GUIDE 98-4

Uncertainty of measurement —

Part 4:

Role of measurement uncertainty in conformity assessment

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ISO/IEC Guide 98-4 was prepared by Working Group 1 of the Joint Committee for Guides in Metrology (as JCGM 106:2012), and was adopted by the national bodies of ISO and IEC.

ISO/IEC Guide 98 consists of the following parts, under the general title *Uncertainty of measurement*:

— *Part 1: Introduction to the expression of uncertainty in measurement*

— *Part 3: Guide to the expression of uncertainty in measurement* (GUM:1995)

— *Part 4: Role of measurement uncertainty in conformity assessment*

The following parts are planned:

— *Part 2: Concepts and basic principles*

— *Part 5: Applications of the least-squares method*

ISO/IEC Guide 98-3 has two supplements:.

— *Supplement 1: Propagation of distributions using a Monte Carlo method*

— *Supplement 2: Extension to any number of output quantities*

The following supplement to ISO/IEC Guide 98-3 is planned:

— *Supplement 3: Modelling*

Given that ISO/IEC Guide 98-3:2008/Suppl.1:2011 is identical in content to JCGM 101:2011, the decimal symbol is a point on the line in the English version and a comma on the line in the French version.

Annex ZZ has been appended to provide a list of corresponding ISO/IEC Guides and JCGM guidance documents for which equivalents are not given in the text.

Joint Committee for Guides in Metrology

JCGM
106
2012

Evaluation of measurement data — The role of measurement uncertainty in conformity assessment

Évaluation des données de mesure — Le rôle de l'incertitude de mesure dans l'évaluation de la conformité

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Contents

Annexes

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.

Introduction

Conformity assessment (see 3.3.1), 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 *specified requirements* (see 3.3.3). ISO/IEC 17000:2004 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 kind of conformity assessment, sometimes called *inspection* (see 3.3.2), the determination that a product fulfils a specified requirement relies on measurement as a principal source of information. ISO 10576-1:2003 [22] sets out guidelines for checking conformity with specified limits in the case where a *quantity* (see 3.2.1) is measured and a resulting *coverage interval* (see 3.2.7) (termed 'uncertainty interval' in ISO 10576-1:2003) is compared with a *tolerance interval* (see 3.3.5). The present document extends this approach to include explicit consideration of risks, and develops general procedures for deciding conformity based on *measurement results* (see 3.2.5), recognizing the central role of *probability distributions* (see 3.1.1) as expressions of uncertainty and incomplete information.

The evaluation of measurement uncertainty is a technical problem whose solution is addressed by JCGM 100:2008, the *Guide to the expression of uncertainty in measurement* (GUM), and by and its Supplements, JCGM 101:2008, JCGM 102:2011 and JCGM 103 [3]. The present document assumes that a quantity of interest, the *measurand* (see 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 particular, it is assumed that corrections have been applied to account for all recognized significant systematic effects.

In conformity assessment, a measurement result is used to decide if an item of interest conforms to a specified requirement. The item might be, for example, a gauge block or digital voltmeter to be calibrated in compliance with ISO/IEC 17025:2005 [23] or verified according to ISO 3650 [24], or a sample of industrial waste water. The requirement typically takes the form of one or two *tolerance limits* (see 3.3.4) that define an interval of permissible values, called a *tolerance interval* (see 3.3.5), of a measurable property of the item. Examples of such properties 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 of the property lies within the tolerance interval, it 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.

In general, deciding whether an item conforms will depend on a number of measured properties and there might be one or more tolerance intervals associated with each property. There may also be a number of possible decisions with respect to each property, given the result of a measurement. Having measured a particular quantity, 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 property 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 possible values of a measurand is, in general, encoded and conveyed by a *probability density function* (see 3.1.3), or a numerical approximation of such a function. Such knowledge is often summarized by giving a best estimate (taken as the *measured quantity value* (see 3.2.6)) together with an associated measurement uncertainty, or a coverage interval that contains the value of the measurand with a stated *coverage probability* (see 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 measurand of interest is not itself observable. The length of a steel gauge 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 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 the possible values of a non-observable measurand [37].

