Introduction

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Glossary

Languages are cornerstones of all communications including communication in sciences. Different traditions in the development of languages means that similar words can have somewhat different meaning in different language areas. French is the mother language of metrology, but international English – not colloquial English – is currently in practice the primary tool for communication in this area.

This chapter summarizes databases, literature, terms and concepts in international English useful in the field of traceability in Laboratory medicine. It was compiled and is maintained by the JCTLM Traceability Education and Promotion Working group which remains grateful for suggestions for improvements sent to smaniguet@bipm.org .

The intention is to provide explanations and examples of traceability-related concepts and terms which complement and aid in the understanding and application of them in practice. The JCTLM Traceability Education and Promotion Working group welcomes critical and constructive dialogs aimed at improving the usefulness of this document in the interest of Laboratory medicine and the patients and populations it servers.

Bureau International des Poids et Mesures, BIPM

International vocabulary of metrology — Basic and general concepts and associated terms (VIM 3)
https://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf

International Standardization organisation, ISO

ISO Online browsing platform: available at https://www.iso.org/obp

IEC Electropedia: available at http://www.electropedia.org/

The IFCC-IUPAC coding system

Nomenclature, Properties and Units (C-NPU) in collaboration with International Union of Pure and Applied Chemistry (IUPAC). The C-NPU maintains the website below to make available the complete contents of the generic C-NPU database for electronic downloading. The website outlines the structure of the NPU terminology and provides instructions for using the database. NPU Laboratory Terminology website: www.npu-terminology.org .

An extensive list of scientific publications from the joint IFCC-IUPAC Committee is available at http://www.npu-terminology.org/

The CLSI Harmonized terminology database

https://htd.clsi.org/listallterms.asp

The VIN - Vocabulary on nominal property, examination, and related concepts for clinical laboratory sciences

Nordin, G., et al. (2018). "Vocabulary on nominal property, examination, and related concepts for clinical laboratory sciences (IFCC-IUPAC Recommendations 2017)." Pure and Applied Chemistry 90(5): 913-935. (1)

Books and brochures

Férard, G., et al. (2017). Compendium of Terminology and Nomenclature of Properties in Clinical Laboratory Sciences. Recommendations 2016. Cambridge, UK, The Royal Society of Chemistry.

The SI Brochure: The International System of Units (SI), 9th Edition
https://www.bipm.org/en/publications/si-brochure/

Barwick, V. J. and Prichard, E. (Eds). Eurachem Guide: Terminology in Analytical Measurement – Introduction to VIM 3 (2011). ISBN 978-0-948926-29-7. Available at https://eurachem.org/images/stories/Guides/pdf/TAM_2011_Final_web.pdf

Nordin, G., et al. (2018). "Vocabulary on nominal property, examination, and related concepts for clinical laboratory sciences (IFCC-IUPAC Recommendations 2017)." Pure and Applied Chemistry 90(5): 913-935.

VIN

https://www.degruyter.com/view/journals/pac/90/5/article-p913.xml?language=en

Laboratory **accreditation**

Procedure by which an authoritative body gives formal recognition that a laboratory is competent to carry out specific tasks. Accreditation does not itself qualify the laboratory to approve any particular product. However, accreditation may be relevant to approval and certification authorities when they decide whether to accept data produced by a given laboratory in connection with their own activities.

(http://www.nist.gov/traceability/traceability_toc.cfm , 2020-10-18)

Catalytic **activity**

Property of a component corresponding to the catalyzed substance rate of conversion of a specified chemical reaction, in a specified measuring system.

NOTE 1: In this document the "component" is an enzyme.

NOTE 2: The quantity "catalytic activity" relates to an amount of active enzyme, not its concentration.

NOTE 3: The coherent derived SI unit is "katal" (kat), equal to "mole per second" (mol s−1).

NOTE 4: The measurement procedure is an essential element of the definition of the measurand.

NOTE 5: In many instances, instead of the conversion rate of the substrate ascribed in the short name of the enzyme analyte, e.g. "creatine" in "creatine kinase", the conversion rate of an indicator substance as substrate of a combined reaction is measured. Then the measurand should be defined as 'catalytic activity of the enzyme as measured by the conversion rate of an indicator substance in a specified system according to a given measurement procedure', e.g. 'catalytic activity of creatine kinase as measured by the rate of conversion of NADP+ in the IFCC reference procedure in human serum'.

(ISO-18153:2003, 3.2, ISO-17511:2020)

Aliquot

Known amount of a homogeneous material, assumed to be taken with negligible sampling error

(ISO-11074:2015)

Analyte

Component represented in the name of a measurable quantity.

EXAMPLE: In the type of quantity "mass of protein in 24-hour urine", "protein" is the analyte. In "amount of substance of glucose in plasma", "glucose" is the analyte. In both cases the long phrase represents the measurand.

(ISO-17511:2020)

Value **assignment**

Process by which reference material property values or attributes obtained by characterization are combined and expressed in accompanying reference material documentation

(ISO-Guide 30:2015)

Production **batch**

lot

Definite amount of material produced during a single manufacturing cycle, and intended to have uniform character and quality.

Note 1: The uniform conditions of manufacture or production of the batch or lot must be such as to ensure a homogeneous product.

Note 2: In statistics, an entire batch may be considered a finite population (totality of items under consideration).

Note 3: See also “lot” in ISO 3534-2:2006.

Note 4: See also the IUPAC Compendium of Analytical Nomenclature.

(ISO-Guide 30:2015)

Calibrant

Reference material used for calibration of equipment or a measurement procedure

(ISO-Guide 30:2015)

Calibration verification **control**

Control provided by a manufacturer for use with a stated in-vitro diagnostic measurement device to confirm that a satisfactory calibration was achieved using the end-user calibrator(s) intended for use with that in-vitro diagnostic measurement device.

(ISO-21151:2020)

International conventional **calibrator**

international conventional calibration material

Calibrator whose quantity value is not metrologically traceable to the SI but is assigned by international agreement

NOTE 1: The quantity is defined with respect to the intended application.

NOTE 2: Adapted from ISO 17511:2003, 3.11.

(ISO-15194:2009)

Characterization of a reference material

Determination of the property values or attributes of a reference material, as part of the production process

Note 1: See also the IUPAC Compendium of Analytical Nomenclature.[5]

(ISO-Guide 30:2015)

Commutability

Property of a reference material, demonstrated by the equivalence of the mathematical relationships among the results of different measurement procedures for a reference material and for representative samples of the type intended to be measured

Note 1: See also ISO/IEC-Guide 99:2007 (2), ISO-17511:2003.

(CLSI EP30-A)

Component(s)

Any relevant component(s), also called analyte(s), of the system shall be named according to an internationally accepted nomenclature, including for example any necessary indications of elementary entity, relative molecular mass or molar mass, oxidation state, multiple forms comprised and, for enzymes, the EC number.

EXAMPLES Aliphatic carboxylate (C10 to C26, non-esterified); Fibrinogen(340 000); Iron(II+III); Lactate dehydrogenase (E.C.1.1.1.27) isoenzyme 1; Basic fibroblast growth factor(human, rec. DNA).

(ISO-15194:2009, 4.1.2)

Calibration and measurement **certificates**

The result of a calibration may be recorded in a document, sometimes called a calibration certificate or a calibration report. It can also refer to a document

accompanying a certified reference material stating one or more property values and their uncertainties, and confirming that the necessary procedures have been carried out to ensure their validity and traceability.

Certifying metrological traceability

Here meaning to formally attest that traceability exists in a given situation.

(http://www.nist.gov/traceability/traceability_toc.cfm , 2020-10-18)

Characteristic

Abstraction of a property

EXAMPLE 'Having a cable for connecting with a computer' as a characteristic of the concept 'cord mouse'.

NOTE 1: Characteristics are used for describing concepts.

(ISO-1087:2019 (3))

Consensus

Group solidarity in sentiment and belief (opinion); operationally, the absence of sustained opposition. JCTLM Acronyms and definitions, 2017-01-27

Commutability of a reference material

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

(VIM 3, 5.15) (4)

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 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: In commutability assessment of a reference material, comparisons among all applicable measurement procedures is desirable.

NOTE 3: Closeness of agreement of measurement results is defined in terms of fitness for purpose as appropriate for the intended use of the reference material.

Note 4 to entry: A commutability statement is restricted to the measurement procedures as specified in a particular comparison.

(ISO 99:2007 5.15, ISO 17511:2020)

Commutability of a reference material

Property of a given 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 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.

NOTE 3: Adapted from ISO/IEC Guide 99:2007 (2), 5.15.

(ISO-15194:2009)

Demonstrating commutability among certified reference materials with any given measurement process does not assure commutability of any certified reference materials across different measurement processes.

Control **material**

Substance, material or article intended by its manufacturer to be used to verify the performance characteristics of an in-vitro diagnostic measurement device.

