
**Medical laboratories — Practical
guidance for the estimation of
measurement uncertainty**

*Laboratoires médicaux — Lignes directrices pratiques pour
l'estimation de l'incertitude de mesure*

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Improved standardization and harmonization of medical laboratory practices worldwide benefits society as patients and healthcare professionals increasingly move within and between healthcare services in the global economy. To help achieve the objective of improved standardization among medical laboratories, ISO 15189 focuses on the application of the quality systems approach in the medical laboratory. Since the first version of ISO 15189 was published in 2003, this international standard has been increasingly adopted worldwide as a desirable (and in some cases mandatory) quality system standard for medical laboratories.

To ensure that measurement results are useful and safe in medical practice and to permit meaningful comparison with medical decision limits and previous results of the same kind in the same individual, medical laboratories require estimates for the overall variability in values reported by their measurement procedures. To achieve this, ISO 15189:2012, 5.5.1.4, requires that “...(medical laboratories)... shall determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients’ samples.” Additionally, “Upon request, the laboratory shall make its estimates of measurement uncertainty available to laboratory users.”

For medical laboratories and healthcare providers, measurement uncertainty (MU) estimates:

- indicate that multiple values are possible for a given measurement;
- provide evidence that the term ‘true value’ of a quantity is a theoretical concept;
- quantify the quality of a result relative to its suitability for use in making medical decisions;
- assume that known medically significant bias is eliminated;
- assist in identifying technical steps to reduce MU;
- allow combination with other sources of uncertainty;
- can be used to determine if medically allowable analytical performance specifications can be achieved;
- support interpretation of patient results close to medical decision limits.

To enable fulfilment of the requirement of ISO 15189 for estimation of MU, it is essential that medical laboratories be provided with a coherent, standardized, and best practice approach to the terminology, principles and statistical methods required for estimation of MU. *Evaluation of measurement data — Guide to the expression of uncertainty in measurement* (GUM) JCGM 100:2008, a definitive reference on the topic of MU, provides in-depth information regarding the mathematical and metrological considerations appropriate for a detailed estimation of elements to be considered in the estimation of MU for a broad range of measuring systems, across many disciplines in science and engineering. In the Scope, GUM subclause 1.2, states that “This document is primarily concerned with the expression of uncertainty in the measurement of a well-defined physical quantity that can be defined by an essentially unique value.” GUM, Scope subclause 1.4, goes on to say that “...(GUM) provides general rules for evaluating and expressing uncertainty in measurement rather than detailed, technology-specific instructions. (GUM) ... does not discuss how the uncertainty of a particular measurement result, once evaluated, may be used for different purposes, for example, to draw conclusions about the compatibility of that result with other similar results, to establish tolerance limits in a manufacturing process, or to decide if a certain course of action may be safely undertaken. Therefore, it may be necessary to develop particular standards based on (GUM) that deal with the problems peculiar to specific fields of measurement or with the various uses of quantitative expressions of uncertainty. These standards may be simplified versions of (GUM) but should include the detail that is appropriate to the level of accuracy and complexity of the measurements and uses addressed.”

This document is therefore concerned with practical approaches to estimation of MU, to be applied in medical laboratory settings for the purpose of estimating MU of values produced by measurement procedures intended to measure a broad range of biological measurands. The measurands of interest

are subject to measurement for the purpose of providing medical diagnostic information to health care practitioners and are typically present in complex biological fluid and tissue matrices. In contemporary medical laboratory settings, the vast majority of these measurements are performed with commercial devices, including automated instrumentation and packaged reagent kits. Characterization of the performance of these measurement procedures in an end-user laboratory environment is typically limited to the gathering of empirical performance data using surrogate quality control samples designed to emulate the intended patient samples. Such data, commonly known as internal quality control (IQC) data, may be appropriate for characterization of repeatability and long-term imprecision of a given measurement procedure. Additional uncertainty information regarding higher order elements of the calibration hierarchy for a given measurement procedure should be available from the manufacturer, and should be accounted for in the medical laboratory's process for estimation of MU. As such, a GUM top down approach is appropriate, and a particular application for use in medical laboratories is outlined in [Clause 6](#).

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Medical laboratories — Practical guidance for the estimation of measurement uncertainty

1 Scope

This document provides practical guidance for the estimation and expression of the measurement uncertainty (MU) of quantitative measurand values produced by medical laboratories. Quantitative measurand values produced near the medical decision threshold by point-of-care testing systems are also included in this scope. This document also applies to the estimation of MU for results produced by qualitative (nominal) methods which include a measurement step. It is not recommended that estimates of MU be routinely reported with patient test results, but should be available on request.

