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Review

Measurement Uncertainty: New Definition, Viewpoints, and Laboratories

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Abstract

The Joint Committee for Guides in Metrology (JCGM) today presents a definition of measurement uncertainty that modifies the previous one and improves the management of scenarios other than scalar (quantitative) measurements, such as classificatory or qualitative (nominal and ordinal) properties. Nominal results are often found in biology and medicine. For the accreditation of medical laboratories and testing laboratories, both ISO 15189 and ISO 17025 require the management of these situations, using the professional expertise of specialists with the support of manufacturers. Some of the members of JCGM WG2 developed a discussion on the concept of measurement uncertainty and raised some criticisms. ISO produces detailed guides for this purpose, such as ISO 20914, ISO 27877, ISO 16393, ISO 20397-2, and ISO 22692. Laboratories now have all the tools they need to meet accreditation requirements on uncertainty.

Keywords: measurement uncertainty; ISO accreditation; medical laboratories; testing laboratories; qualitative properties; NGS

1. Introduction: The New Definition of Uncertainty, Facts of Biology, Medicine and the Real World

On 2 July 2025, the Joint Committee for Guides in Metrology (JCGM, a division of the Bureau International des Poids et Mesures, BIPM, Sèvres, Paris) organized a well-attended internet seminar to present and discuss a new definition of measurement uncertainty (Table 1) [1]. The definition can be found in JCGM GUM-1:2023 (GUM2023) in Section 3.4 [2]. Although not presented by the GUM2023 as a formal definition, this statement can be interpreted as a true definition.

Table 1. Old and new definitions of uncertainty in measurement (MU).

GUM 1995–2008 (2.2.3) [3]	VIM3 2008 (2.26) VIM3 1993 (3.9) [4]	GUM 2023 (3.4) [2]
parameter, associated with the measured value, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.	non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.	the doubt about the true value of the measurand that remains after making a measurement.

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The GUM 2023 [2] makes two substitutions: they replace "parameter" with "doubt" (Table 1) and explain that measurement uncertainty can be represented by a probability distribution, not only by dispersion.

The new definition was endorsed by the International Union of Pure and Applied 37 Chemistry (IUPAC) [5] and by the US National Institute of Standards and Technology (NIST) [6]. According to NIST, the fixed characterization of measurement uncertainty as a "parameter" would hinder the application of methods widely used today, such as the Monte Carlo and Bayesian methods. With the GUM2023 definition, a wider range of results falls within uncertainty, including those of classifications, identifications, examinations, and more [6]. NIST collects many examples of uncertainty from biology and medicine to which the old VIM definition is ill-suited. For example, Coho salmon (Oncorhynchus kisutch) is classified with uncertainty described not by variance and standard deviation, but by the probabilities of alternative species [5]. Another case is that of the reproduction number, R, of COVID-19, i.e., the average number of secondary infections produced by a single infected person [7]. Each research group reports different quantiles of the probability distribution that expresses the uncertainty surrounding R (e.g., the 5th, 25th, 50th, 75th, and 95th percentiles), while most of the procedures used for meta-analysis require the mean and standard deviation of the distribution of R as input [6]. Pressed by practical needs, NIST found the solution for qualitative properties, as in the case of reference material 8256, a fresh frozen fish homogenate prepared from wild-caught coho salmon (Oncorhynchus kisutch) [5], including the identity of a polychlorinated biphenyl (PCB) and the species of a maple tree (genus Acer) [8]. PCB has more than 200 possible values, maple more than 160. Similarly, an animal in the genus Panthera can be compared with five species: tiger, leopard, jaguar, lion, or snow leopard. Possolo A and Meija (one from NIST, the other from National Research Council Canada) are categorical: a measured value, an estimate of the true value of a property, can be quantitative or qualitative, not just quantitative [8,9].