(ISO 18113-1:2009, 3.13, ISO-17511:2020)

International conventional **calibrator**

International conventional calibration material international measurement standard calibrator whose quantity value is not metrologically traceable to the SI but is assigned by international agreement

NOTE 1: The quantity is defined with respect to the intended clinical application.

(ISO-17511:2020)

End-user in-vitro diagnostic measurement device **calibrator**
End-user calibrator

Reference material used as a measurement standard intended for use with one or more in-vitro diagnostic measurement devices measurement procedures intended to examine a particular measurand in human samples

NOTE 1: End user calibrators includes reference materials or calibrators applied internally by the manufacturer to implement a final calibration of the in vitro measurement device, prior to the in vitro measurement devices release and delivery to the end-user, where end-user calibration is not required (i.e. 'factory calibration').

NOTE 2: Factory-generated calibrations or calibration functions include calibration information (equations, formula, functions, parameters, data) stored, e.g., in electronic format, for use with a microprocessor as part of an in vitro diagnostic measurement device measuring system to transform “signal” generated in the course of measuring unknown human samples to an amount of substance or other final measured value.

Equivalence of measured values

Agreement of measured values among different in vitro diagnostic measurement devices intended to measure the same measurand, where the differences in measured values on the same human samples do not affect clinical interpretation

NOTE 1: A conclusion of equivalence of measured values for the same human samples among two or more measurement procedures is based on the differences in measured values being within a pre-defined margin or limit.

(ISO-17511:2020 (5), https://www.harmonization.net)

Harmonization

Achieving standardization by having calibration traceable to an international harmonization protocol as the highest level of metrological traceability when there are no certified reference materials or reference measurement procedures for a given measurand.

https://www.harmonization.net on 2021-02-03

Harmonization

Harmonized

Achievement of equivalent measured quantity values (within clinically meaningful limits) for human samples examined for a stated measurand among two or more in-

vitro diagnostic measurement devices by applying an international consensus protocol in their calibration hierarchies when fit-for-purpose higher order reference materials or reference measurement procedures are not available

Note 1: Harmonization is one of the calibration hierarchy models described in ISO-17511:2020 (5) to achieve metrologically traceable quantity values for human samples.

Note 2: Harmonization is a special case of non-SI traceable standardization where the calibration of two or more in-vitro diagnostic measurement devices is traceable to an international harmonization protocol that defines the highest level of metrological traceability for the stated measurand, but with no traceability to SI.

Note 3: Harmonized is the condition in which harmonization (equivalence among quantity values) is achieved among two or more in-vitro diagnostic measurement devices.

(ISO 21151:2020)

Homogeneity

Uniformity of a specified property value throughout a defined portion of a reference material

Note 1: Tests for homogeneity are described in ISO Guide 35.

Note 2: The 'defined portion' may be, for example, an RM batch or a single unit within the batch. Note 3 to entry: See also IUPAC Compendium of Analytical Nomenclature.

(ISO-Guide 30:2015 (6))

Between-unit **homogeneity**

Uniformity of a specified property value among units of a reference material

Note: It is understood that the term "between-unit homogeneity" applies to any type of package (e.g. vial) and other physical shapes and test pieces.

(ISO-Guide 30:2015 (6))

Within-unit **homogeneity**

Uniformity of a specified property value within each unit of a reference material

(ISO-Guide 30:2015 (6))

International **harmonization** protocol

Description of a process implemented by an international body to achieve equivalence of measured values within medically acceptable limits among two or more in vitro diagnostic measurement devices intended for examination of the same measurand for cases where there are no higher order reference measurement procedures and no fit for purpose certified reference materials or *international conventional calibrators*.

NOTE 1: A harmonization protocol can be used to achieve standardization of measured values for a stated measurand when there are no other higher order reference system components that are suitable for use.

(ISO-17511:2020 (7))

In vitro diagnostic medical **device**
IVD medical device
IVD MD

Device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes and including reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

(ISO-18113-1:2009, 3.27 ISO 17511:2020)

Product **information sheet**

Document containing all the information that is essential for using an reference material other than a certified reference material.

(ISO-Guide 30:2015 (6))

Higher order **reference material**

Certified reference material that meets internationally accepted quality requirement and provides a common metrological reference within the calibration hierarchy to which manufacturers can establish metrological traceability.

NOTE 1: Quality requirements for higher order reference materials are laid out in ISO-15194.

NOTE 2: Higher order reference materials include fit–for–purpose primary reference materials, primary calibrators, secondary calibrators and international conventional calibrators.

NOTE 3: Pure substances constitute the primary measurement standard and ultimate source of higher-order metrological traceability for most traceability chains in chemistry, thermometry and calorimetry in general and for the certification of solution and matrix reference materials in particular (see ISO Guide 35:2017).

NOTE 4: According to Joint Committee for Traceability in Laboratory Medicine (JCTLM) FAQs, a higher order reference material is a certified reference material, meeting internationally accepted quality requirements, to which other measurement results can be referenced, and its measurement uncertainty is completely established. Metrologically, a higher order reference material is a reference material deployed at a higher level in the calibration hierarchy. Certified, highest order reference materials, where available, are used by in vitro diagnostic measurement device manufacturers to assign values to working calibrators. These working calibrators are subsequently used by the manufacturer to assign values to measurands in end-user in vitro measurement device calibrators and control materials for use with in vitro measurement devices in medical laboratories and other IVD testing environments. Higher order RMs are most commonly produced and distributed by national metrology institutes (NMIs), e.g. U.S. National Institute of Standards and Technology (NIST), European Commission Joint Research Centre (EU-JRC), LGC Standards (UK), World Health Organization (WHO), National Institute for Biological Standards and Control (UK), National Institute of Metrology (CN), National Metrology Institute of Japan (JP), Reference Material Institute for Clinical Chemistry Standards (JP), Japanese Industrial Standards Committee (JISC), Centro Nacional de Metrología (MX), etc. Some commercial sources also provide RMs listed by JCTLM.

(ISO 17511:2020 (7))

Reference material certification

Action of a reference material producer that formally establishes the certified values of a certified reference material and states them in a reference material certificate.

Note 1 to entry: Reference material certification is a first-party attestation in accordance with the definition of the term “declaration” (ISO/IEC 17000:2004, 5.4) whereas certification is a third-party attestation in accordance with the definition of the term “certification”.

(ISO/IEC 17000:2004, 5.5, ISO-Guide 30:2015 (6))

Reference material certificate

Document containing the essential information for the use of a CRM, confirming that the necessary procedures have been carried out to ensure the validity and metrological traceability of the stated property values.

Note 1: The required and recommended content of a reference material certificate is described in

(ISO Guide 31, ISO-Guide 30:2015 (6))

Reference material certification report

Document giving detailed information, in addition to that contained in a reference material certificate, e.g. the preparation of the material, methods of measurement, factors affecting accuracy, statistical treatment of results, and the way in which metrological traceability was established

Note 1: See also the IUPAC Compendium of Analytical Nomenclature.

(ISO-Guide 30:2015 (6))

Higher order **reference measurement procedure**

Higher order RMP

Reference measurement procedure meeting internationally accepted quality requirements and providing a common metrological reference within the calibration hierarchy to which manufacturers' can establish metrological traceability and accepted as providing measurement results fit for their intended use in assessing measurement trueness.

NOTE 1: Quality requirements for higher order reference measurement procedures are defined in ISO-15193.

NOTE 2: For reasons of higher cost, equipment complexity and operator training requirements, higher order reference measurement procedures are typically performed in national metrology institutes and/or accredited calibration laboratories.

NOTE 3: In laboratory medicine, reference measurement procedures that meet the requirements of ISO-15193 are considered to be higher order reference measurement procedures.

NOTE 4: According to JCTLM FAQs, higher order reference measurement procedures are well documented, high accuracy measurement procedures used for assigning values to calibration materials. At the highest level the measurement procedures are

frequently expensive to develop, too complicated for routine use and not suitable for high throughput analysis.

(ISO-17511:2020 (7))

Calibration

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”, or with verification of calibration.

NOTE 3: Often, the first step alone in the above definition is perceived as being calibration.

(ISO/IEC Guide 99:2007 2.39 (2), ISO 17511:2020 (7))

Calibration hierarchy

Sequence of calibrations from a reference to the final measuring system, where the outcome of each calibration depends on the outcome of the previous calibration

NOTE 1: Measurement uncertainty necessarily increases along the sequence of calibrations.

NOTE 2: The elements of a calibration hierarchy are one or more measurement standards and measuring systems operated according to measurement procedures.

NOTE 3: 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.

NOTE 4: In this document, a calibration hierarchy is defined as a detailed description of the process for assigning a value of a measurand to a sample using a specified sequence of measurement procedures and reference materials (calibrated by higher order

reference materials and/or measurement procedures for the same type of quantity, where available).

NOTE 5: For purposes of this definition, a sample includes human samples as well as calibration materials, EQA materials or other reference materials.

(ISO/IEC-Guide 99:2007 2.40 (2), ISO-17511:2020 (7))

Calibrator
Calibration material

Calibration material measurement standard used in calibration of a measuring system according to a specified measurement procedure.

