GUIDELINES ON DECISION RULES AND STATEMENTS OF CONFORMITY

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FURTHER INFORMATION

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1. INTRODUCTION

1.1 Preamble

This document is based upon the ILAC (International Laboratory Accreditation Cooperation) document ILAC-G8:09/2019 *Guidelines on Decision Rules and Statements of Conformity*. On the transfer of the role of ILAC to the Global Accreditation Cooperation (Global ACI), the text has been reformatted to be a Global ACI document without any substantive change to the text.

This guidance document has been prepared to assist laboratories in the use of decision rules when declaring statements of conformity to a specification or standard as required by ISO/IEC 17025:2017 [1].

Since ISO/IEC 17025 was first published in 1999, the need for statements of conformity with specifications or standards has developed greatly, together with documents on the concept of decision rules used to make such statements.

The revised ISO/IEC 17025:2017 recognises that no single decision rule can address all statements of conformity across the diverse scope of testing and calibration.

This document provides:

1.1.1 Overall guidance on how to select appropriate decision rules; and

1.1.2 Guidance on compiling the required elements of a decision rule if no standard published rules apply.

NOTE: Where further information is required regarding the mathematics of various decision rules covered in this document the reader is referred to the JCGM 106:2012 [2].

1.2 Purpose

1.2.1 This document provides 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. For cases where legislation mandates certain decision rules to be applied, those must be followed by laboratories.

1.2.2 It must also be noted that there is a difference between overall “Laboratory Risk” and the “Risk” which is associated with a decision rule (Measurement Decision Risk in this case). The latter is directly in the control of recipients of statements of conformity as it is they who specify the decision rules to apply by laboratories. Accordingly, it is the recipient who takes the risk associated with statements, that is, false acceptance or rejection of results

1.3 Scope

This document applies to all laboratories accredited to the requirements of ISO/IEC 17025.

2. DEFINITIONS

For this document the JCGM 106:2012 [2] "*Evaluation of measurement data - The role of measurement uncertainty in conformity assessment"* is taken as the primary reference. Additional documents referenced in this document are listed in Section 10.

2.1 Tolerance Limit (TL) (Specification Limit)
specified upper or lower bound of permissible values of a property

2.2 Tolerance Interval (Specification Interval)
interval of permissible values of a property
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 [3].

2.3 Measured Quantity Value
quantity value representing a measured result. (per clause 2.10 of VIM [6])

2.4 Acceptance Limit (AL)
specified upper or lower bound of permissible measured quantity values

2.5 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". (ASME B89.7.3.1 [3]).

2.6 Rejection Interval
interval of non-permissible measured quantity values
NOTE 1. A rejection interval is called a "rejection zone". (ASME B89.7.3.1 [3])

2.7 Guard Band (w)
interval between a tolerance limit and a corresponding acceptance limit where length $w=|TL-AL|$.

2.8 Decision Rule
rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement. (ISO/IEC 17025:2017 3.7 [1])

2.9 Simple Acceptance
a decision rule in which the acceptance limit is the same as the tolerance limit, i.e. $AL=TL$ (ASME B89.7.3.1 [3]).

2.10 Indication
quantity provided by a measuring instrument or measuring system. (JCGM 200 [6])
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

2.11 Maximum Permissible Error (MPE) (of Indication)
for a measuring instrument, maximum difference, permitted by specifications or regulations, between the instrument indication and the quantity being measured

2.12 Expanded Measurement Uncertainty (U)

The expanded uncertainty *U* is obtained by multiplying the combined standard uncertainty $u_c(y)$ by a *coverage factor k*:

$U = ku_c(y)$

The result of a measurement is then conveniently expressed as $Y = y \pm U$, which is interpreted to mean that the best estimate of the value attributable to the measurand *Y* is *y*, and that $y - U$ to $y + U$ is an interval that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to *Y*. Such an interval is also expressed as $y - U \leq Y \leq y + U$. JCGM 100 [4]

For this document *U* should be taken to be the expanded measurement uncertainty which corresponds to a coverage probability of approximately 95% that is often equal to a coverage factor $k = 2$.

2.13 Test Uncertainty Ratio (TUR)

the ratio of the tolerance, *TL*, of a measurement quantity, divided by the 95% expanded measurement uncertainty of the measurement process where *TUR=TL/U*.

2.14 Specific Risk

is the probability that an accepted item is non-conforming, or that a rejected item does conform. This risk is based on measurements of a single item.

2.15 Global Risk

is the average probability that an accepted item is non-conforming, or that a rejected item does conform. It does not directly address the probability of false accept to any single item, discrete measurement result or individual workpiece.

2.16 Nominal Quantity Value (Nominal)

Rounded or approximate value of a characterising quantity of a measuring instrument or measuring system that provides guidance for its appropriate use.
EXAMPLE 1: 100 Ω as the nominal value marked on a standard resistor.
EXAMPLE 2: 1 000 ml as the nominal quantity value marked on a single-mark volumetric flask.

3. DECISION RULES AND STATEMENTS OF CONFORMITY IN ISO/IEC 17025:2017

ISO/IEC 17025:2017 includes criteria related to decision rules and conformity with requirements in resources and processes related to personnel, contract review and reporting as described below.

3.1 Clause 3.7: a decision rule is defined as "*a rule that describes how measurement uncertainty will be accounted for when stating conformity with a specified requirement*".

