JCTLM

Symposium 2007

Activities and Challenges for International Standardization an Traceability in Laboratory Medicine:

- Session 1:International, regional and National Activities;

- Session 2:Challenges for Internaltional Standardization and traceability.

THE JOINT COMMITTEE ON TRACEABILITY IN LABORATORY MEDICINE

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Centre Hospitalier Universitaire de Québec, Canada

Chair JCTLM

11th APCCB, Beijing, October 2007

Joint Committee for Traceability in Laboratory Medicine

- What is it for?
- What is it?
- Why is it important?
- How is it implemented?
- How does the JCTLM help?

Background

- In the past, In Vitro Diagnostic Medical Devices (IVDs) had to comply with national legislation, when existing, providing rules for placing devices on the market (reagents, manufacturers instructions for use, technical documentation);
- The *in vitro* Diagnostic Medical Devices Directive 98/79/EC published: end of 1998; transposed into National Laws within the EU: end of 1999;
- Harmonization: CE label;
- Transition period:
  - June 2000: progressive introduction of CE marked IVDs;
  - June 2000-Dec 2003: possible to place on the market IVDs without marking (comply to national legislation);
  - Until Dec 2005: those IVDs marketed before Dec 2003 without CE mark can still be distributed.
- Implementation:
  - From Dec 2005: only CE marked devices will be made available on the Community market.

Impact of the implementation of the EU Directive 98/79/EC on the In Vitro Diagnostic Medical Devices and of the Relevant ISO Standards on Patient Care

Practical considerations of the IVD-MD Directive 98/79/EC

- Introduces common regulatory requirements for safety, quality and performance;
- Describes the principal requirements concerning reliability of IVDs with regard to intended utilization;
- Harmonizes the conformity assessment procedures to be followed by manufacturers before IVDs are placed on the market (Common Technical Specifications);
- Certification to the IVD Directive of manufacturers must respect recognized conformity assessment schemes;
- Follow-up assessments on a regular basis to ensure continued compliance (external audits: Notified Bodies);
- Compliance with IVD Directive => CE mark => declaration by the manufacturer that the product meets all the provisions of the legislation.

The IVD Directive of the EU requires that:

"The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order.. "

Annex I - Essential Requirements
Part A. General Requirements, Clause 3

ISO 17511 : Metrological traceability

Objective:

"To enable the results obtained by the calibrated routine procedure to be expressed in terms of the values obtained at the highest available level of the calibration hierarchy ".

For the industry and for the clinical laboratories:

"How to meet this objective ?"

CEN and ISO standards related to metrological traceability of IVD MDs:

- Metrological traceability of values assigned to calibrators and control materials (prEN ISO 17511);
- Presentation of reference measurement procedures (ISO 15193);
- Description of reference materials (ISO 15194);
- Laboratory medicine - Requirements for reference measurement laboratories (prEN ISO 15195);
- Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials (prEN ISO 18153);
- Others.

ISO 17511 : Calibration Hierarchy

With regards to the metrological traceability chain and calibration hierarchy, two broad categories of measurands are distinguished:

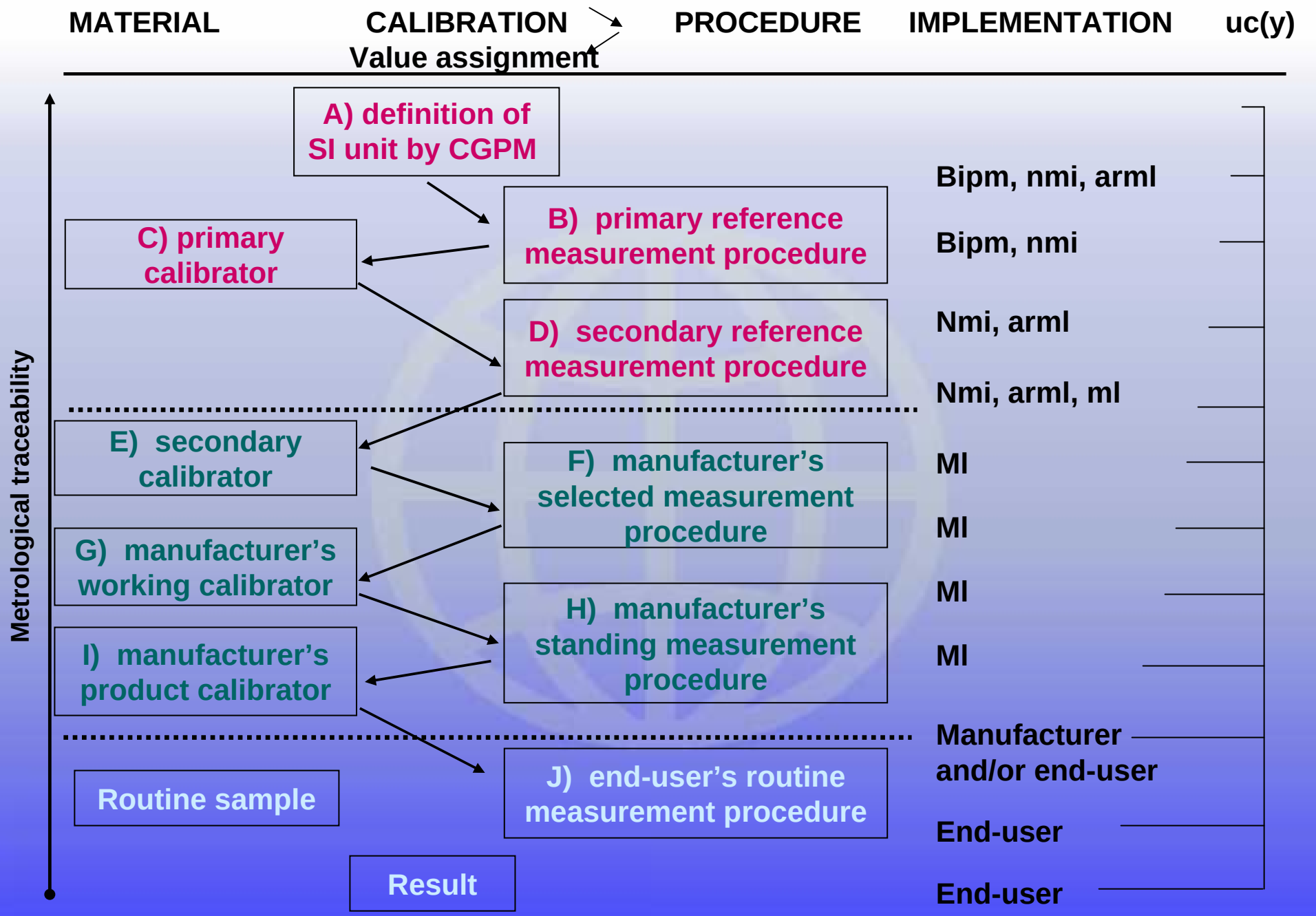
a) **Quantities for which results of measurements are metrologically traceable to SI (Type A analytes)**

b) **Quantities for which results of measurements are not traceable to SI (Type B analytes)**

ISO 17511:
Type A Analytes:

- A primary reference measurement procedure and one or more (certified) primary reference materials (used as calibrators) are available ;

- Approximately 100 types of analytes (electrolytes, glucose, steroid hormones …).