(ISO/IEC-Guide 99:2007 5.12, ISO 17511:2020 (7))

Interlaboratory **comparison**
interlaboratory study
interlaboratory test collaborative study
Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

Note 1: See also “interlaboratory test” in the IUPAC Compendium of Analytical Nomenclature.

Note 2: See also the Codex Alimentarius Commission Procedural Manual.

(ISO/IEC 17043:2010, 3.4, modified — The admitted terms (“interlaboratory study”, “interlaboratory test” and “collaborative study”) and the notes to entry have been added.)

(ISO-Guide 30:2015 (6))

Unbroken chain of **calibrations**

Here taken to mean the complete, explicitly described, and documented series of calibrations that successively link the value and uncertainty of a result of measurement with the values and uncertainties of each of the intermediate reference standards and the highest reference standard to which traceability for the result of measurement is claimed. A calibration is the 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.

(http://www.nist.gov/traceability/traceability_toc.cfm , 2020-10-18)

Unbroken chain of **comparisons**

Complete, explicitly described, and documented series of comparisons that successively link the value and uncertainty of the result of a measurement with the values and uncertainties of each of the intermediate reference standards and the highest reference standard to which traceability for the result of measurement is claimed.

(http://www.nist.gov/traceability/traceability_toc.cfm , 2020-10-18)

Quality control **material**

Reference material used for quality control of a measurement.

(ISO-Guide 30:2015 (6))

Matrix
System matrix

All components of a material system except the analyte.

NOTE 1: The biological system excluding the analyte is the matrix of the material.

(ISO 15194:2002)

Matrix of a material system

Components of a material system, except the analyte

(ISO-15194:2009)

Matrix effect

Influence of a property of the sample, independent of the presence of the analyte (3.1), on the measurement and thereby on the measured quantity value

NOTE 1: A specified cause of a matrix effect is an influence quantity (3.16).

NOTE 2: The term 'matrix effect' is sometimes erroneously used in cases of non-commutability of a material due to causes such as, e.g. a denatured analyte (3.1) or an added non-genuine component (surrogate analyte (3.1)) intended to simulate the measurand (3.26).

Example:

The measurement of the amount-of-substance concentration of sodium ion in plasma by flame emission spectrometry may be influenced by the viscosity of the sample.

(ISO-15194:2002, ISO-17511:2020 (5))

matrix effect

Influence of a property of the sample, independent of the presence of the analyte, on the measurement and thereby on the measured quantity value

NOTE 1 A specified cause of a matrix effect is an influence quantity.

NOTE 2 A matrix effect depends on the detailed steps of the measurement as described in the measurement procedure.

EXAMPLE The measurement of the amount-of-substance concentration of sodium ion in plasma by flame emission spectrometry can be influenced by the viscosity of the sample.

(ISO-1594:2009)

Description of the properties of **reference materials**

A reference material has properties, each of which shall be described according to the following format:

a. System (i.e. the material itself);
b. Any relevant component(s); and
c. Kind-of-quantity (quantity in a general sense)

If the property is a measurable quantity, it shall have a value that is equal to

d. A numerical value multiplied by
e. A unit of measurement

EXAMPLE:

Certified reference material (BCR; CRM 303) – Calcium(II) amount-of-substance concentration (reconstituted) c = 2,472 mmol/l (U=0,019; k=2) where U is the expanded uncertainty of measurement using the coverage factor k.

(ISO-15194:2002)

z score in proficiency testing

Standardized measure of performance, calculated using the participant result, assigned value and the standard deviation for proficiency assessment.

NOTE 1: A common variation on the z score, sometimes denoted z' (commonly pronounced z-prime), is formed by combining the uncertainty of the assigned value with the standard deviation for proficiency assessment before calculating the z score.

Standardized measure of performance, calculated using the participant result, assigned value and the combined standard uncertainties for the result and the assigned value.

(ISO-13528:2015 (8))

Measuring system
Measurement system

Set of one or more measuring instruments and often other devices, including any reagent and supply, assembled, and adapted to give information used to generate measured quantity values within specified intervals for quantities of specified kinds.

NOTE 1: A measuring system may consist of only one measuring instrument.

(ISO-99:2007 3.2, ISO-17511:2020 (5))

Reference material **producer**

Body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference materials it produces

(ISO-Guide 30:2015 (9))

Outlier in proficiency testing

Member of a set of values which is inconsistent with other members of that set.

NOTE 1: An outlier can arise by chance from the expected population, originate from a different population, or be the result of an incorrect recording or other blunder.

NOTE 2: Many schemes use the term outlier to designate a result that generates an action signal. This is not the intended use of the term. While outliers will usually generate action signals, it is possible to have action signals from results that are not outliers.

(ISO-13528:2015 (8))

Production of a reference material

All necessary activities and tasks leading to the release and maintenance of an reference material (certified or non-certified)

Note 1: Activities include, e.g. planning, control, material handling and storage, material processing, assessment of homogeneity and stability, characterization, assignment of

property values and their uncertainties, authorization and issue of reference material certificates or other statements.

(ISO-Guide 30:2015)

Proficiency testing

Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

NOTE 1: For the purposes of this International Standard, the term “proficiency testing” is taken in its widest sense and includes, but is not limited to:

- quantitative scheme — where the objective is to quantify one or more measurands for each proficiency test item.
- qualitative scheme — where the objective is to identify or describe one or more qualitative characteristics of the proficiency test item.
- sequential scheme — where one or more proficiency test items are distributed sequentially for testing or measurement and returned to the proficiency testing provider at intervals.
- simultaneous scheme — where proficiency test items are distributed for concurrent testing or measurement within a defined time period.
- single occasion exercise — where proficiency test items are provided on a single occasion.
- continuous scheme — where proficiency test items are provided at regular intervals.
- sampling — where samples are taken for subsequent analysis and the purpose of the proficiency testing scheme includes evaluation of the execution of sampling; and
- data interpretation — where sets of data or other information are furnished, and the information is processed to provide an interpretation (or another outcome) (ISO-13528:2015 (8)).

Property value of a reference material

Value corresponding to a quantity representing a physical, chemical or biological property of a reference material

(ISO-Guide 30:2015)(9)

Property attribute of a reference material

Value or non-numerical descriptor corresponding to a qualitative characteristic representing a physical, chemical or biological property of a reference material.

(ISO-Guide 30:2015)(9)

External **quality assessment**, EQA

Determination of individual and collective laboratory performance, and performance characteristics of examination procedures by means of interlaboratory comparison

NOTE 1: The primary objectives of EQA are educational and can be supported by additional elements.

(ISO-14136:2004 (10), ISO-1087:2019 (3))

Nominal **scale**

Scale with a set of possible values, for a given kind-of-property, that are each designated by a word or symbol without any relation to magnitude

EXAMPLE Blood group (A, B, AB, 0)

NOTE The values can be listed in any arbitrary order according to practical considerations and convention.

(ISO-14136:2004 (10), ISO-1087:2019 (3))

Ordinal **scale**

Scale with an ordered set of possible values, for properties of a given kind-of-property, that are each designated by a word or symbol used for ranking according to magnitude, but where differences or ratios between values have no arithmetic meaning

EXAMPLES Wording such as "not detected", "weakly positive"," "positive", "strongly positive" or figures such as 0, 1, 2, 3.

(ISO-14136:2004 (10), ISO-1087:2019 (3))

Stability

Characteristic of a reference material, when stored under specified conditions, to maintain a specified property value within specified limits for a specified period of time

Note 1: See also the IUPAC Compendium of Analytical Nomenclature.

(ISO-Guide 30:2015)

Transportation **stability**

Stability of a reference material property for the time period and conditions encountered in transportation to the user of the reference material.

Note 1: Transportation stability has often been referred to as “short term stability”.

(ISO-Guide 30:2015)

Long-term **stability**

Stability of a reference material property over an extended period of time.

International measurement **standard**

Measurement standard recognized by signatories to an international agreement and intended to serve worldwide as the basis for assigning values to other standards for the same quantity.

EXAMPLE 1 The international prototype of the kilogram.

EXAMPLE 2 ERM®-DA470k/IFCC for the calibration of immunoassay-based in-vitro diagnostic devices or control products for the proteins certified. European Commission — Joint Research Centre (JRC), Geel, Belgium.

EXAMPLE 3 Triple point of water — the single combination of pressure and temperature at which liquid water, solid ice, and water vapour coexist in a stable equilibrium, occurring at exactly 273,16 K (0,01 °C; 32,02 °F) at a partial vapour pressure of 611,657 pascals (6,116 57 mbar; 0,006 036 59 atm.).

(ISO-Guide 99:2007 (2), 5.2, ISO-17511:2020)

Subcontractor

Body (organization or company, public or private) that undertakes aspects of the processing, handling, homogeneity and stability assessment, characterization, storage or distribution of the reference material under its own management system on behalf of the reference material producer

Note 1: According to ISO Guide 34, key tasks/aspects of the reference material production process, which cannot be performed by external parties are project planning, assignment and decision on property values and relevant uncertainties, authorization of property values and issuing of reference material certificates or other statements for the reference materials.

