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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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.

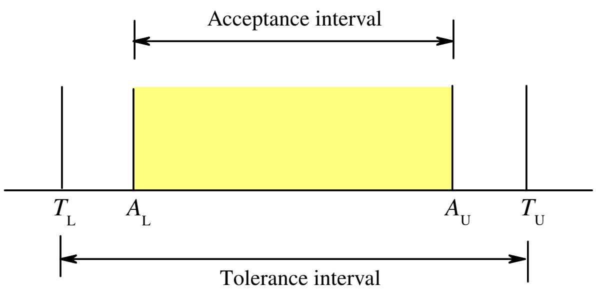

Figure 1 – Binary conformity assessment where decisions are based on measured quantity values. The true value of a measurable property (the measurand) of an item is specified to lie in a tolerance interval defined by limits (T_L, T_U). The item is accepted as conforming if the measured value of the property 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]

3.2.2
quantity value
value of a quantity
value
number and reference together expressing magnitude of a quantity

[JCGM 200:2012 1.19]

3.2.3
true quantity value
true value of a quantity
true value
quantity value consistent with the definition of a quantity

[JCGM 200:2012 2.11]

3.2.4
measurand
quantity intended to be measured

[JCGM 200:2012 2.3]

NOTE In this document, the measurand is a measurable property 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

NOTE A measurement result may be expressed in a number of ways, by giving, for example, (a) a measured quantity value with an associated measurement uncertainty; (b) a coverage interval for the measurand with an associated coverage probability; (c) a PDF; or (d) a numerical approximation to a PDF.

[JCGM 200:2012 2.9]

3.2.6
measured quantity value
value of a measured quantity
measured value
quantity value representing a measurement result

NOTE A measured quantity value is also known as an estimate, or best estimate, of a quantity.

[JCGM 200:2012 2.10]

3.2.7
coverage interval
interval containing the set of true quantity values of a measurand with a stated probability, based on the information available

[JCGM 200:2012 2.36]

3.2.8
coverage probability
probability that the set of true quantity values of a measurand is contained within a specified coverage interval

[JCGM 200:2012 2.37]

3.2.9
indication
quantity provided by a measuring instrument or measuring system

NOTE 1 An indication is often given as the position of a pointer for an analogue output or the displayed or printed number for a digital output.

NOTE 2 An indication is also known as a reading.

[Adapted from JCGM 200:2012 4.1]

3.3 Terms related to conformity assessment

3.3.1
conformity assessment
activity to determine whether specified requirements relating to a product, process, system, person or body are fulfilled

[Adapted from ISO/IEC 17000:2004 2.1]

3.3.2
inspection
conformity assessment by observation and judgement accompanied, as appropriate, by measurement, testing or gauging

[Adapted from ISO 3534-2:2006 4.1.2]

NOTE A measurement performed as part of conformity assessment is sometimes called an inspection measurement.

3.3.3
specified requirement
need or expectation that is stated

NOTE Specified requirements may be stated in normative documents such as regulations, standards and technical specifications.

[ISO/IEC 17000:2004 3.1]

NOTE 1 The term 'expectation' in the context of a specified requirement is not related to the expectation of a random variable; see definition 3.1.5.

NOTE 2 In this document, a typical specified requirement takes the form of a stated interval of permissible values of a measurable property of an item.

EXAMPLE 1 A sample of industrial waste water (the item) is required to have a mass concentration of dissolved mercury (the property) of no greater than 10 ng/L.

EXAMPLE 2 A grocery scale (the item) is required to have an indication R (the property) in the interval [999.5 g $\leq R \leq$ 1 000.5 g] when measuring a standard 1 kg weight.

3.3.4
tolerance limit
specification limit
specified upper or lower bound of permissible values of a property

[Adapted from ISO 3534-2:2006 3.1.3]

3.3.5
tolerance interval
interval of permissible values of a property

[Adapted from ISO 10576-1:2003 3.5]

NOTE 1 Unless otherwise stated in a specification, the tolerance limits belong to the tolerance interval.

NOTE 2 The term 'tolerance interval' as used in conformity assessment has a different meaning from the same term as it is used in statistics.

NOTE 3 A tolerance interval is called a 'specification zone' in ASME B89.7.3.1:2001 [2].

3.3.6
tolerance
specified tolerance
difference between upper and lower tolerance limits

3.3.7
conformance probability
probability that an item fulfills a specified requirement

3.3.8
acceptance limit
specified upper or lower bound of permissible measured quantity values

[Adapted from ISO 3534-2:2006 3.1.6]

3.3.9
acceptance interval
interval of permissible measured quantity values

NOTE 1 Unless otherwise stated in the specification, the acceptance limits belong to the acceptance interval.

NOTE 2 An acceptance interval is called an 'acceptance zone' in ASME B89.7.3.1 [2].

3.3.10
rejection interval
interval of non-permissible measured quantity values

NOTE 1 A rejection interval is called an 'rejection zone' in ASME B89.7.3.1 [2].

3.3.11
guard band
interval between a tolerance limit and a corresponding acceptance limit

NOTE The guard band includes the limits.

3.3.12
decision rule
documented rule that describes how measurement uncertainty will be accounted for with regard to accepting or rejecting an item, given a specified requirement and the result of a measurement

[Adapted from ASME B89.7.3.1-2001 [2]]

3.3.13
specific consumer's risk
probability that a particular accepted item is non-conforming

3.3.14
specific producer's risk
probability that a particular rejected item is conforming

3.3.15
global consumer's risk
consumer's risk
probability that a non-conforming item will be accepted based on a future measurement result

3.3.16
global producer's risk
producer's risk
probability that a conforming item will be rejected based on a future measurement result

3.3.17
measurement capability index
tolerance divided by a multiple of the standard measurement uncertainty associated with the measured value of a property of an item

NOTE In this document the multiple is taken to be 4; see clause 7.6.3

3.3.18
maximum permissible error (of indication)
MPE
for a measuring instrument, maximum difference, permitted by specifications or regulations, between the instrument indication and the quantity being measured

NOTE 1 When more than one maximum difference is specified, the term "maximum permissible errors" is used; for example, a specified maximum negative difference and a specified maximum positive difference.

NOTE 2 The error of indication can be written as $E = R - R_0$, where R is the indication and R_0 denotes the indication of an ideal measuring instrument measuring the same measurand Y. In the testing and verification of a measuring instrument, the error of indication is typically evaluated by measuring a calibrated reference standard.

4 Conventions and notation

For the purposes of this document the following conventions, notation and terminology are adopted.

4.1 In the GUM, the standard uncertainty associated with an estimate y of a measurand Y is written as $u_c(y)$. The subscript "c", denoting "combined" standard uncertainty, is viewed as redundant and is not used in this document. (See JCGM 101:2008 4.10).

4.2 An expression written $A =: B$ means that B is defined by A.

4.3 When there is no potential for confusion, the symbol u, rather than $u(y)$, will be used for notational simplicity. The expanded uncertainty U is generally taken to be $U = ku$ using a coverage factor of $k = 2$; the value of k is given explicitly when there is potential for ambiguity.

4.4 A property of interest (the measurand) is regarded as a random variable Y with possible values η. When Y is measured, evaluation of the measurement data yields a measured quantity value η_m, taken to be a realization of an observable random variable Y_m. In general, the measured value η_m will differ from Y by an unknown error E, say, which depends on random and systematic effects.

4.5 A tolerance interval specifies permissible values of the measurand Y. A conformity assessment decision is based on the measured value η_m and the relation of η_m to a defined acceptance interval.

4.6 Knowledge of the quantities Y and Y_m is encoded and conveyed by conditional PDFs whose forms depend on available information. Conditional PDFs are written with a vertical bar, with information to the right of the bar regarded as given. The PDF for a measurand Y before measurement is $g_{Y|I}(\eta|I)$, where the symbol I denotes prior information.

4.7 Following a measurement of a property of interest, yielding an observed measured value η_{m}, the post-measurement PDF for Y is $g_{Y|\eta_{\mathrm{m}},I}(\eta|\eta_{\mathrm{m}},I)$.

4.8 The analogous PDFs for the possible values η_{m} of the measuring system output quantity Y_{m} are (a), $g_{Y_{\mathrm{m}}|I}(\eta_{\mathrm{m}}|I)$, encoding belief in possible measured values given only the prior information I, and (b), $g_{Y_{\mathrm{m}}|\eta,I}(\eta_{\mathrm{m}}|\eta,I)$, the analogous PDF when, in addition to the prior information I, the measurand is assumed to have a given true value $Y=\eta$.

4.9 In the interests of brevity, in this document explicit display of the fixed prior information I is largely omitted. Also, PDFs for Y and Y_{m} are expressed in terms of symbols g and h respectively, using the following notation in which subscripts are largely suppressed:

— For pre-measurement knowledge of the measurand Y,

$$g_{Y|I}(\eta|I) =: g_0(\eta)\,;$$

— For post-measurement knowledge of the measurand Y,

$$g_{Y|\eta_{\mathrm{m}},I}(\eta|\eta_{\mathrm{m}},I) =: g\,(\eta|\eta_{\mathrm{m}})\,;$$

— Knowledge of possible measured values given only the prior information I,

$$g_{Y_{\mathrm{m}}|I}(\eta_{\mathrm{m}}|I) =: h_0(\eta_{\mathrm{m}})\,;$$

— Knowledge of Y_{m} assuming, in addition to information I, a given value $Y=\eta$ of the measurand,

$$g_{Y_{\mathrm{m}}|\eta,I}(\eta_{\mathrm{m}}|\eta,I) =: h\,(\eta_{\mathrm{m}}|\eta)\,.$$

These PDFs are not independent but are related by Bayes' theorem (see clause 6.2.)

4.10 According to Resolution 10 of the 22nd CGPM (2003) " . . . the symbol for the decimal marker shall be either the point on the line or the comma on the line . . . ". The JCGM has decided to adopt, in its documents in English, the point on the line.

5 Tolerance limits and tolerance intervals

5.1 Conformity assessment measurements

5.1.1 Consider a situation where a property of an item of interest, such as the error of indication of a voltmeter, is measured in order to decide whether or not the item conforms to a specified requirement. Such a test of conformity comprises a sequence of three operations:

— measure the property of interest;

— compare the measurement result with the specified requirement;

— decide on a subsequent action.

5.1.2 In practice, once the measurement result has been obtained, the comparison/decision operations are typically implemented using a previously established and stated *decision rule* (see 3.3.12) that depends upon the measurement result, the specified requirement, and the consequences of an incorrect decision.

5.1.3 Guidance is available regarding the formulation of a decision rule. ISO 14253-1 [21] and ASME B89.7.3.1 [2] provide guidelines for documenting a chosen decision rule and for describing the role of measurement uncertainty in setting acceptance limits. These documents address decision rules involving two or more possible decisions, and include the binary decision rule, with which this document is concerned, as a special case.

5.1.4 A measurement performed as part of a conformity assessment is designed to obtain information sufficient to enable a decision to be made with an acceptable level of risk. An appropriate measurement strategy will balance the cost of reducing measurement uncertainty against the benefit of more certain knowledge of the true value of the measurand.

5.1.5 An inspection measurement together with an associated decision rule is thus closely related to matters such as costs and risks. As such, the design of a satisfactory conformity assessment is often not a purely technical exercise. If the goal is to minimize cost, then given a suitable economic model the problem can be reduced to direct calculation.

5.2 Permissible and non-permissible values: tolerance intervals

5.2.1 In this document, specified requirements for a measurand of interest consist of limiting values, called tolerance limits, that separate intervals of permissible values of the measurand from intervals of non-permissible values [22]. Intervals of permissible values, called tolerance intervals, are of two kinds:

— a one-sided tolerance interval with either an upper or a lower tolerance limit;

— a two-sided tolerance interval with both upper and lower tolerance limits.

In either case, an item conforms to the specified requirement if the true value of the measurand lies within the tolerance interval and is non-conforming otherwise. The above tolerance intervals are illustrated in figure 2.

5.2.2 Seemingly one-sided tolerance intervals often have implied additional limits, for physical or theoretical reasons, that are not explicitly stated [22]. Such tolerance intervals are effectively two-sided, having one specified limit and one implied limit; see examples 4 and 5 below.

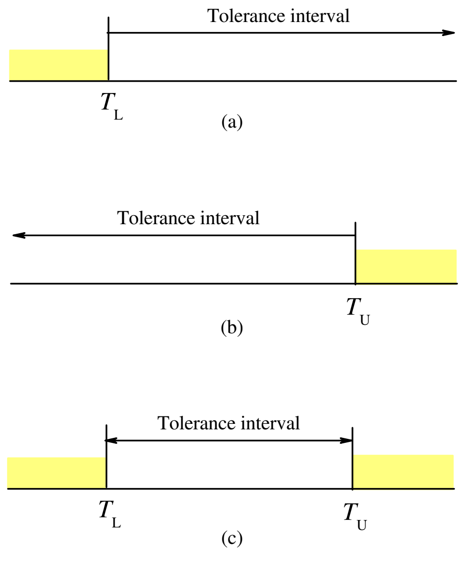

Figure 2 – Tolerance intervals. (a) A one-sided interval having a single lower tolerance limit T_L; (b) a one-sided interval having a single upper tolerance limit T_U; (c) a two-sided interval having lower and upper tolerance limits. The difference $T_U - T_L$ is called the tolerance.

NOTE 1 In some cases, such as food safety or environmental protection, specifying the tolerance limits in conformity assessment measurements may involve uncertainties related to the difficulty in assessing the consequences of incorrect decisions [29]. A related problem in reliability analysis, called completeness uncertainty, is associated with unanalysed contributions to risk [31].

NOTE 2 Matters such as completeness uncertainty bear no relation to the measurement uncertainty associated with an estimate of a measurand resulting from an inspection measurement. In this document the tolerance limits are taken to be fixed constants.

5.3 Examples of tolerance limits

EXAMPLE 1 **Single upper tolerance limit**

The breakdown voltage V_b for a certain type of Zener diode is specified to be no greater than -5.4 V. For a conforming diode, V_b lies in the open interval $V_\text{b} \leq -5.4$ V.

EXAMPLE 2 **Single lower tolerance limit**

A metal container for soft drinks is required to have a bursting strength B of not less than 490 kPa. Conforming values of B lie in the open interval $B \geq 490$ kPa.

EXAMPLE 3 **Explicit upper and lower tolerance limits**

An OIML Class E_1 1 kg weight [25] is specified to have a maximum permissible error (MPE) of 500 µg. This means that the mass m of the weight is specified to be not less than 0.999 999 5 kg and not more than 1.000 000 5 kg. A conforming 1 kg weight is one for which the mass error $E = m - m_0$, with $m_0 = 1$ kg, lies in the interval $-500\ \mu\text{g} \leq E \leq 500\ \mu\text{g}$.

EXAMPLE 4 **Explicit upper and implied lower tolerance limits**

An environmental regulation requires the mass concentration X of mercury in a stream of industrial waste water to be no greater than 10 ng/L, which is an explicit upper tolerance limit. Since the mass concentration cannot be less than zero, there is an implied lower tolerance limit of 0 ng/L. A sample of waste water complies with the regulation if the mass concentration of mercury in the sample lies in the interval $0\ \text{ng/L} \leq X \leq 10\ \text{ng/L}$.

EXAMPLE 5 **Explicit lower and implied upper tolerance limits**

Powdered sodium benzoate, used as a food preservative, is required to have a purity P, expressed as a mass fraction on a dry basis in percent, of no less than 99.0 %, which is an explicit lower tolerance limit. The purity cannot be greater than 100 %, which is an implied upper tolerance limit. A conforming sample of sodium benzoate is one for which the sample purity lies in the interval $99.0\ \% \leq P \leq 100\ \%$.

6 Knowledge of the measurand

6.1 Probability and information

6.1.1 In measurements performed as part of a conformity assessment, knowledge of a property of interest (the measurand) is modelled by a conditional probability density function (PDF) whose form depends on available information. Such information always has two components: that which is available before performing the measurement (called prior information) and the additional information supplied by the measurement [38].