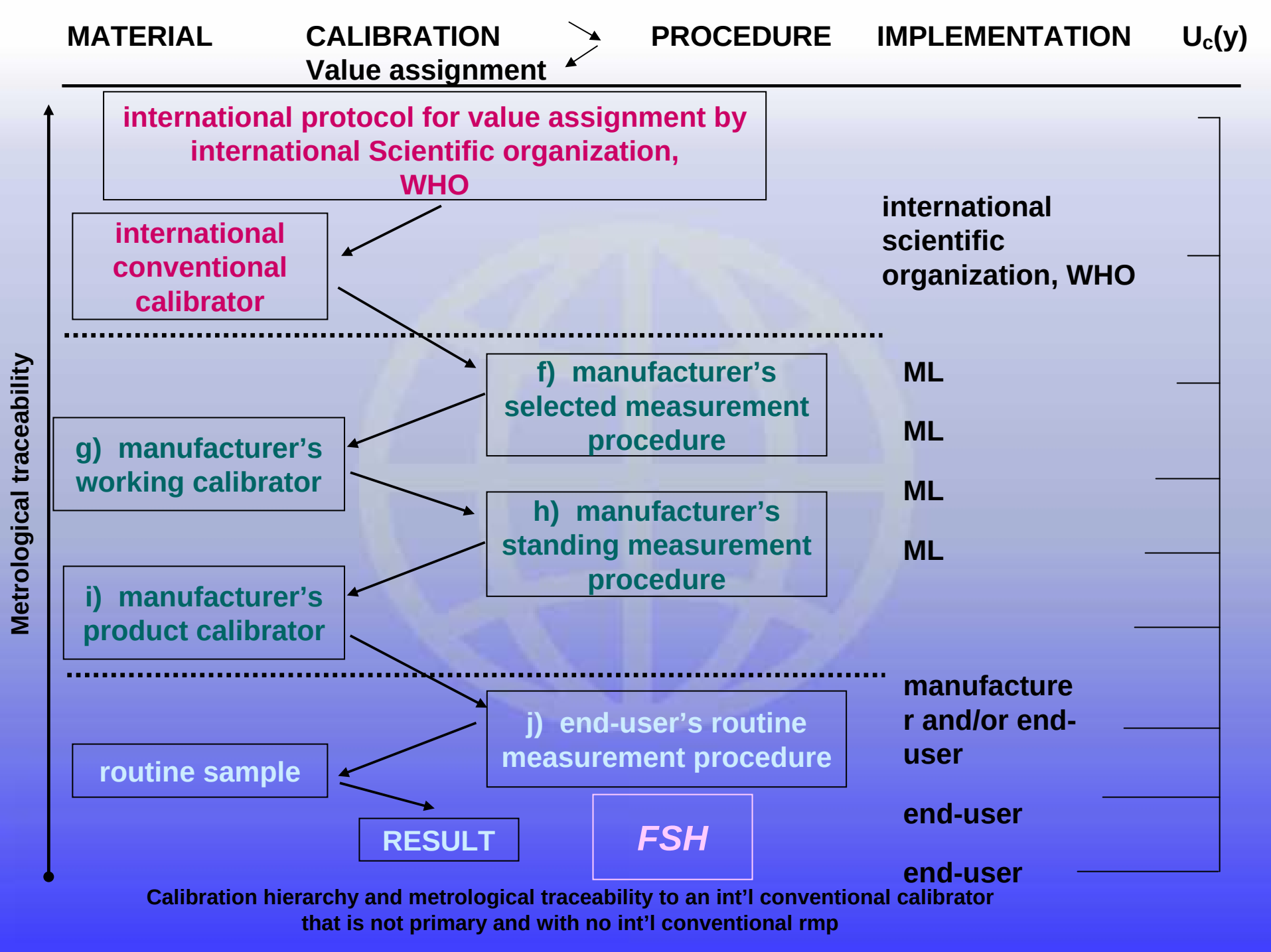


Extensive calibration hierarchy and metrological traceability to SI

ISO 17511:
Type B analytes:

Most analytes in Laboratory Medicine: > 600 types:

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



Calibration hierarchy and metrological traceability to an int'l conventional calibrator that is not primary and with no int'l conventional rmp

THE CHALLENGE

- **How to ensure that values produced by IVDs are traceable to higher order Reference Materials and recognized Reference Measurement Procedures meeting criteria of ISO standards?**

JCTLM

A global initiative,
established
in Paris, June 12, 2002

A joint venture of professionals, metrology institutes, regulators and IVD-industry

http://www.bipm.org

ifcc International Federation Of Clinical Chemistry And Laboratory Medicine

A global initiative

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- Diagnostic Laboratories (IFCC)
- Diagnostic Industry (AdvaMed, EDMA, JACR)
- Metrology Institutes (BIPM)
- Standards Organisation (ISO, CEN)
- Regulatory Bodies (FDA, EC)
- CRM Producers (IRMM, NIST)
- Health Authorities (WHO)
- Accreditation Bodies (ILAC)
- EQAS Organisations (CAP, EQUALM)
- Network of Reference Measurement Laboratories

DECLARATION OF COOPERATION

The **International Committee of Weights and Mesures** (**CIPM**), the **International Federation for Clinical Chemistry and Laboratory Medicine** (**IFCC**), and the **International Laboratory Accreditation Cooperation** (**ILAC**) have agreed to cooperate to establish a Joint Committee for Traceability in Laboratory Medicine, with the acronym **JCTLM**.

The goal of the JCTLM is to provide 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.

Chair IFCC:

Prof Jean Claude Forest
Centre Hospitalier Universitaire de Québec
et Université Laval
Québec
Canada

Secretariat BIPM:

Dr Robert Wielgosz
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France

JCTLM - Structure

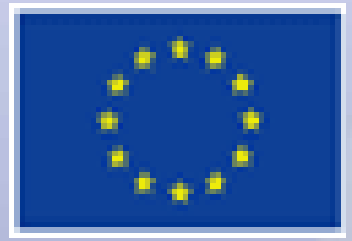
- **JCTLM – Executive Board**
- Chair: JC Forest (IFCC), secretary R. Wielgosz (BIPM)
  Priority setting, Approval of WG's results

- **JCTLM Working Groups: Task oriented**
  - **1. <u>Reference Materials and Reference Measurements procedures</u>**
    Chair: W.May (NIST) and H. Schimmel (IRMM)

  - **2. <u>Reference Measurement Services (Laboratory – Networks)</u>**
    Chair: L. Siekmann (IFCC) and L. Thienpont (IFCC)
    Guidelines for reference laboratories
    Identification of networks