Note 2: The concept “subcontractor” is equivalent to the concept “collaborator”.

Note 3: Advisors, who could be asked for recommendations, but who are not involved in decision making or the execution of any aspects mentioned in the definition above, are not considered as subcontractors.

(ISO-Guide 30:2015 (9))

Assigned **value**

Value attributed to a particular quantity and accepted, sometimes by convention, as having an uncertainty appropriate for a given purpose

(ISO/IEC Guide 43-1:1997, ISO-14136:2004 (10), ISO-1087:2019 (3))

Consensus **value** in proficiency testing

Value derived from a collection of results in an interlaboratory comparison

NOTE 1: The phrase 'consensus value' is typically used to describe estimates of location and dispersion derived from participant results in a proficiency test round, but may also be used to refer to values derived from results of a specified subset of such results or, for example, from a number of expert laboratories.

(ISO-13528:2015 (8))

Target **value**

Accepted reference value

NOTE 1: Examples of target values are assigned values, reference procedure values, and consensus values.

(ISO-14136:2004 (10), ISO-1087:2019 (3))

Reference procedure **value**

Value obtained by a reference measurement procedure.

(ISO-1087:2019 (3))

Calibration

Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or reference material, and the corresponding values realized by standards (4).

Reference **material**, RM

Material, sufficiently homogeneous and stable regarding one or more properties, used in calibration, assignment of a value to another material, or quality assurance

NOTE 1: "Reference material" comprises materials embodying quantities as well as nominal properties.

NOTE 2: Adapted from ISO/IEC-Guide 99:2007, 5.13 (2).

EXAMPLE 1: Human serum with an assigned quantity value for the amount-of-substance concentration of cholesterol, used only as a calibrator, embodies a quantity.

EXAMPLE 2: DNA compound containing a specified nucleic acid sequence embodies a nominal property.

NOTE 3: In this definition, value covers both “quantity value” and “nominal property value”.

NOTE 4: Some reference materials have quantities which are metrologically traceable to a measurement unit outside a system of units. Such materials include those containing antibodies to which International Units (IU) have been assigned by the World Health Organization.

NOTE 5: A reference material is sometimes incorporated into a specially fabricated device, e.g.

- glass of known optical density in a transmission filter holder,
- spheres of uniform particle size mounted on a microscope slide, and
- calibration plate for microtiter plate reader.

(ISO-15194:2009)

Certified Reference **Material**, CRM

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 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.

(VIM 3, 5.14) (4).

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 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).

NOTE 2: Procedures for the production and certified reference material certification are given in ISO-17034:2016 and ISO-Guide 35:2017.

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.

NOTE 5: ISO/REMCO has an analogous definition but uses the modifiers “metrological” and “metrologically” to refer to both quantities and nominal properties.

NOTE 6: Specific requirements for certified reference materials and the content of supporting documentation (in the field of in vitro diagnostic medical devices) are given in ISO 15194.

NOTE 7: For a specified material, a calibration (3.4) certificate provided by an accredited calibration (3.4) laboratory does not confer the status of CRM on these types of materials.

(ISO-99:2007 5.14 ISO-17511:2020)

Certified reference **material**, CRM

Reference material, accompanied by documentation issued by an authoritative body and referring to valid procedures used to obtain a specified property value with uncertainty and traceability.

NOTE 1 Adapted from ISO/IEC Guide 99:2007, 5.14 (2).

EXAMPLE: Human serum containing cholesterol with assigned quantity value and associated measurement uncertainty stated in an accompanying certificate, used as calibrator or trueness control material.

NOTE 2: In this definition, uncertainty covers both “measurement uncertainty” and “uncertainty of nominal value”, such as for identity and sequence, expressed as probabilities. Traceability covers both “metrological traceability” of a quantity value and “traceability of nominal value”.

NOTE 3: “Certified reference material” is a specific concept under “reference material”.

(ISO-15194:2009)

The concept “property values” is used here because the certified reference material can be used either for measurements or for examinations (quantitative or qualitative

measurements). carry either a quantity measured on the ratio scale or a nominal or ordinal scale. “Property values” cover both cases.

The certificate (calibration certificate, calibration report) accompanying the reference material should detail.

1. Confirmation that the necessary procedures have been carried out to ensure the validity and traceability of the property values.
2. The property values.
3. The uncertainty of the property values

The uncertainty of the reported properties should be stated using GUM principles for ratio scale quantities (11). Uncertainties of nominal and ordinal scale properties may be expressed as probabilities (12-16).

International conventional reference **measurement** procedure

International conventional reference measurement procedure yielding values that are not metrologically traceable to the SI but which by international agreement are used as reference values for a defined quantity.

NOTE 1: The quantity is defined with respect to the intended clinical application.

(ISO-17511:2020)

Target **measurement uncertainty**

Target uncertainty

Measurement uncertainty specified as an upper limit and decided on the basis of the intended use of measurement results.

Note 1: For the production of RMs, the term target uncertainty may be used to describe the intended uncertainty for the assigned property value

(ISO-Guide 30:2015, SOURCE: ISO/IEC Guide 99:2007[1], 2.34, modified — Note 1 has been added.)

Harmonization reference **material**

Reference material used as a calibrator for an international harmonization protocol

Note 1: Specifications for these materials are included in the harmonization protocol.

(ISO 21151:2020)

Extent of **equivalence**

An indication of the agreement among measured values of the same quantity assigned to two or more CRMs or ability of different measurement procedures to produce consistent values when used to measure the amount of substance in any given CRM. JCTLM Acronyms and definitions, 2017-01-27

The extent of equivalence can be usefully communicated with Youden or Bland-Altman style graphics that include an indication of measurement uncertainty to identify and place differences among the measured values in perspective.

Harmonization, "a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity".

(CLSI EP30-A, 2010)

"when results are equivalent, but neither a high-order primary reference material nor a reference measurement procedure is available"

(Crit Rev Clin Lab Sci . 2016;53(3):184-96. doi: 10.3109/10408363.2015.1116851)

International harmonization protocol

Harmonization protocol

Standardization process implemented by an international body to achieve equivalence among measured quantity values for two or more in-vitro diagnostic measurement devices intended for examination of the same measurand for cases where there are no higher order reference measurement procedures and no fit-for-purpose certified reference materials or international conventional calibrators

Note 1: A harmonization protocol can be used to achieve standardization of measured values for a stated measurand when there are no other higher order reference system components that are suitable for use.

Note 2: A harmonization protocol defines the highest level of metrological traceability for the stated measurand.

(ISO-21151:2020)

Hierarchical position

"Reference material" is regarded as a type of "measurement standard", and reference materials of higher metrological order shall be classified as measurement standards, in accordance with their positions in the reference measurement system for a given quantity as given in ISO 17511:

a) primary measurement standard.

b) secondary measurement standard.
c) international conventional calibrator.

(ISO-15194:2009)

Higher order

The term “higher-order” was left undefined in the in vitro diagnostic device; however, ISO-15193:2009 and ISO-15194:2009 describe the essential requirements for higher-order reference materials and methods. JCTLM Acronyms and definitions, 2017-01-27

Influence quantity

Quantity that, in a direct measurement, does not affect the quantity that is actually measured, but affects the relation between the indication and the measurement result

EXAMPLE Amount-of-substance concentration of bilirubin in a direct measurement of hemoglobin amount-of-substance concentration in human blood plasma.

(ISO-99:2007 2.52, ISO-17511:2020)

ISO Standards

Normative standards employed by JCTLM in reviewing and judging suitability for listing materials (ISO-15194), methods (ISO-15193) and procedure-defined measurands (ISO 18153) as being of a higher metrological order (ISO-17511) as required in the European Community In Vitro Diagnostic Directive (EC IVDD) (98/79/EC, Annex1 (A) (3) 2nd paragraph) and reference measurement service laboratories (ISO 15195, ISO/IEC 17025:2005).

JCTLM

Joint Committee for Traceability in Laboratory Medicine, Website : http://www.bipm.org/en/committees/jc/jctlm/ and https://www.jctlm.org/

JCTLM Criteria

Reviewing criteria derived from the applicable international standards for certified reference materials, reference measurement procedures and reference measurement services. Primary standards are from the International Organization for Standardization (ISO).

JCTLM Database

Database of available higher order reference materials, reference measurement methods/procedures and of reference measurement services provided by reference

laboratories that are compliant with the JCTLM criteria, website: http://www.bipm.org/jctlm/

Kind-of-quantity

The kind-of-quantity, e. g. mass, amount-of-substance, number fraction, amount-of-substance concentration, shall always be stated. If no simple relationship between component and system can be expressed, reference shall be made to the measurement procedure.

NOTE: Appropriate names and symbols for kind-of-quantities are given in ISO 31 and in publications by IFCC and IUPAC (17).