6.1.2 The PDF for a property of interest (the measurand) encodes and conveys belief in its possible values, given a particular state of knowledge. A poorly known measurand generally has a broad PDF, relative to the requirements of a conformity assessment, indicating a wide interval of possible values compatible with meagre information. Performing a measurement provides fresh information that serves to sharpen the PDF and to narrow the interval of possible values of the measurand.

6.1.3 The effect of a measurement is thus to update a pre-measurement (or prior) state of knowledge, yielding a post-measurement (or posterior) state of knowledge that includes the measurement data. The rule for this transformation is called Bayes' theorem and the underlying mathematical framework is known as Bayesian probability theory. In this document the results of this framework are used without detailed development or proof. A considerable literature is available; see, for example, references [4, 5, 16, 26, 27, 39].

6.2 Bayes' theorem

6.2.1 In conformity assessment, a measurable property Y of an item of interest is regarded as a random variable with possible values denoted by η. Before measuring Y, reasonable belief in its possible values is characterized by a prior (pre-measurement) PDF $g_0(\eta)$ whose form is independent of the measuring system (see clause 4.9).

6.2.2 The prior PDF $g_0(\eta)$ is often assigned based on knowledge acquired by previous measurements of similar items. Methods for assigning a prior PDF for a property of interest are discussed in Annex B.

6.2.3 In a typical inspection measurement, the quantity Y is measured using a procedure designed to provide sufficient information to assess conformity with a specified requirement.

NOTE 1 The same symbol is used for a quantity and for the random variable that represents that quantity (see [GUM 4.1.1 note 1]).

NOTE 2 Guidance on the assignment of PDFs in some common situations is given in JCGM 101:2008 and Annex B.

6.2.4 The output of the measuring system is a quantity regarded as a random variable Y_m, with possible values denoted by η_m. Measurement of Y yields a particular realization, the *measured quantity value* η_m (see clauses 3.2.6 and 4.4), and the resulting posterior (post-measurement) PDF for Y, given this new information, is written as

$$g(\eta|Y_\mathrm{m} = \eta_\mathrm{m}) =: g(\eta|\eta_\mathrm{m}).$$

6.2.5 The prior and posterior PDFs are related by Bayes' theorem

$$g(\eta|\eta_\mathrm{m}) = C g_0(\eta)\, h(\eta_\mathrm{m}|\eta), \tag{1}$$

where, given a measured value η_m, C is a constant chosen such that $\int_{-\infty}^{\infty} g(\eta|\eta_\mathrm{m})\, \mathrm{d}\eta = 1$. The term $h(\eta_\mathrm{m}|\eta)$ in expression (1) is the PDF for the possible values of Y_m, given some particular value $Y = \eta$ of the measurand.

6.2.6 Expressed as a function of η for a measured value η_m, the PDF $h(\eta_\mathrm{m}|\eta)$ is called the likelihood of η given η_m, and is written as

$$h(\eta_\mathrm{m}|\eta) =: \mathcal{L}(\eta; \eta_\mathrm{m}).$$

A measurement can be viewed in terms of stimulus and response or in terms of input and output. In this view, the likelihood function $\mathcal{L}(\eta; \eta_\mathrm{m})$ characterizes the distribution of plausible stimuli or inputs (values of η) that might have caused the observed response or output (measured value η_m).

6.2.7 The form of the likelihood function will depend on the specific measurement problem and the measuring system, as described in a mathematical model, as well as on other relevant information such as historical data, instrument calibrations and the results of measurements of calibrated artefacts or standard reference materials, and experience with similar systems. In many cases of practical interest, the likelihood function can be characterised by a normal (Gaussian) distribution.

6.2.8 Bayes' theorem shows how the posterior (post-measurement) state of knowledge is derived from a combination of prior (pre-measurement) information, encoded in the prior distribution, and information supplied by the measurement, represented by the likelihood function.

6.2.9 In many cases, the measuring system is employed in order to supplement relatively meagre prior knowledge of the measurand with accurate measurement information. In such a case, the posterior (post-measurement) state of knowledge PDF is essentially defined by the likelihood function (encoding the measurement information), i.e.,

$$g(\eta|\eta_\mathrm{m}) = C h(\eta_\mathrm{m}|\eta)$$

to a close approximation, where C is a constant.

6.3 Summary information

6.3.1 Best estimate and standard uncertainty

A measurement result is often summarized by giving an estimate of a measurand and a parameter that characterizes the dispersion of probable values about this estimate. In this document, the estimate y of a property Y is taken to be the *expectation* (see 3.1.5) $E(Y|\eta_\mathrm{m})$. The associated dispersion parameter $u(y) = u$, called the standard uncertainty, is taken to be the *standard deviation* (see 3.1.7) of Y, the positive square root of the *variance* (see 3.1.6) $V(Y|\eta_\mathrm{m})$. $E(Y|\eta_\mathrm{m})$ and $V(Y|\eta_\mathrm{m})$ are given by

$$E(Y|\eta_\mathrm{m}) = y = \int_{-\infty}^{\infty} \eta g(\eta|\eta_\mathrm{m})\,\mathrm{d}\eta, \quad V(Y|\eta_\mathrm{m}) = u^2 = \int_{-\infty}^{\infty} (\eta - y)^2 g(\eta|\eta_\mathrm{m})\,\mathrm{d}\eta.$$

6.3.1.1 The standard uncertainty u characterizes the dispersion of Y about the estimate y. When the PDF for Y is single-peaked (unimodal) and symmetric, the estimate y is also the most probable value of Y, i.e., the mode of the distribution.

6.3.1.2 For a measurement analysed according to JCGM 100:2010 (GUM), evaluation of the measurement data yields an estimate of the measurand (measured quantity value) η_m, and an associated standard uncertainty u_m. The prior information is assumed to be so meagre that the post-measurement PDF $g(\eta|\eta_\mathrm{m})$ can be summarised by the estimate $y = \eta_\mathrm{m}$ and the associated standard uncertainty $u = u_\mathrm{m}$ (see clause 7.6.1).

6.3.2 Coverage intervals

6.3.2.1 Following a measurement, the probability that Y is no greater than a given value a is

$$\Pr(Y \le a|\eta_\mathrm{m}) = G(a) = \int_{-\infty}^{a} g(\eta|\eta_\mathrm{m})\,\mathrm{d}\eta,$$

where $G(z) = \int_{-\infty}^{z} g(\eta|\eta_\mathrm{m})\,\mathrm{d}\eta$ is the distribution function of Y, given data η_m.

6.3.2.2 It follows that the probability p that Y lies in the interval $[a, b]$, with $a < b$, is

$$p = \Pr(a \le Y \le b|\eta_\mathrm{m}) = \int_{a}^{b} g(\eta|\eta_\mathrm{m})\,\mathrm{d}\eta = G(b) - G(a). \tag{2}$$

6.3.2.3 An interval such as $[a, b]$ is called a coverage interval for Y, and p is the associated coverage probability. Guidance on constructing a coverage interval with a desired coverage probability, including the case of a discrete approximation to the distribution function obtained by a Monte Carlo method, is given in JCGM 101:2008.

6.3.2.4 When the PDF for Y is symmetric and unimodal, an important and widely-used coverage interval is centred on the best estimate y, with a length equal to a multiple of the standard uncertainty u. The GUM defines an additional measure of uncertainty called the expanded uncertainty, U, obtained by multiplying the standard uncertainty u by a coverage factor k:

$$U = ku. \tag{3}$$

6.3.2.5 The coverage factor is chosen in order to achieve a desired coverage probability associated with the coverage interval $[y - U, y + U]$. The relationship between k and the associated coverage probability depends on the PDF for Y.

NOTE 1 A coverage interval of the form $[y-U, y+U]$ is sometimes called an uncertainty interval, as in ISO 10576-1:2003 3.7 [22].

NOTE 2 If the PDF for Y is asymmetric, it may be more appropriate to determine the shortest coverage interval for a given coverage probability. See JCGM 101:2008 5.3.4 for guidance on this calculation.

7 Probability of conformity with specified requirements

7.1 General rule for calculation of conformance probability

7.1.1 An item conforms to a specified requirement if the true value of its associated property Y lies in the tolerance interval. Knowledge of Y is conveyed by a PDF $g(\eta|\eta_\mathrm{m})$ so that a statement of conformity is always an inference, with some probability of being true. Denoting the set of permissible (conforming) values of Y by $\mathcal{C}$, the conformance probability, denoted by p_c, is given by

$$p_\mathrm{c} = \Pr\left(Y \in \mathcal{C} | \eta_\mathrm{m}\right) = \int_{\mathcal{C}} g\left(\eta|\eta_\mathrm{m}\right)\,\mathrm{d}\eta. \tag{4}$$

7.1.2 Expression (4) gives the general rule for calculating the probability that an item conforms to a specified requirement based on measurement of a relevant property of the item. Given a two-sided tolerance interval for the measurand Y, for example, with lower limit T_L and upper limit T_U, $\mathcal{C} = [T_\mathrm{L}, T_\mathrm{U}]$ and the conformance probability is

$$p_\mathrm{c} = \int_{T_\mathrm{L}}^{T_\mathrm{U}} g\left(\eta|\eta_\mathrm{m}\right)\,\mathrm{d}\eta.$$

7.1.3 Since the item either does, or does not, conform to specification, the probability that it does not conform is

$$\overline{p}_\mathrm{c} = 1 - p_\mathrm{c}.$$

7.2 Conformance probabilities with normal PDFs

7.2.1 The conformance probability depends on a state of knowledge of a measurand Y as encoded and conveyed by the PDF $g\left(\eta|\eta_\mathrm{m}\right)$. In many cases it is reasonable to characterise knowledge of Y by a *normal distribution* (see 3.1.4) and this probability can be calculated. If the prior distribution is normal and the measuring system (i.e., the likelihood function) is characterised by a normal distribution then the distribution $g\left(\eta|\eta_\mathrm{m}\right)$ is also a normal distribution.

7.2.2 More generally, if the likelihood function is characterised by a normal distribution and the prior information is meagre, then the posterior (post-measurement) PDF will be approximately normal. In such a case, $g\left(\eta|\eta_\mathrm{m}\right)$ can be approximated adequately by a normal distribution with expectation (mean) and standard deviation given by the best estimate y and standard uncertainty u calculated as in clause 6.3.1.

NOTE 1 A normal distribution is completely specified by its expectation (mean) and standard deviation.

NOTE 2 Some properties of normal PDFs are reviewed in Annex A.

7.2.3 Because of their familiarity and widespread use, normal PDFs will be used to illustrate the calculation of conformance probabilities in many examples in this document. Such calculations can be extended to the case where a small number of indications gives rise to a scaled and shifted t-distribution (see JCGM 101:2008 6.4.9).

7.2.4 Suppose that the PDF $g\left(\eta|\eta_\mathrm{m}\right)$ for the measurand Y is (or is well approximated by) a normal distribution specified by a best estimate (expectation) y and standard uncertainty (standard deviation) u. Then $g\left(\eta|\eta_\mathrm{m}\right)$ is given by

$$g\left(\eta|\eta_\mathrm{m}\right) = \frac{1}{u\sqrt{2\pi}} \exp\left[-\frac{1}{2}\left(\frac{\eta - y}{u}\right)^2\right] =: \varphi\left(\eta; y, u^2\right). \tag{5}$$

7.2.5 In general, the estimate y depends on η_m, i.e., $y = y(\eta_\mathrm{m})$. When knowledge of Y is meagre before the measurement, then typically $y \approx \eta_\mathrm{m}$; see clause A.4.4 for an example where this is not the case.

7.2.6 From the steps leading to expression (2), the probability that Y lies in the interval $[a, b]$, given the PDF (5), is

$$\Pr\left(a \leq Y \leq b|\eta_\mathrm{m}\right) = \Phi\left(\frac{b - y}{u}\right) - \Phi\left(\frac{a - y}{u}\right), \tag{6}$$

where $y = y(\eta_\mathrm{m})$ and

$$\Phi(z) = \frac{1}{\sqrt{2\pi}} \int_{-\infty}^{z} \exp(-t^2/2)\,\mathrm{d}t$$

is the standard normal distribution function (see Annex A).

7.3 One-sided tolerance intervals with normal PDFs

7.3.1 Single lower tolerance limit

Figure 3 shows a one-sided tolerance interval with a single lower tolerance limit T_L. Conforming values of a property of interest Y lie in the interval $\eta \geq T_L$. Knowledge of Y following an inspection measurement is conveyed by a normal PDF, shown superimposed on the tolerance interval. The best estimate y lies in the tolerance interval; the shaded region to the left of T_L indicates the probability that the item does not conform with specification. From expression (6), with $a = T_L$, $b \to \infty$, and noting that $\Phi(\infty) = 1$, the conformance probability is

$$p_c = 1 - \Phi\left(\frac{T_L - y}{u}\right). \tag{7}$$

Since $\Phi(t) + \Phi(-t) = 1$, the probability (7) can be written

$$p_c = \Phi\left(\frac{y - T_L}{u}\right). \tag{8}$$

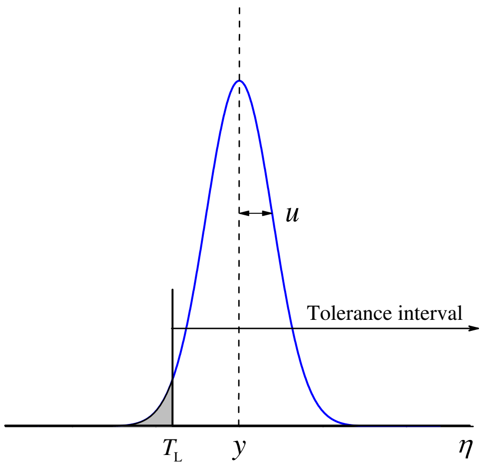

Figure 3 – Tolerance interval with a single lower tolerance limit T_L. Knowledge of a quantity Y (the measurable property of interest) following measurement is characterized by a normal PDF with best estimate y and associated standard uncertainty u. Conforming values of Y lie in the interval $\eta \geq T_L$.

7.3.2 Single upper tolerance limit

Figure 4 shows a normal PDF superimposed on a one-sided tolerance interval with a single upper tolerance limit T_U. Conforming values of a property of interest Y lie in the interval $\eta \leq T_U$. In this case, the shaded region to the right of T_U indicates the probability that the item does not conform with specification. From expression (6), with $a \to -\infty$, $b = T_U$, and noting that $\Phi(-\infty) = 0$, the conformance probability is

$$p_c = \Phi\left(\frac{T_U - y}{u}\right). \tag{9}$$

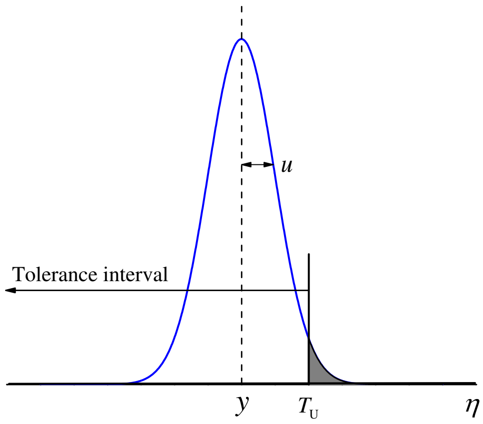

Figure 4 – As figure 3 except with a single upper tolerance limit T_U. Conforming values of Y lie in the interval $\eta \le T_U$.

7.3.3 General approach with single tolerance limits

Probabilities (8) and (9) are of the same form and can be written as

$$p_c = \Phi(z), \tag{10}$$

where $z = (y - T_L)/u$ for a lower limit and $z = (T_U - y)/u$ for an upper limit. In both cases, p_c is greater than or equal to 1/2 for an estimate y in the tolerance interval ($z \ge 0$) and less than 1/2 otherwise. Table 1 shows values of z for several values of the conformance probability p_c.

