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Uncertainty of measurement —

Part 4:
Role of measurement uncertainty in conformity assessment

Incertitude de mesure —

Partie 4: Rôle de l'incertitude de mesure dans l'évaluation de la conformité

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Foreword

In 1997 a Joint Committee for Guides in Metrology (JCGM), chaired by the Director of the Bureau International des Poids et Mesures (BIPM), was created by the seven international organizations that had originally in 1993 prepared the *Guide to the expression of uncertainty in measurement* (GUM) and the *International vocabulary of basic and general terms in metrology* (VIM). The JCGM assumed responsibility for these two documents from the ISO Technical Advisory Group 4 (TAG4).

The Joint Committee is formed by the BIPM with the International Electrotechnical Commission (IEC), the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), the International Organization for Standardization (ISO), the International Union of Pure and Applied Chemistry (IUPAC), the International Union of Pure and Applied Physics (IUPAP), and the International Organization of Legal Metrology (OIML). A further organization joined these seven international organizations, namely, the International Laboratory Accreditation Cooperation (ILAC).

JCGM has two Working Groups. Working Group 1, "Expression of uncertainty in measurement", has the task to promote the use of the GUM and to prepare Supplements and other documents for its broad application. Working Group 2, "Working Group on International vocabulary of basic and general terms in metrology (VIM)", has the task to revise and promote the use of the VIM. For further information on the activity of the JCGM, see www.bipm.org

Documents such as this one are intended to give added value to the GUM by providing guidance on aspects of the evaluation and use of measurement uncertainty that are not explicitly treated in the GUM. Such guidance will be as consistent as possible with the general probabilistic basis of the GUM.

This document has been prepared by Working Group 1 of the JCGM, and has benefited from detailed reviews undertaken by member organizations of the JCGM and National Metrology Institutes.

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Introduction

Conformity assessment, as broadly defined, is any activity undertaken to determine, directly or indirectly, whether a product, process, system, person or body meets relevant standards and fulfills relevant requirements. ISO/IEC 17000:2004 [27] gives general terms and definitions relating to conformity assessment, including the accreditation of conformity assessment bodies and the use of conformity assessment in facilitating trade.

In a particular conformity assessment activity, sometimes called *inspection* [3.3.2], the determination that a product fulfills relevant requirements relies on measurement as a principal source of information. ISO 10576-1:2003 [25] sets out guidelines for checking conformity with specified limits in the particular case where a quantity is measured and a resulting *coverage interval* [3.2.7] (termed 'uncertainty interval' in ISO 10576-1:2003) is compared with a *tolerance interval* [3.3.6]. The present document extends this approach to include explicit consideration of risks, and develops general procedures for deciding conformity based on measurement results, recognizing the central role of probability distributions as expressions of uncertainty and incomplete information.

The evaluation of measurement uncertainty is a technical problem whose solution is addressed by the *Guide to the Expression of Uncertainty in Measurement* (GUM) and its supplements, JCGM 101, JCGM 102 [3] and JCGM 103 [4]. The present document assumes that a quantity of interest, the *measurand* [3.2.4], has been measured, with the result of the measurement expressed in a manner compatible with the principles described in the GUM.

In *conformity assessment* [3.3.1], a measurement is performed in order to decide if an item of interest conforms to a *specified requirement* [3.3.3]. The item might be, for example, a gauge block, a digital voltmeter or a sample of industrial waste water. The requirement typically takes the form of one or two *tolerance limits*]3.3.5[that define an interval of permissible values of a *characteristic* [3.3.4] of the item. Examples of such characteristics include the length of a gauge block, the error of indication of a voltmeter, and the mass concentration of mercury in a sample of waste water. If the *true value* [3.2.3] of the characteristic lies within an interval of permissible values, called a tolerance interval, the item is said to be conforming, and non-conforming otherwise.

NOTE The term 'tolerance interval' as used in conformity assessment has a different meaning from the same term as it is used in statistics.

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In general, deciding whether an item conforms will depend on a number of characteristics and there might be one or more tolerance intervals associated with each characteristic. There may also be a number of possible decisions with respect to each characteristic, given the result of a measurement. Having measured a particular characteristic, for example, one might decide to (a) accept the item, (b) reject the item, (c) perform another measurement and so on. This document deals with items having a single scalar characteristic with a requirement given by one or two tolerance limits, and a binary outcome in which there are only two possible states of the item, conforming or non-conforming, and two possible corresponding decisions, accept or reject. The concepts presented can be extended to more general decision problems.

