA (ng/ml)	12 120	7 70	7 80	

ANALYTICAL BIAS



R. DYBKAER 1975

EQUAS

NEED FOR STANDARDISATION

- Characterisation of Analyte
- Clinical Needs
- Reference Procedure
- Reference Material
- Reference Laboratories

STANDARDISATION

A technical process to reach conformity of measurement procedures by applying highest scientific standards

REFERENCE SYSTEM

REFERENCE METHODS
REFERENCE MATERIALS
REFERENCE LABORATORIES

- **ISO/EN 15195**
  Requirements for **reference measurement laboratories** in laboratory medicine

- **EN 12286**
  Measurements of quantities in samples of biological origins – Presentation of **reference measurement procedures**

- **EN 12287**
  Description of **reference materials**

TRACEABILITY

Property of the result related to national or international standards through an unbroken chain of comparisons all having stated uncertainties

ISO/EN 17511
Measurement of quantities in samples of biological origin – Metrological traceability of values assigned to *calibrators and control materials*

ISO/EN 18153
Measurement of quantities in samples of biological origin - Methodological traceability of values for *catalytic concentration of enzymes* assigned to calibrators and control materials

TRACEABILITY

ISO/EN 17511

Measurement of quantities in samples of biological origin – Metrological traceability of values assigned to *calibrators and control materials*

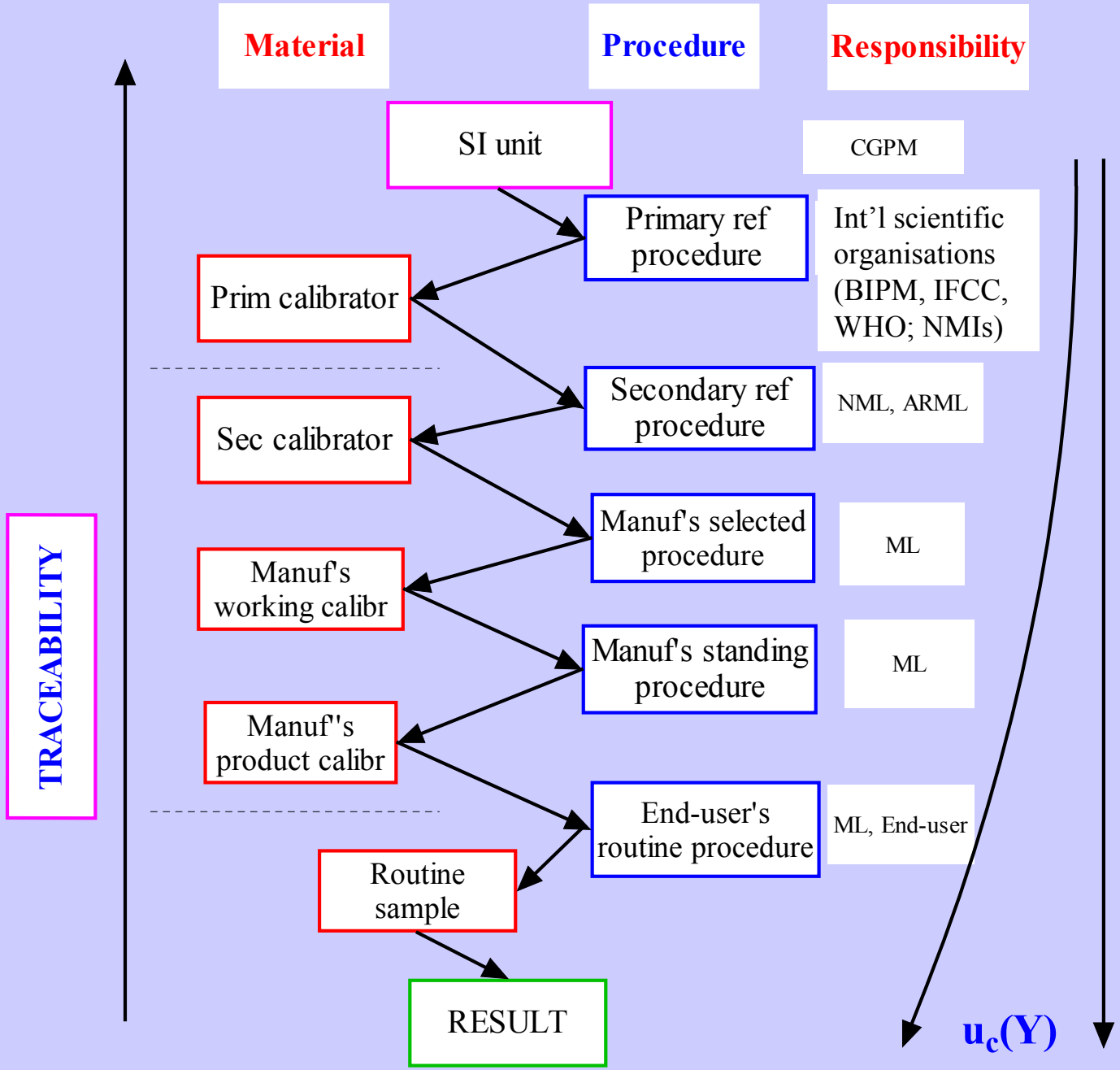
A: traceable to SI
B: non-traceable to SI