Table 1 – Conformance (p_c) and non-conformance ($\overline{p}_c = 1 - p_c$) probabilities for one-sided tolerance intervals and normal PDFs. For a lower limit, $z = (y - T_L)/u$; for an upper limit, $z = (T_U - y)/u$. In both cases, $z \ge 0$ for an estimate y in the tolerance interval

p_c	$\overline{p}_c$	z
0.80	0.20	0.84
0.90	0.10	1.28
0.95	0.05	1.64
0.99	0.01	2.33
0.999	0.001	3.09

EXAMPLE 1 The breakdown voltage V_b of a Zener diode is measured, yielding a best estimate $v_b = -5.47$ V with associated standard uncertainty $u = 0.05$ V. Specification of the diode requires $V_b \le -5.40$ V, which is an upper limit on the breakdown voltage. Then $z = [-5.40 - (-5.47)]/0.05 = 1.40$, and from expression (10), $p_c = \Phi(1.40) = 0.92$. There is a 92 % probability that the diode conforms to specification.

EXAMPLE 2 A metal container is destructively tested using pressurized water in a measurement of its bursting strength B. The measurement yields a best estimate $b = 509.7$ kPa, with associated standard uncertainty $u = 8.6$ kPa. The container specification requires $B \ge 490$ kPa, which is a lower limit on the bursting strength. Then $z = (509.7 - 490)/8.6 = 2.3$ and, from expression (10), $p_c = \Phi(2.3) = 0.99$. There is a 99 % probability that the container conformed to specification prior to the destructive test.

7.4 Two-sided tolerance intervals with normal PDFs

Figure 5 shows a two-sided tolerance interval with tolerance limits T_L and T_U and length $T = T_U - T_L$ defining the tolerance T. As previously, knowledge of a measurand Y is assumed to be conveyed by a normal PDF. The estimate y lies in the tolerance interval and there is a visible fraction of the probability in the region $\eta > T_U$ beyond the upper tolerance limit.

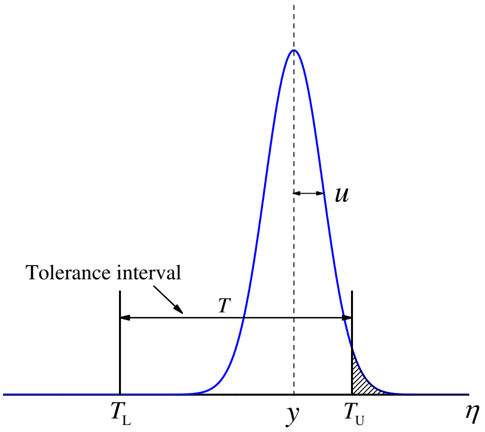

Figure 5 – As figure 3 except with a two-sided tolerance interval. The length, $T_U - T_L$, of the interval is equal to the tolerance T. Conforming values of Y lie in the interval $T_L \le \eta \le T_U$.

Using expression (6) with $b = T_U$ and $a = T_L$ yields the conformance probability

$$p_c = \Phi\left(\frac{T_U - y}{u}\right) - \Phi\left(\frac{T_L - y}{u}\right). \tag{11}$$

EXAMPLE A sample of SAE Grade 40 motor oil is required to have a kinematic viscosity Y at 100 °C of no less than 12.5 mm^2/s and no greater than 16.3 mm^2/s. The kinematic viscosity of the sample is measured at 100 °C, yielding a best estimate $y = 13.6$ mm^2/s and associated standard uncertainty $u = 1.8$ mm^2/s. Following expression (11), form the quantities

$$(T_U - y)/u = (16.3 - 13.6)/1.8 = 1.5, \quad (T_L - y)/u = (12.5 - 13.6)/1.8 = -0.6,$$

so that

$$p_c = \Phi(1.5) - \Phi(-0.6) = 0.93 - 0.27 = 0.66.$$

There is a 66 % probability that the sample of motor oil conforms to specification.

7.5 Conformance probability and coverage intervals

7.5.1 A measurement result can be summarized by giving a coverage interval with an associated coverage probability (see clause 6.3.2) rather than an explicit PDF for a measurand Y. In such a case, a statement of conformance probability can be made by comparing the coverage interval with the tolerance interval. If a coverage interval with coverage probability p lies wholly within the tolerance interval, then p_c cannot be less than p. This observation is illustrated in figure 6, which shows two 95 % coverage intervals near an upper tolerance limit.

7.5.2 Interval (a) extends beyond the tolerance limit and without knowing the form of the PDF for Y, no definite statement can be made about the conformance probability.

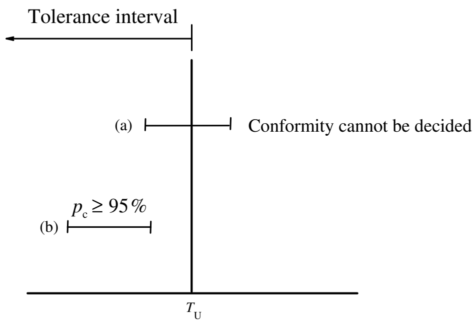

Figure 6 – Two 95 % coverage intervals for a measurand Y near an upper tolerance limit T_U. Interval (a) extends beyond the tolerance limit and the conformity cannot be decided without knowledge of the PDF for Y. Interval (b) lies wholly within the tolerance interval; for this interval $p_c \geq 95$ %.

7.5.3 All values in interval (b) are less than the tolerance limit and there are conforming values of Y that do not belong to this interval, so that $p_c \geq 95$ %.

7.5.4 In general, if $[\eta_{\text{low}}, \eta_{\text{high}}]$ is a coverage interval for Y, with coverage probability p, then

– for a single upper tolerance limit T_U, $p_c \geq p$ if $\eta_{\text{high}} \leq T_U$;

– for a single lower tolerance limit T_L, $p_c \geq p$ if $\eta_{\text{low}} \geq T_L$;

– for a two-sided interval with upper and lower tolerance limits T_U and T_L, $p_c \geq p$ if $\eta_{\text{low}} \geq T_L$ and $\eta_{\text{high}} \leq T_U$.

NOTE 1 Comparison of a coverage interval for a property of interest with an interval of permissible values is the basis for deciding conformity with specification as described in ISO 10576-1 [22].

NOTE 2 Given the PDF for Y, the conformance probability can always be calculated. The PDF for a measurand is more informative than a coverage interval with its associated coverage probability.

NOTE 3 When a conformity assessment of a measuring instrument is performed — particularly when the assessment is regulated by specific standards — the definition of the measurand, and consequently the uncertainty evaluation, may not be straightforward and may require specific attention.

7.6 Measurement capability index C_m

7.6.1 Consider the case where prior information is so meagre that knowledge regarding possible values of a measured property Y can be considered to be completely supplied by the measurement. In such a case, if the distribution for Y is assumed to be a normal PDF $g(\eta|\eta_m) = \varphi(\eta; y, u^2)$, then $y \approx \eta_m$ and $u \approx u_m$ (see clause A.4.4.3). In the following subclauses it is assumed that this is the case, and a measurement result will be summarised by the two parameters (η_m, u_m), taken to be the expectation and standard deviation of a normal PDF.

7.6.2 A parameter that characterises the quality of the measurement, relative to a requirement specified by a tolerance, is called the *measurement capability index* (see 3.3.17) defined by

$$C_m = \frac{T_U - T_L}{4u_m} = \frac{T}{4u_m} = \frac{T}{2U}, \tag{12}$$

where $U = 2u_m$ is the expanded uncertainty with coverage factor $k = 2$.

7.6.3 The factor of 4 in expression (12) is arbitrary; the particular choice is motivated by the widespread use of the coverage interval $[\eta_m - 2u_m, \eta_m + 2u_m]$ in reporting the result of a measurement. In the case where $g(\eta|\eta_m)$ is a normal PDF, the coverage probability for such an interval is approximately 95 %.

7.6.4 There is a close connection between C_m and other derived parameters that have been used to characterize measurement quality in various contexts. Among these are gauging ratio, gauge maker's rule, test uncertainty ratio (TUR) [32] and test accuracy ratio (TAR) [1]. Such parameters are typically stated in ratio form such as a 10-to-1 rule or a TUR of 4:1. Care has to be taken when such rules are encountered because they are sometimes ambiguously or incompletely defined. Definition (12), on the other hand, makes clear that a statement such as $C_\mathrm{m} \geq 4$ means that $u_\mathrm{m} \leq T/16$.

7.6.5 In the calibration or verification of a measuring instrument, a specified requirement is often expressed in terms of a *maximum permissible error* (*of indication*) (see 3.3.18). Such a requirement means that when the instrument is used to measure a quantity Y, the error of indication must lie in an interval defined by specified upper and lower limits. In the common case of a symmetric interval $[-E_\mathrm{max}, E_\mathrm{max}]$, the tolerance is $T = 2E_\mathrm{max}$ and the measurement capability index is

$$C_\mathrm{m} = \frac{2E_\mathrm{max}}{2U} = \frac{E_\mathrm{max}}{U}.$$

In this expression, U is the expanded uncertainty, for a coverage factor $k = 2$, associated with a measurement of the error of indication of the instrument.

7.7 Measurement capability index and conformance probability

7.7.1 For a normal PDF, expression (11) gives the conformance probability p_c in terms of a particular pair of tolerance limits $(T_\mathrm{L}, T_\mathrm{U})$ and a particular measurement result summarized by (y, u). Taking $y = \eta_\mathrm{m}$ and $u = u_\mathrm{m}$, this expression can be re-written in a form suitable for a general measurement problem by defining a quantity

$$\widetilde{y} = \frac{\eta_\mathrm{m} - T_\mathrm{L}}{T}. \qquad (13)$$

For an estimate η_m in the tolerance interval, $\widetilde{y}$ lies in the interval $0 \leq \widetilde{y} \leq 1$.

7.7.2 For a normal post-measurement PDF $\varphi\left(\eta; \eta_\mathrm{m}, u_\mathrm{m}^2\right)$, expression (11) can then be written, using expressions (12) and (13),

$$p_\mathrm{c} = \Phi\left[4C_\mathrm{m}(1-\widetilde{y})\right] - \Phi(-4C_\mathrm{m}\widetilde{y}) = p_\mathrm{c}(\widetilde{y}, C_\mathrm{m}), \qquad (14)$$

so that p_c is completely determined by the two quantities $\widetilde{y}$ and C_m.

7.7.3 It is often the case that the standard uncertainty u_m associated with an estimate η_m has a fixed value that depends on the design of the measuring system, but is independent of η_m. A series of water samples, for example, might be inspected to determine, for each sample, a concentration of dissolved mercury, using a measurement procedure that yields different estimates, each having the same associated standard uncertainty u_m. In such a case the measurement capability index $C_\mathrm{m} = T/4u_\mathrm{m}$ is fixed, and a question as to whether or not a measured property conforms to specification with an acceptable probability can be decided based on the estimate η_m, using expressions (13) and (14) with C_m fixed.

NOTE A case where the standard uncertainty u_m is proportional to the estimate η_m is treated in [13, Appendix A].

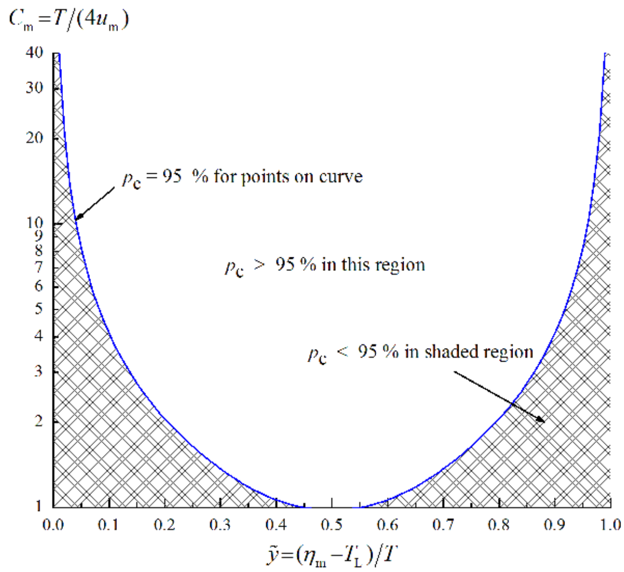

Figure 7 – Measurement capability index $C_\mathrm{m} = T/(4u_\mathrm{m})$ versus $\widetilde{y} = (\eta_\mathrm{m} - T_\mathrm{L})/T$, showing the locus of constant 95 % conformance probability p_c. The curve separates regions of conformity and non-conformity at a 95 % level of confidence. The post-measurement distribution for the measurand Y is taken to be the normal PDF $\varphi\left(\eta; \eta_\mathrm{m}, u_\mathrm{m}^2\right)$.

7.7.4 There is an infinite number of pairs $(\widetilde{y}, C_\mathrm{m})$ that yield a given conformance probability p_c via expression (14). Figure 7 shows C_m versus $\widetilde{y}$ along a curve of constant 95 % conformance probability for estimates η_m within the tolerance interval $0 \leq \widetilde{y} \leq 1$. The curve separates regions of conformity (unshaded) and non-conformity (shaded) at a 95 % level of confidence.

7.7.5 The horizontal axis in figure 7 corresponds to $C_\mathrm{m} = 1$, or $u_\mathrm{m} = T/4$. For this relatively large standard uncertainty it can be seen that $p_\mathrm{c} \geq 95$ % only for $0.45 \leq \widetilde{y} \leq 0.55$. If the measured property was required to conform to specification with at least a 95 % level of confidence, an acceptable estimate η_m would thus have to lie in the central approximately 10 % of the tolerance interval.

8 Acceptance intervals

8.1 Acceptance limits

8.1.1 A decision to accept an item as conforming, or reject it as non-conforming, to specification is based on a measured value η_m of a property of the item in relation to a stated decision rule that specifies the role of measurement uncertainty in formulating acceptance criteria. An interval of measured values of a property that results in acceptance of the item is called an *acceptance interval* (see 3.3.9), defined by one or two *acceptance limits* (see 3.3.8).

8.1.2 As suggested in the Introduction, acceptance limits and corresponding decision rules are chosen in such a way as to manage the undesired consequences of incorrect decisions. There are a number of widely used decision rules that are simple to implement. They can be applied when knowledge of a property of interest is summarised in terms of a best estimate and corresponding coverage interval. Two such decision rules are described in the following subclauses.

8.2 Decision rule based on simple acceptance

8.2.1 An important and widely used decision rule is known as simple acceptance [2] or shared risk [20]. Under such a rule, the producer and user (consumer) of the measurement result agree, implicitly or explicitly, to accept as conforming (and reject otherwise) an item whose property has a measured value in the tolerance interval. As the alternative name 'shared risk' implies, with a simple acceptance decision rule the producer and user share the consequences of incorrect decisions.

8.2.2 In practice, in order to keep the chances of incorrect decisions to levels acceptable to both producer and user, there is usually a requirement that the measurement uncertainty has been considered and judged to be acceptable for the intended purpose.

8.2.3 One approach to such consideration is to require, given an estimate of a measured quantity, that the associated expanded uncertainty U, for a coverage factor $k = 2$, must satisfy $U \leq U_{\max}$, where $U_{\max}$ is a mutually agreed maximum acceptable expanded uncertainty. This approach is illustrated by the following example.

EXAMPLE In legal metrology [40], a decision rule based on simple acceptance has been used in the verification of measuring instruments. Consider such an instrument that is required to have an error of indication in the interval $[-E_{\max}, E_{\max}]$. The instrument is accepted as conforming to the specified requirement if it meets the following criteria:

(a) in measuring a calibrated standard, the best estimate e of the instrument error of indication E satisfies

$$|e| \leq E_{\max}, \text{ and}$$

(b) the expanded uncertainty for a coverage factor $k = 2$ associated with the estimate e satisfies

$$U \leq U_{\max} = E_{\max}/3.$$

In terms of the measurement capability index, criterion (b) is equivalent to the requirement that $C_{\mathrm{m}} \geq 3$ (see clause 7.6).

8.2.4 Another practical acceptance decision rule follows from what is referred to as the "accuracy method" described in IEC Guide 115 [19]. In this approach, a well-characterised test method is used and sources of uncertainty are minimised by (a) use of measuring instruments with maximum permissible errors within specified limits, (b) environmental influences, such as temperature and relative humidity, maintained within specified limits, (c) well-documented control of laboratory procedures, and (d) well-documented competency of measurement personnel.

