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Decision rules applied to conformity assessment

Contents

1 – Introduction

Conformity assessment is a common activity performed in testing, inspection and calibration, required to assure the compliance of products, materials, services and systems to requirements defined by standards, regulations and legal frameworks, being defined to establish confidence for consumers and for the safety and quality of life. It has today a major impact in the Global Economy because it implies accepting and rejecting items with direct impact in risk analysis, business decisions and reputational and financial costs.

To establish procedures in order to perform conformity assessment in practical situations (e.g. conformity with metric tolerances) objective criteria are needed in what is called "decision rules", which are intended to define the limits of conformity assessment "conformance zone" and, considering a probabilistic approach, the "acceptance zone" (measurement results including uncertainty that are considered acceptable). The conventional approach of decision rules was based on the comparison of single or intervals of limits of conformity with single measurement results, being the typical decision rule directly obtained from inequalities of these comparisons. The recent development of a probabilistic approach in measurement, introducing measurement uncertainty as a parameter to express the variability of measurement, had a significant impact in decision process, as it implies the need to consider the comparison through a probabilistic view.

The following figure shows three possible situations of measurement results and their uncertainties within a conformity interval to which a decision rule should be applied. In Figure 1, we can state that the case A is clearly as "in conformity", the case C is "out of conformity", but in case B we have an undefined situation that needs a formal criteria based on the confidence interval expected, to be used to decide about it's conformity.
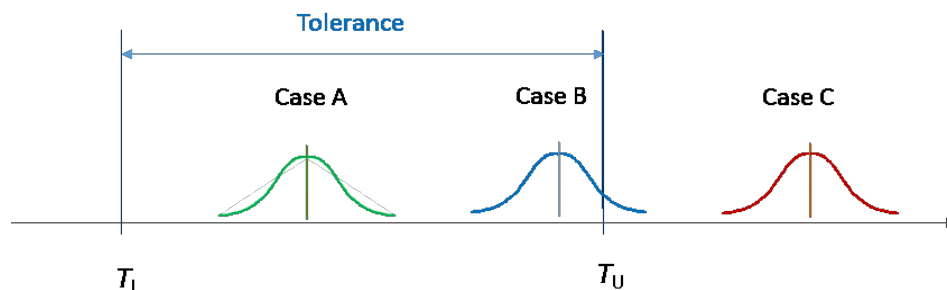

Figure 1 – Representation of three different measurement results and a tolerance interval

Regarding the approach in this document it should be mentioned that it is based in the assumption that the uncertainty of measurement is represented by a Gaussian Probability Distribution Function (PDF), which is consistent with the typical measurement results (being assumed the applicability of the Central Limit Theorem).

2 – Risk assessment and errors type I and type II

When performing conformity assessment, there are probabilities related to two types of incorrect decisions, one for the supplier (α) and one for the consumer (β), defined as percentage risk, being the calculation procedure addressed in the [JCGM 106: 2012]. In this framework, the decision matrix can be expressed by:

$$P = \begin{bmatrix} (1-\alpha) & \alpha \\ \beta & (1-\beta) \end{bmatrix}$$

where the probabilities of making the correct decisions are found in the diagonal elements $(1 - \alpha)$ and $(1 - \beta)$ and the risks of incorrect decisions in the off-diagonal elements α and β. These errors are also known as Type I (α) and type II (β) errors, respectively meaning that conforming products are incorrectly rejected or non-conforming products are incorrectly accepted. Table 1 shows another common representation of these errors, their probabilities and relation to decision.

	Decision	
	Accept H_0	Reject H_0
H_0 (True)	Correct decision	Type I error (α error)
H_0 (False)	Type II error (β error)	Correct decision

Table 1 – Conformity assessment probabilities related to correct or incorrect decision

