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In vitro diagnostic medical devices — Requirements for reference measurement procedures

Dispositifs médicaux de diagnostic in vitro — Exigences relatives aux procédures de mesure de référence

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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This third edition cancels and replaces the second edition (ISO 15193:2009), which has been technically revised.

The main changes are as follows:

— incorporated requirements, concepts and definitions for consistency with ISO 17511, ISO 15194, and ISO 15195;

— adapted content to make the document applicable to all types of measurands;

— revised Clause 4 to present requirements more transparently;

— added 4.1 added to emphasize quality requirements for a reference measurement procedure (MP);

— updated and summarized aspects of validation in 4.15.

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Reference measurement systems are needed to enable the results produced by end user measurement procedures (MPs) to be metrologically traceable to either measurement standards, or measurement procedures, or both of the highest metrological level. Such systems exist within a metrological traceability chain/calibration hierarchy as described in ISO 17511. In the context of in vitro diagnostic (IVD) medical devices, traceability to the highest metrological level reduces the risk of harm to patients by avoiding inconsistent results from different measuring systems.

Reference measurement procedures play a crucial role in this metrological traceability system, because they can be used for the following:

a) assessing performance properties of measuring systems – comprising measuring instruments, auxiliary equipment as well as reagents,

b) assessing whether there is a functional interchangeability of different end user measurement procedures purporting to measure the same quantity,

c) assigning quantity values to reference materials that are then used for purposes of calibration or measurement trueness control of measurement procedures, and

d) detecting analytical influence quantities in biological samples measured using end user measurement procedures.

For medical laboratory measurements, in particular, it is important to both patient care and health screening that the measurement results reported by different end user measuring systems be equivalent, comparable over time, reproducible and accurate. Establishing metrological traceability of an end user measuring system to a reference measurement procedure enables equivalent results to be reported. A reference measurement procedure should be specified, especially when

— it is required by e.g. standards, technical specifications, or technical regulations,

— quantity values are to be stated by the manufacturer, and

— technical requirements have a direct relationship to the performance of a product or process.