6 A new JCTLM Task Force focusing on the implementation of reference measurement systems

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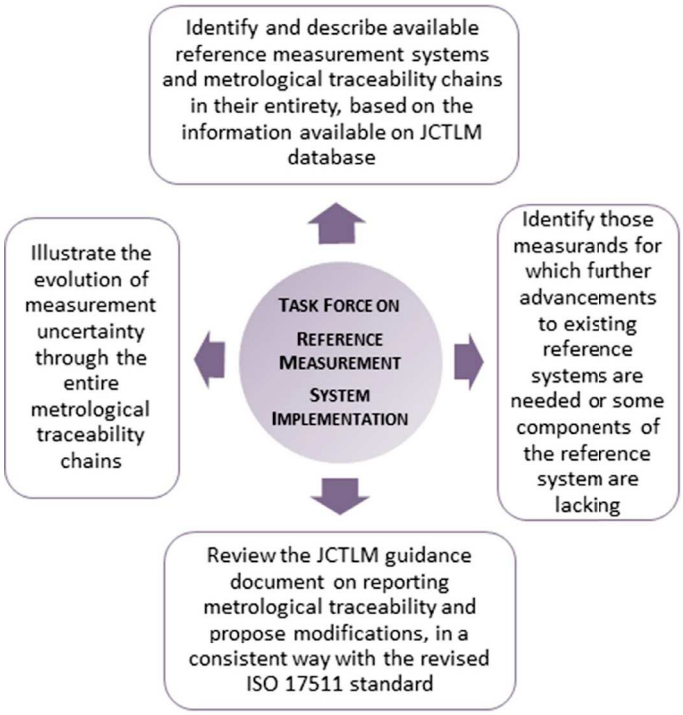
Only a brief description of metrological traceability and associated uncertainty is often provided with commercial calibrators. The information is often limited to the name of higher-order reference materials and/or reference procedures to which the assay calibration is traceable, without any description of implementation steps. Information such as the applied calibration hierarchy, the measurement uncertainty associated with calibrator, and the employed acceptable uncertainty limits is often partly reported. To fully verify the characteristics of commercial measuring systems, laboratory users should be able to access the following: a) an indication of higher-order references (materials and/or procedures) used to assign traceable values to calibrators, b) which internal calibration hierarchy has been applied by the manufacturer and a detailed description of each step, and c) the combined measurement uncertainty value of commercial calibrators, and which, if any, acceptable limits for uncertainty of calibrators were applied in the validation of the measuring system.

Accumulated experience is showing that standardization projects not only have to address metrological traceability but should also consider the efficacy of its implementation. Previous analyses highlighted how strongly the measurement uncertainty may be dependent on the type of traceability chain adopted by the IVD manufacturers to implement the traceability of their calibrators. It has been shown that the selection of different types of traceability chains (all employing reference materials and procedures listed in the JCTLM database) may lead to different combined uncertainties at the level of commercial calibrators, not always permitting to fulfil the suitable uncertainty budget at the level of clinical sample measurements. Therefore, in order to aid IVD manufacturers in the implementation of metrological traceability, the identification and definition of available reference measurement systems and of metrological traceability chains in their entirety and not just in their main components (i.e., reference materials and methods) can be extremely helpful. With this in mind, the JCTLM Executive Committee approved, during its last annual meeting, the creation of the JCTLM Task Force on Reference Measurement System Implementation (TF-RMSI), with the aim to provide guidance on reference measurement system implementation to the IVD community. This activity will be timely with the upcoming publication of the revised ISO 17511 standard that lays out the requirements for establishing reference measurement systems and their implementation by IVD manufacturers.



The figure shows the terms of reference for TF-RMSI. A key output will be the identification of available reference measurement systems and metrological traceability chains in their entirety. The illustration of the evolution of measurement uncertainty through the entire metrological traceability chains and the identification of measurands for which further advancements to existing reference systems are needed or some components of the reference system are lacking will allow to indicate areas for improvement for reference providers and IVD manufacturers and to help prioritise future efforts. Based on the work of the TF-RMSI and the content of the revised ISO 17511 standard, the JCTLM guidance document on reporting metrological traceability will be reviewed. The progress of the TF-RMSI activity will be reported at future meetings of JCTLM members and stakeholders, where next steps on promotion of this work and future collaborative efforts between JCTLM and appropriate organizations will be proposed.

Selected references

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- Braga F, Panteghini M. Defining permissible limits for the combined uncertainty budget in the implementation of metrological traceability. *Clin Biochem* 2018;57:7-11.