

## PREAMBLE

The goal of obtaining comparability of laboratory diagnostic test results will be reached only when common reference systems can be established for worldwide use. A critical step in reaching this goal is achieving traceability of values obtained using reference measurement procedures and reference materials to a universally recognized and accepted reference point such as the International System of Units (SI). Recently, traceability requirements for medical devices to be imported into the European Community have been codified. The European Community In Vitro Diagnostic Directive (EC IVDD) states 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."** (98/79/EC, Annex I (A) (3) 2<sup>nd</sup> paragraph).

The Joint Committee on Traceability in Laboratory Medicine (JCTLM) was created 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. These are embodied in ISO 17511, 17025 and 18153. The JCTLM created two working groups:

- WG1 Reference Materials and Reference Measurement Procedures
- WG2 Reference Measurement Services.

The Declaration of Cooperation between the International Committee of Weights and Measures (CIPM), the International Federation for Clinical Chemistry and Laboratory Medicine (IFCC), and the International Laboratory Accreditation Cooperation (ILAC) for establishment of the JCTLM can be found at <http://www.bipm.org/en/convention/mou/jctlm.html>

JCTLM WG1 is charged with establishing a process for identifying, reviewing against agreed upon criteria, and publishing List(s) of Higher Order Certified Reference Materials and Reference Measurement Procedures required for industry compliance with the EC IVDD.

Nominated reference materials and measurement methods/procedures were categorized according to the criteria described in ISO 15194 and ISO 15193. Two Lists of Higher Order Reference Materials and Reference Measurement Methods/Procedures will be published:

- List I. Certified reference materials and reference measurement methods for well-defined chemical entities or internationally recognized reference method-defined measurands. Reference materials and measurement methods included in this category are those that provide values that are traceable to the SI units; e.g., electrolytes, enzymes, drugs, metabolites and substrates, non-peptide hormones, and some proteins.
- List II. Reference materials for which values of the measurands are not SI-traceable but are assigned by or traceable to an internationally agreed upon protocol, e.g., reference materials for blood typing, coagulation factors, microbial serology, nucleic acids, and some proteins and purified substances. List II also contains a group of purified substances which, due to the absence of reference measurement procedures, should not be directly used for calibration of routine methods unless commutability is established and/or matrix effect independent internationally recognized standardized value transfer protocols to commutable samples are applied.

The general procedures by which reference materials and reference measurement methods/procedures have been evaluated for listing are provided in the JCTLM Quality System Document which is available on the BIPM and IFCC websites at <http://www.bipm.org/en/committees/jc/jctlm/jctlm-db/> and <http://www.ifcc.org> respectively. JCTLM WG2 is establishing criteria and processes for listing reference measurement services of laboratories.

New materials, reference methods/procedures and reference measurement services will be considered for listing periodically, but not less frequently than biennially. Listed materials are expected to be available for at least eighteen months after initial posting. However, because usage rates for listed materials cannot be predicted accurately, producers must be contacted by anyone intending to use the listed material to determine availability of the current materials and projected times for production of new lots. It is the responsibility of the producer to notify the JCTLM Secretariat if a material ceases to be available.