3.2 Clause 6.2.6 requires that the laboratory shall authorise personnel to perform "*analysis of results, including statements of conformity or opinions and interpretations*".

3.3 Clause 7.1.3 requires that "*When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.*"

3.4 Clause 7.8.3.1b) states "*where relevant, a statement of conformity with requirements or specifications*" and clause 7.8.3.1c) states "*where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent), when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the measurement uncertainty affects conformity to a specification limit*".

3.5 Clause 7.8.4.1a) states "*the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent).*" Clause 7.8.4.1e) also states "*where relevant, a statement of conformity with requirements or specifications*".

3.6 Clause 7.8.6.1 states "*When a statement of conformity to a specification or standard for test or calibration is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule.*"

3.7 Clause 7.8.6.2 requires that "*the laboratory shall report on the statement of conformity, such that the statement clearly identifies:*

a) to which results the statement of conformity applies;
b) which specifications, standard or parts thereof are met or not met;
c) *the decision rule applied (unless it is inherent in the requested specification or standard).*"

4. MEASUREMENT UNCERTAINTY AND DECISION RISK OVERVIEW

When performing a measurement and subsequently making a statement of conformity, for example, in or out-of-tolerance to manufacturer's specifications or Pass/Fail to a particular requirement, there are two possible outcomes:

a. A correct decision is made regarding conformance to specification
b. An incorrect decision is made regarding conformance to specification

Each measured value has an associated measurement uncertainty. Figure 1 shows two identical measurements but with different measurement uncertainties [3]. The expanded measurement uncertainty in the lower result (case A) lies entirely within the tolerance limit. The upper result (case B) has significantly larger measurement uncertainty. The risk of falsely accepting a result in case B is higher due to the larger measurement uncertainty. (i.e. See "What is the level of risk?" in Figure 1).

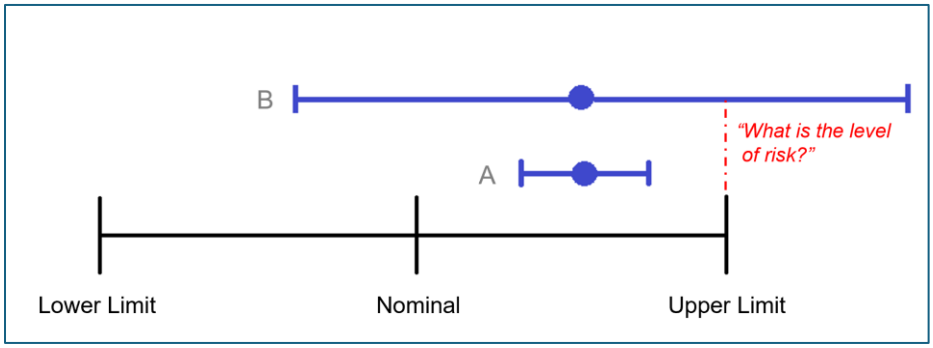


Figure 1. Illustration of Measurement Decision Risk

5. GUARD BANDS AND DECISION RULES

5.1 Guard Bands

The use of guard bands can reduce the probability of making an incorrect conformance decision. It is basically a safety factor built into the measurement decision process by reducing the acceptance limit below that of the specification/tolerance limit. This is often done to account for measurement uncertainty as is described later in this section.

This guidance document refers to Guard Bands where the length of the Guard Band (*w*) is the Tolerance/specification Limit (*TL*) minus the Acceptance Limit (*AL*) or $w = TL - AL$. This means that if the measurement result is below the Acceptance Limit (*AL*), then the measurement is accepted as conforming to specification. See Figure 2 below.

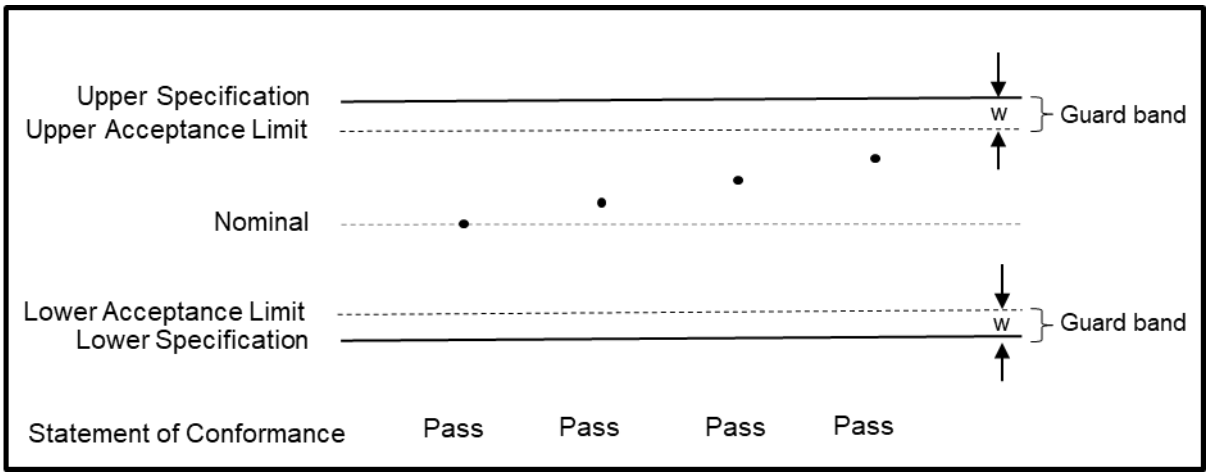


Figure 2 Graphical representation of a Guard Band

With guard band terminology there are often upper and lower limits for a tolerance. For simplicity, most of this document deals with an upper tolerance limit. For two-sided tolerances, the user needs to include the lower limits as well.