Both incorrect decisions expressed by α and β imply costs and economic risk, as presented in [Pendrill, 2007] and displayed in Figure 2 (adapted from the reference mentioned). This Figure intends to show the perspective of supplier regarding income and costs due to conformity assessment (in green the profits and in red the loss).
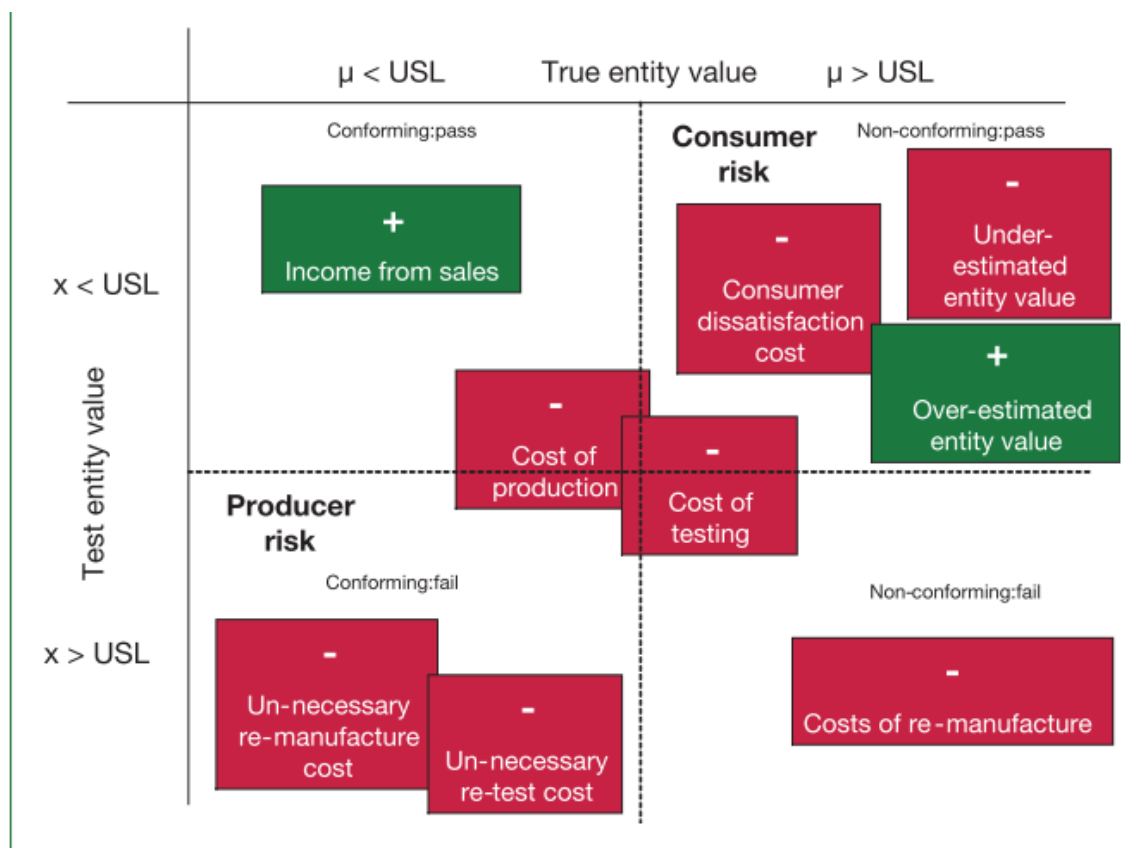

Figure 2 –Supplier income and costs due to conformity (adapted from [Pendrill, 2007]

3 – A general approach to conformity assessment procedure

Decisive for the proper definition of a decision rule is the question what should be proved by the conformity assessment: compliance or non-compliance with a specification or a limit value. Based on the answer either the supplier's risk ($α$) or the consumer's risk ($β$) has to be specified.

The definition of a procedure intended to perform conformity assessment can be based on the following steps:

   a. The specification of a measurand (Y) and the measurement item to be tested.

   b. The experimental / analytical results (estimates y of the measurand Y).

   c. The measurement standard uncertainty, $u(y)$, and for a certain confidence level, the expanded uncertainty (being known the confidence level required a k factor should be considered, e. g., for a Gaussian sample, is commonly used k = 2,00 for a confidence interval of 95%).

   d. The specification of a single tolerance limit (upper or lower) or tolerance interval limits.

   e. The definition of the **acceptance zone**, **rejection zone** and **guard band** assuming a probability of type I error (supplier's risk $α$) or type II error (consumer's risk $β$).

   f. A **decision rule**

The terminology in this guide and presented below is adopted according the definitions presented in [EURACHEM Guide:2007] and based on [ASME B89.7.3.1:2001].