(ISO-15194:2009, 4.1.3)

KCDB

The BIPM key comparison database, Website : http://kcdb.bipm.org/

List I

Certified reference materials and reference measurement methods for well-defined chemical entities or internationally recognized reference method-defined measurands. Reference materials and measurement methods included in this category are those that provide values that are traceable to the SI units; e.g., electrolytes, enzymes, drugs, metabolites and substrates, non-peptide hormones, and some proteins.

List II

Reference materials for which values of the measurands are not SI-traceable but are assigned by or traceable to an internationally agreed upon protocol, e.g., reference materials for blood typing, coagulation factors, infectious diseases, nucleic acids, and some proteins and purified substances. List II also contains a group of purified substances which, due to the absence of reference measurement procedures, should not be directly used for calibration of routine methods unless commutability is established and/or matrix effect independent internationally recognized standardized value transfer protocols to commutable samples are applied.

List III, Certified Reference Materials for nominal properties

Lifetime of a reference material

Time interval during which RM properties retain their assigned values within their associated uncertainties

Note 1: The lifetime is often determined retrospectively, i.e. after RM properties no longer retain assigned values or attributes.

(ISO-Guide 30:2015)

Manufacturer

Entity with responsibility for design, manufacture, fabrication, assembly, packaging or labelling of an in vitro measurement device, for assembling a measuring system, or adapting an in vitro measurement device before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that entity or on their behalf by a third party

NOTE 1: An entity includes but is not limited to an individual, a corporation (or other legally established business), an association, an institution, or a medical laboratory. An entity should be identifiable in terms of a separate and distinct existence and objective reality.

NOTE 2: The manufacturer has ultimate legal responsibility for ensuring conformance with all applicable regulatory requirements for the in vitro measurement device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another entity by the Regulatory Authority within that jurisdiction.

NOTE 3: The manufacturer's responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

NOTE 4: 'Design and/or manufacture', as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, re-labelling, sterilization, installation, or remanufacturing of an in vitro measurement device; or putting a collection of in vitro measurement devices, and possibly other products, together for a medical purpose.

NOTE 5: Any entity that assembles or adapts an in vitro measurement device that has already been supplied by a manufacturer for purposes of an examination to be performed on a human sample in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the in vitro measurement device.

NOTE 6: Any entity who changes the intended use of, or modifies, an in vitro measurement device without acting on behalf of the original manufacturer and who

makes it available for use under their own name, should be considered to be the manufacturer of the modified device.

NOTE 7: An authorized representative, distributor or importer who only adds its own address and contact details to the in vitro measurement device or the packaging, without obscuring or changing the existing labelling, is not considered a manufacturer.

NOTE 8: To the extent that an accessory is subject to the regulatory requirements of (an in vitro measurement device), the entity responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

(ISO-18113-1:2009, 3.36, ISO-17511:2020)

Measurand

Quantity intended to be measured.

NOTE 1: Specification of a measurand requires 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 to entry: In the second edition of the VIM and in IEC 60050-300:2001, the measurand is defined as the "quantity subject to measurement".

NOTE 3: The measurement, including the *measuring system* and the conditions under which the measurement is carried out, could change the phenomenon, body, or substance such that the quantity being measured can differ from the measurand as defined. In this case, adequate correction is necessary.

EXAMPLE The length of a steel rod in equilibrium at 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*.

NOTE 5: In laboratory medicine, the description of the measurand includes the name of the quantity (e.g. amount of substance concentration), the component/analyte (e.g. β-D-glucose), and the biological system in which it is found (e.g. blood plasma).

(ISO 18113-1:2009, 3.39, ISO 17511:2020, VIM 3) (4)

Due to its selectivity for a particular epitope or molecular structure that is part of the measurand, a higher order reference measurement procedure that is calibrated with a particular primary calibrator shall define the measurand.

EXAMPLE In the IFCC reference measurement system for hemoglobin A1c (HbA1c), the measurand is defined as the molar fraction of beta chains of hemoglobin A1 with glycation at the N-terminal valine or epsilon-amino acid residues (HbA1c) relative to the non-glycated fraction of beta chain hemoglobin A (HbA0), in whole blood. The analyte is defined as hemoglobin (Hb) that is irreversibly glycated at one or both N-terminal valines and epsilon-amino acids of the beta chains.

(ISO-17511:2020)

Measurement

Process of experimentally obtaining one or more, quantity values that can reasonably be attributed to a quantity.

NOTE 1 Measurement does not apply to nominal properties.

NOTE 2 Measurement implies comparison of quantities or counting of entities.

NOTE 3 Measurement presupposes a description of the quantity commensurate with the intended use of a measurement result, a measurement procedure, and a calibrated measuring system operating according to the specified measurement procedure, including the measurement conditions.

(VIM 3, 2.1) (4)

Measurement **method**

Method of measurement, generic description of a logical organization of operations used in a measurement,

NOTE Measurement methods may be qualified in various ways such as:

- substitution measurement method,
- differential measurement method, and
- null measurement method.

or

- direct measurement method, and
- indirect measurement method.

IEC 60050-300:2001, ISO 99:2007 2.5 ISO 17511:2020, VIM 3 2.5 (2.4) (4)

Measurement **principle**

Principle of measurement

Phenomenon serving as a basis of a measurement

EXAMPLE 1 Thermoelectric effect applied to the measurement of temperature.

EXAMPLE 2 Energy absorption applied to the measurement of amount-of-substance concentration.

EXAMPLE 3 Lowering of the concentration of glucose in blood in a fasting rabbit applied to the measurement of insulin concentration in a preparation.

NOTE The phenomenon can be of a physical, chemical, or biological nature.

VIM 3, 2.4 (2.3) (4),

Measurement **procedure**

Detailed description of a measurement according to one or more measurement principles and to a given measurement method, based on a measurement model and including any calculation to obtain a measurement result

NOTE 1 A measurement procedure is usually documented in sufficient detail to enable an operator to perform a measurement.

NOTE 2 A measurement procedure can include a statement concerning a target measurement uncertainty.

NOTE 3 A measurement procedure is sometimes called a standard operating procedure, abbreviated SOP.

(VIM 3 (4), ISO 17511:2020, ISO 99:2007)

Measurement **result**

Result of measurement set of quantity values being attributed to a measurand together with any other available relevant information, VIM 3 2.9 (3.1)

NOTE 1: A measurement result generally contains “relevant information” about the set of quantity values, such that some may be more representative of the measurand than others. This may be expressed in the form of a probability density function (PDF).

NOTE 2: A measurement result is generally expressed as a single measured quantity value and a measurement uncertainty. If the measurement uncertainty is considered to be negligible for some purpose, the measurement result may be expressed as a single

measured quantity value. In many fields, this is the common way of expressing a measurement result.

NOTE 3: In the traditional literature and in the previous edition of the VIM, measurement result was defined as a value attributed to a measurand and explained to mean an indication, or an uncorrected result, or a corrected result, according to the context.

The concept of traceability covers both measurement results of quantity values and of nominal property values such as chemical identity and sequence.

Internal measurement assurance program

Program of sufficient complexity, within an organization, to provide credibility to the measurement uncertainty and measurement result for which traceability is to be established. An internal measurement assurance program usually involves monitoring the performance (e.g., stability, reproducibility) of the instrument, standard, or measurement system, before and after it is characterized, calibrated, or used to obtain the traceable measurement result.

VIM 3, (4)

Nominal property

Property of a phenomenon, body, or substance, where the property has no magnitude

EXAMPLE 1: Sex of a human being.

EXAMPLE 2: Color of a paint sample.

EXAMPLE 3: Color of a spot test in chemistry.

EXAMPLE 4: ISO two-letter country code.

EXAMPLE 5: Sequence of amino acids in a polypeptide.

NOTE 1: A nominal property has a value, which can be expressed in words, by alphanumerical codes, or by other means.

NOTE 2: ‘Nominal property value’ is not to be confused with nominal quantity value.

VIM 3, (4)

Quantities can be used for measurement, but nominal properties cannot be used for measurement. The term “examination” is used for the activity of investigating nominal properties (1, 18).

Proficiency evaluation materials

Homogeneous material or artifact that is used to test and evaluate the measurement performance of different measuring systems for specific tasks.
[http://www.nist.gov/traceability/traceability_toc.cfm , 2020-10-18]

Properties

A CRM shall have metrological and commutability properties, allowing it to act as a higher metrological order measurement standard within a calibration hierarchy, or as a trueness control material of higher metrological order as defined in ISO 17511 or ISO 18153.

(ISO-15194:2009)

Provider of the result of a measurement

The individual or organization that supplies for use the result of measurement for which metrological traceability is being asserted.

(http://www.nist.gov/traceability/traceability_toc.cfm , 2020-10-18)

Quantity

Property of a phenomenon, body, or substance, where the property has a magnitude that can be expressed as a number and a reference

NOTE 1: The generic concept 'quantity' can be divided into several levels of specific concepts, as shown in the following table. The left-hand side of the table shows specific concepts under 'quantity'. These are generic concepts for the individual quantities in the right-hand column.