8.2.5 By controlling sources of variability within prescribed limits, the measurement uncertainty associated with a best estimate of a measurand is assumed to be negligible, is not explicitly evaluated, and plays no role in an accept/reject decision. The approach of IEC Guide 115 Procedure 2 (the "accuracy method") formalizes the current practice of electrotechnical testing laboratories in using state-of-the-art measuring equipment and routine, well established test methods.

8.2.6 Depending upon the relative width of the tolerance interval and the coverage interval, a simple acceptance decision rule, or similar decision rule, can often support the quality objectives of measurements and calibrations carried out in support of conformity assessments.

8.3 Decision rules based on guard bands

8.3.1 General considerations

8.3.1.1 Accepting or rejecting an item when the measured value of its property of interest is close to a tolerance limit may result in an incorrect decision and lead to undesirable consequences. Such incorrect decisions are generally of two kinds in the case of a single upper tolerance limit [illustrated in figure 8, outcomes (b) and (c)].

8.3.1.2 With a decision rule based on simple acceptance and the common case of a symmetric unimodal PDF (such as a normal distribution) for the measurand, the probability of accepting a non-conforming item [figure 8, (b)] or rejecting a conforming item [figure 8, (c)] can be as large as 50 %. This would happen, for example, if the measured value of a property lay very close to the tolerance limit. In such a case about 50 % of the PDF for the measurand would lie on either side of the limit, so that whether the item is accepted or rejected, there would be a 50 % chance of an incorrect decision.

8.3.1.3 Either of these probabilities can be reduced, at the cost of increasing the other, by choosing acceptance limits offset from the tolerance limits, a conformity decision strategy called guardbanding; see references [6, 7, 8, 9, 12, 17, 44].

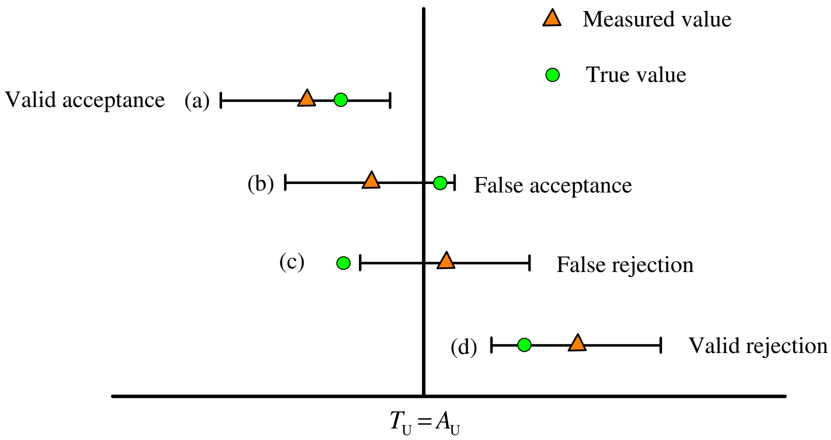

Figure 8 – **Simple acceptance decision rule near an upper tolerance limit T_U, with four 95 % coverage intervals. For such a decision rule, the acceptance limit A_U coincides with the tolerance limit. Decisions to accept or reject inspected items are based on measured values (triangles); the true values (circles) cannot be known. Cases (b) and (c) lead to incorrect decisions called false acceptance and false rejection, respectively (see clause 9.3.2). In case (c) the true value of the measurand lies (unknowingly) outside the 95 % coverage interval.**

8.3.2 Guarded acceptance

8.3.2.1 The risk of accepting a non-conforming item can be reduced by setting an acceptance limit A_U inside the tolerance interval, as shown in figure 9. The interval defined by T_U and A_U is called a *guard band* (see 3.3.11), and the resulting decision rule is called guarded acceptance.

NOTE Guarded acceptance is also known as stringent acceptance [2] and positive compliance for acceptance [18].

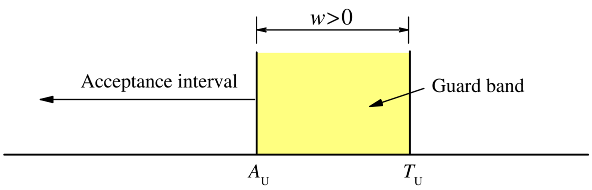

Figure 9 – **Decision rule based on guarded acceptance. An upper acceptance limit A_U inside an upper tolerance limit T_U defines an acceptance interval that reduces the probability of falsely accepting a non-conforming item (consumer's risk). By convention, the length parameter w associated with a guarded acceptance guard band is taken to be positive: $w = T_U - A_U > 0$.**

8.3.2.2 The difference between a tolerance limit and a corresponding acceptance limit defines a length parameter w for a guard band, viz.

$$w = T_U - A_U.$$

For a guarded acceptance decision rule, $w > 0$.

8.3.2.3 In many applications, the length parameter w is taken to be a multiple of the expanded uncertainty for a coverage factor $k = 2$, $U = 2u$, viz.

$$w = rU,$$

with the multiplier r chosen to assure a minimum conformance probability for an item that is accepted. A common choice is $r = 1$, in which case $w = U$.

EXAMPLE ISO 14253-1 [21] establishes a default guarded acceptance decision rule for demonstrating conformity with specification. Figure 10 is adapted from ISO 14253-1, figure 7. In the case of a two-sided tolerance interval, upper and lower acceptance limits are offset from the corresponding tolerance limits by guard bands with length parameter $w = U = 2u$.

The aim of the guard bands, with $w = 2u$, is to ensure that for any measured value lying within the acceptance interval, the probability of accepting a nonconforming item is at most 2.3 %, assuming a normal PDF for the measured quantity. This maximum probability occurs if the measured value of the property coincides with an acceptance limit. For measured values away from the acceptance limits, the probability of a false acceptance will be less than the maximum.

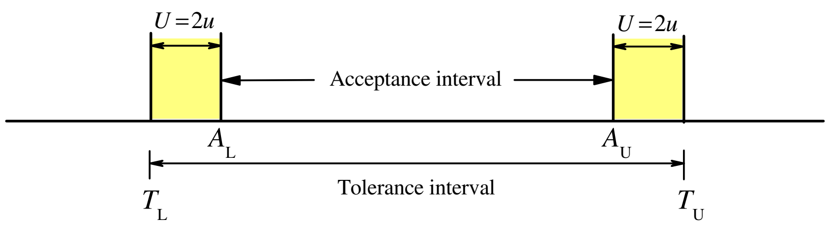

Figure 10 – Two-sided acceptance interval created by reducing the tolerance interval on either side by the $k = 2$ expanded uncertainty $U = 2u$. This is the default decision rule established in ISO 14253-1 [21].

In ISO 14253-1, an acceptance interval is called a conformance zone, and a tolerance interval is called a specification zone. The labels in figure 10 follow the conventions of this document.

8.3.3 Guarded rejection

8.3.3.1 An acceptance limit outside a tolerance interval, as shown in figure 11, can be chosen so as to increase the probability that a rejected item is truly non-conforming. Such a guarded rejection decision rule is often employed when one wants clear evidence that a limit has been exceeded prior to taking a negative action.

NOTE Guarded rejection is also known as stringent rejection [2] and positive non-compliance for rejection [18].

8.3.3.2 The length parameter w for a guarded rejection guard band is $w = T_U - A_U < 0$.

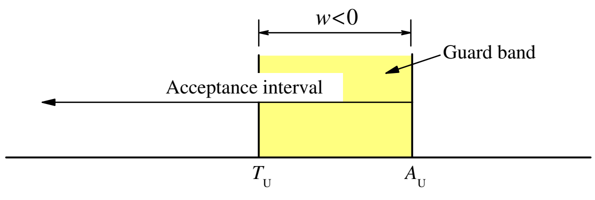

Figure 11 – Decision rule based on guarded rejection. An upper acceptance limit A_U outside an upper tolerance limit T_U defines an acceptance interval that reduces the probability of falsely rejecting a conforming item (producer's risk). The length parameter w associated with a guarded rejection guard band is $w = T_U - A_U < 0$.

EXAMPLE 1 **Speed limit enforcement**

In highway law enforcement, the speed of motorists is measured by police using devices such as radars and laser guns [42]. A decision to issue a speeding ticket, which may potentially lead to an appearance in court, must be made with a high degree of confidence that the speed limit has actually been exceeded.

Using a particular Doppler radar, speed measurements in the field can be performed with a relative standard uncertainty $u(v)/v$ of 2 % in the interval 50 km/h to 150 km/h. Knowledge of a measured speed v in this interval is assumed to be characterised by a normal PDF with expectation v and standard deviation $0.02v$.

Under these conditions one can ask, for a speed limit of $v_0 = 100$ km/h, what threshold speed $v_{\max}$ (acceptance limit) should be set so that for a measured speed $v \geq v_{\max}$ the probability that $v \geq v_0$ is a least 99.9 %?

This mathematical problem is equivalent to the calculation of a conformance probability for a one-sided tolerance interval (see clause 7.3). Here a value of $z = (v_{\max} - v_0)/(0.02v_{\max})$ is needed for which 99.9 % of the probability lies in the region $V \geq v_0$. From table 1 on page 15 it is seen that $z = 3.09$, so that

$$v_{\max} = \frac{v_0}{1 - 0.02z} = \frac{100}{1 - 0.02 \times 3.09} \text{ km/h} \approx 107 \text{ km/h}.$$

The interval [100 km/h $\leq v \leq$ 107 km/h] is a guard band that ensures a probability of at least 99.9 % that the speed limit has been exceeded for a measured speed of 107 km/h or greater.

EXAMPLE 2 **Drugs in live animals and animal products**

The anabolic steroid nandrolone belongs to a group of substances banned as growth promoters in food-producing animals. The substance occurs naturally in some live animals and consequently a threshold (tolerance) limit T equal to 2.00 µg/L has been established.

In a screening test for nandrolone, a measured concentration exceeding the threshold value with a probability of 95 % or greater is considered suspect and should be followed up by a confirmation procedure.

In performing a screening test, a laboratory wishes to set a decision (acceptance) limit A given by

$$A = T + g,$$

where $g = |w|$ is a guard band (see figure 11), such that for a measured concentration value $y \geq A$ the probability that $Y \geq T$ is at least 95 %.

The laboratory validates its measurement procedure by spiking ten blank samples at a concentration level close to the threshold. The samples are measured under within-laboratory reproducibility conditions, yielding an observed reproducibility standard deviation s (ISO 3534-2, 3.3.12) of 0.20 µg/L.

From the spiking experiment, the laboratory concludes that its measurements are free from significant systematic errors. The measurement uncertainty is dominated by reproducibility effects and the PDF for nandrolone concentration Y is thus taken to be a scaled and shifted t-distribution (see JCGM 101:2008 6.4.9) with $\nu = 9$ degrees of freedom.

From a table or appropriate software for the t-distribution (one-sided, $\nu = 9$ degrees of freedom, 95 % probability), the guard band is calculated as

$$g = t_{0.95;9} \times s = 1.83 \times 0.20 \text{ µg/L} = 0.37 \text{ µg/L}.$$

A sample with measured value y of nandrolone concentration greater than or equal to

$$A = (2.00 + 0.37) \text{ µg/L} = 2.37 \text{ µg/L}$$

is thus considered suspect.

9 Consumer's and producer's risks

9.1 General

9.1.1 In conformity assessment using a binary decision rule, a property of an item is measured and the item is accepted as conforming if the measured value of the property lies in a defined acceptance interval. A measured value outside the acceptance interval leads to rejection of the item as non-conforming. Figure 12, which reproduces figure 1 on page viii, illustrates the intervals of interest, showing a tolerance interval (of conforming values) and an acceptance interval (of permissible measured values).

9.1.2 The use of guard bands provides a way to limit the probability of making an incorrect conformance decision based on measurement information as summarised by a coverage interval. The present clause is concerned with a more precise evaluation of such probabilities for a production process. The evaluated probabilities depend on two factors, the production process and the measuring system.

9.1.3 If the measuring system were perfectly accurate, all conformance decisions would be correct and all risks would be zero. An increase in measurement uncertainty means an increase in the probability of an incorrect decision, and the probability is greatest when measured values are close to the tolerance limits.

9.1.4 The risks also depend on the nature of the production process. If the process rarely produces an item whose property of interest is near the tolerance limits, there is less opportunity for incorrect decisions to be made. Conversely, if a process produces items with properties likely to be close to tolerance limits, the uncertainties associated with the measurements are brought into play. The remainder of this clause shows how the contributions of both factors can be evaluated.

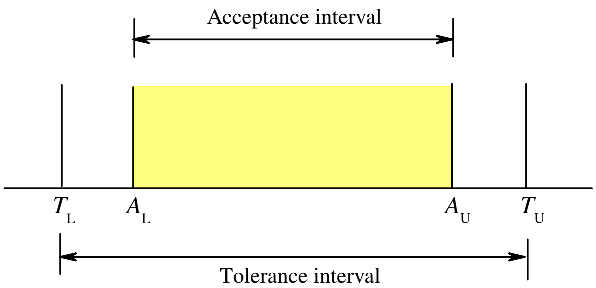

Figure 12 – Binary conformity assessment where decisions are based on measured quantity values. The true value of a measurable property (the measurand) of an item is specified to lie in a tolerance interval defined by limits $(T_{\mathrm{L}}, T_{\mathrm{U}})$. The item is accepted as conforming if the measured value of the property lies in an acceptance interval defined by limits $(A_{\mathrm{L}}, A_{\mathrm{U}})$, and rejected as non-conforming otherwise.

9.2 PDFs for production process and measuring system

9.2.1 Consider a process that produces a sequence of items, each having a measurable property Y with possible values η. The process might be a machine producing resistors of nominal resistance $10\ \mathrm{k}\Omega$ or a sampling process yielding vials of ocean water containing dissolved mercury. For an item chosen at random from the process, knowledge of property Y before it is measured is conveyed by a prior PDF $g_0(\eta)$. The PDF $g_0(\eta)$ can be said to characterize the production process, and is sometimes called the process probability density. The form of $g_0(\eta)$ is typically assigned based on knowledge acquired by measuring the property of interest in a sample of produced items.

NOTE Assigning a prior PDF based on a measured sample of items is discussed in Annex B.

9.2.2 Conformity assessment of a produced item is realized by a measurement of the property of interest. The output of the measuring system is a quantity regarded as an observable random variable Y_{m} whose possible values η_{m}, assuming a known input value $Y = \eta$, are encoded and conveyed by a PDF $h(\eta_{\mathrm{m}}|\eta)$. The form of $h(\eta_{\mathrm{m}}|\eta)$ is assigned based on the design of the measuring system, information supplied by calibrations and knowledge of relevant influence quantities such as environmental parameters and material properties.

9.3 Possible outcomes of an inspection measurement with a binary decision rule

9.3.1 Let $\mathcal{C}$ and $\widetilde{\mathcal{C}}$ denote, respectively, intervals of conforming and non-conforming values of Y, and let $\mathcal{A}$ and $\widetilde{\mathcal{A}}$ denote, respectively, intervals of acceptable and non-acceptable values of Y_{m}. In figure 12, for example, $\mathcal{C}$ corresponds to values of Y in the interval $T_{\mathrm{L}} \le Y \le T_{\mathrm{U}}$, and $\mathcal{A}$ corresponds to values of Y_{m} in the interval $A_{\mathrm{L}} \le Y_{\mathrm{m}} \le A_{\mathrm{U}}$.

9.3.2 With a binary decision rule there are four possible outcomes of a conformity assessment test that yields a measured quantity value η_m:

Valid acceptance: the item is accepted ($Y_m = \eta_m \in \mathcal{A}$) and conforms with specification ($Y \in \mathcal{C}$). This is a desired outcome of the conformity assessment test, leading to acceptance of a conforming item.

False acceptance: the item is accepted ($Y_m = \eta_m \in \mathcal{A}$) but does not conform with specification ($Y \in \widetilde{\mathcal{C}}$). This is an incorrect decision whose probability is called consumer's risk, because the cost associated with such a mistake is often borne by a consumer, or user, who accepts the item as fit for its purpose and acts accordingly.

NOTE False acceptance is also known as a pass error or a false positive.