   Decision rule: a documented rule that describes how measurement uncertainty will be allocated with regard to accepting or rejecting a product according to its specification and the result of a measurement.

   Acceptance zone: the set of values of a characteristic, for a specified measurement process and decision rule, that results in product acceptance when a measurement result is within this zone.

   Rejection zone: the set of values of a characteristic, for a specified measurement process and decision rule, that will give noncompliance when a measurement result is within this zone.

   Guard band: the magnitude of the offset from the specification limit to the acceptance or rejection zone boundary

   Type I error ($α$) = probability that tested sample is compliant, even though a non-compliant measurement is obtained (FN)

   Type II error ($β$) = probability that the tested sample is non-compliant, even though a compliant measurement is obtained (FP)
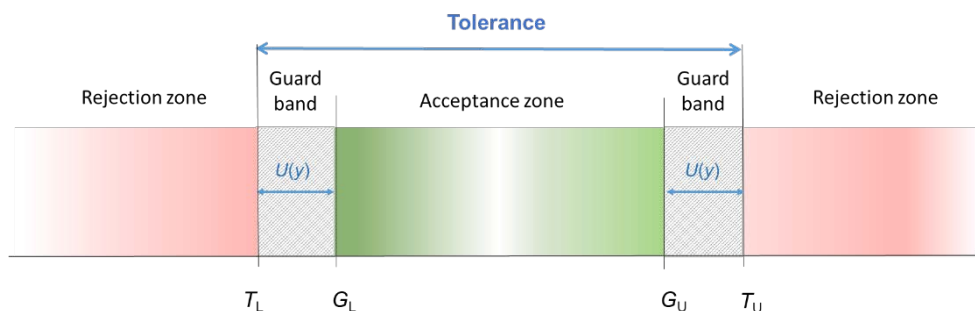
Figure 3a) – Example of areas defined for a tolerance interval in order to minimise the consumer's risk

Legend: TU – Tolerance upper limit ; GU –Acceptance zone upper limit ; TL – Tolerance lower limit ;
GL –Acceptance zone lower limit; $U(y)$ – expanded uncertainty of the measurement.
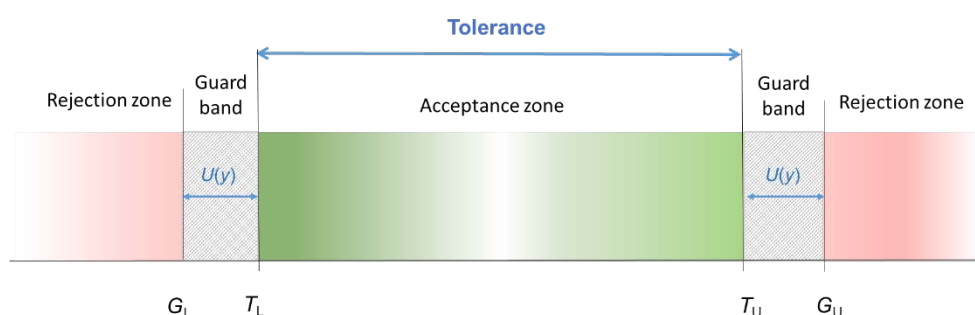

Figure 3b) – Example of areas for the tolerance interval in order to minimise the supplier's risk

Figure 3a) is an example for an acceptance zone defined in order to minimise the consumer's risk ($β$). In other cases it is important to minimise the supplier's risk ($α$), e.g. concerning rejection in business-to-business sales [e.g. ISO 14253-1:1998] or in court cases because of violation of limit values. This approach is demonstrated in figure 3b). While in the first case the guard bands are within the tolerance zone, they are outside the tolerance zone in the second case. Thus in figure 3a) the focus is on high confidence of correct acceptance (guarded acceptance) while in figure 3b) it is on high confidence of correct rejection (guarded rejection).

For the cases using guard bands, particularly suitable for measurement results with fixed uncertainty, a simple strategy to establish a decision rule is to compare the measurement results with the acceptance zone limits, being considered in compliance (accepted) if the measured value is inside this zone and non-compliant (rejected) otherwise.

If measurement results could have variable values of uncertainty, a different approach without considering guard bands is recommended requiring an approach ideally based on the definition of a test of hypothesis as support for the decision rule.