NOTE 2: A reference can be a measurement unit, a measurement procedure, a reference material, or a combination of such.

NOTE 3: Symbols for quantities are given in the ISO 80000 and IEC 80000 series Quantities and units.

The symbols for quantities are written in italics. A given symbol can indicate different quantities.

NOTE 4: The preferred IUPAC-IFCC format for designations of quantities in laboratory medicine is "System—Component; kind-of-quantity".

EXAMPLE "Plasma (Blood)-Sodium ion; amount-of-substance concentration equal to 143 mmol/l in a given person at a given time".

NOTE 5: A quantity as defined here is a scalar. However, a vector or a tensor, the components of which are quantities, is also considered to be a quantity.

NOTE 6: The concept 'quantity' may be generically divided into, e.g. 'physical quantity', 'chemical quantity', and 'biological quantity', or base quantity and derived quantity.

(VIM 3, 1.1) (4)

"In metrology quantity is not a synonym of amount and as such has never been so defined in earlier editions of VIM. Quantity is a generic concept for things we measure, e.g. length, mass, time and concentration." (19)

The beginning of all endeavors for measuring is to describe the particular quantity we intend to measure – the measurand.

Quantity value

If the property is a differential quantity (e.g. Celsius temperature) or a rational quantity (e.g. thermodynamic temperature), it shall have a value consisting of a product of numerical value and measurement unit, together with a measurement uncertainty.

The number of significant figures of a quantity value shall be chosen so that the measurement uncertainty lies on the last or, if the first significant figure of the uncertainty measure is 1 or 2, on the two last figures. For numerical values with more than four figures on either side of the decimal mark, these should be separated by a space in groups of three, counting from the mark to the left or right.

The measurement unit chosen shall be an SI unit, whenever possible, or other internationally accepted measurement unit.

The measurement uncertainty shall be calculated and expressed consistent with ISO/IEC Guide 98-3.

(ISO-15195:2009, 4.1.4)

Reference

A measurement unit, a measurement procedure, a reference material, or a combination of such. A reference is the essence when defining a *unit of measurement* - a definite magnitude of a quantity used as a *standard* for measurement of the same kind of quantity.

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

RM

Generic name for specialized materials used for calibration and validation as well as process control. (4)

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

Material, sufficiently homogeneous and stable regarding one or more properties, used in calibration, assignment of a value to another material, or quality assurance

NOTE 1: “Reference material” comprises materials embodying quantities as well as nominal properties.

NOTE 2: Adapted from ISO/IEC Guide 99:2007, 5.13 (2).

EXAMPLE 1: Human serum with an assigned quantity value for the amount-of-substance concentration of cholesterol, used only as a calibrator, embodies a quantity.

EXAMPLE 2: DNA compound containing a specified nucleic acid sequence embodies a nominal property.

NOTE 3: In this definition, value covers both “quantity value” and “nominal property value”.

NOTE 4: Some reference materials have quantities which are metrologically traceable to a measurement unit outside a system of units. Such materials include those containing antibodies to which International Units (IU) have been assigned by the World Health Organization.

NOTE 5: A reference material is sometimes incorporated into a specially fabricated device, e.g.

- glass of known optical density in a transmission filter holder,
- spheres of uniform particle size mounted on a microscope slide, and
- calibration plate for microtiter plate reader.

(ISO-15194:2009)

Reference material (RM) is a generic term, and properties can be quantitative or qualitative, e.g., identity of substances or species.
(http://www.nist.gov/traceability/traceability_toc.cfm , 2020-10-18)

Reference Measurement Procedure
RMP

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, 2.7) (4)

Reference measurement procedure, thoroughly investigated measurement procedure shown to have an uncertainty of measurement commensurate with the intended use,

especially in assessing the trueness of other measurement procedures for the same quantity and in characterizing reference materials

NOTE 1: Adapted from ISO 15193.

NOTE 2: When several reference measurement procedures exist for a given measurable quantity, it can be possible to arrange them in a hierarchy according to size of uncertainty of measurement. A primary reference measurement procedure is sometimes termed a “definitive method of measurement”, but not by VIM:1993.

NOTE 3: The Consultative Committee on Amount of Substance (CCQM) of BIPM has defined a “primary method of measurement” as a method having the highest metrological qualities, whose operation can be completely described and understood, for which a complete uncertainty statement can be written down in terms of SI units, and whose results are, therefore, accepted without reference to a standard of the quantity being measured. For amount of substance, the following principles of measurement were identified as suitable for primary measurement procedures: isotope dilution-mass spectrometry, coulometry, gravimetry, titrimetry, and determination of colligative properties such as freezing point depression. BIPM, Comité Consultatif pour la Quantité de Matière, 1995.

NOTE 4: The Analytical Chemistry Division of IUPAC describes an allied concept, “absolute method”, wherein calculations are based on universal quantities and fundamental physical constants only.

(ISO-15195:2003)

Reference measurement procedure, thoroughly investigated measurement procedure shown to yield values having an uncertainty of measurement commensurate with its intended use, especially in assessing the trueness of other measurement procedures for the same quantity and in characterizing reference materials

(EN-12286:1998, 3.7)

Reference measurement procedure, thoroughly investigated measurement procedure shown to yield values having an uncertainty of measurement commensurate with its intended use, especially in assessing the trueness of other measurement procedures for the same quantity and in characterizing reference materials

(EN-12286:1998, 3.7, ISO-14136:2004 (10))

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.

In simple language:

a reference measurement procedure is a measurement procedure which:

- Provides measurements which have been thoroughly assessed for bias
- Has been validated to measure what it is intended to measure
- Provides the results that the users need

Reference Measurement Laboratory
RML
A laboratory that meets the requirements specified in ISO-15195 as a calibration laboratory. Reference measurement laboratories should implement reference measurement procedures and produce results of measurement that are accurate and traceable to national or international primary reference materials when such are available. Whenever possible, traceability should be established to a reference material which forms an embodiment of the SI unit

(ISO-17511:2020).

This International Standard may form a basis for the accreditation of a reference measurement laboratory that applies for official recognition of the performance of a reference measurement procedure. Reference measurement laboratories are usually accredited by national accrediting bodies.

Reference measurement procedure

Measurement procedure accepted as providing measurement results fit for their 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

NOTE 1 Adapted from ISO/IEC Guide 99:2007, 2.7.

NOTE 2 The roles of reference measurement procedures are detailed in ISO 17511 and ISO 18153.

NOTE 3 In ISO terminology, trueness is related to bias, systematic effect and systematic error, whereas accuracy is related to both trueness (with its relations) and precision, which itself is related to standard deviation, random effect and random error.

NOTE 4 The term “reference measurement procedure” is intended to be understood as a measurement procedure of higher order.

ISO-15193-2009

Reference quantity value
Reference value
Quantity value used as a basis for comparison with values of quantities of the same kind.

NOTE 1: A reference quantity value can be a true quantity value of a measurand, in which case it is unknown, or a conventional quantity value, in which case it is known.

NOTE 2: A reference quantity value with associated measurement uncertainty is usually provided with reference to

a) a material, e.g. a certified reference material,
b) a device, e.g. a stabilized laser,
c) a reference measurement procedure,
d) a comparison of measurement standards.
(VIM 3, 5.18, (4))

Certified reference materials (CRM) and reference measurement methods provide reference quantity values and associated measurement uncertainties. These quantity values and associated measurement uncertainties are reported in certificates of measurement.

Certified reference materials and the values assigned to them can be used to measure the bias/trueness of a measurement procedure.

Property

Feature of an object

EXAMPLE 1: ‘Being made of wood’ as a property of a given ‘table’.

EXAMPLE 2: ‘Belonging to person A’ as a property of a given ‘pet’.

EXAMPLE 3: ‘Having been formulated by Einstein’ as a property of the equation ‘E = mc2’.

EXAMPLE 4: ‘Being compassionate’ as a property of a given ‘person’.

EXAMPLE 5: ‘Having a given cable’ as a property of a given ‘computer mouse’.

NOTE 1: One or more objects can have the same property.

(ISO-1087:2019 (3))

Reference material

RM

Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

Note 1: Reference material is a generic term.

Note 2: Properties can be quantitative or qualitative, e.g. identity of substances or species.

Note 3: Uses may include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.

Note 4: ISO/IEC Guide 99:2007 has an analogous definition (5.13) (2), but restricts the term “measurement” to apply to quantitative values. However, Note 3 of ISO/IEC Guide 99:2007, 5.13 (VIM) (2), specifically includes qualitative properties, called “nominal properties”.

(ISO-Guide 30:2015)

Certified **reference material**

CRM

Reference material (RM) characterized by a metrologically valid procedure for one or more specified properties, accompanied by an RM certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

Note 1: The concept of value includes a nominal property or a qualitative attribute such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities or levels of confidence.