NOTE See [Annex B](#) for an example of application of the MU.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1 analyte

component represented in the name of a measurand

Note 1 to entry: Constituent of a sample with a measurable property.

EXAMPLE In the measurand (measured quantity) "mass of total protein in 24-hour urine", "total protein" is the analyte (and "mass" is the property.) In "amount of substance concentration of glucose in plasma", "glucose" is the analyte (and "amount of substance concentration" is the property.)

[SOURCE: ISO 18113-1:2009, modified]

Note 2 to entry: JCGM 200:2012, 5.4, states that a primary measurement standard may be "...prepared by dissolving a known amount of substance of a chemical component to a known volume of solution".

3.2 calibration

operation that, under specified conditions, in a first step, establishes a relation between the quantity values with associated measurement uncertainties provided by measurement standards (calibrators) and their corresponding indications and, in a second step, uses this relationship to establish a measurement result from an indication (for an unknown sample).

Note 1 to entry: 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 MU.

Note 2 to entry: Calibration should not be confused with adjustment of a measuring system, often mistakenly called "self-calibration", nor with verification of calibration.

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

[SOURCE: JCGM 200:2012, 2.39, modified]

3.3

calibrator

measurement standard used in calibration

[SOURCE: JCGM 200:2012, 5.12]

Note 1 to entry: In this document, calibrator is synonymous with calibration material.

Note 2 to entry: A calibrator is a measurement standard used in the calibration of a measuring system according to a specified measurement procedure.

3.4

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 measurement procedures, and the relation obtained among the measurement results for other specified materials

Note 1 to entry: The reference material in question is usually a calibrator and the other specified materials are usually routine samples.

[SOURCE: JCGM 200:2012, 5.15]

Note 2 to entry: It is typical that there are more than two measurement procedures available and comparison among all applicable measurement procedures is desirable.

Note 3 to entry: The requirement for the closeness of agreement shall be appropriate for the intended use of the reference material.

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

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3.5 <https://standards.iteh.ai/catalog/standards/iso/46d5b2f9-de6c-4482-adac-6f7226c6c657/iso-ts-20914-2019> **component**

constituent of a mixture the amount or concentration of which can be varied independently

[SOURCE: International Union of Pure and Applied Chemistry (IUPAC) Compendium of Chemical Terminology (Gold Book) Version 2.3.3 2014-02-24, modified]

Note 1 to entry: See also *analyte* (3.1).

3.6

coverage factor

k

number larger than one by which a standard uncertainty value (u) is multiplied to obtain an *expanded uncertainty*, U (3.9)

Note 1 to entry: A coverage factor is usually symbolized k .

[SOURCE: JCGM 200:2012, 2.38, modified]

3.7

coverage interval

interval containing the set of true quantity values of a measurand with a stated probability, based on the information available

Note 1 to entry: A coverage interval does not need to be centred on the chosen measured quantity value (see JCGM 101:2008).

Note 2 to entry: A coverage interval should not be termed “confidence interval” to avoid confusion with the statistical concept (see GUM:1995, 6.2.2).

Note 3 to entry: A coverage interval can be derived from an expanded MU (see GUM:1995, 2.3.5).

[SOURCE: JCGM 200:2012, 2.36]

Note 4 to entry: The term ‘true’ is considered redundant by GUM. For this document the term ‘value of the measurand’ is used.

3.8

end-user calibrator

end-user in vitro diagnostic medical device (IVD MD) calibrator

reference material used as a measurement standard (calibrator) intended for use with one or more measurement procedures intended to examine a particular measurand in human samples

3.9

expanded measurement uncertainty

U

expanded uncertainty

(multiplication) product of a u by a (coverage) factor k larger than the number one

[SOURCE: JCGM 200:2012, 2.35, modified]

Note 1 to entry: A measured value $x \pm [k \times u(y)]$, with coverage factor $k = 2$, means that the laboratory believes (≈ 95 % level of confidence) that the value of the measurand lies in the interval of values defined by the following formula:

$$x \pm [k \times u(y)]$$

where

X is the measured value;

K is the coverage factor (usually 2 for ≈ 95 % confidence);

$u(y)$ is the standard uncertainty of a measured value, y .

3.10

external quality assessment

EQA

international, national or local program designed to provide regular, external, independent quality assessment of a medical laboratory’s analytical performance, and assist in detecting bias of reported results compared to other laboratories.

Note 1 to entry: Also known as Proficiency Testing (PT)^[19-21].

Note 2 to entry: EQA is the term used in this document.