4 – Decision rule applied to conformity assessment with a single tolerance without guard band

Given a **single tolerance upper limit**, T_U, and a measurement estimate y with measurement standard uncertainty of $u(y)$, a *decision rule* should define a probability of conformity (P_c) assuming a probability of type I error ($α$).
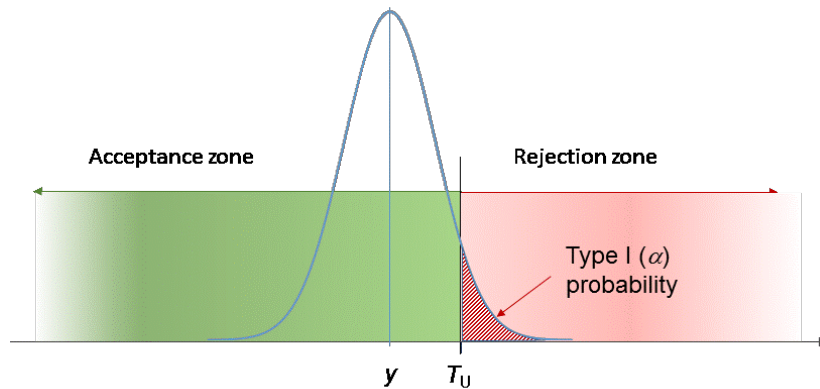
Figure 4 – Example with single upper tolerance

Decision rule

Acceptance if the hypothesis H_0: $P(Y \leq T_U) \geq (1 - \alpha)$ is true;

Rejection if the hypothesis H_0 is false, $P(Y \leq T_U) < (1 - \alpha)$.

Expression to test: $P_C = P(\eta \leq T_U) = \Phi\left(\frac{T_U - y}{u(y)}\right)$

Example:

Consider a measurement estimate y = 2,7 mm with a standard uncertainty of $u(y)$ = 0,2 mm, a single tolerance upper limit of T_U = 3,0 mm, and a specification of conformity (1 -α) of 0,95 (95 %) thus assuming a type I error α = 0,05 (5 %).

With the experimental result and tolerance limit, assuming a Gaussian PDF, the decision rule will be:

Acceptance if the hypothesis H_0: $P(Y \leq 3,0 \text{ mm}) \geq 0,95$ is true

To estimate probabilities related with the example given, the conformance probability (P_c) need to be calculated using the general expression for Gaussian PDFs:

$$P_C = P(\eta \leq T_U) = \Phi\left(\frac{T_U - y}{u(y)}\right)$$

$$P_C = \Phi\left(\frac{3,0 - 2,7}{0,2}\right) = \Phi(1,5) \approx 0,933 \ (93,3 \ \%) < 0,95$$

Then the hypothesis H_0 is false and the decision is of non-conformity.

> Note: The value of $\Phi(z)$ can be obtained using tables of standard normal PDF or software having functions to perform this type of calculations, e.g.:
>
> MS Excel function NORMDIST(x, mean, standard deviation, cumulative), for this case. NORMDIST(3.0;2.7;0.2;TRUE) would calculate the result (0.933).

In a similar way, given a **single tolerance lower limit**, T_L, and a measurement estimate y with measurement standard uncertainty of $u(y)$, a *decision rule* should define a probability of conformity (P_c) assuming a probability of type I error (α).
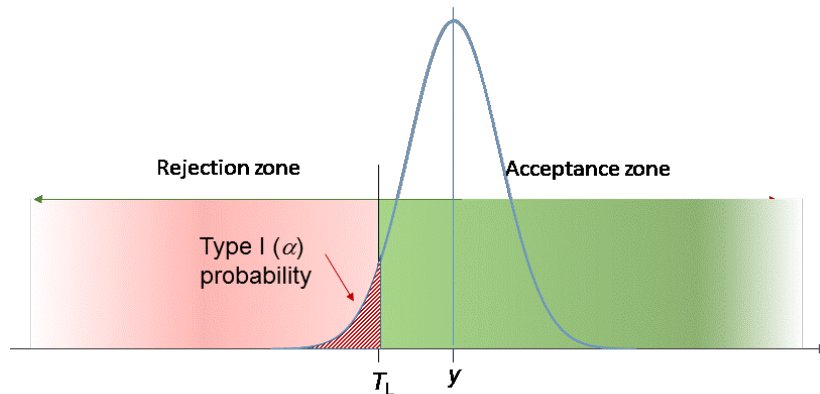

Figure 5 – Example with single lower tolerance

Decision rule

Acceptance if the hypothesis H$_0$: $P(Y \geq T_L) \geq (1 - \alpha)$ is true;

Rejection if the hypothesis H$_0$ is false, $P(Y \geq T_L) < (1 - \alpha)$.

