Metrological Traceability in Laboratory Medicine, Definitions: Formal and for everyday use

Term	Every day – Easy to understand definition	Formal Definition	Source
Calibration	**The determination of the relationship between an instrument response and the concentration of substance being measured.**	operation that, under specified conditions, in a first step, establishes a relation between the **quantity values** with **measurement uncertainties** provided by **measurement standards** and corresponding **indications** with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a **measurement result** from an indication NOTE 1 A calibration may be expressed by a statement, calibration function, **calibration diagram**, **calibration curve**, or calibration table. In some cases, it may consist of an additive or multiplicative **correction** of the indication with associated measurement uncertainty. NOTE 2 Calibration should not be confused with **adjustment of a measuring system**, often mistakenly called "self-calibration", nor with **verification** of calibration. NOTE 3 Often, the first step alone in the above definition is perceived as being calibration.	**VIM** http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf
Calibrator	**A (certified) reference material used for calibration**	**measurement standard** used in **calibration** NOTE The term "calibrator" is only used in certain fields.	**VIM 3** http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf
Certified Reference Material (CRM)	**A reference material with a certificate, normally provided by a manufacturer or specialist supplier, to calibrate or validate a measurement system**	**reference material**, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures EXAMPLE Human serum with assigned **quantity value** for the concentration of cholesterol and associated **measurement uncertainty** stated in an accompanying	**VIM 3** http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf

		certificate, used as a **calibrator** or **measurement trueness**control material. NOTE 1 'Documentation' is given in the form of a 'certificate' (see ISO Guide 31:2000). NOTE 2 Procedures for the production and certification of certified reference materials are given, e.g. in ISO Guide 34 and ISO Guide 35. NOTE 3 In this definition, "uncertainty" covers both 'measurement uncertainty' and 'uncertainty associated with the value of a **nominal property**', such as for identity and sequence. "Traceability" covers both '**metrological traceability** of a quantity value' and 'traceability of a nominal property value'. NOTE 4 Specified quantity values of certified reference materials require metrological traceability with associated measurement uncertainty (Accred. Qual. Assur.:2006) [45]. NOTE 5 ISO/REMCO has an analogous definition (Accred. Qual. Assur.:2006) [45] but uses the modifiers "metrological" and "metrologically" to refer to both quantity and nominal property.	
Commutability	**The ability of a reference material to behave in the same way as a human sample when measured with a routine test kit.**	property of a **reference material**, demonstrated by the closeness of agreement between the relation among the **measurement results** for a stated **quantity** in this material, obtained according to two given **measurement procedures**, and the relation obtained among the measurement results for other specified materials NOTE 1 The reference material in question is usually a **calibrator** and the other specified materials are usually routine samples. NOTE 2 The measurement procedures referred to in the definition are the one preceding and the one following the reference material (calibrator) in question in a **calibration hierarchy** (see ISO 17511). NOTE 3 The stability of commutable reference materials	**VIM 3** http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf

		should be monitored regularly.	
International System of Units	**Units for reporting measurement results that have been internationally agreed, with seven defined base units: the metre, the kilogram, the second, the ampere, the kelvin, the mole, and the candela.**	**system of units**, based on the **International System of Quantities**, their names and symbols, including a series of prefixes and their names and symbols, together with rules for their use, adopted by the General Conference on Weights and Measures (CGPM) NOTE 1 The SI is founded on the seven **base quantities** of the **ISQ** and the names and symbols of the corresponding **base units** that are contained in the following table. NOTE 2 The base units and the **coherent derived units** of the SI form a coherent set, designated the "set of coherent SI units". NOTE 3 For a full description and explanation of the International System of Units, see the current edition of the SI brochure published by the Bureau International des Poids et Mesures (BIPM) and available on the BIPM website. NOTE 4 In **quantity calculus**, the quantity 'number of entities' is often considered to be a base quantity, with the base unit one, symbol 1. NOTE 5 The SI prefixes for **multiples of units** and **submultiples of units** are:	**VIM 3** http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf
Limit of detection	**The smallest concentration that can be detected with reasonable certainty by a given analytical procedure.**	**measured quantity value**, obtained by a given **measurement procedure**, for which the probability of falsely claiming the absence of a component in a material is β, given a probability α of falsely claiming its presence NOTE 1 IUPAC recommends default values for α and β equal to 0.05. NOTE 2 The abbreviation LOD is sometimes used. NOTE 3 The term "sensitivity" is discouraged for 'detection limit'.	**VIM 3** http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf
Measurand	**What the practitioner sets out to measure.**	**quantity** intended to be measured NOTE 1 The specification of a measurand requires	**VIM 3**