A guard band which has a length equal to zero, *w* = 0, infers that acceptance is when a measurement result is below a tolerance limit. This is called *simple acceptance*. Simple acceptance is also called “shared risk” because the probability to be outside the tolerance limit may be as high as 50% in the case when a measurement result is exactly on the tolerance limit (assuming a symmetric normal distribution of the measurements).

5.2 Decision Rules

A binary decision rule exists when the result is limited to two choices (pass or fail). A non-binary decision rule exists when multiple terms may express the result (pass, conditional pass, conditional fail, fail). These are further explained below.

5.2.1 Binary Statement for Simple Acceptance Rule ($w = 0$)

Statements of conformity are reported as:

- Pass - the measured value is below the acceptance limit, *AL* = *TL*.
- Fail - the measured value is above the acceptance limit, $AL = TL$.

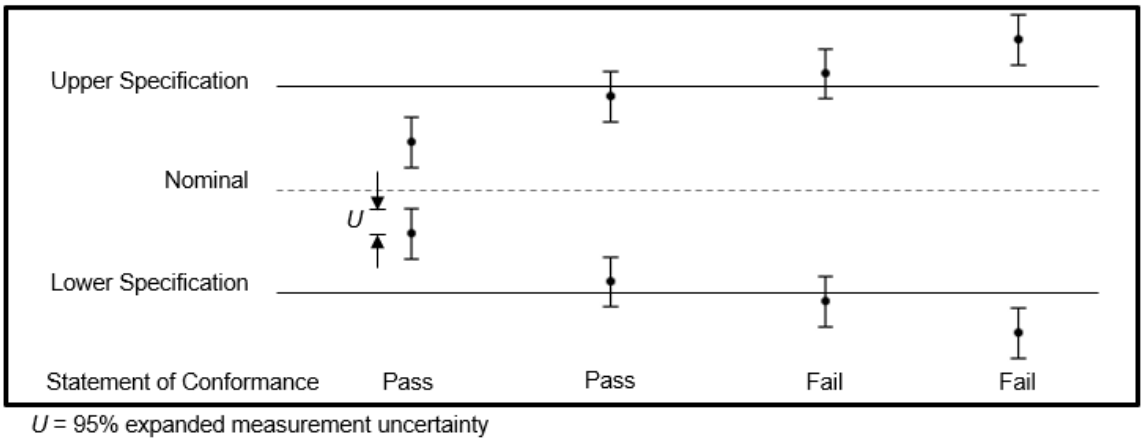


Figure 3 Graphical representation of a Binary statement - Simple Acceptance

5.2.2 Binary Statement with Guard Band

Statements of conformity are reported as:

- Pass - acceptance based on guard band; the measurement result being below the acceptance limit, $AL = TL - w$.
- Fail - rejection based on guard band; if the measurement result is above the acceptance limit, $AL = TL - w$

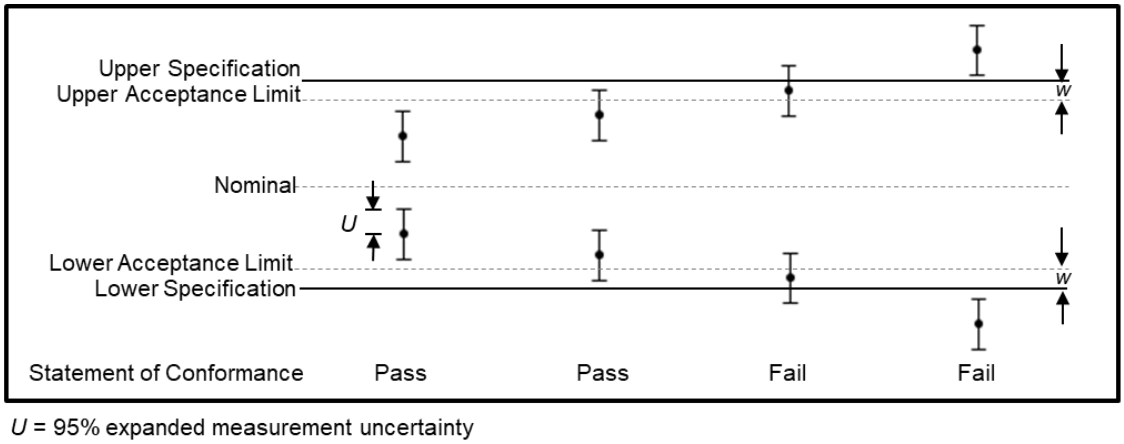


Figure 4 Graphical representation of a Binary statement with a guard band

5.2.3 Non-binary Statement with Guard Band

Statements of conformity are reported as:

- Pass - the measured result is below the acceptance limit, $AL = TL - w$.
- Conditional Pass - the measured result is inside the guard band and below the tolerance limit, in the interval $[TL - w, TL]$.
- Conditional Fail - the measured result is above the tolerance limit but below the tolerance limit added to the guard band, in the interval $[TL, TL + w]$.
- Fail - the measured result is above the tolerance limit added to the guard band, $TL + w$.

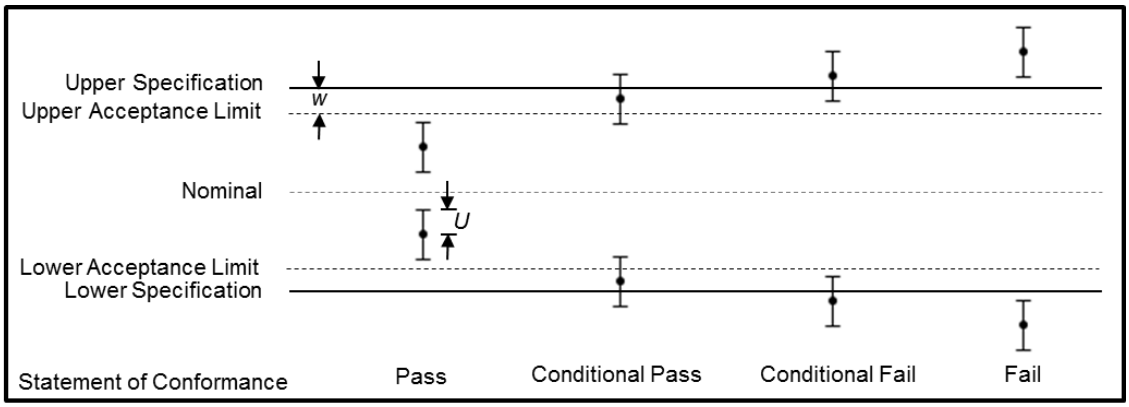


Figure 5: Graphical representation of a non-Binary statement with a guard band (shown for $w = U$)

It should be considered that a measurement may result in a decision on conformity (acceptance) using one guard band and rejection if a larger guard band is used. Therefore conformity with a requirement is inherently connected to the decision rule employed. It is therefore expected that the decision rule is agreed before the measurements are taken. (clause 7.1.3 [1])

6. TAKING MEASUREMENT UNCERTAINTY INTO ACCOUNT

6.1 Measurement Uncertainty, Indirectly Taken into Account

If measurement uncertainty is taken directly into account, the acceptance interval will be a restricted part of the tolerance as described in Section 6.2. The larger the measurement uncertainty is, the smaller the acceptance interval gets. This will result in fewer accepted results than if measurement uncertainty had been smaller. See figure 6.

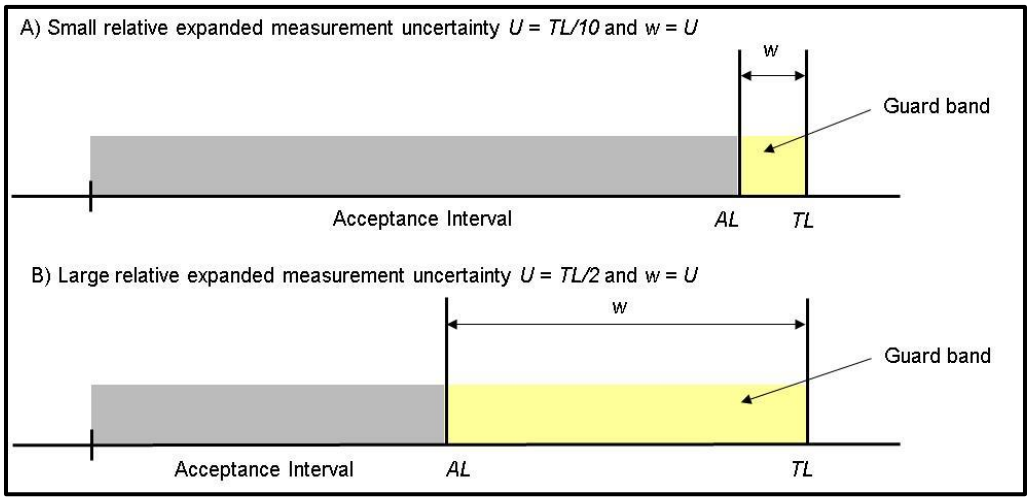


Figure 6: Acceptance interval for a case where expanded measurement uncertainty is small compared to tolerance A) and large B) for the same tolerance limit *TL*. A large guard band narrows the distribution function of accepted items.

In order to avoid dependency on guard bands among laboratories, regulators often take measurement uncertainty indirectly into account. This may be done in numerous ways depending on the area of testing or calibration. Some examples are:

- OIML R76-1:2006 (NAWIs) cl. 3.7.1 where it is required that *"…the standard masses used for the type examination or verification of an instrument …. shall not have an error greater than 1/3 of the MPE. If they belong to class E2 or better, their uncertainty is allowed to be not greater than 1/3 of the MPE of the instrument (the tolerance)*"

- OIML R117-1:2007 Dynamic measuring systems for liquids other than water Part 1: Metrological and technical requirements A.2 Uncertainties of measurement: *When a test is conducted, the expanded uncertainty of the determination of errors on indications of volume or mass shall be less than one-fifth of the maximum permissible error (MPE) (the tolerance)*

- WADA Technical Document – TD2014DL *The decision limit DL shall be calculated as the sum of the value T and the guard band (g), where (g) is calculated based on the relevant WADA maximum acceptable value of the combined standard uncertainty (u_cMax)*

  $$DL = T + g, \text{ and } g = k \cdot u_c Max, \text{ with } k = 1.645$$

  In most cases, u_cMax is assigned using data from the combined participant results obtained from relevant rounds of the External Quality Assessment Scheme (EQAS). Note: This corresponds to a guard band *w* that is fixed for all laboratories no matter their own measurement uncertainty. The term *T* is equal to the tolerance limit *TL*.

- Cases in highway law enforcement, where 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. See Example 1, page 22 of JCGM 106 [2], for how an appropriate guard band be implemented such that the measured speed has a 99.9% certainty of exceeding the legal limit.

- Cases where test standards have taken typical measurement uncertainty into account when setting the tolerance limits and the acceptance limit then equals the tolerance limit.

- Cases where a customer specifies a guard band to be used for deciding on conformity with specification. Such guard bands may be fixed, but may also be based on the measurement uncertainty which is detailed below.

As can be seen from the bullet list, decision rules can be not only very different but also very complicated.

6.2 Measurement Uncertainty Taken Directly into Account

ISO/IEC 17025:2017 requires that laboratories evaluate measurement uncertainty and that they apply a documented decision rule when making statements of conformity.

As mentioned previously, the approach adopted may significantly vary dependent on the situation and different guard bands may be applied.

Often the guard band is based on a multiple *r* of the expanded measurement uncertainty *U* *where* $w = rU$. For a binary decision rule, a measured value below the acceptance limit *AL* = *TL* – *w* is accepted.

While it is common to use a guard band *w* = *U*, there may be cases where a multiplier other than 1 is more appropriate. Table 1 provides examples of different guard bands to achieve certain levels of specific risk, based on the customer application.

Decision rule	Guard band w	Specific Risk
6 sigma	3 *U*	< 1 ppm PFA
3 sigma	1,5 *U*	< 0.16% PFA
ILAC G8:2009 rule	1 *U*	< 2.5% PFA
ISO 14253-1:2017 5]	0,83 *U*	< 5% PFA
Simple acceptance	0	< 50% PFA
Uncritical	*-U*	Item rejected for measured value greater than $AL = TL + U$ < 2.5% PFR
Customer defined	*rU*	Customers may define arbitrary multiple of *r* to have applied as guard band.

Table 1. PFA – Probability of False Accept and PFR – Probability of False Reject (Assumes a single sided specification and normal distribution of measurement results)

6.3 Specific vs. Global [Average] Risk in Calibration

If the laboratory only measures a single instrument and has no history of calibration results for that serial number, or if it has no information on the behaviour of that model as a population, that can be considered to be a situation with “meagre prior information” (see 7.2.2 of JCGM 106 [2]). Some take the view that when a laboratory receives an instrument for calibration (and subsequent verification to manufacturer’s tolerance) with meagre prior information, that the laboratory can only provide specific risks.

Some customers take steps to actively reduce the probability that instruments submitted for calibration and verification will be returned “Failed”. They do so by operating a “Calibration system” (See 5.3.4 of Z540.3 [7]) such that calibration records (measurement reliability) are monitored by model number, and calibration intervals are actively managed to achieve a desired target reliability (See 5.4.1 of Z540.3 [7]), where target reliability refers to the percentage of instruments that “Pass” calibration. The end result is a process by which the instrument submitted is part of a customer device population. If that process “rarely results in an instrument whose property of interest is near the tolerance limits, there is less opportunity for incorrect decisions to be made” (See 9.1.4 of JCGM 106 [2]).

Thus, average probability of false accept and false reject (global risk) can be applied by evaluation of the joint probability density consisting of customer managed device population and laboratory managed calibration process uncertainty (See equations 17 and 19 of JCGM 106 [2]). References [8] and [9] provide simple techniques for estimating global risk.

When a customer actively manages calibration intervals as mentioned here, during contract negotiation with laboratories for services compliant with ISO/IEC 17025:2017, they can direct the laboratory to use the average global risk associated with decision rules when reporting results per clause 7.8.2.2 [1]. As already clarified in definition 3.15 an instrument passing a global risk criteria e.g. 2% probability for false acceptance (2% PFA) may not pass a specific risk with a guard band equal to the expanded measurement uncertainty and may have a specific risk for false acceptance that can be as high as close to 50%. This is similar to the criteria for approval of instruments mostly utilised in legal metrology. Generally the output from decision rules based on OIML principles (e.g. *TUR* > 3:1 or 5:1) and global risk with approximately 2% PFA may provide the same results in terms of number of falsely rejected instruments.

6.4 Consideration of Both False Accept and False Reject Risks

“Binary decision rules, acting to reduce the consumer’s risk, will always increase the producer’s risk” (see page 31 of JCGM 106 [2]). This statement applies to any decision rule which employs a guard band to improve or set a minimum false accept risk.

Initially, a customer submitting an item for calibration or testing to a laboratory may only care about their “consumer false accept risk”. However, when a laboratory returns an item as “Failed”, the customer will need to investigate the impact on the products their organisation produces which can often lead to expensive recalls.

7. DECISION RULE SELECTION FLOW CHART

Where choices of decision rules are available, customers and laboratories will need to discuss levels of risk regarding the probability of false acceptance and false rejects associated with available decision rules. No single decision rule can address the diverse scope of testing and calibration covered by ISO/IEC 17025.

Some disciplines, industries or regulators have determined decision rules appropriate for their use and published them in specifications, standards or regulations.

Figure 7 provides general guidance for the selection of decision rules.

Here are suggestions on how to use the flow chart:

1. Some calibration or testing applications do not require a statement of conformance to a metrological specification. Examples may include some precision masses, efficiency of power sensors, etc. In these cases, you should (shall for a calibration) report the measured result and the GUM [4] measurement uncertainty.

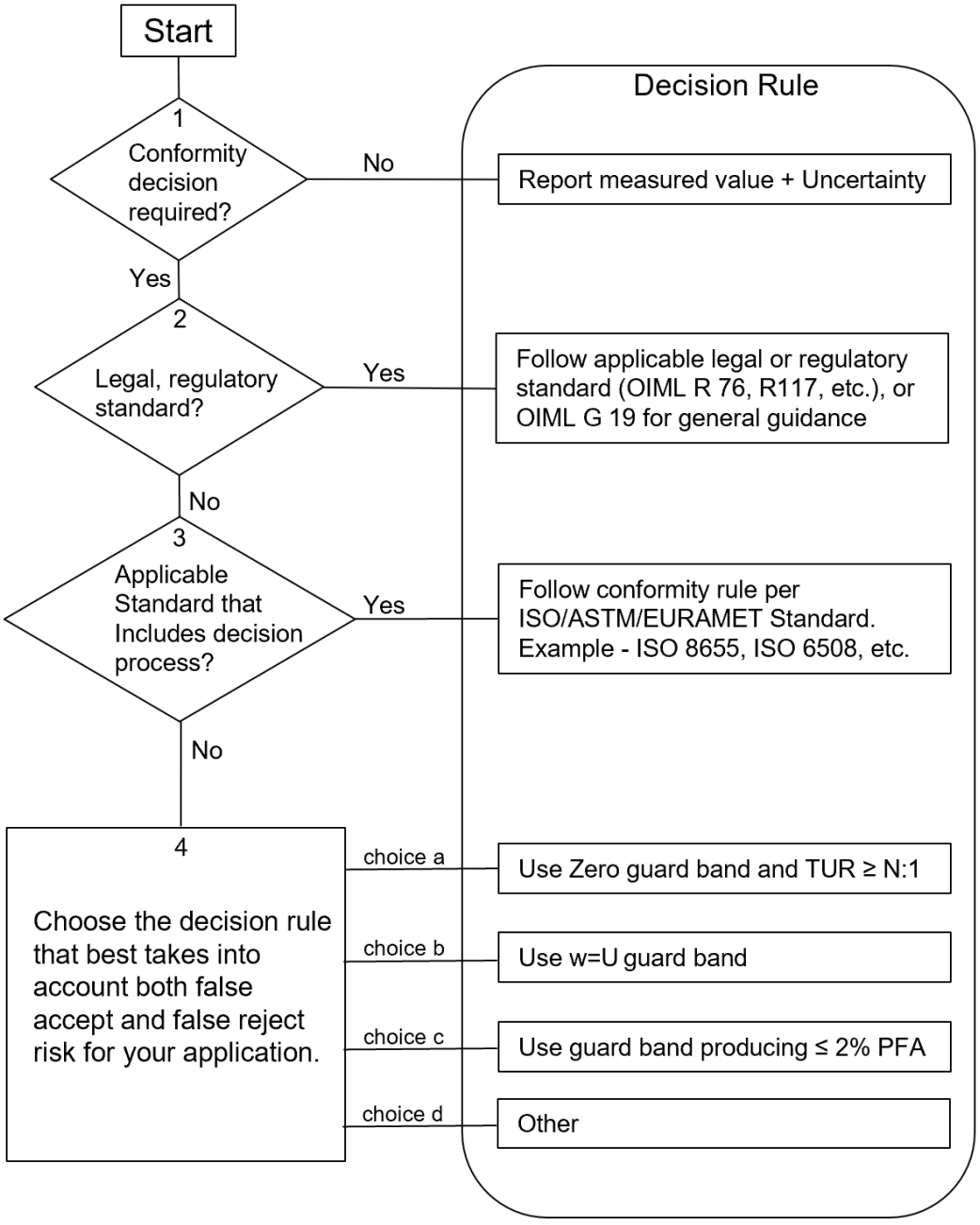


Figure 7. Pass/Fail Conformity Decision Rule selection flow chart.

2. If the measurement result is governed by legal or regulatory standards or rules, then use the decision rule as prescribed in the appropriate standard. For guidance on conformity assessment decisions in legal metrology, see OIML Guide G 19 [10].

3. The next scenario to consider is if your application already has measurement decision rules governed by a published standard guidance document. (Examples: ISO 14253, ISO 8655, ISO 6508, etc). Generally, in these cases, standard test methods are prescribed and often compliance limits already have a guard band built in to the limit, so any further guard banding to limit risk is not necessary.

4. If you reach decision box 4, it generally means that no specific published decision rule already governs your application. Laboratories and customers may select from standard decision rules shown or choose to self-document their own rule (See appendix B). Examples of "other" guidance on conformity assessment decisions include, EUROLAB Technical Report No.1-2017 [11], EURACHEM/CITAC Guide [12]
Note: If you select a rule using TUR ≥ N:1, be sure to specify what action to take for any measurements that result in a TUR below the defined rule.

8. DECISION RULE DOCUMENTATION AND APPLICATION

It is the responsibility of the laboratory to agree on a service with the customer. Clause 7.1.3 [1] indicates that the request for a statement of conformity must come from the customer. However, calibration laboratories may offer standard service deliverables with differing amounts of guard band (including zero) to provide the customer with choices of levels of risk.

Similarly, Clause 7.8.3.1 b [1] states that "*test laboratories shall provide statements of conformity if this is necessary for the interpretation of the results*".

In all cases, decision rules need to be compatible with the customer, regulation or standard requirements. They need to be agreed and documented, before the work starts. It must be clear that the tolerance limits are consistent with the requirements and that all measurement uncertainty and other calculations are performed consistent to the ISO/IEC 17025:2017 requirements. The agreed decision rule employed for statements of conformance must be clearly documented in the measurement report.

Documentation supporting the decision rule should align with the complexity of the decision rule. The necessary documentation includes:

a) Documentation of other supporting factors such as statistical assumptions including type of risk, specific or global and measurement uncertainty. (clause 7.8.6.1 [1])
NOTE: for more information on specific and global risk see para 5.3.
b) Documentation of the type of conformity assessment and statements of conformance. (clause 7.8.6.2 [1])
NOTE: for more info on decision rules and conformity statements see Section 3.
c) Compatibility of decision rule documentation with test and calibration records. (clause 7.8.6.2 [1])

APPENDIX A provides a sample checklist for both the Laboratory and the Assessor to follow and APPENDIX B provides some examples of documentation that may be required.

9. SUMMARY

The concept of decision rules applicable to statements of conformity with specifications or standards is not new. However, ISO/IEC 17025:2017 provides further clarity and emphasis by requiring laboratories to:

1) understand the needs of customers relating to statements of conformity they may require and that this be confirmed at the test / calibration request stage. The request review stage is to take into account the application of the statements and agree with the customer the decision rules to apply based on the risk the customer will accept;

2) include the decision rule in reports covering statements of conformity (unless the rule is inherent in the specification or standard).

10. REFERENCES

1. ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*

2. JCGM 106:2012, Evaluation of measurement data – *The role of measurement uncertainty in conformity assessment.*
Note: this document is also available as ISO/IEC Guide 98-4:2012

3. ASME, B89.7.3.1-2001, *Guidelines for Decision Rules: Considering Measurement Uncertainty in Determining Conformance to Specifications.*

4. JCGM 100:2008, (GUM), *Evaluation of measurement data - Guide to the Expression of Uncertainty in Measurement.*

5. 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 specification*.

6. JCGM 200:2012, (VIM), *International Vocabulary of Basic and General Terms in Metrology*, Third Edition

7. NCSLI International, ANSI/NCSL Z540.3:2006 *Requirements for the Calibration of Measuring and Test Equipment*, Boulder, Colorado, USA

8. Deaver, D, and Somppi, J., "*A study of and recommendation for applying the false acceptance risk specification of Z540.3*", Proc., NCSL Workshop & Symposium, 2007.

9. Dobbert, M., "*A Guard-Band Strategy for Managing False-Accept Risk*", Proc., NCSL Workshop & Symposium, 2008.

10 Guide OIML G 19, *The role of measurement uncertainty in conformity assessment decisions in legal metrology,* 2017.

11. EUROLAB Technical Report No.1/2017, *Decision rules applied to conformity assessment.*

12. EURACHEM / CITAC Guide, *Use of uncertainty information in compliance assessment, 2007.*

11. AMENDMENT TABLE

Section	Previous Version	Summary Of Changes
All	ILAC_G8_09_2019 *Guidelines on Decision Rules and Statements of Conformity*	Reformatted to Global Accreditation Cooperation Incorporated format. No changes to content.

APPENDIX A - SAMPLE CHECKLIST FOR MEETING THE REQUIREMENTS OF ISO/IEC 17025:2017

a) Documentation and records reflecting customer agreement requesting statement of conformity to a specification or standard. (clause 7.1.3 [1])

b) Records of the selection of test limits and associated tolerances and compatibility with customer requirements (clause 7.1.3 [1])

c) A documented decision rule for calculating, controlling, and reporting levels of risk associated with statement of conformity. (clause 7.1.3 [1])

d) Documentation of laboratory personnel that include the knowledge, skill, and authorisation to apply the decision rule and make statements of conformity. (clause 6.2.6 c [1])

e) Documentation of the calculation or estimation of level of risk and measurement uncertainty. (clause 7.8.6.1 [1])

f) Documentation of other supporting factors such as statistical assumptions including type of risk (i.e. specific or global) and measurement uncertainty. (clause 7.8.6.1 [1])
NOTE: for more information on specific and global risk see Section 6.3 of this document.

g) Documentation of the conformity assessment type and statements of conformance. (clause 7.8.6.2 [1])

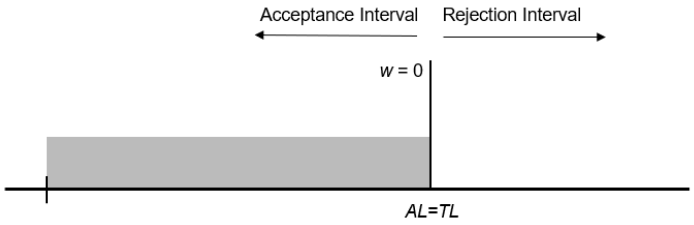
NOTE: for more info see Section 5.2 of this document.

h) Decision rule documentation to be included with test and calibration records. (clause 7.8.6.2 [1])

APPENDIX B – EXAMPLES OF DECISION RULES

Example 1: Simple acceptance (choice a in figure 7)

The customer agrees that Pass/Fail decisions are based on acceptance limits chosen based on simple acceptance ($w = 0, AL = TL$). The expanded measurement uncertainty calculated per the GUM must be less than 1/3 of the tolerance limits based on the manufacturer's specifications ($TUR > 3:1$). Statements of conformity are binary. The estimate of the measurand is assumed to have a normal probability distribution and specific risk is used for the risk calculation. In this case, the risk that accepted items are outside the tolerance limit is up to 50%. The risk of false reject is up to 50%[1] for measured results outside the tolerance.

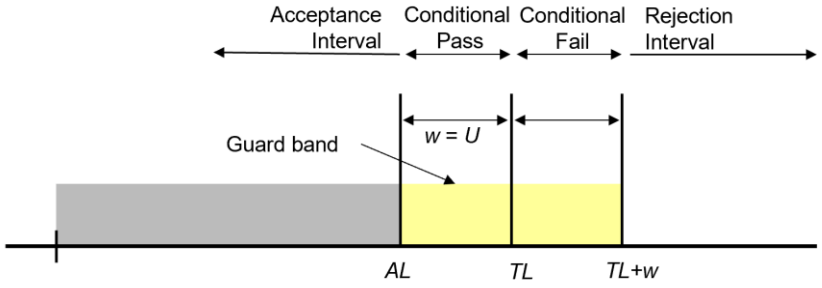


Statements of conformity are reported as:

- Passed - The measured values were observed in tolerance at the points tested.
- Failed - One or more measured values were observed out of tolerance at the points tested.

Example 2: Non-binary acceptance based on guard band $w = U$ (choice b in figure 7)

The customer agrees that decisions are based on guard banded acceptance limits. ($w = U$, $AL = TL - w$) where *U* is the expanded measurement uncertainty calculated per the GUM. Statements of conformity are non–binary. The estimate of the measurand is assumed to have a normal probability distribution and specific risk is used for the risk calculation. In this case the risk of accepted items to be outside the tolerance limit is < 2.5%. For rejected items the risk to be inside the tolerance limit is < 2.5%. When the measured result is close to the tolerance, the risk of false accept and false reject is up to 50%.



[1] Since both false accept and false reject risk can be 50%, this rule is sometimes called "shared risk".

Measurement results are reported as:

- Pass - The measured values were observed in tolerance at the points tested. The specific false accept risk is up to 2.5%.

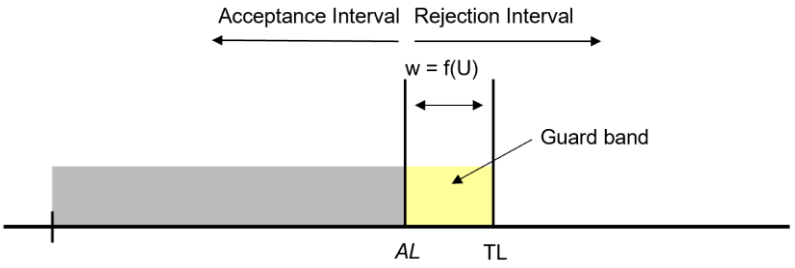
- Conditional Pass - The measured values were observed in tolerance at the points tested. However, a portion of the expanded measurement uncertainty intervals about one or more measured values exceeded tolerance. When the measured result is close to the tolerance, the specific false accept risk is up to 50%.

- Conditional Fail- One or more measured values were observed out of tolerance at the points tested. However, a portion of the expanded measurement uncertainty intervals about one or more measured values were in tolerance. When the measured result is close to the tolerance, the specific false reject risk is up to 50%.

- Fail - One or more measured values were observed out of tolerance at the points tested. The specific false reject risk is up to 2.5%.

Example 3: Binary acceptance based on guard band (≤ 2.0% global risk) (choice c in figure 7)

The customer agrees that decisions are based on guard banded acceptance limits, *AL*, to result in less than 2% false accept [global] risk. For this case the acceptance limit, *AL*, is given by [8] $\mathrm{AL} = \sqrt{\mathrm{TL}^2\text{-}\mathrm{U}^2}$ and *U* is the expanded measurement uncertainty calculated per the GUM [4]. Note: other formulas for calculating an acceptance limit, *AL*, to achieve < 2% global risk are given in [9]. Statements of conformity are binary. The estimate of the measurand is assumed to have a normal probability distribution. The risk of accepted items to be outside the tolerance limit is ≤ 2.0%.



Statements of conformity are reported as:

- Passed - The measured values were observed in tolerance at the points tested with a global false accept risk of less than or equal to 2%.

- Failed - One or more measured values were either observed out of tolerance at the points tested or the global false accept risk for one or more measured values was greater than 2%.