Expression to test: $P_C = P(\eta \geq T_L) = 1 - P(\eta \leq T_L) = 1 - \Phi\left(\frac{T_L - y}{u(y)}\right) = \Phi\left(\frac{y - T_L}{u(y)}\right)$

Example:

Consider a measurement estimate y = 0,012 g with a standard uncertainty of $u(y)$ = 0,001 g, a single tolerance lower limit of T_L = 0,010 g, and a specification of conformity $(1 - \alpha)$ of 0,99 (99 %) thus assuming a type I error α = 0,01 (1 %).

With the experimental result and tolerance limit, assuming a Gaussian PDF, the *decision rule* will be:

Acceptance if the hypothesis H$_0$: $P(Y \geq 0,010 \text{ g}) \geq 0,99$ is true.

To estimate probabilities related with the example given, the conformance probability (P$_c$) need to be calculated using the general expression for Gaussian PDF:

$P_C = \Phi\left(\frac{y - T_L}{u(y)}\right)$

$P_C = \Phi\left(\frac{0,012 - 0,010}{0,001}\right) = \Phi(2,0) \approx 0,977 \ (97,7 \ \%) < 0,99$

Then the hypothesis H$_0$ is false and the decision is of non-conformity.

> Note: The value of $\Phi(z)$ can be obtained using tables of standard normal PDF or software having functions to perform this type of calculations, e.g.:
>
> MS Excel function NORMDIST(x, mean, standard deviation, cumulative), for this case, NORMDIST(0,012;0,010;0,002;TRUE) would give the result (0,977).

5 – Decision rule applied to conformity assessment with single tolerance and guard band

In the case that measurement estimates, *y*, are obtained with a known standard uncertainty, $u(y)$, a *decision rule* may be established considering a *guard band*, allowing to accept a measurement estimate by direct comparison with the acceptance interval.
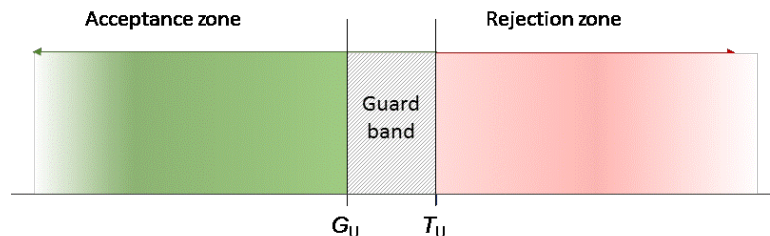

Figure 6 – Guard band between acceptance and rejection zones for a single upper tolerance

For the case of a single tolerance upper limit, T_U, being known the standard uncertainty, $u(y)$, and the probability of type I error (α), the guard band upper limit can be obtained by using the definition of the Gaussian PDF …

$$\Phi\left(\frac{T_U - y}{u(y)}\right) = 1 - \alpha$$

$$\left(\frac{T_U - y}{u(y)}\right) = \Phi^{-1}(1 - \alpha)$$

$$G_U = y = T_U - u(y) \cdot \left[\Phi^{-1}(1 - \alpha)\right]$$

Example:

Consider a measurement estimate y = 18,9 ºC with a standard uncertainty of $u(y)$ = 0,3 ºC, a single tolerance lower limit of T_L = 20,0 ºC, and a specification of conformity $(1 - \alpha)$ of 0,95 (95 %), thus assuming a type I error α = 0,05 (5 %).

To calculate the guard band upper limit, equation XX can be used,

$$G_U = 20 - 0,3 \cdot \left[\Phi^{-1}(0,95)\right] = 20 - 0,3 \cdot 1,64 \approx 19,5 \,°C.$$

Then the hypothesis H₀ is false and the decision is of non-conformity.