2. Uncertainty and ISO Accreditation

Testing laboratories and medical laboratories are accredited according to ISO 17025 [10] and ISO 15189 [11], respectively. The uncertainty in ISO 15189 is very different from ISO 17025 (Table 2). ISO 17025 does not include uncertainty in the glossary, but it does contain Chapter 7.6 ("Evaluation of measurement uncertainty"), where the requirement to estimate measurement uncertainty is established (7.6.1 and 7.6.3), but special cases are allowed, such as when "the test method precludes rigorous evaluation of measurement uncertainty" "shall be estimated from the theoretical principles or practical experience", as well as in the case of a "well-recognized test method", and it is not required to "evaluate measurement uncertainty for each result". Outside of these cases, ISO 17025 does not provide exceptions from the 7.5.3 requirement.

Unlike ISO 17025, ISO 15189 includes uncertainty in its glossary, drawing it evenly from ISO/IEC Guide 99:2007 2.26 (VIM3) [12] and ISO/TS 20914:2019 3.26 [13].

Uncertainty is of great concern to medical laboratories and thus ISO 15189, so much so that it feels the need to add as many as eight notes. In these notes, ISO recalls systematic deviation (3.19 Note 1), reduces the SD parameter to a simple nonexhaustive "example" (3.19 Note 2), suitable for "type A" components (3.19 Note 3), affirms the multiplicity of uncertainties in relation to the level of the result (3.19 Note 4), describes the meaning of uncertainty as the probability of the surroundings of the results (3.19 Notes 6 and 8), and provides the cue for calculation from calibration and quality control (3.19 Note 7).

ISO 15189 calls for using uncertainty for verification of methods (Clause 3.32), acceptance of instruments (Clause 6.4.3), and traceability of results (Clause 6.5.3).

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Like ISO 17025, ISO 15189 devotes many requirements to uncertainty estimation (Clause 7.3.4), but with more detail. It inserts assessment of "relevance," requiring comparison to performance specifications, addressing ISO 20914 for the implementation of principles, periodic review, documentation of difficulties or limitations, exclusion from the presentation of results but availability upon request, user support for other sources of uncertainty (such as biological variability), extension to qualitative results obtained by threshold and those obtained by quantitative measurement steps, and use for validation and verification of methods.

Table 2. Uncertainty and ISO accreditation of laboratories.

ISO 17025 [10]	ISO 15189 [11]
• Shall be evaluated (7.6.1 and 7.6.3) • Shall be estimated from the theoretical principles or practical experience when rigorous evaluation is precluded • Shall not be estimated for well-recognized test method • Shall not be estimated for each result	• with systematic deviation (3.19 Note 1) • SD parameter a simple "example" (Note 2), suitable for "type A" components (Note 3), • multiplicity in relation to the level of the result (Note 4), • means the probability of the surroundings of the results (Notes 6 and 8), • calculation from calibration and quality control (Note 7). • used for verification of methods (Clause 3.32), acceptance of instruments (Clause 6.4.3), and traceability of results (clause 6.5.3) • shall be evaluated and maintained (7.3.4) • assessment of "relevance," (7.3.4) • comparison to performance specifications (7.3.4 a), • ISO 20914 for implementation (7.3.4 a), • periodic review (7.3.4 b), • documentation of difficulties or limitations (7.3.4 c), • exclusion from presentation of results (7.3.4 d), • availability upon request (7.3.4 d), • user-support to other sources (7.3.4 e), • extension to qualitative results obtained by threshold (7.3.4 f), • extension to qualitative results obtained by quantitative measurement steps (7.3.4 g), • use for validation and verification of methods (7.3.4 h)

ISO/TS 20914:2019 [13] confirms and reinforces the guidance of ISO 15189. It should be noted that ISO 20914 predates the new 2022 edition of ISO 15189, so it is already derived from the 2012 edition. ISO 20914 extends uncertainty from the laboratory to point-of-care (POCT) services, from numbers to measurement names, reserves reporting on demand, bases the concept on long-term imprecision (uRw), provides for use as absolute (u), relative (urel) or percentage (%urel), and calls out multiplicity if you have multiple levels of CQI.

The GUM of 2008 (ISO/IEC Guide 98-1:2009, revised 2024 [14,15]) already contained part of the solution to practical difficulties, where it states that (4.1.1) in most cases, a measurand Y is not measured directly, but is determined by N other quantities X1, X2, . . ., XN. The passage is confirmed to be identical in the GUM 2023 (ISO/IEC Guide 98-1:2024) [13]. As in "General Principle" (3.4.8 of 2008, Section 4.1 of 2023), where we read that the assessment of measurement uncertainty is neither a routine nor a purely mathematical task, but it depends on detailed knowledge of the nature of the measurand and the measurement. Furthermore, (4.1.2) the input quantities X1, X2, . . ., XN . . . may themselves be considered as measurands and may depend on other quantities, including corrections and correction factors for systematic effects.