Note 2: Metrologically valid procedures for the production and certification of RMs are given in, among others, ISO Guides 34 and 35.

Note 3: ISO Guide 31 gives guidance on the contents of RM certificates. Note 4 to entry: ISO/IEC Guide 99:2007 has an analogous definition (5.14) (2).

(ISO-Guide 30:2015)

Candidate **reference material**

Material, intended to be produced as a reference material (RM)

Note 1: A candidate material has yet to be characterized and tested to ensure that it is fit for use in a measurement process. To become an RM, a candidate material needs to be investigated to determine if it is sufficiently homogeneous and stable with respect to one or more specified properties and is fit for its intended use in the development of measurement and test methods that target those properties.

Note 2: A candidate reference material may be an RM for other properties, and a candidate reference material for the target property.

(ISO-Guide 30:2015)

Matrix reference material

Reference material that is characteristic of a real sample

EXAMPLE Soil, drinking water, metal alloys, blood.

Note 1: Matrix reference materials may be obtained directly from biological, environmental or industrial sources.

Note 2: Matrix reference materials may also be prepared by spiking the component(s) of interest into an existing material.

Note 3: A chemical substance dissolved in a pure solvent is not a matrix material.

Note 4: Matrix materials are intended to be used in conjunction with the analysis of real samples of the same or a similar matrix.

(ISO-Guide 30:2015)

Primary **reference measurement procedure**
Primary reference procedure
Reference measurement procedure used to obtain a measurement result without relation to a measurement standard for a quantity of the same kind.

EXAMPLE: The volume of water delivered by a 50 ml pipette at 20 °C is measured by weighing the water delivered by the pipette into a beaker, taking the mass of beaker plus water minus the mass of the initially empty beaker, and correcting the mass difference for the actual water temperature using the volumic mass (mass density).

NOTE 1: The Consultative Committee for Amount of Substance – Metrology in Chemistry (CCQM) uses the term “primary method of measurement” for this concept.

NOTE 2: Definitions of two subordinate concepts, which could be termed “direct primary reference measurement procedure” and “ratio primary reference measurement procedure”, are given by the CCQM (5th Meeting, 1999)

(VIM 3, 2.8) (4)

Reference measurement systems

Combinations of fit for the intended use certified reference materials and reference measurement methods that provide traceability - a calibration hierarchy for transfer of trueness to routine measurement methods.

RELA

IFCC External Quality assessment scheme for Reference Laboratories in Laboratory Medicine.

Its homepage http://dgkl-rfb.de:81/ and procedures http://www.dgkl-rfb.de:81/IFCC_EQAS_ProcManual.pdf (20-22)

RELA Advisor

Qualified individual appointed by the Executive Committee of the JCTLM to assist the Database WG to review the services nominated for assessment by JCTLM and/or listed in the Database

Selectivity
Analytical selectivity
Selectivity of a measuring system
Property of a measuring system, used with a specified measurement procedure, whereby it provides measured quantity values for one or more measurands such that the values of each measurand are independent of other measurands or other quantities in the phenomenon, body, or substance being investigated

EXAMPLE 1: Capability of a measuring system including a mass spectrometer to measure the ion current ratio generated by two specified compounds without disturbance by other specified sources of electric current.

EXAMPLE 2: Capability of a measuring system to measure the power of a signal component at a given frequency without being disturbed by signal components or other signals at other frequencies.

EXAMPLE 3: Capability of a receiver to discriminate between a wanted signal and unwanted signals, often having frequencies slightly different from the frequency of the wanted signal.

EXAMPLE 4: Capability of a measuring system for ionizing radiation to respond to a given radiation to be measured in the presence of concomitant radiation.

EXAMPLE 5: Capability of a measuring system to measure the amount-of-substance concentration of creatininium in blood plasma by a Jaffé procedure without being influenced by the glucose, urate, ketone, and protein concentrations.

EXAMPLE 6: Capability of a mass spectrometer to measure the amount-of-substance abundance of the 28Si isotope and of the 30Si isotope in silicon from a geological deposit without influence between the two, or from the 29Si isotope.

NOTE 1: In physics, there is often only one measurand; the other quantities are of the same kind as the measurand, and they are input quantities to the measuring system.

NOTE 2: In chemistry, the measured quantities often involve different components in the system undergoing measurement and these quantities are not necessarily of the same kind.

NOTE 3: In chemistry, selectivity of a measuring system is usually obtained for quantities with selected components in concentrations within stated intervals.

NOTE 4: Selectivity as used in physics (see Note 1) is a concept close to specificity as it is sometimes used in chemistry.

(VIM 3, 4.13)

Property of a measuring system, used with a specified measurement procedure, whereby it provides measured quantity values for one or more measurands such that the values of each measurand are independent of other measurands or other quantities in the phenomenon, body, or substance being investigated

EXAMPLE: Capability of a measuring system to measure the amount-of-substance concentration of creatinine in blood plasma without being influenced by the other components present in the sample.

NOTE 1: In chemistry, selectivity of a measuring system is usually obtained for quantities with selected components in concentrations within stated intervals.

NOTE 2: Selectivity as used in physics is a concept close to specificity as it is sometimes used in chemistry.

(ISO/IEC-Guide 99:2007 (2) 4.13, ISO 17511:2020)

SI

The International System of Units
International decimal system of weights and measures derived from and extending the metric system of units. It was adopted by the 11th General Conference on Weights and Measures (CGPM) in 1960. https://www.bipm.org/en/publications/si-brochure/ .

Specified **reference**

Here taken to mean "specified reference measurement standard", where: (1) specified here means explicitly set forth in supporting documentation, and (2) a reference measurement standard, which, according to the VIM, is a measurement standard, generally having the highest metrological quality available at a given location or in a given organization, from which measurements there are derived. A national measurement standard is a standard recognized by a national authority to serve in a state or economy as the basis for assigning quantity or nominal property values to other standards of the quantity or kind concerned. An international measurement standard is a standard recognized by signatories to an international agreement and intended to serve worldwide.

(http://www.nist.gov/traceability/traceability_toc.cfm, 2020-10-18)

Measurement **standard**
Standard
Realization of the definition of a given quantity, with stated quantity value and associated measurement uncertainty, used as a reference

EXAMPLE 1: 1 kg mass measurement standard with an associated standard measurement uncertainty of 3 μg.

EXAMPLE 2: Set of reference solutions of cortisol in human serum having a certified quantity value with measurement uncertainty for each solution.

EXAMPLE 3: Reference material providing quantity values with measurement uncertainties for the mass concentration of each of ten different proteins.

NOTE 1: A “realization of the definition of a given quantity” can be provided by a measuring system, a material measure, or a reference material.

NOTE 2: A measurement standard is frequently used as a reference in establishing measured quantity values and associated measurement uncertainties for other quantities of the same kind, thereby establishing metrological traceability through calibration of other measurement standards, measuring instruments, or measuring systems.

NOTE 3: The term “realization” is used here in the most general meaning. It denotes three procedures of “realization”. The first one consists in the physical realization of the measurement unit from its definition and is realization sensu stricto. The second, termed “reproduction”, consists not in realizing the measurement unit from its definition but in setting up a highly reproducible measurement standard based on a

physical phenomenon, as it happens, e.g. in case of use of frequency-stabilized lasers to establish a measurement standard for the metre, of the Josephson effect for the volt or of the quantum Hall effect for the ohm. The third procedure consists in adopting a material measure as a measurement standard. It occurs in the case of the measurement standard of 1 kg.

NOTE 4: A standard measurement uncertainty associated with a measurement standard is always a component of the combined standard measurement uncertainty (3.33) in a measurement result obtained using the measurement standard (see ISO/IEC Guide 98-3:2008 — GUM, 2.3.4). Frequently, this component is small compared with other components of the combined standard measurement uncertainty.

NOTE 5: Quantity (3.38) value and measurement uncertainty (3.48) must be determined at the time when the measurement standard is used.

NOTE 6: Several quantities (3.38) of the same kind or of different kinds may be realized in one device which is commonly also called a measurement standard.

(ISO-17511:2020, ISO-99:2007)

Primary measurement **standard**

Primary standard

Measurement standard whose quantity value and measurement uncertainty are established using a primary measurement procedure

EXAMPLE: Primary measurement standard of amount-of-substance concentration prepared by dissolving a known amount of substance of a chemical component to a known volume of solution.

NOTE 1: Adapted from ISO/IEC Guide 99:2007, 5.4 (2).

NOTE 2: The concept of “primary measurement standard” is equally valid for base quantities and derived quantities.

NOTE 3: Further explanation of the role of primary measurement standards within a calibration hierarchy can be found in ISO-17511 and ISO-18153.

(ISO-15194:2009)

Measurement standard that is designated or widely acknowledged as having the highest metrological qualities and whose property value is accepted without reference to other standards of the same property or quantity, within a specified context

Note 1: See also ISO/IEC Guide 99:2007 (2)

(ISO-Guide 30:2015)

Secondary measurement **standard**

Measurement standard whose property value is assigned by comparison with a primary measurement standard of the same property or quantity

Note 1: See also ISO/IEC Guide 99:2007.