	In the phrase, the concentration of glucose in plasma was 10 mmol/L, 'concentration of glucose in plasma' is the measurand. **In addition, glucose is the analyte being measured and plasma the material on which the measurement is performed.**	knowledge of the **kind of quantity**, description of the state of the phenomenon, body, or substance carrying the quantity, including any relevant component, and the chemical entities involved. NOTE 2 In the second edition of the VIM and in IEC 60050-300:2001, the measurand is defined as the "particular quantity subject to measurement". NOTE 3 The **measurement**, including the **measuring system** and the conditions under which the measurement is carried out, might change the phenomenon, body, or substance such that the quantity being measured may differ from the measurand as defined. In this case, adequate **correction** is necessary. EXAMPLE 1 The potential difference between the terminals of a battery may decrease when using a voltmeter with a significant internal conductance to perform the measurement. The open-circuit potential difference can be calculated from the internal resistances of the battery and the voltmeter. EXAMPLE 2 The length of a steel rod in equilibrium with the ambient Celsius temperature of 23 °C will be different from the length at the specified temperature of 20 °C, which is the measurand. In this case, a correction is necessary. NOTE 4 In chemistry, "analyte", or the name of a substance or compound, are terms sometimes used for 'measurand'. This usage is erroneous because these terms do not refer to quantities.	http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf
Measurement uncertainty	**The smallest range of values that reasonably includes the true value of a measurand, i.e. X ± Y, where X is the measurement result and Y, which by convention is greater than or equal to zero, is the uncertainty of X.** **This is the reliability range of a measurement result expressed as a plus / minus value.**	non-negative parameter characterizing the dispersion of the **quantity values** being attributed to a **measurand**, based on the information used NOTE 1 Measurement uncertainty includes components arising from systematic effects, such as components associated with **corrections** and the assigned quantity values of **measurement standards**, as well as the	**VIM 3** http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf

	Many things can influence how well a measurement result can be made; such as the operating conditions, instrument used etc.	**definitional uncertainty**. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated. NOTE 2 The parameter may be, for example, a standard deviation called **standard measurement uncertainty** (or a specified multiple of it), or the half-width of an interval, having a stated **coverage probability**. NOTE 3 Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by **Type A evaluation of measurement uncertainty** from the statistical distribution of the quantity values from series of **measurements** and can be characterized by standard deviations. The other components, which may be evaluated by **Type B evaluation of measurement uncertainty**, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information. NOTE 4 In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.	
Metrology	**The branch of science that deals with measurement**	science of **measurement** and its application NOTE Metrology includes all theoretical and practical aspects of measurement, whatever the **measurement uncertainty** and field of application.	**VIM 3** **http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf**
Reference laboratory	**Calibration Laboratory** **A specialized laboratory operating reference measurement procedures for the accurate value assignment of reference materials.**	laboratory that performs a reference measurement procedure and provides results with stated uncertainties NOTE ISO/IEC 17025 uses the term “calibration laboratory”.	**ISO 15195:2003**

Reference material	**Generic name for specialised materials used for calibration and validation as well as process control**	material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in **measurement** or in examination of **nominal properties** NOTE 1 Examination of a nominal property provides a nominal property value and associated uncertainty. This uncertainty is not a **measurement uncertainty**. NOTE 2 Reference materials with or without assigned **quantity values** can be used for **measurement precision** control whereas only reference materials with assigned quantity values can be used for **calibration** or **measurement trueness** control. NOTE 3 'Reference material' comprises materials embodying **quantities** as well as nominal properties. EXAMPLE 1 *Examples of reference materials embodying quantities*: a) water of stated purity, the dynamic viscosity of which is used to calibrate viscometers; b) human serum without an assigned quantity value for the amount-of-substance concentration of the inherent cholesterol, used only as a measurement precision control material; c) fish tissue containing a stated mass fraction of a dioxin, used as a **calibrator**. EXAMPLE 2 *Examples of reference materials embodying nominal properties*: a) colour chart indicating one or more specified colours; b) DNA compound containing a specified nucleotide sequence; c) urine containing 19-androstenedion	**VIM 3** http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf
Reference Measurement Procedure	**Highly accurate, and often technically complex and resource intensive, procedure used by a specialized laboratory to assign a value to a reference material.**	**measurement procedure** accepted as providing **measurement results** fit for their intended use in assessing **measurement trueness** of **measured quantity values** obtained from other measurement procedures for **quantities** of the same **kind**, in **calibration**, or in characterizing **reference materials**	**VIM 3** http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf

Traceability	**A demonstrable link between a patient sample/routine measurement result and a Reference Measurement Procedure /Certified Reference Material.**	property of a **measurement result** whereby the result can be related to a reference through a documented unbroken chain of **calibrations**, each contributing to the **measurement uncertainty** NOTE 1 For this definition, a 'reference' can be a definition of a **measurement unit** through its practical realization, or a **measurement procedure** including the measurement unit for a non-**ordinal quantity**, or a **measurement standard**. NOTE 2 Metrological traceability requires an established **calibration hierarchy**. NOTE 3 Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed. NOTE 4 For **measurements** with more than one **input quantity in the measurement model**, each of the input **quantity values** should itself be metrologically traceable and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity value should be commensurate with its relative contribution to the measurement result. NOTE 5 Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes. NOTE 6 A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.	**VIM 3** http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf

		NOTE 7 The ILAC considers the elements for confirming metrological traceability to be an unbroken **metrological traceability chain** to an **international measurement standard** or a **national measurement standard**, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals (see ILAC P-10:2002). NOTE 8 The abbreviated term "traceability" is sometimes used to mean 'metrological traceability' as well as other concepts, such as 'sample traceability' or 'document traceability' or 'instrument traceability' or 'material traceability', where the history ("trace") of an item is meant. Therefore, the full term of "metrological traceability" is preferred if there is any risk of confusion.	
Trueness	**How close a measurement result is to what we think is the correct value.** **The comparison of how close the measurement result is to the correct value can be validated by measuring an appropriate certified reference material.**	closeness of agreement between the average of an infinite number of replicate **measured quantity values** and a **reference quantity value** NOTE 1 Measurement trueness is not a **quantity** and thus cannot be expressed numerically, but measures for closeness of agreement are given in ISO 5725. NOTE 2 Measurement trueness is inversely related to **systematic measurement error**, but is not related to **random measurement error**. NOTE 3 "Measurement accuracy" should not be used for 'measurement trueness'.	**VIM 3** http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf