LAB 48

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Decision Rules and Statements of Conformity

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Contents

Changes since last edition

Minor corrections:

1. Replace symbol used for guard band factor k with k_w to avoid potential for confusion with coverage factor used to define coverage intervals when reporting measurement results
2. Correction to example following C.6 to state the correct degrees of freedom (3 not 5)
3. Correction to equation D.4, introducing missing terms for degrees of freedom
4. Correction to step 4 in procedure for establishing coverage factor for double-sided acceptance intervals, removing superfluous equation

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Introduction

The general requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate to a quality system, are technically competent and are able to generate technically valid results are contained within ISO/IEC 17025:2017. This international standard forms the basis for international laboratory accreditation and in cases of differences in interpretation remains the authoritative document at all times.

Additional guidance for the purposes of accreditation is provided by ILAC in the form of policy requirements and guidance. In particular, ILAC G8:09/2019 'Guidelines on Decision Rules and Statements of Conformity' provides an overview of the requirements stated in ISO/IEC 17025:2017 that concern statements of conformity (not reproduced here) and describes how certain Decision Rules can be selected and how uncertainty can (and must) be taken into account by either 'direct' or 'indirect' means. It also provides a limited number of worked examples.

The stated purpose of ILAC-G8 is to provide *"an overview for assessors, laboratories, regulators and customers concerning decision rules and conformity with requirements. It does not enter into the details regarding underlying statistics and mathematics but refers readers to the relevant literature. This means that some laboratories, their personnel and their customers may be required to improve their knowledge related to decision rule risks and associated statistics."* This UKAS guidance document, LAB 48, provides some supporting material and additional guidance examples to assist in that process.

The material provided here is quite varied, but it is not intended to cover all possible decision scenarios, rather it is intended to demonstrate various principles. In keeping with the diverse nature of practical conformity decision scenarios the format and structure of the examples is also intentionally diverse.

The main body of this document begins with several examples that address various hypothetical Decision Rule (DR) scenarios. Later examples demonstrate how conformance probability and specific risk may be calculated for various situations and how suitable Decision Rules might be defined.

Finally, several Appendices are provided that give a glossary of some of the terminology used in the main body examples, as well as an overview of how conformance probability and risk can be calculated using standard Excel Worksheet functions in situations where the measurement uncertainty can be described by a Gaussian probability density function (PDF) or a PDF based upon a t-distribution (the same approach remains valid for other PDFs). This later material is provided to support several of the examples, however, as will be seen, evaluation of probability and risk are often not routinely required.

Example 1: Test standard is a "validated" method

Certain types of test are conducted using what is termed a 'validated' method or procedure. These range greatly in robustness from, for example, fully validated analytical methods (e.g. following ISO 5725) through to 'industry accepted' methods (e.g. based on *ad hoc* accepted norms).

The degree to which uncertainty has already been incorporated into a method or standard may be clear and explicit, for example a method uncertainty may be stated which simply needs to be combined with lab-specific factors into a final measurement uncertainty. In these cases, deciding how to take account of measurement uncertainty is usually clear. For example, in the field of regulated environmental testing (such as MCERTS soil and water testing) the measurement uncertainty is usually taken into account through defined performance characteristics for precision (repeatability and/or reproducibility) and bias (method and/or lab) that have been established during validation to be the significant contributors to uncertainty in the methods. Alternatively, in other situations (such as in MCERTS stack emission testing) a more rigorous evaluation of uncertainty is required and need to make a conformity decision is avoided by simply reporting the results (i.e. measured value and a rigorously evaluated measurement uncertainty) together with a statement of the relevant limit value. In a more general sense this (latter) approach has the advantage that the customer makes their decision on the acceptability of the result at their convenience, rather than committing to having their decision recorded on the test or calibration report at the time of measurement.

In other cases, there may be no consideration of uncertainty within the standard, in which case the laboratory must ascertain whether the customer wishes the uncertainty to be *directly* taken into account, as may be possible using the approach described in Appendix C and demonstrated in certain of the later examples. Alternatively, the customer may ask that an *indirect* account should be taken as in several of the next examples.

Example 2: Test scenario with no uncertainty in the outcome

In certain test scenarios there is no uncertainty in the outcome. Instead the outcome is influenced by the conditions under which the test is performed, and these *are* subject to measurement uncertainty.

For example, suppose that the packaging for transportation of a fragile item is to be tested by packing a certain type of glass bottle and then, under specified conditions, dropping the package before unpacking and inspecting the bottle for damage.

The specification and decision rule might be defined as follows:

Specification for test on integrity of packaging containing a glass bottle:

The packaged bottle should remain intact when dropped under the following conditions - height h in range 0.99 m to 1.05 m; temperature T in range 18 °C to 23 °C

Decision Rule

Several rules can be established that take account of measurement uncertainty that has already been evaluated by the laboratory[1]. For example:

> "PASS" if bottle is unbroken AND measurement conditions conform to Simple Acceptance criteria for h and T (i.e. 0.99 m $\leq h \leq$ 1.05 m; 18 °C $\leq T \leq$ 23 °C), *provided also* that $u(h) \leq$ 0.5 cm, $u(T) \leq$ 0.5 °C;
>
> "FAIL" otherwise.

Note that, as demonstrated above, a so called 'Simple Acceptance' decision rule is one in which the Acceptance Interval (range of accepted measurement values) is the same as the Tolerance Interval. In isolation, a Simple Acceptance decision rule does not meet the requirements of a Decision Rule as defined in ISO/IEC 17025:2017 as measurement uncertainty is not taken into account either directly or indirectly. (See Appendix E for further discussion)

The decision rule could alternatively have been expressed in terms of conformance probability for the test conditions, e.g.

> "PASS" if bottle is unbroken AND conformance probability, p_c > 99 % for test conditions h and T;
>
> "FAIL" otherwise.

(See Appendix C for calculation of p_c)

[1] "Already evaluated", since it is an accreditation requirement to evaluate the uncertainty of all key measurements.

Example 3: Test scenario in which a customer asks a laboratory to "ignore uncertainty"

At some point it is likely that a customer will approach a laboratory and ask them to make a conformity decision that "ignores uncertainty".

Accredited reporting of the outcome for such a decision is not permitted by ISO/IEC 17025:2017 nor by ILAC-G8:09/2019 which require that uncertainty should be taken into account (directly or indirectly) when conformity decisions are made. (See Appendix E for further explanation of why rules that take no account of uncertainty are not appropriate.)

The laboratory therefore needs to establish how their customer would like them to proceed.

Fortunately, in practice most customers usually *do* have some, albeit unrecognised or unstated expectation concerning the 'reliability' of the measurement they are asking for. Would they be really be happy with uncertainty of say 10, or a hundred, or a thousand times the specification?

Example

Suppose that a laboratory is approached to test the breaking strain of a sample of thread. The customer declares that the thread is required to remain intact for loads up to 10 N and states that they would like the laboratory to 'ignore uncertainty' since there is no uncertainty requirement mentioned in the associated standard.

During contract review, the laboratory responds by explaining that, for the decision to be reported under their accreditation, uncertainty *cannot* be ignored. The laboratory also explains that, being accredited for the test, they have already established that the applied load can be measured with an expanded uncertainty of better than 0.1 N (k = 2 for approximately 95% coverage probability). Also, to reduce the risk of false acceptance, the laboratory proposes to apply a measured load of 10.1 N

The customer confirms that, in choosing an accredited provider, *they had in fact already assumed that the uncertainty would be appropriate for the test* and that they are therefore content to have the measurement performed under these conditions. The customer also confirms that they would like a binary, PASS/FAIL decision.

Therefore, in this case the outcome might be…

<u>Agreed and reported specification:</u> Conforming thread remains intact under load of 10.1 N

<u>Agreed and reported Decision Rule:</u> "PASS" if the thread remains intact under an applied load of 10.1 N, AND the expanded uncertainty of the measured load is no larger than 0.1 N (k = 2 for approximately 95% coverage probability).

<u>Reported decisions:</u>

Thread remains intact for load L = 10.1 N: PASS

Thread is damaged by load L = 10.1 N: FAIL

The conformance probability for this result can be calculated using (Appendix C.2)

$$p_c = 1 - \mathrm{NORM.DIST}(10, 10.1, 0.1/2, \mathrm{TRUE}) = 0.97725$$

i.e. the probability of false acceptance (*PFA*) is (Appendix C.7)

$$PFA = 1 - p_c = 2.3\ \%$$

Example 4: Test standard does not mention measurement uncertainty

It is a common occurrence for a testing standard to make no mention of measurement uncertainty. There are many possible reasons for this: the standard may predate the GUM (1995) and widespread use of the 'uncertainty framework'; for some reason the authors of the standard may have chosen not to state their requirements or assumptions about the uncertainty that would be achieved in conducting the tests with specified equipment; or the standard may simply be deficient.

Whatever the reason, ISO/IEC 17025:2017 and ILAC-G8:09/2019 require measurement uncertainty to be taken into account, whether directly or indirectly (not least so that the conformity decision is metrologically traceable).

At first sight this seems to present a problem, however the situation is similar to that described in the earlier example in which a customer asks a laboratory to "ignore uncertainty".

Example

Suppose that a laboratory is asked to perform a calibration described in a standard 'ABC123' which defines a hierarchy of equipment and specifies equipment 'accuracy' requirements in terms or 'maximum permissible error' but does not mention measurement uncertainty. The customer states that they would like the laboratory to 'ignore uncertainty' as there is no uncertainty requirement stated in the standard.

During contract review, the laboratory responds confirming that they are able to meet the 'accuracy' requirements and perform the relevant measurements, but for conformity statements to be reported under their accreditation the measurement uncertainty *cannot* be ignored.

The laboratory further explains that in certain cases there could be an undesirable situation where a laboratory's test equipment meets the 'accuracy' (residual error) requirement within the standard but has measurement uncertainties that are larger than the specification owing to factors such as instrument drift and other measurement effects, which would increase the probability of false acceptance.

The laboratory explains however, that in their case the measurement uncertainties are no larger than the accuracy requirement within the standard and provides the customer with the value of the upper limits of the expanded uncertainty ($k = 2$ for 95 % coverage probability) expected for each measurement.

The customer confirms that the proposed limits on measurement uncertainties are appropriate for their requirements. The customer also confirms that they would like a binary, PASS/FAIL decision.

Therefore, in this case…

Agreed and reported specification:
Calibration and tolerances as defined by the accuracy requirements in ABC123.

Agreed and reported Decision Rule:
"PASS" indicates that the instrument conforms with the relevant accuracy requirements of the testing standard AND the expanded measurement uncertainty ($k = 2$ for approximately 95 % coverage probability) is no greater in magnitude than the accuracy requirements defined in table X of ABC123.

Example 5: Double sided tolerance limit, DR: p_c ≥ 95 %

A customer's acceptance criteria (specification) for a 2 MPa pressure transducer is that "calibration errors should be no larger than 0.5 % of nominal full scale" but they have not specified a decision rule.

The laboratory therefore proposes the following rule:

DR: At each measured calibration pressure, report as "Pass" when there is at least 95 % probability that the error meets specification. Otherwise report as "Fail".

A set of calibration results can then be reported as follows:

Specification: Calibration errors should be no more than ±0.5 % of nominal full scale, 2 MPa

Decision Rule: At each measured calibration pressure, report as "Pass" when there is at least 95 % probability that the error meets specification. Otherwise report as "Fail".

Uncertainty of measurement for e is $U(e)$ = 0.004 MPa = 0.2 % FS

The reported expanded uncertainty $U(e)$ is based on a standard uncertainty multiplied by a coverage factor k = 2, providing a coverage probability of approximately 95 %. The uncertainty evaluation has been carried out in accordance with UKAS requirements.

Results:

Indicated pressure p_{ind} /MPa	Transducer error $e_{\%\mathrm{FS}}$ /%	Decision	Conformance probability
1.995	0.25	Pass	0.994
1.494	0.30	Pass	0.977
0.993	0.35	Fail	0.933
0.492	0.40	Fail	0.841
0.083	0.35	Fail	0.933
-0.006	0.30	Pass	0.977

Where, at each reference pressure, p_{ref}, the transducer error is calculated from

$$e_{\%\mathrm{FS}} = \frac{100 \times \left(p_{ref} - p_{ind}\right)}{2\ \mathrm{MPa}}$$

In use, corrected pressure, $p = p_{ind} + e_{\%\mathrm{FS}} \times \frac{2}{100}$

In this example the conformance probability has been calculated for each measurement of transducer error with standard uncertainty $u = 0.1$ % FS.

For example, conformance probability for p_{ind} = 1.995 MPa is evaluated from (Appendix C.3)

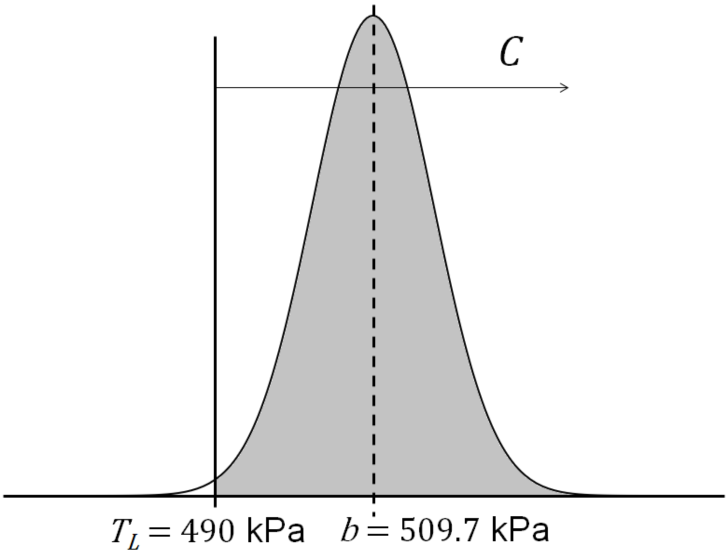
$p_c = \mathrm{NORM.DIST}(T_U, e_{\%\mathrm{FS}}, u, \mathrm{TRUE}) - \mathrm{NORM.DIST}(T_L, e_{\%\mathrm{FS}}, u, \mathrm{TRUE})$ i.e.

$$p_c = \mathrm{NORM.DIST}(0.5, 0.25, 0.1, \mathrm{TRUE}) - \mathrm{NORM.DIST}(-0.5, 0.25, 0.1, \mathrm{TRUE}) = 0.994$$

(See Appendix C for details of this calculation)

Example 6: Single sided lower tolerance limit (JCGM106 7.3.3 Ex 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 $B \geq$ 490 kPa, which is a lower limit on the bursting strength.



The conformance probability p_c is therefore (see Appendix C.2)

$p_c = 1 - \mathrm{NORM.DIST}(490, 509.7, 8.6, \mathrm{TRUE}) = 0.99$

i.e. the conformance probability for this container is 99 %

If a decision is taken to *accept* it as conforming the probability of false acceptance is (C.7)

$PFA = 1 - p_c = 1\,\%$

Possible Decision Rules for this conformity decision might therefore be defined in terms of p_c or PFA, for example:

DR: “ACCEPT when $p_c \geq 95\,\%$; REJECT otherwise”

or equivalently

DR: “ACCEPT when $PFA \leq 5\,\%$; REJECT otherwise”

This result might be reported as:

“ACCEPT, with a conformance probability of 99 % which meets acceptance criterion of $p_c \geq 95\%$”

or equivalently

“ACCEPT, with probability of false acceptance of 1 % which meets acceptance criterion of $PFA \leq 5\,\%$”

Supposing instead that b = 495.2 kPa.

In this case

$p_c = 1 - \mathrm{NORM.DIST}(490, 495.2, 8.6, \mathrm{TRUE}) = 0.73$

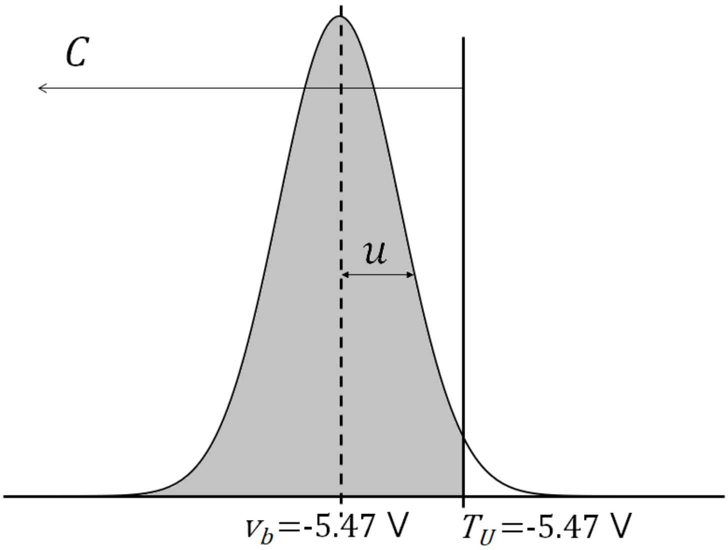
This result might therefore be reported as:

> "REJECT, with a conformance probability of only 73 % which does not meet acceptance criterion of $p_c \geq 95\%$"
>
> or
>
> "REJECT, unable to meet PFA requirements"

Example 7: Single sided upper tolerance limit (JCGM106 7.3.3 Ex 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 $V_b = -5.40$ V, which is an upper limit on the breakdown voltage.



The conformance probability p_c is represented by the portion of the PDF within conformity interval C where (C.1)

$$p_c = \text{NORM.DIST}(-5.4, -5.47, 0.05, \text{TRUE}) = 0.92$$

i.e. the conformance probability for this diode is 92 %

If a decision is taken to accept it as conforming the probability of false acceptance is (C.7)

$$PFA = 1 - p_c = 8\ \%$$

Possible Decision Rules for this conformity decision might therefore be defined in terms of p_c or PFA, for example:

DR: “ACCEPT when $p_c \geq 0.95$; ($PFA < 5$ %)

REJECT when $p_c \leq 0.90$; ($PFA > 10$ %)

UNDETERMINED otherwise”

This result for the example above might be reported as:

“UNDETERMINED, with a conformance probability of 0.92 which does not meet criteria for acceptance ($p_c \geq 0.95$) or rejection ($p_c \leq 0.90$)”

Example 8: Single sided upper tolerance limit, DR: Pass when $PFA \leq PFA_{max}$

Suppose that in the testing of Zener diode breakdown voltage as described previously, a probability of false acceptance of up to 0.5 % is allowed.