> Note: The value of $\Phi^{-1}(1-\alpha)$ can be obtained using tables of critical values of the normal PDF or software having functions to perform this type of calculations, e.g.: MS Excel function NORMINV(probability; mean; standard deviation), for this case NORMINV(0,95;0;1)would give the result (1,64).

A common practice is to evaluate the expanded uncertainty for the confidence interval intended to guard and use it directly to define the guard band upper limit, for the case of 95% confidence interval and using the previous example,

$$U_{95}(y) = k_{95} \cdot u(y) = 2,00 \cdot 0,3 = 0,6 \,°C$$

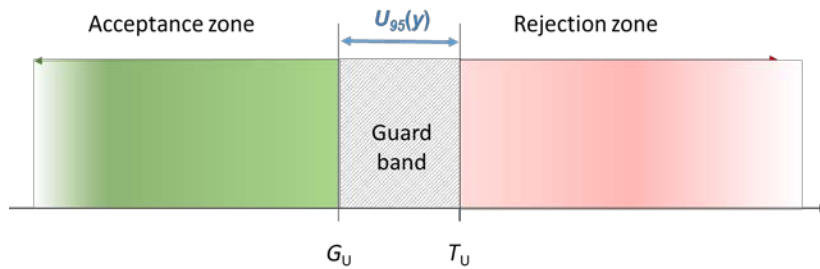$$G_U = T_U - U_{95}(y) = 20,0 - 0,6 = 19,4 \,°C$$

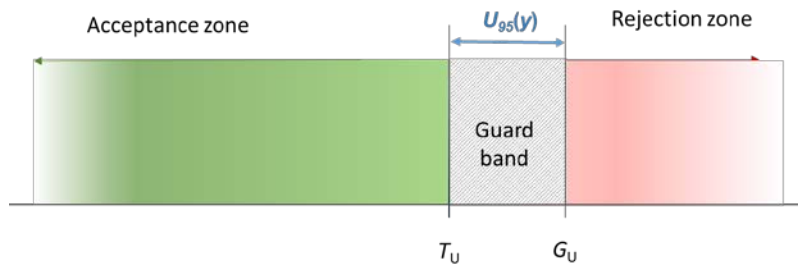*Figure 7a – Guard band for upper tolerance and guarded acceptance defined with an expanded uncertainty of 95%*

Figure 7 b) Guard band for upper limit and guarded rejection

In the case of guarded rejection G_u is given by:

$$G_U = y = T_U + u(y) \cdot \left[\Phi^{-1}(1 - \alpha)\right]$$

Example [s. JCGM 106:2012]:

For speed limit enforcement the speed of a car can be measured using a Doppler radar. This measurement can be performed with a relative standard uncertainty $u(v)/v$ of 2 % in the interval 50 km/h to 150 km/h.

The speed limit on a motor way might be set to 100 km/h. Because of the principle "in dubio pro reo" (Latin for "when in doubt, for the accused") a level of significance of $(1 - \alpha) = 0,999$ is used.

$$G_U = y = 100 + 2 \cdot \left[\Phi^{-1}(0,999)\right] = 100 + 2 \cdot 3,09 \approx 107 \text{ km/h}$$

Thus the guard band is [100 km/h ≤ v ≤ 107 km/h]. If the measured value is 107 km/h or greater, the probability that the speed limit has been exceeded is at least 99.9 %.

6 – Decision rule applied to conformity assessment with a tolerance interval without guard band

Given a **tolerance interval** defined by a **lower limit**, T_L, and an **upper limit**, T_U, and a measurement estimate y with measurement standard uncertainty of $u(y)$, a decision rule should define a probability of conformity (P_c) assuming a probability of type I error (α).
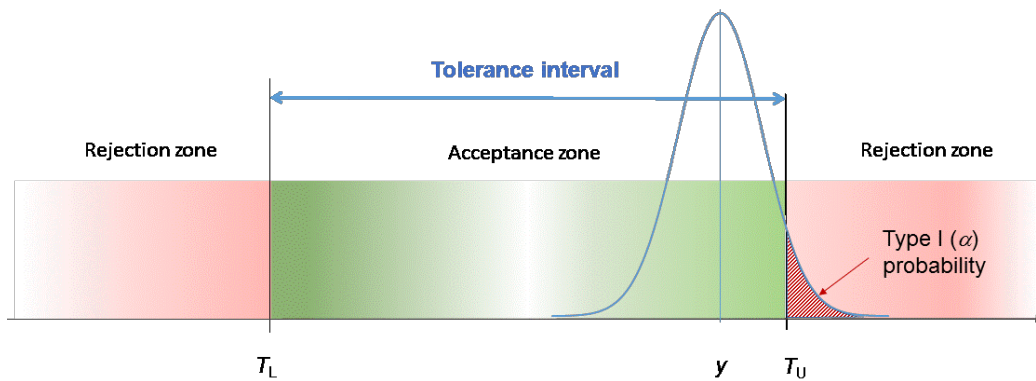
Figure 8 – Example of a tolerance interval

