

Appendix IV

The JCTLM Framework: A Framework for the international recognition of available higher-order reference materials, available higher-order reference measurement procedures and calibration (reference) 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 services for laboratory medicine, a Joint Committee for Traceability in Laboratory Medicine (JCTLM) has been formed. Its Executive Committee oversees the JCTLM, and is the impartial final decision making organ. With the creation of the JCTLM a Framework has been established which can be used for the international recognition of such materials, procedures and measurement services from laboratories.

Framework

The JCTLM Framework lays down a process whereby reference materials and reference measurement procedures and reference measurement services are examined with respect to conformity with appropriate international documentary standards.

The output of the Framework is a database of available higher-order reference materials and higher-order reference measurement procedures as well as reference measurement services provided by calibration (reference) laboratories that can be used by the IVD industry and other users to meet requirements for metrological traceability for in vitro diagnostic and laboratory medicine measurements.

Process, Technical Basis and Procedures

The technical basis of the process is the evaluation by the JCTLM Database Working Group of nominated reference materials and reference measurement methods and their implementation in reference measurement laboratories against relevant international documentary standards.

The relevant standards with which compliance is evaluated are listed in the Quality Manual of the JCTLM Working Group, and the list updated when necessary.

The proper use of the higher-order reference materials and reference measurement procedures calls for the existence of competent calibration laboratories for specified measurands. Such calibration laboratories will have demonstrated their technical competence in the operation of a reference measurement procedure of higher order for a given measurand with demonstrated metrological 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. The standards on which calibration laboratory accreditation is based are listed in the Quality Manual of the JCTLM Working Group, and the list updated when necessary.

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

The higher-order reference materials, reference measurement methods and reference measurement services that are endorsed by this process will be published in a database by the BIPM and will be publicly available with links from the IFCC website and other websites as necessary.

Users of the JCTLM Database

The JCTLM Database has been established for use by all interested parties, including:

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

In using the data, users recognize the Framework that has been established to enable the development of the database, and are advised to make reference to the JCTLM and associated database 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 JCTLM Executive Committee Member.

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 JCTLM Executive Committee Member.

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