(ISO-Guide 30:2015)

Working measurement **standard**
Working standard
Manufacturer's working calibrator
Manufacturer's master calibrator
Measurement standard that is used to calibrate or verify measuring instruments or measuring systems.

NOTE 1: A working measurement standard is usually calibrated (value assigned) with reference to a reference measurement standard.

NOTE 2: In relation to verification, the terms "check standard" or "control standard" are also sometimes used.

NOTE 3: A manufacturer may choose to prepare a manufacturer's working calibrator, which is intended to transfer trueness by means of calibration to end-user in vitro diagnostic measurement device calibrators.

NOTE 4: A working measurement standard is sometimes implemented as a surrogate reference material in lieu of a more expensive higher order reference material.

(ISO/IEC-Guide 99:2007 (2) 5.7, ISO-17511:2020)

National or international **standards,** here meaning measurement standards. Standards (national) recognized by a national decision to serve, in a country, as the basis for assigning values to other standards of the quantity concerned; standards (international) recognized by an international agreement to serve internationally as the basis for assigning values to other standards of the quantity concerned. (http://www.nist.gov/traceability/traceability_toc.cfm, 2020-10-18)

Secondary **measurement standard**

Secondary standard

Measurement standard whose quantity value and measurement uncertainty are assigned through calibration with respect to a primary measurement standard for a quantity of the same kind

NOTE 1: The relation can be obtained directly between the primary measurement standard and the secondary measurement standard or involve an intermediate measuring system calibrated by the primary standard and assigning a measurement result to the secondary standard.

NOTE 2: Adapted from ISO/IEC-Guide 99:2007, 5.5 (2).

EXAMPLE: NIST Standard Reference Material 1951b, Lipids in Frozen Human Serum is a secondary measurement standard that is calibrated using NIST Standard Reference Material 1911c, Cholesterol of known purity.

NOTE 3: "Measurement standard" includes "reference material".

NOTE 4: Further explanation of the role of secondary measurement standards within a calibration hierarchy can be found in ISO-17511 and ISO-18153.

(ISO-15194:2009)

Standard Reference Data (SRD)

Quantitative information, related to a measurable physical or chemical property of a substance or system of substances of known composition and structure, which is critically evaluated as to its reliability (Standard Reference Data Act, 15 U.S.C. 290 Sec. 2(a)). (http://www.nist.gov/traceability/traceability_toc.cfm , 2020-10-18)

Standardization

Achieving equivalent results among different measurement procedures by having calibration traceable to higher order references.

https://www.harmonization.net on 2021-02-03

Standardization
Standardized
Achievement of equivalent measured quantity values (within clinically meaningful limits) for human samples examined for a stated measurand among two or more IVD MDs, where each "standardized" IVD MD is calibrated according to a defined hierarchy of relationships to higher order references (materials and/or measurement procedures)

Note 1: Standardization of an IVD MD is achieved preferably by implementation of a calibration system that is traceable to higher order references, ideally with traceability to SI.

Note 2: Not all standardization approaches result in traceability of final measured values to SI but may be the best available means for achieving equivalent results for human samples among different in-vitro diagnostic measurement devices. Such standardization approaches should be replaced when an approach becomes available that provides traceability to SI.

Note 3: Standardized is the condition in which standardization of results for human samples is achieved among two or more IVD MDs.

(ISO-21151:2020)

Survey **sample**

Sample sent to participants for selected examination, where the result is returned to the EQAS organisation for independent assessment of performance.

(ISO-087:2019)

System

The system is the material itself or a specified part of the material.

EXAMPLES: Reconstituted lyophilized plasma (as a system) for which there is a certified amount-of-substance concentration and measurement uncertainty of 17β-Estradiol (as a component); reconstituted lyophilized haemolysate (as a material) containing Haemoglobin β chains (as a system) for which there is a certified amount-of-substance fraction and measurement uncertainty of N-(1-deoxyfructos-1-yl) haemoglobin β chains (as a component).

(ISO-15194:2009, 4.1.1)

Construction of **systematic designations**

A systematic name and value shall consist of elements as specified in the description of quantity value

EXAMPLE 1 A systematic name of a calibrator for a hematology analyzer can be secondary reference material for calibration (Responsible body NN; Product no 4132), for example:

- Erythrocytes; number concentration = (4,71 ± 0,09) 1012/l; average and expanded uncertainty (k = 2, with level of confidence 0,95);

- Leukocytes; number concentration = (6,52 ± 0,25) 109/l; average and expanded uncertainty (k = 2, with level of confidence 0,95);
- Thrombocytes; number concentration = (240 ± 12) 109/l; average and expanded uncertainty (k = 2, with level of confidence 0,95).

EXAMPLE 2 Certified reference material (Human serum; BCR; CRM 303)--Calcium(II); amount-of-substance concentration (reconstituted) c = 2,472 mmol/l (U = 0,019 mmol/l; k = 2), where U is the expanded uncertainty of measurement using the coverage factor k.

(ISO-15194:2009)

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. (4)

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.

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.

The concept of traceability covers both measurement results of quantity values and of nominal property values such as chemical identity and sequence.

Assuring metrological **traceability,** to provide support for the claim of traceability of the result of a given measurement.

Metrological **traceability**

The "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.

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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.

(VIM3 2.41, 6.10) (4).

Metrological **traceability chain**

Traceability chain (4)

Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference

NOTE 1: A metrological traceability chain is defined through a calibration hierarchy.

NOTE 2: A metrological traceability chain is used to establish metrological traceability of a measurement result.

NOTE 3: 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.

Transferability

"The results produced by medical laboratories should be traceable to reference materials and/or reference measurement procedures of higher order, whenever these are available. This is necessary in order to allow *transferability* of measurement results in patient samples irrespective of the place and time of measurement." ISO 15195:2003

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. (4).

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'.

Stated **uncertainties**

Uncertainty of measurement that: (1) fulfils the International vocabulary of metrology - Basic and general concepts and associated terms (4) definition as the parameter, associated with the result of a measurement, that characterizes the dispersion of values that could reasonably be attributed to the measurand; (2) is evaluated and expressed according to the general rules given in the ISO Guide to the Expression of Uncertainty in Measurement (11); and (3) is explicitly set forth in supporting documentation. (http://www.nist.gov/traceability/traceability_toc.cfm, 2020-10-18)

Uncertainty of measurement
Measurement uncertainty
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, as in the case of corrections to the assigned quantity values of measurement standards. Sometimes estimated systematic effects are not corrected for, but instead, the 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 can be evaluated by Type B evaluation of measurement uncertainty, may 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.

NOTE 5: Type A evaluation of measurement uncertainty is defined as evaluation of a component of measurement uncertainty by a statistical analysis of measured quantity values obtained under defined measurement conditions [adapted from VIM, 2.28].

NOTE 6: Type B evaluation of measurement uncertainty is defined as evaluation of a component of measurement uncertainty determined by means other than a Type A evaluation. This may include standard deviations (a) obtained from information associated with authoritative published quantity values, (b) associated with quantity values of CRMs, (c) obtained from a calibration certificate, (d) obtained from experience or other means [adapted from VIM, 2.29].

(ISO/IEC-Guide 99:2007 (2) 2.26, ISO-17511:2000)

Maximum allowable measurement **uncertainty**

Umax(y), maximum fit for purpose measurement uncertainty for measurement results produced by a given, measurement procedure, and specified as an upper limit based on an evaluation of medical requirements.

NOTE 1: ISO/IEC-Guide 99:2007 4.26 (2), defines maximum permissible measurement error. In modern English usage, the difference between the terms allowed and permitted is analogous to the difference between the concepts of tolerance (allowed) and authorization (permitted). Authorization implies a statutory, mandated, or legal requirement. For most measurands in laboratory medicine there are no legal limits of performance, therefore allowable is the preferred adjective in the context of this definition.

NOTE 2: In this document, the maximum allowable measurement uncertainty (3.25) specification for an IVD MD (3.21) is abbreviated Umax(y).

(ISO-17511:2020 (5))

Period of **validity** of a reference material

Time interval during which the producer of the reference material warrants its stability

Note 1: The period of validity may be expressed as a specific date or an otherwise defined period of time.

Note 2: The period of validity is designed to be within the lifetime of an reference material.

(ISO-Guide 30:2015 (9))

Value

The results used in patient care or in epidemiological investigations together with their corresponding reference intervals and/or decision limits.

Certified **value**

Value, assigned to a property of a reference material that is accompanied by an uncertainty statement and a statement of metrological traceability, identified as such in the reference material certificate.

(ISO-Guide 30:2015 (9))

Indicative **value**
Information value
Informative value
Value of a quantity or property, of a reference material, which is provided for information only.

Note 1: An indicative value cannot be used as a reference in a metrological traceability chain.

(ISO-Guide 30:2015)

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