- **Int'l Rreference measurement procedure and int'l calibrator**
- **Int'l Reference measurement procedure but no int'l calibrator**
- **Int'l calibrator but no int'l reference measurement procedure**
- **Manufacturer's measurement procedure but neither int'l reference measurement procedure nor int'l calibrator**

EU Lex: Directive 98/79 EC

application on in vitro diagnostic medical reagents

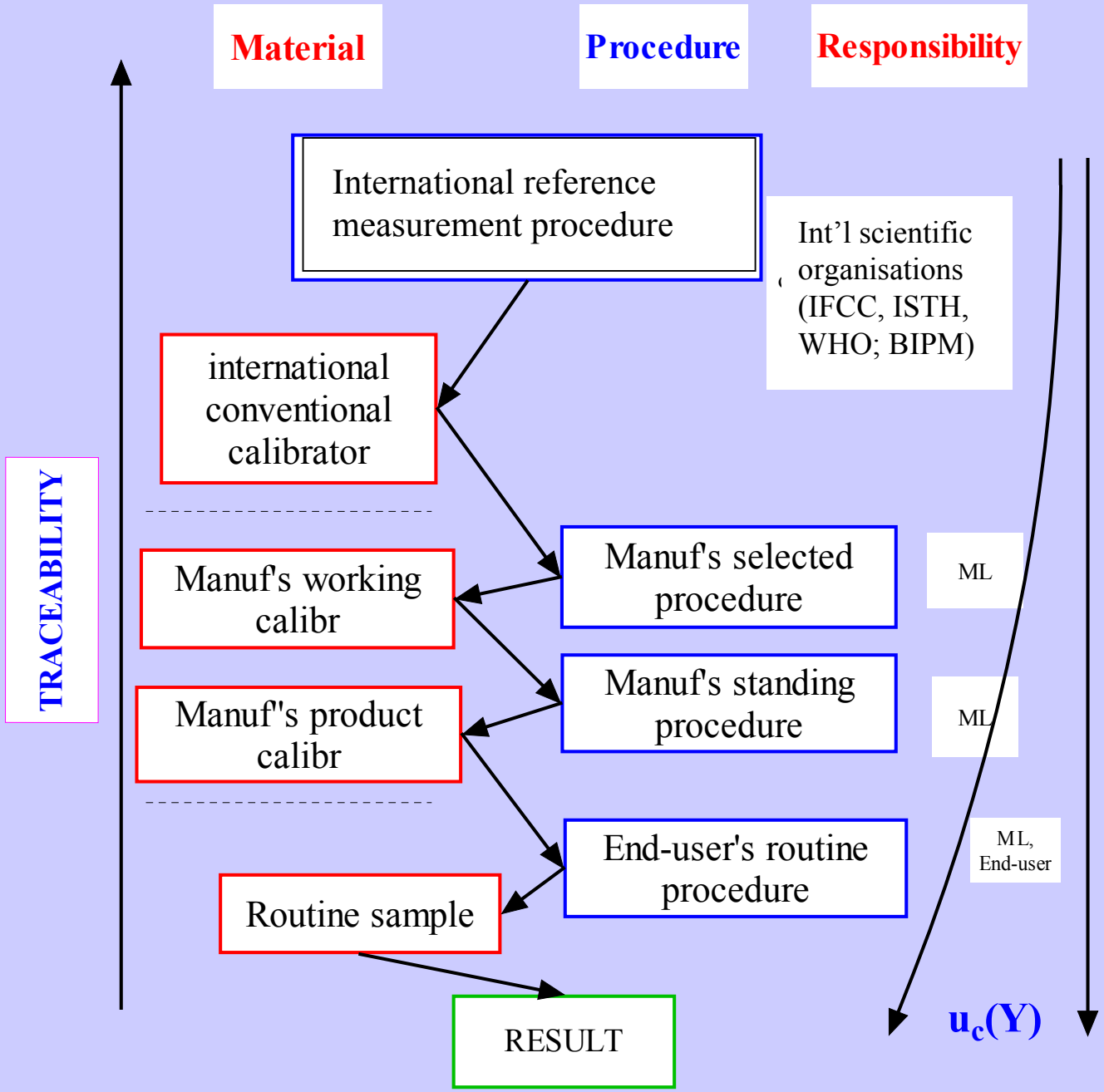
EN 17511
Traceable to SI



A. Kallner

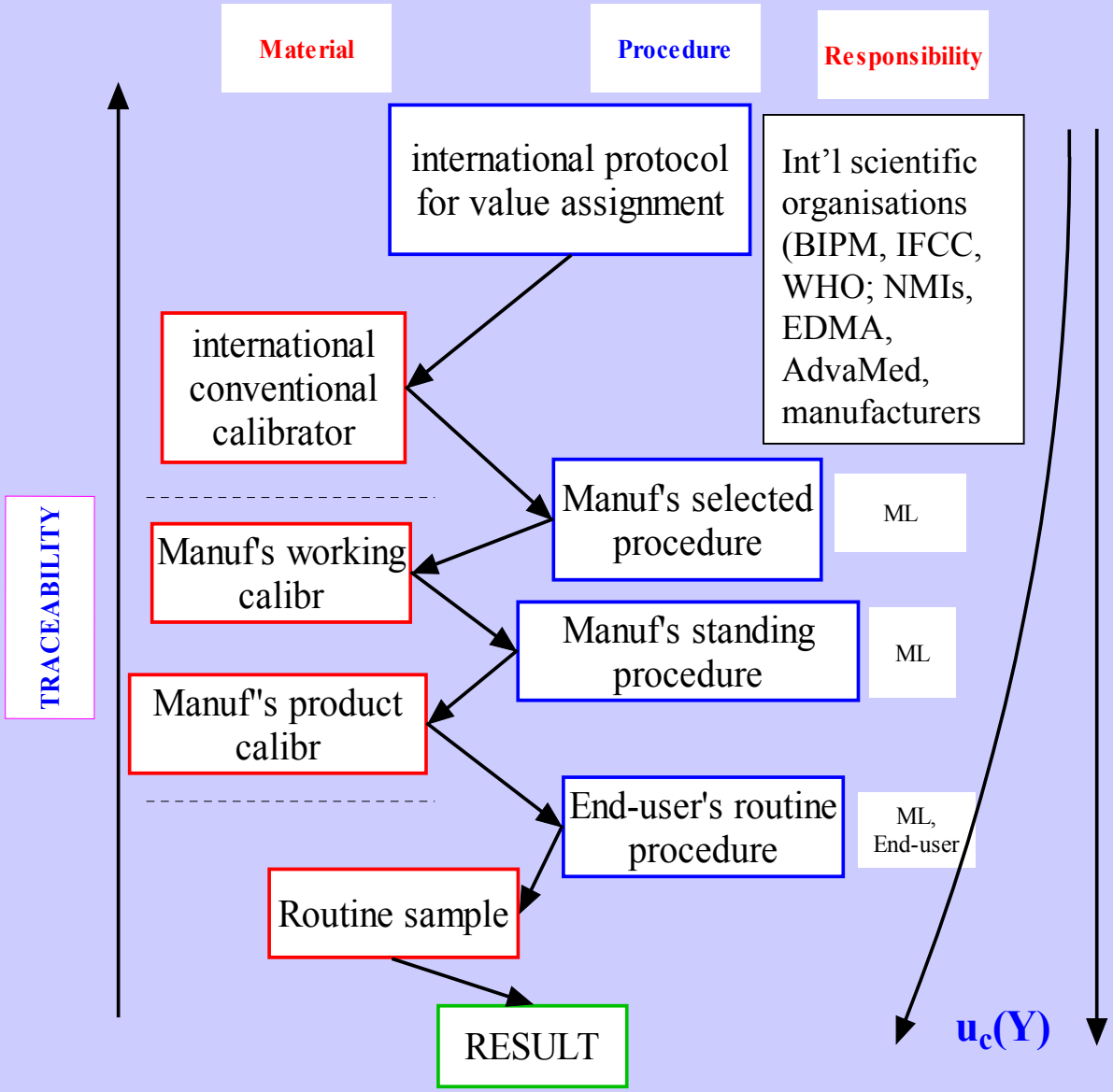
EN 17511
No prim ref proc, no prim ref material