In the evaluation of measurement data, knowledge of the true value of a characteristic of interest is, in general, encoded and conveyed by a *probability density function* [3.1.2], or a numerical approximation of such a function. Such knowledge is often summarized by giving a best estimate (taken as the *measured quantity value* [3.2.6]) together with an associated measurement uncertainty, or a coverage interval that contains the true value with a stated *coverage probability* [3.2.8]. An assessment of conformity with specified requirements is thus a matter of probability, based on information available after performing the measurement.

In a typical measurement, the characteristic of interest is not itself observable. The true length of a steel block, for example, cannot be directly observed, but one could observe the indication of a micrometer with its anvils in contact with the ends of the block. Such an indication conveys information about the true length of the block through a measurement model that includes the effects of influence quantities such as thermal expansion and micrometer calibration. In conformity assessment, an accept/reject decision is based on observable data (measured quantity values, for example) that lead to an inference regarding plausible true values of a non-observable measurand [43].

Because no measurement provides complete information, there is always the risk of a mistake in deciding whether or not an item conforms to a specified requirement based on the measured value of a characteristic. Such mistakes are of two types: an item accepted as conforming may actually be non-conforming, and an item rejected as non-conforming

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may actually be conforming.

By defining an *acceptance interval* [3.3.10] of permissible measured values of a characteristic, the risks of mistaken accept/reject decisions associated with measurement uncertainty can be balanced in such a way as to minimize the costs associated with such mistakes. This document addresses the technical problem of calculating the *conformance probability* [3.3.8] and the probabilities of the two types of mistake, given a probability density function (PDF) for the characteristic, the tolerance limits and the limits of the acceptance interval.

A particular acceptance interval, and its relation to a corresponding tolerance interval is shown in figure 1.

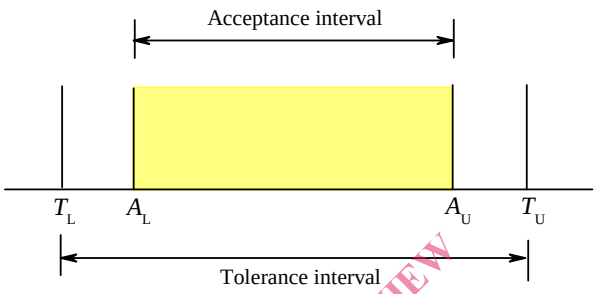

Figure 1 – Illustration of the limiting values associated with a typical conformity assessment decision. The true value of a measurable characteristic of an item is required to lie in a tolerance interval defined by tolerance limits (T_L, T_U). The item is accepted as conforming with specification if the measured value of its characteristic lies in an acceptance interval defined by acceptance limits (A_L, A_U), and rejected otherwise.

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Choosing the tolerance limits and acceptance limits are business or policy decisions that depend upon the consequences associated with deviations from intended product quality. A general treatment of the nature of such decisions is beyond the scope of this document; see, for example, references [18, 19, 40, 41, 42, 50].

NOTE Citations of the form [JCGM 101 3.4] are to the indicated (sub)clauses of the cited reference.

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Uncertainty of measurement —

Part 4:
Role of measurement uncertainty in conformity assessment

1 Scope

This document provides guidance and procedures for assessing the conformity of an item (entity, object or system) with specified requirements. The item might be, for example, a gauge block, a grocery scale or a blood sample. The procedures can be applied where the following conditions exist:

— the item is distinguished by a single scalar *quantity* [3.2.1], or characteristic, defined to a level of detail sufficient to be reasonably represented by an essentially unique true value;

— an interval of permissible true values of the characteristic is specified by one or two tolerance limits;

— the characteristic can be measured and the *measurement result* [3.2.5] expressed in a manner consistent with the principles of the GUM, so that

— knowledge of the true value of the characteristic can be reasonably described by (a) a probability density function (PDF), (b) a *distribution function* [3.1.1], (c) numerical approximations to such functions, or (d) a best estimate, together with a coverage interval and an associated coverage probability.

The procedures developed in this document can be used to realize an interval, called an acceptance interval, of permissible measured values of the characteristic. Acceptance limits can be chosen so as to balance the risks associated with accepting non-conforming items (consumer's risk) or rejecting conforming items (producer's risk).