3.11

indication

quantity value provided by a measuring instrument or a measuring system

Note 1 to entry: An indication may be presented in visual or acoustic form or may be transferred to another device. An indication is often given by the position of a pointer on the display for analog outputs, a displayed or printed number for digital outputs, a code pattern for code outputs, or an assigned quantity value for material measures.

[SOURCE: JCGM 200:2012, 4.1]

3.12

intermediate precision condition of measurement

condition of measurement, out of a set of conditions that includes the same measurement procedure, same location, and replicate measurements on the same or similar objects over an extended period of time, but may include other conditions involving changes

Note 1 to entry: The changes can include new calibrations, calibrators, operators, and measuring systems.

Note 2 to entry: A specification for the conditions should contain the conditions changed and unchanged, to the extent possible.

[SOURCE: JCGM 200:2012, 2.22]

Note 3 to entry: For this document, the term long-term precision (u_{Rw}) is used to mean precision data for a given measurement procedure obtained over an extended period of time that at some point includes the effects of all or most changes in measuring conditions, for example, consumable lot changes, re-calibrations, etc. Such changes should be defined for each measurement procedure [see 3.33 repeatability condition of measurement (JCGM 200:2012, 2.20); see 3.40 uncertainty component under conditions of within-laboratory precision (u_{Rw})].

Note 4 to entry: Changed conditions may include instrument maintenance where appropriate.

Note 5 to entry: u_{Rw} is often the major contributor to the combined standard uncertainty of a measurement result in the medical laboratory.

3.13

internal quality control

IQC

set of procedures and specified materials used by laboratory staff for the repetitive monitoring of analytical performance of measuring systems

3.14

long-term precision

u_{Rw}
see 3.12, 3.40

Note 1 to entry: Both the term 'long-term precision' and the symbol u_{Rw} are used in this document when referring to an uncertainty estimate based on data observed under intermediate precision conditions of measurement.

3.15

maximum allowable measurement uncertainty

target measurement uncertainty

maximum fit for purpose MU for measurement results produced by a given measurement procedure, and specified as an upper limit based on an evaluation of medical requirements

[SOURCE: JCGM 200:2012, 2.34 and 4.26, modified]

Note 1 to entry: JCGM 200:2012, 4.26, 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 to entry: The maximum allowable MU is considered to represent fit-for-purpose performance based on use of a measurement result for a medical decision.

3.16

measurand

quantity intended to be measured

Note 1 to entry: 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 “particular quantity subject to measurement”.

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

EXAMPLE 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 to entry: 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.

[SOURCE: JCGM 200:2012, 2.3]

Note 5 to entry: 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.)

[SOURCE: ISO 18113-1:2009, 3.39]

3.17

measurement

process of experimentally obtaining one or more quantity values that can be reasonably attributed to a quantity

Note 1 to entry: Measurement does not apply to nominal properties.

Note 2 to entry: Measurement implies comparison of quantities or counting of entities.

Note 3 to entry: 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.

[SOURCE: JCGM 200:2012, 2.1]

Note 4 to entry: A measurand is the quantity intended to be measured by a medical laboratory. See 3.17.

3.18

measurement bias

estimate of a systematic measurement error

[SOURCE: JCGM 200:2012, 2.18]

Note 1 to entry: Difference between the accepted value of a commutable reference material and the mean value of replicate measurements produced under repeatability conditions by a medical laboratory measurement procedure

Note 2 to entry: Difference between the mean value of replicate measurements produced by a reference measurement procedure and the mean value of replicate measurements produced under repeatability conditions by a medical laboratory measurement procedure.

Note 3 to entry: Because of measurement imprecision, values for measurement bias cannot be exactly known.

3.19

measurement error

measured quantity value minus a reference quantity value

[SOURCE: JCGM 200:2012, 2.16]

Note 1 to entry: In general, a measurement has imperfections that give rise to an error in the measurement result. Traditionally, an error is viewed as having two components, namely, a random component and a systematic component.

Note 2 to entry: Error is an idealized concept and errors cannot be known exactly.

[SOURCE: JCGM 100:2008; 3.2.1, Notes 1 and 2]

3.20

measurement method

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

Note 1 to entry: Measurement methods may be qualified in various ways such as:

- substitution measurement method;
- differential measurement method;
- null measurement method;
- direct measurement method;
- indirect measurement method.

Note 2 to entry: See IEC 60050-300:2001.

[SOURCE: JCGM 200:2012, 2.5]

3.21

measurement precision

precision

closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions

Note 1 to entry: Measurement precision is usually expressed numerically by measures of imprecision, such as variance, standard deviation (SD), or coefficient of variation (C_V) under the specified conditions of measurement.