E.g.:
HbA1c



No prim. int'l conventional calib., no int'l conventional ref. procedure,

E.g.:
Hep B surface Ag
Choriogonadotropin



A. Kallner

JCTLM

- Prioritize analytes based on medical needs
- Coordinate development of reference materials/methods
- Develop interpretive guidelines for manufacturers, NMIs, clinical laboratories and medical practitioners to assist implementation of traceability requirements

U.S. Department of Health and Human Services
Food and Drug Administration

AdvaMed
Advanced Medical Technology

JCTLM

A JOINT VENTURE OF PROFESSIONALS

from Diagnostic Laboratories (IFCC)
from Metrology (BIPM)
from Certifying Bodies (FDA)
from Diagnostic Industry (AdvaMed, EDMA, JACR)
from Health Authorities (WHO)
from Accreditation Bodies (ILAC)

CONSENSUS

JCTLM

OBJECTIVE - PURPOSE

- To support comparability and equivalence of measurement results in Laboratory Medicine, through *world-wide* accepted traceability effort following the principles of metrology

- To support IVD manufacturers in registration and licensing the CE label conforming with the EU directive.

SCIENTIFIC DIVISION
REFERENCE LABORATORIES

- Enzymes
- HbA1c
- Cortisol
- others

Not-SI-traceable

Collaboration with

Metrology Institutes
Industry

JCTLM

FUTURE

- Workshop, Paris, June 2002
  - Foundation of JCTLM
  - Promotors: IFCC, CIPM/BIPM, WHO, ILAC
- Priority Setting (medical needs)
  - What is needed - not what is easy
- Working-Groups
  - Reference Materials
  - Reference Measurement Procedures
  - Costs - Benefits
- Network of Reference Laboratories
- Reckognition by Authorities (NMIs)

Focus on Standardisation and Traceability

- Needs for Patients
- Excellence in Analytical Performance based on modern concepts of metrology and science

...will add QUALITY and VALUE to CLINICAL CHEMISTRY and LABORATORY MEDICINE