Suppose also that the measurement uncertainty is the same, u = 0.05 V for *all* measurements of breakdown voltage made using this system.

In this case we can establish a *fixed value for an upper acceptance limit* A_U corresponding to PFA_{max} = 0.5 % . Where (Appendix D.3)

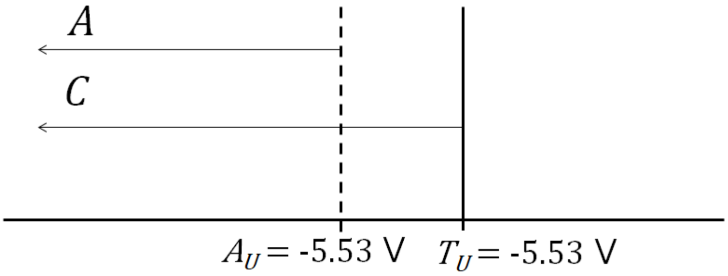
$A_U = T_U - k_w.u$

The required guard band factor can be calculated or found in tables (Appendix D.1) to be

$k_w = \mathrm{NORM.S.INV}(1 - PFA_{max}) = \mathrm{NORM.S.INV}(0.995) = 2.58$

therefore

A_U = -5.53 V



The region between A_U and T_U is known as a 'guard band'.

Now when any measurements are performed (with u = 0.05 V), all that is required is to test whether the result is within the acceptance interval ($v_b \leq$ -5.53 V) to accept a diode as conforming.

Possible Decision Rules for this conformity decision might therefore be defined in terms of PFA or p_c or A_U for example:

DR: "PASS when $PFA < 0.5$ % ($p_c \geq 0.995$); FAIL otherwise"

or equivalently

DR: "PASS when the measured value does not exceed an upper acceptance limit A_U, which is defined in terms of the upper tolerance limit T_U and a guard band that is calculated to ensure a conformance probability of at least 99.5 %; FAIL otherwise"

Results might be reported as:

"PASS, with $PFA \leq 0.5$ % "; or equivalently

"PASS, measured value does not exceed the upper acceptance limit"

or

"FAIL, unable to meet PFA requirements"

Example 9: Single sided upper tolerance limit, DR: Accept when $\boldsymbol{PFA} \leq \boldsymbol{PFA_{max}}$

A machine is designed to shred pruned tree branches up to a diameter of 50 mm. Larger diameter branches will go through the machine, but the owner of the machine does not wish this to happen more frequently than 10 % of the time. He therefore uses a simple calliper to measure the diameter with a standard uncertainty of $u = 5$ mm.

What limit should he place on measured diameter? Or in other words, what size Guard Band should be applied?

The owner wishes to only falsely accept (i.e. attempt to shred an oversized branch) 10 % of the time, i.e.

PFA_{max} = 0.1

Upper tolerance limit is T_U = 50 mm

So (Appendix D.3)

$A_U = T_U - k_w.u$

where k is found by using the Table in Appendix D, or by calculation (D.1)

$k_w = \mathrm{NORM.S.INV}(1 - 0.1) = \mathrm{NORM.S.INV}(0.9) = 1.28$

Hence

A_U = 50 – 1.28 x 5 = 43.5 mm

The owner should only accept branches measured to have a diameter of 43.5 mm or less.

Possible Decision Rules for this conformity decision might therefore be defined in terms of PFA, for example:

DR: “ACCEPT when measured diameter < 43.5 mm, for $PFA < 10$ % ; REJECT otherwise”

Example 10: Single sided lower tolerance limit, DR: Accept when $PFA \leq PFA_{max}$

In some situations, we may be more interested in *not* rejecting potentially conforming items i.e. we are prepared to Accept, even when the chance of falsely accepting is high. (This is a so-called *relaxed acceptance* scenario, in which the range of acceptable measurement results is *wider* that the tolerance range for the measurand).

For example, a gold miner performs initial grading by measuring the apparent density of each ore sample. Gold ore has a typical density of 19320 kg m^{-3}.

Because of the potential value of the ore he is happy to bear the cost associated with a high probability of false acceptance at this stage of his process, up to a maximum of 99.5 %.

Possible Decision Rules for this conformity decision might therefore be defined in terms of PFA or p_c, for example:

DR: "Accept when $PFA \leq 99.5$ %; Reject otherwise"

or equivalently

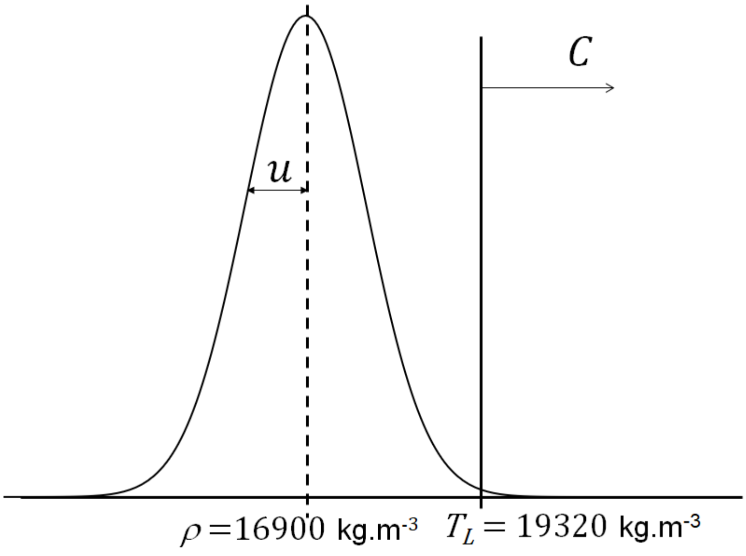
DR: "Accept when $p_c \geq 0.5$ %; Reject otherwise"

For example, if a sample has an apparent density ρ = 16900 kg m^{-3} with an associated standard uncertainty u = 1000 kg m^{-3} the miner calculates that (C.2)

$$p_c = 1 - \text{NORM.DIST}(19320, 16900, 1000, \text{TRUE}) = 0.8\ \%$$

and (C.7)

$$PFA = 1 - p_c = 99.2\ \%$$



The result for this particular sample might then be reported as:

"Accepted as conforming, having a probability of false acceptance of no more than 99.5 %" or

"Accepted as conforming, having a conformance probability of at least 0.5 %"

If a second sample has an apparent density ρ = 16500 kg m^{-3} also with an associated uncertainty of u = 1000 kg m^{-3} the miner calculates that

$$p_c = 1 - \text{NORM.DIST}(19320, 16500, 1000, \text{TRUE}) = 0.2\ \%$$

$$PFA = 1 - p_c = 99.8\ \%$$

This result might then be reported as:

"Rejected as non-conforming, unable to meet PFA requirements"

or

"Rejected as non-conforming, having a conformance probability of less than 0.5 %"

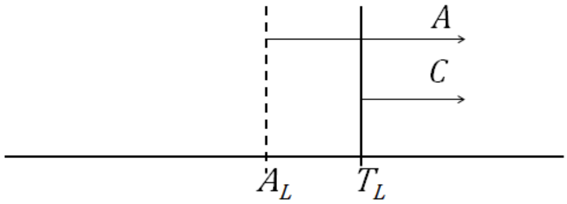
If the uncertainty of the process is always u = 1000 kg m^{-3} the miner can establish a guard band, i.e. calculate a fixed value for a lower acceptance limit A_L corresponding to PFA_{max} = 99.5 % i.e. (using D.2 and D.1)

$$A_L = T_L + k_w.u$$

$$k_w = \text{NORM.S.INV}(1 - PFA_{max}) = \text{NORM.S.INV}(0.005) = -2.58$$

hence

A_L = 16744 kg m^{-3}



Now when any measurements are performed (with u = 1000 kg m^{-3}), all that is required is to test whether the result is within the acceptance interval ($\rho \geq$ 16744 kg m^{-3}) to accept a sample for further grading.

A possible Decision Rule for this conformity decision might therefore be defined in terms of

DR: "ACCEPT when the measured value exceeds a lower acceptance limit A_L, which is defined in terms of the lower tolerance limit T_L and a guard band that is calculated to ensure a conformance probability of at least 0.5 %; REJECT otherwise"

The corresponding conformity statement could be the same as above.

"ACCEPT, the measured value meets or exceeds the lower acceptance limit"

Example 11: Single sided upper tolerance limit, DR: Accept when $PFA \leq PFA_{max}$ (JCGM106 8.3.3.2 Ex 1)

In highway law enforcement, the speed of motorists is measured by police using devices such as radars and laser guns. 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 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 0.02 v.

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_0 is exceeded is at least 99.9 %?

In this example, the tolerance interval corresponds to speeding motorists. To minimize the risk of false prosecution the test requires PFA_{max} = 0.001. Therefore, at the acceptance limit the probability must be better than p_c = 0.999

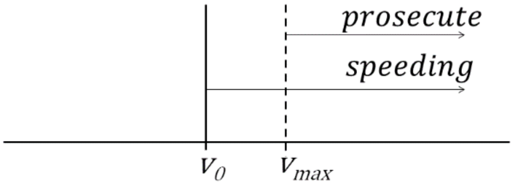
Possible Decision Rules for this conformity decision might therefore be defined in terms of PFA or p_c, for example:

DR: "Prosecute when $PFA \leq$ 0.1 % ; Reject otherwise"; or equivalently

DR: "Prosecute when $p_c \geq$ 0.999 ; Reject otherwise"; or

DR: "Prosecute when measured speed $v \geq v_{max}$ (the probability that v_0 is exceeded is at least 99.9 %?

$$k_w = \text{NORM.S.INV}(1 - PFA_{max}) = \text{NORM.S.INV}(0.999) = 3.09$$



Lower limit of speeding motorists is v_0 = 100 km/h and (D.2)

$$A_L = T_L + k_w . u$$

hence

$$v_{max} = v_0 + k_w \times (0.02 \times v_{max})$$

therefore

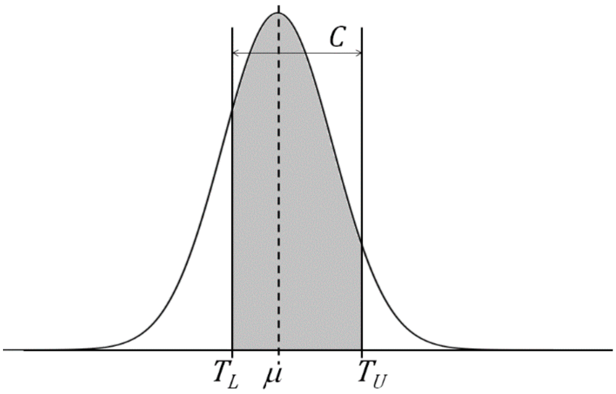
$$v_{max} = \frac{v_0}{1-0.02k_w} = \frac{100}{1-0.062} \approx 107 \text{ km/h}$$

To ensure that on average only 0.1 % of drivers are falsely prosecuted the detected speed should be in excess of 107 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 12: Double sided tolerance limits (JCGM106 7.4)

A sample of SAE Grade 40 motor oil is required to have a kinematic viscosity 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 μ = 13.6 mm^2/s and associated standard uncertainty u = 1.8 mm^2/s.



The conformance probability p_c is represented by the portion of the PDF within the interval C i.e. (Appendix C.3)

$$p_c = \text{NORM.DIST}(16.3, 13.6, 1.8, \text{TRUE}) - \text{NORM.DIST}(12.5, 13.6, 1.8, \text{TRUE}) = 0.66$$

i.e. the conformance probability for this oil sample is 66 %

If a decision is taken to accept it as conforming the probability of false acceptance is (C.7)

$$PFA = 1 - p_c = 34\ \%$$

Possible Decision Rules for this conformity decision might therefore be defined in terms of p_c or PFA, for example:

DR: “Accept when $p_c \geq 0.6$; Reject otherwise”

or

DR: “Accept when $PFA \leq 40$ % ; Reject otherwise”

This result might then be reported as:

“Conforming, having a conformance probability of 66 %”

or

“Conforming, having a probability of false acceptance of 34 %”

However, if the associated standard uncertainty was u = 2.2 mm²/s this would instead result in a conformance probability of

$$p_c = \mathrm{NORM.DIST}(16.3, 13.6, 2.2, \mathrm{TRUE}) - \mathrm{NORM.DIST}(12.5, 13.6, 2.2, \mathrm{TRUE}) = 0.58$$

i.e. the conformance probability for this (same) oil sample is 58 %

If a decision is taken to accept it as conforming the probability of false acceptance is

$PFA = 1 - p_c = 42\ \%$

Applying the same Decision Rule, this result might then be reported as:

"Not conforming, having a conformance probability of only 58 %"

or

"Not conforming, unable to meet PFA requirements "

Suppose that instead of suggesting a Gaussian distribution for likely values of the measurand, the uncertainty evaluation indicates that a t-distribution is more appropriate, having say $\nu = 3$ degrees of freedom. For the original example above, the conformance probability is now found (Appendix C.6) to be

$$p_c = \mathrm{T.DIST}\left(\left(\frac{16.3-13.6}{1.8}\right), 3, \mathrm{TRUE}\right) - \mathrm{T.DIST}\left(\left(\frac{12.5-13.6}{1.8}\right), 3, \mathrm{TRUE}\right) = 0.593$$

(which in this case, according to the possible Decision Rule proposed, would change the conformity decision from Accept to Reject).

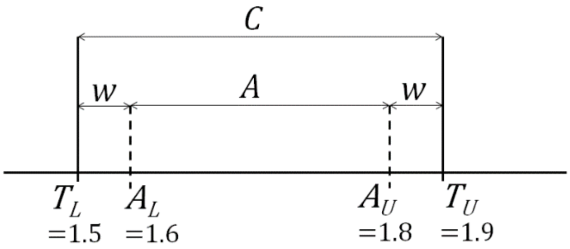
Example 13: Double sided tolerance limit, DR1: $w = 2u$; DR2: 'Constrained' Simple Acceptance with $u \leq u_{max}$

Suppose that requirements for a material specify that the surface roughness r for a sample should be in the range $(T_L = 1.5) \leq r \leq (T_U = 1.9)$

Two possible decision rules that might be considered are…

DR1: A guard band of $w = 2.u_{\max}$ at each side of the tolerance interval. i.e. accept as conforming all results r where $A_L \leq r \leq A_U$ (with limits $A_L = (T_L + w)$ and $A_U = (T_U - w)$)

For standard uncertainty u = 0.05 this corresponds to acceptance when 1.6 ≤ r ≤ 1.8



DR2: Simple Acceptance $(A_L = T_L) \leq r \leq (A_U = T_U)$ AND $u \leq 0.05$; or equivalently

Simple Acceptance $(A_L = T_L) \leq r \leq (A_U = T_U)$ AND Test Uncertainty Ratio (TUR) ≥ 2

$(TUR = (T_U - T_L)/4u)$

Outcomes for some possible measured values r with u = 0.05

r	Decision DR1	Decision DR2	$PFA = 1 - p_c$ (associated with PASS decisions)
1.7	PASS	PASS	0.01 %
1.75	PASS	PASS	0.14 %
1.8	PASS	PASS	2.3 %
1.85	FAIL	PASS	16 %
1.9	FAIL	PASS	50 %
>1.9	FAIL	FAIL	

Note that:

DR1 - Risk can be stated as "PFA no worse than 2.3 %" for all measured values 1.6 ≤ r ≤ 1.8

(For a PFA 'no worse than 5 %' , narrower guard bands of 1.645 u could be applied)

DR1 – rejection rate is higher than DR2

DR2 – Risk can be stated as "PFA no worse than 50 %" for all measured values 1.5 ≤ r ≤ 1.9

The choice of Decision Rule may depend for example upon how important it is to maintain low PFA, or how important it is to maintain a low rejection rate.

Example 14: Inspection of levels (conformity decisions for discrete measurements)

In its simplest form, the basic GUM law of propagation of uncertainties (LPU) approach to uncertainty evaluation is based upon two *assumptions*: the Central Limit Theorem applies i.e. the 'output' probability density function is taken to be Gaussian for the combination of 'input' quantities; and the variance in the output (the square of the standard uncertainty) is the sum of variances for the input quantities.

When these two assumptions apply, calculating the probability of conformity with a specification is usually a matter of establishing the proportion of the 'output' Gaussian distribution that overlaps the specification.

It is often incorrectly assumed that GUM LPU *always* applies or that it is 'close enough' that it can always be used. In fact, this is not the case and various methods are available to establish a 'better' understanding or representation of the uncertainty (e.g. Welch-Satterthwaite approach for dominant type A contributions with low degrees of freedom).

The GUM allows for other situations to apply and allows other means of evaluation within the general GUM framework. Such an approach is necessary in the case highlighted below. The approach makes use of the probabilistic nature of uncertainty evaluation and allows for the discrete nature of the measurements.

Example measurement and conformity scenario

Suppose that a measurement can have only discrete values on a progressive scale of distinct levels. For example, visual evaluation of colour fading when compared against a reference scale.

Specification for conformity is stated in terms of acceptable levels.

Example a:

The uncertainty is entirely determined by the ability to resolve adjacent levels and is such that when measurement result is level 'm' there is an equal probability of the 'true' level being $(m-1)$, m, or $(m+1)$

Specification: A conforming result will be at or between levels a and b

Decision Rule: A Simple Acceptance rule is to be applied. In addition, measurement uncertainty must be "entirely determined by the ability to resolve *adjacent* levels i.e. if measurement result is level 'm' then there is an *equal probability* of the 'true' level being $(m-1)$, m, or $(m+1)$"

Numerical example:

Suppose a scale is defined as (0, 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0…)

Suppose also that the specification is that result must be 2.0 ± 0.5, i.e. conforming values are 1.5, 2.0, or 2.5

Now suppose that measurement result is 1.5

As this result is within specification the result 'conforms' (Simple Acceptance criteria).

If the Decision Rule is provided *to* the laboratory there is no (ISO 17025:2017) requirement upon them to evaluate the associated risk. The result can simply be reported as 'conforming' in terms of the associated specification and Decision Rule.

If, however the Rule is defined *by* the laboratory then the Risk is established as follows… for the observed result (1.5) there are three possible 'true' values that are *equally probable* according to our knowledge of the uncertainty. These are (1.0, 1.5, 2.0). Of these possible values two are conforming (1.5 and 2.0) and one is not (1.0). The probability of conformity is therefore 2/3 i.e. 66.7 %, and the probability of false acceptance is 1/3 i.e. 33.3 %.

Suppose instead that the result was 2.0. In this case, the three possible 'true' values that are equally probable according to our knowledge of the uncertainty are (1.5, 2.0, 2.5). Of these possible values all three are conforming so the probability of conformity is therefore 100 %.

This probability of conformity of course depends upon the fact that the uncertainty is "entirely determined by the ability to resolve *adjacent* levels". If there is any doubt that the uncertainty could be larger the '100 %' claim cannot be made (although it may in practice be 'approximately 100 %').

For completeness, if the result was 2.5 the three possible 'true' values that are equally probable according to our knowledge of the uncertainty are (2.0, 2.5, 3.0). Of these possible values two are conforming. The probability of conformity is therefore 2/3 i.e. 66.7 %, and the probability of false acceptance is 1/3 i.e. 33.3 %.

On average, for all conforming results this example has probability of conformity, p_c of 78 % i.e. a PFA of 22 %.

Other possible scenarios might exist.

Example b:

As for Example (a) except that uncertainty is such that the *observed level m is twice as likely as an adjacent level*: $p(m-1) = 0.25$, $p(m) = 0.5$, $p(m+1) = 0.25$

The numerical example then gives for conforming results:

Result	p_c	PFA
1.5	75 %	25 %
2.0	100 %	0 %
2.5	75 %	25 %

On average, for all conforming results this example has probability of conformity, p_c of 83 % i.e. a PFA of 17 %

Example c:

As for Example (a) except that the specification now only permits two acceptable levels (1.5, 2.0)

The numerical example then gives for conforming results:

Result	p_c	PFA
1.5	67 %	33 %
2.0	67 %	33 %

On average, for all conforming results this example has probability of conformity, p_c of 67 % i.e. a PFA of 33 %

Example d:

As for Example (b) except that the specification now only permits two acceptable levels (1.5, 2.0)

Numerical example then gives for conforming results:

Result	p_c	PFA
1.5	75 %	25 %
2.0	75 %	25 %

On average, for all conforming results this example has probability of conformity, p_c of 75 % i.e. a PFA of 25 %

Appendix A: Glossary

Terminology used in this document is consistent with ISO/IEC Guide 98-4:2012 (JCGM 106).

T_U upper limit of conformity

T_L lower limit of conformity

C conformance interval, corresponding to conforming values for a *measurand*, usually described in terms of a 'tolerance' or 'specification'

A_U upper limit of acceptance

A_L lower limit of acceptance

A acceptance interval, corresponding to *measured values* that are accepted as demonstrating conformity for the measurand.

Y variable used to represent a measurand

η variable describing possible values of a measurand Y

y_m measured estimate of the value of the measurand

u, u_m standard uncertainty associated with the measured quantity

PFA probability of false acceptance, sometimes known as 'consumers risk'

PFR probability of false rejection, sometimes known as 'producers' risk'

p_c conformance probability

k_w guard band factor, used to define a guard band w as a multiple of measurement uncertainty $w = k_w.u$

CAUTION: The symbol k is commonly used to represent the guard band factor (hence its use here). It should not be confused with the coverage factor that is used to establish an expanded uncertainty e.g. to define a coverage interval for a measurement result.

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

Simple Acceptance: condition under which an Acceptance Interval is defined to be the same as a Conformity Interval, $A = C$. Simple Acceptance *on its own* does not constitute a Decision Rule (as explained in Appendix E)

Guard band: interval between conformity limit and acceptance limit, usually defined as some multiple of the uncertainty with the purpose of limiting the probability of false acceptance.

Appendix B: Measurement results and specifications

A probability distribution, for example described by a probability density function (PDF), gives the probability that possible values of a measurand Y lie within a stated interval

For measurements where the uncertainty has been evaluated using the 'law of propagation of uncertainties' approach as described in the GUM (and other guides such as M3003) the probability distribution for the measurand is usually a Gaussian (or 'normal') distribution with expectation y_m and standard deviation u_m.

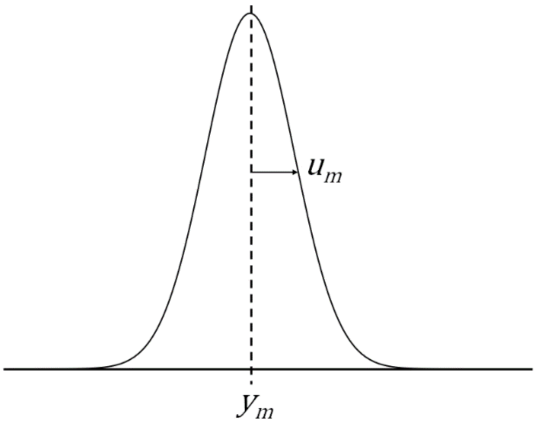


Figure 1: A Gaussian PDF

In this situation the PDF is the Gaussian PDF described by the function

$$g(\eta; y_m, u_m) = \frac{1}{u_m\sqrt{2\pi}} \exp\left[-\frac{1}{2}\left(\frac{\eta - y_m}{u_m}\right)^2\right]$$

for possible values η of the measurand.

With this knowledge we can evaluate the probability that the measurand has a value that is consistent with some defined specification.

A specification can be defined in terms of a tolerance interval C as illustrated in the following figures

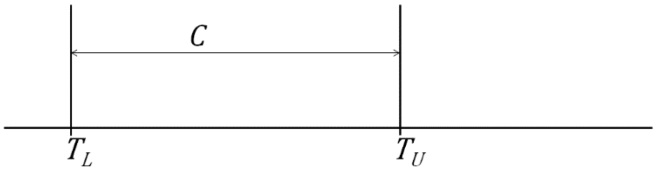


Figure 2: A double sided tolerance interval with both upper and lower limits. Conforming values are between these limits

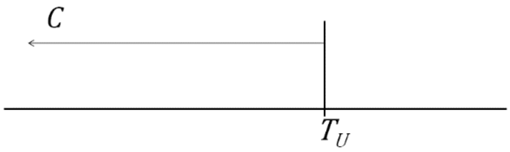


Figure 3: For a single upper limit conforming values of Y are less than or equal to the limit value

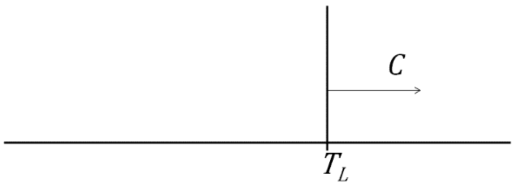


Figure 4: For a single lower limit conforming values of Y are greater than or equal to the limit value

Appendix C: Conformance probability and risk

The values of Y that fall within the tolerance interval C represent conforming values of the measurand that could have given rise to the measurement result. For a Gaussian distribution, the area under the PDF defined by these values is the conformance probability p_c

$$p_c = \int_C g(\eta; y_m, u_m) d\eta$$

For example, in the figure below the *shaded* region of the PDF is within the tolerance interval and represents *conforming* values of the measurand that can be associated with the measurement result. Whereas the unshaded region represents *non-conforming* values of the measurand that can similarly *also* be attributed to the measurement result.

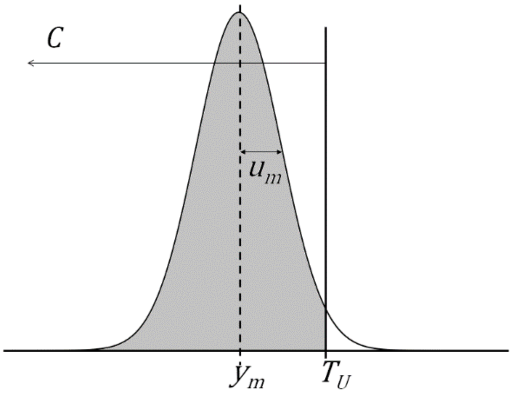


Figure 5: A measured value within a tolerance interval that is defined by a single upper limit

Definite Integrals of the Gaussian PDF can be calculated using the Excel function NORM.DIST where

$$\int_{-\infty}^{T} g(\eta; y_m, u_m) d\eta = \mathrm{NORM.DIST}(T, y_m, u_m, \mathrm{TRUE})$$

Conformance probability for an *upper* limit is therefore

$$p_c = \mathrm{NORM.DIST}(T_U, y_m, u_m, \mathrm{TRUE}) \qquad \text{C.1}$$

Similarly, conformance probability for a *lower* limit is

$$p_c = 1 - \mathrm{NORM.DIST}(T_L, y_m, u_m, \mathrm{TRUE}) \qquad \text{C.2}$$

And conformance probability for a *two-sided* limit is therefore

$$p_c = \mathrm{NORM.DIST}(T_U, y_m, u_m, \mathrm{TRUE}) - \mathrm{NORM.DIST}(T_L, y_m, u_m, \mathrm{TRUE}) \qquad \text{C.3}$$

For example, suppose that in the case shown above $T_U = 1.96$, $y_m = 0$, $u_m = 1$ then

$$p_c = \int_{-\infty}^{T_U} g(\eta; y_m, u_m) d\eta = \text{NORM.DIST}(1.96{,}0{,}1, \text{TRUE})$$

i.e.

$$p_c = \text{NORM.DIST}(1.96, 0, 1, \text{TRUE}) = 0.975 = 97.5\ \%$$

The corresponding equations for calculating conformance probability for a t-distribution with ν degrees of freedom are:

Conformance probability for an ***upper*** limit

$$p_c = \text{T.DIST}\left(\left(\frac{T_U - y_m}{u}\right), \nu, \text{TRUE}\right) \quad \text{C.4}$$

Conformance probability for a ***lower*** limit

$$p_c = 1 - \text{T.DIST}\left(\left(\frac{T_L - y_m}{u}\right), \nu, \text{TRUE}\right) \quad \text{C.5}$$

And conformance probability for a ***two-sided*** limit

$$p_c = \text{T.DIST}\left(\left(\frac{T_U - y_m}{u}\right), \nu, \text{TRUE}\right) - \text{T.DIST}\left(\left(\frac{T_L - y_m}{u}\right), \nu, \text{TRUE}\right) \quad \text{C.6}$$

For example, suppose that in the case shown above $T_U = 1.96$, $y_m = 0$, $u_m = 1$ and $\nu = 3$ then

$$p_c = \text{T.DIST}\left(\left(\frac{1.96 - 0}{1}\right), 3, \text{TRUE}\right) = 0.928 = 92.8\ \%$$

With knowledge of the conformance probability it becomes possible to evaluate the risk associated with a decision to accept or reject a result. For example, consider a decision based upon a measurement of some property of an item whose specification has a lower tolerance limit, T_L defining a single-sided tolerance interval C: $[T_L,\infty)$. When the measured value y_m is close to the limit value, a proportion of the PDF can be located both above and below the limit. Two scenarios are possible in this case:

a. The measured value is *within* the tolerance interval i.e. $y_m \geq T_L$

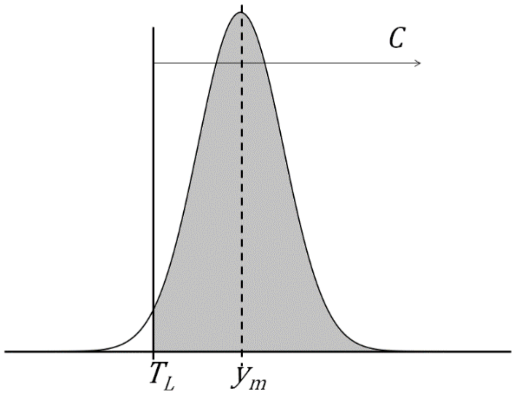


Figure 6: measured value within a tolerance interval that is defined by a single lower limit

The value of y_m suggests that the item *does* conform, however there are possible values for the measurand (unshaded region) that are *not* conforming. If a decision is taken that the item *is* conforming this (unshaded) area represents the probability of false acceptance (PFA).

b. The measured value is outside the tolerance interval i.e. $y_m < T_L$

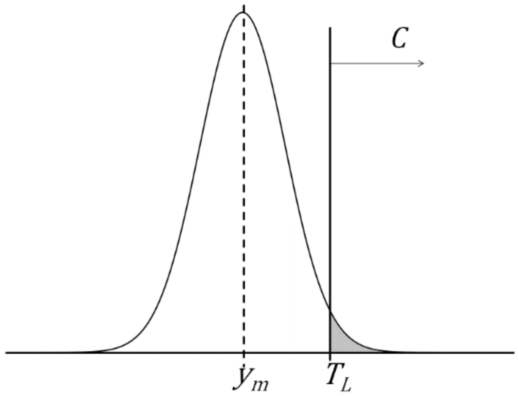


Figure 7: measured value outside a tolerance interval that is defined by a single lower limit

The value of y_m suggests that the item does *not* conform however there are possible values for the measurand that *are* conforming. If a decision is taken that the result is non-conforming this (shaded) region represents the probability of false rejection (PFR).

Note that in some situations the probabilities of false acceptance and false rejection are called the 'specific consumers risk' and 'specific producer's risk' – when an item has been falsely accepted as conforming it is the consumer that bears the cost, whereas when an item is falsely rejected it is the producer who bears the cost.

These examples also illustrate the relationship between conformance probability and the associated 'specific' risks:

$PFA = 1 - p_c$ (applicable only when conformity has been accepted) C.7

$PFR = p_c$ (applicable only when conformity has been rejected) C.8

For example, suppose that in case a) $T_L = 0,\ y_m = +1.64,\ u_m = 1$ then

$$p_c = \int_{T_L}^{\infty} g(\eta; y_m, u_m) d\eta \ = \ 1 - \int_{-\infty}^{T_L} g(\eta; y_m, u_m) d\eta \ = \ 1 - \mathrm{NORM.DIST}(0{,}1.64{,}1, \mathrm{TRUE})$$

i.e. $p_c = 1 - \mathrm{NORM.DIST}(0, 1.64, 1, \mathrm{TRUE}) = 0.95 = 95\ \%$

If in this case a decision was made to 'Accept', the probability of false acceptance would be $PFA = 1 - p_c = 5\ \%$

because statistically speaking, 5% of the possible non-conforming values for the measurand could have resulted in the 'conforming' result y_m

Similarly, suppose that in case b) above we have $T_L = 0,\ y_m = -1.64,\ u_m = 1$ then

$$p_c = \int_{T_L}^{\infty} g(\eta; y_m, u_m) d\eta \ = \ 1 - \int_{-\infty}^{T_L} g(\eta; y_m, u_m) d\eta \ = \ 1 - \mathrm{NORM.DIST}(0, -1.64{,}1, \mathrm{TRUE})$$

i.e. $p_c = 1 - \mathrm{NORM.DIST}(0, -1.64, 1, \mathrm{TRUE}) = 0.05 = 5\ \%$

In this case if a decision was made to ‘Reject’, the probability of false rejection would be
$PFR = p_c = 5\,\%$

because statistically speaking, 5% of the possible conforming values for Y could have resulted in the ‘non-conforming’ result y_m

To restrict or minimise the risk of making incorrect decisions, constraints can be placed on the measured values that are accepted or rejected as conforming. These constraints define an acceptance interval A

The difference between the acceptance interval and the tolerance interval is the guard band w

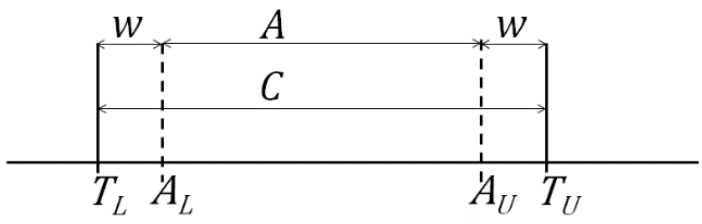


Figure 8: Tolerance interval C and 'stringent' acceptance interval A with associated guard bands w

The choice of where to place the limits of the acceptance interval A_U and/or A_L either determines PFA_{max} or alternatively, the choice of PFA_{max} determines the acceptance limits. PFA_{max} is the largest value that PFA can have whilst the decision is to Accept, similarly, PFR_{max} is the largest value that PFR can have whilst decision is to Reject.

A common form of guard band is chosen to establish at least 95 % confidence in the decision to accept a result[2] (as conforming on the basis of a measured value y_m with associated standard uncertainty u_m) i.e. the acceptance limits are chosen so that PFA_{max} = 5 %. For a single-sided tolerance interval this corresponds to a guard band $w = 1.645\, u_m$. For the same coverage probability, the *same* single-sided guard band factor applies for a double-sided tolerance interval when only one side of the PDF significantly overlaps a tolerance limit. If significant overlap of both limits occurs the procedure outlined in Appendix D can be followed to establish a suitable guard band factor.

Note that in situations where the measurement potentially results in a different value of u_m each time the measurement is performed, such as usually occurs in calibration scenarios, it is likely to be necessary to evaluate p_c (and hence PFA or PFR) on a case by case basis. In such situations the interval corresponding to PFA (or PFR) varies on a case by case basis and an acceptance *limit* cannot be defined *a priori* (i.e. before the measurement is performed and u_m is evaluated).