For a particular measured item accepted as conforming, given a measured value $Y_m = \eta_m \in \mathcal{A}$, the probability of false acceptance is called the *specific consumer's risk* (see 3.3.13) [38], denoted by R^*_C. From the definition (4) of conformance probability it can be seen that R^*_C is given by

$$R^*_C = 1 - p_c,$$

for a measured value η_m in the acceptance interval. For an item chosen at random from the production process, the probability that it will be falsely accepted following a measurement is called the *global consumer's risk* (see 3.3.15) [38], denoted by R_C. Calculation of R_C is considered in clause 9.5.

Valid rejection: the item is rejected ($Y_m = \eta_m \in \widetilde{\mathcal{A}}$) and does not conform with specification ($Y \in \widetilde{\mathcal{C}}$). This is a desired outcome of the conformity assessment test, leading to rejection of a non-conforming item.

False rejection: the item is rejected ($Y_m = \eta_m \in \widetilde{\mathcal{A}}$) but actually conforms with specification ($Y \in \mathcal{C}$). This is another incorrect decision whose probability is called producer's risk, because the cost associated with such a mistake is often borne by a producer who cannot sell an item that has failed a test of conformity.

NOTE False rejection is also known as a fail error or a false negative.

For a particular measured item rejected as non-conforming, given a measured value $Y_m = \eta_m \in \widetilde{\mathcal{A}}$, the probability of false rejection is called the *specific producer's risk* (see 3.3.14) [38], denoted by R^*_P. From the definition (4) of conformance probability it can be seen that R^*_P is given by

$$R^*_P = p_c,$$

for a measured value η_m outside the acceptance interval. For an item chosen at random from the production process, the probability that it will be falsely rejected following a measurement is called the *global producer's risk* (see 3.3.16) [38], denoted R_P. Calculation of R_P is considered in clause 9.5.

9.4 The joint PDF for Y and Y_m

9.4.1 As seen in clause 9.3.2, the specific consumer's risk and specific producer's risk R^*_C and R^*_P are simply related to the conformance probability for a particular measured item, given the result of a measurement. If the value of the property Y is outside the tolerance interval and a measured value Y_m is within the acceptance interval, then a consumer's risk has been realised. The probability that these two events occur, i.e., the global consumer's risk, is specified by a joint probability distribution that depends on the production process and the measuring system.

9.4.2 The joint probability density can be written as a product of densities that are already known. In words, the probability that the value of the measurand Y is outside the tolerance interval and measured value Y_m is within the acceptance interval is given by the probability that the production process produces an item with a true value of Y

outside the tolerance interval multiplied by the probability that the measuring system produces a measured value Y_{m} within the acceptance interval, given that the measurand Y is outside the tolerance interval.

9.4.3 Similarly, the global producer's risk is defined in terms of the same joint probability distribution. If the tolerance interval, the production process and the measuring system are regarded as fixed, the global consumer's risk and global producer's risk are determined by the acceptance limits. The acceptance limits can thus be set to achieve an acceptable balance of the two kinds of risk. In general it is not possible to set the acceptance limits to minimise both the consumer's and producer's risks simultaneously: decreasing one will increase the other.

9.4.4 In the quality control and conformity assessment literature, the terms 'consumer's risk' and 'producer's risk' are generally used in the sense of global risks, as described above.

9.4.5 For a given production process and measuring system, knowledge of the possible outcomes of a conformity assessment test of an item selected at random is described by a joint probability density function. For such a randomly selected item, the probability that (a) the value of the measurand Y lies in the interval $\eta \le Y \le \eta + \mathrm{d}\eta$ and that (b) a measurement of Y would yield a measured value Y_{m} in the interval $\eta_{\mathrm{m}} \le Y_{\mathrm{m}} \le \eta_{\mathrm{m}} + \mathrm{d}\eta_{\mathrm{m}}$ is given by

$$\Pr\left(\eta \le Y \le \eta + \mathrm{d}\eta \text{ and } \eta_{\mathrm{m}} \le Y_{\mathrm{m}} \le \eta_{\mathrm{m}} + \mathrm{d}\eta_{\mathrm{m}}\right) = f(\eta, \eta_{\mathrm{m}})\mathrm{d}\eta\,\mathrm{d}\eta_{\mathrm{m}}, \tag{15}$$

where $f(\eta, \eta_{\mathrm{m}})$ is the joint PDF for Y and Y_{m}.

9.4.6 Using the product (or multiplication) rule of probability theory, the joint density $f(\eta, \eta_{\mathrm{m}})$ can be factorized in two ways, according to

$$f(\eta, \eta_{\mathrm{m}}) = g_{0}(\eta)\, h\left(\eta_{\mathrm{m}}|\eta\right) \tag{16a}$$

and

$$f(\eta, \eta_{\mathrm{m}}) = h_{0}(\eta_{\mathrm{m}})\, g\left(\eta|\eta_{\mathrm{m}}\right). \tag{16b}$$

9.4.7 The two PDFs on the right in expression (16a) are the two probability densities described in clause 9.2. Given the forms of these PDFs, the two probability densities on the right-hand side of expression (16b) can be calculated, if desired. Such a calculation is illustrated in Annex A (see clauses A.4.3 and A.4.4).

9.5 Calculation of global risks

9.5.1 Historical context

9.5.1.1 In the following subclauses, formulae are developed for calculating the global risks of incorrect decisions. Such calculations have traditionally been performed using measured frequency distributions of the various outcomes when a large sample of nominally identical items are measured. The global consumer's risk, in such an approach, is equal to the fraction of items in a measured sample that are accepted for use but do not conform with a specified requirement. Such non-conformance, for a particular item, has to be demonstrated after the fact by a separate measurement with an uncertainty much smaller than that of the measuring system used in the conformity assessment.

9.5.1.2 The global risks below are calculated using probability distributions rather than frequency distributions, so that it is not necessary to consider an ensemble of measured items that may not, in fact, exist. Numerically, the calculated probabilities will always agree, on average, with measured frequencies. Thus acceptance limits can be chosen to yield acceptable fractions of mistakenly accepted or rejected items, on average, in the conformity assessment of items in a sample.

9.5.2 General formulae

9.5.2.1 Given the joint PDF (16a) and the two probability densities $g_{0}(\eta)$ and $h\left(\eta_{\mathrm{m}}|\eta\right)$, the probabilities of each of the four possible outcomes described above (see clause 9.3) can be calculated. These probabilities are simply the respective volumes under the joint probability density $f(\eta, \eta_\mathrm{m})$, integrated over the four regions that describe all possible outcomes.

9.5.2.2 Of particular interest are the global consumer's risk and global producer's risk, calculated as follows:

— For a measured value in the acceptance interval and a value of Y outside the tolerance interval, the global consumer's risk is

$$R_\mathrm{C} = \int_{\widetilde{\mathcal{C}}} \int_{\mathcal{A}} g_0(\eta)\, h\left(\eta_\mathrm{m}|\eta\right)\, \mathrm{d}\eta_\mathrm{m} \mathrm{d}\eta. \tag{17}$$

— For a measured value outside the acceptance interval and a value of Y within the tolerance interval, the global producer's risk is

$$R_\mathrm{P} = \int_{\mathcal{C}} \int_{\widetilde{\mathcal{A}}} g_0(\eta)\, h\left(\eta_\mathrm{m}|\eta\right)\, \mathrm{d}\eta_\mathrm{m} \mathrm{d}\eta. \tag{18}$$

9.5.2.3 Expressions (17) and (18) are general formulae for the calculation of global consumer's and producer's risks. Depending on the particular form of the PDFs $g_0(\eta)$ and $h\left(\eta_\mathrm{m}|\eta\right)$, explicit evaluation of R_C and R_P may have to be performed numerically.

9.5.3 Special case: Binary decision rule

9.5.3.1 For the particular binary conformity assessment illustrated in figure 12, formulae (17) and (18) become

$$R_\mathrm{C} = \left(\int_{-\infty}^{T_\mathrm{L}} + \int_{T_\mathrm{U}}^{\infty} \right) \int_{A_\mathrm{L}}^{A_\mathrm{U}} g_0(\eta)\, h\left(\eta_\mathrm{m}|\eta\right) \mathrm{d}\eta_\mathrm{m}\, \mathrm{d}\eta, \tag{19}$$

and

$$R_\mathrm{P} = \left(\int_{-\infty}^{A_\mathrm{L}} + \int_{A_\mathrm{U}}^{\infty} \right) \int_{T_\mathrm{L}}^{T_\mathrm{U}} g_0(\eta)\, h\left(\eta_\mathrm{m}|\eta\right) \mathrm{d}\eta\, \mathrm{d}\eta_\mathrm{m}. \tag{20}$$

9.5.3.2 Use of expressions (19) and (20) in the case where the joint PDF (15) is a product of normal distributions is illustrated in the following example. Properties of normal distributions, including the particular forms of expressions (19) and (20), are discussed in Annex A.

EXAMPLE **Manufacture of precision resistors**

A supplier of electrical components produces wire-wound precision resistors of nominal resistance 1 500 Ω. For each resistor (the item), the resistance Y (the property of interest) is specified to lie in a tolerance interval defined by the limits $T_\mathrm{L} = 1\,499.8$ Ω and $T_\mathrm{U} = 1\,500.2$ Ω.

A machine for producing such resistors is evaluated by measuring a sample of its output, using a high-accuracy ohmmeter with negligible measurement uncertainty. A histogram of the measured values appears normal in shape, centred on the nominal value with a standard deviation $\sigma = 0.12$ Ω. Based on this information, a normal PDF $g_0(\eta) = \varphi\left(\eta; y_0, u_0^2\right)$ is assigned to model the production process, with $y_0 = 1\,500$ Ω and $u_0 = \sigma = 0.12$ Ω.

For a typical resistor produced by this machine, the conformance probability is

$$p_\mathrm{c} = \int_{T_\mathrm{L}}^{T_\mathrm{U}} g_0(\eta)\, \mathrm{d}\eta = \int_{1\,499.8}^{1\,500.2} \varphi\left(\eta; 1\,500, 0.12^2\right) \mathrm{d}\eta \approx 0.90 = 90\ \%. \tag{21}$$

If the supplier simply shipped every resistor produced, about 10 % of them would be non-conforming, which for economic reasons is judged to be unacceptable. By purchasing a more expensive production machine the process variability could be reduced. In this case it is decided, considering the relative costs, to keep the existing machine and implement an inspection process to detect and remove non-conforming resistors.

In production, the resistors are inspected for conformity with specification using a calibrated high-speed ohmmeter. A normal PDF $h(\eta_\mathrm{m}|\eta) = \varphi\left(\eta_\mathrm{m}; \eta, u_\mathrm{m}^2\right)$, with $u_\mathrm{m} = 0.04\ \Omega$, is assigned to encode and convey belief in the interval of measured values that might be observed when measuring a known resistance $Y = \eta$. The assignment is based on a model of the measuring system and an evaluation of the measurement uncertainty, including the uncertainty associated with the ohmmeter calibration.

In order to reduce the probability of shipping resistors that do not meet specification (the consumer's risk), acceptance limits $A_\mathrm{L} = 1\,499.82\ \Omega,\ A_\mathrm{U} = 1\,500.18\ \Omega$ are chosen inside the tolerance interval(see figure 12, page 24), creating a guarded acceptance interval with symmetric guard bands of length

$$w = (1\,500.2 - 1\,500.18)\ \Omega = 0.02\ \Omega = 0.25U.$$

The consumer's and producer's risks are then calculated from expressions (A.15)–(A.17) with

$$\varphi_0(z) = (1/\sqrt{2\pi})\exp\left(-z^2/2\right)$$

and

$$F(z) = \Phi\left(\frac{A_\mathrm{U} - y_0 - u_0 z}{u_\mathrm{m}}\right) - \Phi\left(\frac{A_\mathrm{L} - y_0 - u_0 z}{u_\mathrm{m}}\right) = \Phi(4.5 - 3z) - \Phi(-4.5 - 3z).$$

Numerical integration yields

$$R_\mathrm{C} = \int_{-\infty}^{-1.667} F(z)\varphi_0(z)\,\mathrm{d}z + \int_{1.667}^{\infty} F(z)\varphi_0(z)\,\mathrm{d}z = 0.01 = 1\ \%,$$

and

$$R_\mathrm{P} = \int_{-1.667}^{1.667} [1 - F(z)]\varphi_0(z)\,\mathrm{d}z = 0.07 = 7\ \%.$$

Interesting features of this conformity assessment procedure can be noted by considering an average sample of 100 resistors produced by the machine, measured, and accepted or rejected as suitable for use:

— given the properties of the production process, 90 of the resistors conform with specification and 10 do not conform (see expression (21));

— of the 90 conforming resistors, 83 are accepted and 7 falsely rejected as non-conforming;

— of the 10 non-conforming resistors, 9 are rejected and one falsely accepted as conforming;

— 84 of the resistors are accepted; of these, $83/84 \approx 99$ % conform, with about 1 % out of tolerance. This is the goal of the inspection measurement, reducing the proportion of non-conforming resistors, among those accepted for use, from 10 % to 1 %;

— of the 16 resistors that are rejected, $7/16 \approx 44$ % actually conform with specification. This is a price to be paid for reducing the risk of accepting non-conforming products.

9.5.4 Setting acceptance limits

9.5.4.1 In the example above, the global risks R_C and R_P were calculated given known acceptance limits A_L and A_U. In most real applications, a desired level of risk is chosen based on a cost analysis and acceptance limits are calculated so as to ensure that the desired risk level is achieved. Such calculations are not straightforward. A practical approach to such problems is via graphical solution, as illustrated in the following example.

EXAMPLE **Ball bearing production**

A manufacturer produces large numbers of precision ball bearings. The performance specification for these bearings (the items) requires that, for each of them, the radial error motion (the property of interest) be less than 2 µm. Radial error motion of a bearing is undesired motion perpendicular to the axis of rotation. For a perfect bearing, the radial error motion would be zero; any real bearing will have a positive radial error motion.

In order to characterize the production process, the radial error motions of a large sample of bearings are measured, using a high-accuracy test apparatus with negligible measurement uncertainty. For this sample, the average observed radial error motion is $\overline{y} = 1$ µm, with an associated sample standard deviation $s = 0.5$ µm.

Prior to shipment, bearings are tested for conformity with specification. In these tests the radial error motion is measured using a calibrated test apparatus. The measuring system is characterized by a normal PDF $\varphi\left(\eta_{\mathrm{m}}; \eta, u_{\mathrm{m}}^2\right)$ with a standard uncertainty of $u_{\mathrm{m}} = 0.25$ µm.

For economic reasons, the fraction of non-conforming bearings sold to customers as conforming (the global consumer's risk) must be held to 0.1 % or less. How can an acceptance limit A be chosen to satisfy this requirement?

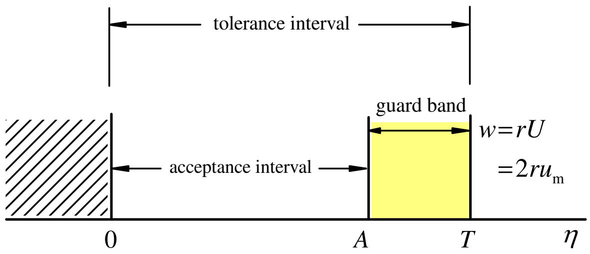

Figure 13 – Tolerance and acceptance intervals for the conformity assessment of ball bearings. Permissible values of radial error motion Y lie in the interval $0 \leq \eta \leq T$. The acceptance limit A is separated from the tolerance limit T by a guard band with length parameter $w = rU = 2ru_{\mathrm{m}}$. The decision rule in this case is guarded acceptance, with $w > 0$.