Two types of conformity assessment problems are addressed. The first is the setting of acceptance limits that will assure that a desired conformance probability for a single measured item is achieved. The second is the setting of acceptance limits to assure an acceptable level of confidence on average as a number of (nominally identical) items are measured. Guidance is given for their solution.

This document contains examples to illustrate the guidance provided. The concepts presented can be extended to more general conformity assessment problems based on measurements of a set of scalar characteristics.

The audience of this document includes quality managers, members of standards development organizations, accreditation authorities and the staffs of testing laboratories, inspection bodies, certification bodies and regulatory agencies.

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2 Normative references

The following referenced documents are indispensable for the application of this document.

JCGM 100:2008. Guide to the expression of uncertainty in measurement (GUM).

JCGM 101:2008. Evaluation of measurement data — Supplement 1 to the "Guide to the expression of uncertainty in measurement" — Propagation of distributions using a Monte Carlo method.

JCGM 200:2008. International vocabulary of metrology — Basic and general concepts and associated terms.

ISO/IEC 17000:2004. Conformity assessment — Vocabulary and general principles.

ISO 3534-1:2006. Statistics – Vocabulary and symbols – Part 1: Probability and general statistical terms.

ISO 3534-2:2006. Statistics – Vocabulary and symbols – Part 2: Applied statistics.

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3 Terms and definitions

For the purposes of this document the definitions of JCGM 100:2008, JCGM 101:2008 and JCGM 200:2008 apply, unless otherwise indicated. Some of the most relevant definitions from these documents are given succinctly below. Supplementary information, including notes and examples, can be found in the normative references.

Further definitions are also given, including definitions taken, or adapted, from other sources, which are especially important in conformity assessment.

For definitions that cite other documents, a NOTE that occurs prior to such citation is a part of the cited entry; other NOTES are particular to the present document.

In this document, the terms "indication" and "maximum permissible error (of indication)" are taken to be quantities rather than values, as in JCGM 200:2008.

3.1 Terms related to probability

3.1.1
distribution function

function giving, for every value ξ, the probability that the random variable X be less than or equal to ξ:

$$G_X(\xi) = \Pr(X \leq \xi)$$

3.1.2
probability density function
PDF

derivative, when it exists, of the distribution function

$$g_X(\xi) = \mathrm{d}G(\xi)/\mathrm{d}\xi$$

NOTE $g_X(\xi)\,\mathrm{d}\xi$ is the "probability element"

$$g_X(\xi)\,\mathrm{d}\xi = \Pr(\xi < X < \xi + \mathrm{d}\xi)$$

3.1.3
normal distribution

probability distribution of a continuous random variable X having the probability density function

$$g_X(\xi) = \frac{1}{\sigma\sqrt{2\pi}} \exp\left[-\frac{1}{2}\left(\frac{\xi-\mu}{\sigma}\right)^2\right],$$

for $-\infty < \xi < +\infty$

NOTE 1 μ is the expectation and σ is the standard deviation of X.

NOTE 2 The normal distribution is also known as a Gaussian distribution.

3.1.4
expectation

for a continuous random variable X characterized by a PDF $g_X(\xi)$,

$$E(X) = \int_{-\infty}^{\infty} \xi g_X(\xi)\,\mathrm{d}\xi$$

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NOTE 1 Not all random variables have an expectation.

NOTE 2 The expectation of the random variable $Z = F(X)$, for a given function $F(X)$, is

$$E(Z) = E(F(X)) = \int_{-\infty}^{\infty} F(\xi) g_X(\xi)\, \mathrm{d}\xi$$

3.1.5
variance

for a continuous random variable X characterized by a PDF $g_X(\xi)$,

$$V(X) = \int_{-\infty}^{\infty} [\xi - E(X)]^2 g_X(\xi)\, \mathrm{d}\xi$$

NOTE Not all random variables have a variance.

3.1.6
standard deviation

positive square root of the variance

3.2 Terms related to metrology

3.2.1
quantity

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

3.2.2
quantity value
value of a quantity
value

number and reference together expressing magnitude of a quantity

3.2.3
true quantity value
true value of a quantity
true value

quantity value consistent with the definition of a quantity

3.2.4
measurand

quantity intended to be measured

NOTE In this document, the measurand is a measurable characteristic of an item of interest.

3.2.5
measurement result
result of measurement

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

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