Similarly, if a guard band is arbitrarily defined or is not defined in terms of u_m – it will be necessary to calculate p_c in order to report PFA (or PFR).

However, if the uncertainty is known to be fixed, as is often the case for measurement scenarios such as production testing or other scenarios in which the uncertainty is dominated by the process itself, then a fixed acceptance limit can be calculated that corresponds to PFA_{max}.

In practical situations the precise value of PFA may sometimes not be of interest for an individual result. Conformity can then be established with $PFA \leq PFA_{max}$ by requiring only that y_m is within the acceptance interval A .

[2] Similar choices can be made to set PFR_{max} in situations where the purpose of the decision process is to decide whether to reject a result.

Appendix D: Guard-band factor k_w

Single-sided specifications

For single sided specifications, the required size of a guard band can be determined as a multiple of the standard uncertainty, $w = k_w.u$ where guard band factor k_w is found for a Gaussian PDF by solving the equation

$$1 - PFA_{max} = \int_{-\infty}^{k_w} g(\eta; 0,1)d\eta$$

Using Excel Worksheet functions this is

$$k_w = \mathrm{NORM.S.INV}(1 - PFA_{max}) \quad \text{D.1}$$

Hence

$$A_L = T_L + k_w.u \quad \text{D.2}$$

$$A_U = T_U - k_w.u \quad \text{D.3}$$

Table of guard band factors for selected values of PFA_{max} for a single limit and a Gaussian PDF

PFA_{max} /%	k_w
0.1	3.0902
0.2275	2.8373
0.25	2.8070
0.455	2.6083
0.5	2.5758
1.0	2.3263
2.275	2.0000
2.5	1.9600
4.55	1.6901
5.0	1.6449
10.0	1.2816

For PDFs based upon a t-distribution the corresponding Excel function is T.INV i.e.

$$k_w = \mathrm{T.INV}(1 - PFA_{max}, \upsilon) \quad \text{D.4}$$

CAUTION: The symbol k is (unfortunately) commonly used to represent the guard band factor (hence its use here). It should not be confused with the coverage factor that is used to establish an expanded uncertainty e.g. to define a coverage interval for a measurement result.

Double-sided specifications

The single-sided guard band factor can often be applied to establish guard bands for double-sided intervals.

A check can be performed to ensure that the guard band is consistent with the stated maximum risk of false acceptance.

The process is as follows:

1. identify PFA_{max}, T_U, T_L, and u
2. first, calculate PFA for a double-sided specification (using C.7 with C.3 or C.6 as appropriate) with $y_m = (T_U + T_L)/2$
3. if $PFA > PFA_{max}$ then it is not possible to define an Acceptance Interval consistent with PFA_{max}
4. otherwise… calculate the single-sided guard band factor k_w using D.1 or D.4 as appropriate
5. calculate $A_L = T_L + k_w.u$ (and for later use calculate $A_U = T_U - k_w.u$)
6. calculate PFA for a double-sided specification (using C.7 with C.3 or C.6 as appropriate) with $y_m = A_L$
7. if $PFA \approx PFA_{max}$ then the PDF does not extend 'significantly'[3] beyond *both* limits for a value at the limit of acceptance. The *single-sided* guard band factor (D.1 or D.4) is therefore suitable for a *double-sided* specification at the proposed PFA_{max}
8. if instead PFA is 'significantly' larger than PFA_{max} a different guard band factor is required. Precise calculation of the factor is not a straightforward procedure and it is probably best obtained empirically… e.g. by progressively increasing k_w and repeating steps 5. and 6. until an acceptable interval is found, i.e. $PFA \approx PFA_{max}$

For example, suppose that we require $PFA_{max} = 0.050$ for a Gaussian PDF with
$T_L = -4$
$T_U = 4$
$u = 1$

In this case we find that $PFA = 0.0500$ when $y_m = (T_U + T_L)/2$
therefore, a guard band for $PFA_{max} = 0.050$ exists

the single-sided guard band factor is
$k_w = \text{NORM.S.INV}(1 - 0.05) = 1.64485$
$A_L = -4 + 1.64485 \times 1 = -2.35515$
$A_U = 4 - 1.64485 \times 1 = 2.35515$
Hence, for a double-sided specification, when $y_m = A_L$ we calculate
$PFA = 0.05000$
Since $PFA \approx PFA_{max}$ we can use the single-sided guard band factor for the double-sided specification.

Suppose instead that $u = 2$. Following the same steps, we now find that
$A_L = -4 + 1.64485 \times 2 = -0.71030$
$A_U = 4 - 1.64485 \times 2 = 0.71030$
and, for the double-sided specification, when $y_m = A_L$ we calculate
$PFA = 0.05926$
which we may decide is 'significantly' larger than PFA_{max}

[3] Deciding what is 'significant' depends upon the application and cannot be dictated in advance for all situations.

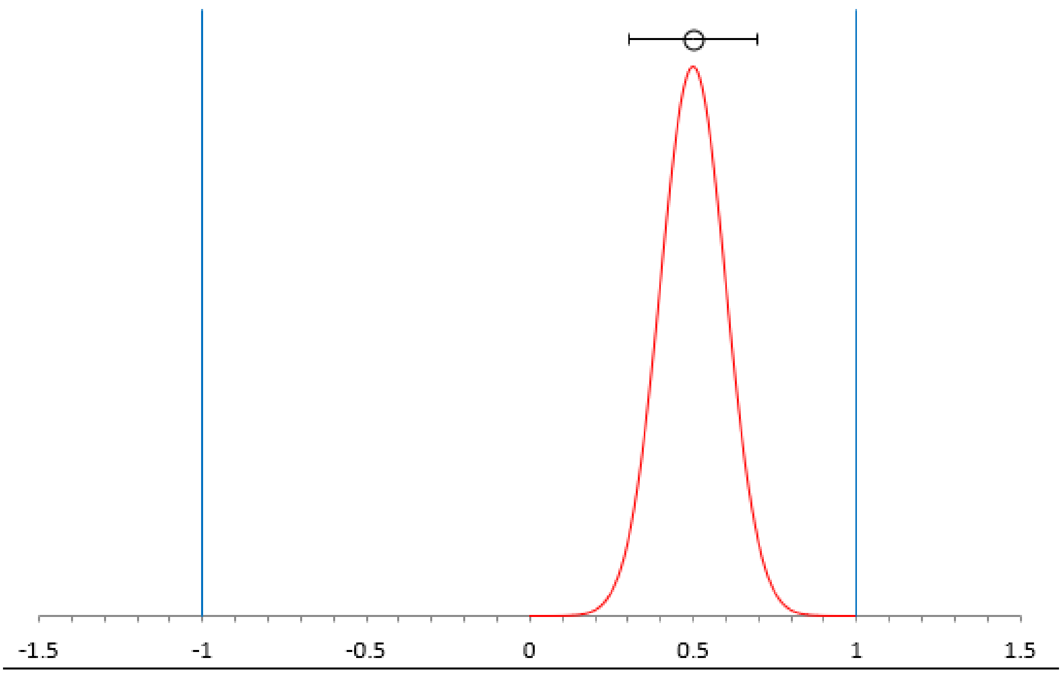
If we increase k_w by small increments and repeat the calculations for each new value, we find that when
$k_w = 1.79$, $PFA = 0.05028$, $A_L = -0.42$, $A_U = 0.42$
$k_w = 1.80$, $PFA = 0.04983$, $A_L = -0.40$, $A_U = 0.40$
$k_w = 1.796$, $PFA = 0.05001$, $A_L = -0.408$, $A_U = 0.408$
allowing us to select an appropriate guard band factor.

Appendix E: The problem with decision rules that do not take account of measurement uncertainty

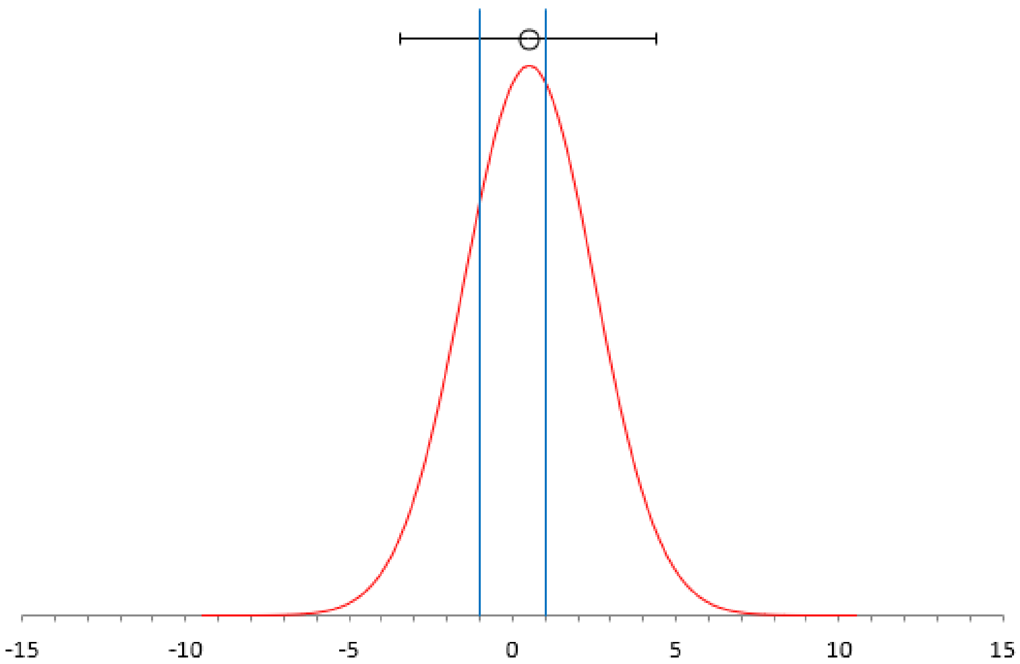
Conformity statements under ISO/IEC 17025:2017 require a Decision Rule (3.7) that takes account of measurement uncertainty. Some people argue that it is possible to ‘take account’ by ignoring it, if that is what the customer requests; however this seems to require a rather contradictory belief that you can be ‘doing something’ by ‘not doing something’ (is it possible to ‘obey a red stop light’ by ‘not obeying a red stop light’?)