The conformity assessment problem is illustrated in figure 13. A conforming ball bearing is specified to have a radial error motion Y in the interval $0 \leq \eta \leq T$. Since the radial error motion is always positive, with measured values close to zero, the prior PDF for the radial error Y will be modelled by a gamma probability density (see Annex B, clause B.3). Based on the sample measurements, the expectation and standard uncertainty of the prior PDF are assigned to be $y_0 = \overline{y} = 1$ µm and $u_0 = s = 0.5$ µm. Using expressions (B.14), the parameters α and λ are calculated:

$$\alpha = \frac{1^2}{(0.5)^2} = 4, \qquad \lambda = \frac{1}{(0.5)^2} = 4.$$

From definition (B.11) of the gamma probability density, the prior PDF for bearing radial error Y is then

$$g_0(\eta) = \mathrm{gamma}\,(\eta; 4, 4) = \frac{128}{3}\eta^3 e^{-4\eta}, \quad \eta \geq 0. \tag{22}$$

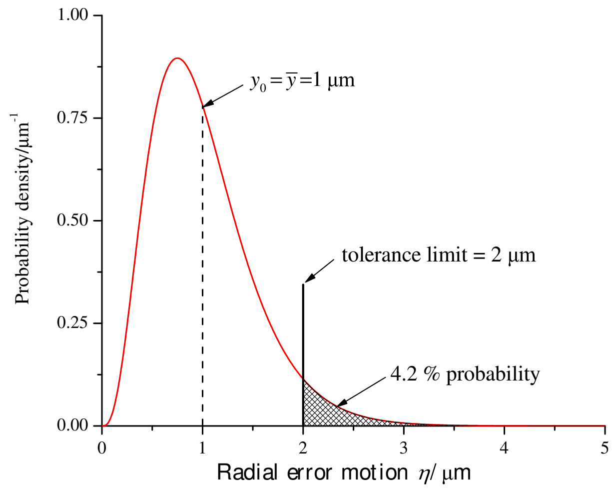

Figure 14 – Gamma prior PDF given by expression (22), assigned based on the frequency distribution of measured radial error motions for a sample of ball bearings. The tolerance interval is the region $0 \le \eta \le 2$ µm. The expectation of the distribution is the prior estimate $y_0 = 1$ µm, with an associated standard uncertainty $u_0 = 0.5$ µm. Because the distribution is not symmetric, the most probable value of Y (the mode of the distribution, here equal to 0.75 µm) is not equal to y_0.

This PDF is shown in figure 14. The probability that a ball bearing chosen at random from the production process would display a radial error motion greater than 2 µm is indicated by the cross-hatched region. This non-conformance probability is

$$\overline{p}_\text{c} = \int_2^\infty \text{gamma}\,(\eta; 4, 4)\ \text{d}\eta = 0.042,$$

which means that if all ball bearings produced were shipped without being measured, about 4.2 % of them would be non-conforming. The post-process measuring system is designed to detect non-conforming bearings so that they will not be shipped. An acceptance limit is desired to reduce the consumer's risk R_C to 0.1 % or less. For the conformity assessment decision rule shown in figure 13, the tolerance interval corresponds to $0 \le Y \le T$ and the acceptance interval to $0 \le Y_\text{m} \le A$. In a manner analogous to the steps leading to expressions (19) and (20), the global consumer's and producer's risks are evaluated as

$$R_\text{C} = \int_T^\infty \int_0^A g_0(\eta)\, h(\eta_\text{m}|\eta)\ \text{d}\eta_\text{m}\,\text{d}\eta, \qquad R_\text{P} = \int_0^T \int_A^\infty g_0(\eta)\, h(\eta_\text{m}|\eta)\ \text{d}\eta_\text{m}\,\text{d}\eta.$$

For a measuring system characterized by a normal PDF $h(\eta_\text{m}|\eta) = \varphi\left(\eta_\text{m}; \eta, u_\text{m}^2\right)$, making the substitutions $z = (\eta_\text{m} - \eta)/u_\text{m}$, $\text{d}z = \text{d}\eta_\text{m}/u_\text{m}$, and performing the integrations over z, these expressions become

$$R_\text{C} = \int_T^\infty \left[\Phi\left(\frac{A-\eta}{u_\text{m}}\right) - \Phi\left(-\frac{\eta}{u_\text{m}}\right)\right] g_0(\eta)\ \text{d}\eta, \qquad R_\text{P} = \int_0^T \left[1 - \Phi\left(\frac{A-\eta}{u_\text{m}}\right)\right] g_0(\eta)\ \text{d}\eta.$$

From figure 13 it can be seen that $A = T - 2ru_\text{m}$. Here $T = 2$ µm and $u_\text{m} = 0.25$ µm. Then setting $g_0(\eta)$ equal to the gamma PDF of expression (22) yields the explicit results

$$R_\text{C}(r) = \frac{128}{3} \int_2^\infty \left[\Phi(8 - 2r - 4\eta) - \Phi(-4\eta)\right] \eta^3 e^{-4\eta}\ \text{d}\eta, \tag{23}$$

$$R_\text{P}(r) = \frac{128}{3} \int_0^2 \left[1 - \Phi(8 - 2r - 4\eta)\right] \eta^3 e^{-4\eta}\ \text{d}\eta. \tag{24}$$

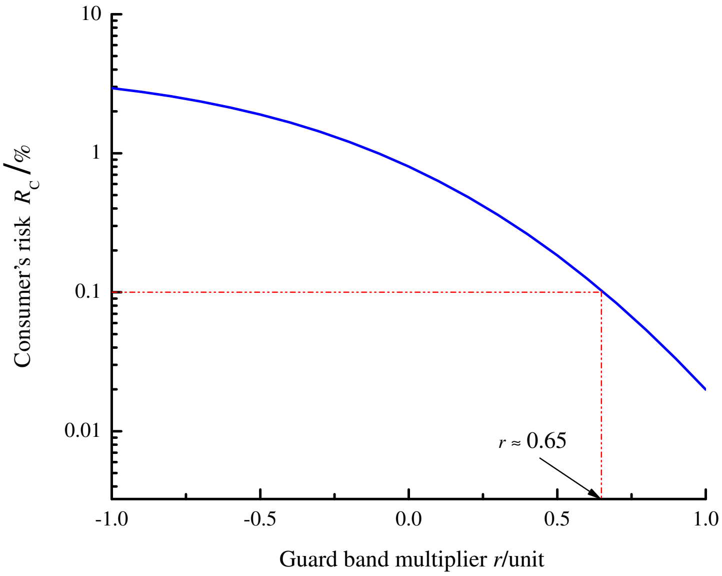

Figure 15 – **Global consumer's risk R_C versus guard band multiplier r. For $r \approx 0.65$, the acceptance limit is $A = T - 2(0.65)u_m = 1.7$ µm, and the desired risk $R_C = 0.1$ % is achieved.**

These integrals cannot be evaluated in closed form, but they can be calculated numerically for any chosen values of the guard band multiplier r.

Figure 15 shows the global consumer's risk R_C for $-1 \leq r \leq 1$. Positive r corresponds to $A < T$ (guarded acceptance) and negative r corresponds to $A > T$. For $r = 0$ there is no guard band ($A = T$), a decision rule called shared risk or simple acceptance (see clause 8.2). The figure shows that the desired level of risk, $R_C = 0.1$ %, is achieved for a guard band multiplier $r \approx 0.65$. This results in a guarded acceptance interval with acceptance limit

$$A = T - 2ru_m = (2 - 2 \times 0.65 \times 0.25)\ \mu\text{m} \approx 1.7\ \mu\text{m}.$$

This choice of acceptance limit solves the decision problem.

In conformity assessment with a binary decision rule, acting to reduce the consumer's risk will always increase the producer's risk. This general rule is well illustrated by figure 16 which shows R_P versus R_C, calculated numerically from formulae (23) and (24), for the ball bearing example. For $r = 0.65$, the global producer's risk R_P is about 7.5 %. This means that about 75 of every 1000 ball bearings that fail inspection would actually conform with specification, resulting in the loss of revenue that would accrue if these good bearings were sold.

The generation of an increasing amount of conforming scrap is a cost of guarded acceptance, which seeks to reduce the acceptance and shipment of non-conforming products. In practice a supplier must choose an operating point along a curve such as that shown in figure 16 that will balance the risks and yield an optimal outcome. The choice of such an operating point is a business or policy decision that requires an economic analysis of the decision problem.

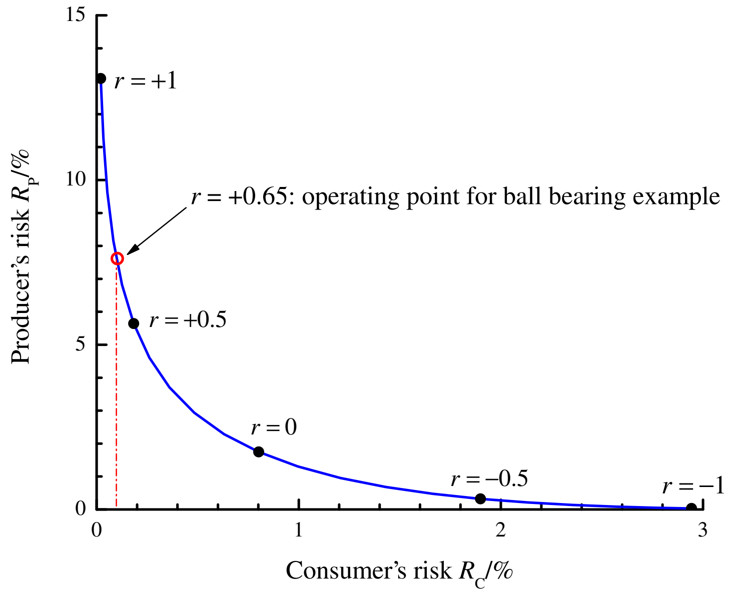

Figure 16 – **Global risks R_P versus R_C for the ball bearing example. Any point on the curve corresponds to a particular value of r, the guard band multiplier, with several particular values identified. Acting to reduce consumer's risk by moving the acceptance limit farther inside the tolerance interval (increasing r) always increases the risk of falsely rejecting conforming bearings. An economic analysis is required to choose an optimal decision rule. The open circle marks the operating point in the worked example.**

9.5.5 General graphical approach

9.5.5.1 For a process with given tolerance T, normal prior PDF $g_0(\eta) = \varphi\left(\eta; y_0, u_0^2\right)$ and normal measuring system PDF $h(\eta_\mathrm{m}|\eta) = \varphi\left(\eta_\mathrm{m}; \eta, u_\mathrm{m}^2\right)$, a graph such as that shown in figure 17 can be created to aid in setting acceptance limits.

9.5.5.2 In this example it is assumed that prior information is meagre in the sense that $u_\mathrm{m}^2 \ll u_0^2$, so that the estimate $y \approx \eta_\mathrm{m}$ with associated standard uncertainty $u \approx u_\mathrm{m}$ (see clause A.4.4.3).

9.5.5.3 The figure shows R_P versus R_C for the particular case where $u_0 = T/6$.

9.5.5.4 The five curves in the figure correspond to values of the measurement capability index $C_\mathrm{m} = T/(4u_\mathrm{m})$ in a range from 2 to 10, and along each curve solid points locate guard bands with various length parameters, from $w = -U$ to $w = U$, with the expanded uncertainty U equal to $2u$.

9.5.5.5 To use this particular graph it would be necessary to note that

— the process is assumed to be centred, so that the prior estimate y_0 of the measurand lies at the midpoint of the tolerance interval;

— the upper and lower guard bands are assumed to have length parameters that are equal in absolute value (a symmetric acceptance interval);

— R_P and R_C are calculated assuming normal process and measuring system PDFs;

— for measurement capabilities other than the five values shown, interpolation is possible;

— it is also possible to interpolate along the curves to estimate the guard bands.

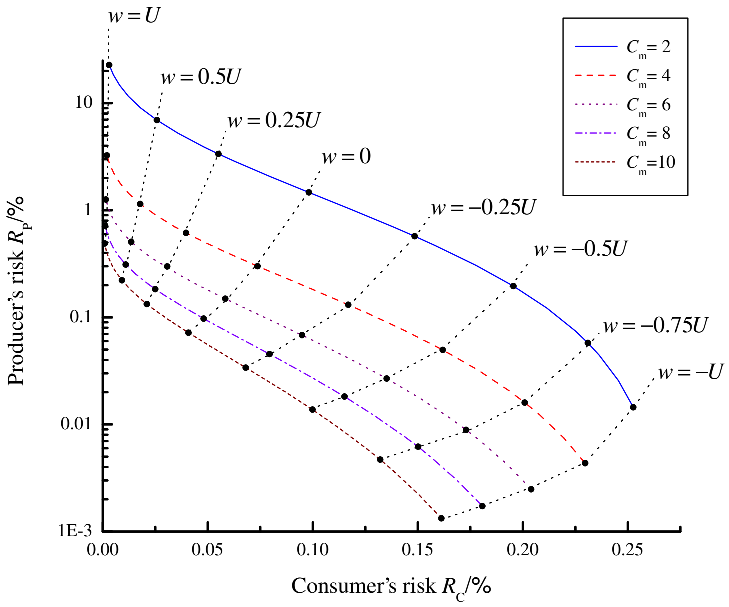

Figure 17 – Global risks R_P versus R_C for a binary conformity assessment with prior standard uncertainty $u_0 = T/6$. The five curves correspond to values of the measurement capability index $C_\mathrm{m} = T/(4u_\mathrm{m})$ in an interval from 2 to 10. The solid points locate guard bands with length parameters from $w = -U$ to $w = U$, with $U = 2u$. Positive values of w correspond to guarded acceptance, with acceptance limits inside the tolerance limits as in figure 12 on page 24.

9.5.6 The value of reduced measurement uncertainty

9.5.6.1 Reducing the uncertainty associated with the result a of conformity assessment measurement will also reduce the probability of making an incorrect accept/reject decision. This observation is well illustrated in figure 17 by the dotted lines that mark the loci of the various guard bands.

9.5.6.2 For a simple acceptance decision rule ($w = 0$) it is seen, for example, that if the measurement uncertainty were such that $C_\mathrm{m} = T/(4u_\mathrm{m}) = 2$, then the consumer's risk would be $R_\mathrm{C} \approx 0.1$ % and the corresponding producer's risk would be $R_\mathrm{P} \approx 1.5$ %.

9.5.6.3 Investing in an improved measuring system with $C_\mathrm{m} = 10$ would reduce these risks to $R_\mathrm{C} \approx 0.04$ % and $R_\mathrm{P} \approx 0.07$ % respectively. Whether such a reduction in measurement uncertainty would be economically desirable depends on the tradeoff between the cost of the improved metrology and the money saved via fewer decision mistakes.

9.5.6.4 Improving the production process (reducing the prior standard uncertainty u_0) will have a similar effect in reducing both consumer's and producer's risks, and will involve a similar kind of cost/benefit analysis.

Annex A
(informative)
Normal distributions

A.1 Normal probability density function

A.1.1 Assume that a quantity of interest Y is measured, yielding a best estimate y and an associated standard uncertainty $u(y) = u$. In many cases the dispersion of probable values η of Y about the estimate y, given a measured value η_{m}, is well characterized by a normal probability density function (PDF), given by

$$g\left(\eta|\eta_{\mathrm{m}}\right) = \frac{1}{u\sqrt{2\pi}} \exp\left[-\frac{1}{2}\left(\frac{\eta - y}{u}\right)^2\right] =: \varphi(\eta; y, u^2), \tag{A.1}$$

where $y = y(\eta_{\mathrm{m}})$. In many conformity assessment measurements, $y \approx \eta_{\mathrm{m}}$, but this is not always the case; see clause A.4.4.