Note 2 to entry: The 'specified conditions' can be, for example, repeatability conditions of measurement, intermediate precision conditions of measurement, or long-term conditions of measurement (see ISO 5725-1:1994).

Note 3 to entry: Measurement precision is used to define measurement repeatability, intermediate measurement precision, and long-term measurement imprecision.

[SOURCE: JCGM 200:2012, 2.15]

Note 4 to entry: Imprecision denotes the statistical measure or metric related to the degree of closeness or dispersion, such as SD, CV, range, etc. In this context, a measurement procedure is of good precision when the imprecision is low, and of bad precision when the imprecision is high relative to the precision needed to make medical decisions based on the value of the quantity measured.

3.22

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 to entry: A measurement procedure is usually documented in sufficient detail to enable a competent operator to perform a measurement.

[SOURCE: Modified – added "competent"]

Note 2 to entry: A measurement procedure can include a statement concerning a target MU.

Note 3 to entry: A measurement procedure is sometimes called a standard operating procedure, abbreviated SOP.

[SOURCE: JCGM 200:2012, 2.6]

Note 4 to entry: Target MU as described in Note 2 of JCGM 200:2012, 2.6, is referred to as maximum allowable measurement uncertainty in this document. See [3.15](#).

3.23

measurement repeatability

measurement precision under a set of repeatability conditions of measurement

[SOURCE: JCGM:200:2012, 2.21]

Note 1 to entry: See [3.33](#).

3.24

measurement result

set of quantity values being attributed to a measurand together with any other available relevant information

Note 1 to entry: 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 to entry: A measurement result is generally expressed as a single measured quantity value and a MU. If the MU 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.

[SOURCE: JCGM 200:2012, 2.9]

3.25

measurement standard

realization of the definition of a given quantity, with stated quantity value and associated MU, used as a reference

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

EXAMPLE 2 Set of reference solutions of cortisol in human serum having a certified quantity value with MU 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 to entry: 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 to entry: A measurement standard (calibrator) is frequently used as a reference in establishing measured quantity values and associated MU for other quantities of the same kind, thereby establishing metrological traceability through calibration of other measurement standards, measuring instruments, or measuring systems.

Note 3 to entry: 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 to entry: A standard MU associated with a measurement standard is always a component of the combined standard MU (See JCGM 100:2008, 2.3.4) in a measurement result obtained using a procedure calibrated with the measurement standard. Frequently, this component is smaller when compared with other components of the combined standard MU.

Note 5 to entry: Quantity value and MU must be determined at the time when the measurement standard is used.

Note 6 to entry: Several quantities of the same kind or of different kinds may be realized in one device which is commonly also called a measurement standard.

Note 7 to entry: The word “embodiment” is sometimes used in the English language instead of “realization”.

Note 8 to entry: In science and technology, the English word “standard” is used with at least two different meanings: as a specification, technical recommendation, or similar normative document (in French « norme ») and as a measurement standard (in French « étalon »). This vocabulary is concerned solely with the second meaning.

[SOURCE: JCGM 200:2012, 5.1]

3.26

measurement uncertainty

MU

parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

Note 1 to entry: MU 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 MU components are incorporated.

Note 2 to entry: The parameter may be, for example, a SD called standard MU (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

Note 3 to entry: MU comprises, in general, many components. Some of these may be evaluated by Type A evaluation of MU from the statistical distribution of the quantity values from series of measurements and can be characterized by SD. The other components, which may be evaluated by Type B evaluation of MU, can also be characterized by SD or evaluated from probability density functions based on experience or other information.

Note 4 to entry: In general, for a given set of information, it is understood that the MU is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

[SOURCE: JCGM 200:2012, 2.26]

Note 5 to entry: All measurements have bias and imprecision. For example, replicate measurements of a sample performed under repeatability conditions generally produce different values for the same measurand. Because the different values could all be reasonably attributed to the same amount of measurand, there is uncertainty as to which value should be reported as the value of the measurand.

Note 6 to entry: Based on available data about the analytical performance of a given measurement procedure, an estimation of MU provides an interval of values that is believed to include the actual value of the measurand, with a stated level of confidence.

Note 7 to entry: Available data about the analytical performance of a given measurement procedure typically comprise uncertainty of calibrator assigned values and long-term imprecision of IQC materials.

Note 8 to entry: In medical laboratories, most measurements are performed in singleton, and are taken to be an acceptable estimate of the value of the measurand, while the MU interval indicates other results that are also possible.

3.27

measuring 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 to entry: A measuring system may consist of only one measuring instrument.

[SOURCE: JCGM 200:2012, 3.2]