Because of uncertainty in measurement, there is always the risk of incorrectly deciding whether or not an item conforms to a specified requirement based on the measured value of a property of the item. Such incorrect decisions are of two types: an item accepted as conforming may actually be non-conforming, and an item rejected as non-conforming may actually be conforming.

By defining an *acceptance interval* (see 3.3.9) of permissible measured values of a measurand, the risks of incorrect accept/reject decisions associated with measurement uncertainty can be balanced in such a way as to minimize the costs associated with such incorrect decisions. This document addresses the technical problem of calculating the *conformance probability* (see 3.3.7) and the probabilities of the two types of incorrect decisions, given a probability density function (PDF) for the measurand, 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.

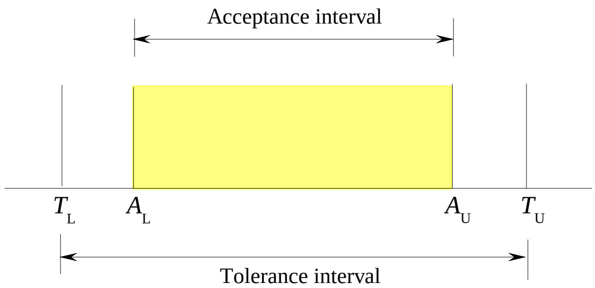

Figure 1 – Binary conformity assessment where decisions are based on measured quantity values. The true value of a measurable property (the measurand) of an item is specified to lie in a tolerance interval defined by limits (T_L, T_U). The item is accepted as conforming if the measured value of the property lies in an interval defined by *acceptance limits* (see 3.3.8) (A_L, A_U), and rejected as non-conforming otherwise.

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 [14, 15, 34, 35, 36, 44].

Evaluation of measurement data — The 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* (see 3.2.1) (a measurable property) defined to a level of detail sufficient to be reasonably represented by an essentially unique true value;

NOTE The GUM provides a rationale for not using the term 'true', but it will be used in this document when there is otherwise a possibility of ambiguity or confusion.

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

— the property can be measured and the *measurement result* (see 3.2.5) expressed in a manner consistent with the principles of the GUM, so that knowledge of the value of the property can be reasonably described by (a) a *probability density function* (see 3.1.3) (PDF), (b) a *distribution function* (see 3.1.2), (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 property of interest. 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 measurands. Documents such as references [19, 13] cover sector-specific aspects of conformity assessment.

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

2 Normative references

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

JCGM 100:2008. Evaluation of measurement data — 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 102:2011. Evaluation of measurement data — Supplement 2 to the "Guide to the expression of uncertainty in measurement" — Extension to any number of output quantities.

JCGM 200:2012. International vocabulary of metrology — Basic and general concepts and associated terms (VIM3).

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.

3 Terms and definitions

For the purposes of this document the definitions of JCGM 100:2010, JCGM 101:2008 and JCGM 200:2012 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, in contrast with JCGM 200:2012.

NOTE Citations of the form [JCGM 101:2008 3.4] are to the indicated (sub)clauses of the cited reference.

3.1 Terms related to probability

3.1.1
probability distribution
distribution
probability measure induced by a random variable

NOTE There are numerous, equivalent mathematical representations of a distribution, including distribution function (see clause 3.1.2), probability density function, if it exists (see clause 3.1.3), and characteristic function.

[Adapted from ISO 3534-1:2006 2.11]

3.1.2
distribution function
function giving, for every value ξ, the probability that the random variable X be less than or equal to ξ:

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

[JCGM 101:2008 3.2]

3.1.3
probability density function
PDF
derivative, when it exists, of the distribution function

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

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

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

[Adapted from JCGM 101:2008 3.3]

3.1.4
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* (see 3.1.5) and σ is the *standard deviation* (see 3.1.7) of X.

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

[JCGM 101:2008 3.4]

3.1.5
expectation
for a continuous random variable X characterized by a PDF $g_X(\xi)$,

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

NOTE 1 The expectation is also known as the mean.

NOTE 2 Not all random variables have an expectation.

NOTE 3 The expectation of the random variable $Z = F(X)$, for a given function $F(X)$, is

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

[JCGM 101:2008 3.6]

3.1.6
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.

[JCGM 101:2008 3.7]

3.1.7
standard deviation
positive square root of the variance

[JCGM 101:2008 3.8]

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

[JCGM 200:2012 1.1]