A.2 Integrals of normal PDFs

A.2.1 In computing coverage probabilities, conformance probabilities and/or consumer's and producer's risks, one often has to evaluate integrals of normal PDFs between finite or semi-infinite limits. Such integrals cannot be evaluated in closed form and are therefore evaluated numerically and tabulated. In order to simplify the notation it is convenient to introduce the standard normal PDF, $\varphi_0(t)$, defined by

$$\varphi_0(t) = \frac{1}{\sqrt{2\pi}} \exp(-t^2/2) = \varphi(t; 0, 1). \tag{A.2}$$

A.2.2 There are two common ways that one finds integrals of normal PDFs expressed:

(a) the standard normal distribution function, $\Phi(t)$, defined by

$$\Phi(z) = \frac{1}{\sqrt{2\pi}} \int_{-\infty}^{z} \exp(-t^2/2)\,\mathrm{d}t = \int_{-\infty}^{z} \varphi_0(t)\,\mathrm{d}t, \tag{A.3}$$

and

(b) the error function, $\mathrm{erf}(z)$, defined by

$$\mathrm{erf}(z) = \frac{2}{\sqrt{\pi}} \int_0^z \exp(-t^2)\,\mathrm{d}t. \tag{A.4}$$

These functions are simply related; from definitions (A.3) and (A.4) it is seen that

$$\Phi(z) = \frac{1}{2}\left[1 + \mathrm{erf}(z/\sqrt{2})\right]. \tag{A.5}$$

A.2.3 Consider the probability that the Y lies in the interval $a \le Y \le b$, given a measured value η_{m}. For the normal PDF of expression (A.1) this probability is given by

$$\Pr(a \le Y \le b|\eta_{\mathrm{m}}) = \frac{1}{u\sqrt{2\pi}} \int_a^b \exp\left[-\frac{1}{2}\left(\frac{\eta - y}{u}\right)^2\right] \mathrm{d}\eta.$$

Setting $z = (\eta - y)/u$ and $\mathrm{d}z = \mathrm{d}\eta/u$, this expression becomes

$$\Pr(a \le Y \le b|\eta_{\mathrm{m}}) = \int_{(a-y)/u}^{(b-y)/u} \varphi_0(z)\mathrm{d}z = \Phi\left(\frac{b-y}{u}\right) - \Phi\left(\frac{a-y}{u}\right), \tag{A.6}$$

using expressions (A.2) and (A.3).

A.3 Coverage probabilities for normal PDFs

A.3.1 In a common special case, points a and b define a coverage interval (or uncertainty interval) of width $2U$ about the estimate y, where $U = ku$ is the expanded uncertainty for a stated coverage factor k (see clause 6.3.2). Then $a = y - ku$, $b = y + ku$ and expression (A.6) becomes

$$\Pr(|Y - y| \leq ku|\eta_\mathrm{m}) = \Phi(k) - \Phi(-k) = \mathrm{erf}(k/\sqrt{2}) = P(k).$$

The coverage probabilities (or levels of confidence) for $k = 1, 2,$ and 3 are then:

$$P(1) = \Phi(1) - \Phi(-1) = \mathrm{erf}(1/\sqrt{2}) = 0.683 = 68.3\ \%,$$

$$P(2) = \Phi(2) - \Phi(-2) = \mathrm{erf}(2/\sqrt{2}) = 0.955 = 95.5\ \%,$$

$$P(3) = \Phi(3) - \Phi(-3) = \mathrm{erf}(3/\sqrt{2}) = 0.997 = 99.7\ \%.$$

A.4 Normal process and measurement probability densities

A.4.1 Prior PDF $g_0(\eta)$ for the measurand Y

A.4.1.1 Before performing a measurement, knowledge of a measurand Y is often well characterized by a normal prior PDF. Denoting the best estimate by y_0 and the associated standard uncertainty by u_0, this prior PDF is given by

$$g_0(\eta) = \varphi\left(\eta; y_0, u_0^2\right) = \frac{1}{u_0\sqrt{2\pi}} \exp\left[-\frac{1}{2}\left(\frac{\eta - y_0}{u_0}\right)^2\right] = \sqrt{\frac{w_0}{2\pi}} \exp\left[-\frac{w_0}{2}(\eta - y_0)^2\right]. \tag{A.7}$$

In the last expression a weight $w_0 = 1/u_0^2$ has been introduced to simplify the subsequent development.

A.4.2 PDF $h(\eta_\mathrm{m}|\eta)$ for Y_m, given a value $Y = \eta$

A.4.2.1 Assume that the measuring system used in a conformity assessment is characterised, via the likelihood function, by a normal PDF. If such a system is used to measure a property of interest with an assumed value $Y = \eta$ the PDF conveying belief in the possible values of Y_m is then given by

$$h(\eta_\mathrm{m}|\eta) = \varphi\left(\eta_\mathrm{m}; \eta, u_\mathrm{m}^2\right) = \frac{1}{u_\mathrm{m}\sqrt{2\pi}} \exp\left[-\frac{1}{2}\left(\frac{\eta_\mathrm{m} - \eta}{u_\mathrm{m}}\right)^2\right] = \sqrt{\frac{w_\mathrm{m}}{2\pi}} \exp\left[-\frac{w_\mathrm{m}}{2}(\eta_\mathrm{m} - \eta)^2\right], \tag{A.8}$$

where $w_\mathrm{m} = 1/u_\mathrm{m}^2$.

A.4.2.2 The normal PDF of expression (A.8) reasonably characterizes a measurement analyzed according to the procedure described in the GUM, in the case where the conditions necessary for the validity of the central limit theorem exist. The GUM assumes no prior knowledge of the measurand, so that the dispersion of values that could reasonably be attributed to a measurand following a measurement is characterized by the standard uncertainty u_m.

A.4.3 Marginal PDF $h_0(\eta_\mathrm{m})$ for Y_m

A.4.3.1 It is of interest to ask, and of practical value to know, what measured value η_m might be realized if an item were chosen at random from a production process and the property of interest Y measured. For a process characterized by the prior PDF of expression (A.7) and measuring system characterized by the PDF of expression (A.8), the desired PDF can be calculated as a marginal probability density, using expression (16a), as follows:

$$\begin{aligned} h_0(\eta_{\mathrm{m}}) &= \int_{-\infty}^{\infty} g_0(\eta)\, h(\eta_{\mathrm{m}}|\eta)\, \mathrm{d}\eta \\ &= \frac{\sqrt{w_0 w_{\mathrm{m}}}}{2\pi} \int_{-\infty}^{\infty} \exp\left[-\frac{1}{2}\left(w_0(\eta - y_0)^2 + w_{\mathrm{m}}(\eta_{\mathrm{m}} - \eta)^2\right)\right] \mathrm{d}\eta \\ &= \frac{1}{\sqrt{2\pi}} \sqrt{\frac{w_0 w_{\mathrm{m}}}{w_0 + w_{\mathrm{m}}}} \exp\left[-\frac{1}{2}\frac{w_0 w_{\mathrm{m}}}{w_0 + w_{\mathrm{m}}}(\eta_{\mathrm{m}} - y_0)^2\right] \\ &= \frac{1}{u_{\eta_{\mathrm{m}}}\sqrt{2\pi}} \exp\left[-\frac{1}{2}\left(\frac{\eta_{\mathrm{m}} - y_0}{u_{\eta_{\mathrm{m}}}}\right)^2\right] \\ &= \varphi\left(\eta_{\mathrm{m}}; y_0, u_{\eta_{\mathrm{m}}}^2\right), \end{aligned} \tag{A.9}$$

where

$$u_{\eta_{\mathrm{m}}} = \sqrt{\frac{w_0 + w_{\mathrm{m}}}{w_0 w_{\mathrm{m}}}} = \sqrt{u_0^2 + u_{\mathrm{m}}^2}. \tag{A.10}$$

A.4.3.2 The PDF $h_0(\eta_{\mathrm{m}})$ is seen to be a normal distribution with expectation y_0 and associated standard uncertainty $u_{\eta_{\mathrm{m}}}$ given by expression (A.10).

A.4.3.3 The expectation $E(Y_{\mathrm{m}}) = y_0$ follows from the assumption that the measuring system has been corrected for all recognized significant systematic errors and is thus free from bias.

A.4.3.4 The standard uncertainty $u_{\eta_{\mathrm{m}}}$ in expression (A.10) is seen to be the quadrature sum of the standard uncertainties associated with the process and measuring system PDFs. The two sources of uncertainty (an uncertain process and an imperfect measuring system) combine in a natural way in their effects on knowledge of possible measured values of a property of interest. Given a high-accuracy measuring system, in the sense that $u_{\mathrm{m}} \ll u_0$, then $u_{\eta_{\mathrm{m}}} \approx u_0$ and uncertainty about possible measured quantity values is almost all due to incomplete information about the production process.

A.4.4 Posterior (post-measurement) PDF $g(\eta|\eta_{\mathrm{m}})$ for Y

A.4.4.1 Equating the right-hand sides of expressions (16a) and (16b), on page 26, and rearranging yields the PDF for the measurand Y following a measurement that yields a measured value η_{m}:

$$g(\eta|\eta_{\mathrm{m}}) = \frac{g_0(\eta)\, h(\eta_{\mathrm{m}}|\eta)}{h_0(\eta_{\mathrm{m}})}. \tag{A.11}$$

Comparison with expression (1) on page 11 shows this result to be a statement of Bayes' theorem, with the denominator $h_0(\eta_{\mathrm{m}})$ given by expression (A.9). Substituting the normal PDFs of expressions (A.7)–(A.9) into expression (A.11) yields

$$\begin{aligned} g(\eta|\eta_{\mathrm{m}}) &= \sqrt{\frac{w_0 + w_{\mathrm{m}}}{2\pi}} \exp\left[-\frac{w_0 + w_{\mathrm{m}}}{2}\left(\eta - \frac{w_0 y_0 + w_{\mathrm{m}}\eta_{\mathrm{m}}}{w_0 + w_{\mathrm{m}}}\right)^2\right] \\ &= \frac{1}{u\sqrt{2\pi}} \exp\left[-\frac{1}{2}\left(\frac{\eta - y}{u}\right)^2\right] \\ &= \varphi\left(\eta; y, u^2\right), \end{aligned} \tag{A.12}$$

where

$$y = \frac{w_0 y_0 + w_{\mathrm{m}}\eta_{\mathrm{m}}}{w_0 + w_{\mathrm{m}}}, \tag{A.13}$$

and

$$u = \frac{1}{\sqrt{w_0 + w_{\rm m}}} = \frac{1}{\sqrt{\frac{1}{u_0^2} + \frac{1}{u_{\rm m}^2}}} = \frac{u_0 u_{\rm m}}{\sqrt{u_0^2 + u_{\rm m}^2}}. \tag{A.14}$$

A.4.4.2 Bayes' theorem shows the effect of new information about the measurand Y conveyed by the measured value $\eta_{\rm m}$ and the associated standard uncertainty $u_{\rm m}$. The posterior probability density (A.12) is seen to be a normal distribution whose expectation (best estimate) y, expression (A.13), is a weighted average of y_0 and $\eta_{\rm m}$, with the weights equal to the reciprocals of the corresponding associated variances.

A.4.4.3 From expression (A.14) it is seen that the standard uncertainty u associated with the estimate y is always less than both u_0 and $u_{\rm m}$. There are two cases of special interest that are commonly encountered in practice.

— If prior knowledge is so meagre that no attempt is made to assign an explicit prior PDF to the measurand Y, then $u_{\rm m} \ll u_0$ so that $w_{\rm m} \gg w_0$. From expression (A.14) it follows that

$$y \approx \eta_{\rm m}, \qquad u \approx u_{\rm m},$$

and all relevant knowledge of the possible values of Y can be said to derive from the measurement itself. Such measurements are the focus of the GUM, which is a guide to the evaluation of $u_{\rm m}$ given an appropriate measurement model.

— In a typical calibration, a measuring instrument is used to measure a reference standard that realizes an estimate y_0 of a quantity Y with a small associated standard uncertainty u_0. For such a calibration, the systematic error of the instrument is poorly known *a priori* in the sense that $u_0 \ll u_{\rm m}$, or $w_0 \gg w_{\rm m}$. The posterior PDF for Y is then such that, again using expression (A.14),

$$y \approx y_0, \qquad u \approx u_0.$$

In accord with common sense, knowledge of the reference standard is unchanged by the calibration measurement. The instrument reading, however, conveys information about the error of indication of the instrument, which is the quantity of interest in a calibration.

A.5 Risk calculations with normal PDFs and a binary decision rule

A.5.1 General formulæ for the calculation of global consumer's and producer's risks were derived in clause 9.5, and the special case of a conformity assessment with a binary decision rule was treated in clause 9.5.3. It is of interest to derive expressions for the global risks in the common case of a binary decision rule where prior knowledge of a measurand and the possible outputs of a measuring system are both described by normal distributions.

A.5.2 Given normal distributions, expressions (A.7) and (A.8), for the PDFs characterizing the production process and the measuring system, the joint PDF $f(\eta, \eta_{\rm m})$, (expression (16a) on page 26), for the outcome of a measurement is

$$f(\eta, \eta_{\rm m}) = g_0(\eta)\, h\left(\eta_{\rm m}|\eta\right) = \frac{1}{2\pi u_0 u_{\rm m}} \exp\left\{ -\frac{1}{2}\left[\left(\frac{\eta - y_0}{u_0}\right)^2 + \left(\frac{\eta_{\rm m} - \eta}{u_{\rm m}}\right)^2 \right] \right\}.$$

Letting $v = (\eta_{\rm m} - \eta)/u_{\rm m}$, $\mathrm{d}v = \mathrm{d}\eta_{\rm m}/u_{\rm m}$ and $z = (\eta - y_0)/u_0$, $\mathrm{d}z = \mathrm{d}\eta/u_0$ and substituting into expressions (19) and (20) yields, after simplification, the global consumer's and producer's risks:

$$R_{\rm C} = \int_{-\infty}^{\frac{T_{\rm L} - y_0}{u_0}} F(z)\varphi_0(z)\,\mathrm{d}z + \int_{\frac{T_{\rm U} - y_0}{u_0}}^{\infty} F(z)\varphi_0(z)\,\mathrm{d}z \tag{A.15}$$

and

$$R_{\mathrm{P}} = \int_{\frac{T_{\mathrm{L}}-y_0}{u_0}}^{\frac{T_{\mathrm{U}}-y_0}{u_0}} (1 - F(z))\, \varphi_0(z)\, \mathrm{d}z. \qquad \text{(A.16)}$$

In these expressions, $\varphi_0(z) = (1/\sqrt{2\pi}) \exp(-z^2/2)$ is the standard normal PDF and

$$F(z) = \Phi\left(\frac{A_{\mathrm{U}} - y_0 - u_0 z}{u_{\mathrm{m}}}\right) - \Phi\left(\frac{A_{\mathrm{L}} - y_0 - u_0 z}{u_{\mathrm{m}}}\right), \qquad \text{(A.17)}$$

where $\Phi(t)$ is the standard normal distribution function.

Annex B
(informative)
Prior knowledge of the measurand

B.1 Statistical process control

B.1.1 In many conformity assessments, knowledge of a measurand Y prior to making a measurement is not explicitly considered in making accept/reject decisions. In such cases, which are typical of measurements analyzed according to principles described in the GUM, there is an implicit assumption that prior knowledge of Y is so meagre as to have a negligible effect on the outcome of the decision.

B.1.2 For a process in which a number of nominally identical items are produced over time, the nature of the process can be studied by periodically measuring a sample of its output. Statistics generated in the course of such measurements, such as a moving sample average and a sample standard deviation, provide information about the stability of the process so that it can be adjusted as necessary to meet production quality criteria. The generation and use of measurement information in this way forms the basis of statistical process control (SPC). A sizable literature is available; see for example references [33, 43].

B.1.3 The behaviour of a process in SPC is commonly summarized by assuming that a sample of items measured for quality control purposes comprises a set of realizations of a stable frequency distribution. The mean value μ and standard deviation σ of this distribution are estimated from the sample statistics.

NOTE A process for which mean values and standard deviations show acceptable variation with respect to specified limits, from sample to sample, is known as a stable process.

B.1.4 The prior PDF $g_0(\eta)$ for a measurand Y then takes the mathematical form of the frequency distribution suggested by a histogram of measured quantity values. The property of interest for an item chosen at random from the process would then be assigned a best estimate $y_0 = \mu$ and associated standard uncertainty $u_0 = \sigma$.

B.1.5 This typical SPC procedure has two principal shortcomings: (a) reliable process modelling by use of a histogram usually requires a large sample, which might not be available, and (b) the uncertainty associated with the sample measurements is ignored and plays no role in assigning the PDF $g_0(\eta)$. The following approach addresses both of these problems and reduces to the SPC result in the appropriate limits.

B.2 An item chosen at random from a measured sample of items

B.2.1 Consider a sample of n items, each having a property Y of interest in a conformity assessment. The sample is collected over an appropriate period of time from a production process that is assumed to be stable. Examples include:

— a sample of n gauge blocks, each characterized by a length L;

— a sample of n digital voltmeters, each characterized by an error of indication E when measuring a standard reference voltage;

— a sample of n fibre optic connectors, each characterized by an insertion loss Λ.