Therefore, we can assume that the GUM is not rigid at all. The standard deviation is just one example. The input quantities can be indifferent (4.1.3) single observations, repeated observations or judgments based on experience, influences such as ambient temperature, barometric pressure, and humidity, external sources such as calibrators, certified reference materials and reference data obtained from manuals, etc.

3. The Point of View of Reagent or IVD Manufacturers and ISO/TC 334

Recognizing the limitations of the state-of-the-art guidance on uncertainty, ISO responds to the practical need with ISO 33406 (reference materials with qualitative values) [16]. ISO 33406 (published by ISO/TC 334 reference materials) uses the term "confidence" instead of "uncertainty" for doubt assigned to a qualitative property. ISO 33406 allows confidence/uncertainty to be expressed qualitatively, using an ordinal scale (e.g., very confident, confident, moderately confident), as long as it is understandable to the user. ISO 33406 also allows quantitative confidence statements, such as a likelihood ratio or a probability distribution of values. It also allows the use of confidence measures derived from false response rates, such as sensitivity and specificity.

According to ISO 33406, if the qualitative property depends on the measurement of one or more quantitative values, the confidence in the assigned qualitative values depends on controlling the uncertainties related to the intermediate measurements.

One finds the same approach in ISO 17822 [17], at Definition 3.8 (certified reference material, CRM). ISO 17822 states that if the value includes a nominal property or qualitative attribute, such as an identity or sequence, uncertainties can be expressed as probabilities or confidence levels.

Parties involved in medical measurement, quality assurance, and diagnostic systems face practical problems. Manufacturers of diagnostic devices and consumables, such as reference materials, are responsible for assigning certain performance characteristics to their products, including uncertainty. NIST, a producer of reference materials, has adopted its own solution [9]. NIST has chosen to answer two questions on measurement and statistics: measurements are not only those processes from which numbers are obtained; uncertainty should not be expressed only by dispersion parameters (variance and standard deviation). NIST found a solution for qualitative properties, as in the case of reference material 8256, where a Next Generation DNA Sequencer was used to sequence the genome [5], as well as in 8257, 8258, 8259 for seafood [18].

4. The Laboratories' Point of View

We must acknowledge that the 2008 definition of uncertainty (JCGM 2008 2.2.3) [3], when taken in isolation and literally, has caused embarrassment and difficulty for laboratories engaged in accreditation requirements and for the bodies responsible for verification. The difficulties are manifested by the abandonment of uncertainty estimation in cases where the final test result is not a number or is otherwise obtained by a process consisting of several steps. In these situations, the laboratory often declares that the uncertainty estimate is "not applicable".

The drafters of ISO 17025 already perceived this embarrassment, adding to Clause 7.6.3 ("measurement uncertainty in testing") the comment "*When the test method precludes a rigorous assessment of measurement uncertainty, an estimate shall be made based on knowledge of theoretical principles or practical experience regarding the performance of the method.*"

Unlike ISO 17025, ISO 15189 does not take into account the knowledge and experience of the laboratory, but categorically requires the use of positive and negative samples (Point 7.3.4 letter f) for the uncertainty of qualitative results based on thresholds. Furthermore (letter g), uncertainty in the intermediate measurement stages or in quality control results that produce quantitative data must be considered. Finally, ISO 15189 refers to ISO/TS 20914 [13], which provides details and examples on uncertainty. ISO 15189 does not comment on qualitative results obtained directly, without transparent quantitative measurements in the laboratory.

ISO 15189 and ISO 20914 therefore follow the GUM's recommendation, requiring medical laboratories to estimate the uncertainties of input measurements when the final result is nominal. The example of the anion gap (ΔcAG) is described in ISO 20914 in the same way as Possolo from NIST [6]: ΔcAG is the linear combination of the concentrations of two cations and two anions (Na^+, K^+, Cl^-, HCO^{3-}), so the uncertainty associated with the ΔcAG value is composed of the uncertainties of the concentrations of the individual ions.