Besides the grammatical and logical inconsistency in this approach, others also argue that it is allowable because ‘the customer accepts the risk associated with ignoring uncertainty’. This too is a flawed argument as will be shown by a simple example.

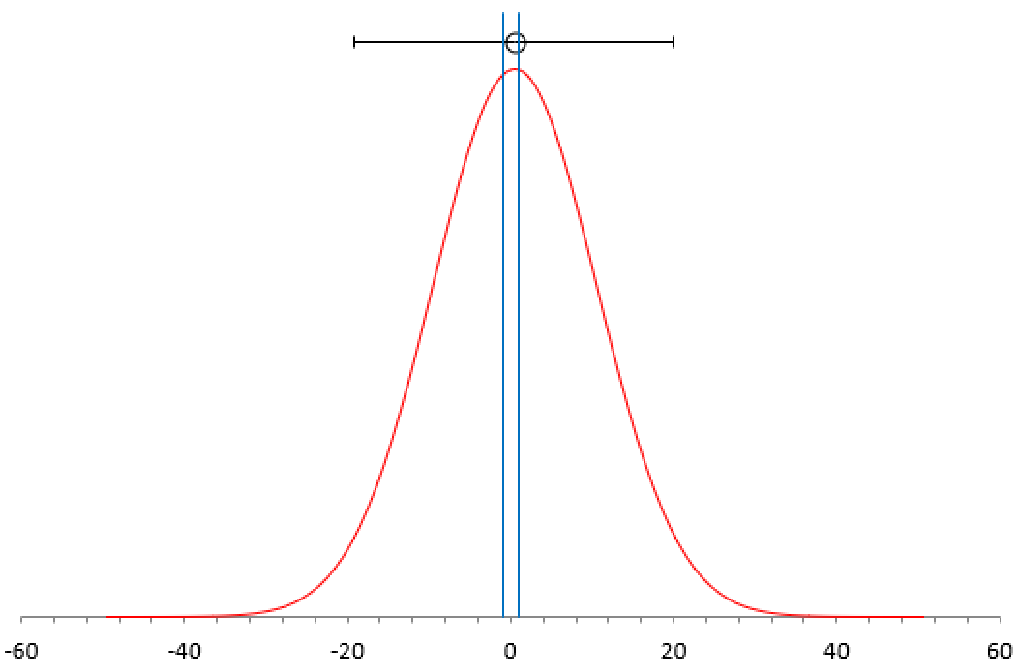
> Suppose that for some hypothetical reason Simple Acceptance with no account of measurement uncertainty *was* defined to be an acceptable Decision Rule i.e. PASS when the measured value is within the stated tolerance interval and uncertainty plays *no part* in the decision process…
>
> Suppose also that, for a particular measurement there is a tolerance of ±1 and the measured value equals 0.5
>
> As the value is within the tolerance interval the result is therefore declared to be a PASS regardless of the measurement uncertainty
>
> In fact, *all of the following measurement scenarios* will result in a PASS according to this rule…



$u = 0.1$, $p_c = 100\%$: PASS according to Simple Acceptance rule with no account for u



$u = 2$, $p_c = 37\ \%$: PASS according to Simple Acceptance rule with no account for u



$u = 10$, $p_c = 8\ \%$: PASS according to Simple Acceptance rule with no account for u

To reiterate, all of these scenarios (and an infinite number of others) are possible if there is "no account" taken of measurement uncertainty and the associated Risk will vary on a case by case basis.

It isn't therefore possible to 'accept the risk associated with ignoring uncertainty' as the risk is not only undefined, it is *undefinable when uncertainty is ignored*.

It *cannot* be argued in defence that "in practice this wouldn't be allowed to happen" and *at the same time* claim to "ignore uncertainty".

Suppose further, in this hypothetical situation, that a customer *did* understand that the risk was undefined and *still* wished to proceed, it begs the question 'for what legitimate purpose?' If (for some yet to be justified reason) such a Decision *were* to be allowed then, as in all cases, to avoid misrepresentation of the outcome the decision would need to be accurately reported… for example:

> "Decision Rule: Simple Acceptance rule ignoring uncertainty, by which it is not possible to state any level of confidence or risk associated with the Decision"

It does not seem likely that this would be welcome, but to omit the final part of the sentence would misrepresent the basis for the Decision.

A further consequence of ignoring measurement uncertainty is that the outcome of such a conformity decision is not 'metrologically' traceable i.e. it *could not be used to provide traceability* for any subsequent measurement activity such as calibration, testing, inspection or certification.

It is not 'metrologically traceable' because it is not the result of an unbroken chain of measurements and associated uncertainties. In statistical terms it is not possible to establish a PDF for the measurand based upon a conformity statement using a rule that does not somehow, directly or indirectly, take account of measurement uncertainty.

Finally, it should also be noted that rules such as 'Simple Acceptance *ignoring* measurement uncertainty in the decision process but *reporting* measurement uncertainty together with the Decision outcome' are also *not* consistent with the ISO/IEC 17025:2017 definition of a *Decision Rule* because uncertainty has not been involved in the decision process.

Reporting the uncertainty *post-decision* might allow risk to *subsequently* be evaluated, but it has not influenced the *earlier* decision to accept or otherwise – it therefore represents a situation where a decision is made regardless of risk.

The solution…

Often, in circumstances where 'the customer asks' the laboratory to 'ignore uncertainty' it is because they do not have sufficient understanding of uncertainty or of risk to realise what they are asking for. Usually however the customer actually does have some unarticulated belief about the appropriateness of the measurements - in other words there is some *implicit* idea of a point beyond which the uncertainty is too large.

Quantitatively establishing and applying that 'point' *takes measurement uncertainty into account*.

Simple Acceptance criteria can be therefore used as the basis for identifying the acceptance interval provided that it is used *together with* an identified constraint on the uncertainty, for example by agreeing an upper limit for measurement uncertainty or agreeing a limit to the test uncertainty ratio (TUR).

Agreeing the limits for measurement uncertainty is a matter for review between the laboratory and their customer. The laboratory might for example point out that, being an accredited laboratory, they have *already* established values for the likely uncertainty of all key measurements...

To summarise:

A rule such as Simple Acceptance with no account for measurement uncertainty is ***not*** an appropriate Decision Rule under ISO/IEC 17025:2017.

- At best it would simply be technically worthless, having undefinable risk and no metrological traceability

- At worst it is misleading, using a laboratory's accreditation status to pass off a meaningless decision as something more credible than it is

Rules based upon Simple Acceptance criteria can be a part of a valid Decision Rule when used *together with* indirect accounting for measurement uncertainty. Under these conditions

- It provides traceability (a PDF can be established if required)

- There is a definable risk in the decision outcome

Reference documents

ISO/IEC 17025:2017 “General requirements for the competence of testing and calibration laboratories”

ILAC-G8:09/2019 “Guidelines on Decision Rules and Statements of Conformity”

ISO/IEC Guide 98-3:2008 (JCGM 100) “Guide to the expression of uncertainty in measurement (GUM)”

UKAS, M3003 “The Expression of Uncertainty and Confidence in Measurement (Edition 4, October 2019)”

ISO/IEC Guide 98-4:2012 (JCGM 106) “Uncertainty of measurement - Part 4: Role of measurement uncertainty in conformity assessment”

ISO 10576-1:2003 “Statistical methods – Guidelines for the evaluation of conformity with specified requirements”

ASME B89.7.4.1-2005 “Measurement Uncertainty and Conformance Testing: Risk Analysis”

ASME B89.7.3.1-2001 “Guidelines for Decision Rules: Considering Measurement Uncertainty in Determining Conformance to Specifications”

BS EN ISO 14253-1:2017 “Geometrical product specifications (GPS) - Inspection by measurement of workpieces and measuring equipment Part 1: Decision rules for verifying conformity or nonconformity with specifications (BS EN ISO 14253-1:2017)”

ISO 5725-1:1994 “Accuracy (trueness and precision) of measurement methods and results - Part 1: General principles and definitions”

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