

Appendix III

The JCTLM Framework: A Framework for the international recognition of available higher- order reference materials, available higher-order reference measurement procedures and reference measurement laboratories for laboratory medicine

Preamble

In response to the need to establish lists of available higher-order reference materials, available higher-order reference measurement procedures and reference measurement laboratories for laboratory medicine, a Joint Committee for Traceability in Laboratory Medicine (JCTLM) has been formed. Its Executive, made up of representatives from the BIPM, IFCC and ILAC, oversees the Joint Committee. With the creation of the JCTLM a Framework has been established which can be used for the international recognition of such materials, procedures and laboratories.

The Framework

The JCTLM Framework lays down a process whereby reference materials and reference measurement procedures are examined with respect to conformity with appropriate international documentary standards, and whereby reference material properties are verified by measurements made in institutes with demonstrated competence in the field.

The outputs of the Framework are databases of available higher-order reference materials and higher-order reference measurement procedures as well as reference laboratories that can be used by the IVD industry and other users to meet requirements for traceability for *in vitro* diagnostic and laboratory medicine measurements.

The Process, Technical Basis and Procedures

The technical basis of the process is:

- (a) the evaluation by the JCTLM Working Groups of nominated reference materials and reference measurement procedures and their implementation in reference measurement laboratories against relevant ISO Standards and Guides, and WHO Guidelines; and
- (b) measurements to demonstrate the comparability of reference materials, the properties of which are expressed in SI units or, if not yet possible, international units of the WHO or other internationally agreed units.

Where measurements are required, these will be carried out by laboratories that have previously demonstrated their competence through their performance in relevant

international comparisons, for example in the CIPM MRA key comparisons or the IFCC EQAS for Reference Laboratories.

The proper use of the higher-order reference materials and reference measurement procedures calls for the existence of networks of competent reference measurement laboratories for specified measurands. Such reference measurement laboratories will have demonstrated their technical competence in the operation of a reference measurement procedure of higher order for a given measurand with demonstrated traceability and measurement uncertainty. The technical competence of the laboratories shall be demonstrated by their performance in international comparisons, and their operation of an appropriate quality system. International recognition of the implementation of the quality system is achieved via accreditation or equivalent documented peer review.

Publication of the database of higher-order reference materials, reference measurement procedures and reference laboratories

The higher-order reference materials, reference measurement procedures and reference laboratories that are endorsed by this process will be published in databases by the BIPM and the IFCC and will be publicly available on the BIPM and IFCC websites with links from other websites as necessary.

Users of the Databases

The databases have been established for use by all interested parties, notably:

- IVD-industry
- quality assurance organizations in the field of laboratory medicine
- regulatory authorities
- international organizations
- NMIs and other producers of higher-order reference materials
- professional societies in the field of laboratory medicine

In using the data, users recognize the Framework that has been established to enable the development of these databases, and are advised to make reference to the JCTLM Framework and associated databases in any relevant documentation they produce.

Responsibility

It is wholly the responsibility of the producers of the materials listed in the database that they meet their stated specifications and continue to be available, and not the responsibility of the JCTLM or the BIPM, IFCC or ILAC.

Responsibility for reference measurement procedures meeting their stated specifications remains with the laboratory that performs the measurement, and is not the responsibility of the JCTLM or the BIPM, IFCC or ILAC.

This Framework is of an exclusively recommendatory nature. It will not create any binding legal effect in national and international law.