ISO 15189 and ISO 20914 have not yet addressed cases in which the nominal result is obtained directly, without prior measurements or quality metrics. Although the issue has been proposed for the revision of ISO 20914, it has been decided to allow knowledge and awareness to mature. The guidelines in documents such as ISO 16393 [19] will sooner or later be developed and incorporated into the standards, thus adding calculations to the measurements.

Laboratories are advised to take into account, in relation to uncertainties, the link with internal quality control [20], based on ISO 20397-2 [21], ISO 16393 [19], and ISO 27877 [22]. In particular, ISO 20397-2 and ISO/TS 22692 [23] apply to multiphase processes (such as NGS), providing quality metrics that form the basis for uncertainty construction. ISO 16393 is for the qualitative results of molecular methods. ISO/TR 27877 [17] collects solutions for binary results.

5. The Discussion Among Metrologists

Six members of JCGM WG2, led by Mari (Mari-WG2), developed a discussion on the concept of measurement uncertainty (Table 3) [24], based on the principles of ISO 1087 [25].

Table 3. Mari-WG2 objections to the GUM-2023 proposal for MU.

GUM-2023 Proposal [2]	Mari-WG2 Objections [25]
the doubt	psychological entity instead of a mathematical one
about the true value	we generally do not know the true value
making a measurement	only applicable to single-valued measurands and definitional uncertainty zero
change the definition in the GUM95 and VIM3	conceptual continuity should not be underestimated

The Mari-WG2 group disapproves of the use of a psychological concept instead of a mathematical one, basically arguing that these are two different and incompatible disciplines. The Mari-WG2 group disapproves of the reference to theoretical true value instead of measured value, arguing that the diatribe over the concept of "true value" is not yet over and that the only value always known is a measured value, not a "true" value.

This note does not intend to analyze and challenge in detail the metrological criticisms of Mari-WG2. However, we can express some misgivings on the points of "true value," "psychology," "definitional" uncertainty, and the "opportunity of innovation".

The GUM95-VIM3 uses tools that are very close to practical, albeit narrow; one measurement result and one parameter, while the GUM2023-JCGM tries to broaden the vision. In our view, "doubt" is not only a specialized concept in psychology, but a term of common language and everyday experience, attested in general vocabulary.

We can note that the GUM and VIM (Sections 3.1 and D.3.5 of GUM 2008) consider true value an obvious, redundant word, equivalent to "value of a measurand or quantity". The "true" value is included in the concepts of "accuracy" (B.2.14), "error" (B.2.19), and "systematic deviation" (B.2.22). Similarly, the "true" value appears in VIM3 in the definition of "true" value (2.11) in the measurement result (2.10). Thus, the measurement is still an (imperfect) attempt to estimate the "true" value.

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The Mari-WG2 group complains that the GUM-2023 definition seems designed for cases with unique value and zero definitional uncertainty. “Definitional” uncertainty (VIM3 2.27, called “intrinsic” by the GUM) would be that which cannot be reduced in any way. It corresponds in medicine to “biological variability”. We do not know whether the criticism about definitional uncertainty is well-founded. However, the GUM2023-JCGM does not explicitly state that it wants to exclude cases with definitional uncertainty greater than zero, thus with multiple “true” values.

A fourth argument is added by Mari-WG2 to the formal and purely metrological arguments. The “opportunity” described as “conceptual continuity should not be underestimated”.

The “opportunity” argument is legitimate but debatable and can be pitted against practical necessity. The “conceptual continuity” appears to be outdated, in fact by practices applied by manufacturers such as NIST and by ISO itself.

6. Conclusions and What the Laboratory Has to Do to Obtain ISO Accreditation

Possolo of the National Institute of Standards and Technology (NIST) explains that, when defining “measurement uncertainty” one ought to distinguish what this is from how it is represented [6]. He uses Napoleon as an analogy: the same man can be depicted either in the triumphant portrait of him crossing the Alps, or with the much simpler clothes and more somber attitude while in exile at St. Helena, which are captured in William Orchardson’s (1892) painting.