B.2.2 For each of the n items the property of interest is measured, yielding a set of estimates $y_1, \ldots, y_n$ and an associated standard measurement uncertainty $\widetilde{u}$. The uncertainty $\widetilde{u}$ depends on the procedure used to measure the samples and is assumed to be the same for all of the measurements. The properties of the sample are then summarized by calculating a sample mean $\overline{y}$ and sample variance s^2 defined by

$$\overline{y} = \frac{1}{n}\sum_{k=1}^{n} y_k, \tag{B.1}$$

and

$$s^2 = \frac{1}{n}\sum_{k=1}^{n}(y_k - \overline{y})^2. \tag{B.2}$$

NOTE The sample variance is often defined by dividing the sum $\sum_{k=1}^{n}(y_k - \overline{y})^2$ by $n-1$ rather than n. The resulting quantity can be shown to be an unbiased estimator of the variance σ^2 of a frequency distribution from which the data samples are assumed to be drawn. In defining s^2 in expression (B.2), the goal is not to estimate an unknown variance but rather to characterise the dispersion of the sample values about their mean. If the data are assumed to be a random sample from a normal frequency distribution $\varphi\left(\eta; \mu, \sigma^2\right)$, then the sample variance (B.2) can be shown to be the maximum likelihood estimator of σ^2 [10].

B.2.3 One of the measured items is selected at random (with probability $1/n$) and taken to be representative of the production process. Let Y_r denote the property of interest for the randomly-selected item. Information relevant to the possible values η of Y_r consists only of the sample statistics (B.1) and (B.2), the individual estimates $y_1, \ldots, y_n$ being discarded once the measurements have been performed. Summary properties of the PDF for Y_r can be calculated as follows.

B.2.4 Let $f_\mathrm{r}(\eta)$ be the PDF for Y_r and denote the PDFs for the n sample properties $Y_1, \ldots, Y_n$ by $f_k(\eta)$, $k = 1, \ldots, n$. Noting that each of the n items is equally likely to have been selected, $f_\mathrm{r}(\eta)$ can be written as the marginal PDF

$$f_\mathrm{r}(\eta) = \frac{1}{n}\sum_{k=1}^{n} f_k(\eta), \tag{B.3}$$

called, appropriately, a finite mixture distribution [41].

B.2.5 The form of a particular PDF $f_k(\eta)$ is generally not known, but since it conveys knowledge of the property Y_k of the kth measured item,

$$E(Y_k) = y_k = \int_{-\infty}^{\infty} \eta f_k(\eta)\,\mathrm{d}\eta, \tag{B.4}$$

and

$$V(Y_k) = \widetilde{u}^2 = \int_{-\infty}^{\infty} (\eta - y_k)^2 f_k(\eta)\,\mathrm{d}\eta. \tag{B.5}$$

Given these results and the PDF $f_\mathrm{r}(\eta)$ of expression (B.3), the estimate y_r of the property Y_r and associated standard uncertainty u_r can then be calculated.

B.2.6 For the estimate y_r we have, by definition

$$y_\mathrm{r} = \int_{-\infty}^{\infty} \eta f_\mathrm{r}(\eta)\,\mathrm{d}\eta = \frac{1}{n}\sum_{k=1}^{n}\int_{-\infty}^{\infty} \eta f_k(\eta)\,\mathrm{d}\eta = \frac{1}{n}\sum_{k=1}^{n} y_k,$$

where expression (B.4) has been used in the last step. Comparing this result with expression (B.1) shows that the *a priori* estimate of Y is equal to the sample mean:

$$y_\mathrm{r} = \overline{y}. \tag{B.6}$$

B.2.7 The associated variance of Y, whose positive square root is the standard uncertainty, is then given by

$$u_\mathrm{r}^2 = \int_{-\infty}^{\infty} (\eta - \overline{y})^2 f_\mathrm{r}(\eta)\,\mathrm{d}\eta = \frac{1}{n}\sum_{k=1}^{n}\int_{-\infty}^{\infty} (\eta - \overline{y})^2 f_k(\eta)\,\mathrm{d}\eta. \tag{B.7}$$

Now writing

$$(\eta - \overline{y})^2 = (\eta - y_k + y_k - \overline{y})^2 = (\eta - y_k)^2 + (y_k - \overline{y})^2 + 2(\eta - y_k)(y_k - \overline{y}),$$

using expressions (B.4) and (B.5), and substituting into expression (B.7) leads to the result

$$u_{\mathrm{r}}^2 = \widetilde{u}^2 + \frac{1}{n}\sum_{k=1}^{n}(y_k - \overline{y})^2. \tag{B.8}$$

B.2.8 The sum on the right-hand side of expression (B.8) is seen to be the sample variance s^2 [see expression (B.2)] so that

$$u_{\mathrm{r}}^2 = \widetilde{u}^2 + s^2, \tag{B.9}$$

and the standard uncertainty associated with the prior estimate y_0 is

$$u_{\mathrm{r}} = \sqrt{\widetilde{u}^2 + s^2}. \tag{B.10}$$

B.2.9 The standard uncertainty u_{r} given by expression (B.10) is seen to be a quadrature [or root-sum-square (RSS)] combination of two components which are just the two parameters that summarize the sample data: a term $\widetilde{u}^2$ due to the common standard uncertainty associated with the sample measurements, and a term s^2 that characterizes the variability of the estimates $y_1, \ldots, y_n$.

NOTE Variability due to process variation and lack of measurement repeatability are combined in the observed sample variance s^2. The standard uncertainty $\widetilde{u}$ should include a component that captures the effect of measurement variation.

B.2.10 The calculated estimate and sample variance for the randomly selected item, expressions (B.6) and (B.7), are then taken to characterize future production of the process, assumed to be stable and free of drift. The logical model has a metrologist or inspector reasoning as follows:

> "I have chosen a future item from the production process. What can I say about the property Y of this item before it is measured? Based on the results of the sample measurements, I believe that the best estimate of Y is $y_0 = y_{\mathrm{r}}$, given by expression (B.6), with an associated variance $u_0^2 = u_{\mathrm{r}}^2$ given by expression (B.9). This is the extent of my knowledge. Given this information and the principle of maximum entropy (see JCGM 101:2008 6.3 and reference [45]), I will assign a normal PDF to convey and encode my prior knowledge of the property Y for this item."

B.2.11 This leads to the following normal (or Gaussian) distribution to encode prior knowledge of property Y:

$$g_{\mathrm{o}}(\eta) = \frac{1}{u_0\sqrt{2\pi}} \exp\left[-\frac{1}{2}\left(\frac{\eta - y_0}{u_0}\right)^2\right] = \varphi\left(\eta; y_0, u_0^2\right),$$

with $y_0 = \overline{y}$ and $u_0^2 = \widetilde{u}^2 + s^2$.

B.2.12 In the common case where $s^2 \gg \widetilde{u}^2$, uncertainty in the value of a property of an item chosen at random from the production process is dominated by process variability. Then $u_0 \approx \sigma \approx s$, where the process is modelled by a frequency distribution with a standard deviation σ estimated by the sample standard deviation s.

B.3 A positive property near a physical limit

B.3.1 The normal PDF has an infinite range. In the case of a property (measurand) that is strictly positive, an assigned normal PDF will distribute a fraction of its probability over negative (and thus impossible) values of the property. For a property whose best estimate is within a few times its associated standard uncertainty of zero, this fraction of the probability can be significant. In such a case, assigning a normal PDF would be an unreasonable way to encode knowledge of the measurand.

B.3.2 Many well-known PDFs are restricted to positive values of their arguments. Depending on available information, such a PDF can serve to model knowledge of a measurand Y near a physical limit. In the case where knowledge of $Y \geq 0$ is limited to an estimate and associated variance, as in clause B.2, the principle of maximum entropy leads to the assignment of a normal distribution that is truncated at zero [11]. If values of Y near zero are believed to have negligible probability, assigning a prior PDF $g_0(\eta)$ that approaches zero as $\eta \to 0$ might be appropriate. One such distribution is the gamma PDF, whose use will serve as an example.

B.3.3 The gamma PDF, with positive parameters α and λ, is defined by

$$\mathrm{gamma}\,(\eta; \alpha, \lambda) = \frac{\lambda^\alpha}{\Gamma(\alpha)} \eta^{\alpha-1} e^{-\lambda\eta}, \quad \eta \geq 0, \tag{B.11}$$

where $\Gamma(\alpha)$ is the gamma function:

$$\Gamma(\alpha) = \int_0^\infty x^{\alpha-1} e^{-x}\,\mathrm{d}x.$$

NOTE 1 Special cases of the gamma PDF include $\mathrm{gamma}\,(\eta; 1, \lambda)$ (an exponential PDF with parameter λ) and $\mathrm{gamma}\,(\eta; n/2, 1/2)$ (a chi-squared PDF with n degrees of freedom).

NOTE 2 It is possible to define a 3-parameter gamma distribution by replacing η with $(\eta - \gamma)$ in expression (B.11), where the parameter γ becomes the left end-point and the distribution is restricted to the interval $\eta \geq \gamma$.

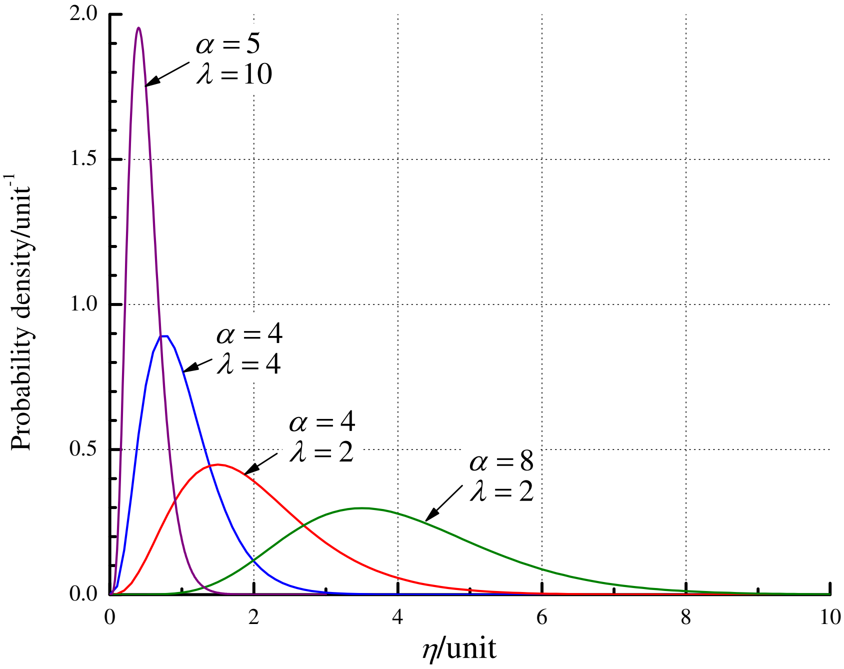

Figure B.1 – **Several** $\mathrm{gamma}\,(\eta; \alpha, \lambda)$ **PDFs, calculated according to expression (B.11), for selected parameter pairs** (α, λ).

B.3.4 Figure B.1 shows four gamma PDFs for particular values of α and λ. The expectation and variance of the gamma PDF are given by

$$E(Y) = y_0 = \frac{\alpha}{\lambda}, \qquad V(Y) = u_0^2 = \frac{\alpha}{\lambda^2}, \tag{B.12}$$

and the maximum value (mode) of the distribution occurs when

$$\eta = \frac{\alpha - 1}{\lambda}. \tag{B.13}$$

B.3.5 Given a particular state of prior information, appropriate values of α and λ can be estimated using these expressions. In the case where knowledge of a property (measurand) Y is obtained by measuring a sample of produced items, the prior estimate and associated variance are estimated by the sample statistics: $y_0 = \overline{y}$ and $u_0^2 = s^2$. Expressions (B.12) can then be solved for the gamma PDF parameters:

$$\alpha = \frac{\overline{y}^2}{s^2}, \qquad \lambda = \frac{\overline{y}}{s^2}. \tag{B.14}$$

These estimates are the so-called 'method of moments' estimates, and may be unsatisfactory for a small sample size. Alternatives are the maximum likelihood estimates, but these typically require some form of numerical optimization or the solution of a system of non-linear equations.

B.3.6 An example using a gamma PDF in the calculation of consumer's and producer's risks is given in clause 9.5.4.

B.3.7 Useful information on properties and uses of probability distributions can be found in the books of Evans, Hastings and Peacock [30] and Johnson, Kotz and Balakrishnan [28].

Annex C
(informative)
Glossary of principal symbols

NOTE The term *probability density function* is abbreviated as PDF.

$\mathcal{A}$	interval of acceptable measured values Y_{m}
$\widetilde{\mathcal{A}}$	interval of non-acceptable measured values Y_{m}
A_{L}	lower acceptance limit
A_{U}	upper acceptance limit
a	lower limit of the interval in which a random variable is known to lie
b	upper limit of the interval in which a random variable is known to lie
$\mathcal{C}$	interval of conforming values of a property of interest (measurand) Y
$\widetilde{\mathcal{C}}$	interval of non-conforming values of a property of interest (measurand) Y
C_{m}	measurement capability index
$E(X)$	expectation of a random variable X
$E(Y\|\eta_{\mathrm{m}})$	conditional expectation of a measurand Y, given a measured quantity value η_{m}
E_{max}	maximum permissible error of indication for a measuring instrument
$\mathrm{erf}(z)$	error function with variable z
$f(\eta, \eta_{\mathrm{m}})$	joint PDF with variables η and η_{m} for quantities Y and Y_{m}
$G_X(\xi)$	distribution function with variable ξ for the quantity X
$\mathrm{gamma}(\eta; \alpha, \lambda)$	gamma PDF with variable η and parameters α and λ
$g\,(\eta\|\eta_{\mathrm{m}})$	PDF with variable η for a measurand Y, given a measured quantity value η_{m}
$g_{0}(\eta)$	PDF with variable η for a measurand Y prior to measurement
$g_{0}(\eta\|I)$	prior PDF with variable η for a measurand Y with explicit display of prior information I; same as $g_{0}(\eta)$
$g_X(\xi)$	PDF with variable ξ for the quantity X
$h\,(\eta_{\mathrm{m}}\|\eta)$	PDF with variable η_{m} for the output quantity Y_{m} of a measuring system, given an assumed true value η of a measurand Y
$h_{0}(\eta_{\mathrm{m}})$	marginal PDF with variable η_{m} for the output quantity Y_{m} of a measuring system
k	coverage factor
$\mathcal{L}\,(\eta; \eta_{\mathrm{m}})$	likelihood of a true value η given a measured quantity value η_{m}
p	coverage probability
p_{c}	conformance probability
$\overline{p}_{\mathrm{c}}$	probability of non-conformance
R_{C}	global consumer's risk
R_{C}^{*}	specific consumer's risk
R_{P}	global producer's risk
R_{P}^{*}	specific producer's risk

s^2	sample variance
T	tolerance
T_{L}	lower tolerance limit
T_{U}	upper tolerance limit
U	expanded uncertainty
u	standard uncertainty
u_0	standard uncertainty associated with estimate y_0 of a measurand Y before performing a measurement
u_{m}	standard uncertainty associated with a measured quantity value η_{m} when prior knowledge of the measurand is negligible
$V(X)$	variance of a random variable X
$V(Y\|\eta_{\mathrm{m}})$	conditional variance of a measurand Y, given a measured quantity value η_{m}
w	length parameter of a guard band
Y	measurable property (measurand) of an item, taken to be a random variable
Y_{m}	output of a measuring system, taken to be a random variable
$\bar{y}$	sample mean
y_0	expectation of Y before performing a measurement
$\tilde{y}$	scaled measured quantity value
α	parameter of a gamma PDF
$\Gamma(z)$	gamma function with variable z
η	variable describing possible values of a measurand Y
λ	parameter of a gamma PDF
$\Phi(z)$	standard normal distribution function with variable z
$\varphi_0(z)$	standard normal PDF with variable z
$\varphi\left(\eta; y, u^2\right)$	normal (Gaussian) PDF with variable η, expectation y and variance u^2

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