# Standardization in Laboratory Medicine: activities, goals, and further issues

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The standardization of measurements is of high priority in Laboratory Medicine, its purpose being to achieve closer comparability of results obtained using routine analytical systems. In order to achieve standardization, an approach is required that provides reliable transfer of the measurement values from the highest hierarchical level to methods which are routinely used in the clinical laboratories. Such a structure is presented by the reference measurement system, based on the concepts of metrological traceability and a hierarchy of analytical measurement procedures.

Since the development of metrologically sound reference systems is a complicated and expensive process, it is clear that the objective of improving standardization in Laboratory Medicine will only be achieved if the problems are dealt with not on a national level but through international cooperation. This was the reason for the creation of the Joint Committee on Traceability in Laboratory Medicine (JCTLM), which has made publicly available a list of higher order reference materials and reference methods for analytes measured in Laboratory Medicine, identified by a thorough review process for conformity with appropriate ISO standards (http://www.bipm.org/en/committees/jc/jctlm/jctlm-db). JCTLM has also published the list of reference laboratories that fulfil established selection criteria and are able to deliver a reference measurement service.

As soon as a new reference measurement system is implemented, clinical validation of the correctly calibrated routine methods should take place. In specific cases, in order to maintain the value of clinical experience, correlation of measurement results obtained with the new traceable calibration to results of measurements obtained with the previous not standardized calibration should be established.

Other important issues concerning the implementation of a metrologically-correct approach for result standardization should also be defined. Firstly, a clear definition of the clinically allowable error of measurements is required. Secondly, a post-market surveillance of the performance of diagnostic products should be established through the organization of appropriate External Quality Assessment Schemes (EQAS). The applicability of the true value concept in EQAS requires, however, the availability of control materials with target values assigned by reference methods and that these materials behave exactly as human patient specimens. True value assignment to commutable EQAS materials will allow an objective evaluation of the performance of commercial systems, together with an accuracy-based (instead of inferior consensus group-based) grading of the competency of participating clinical laboratories.

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