To drop the theoretical metrology concepts into the real world, we need to solve two difficulties, one of measurement and one of statistics. NIST and IUPAC do not believe that measurements are just the processes from which numbers are obtained. Even on statistics, NIST and IUPAC do not believe that uncertainty is always expressed by the parameters of statistics (variance and type deviation).

We must recognize that the 2008 definition of uncertainty (JCGM 2008 2.2.3) [3], amputated, taken in isolation, and verbatim has caused embarrassment and difficulty for laboratories engaged in accreditation requirements and for bodies responsible for verification. Medical, genetics, and forensic testing laboratories sometimes find themselves embarrassed when encountering Clause 7.3.4 of ISO 15189 or, in the case of ISO 17025, Clause 7.6.3 of measurement uncertainty estimation. Thanks to the new definition, supported by JCGM, implemented by ISO and NIST, something will improve, especially for multi-step examination processes and measurements with categorical (qualitative) results.

Measurement uncertainty is treated very differently by ISO 17025 and ISO 15189. No one-size-fits-all rules can be given. ISO 17025 goes so far as to glue uncertainty to the single final result to be delivered to the user (Clause 7.8.3.1). ISO 15189, on the other hand, clearly excludes uncertainty from the results report and brings it in with the validation and verification features of the examination method, recommending reporting the estimate only to those who explicitly request it, but along with reservations and additions.

The metrology specialists’ comments are formally unobjectionable, but manufacturers’ and laboratories’ initiatives from NIST and ISO confirm that the uncertainty of the GUM95-VIM3 leaves some open problems unresolved.

Innovations in metrological definitions may elicit puzzlement and even resistance from those who are fond of tradition and fear responsibility for making mistakes. Instead, it is not a matter of punishing errors, but of expanding basic concepts to different scenarios of reality. The laboratory requirements referred to in this note pose a non-negligible risk to laboratories.

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The uncertainty requirements of ISO 17025 and ISO 15189 seem to present some difficulties, particularly for emerging technologies such as molecular technologies. Some are tempted to say that the uncertainty requirement in some cases is "not applicable". We do not find this in the literature, but in field experience. However, we cannot assume that laboratories, with the diffusion of new technologies, are gradually trying to move away from metrology, because they do not perform measurements or examinations. Alternatively, we can assume that there is something in the current metrology definitions that encourages misunderstandings. The new JCGM metrology definition, supported by NIST, seeks some way to remedy this.

Points of scientific interest such as the relationship between "measurement uncertainty" and "measurement error" are not developed in this note. Neither is the usefulness of communicating the uncertainty estimate to users for "educational" purposes, although excluded by ISO 15189.

ISO 17025 and ISO 15189 accreditation requirements are complemented by effective and now indispensable regulatory tools. ISO sets standards for multiphase processes (such as NGS) and for the qualitative results of molecular methods. ISO/TR 27877 collects solutions for binary results; NIST and ISO 33406 work in the real world of reference materials and are not held back by formalisms, so must provide concrete solutions for "uncertainty" (or "confidence").

We therefore have now both theoretical foundations and guides to practice the uncertainty of measurement. Metrology vocabulary updates definitions, and ISO provides increasingly detailed instructions. The tools provided by standardization and metrology today give us sound general approaches for estimating measurement uncertainty in medical, testing, and forensic laboratories. Therefore, it is no longer permissible to respond to ISO requirements with a laconic "not applicable."

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Abbreviations

The following abbreviations are used in this manuscript:

ISO	International Organization for Standardization
JCGM	Joint Committee for Guides in Metrology
NIST	National Institute of Standards and Technology
BIPM	Bureau International des Poids et Mesures
GUM2023	JCGM GUM-1:2023. Guide to the Expression of Uncertainty in Measurement—Part 1: Introduction.
VIM3	International Vocabulary of Metrology
GUM	Guide to the Expression of Uncertainty in Measurement
CRM	Certified Reference Material
IUPAC	International Union of Pure and Applied Chemistry
ATE	Maximum Allowable Error
CLSI	Clinical and Laboratory Standards Institute
NGS	Next Generation Sequencing

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