A Clearer implementation of the IVD Directive

EU - IVD - Directive



JCTLM

Ref. Materials, Methods, Labs

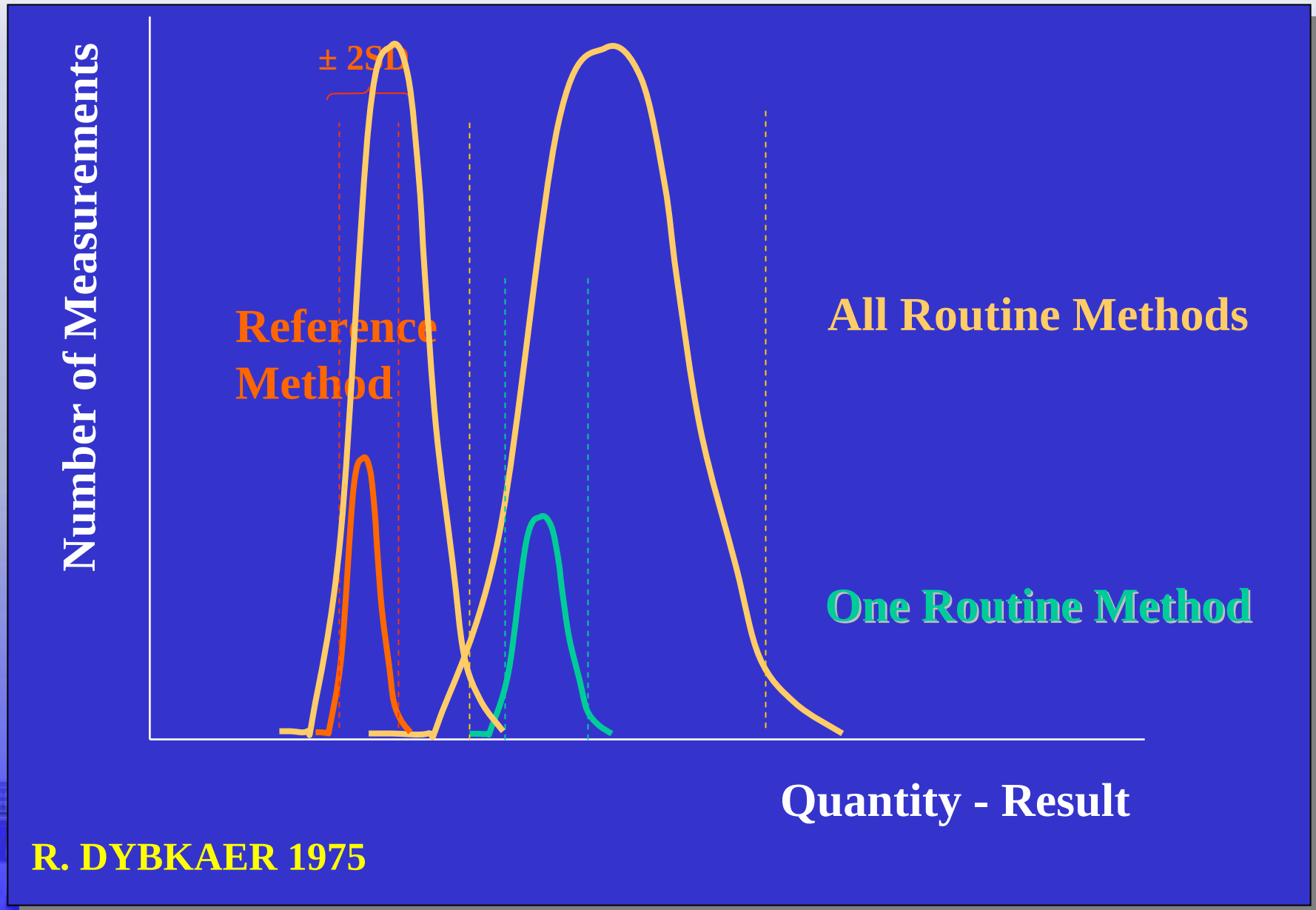
EU-DG-Enterprise
Official Recognition
of JCTLM Products

IVD Industry
Conformity and Traceability
Uniform Calibration
Harmonisation of Patient Results

Harmonization of patient results (comparability)

- Reduction of errors of diagnostics or of risk assessment;
- Comparable Reference Intervals;
- Decision levels: These are used by physicians without regard to the methodology used in their setting (evidence based medicine, guidelines).

ANALYTICAL BIAS



Reference Measurement Systems

- Reference measurement procedures
- Reference materials
- Networks of reference laboratories
- Reference intervals and decision limits

Sponsoring Organizations

Intergovernmental Treaty Organization for Measurement Standards

International NGO for Professionals in Laboratory Medicine

International NGO for Accreditation Bodies