Decision rule

Acceptance if the hypothesis H$_0$: $P(T_L \leq Y \leq T_U) \geq (1 - \alpha)$ is true;

Rejection if the hypothesis H$_0$ is false, $P(T_L \leq Y \leq T_U) < (1 - \alpha)$.

$$P_C = P(T_L \leq \eta \leq T_U) = \Phi\left(\frac{T_U - y}{u(y)}\right) - \Phi\left(\frac{T_L - y}{u(y)}\right)$$

Example:

Consider a measurement estimate y = 23,5 kN with a standard uncertainty of $u(y)$ = 0,5 kN, a tolerance interval of [20 kN, 25 kN], and a specification of conformity $(1 - \alpha)$ of 0,95 (95 %), thus assuming a type I error α = 0,05 (5 %).

With the experimental result and tolerance interval, assuming a gaussian PDF, the decision rule will be:

Acceptance if the hypothesis H$_0$: $P(22 \leq Y \leq 25) \geq 0,95$ is true

To estimate probabilities related with the example given, the conformance probability (P$_c$) need to be calculated using the general expression for Gaussian PDF:

$$P_C = P(T_L \leq \eta \leq T_U) = \Phi\left(\frac{T_U - y}{u(y)}\right) - \Phi\left(\frac{T_L - y}{u(y)}\right)$$

$$P_C = \Phi\left(\frac{25 - 23,5}{0,5}\right) - \Phi\left(\frac{22 - 23,5}{0,5}\right) = \Phi(3,0) - \Phi(-3,0) = 0,9987 - 0,0013 \approx 0,997 \ (99,7 \ \%) \ > \ )$$
0,95

Then the hypothesis H$_0$ is true and the decision is of conformity.

7 – Decision rule applied to conformity assessment with a tolerance interval and guard band

The conformity assessment applied to a tolerance interval can also be developed using guard bands in the case where measurement estimates, *y*, are obtained with a known standard uncertainty, *u(y)*.

In this case, guard band limits for a confidence level of (1 – α) can be obtained, considering a symmetric error of α/2 at each tail of the PDF. A common approach adopted for guarded acceptance is to consider that:

$$G_\mathrm{U} = T_\mathrm{U} - U(y)$$

$$G_\mathrm{L} = T_\mathrm{L} + U(y)$$

with the expanded uncertainty $U(y)$ obtained for a (1 – α) confidence level

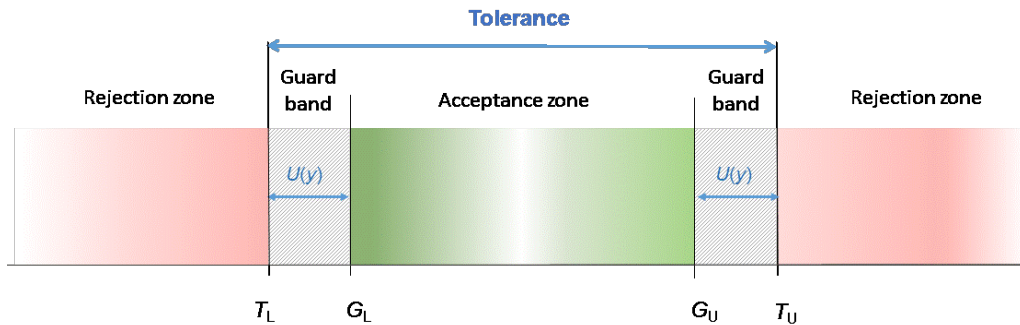*Figure 9 – Example of a guard band applied to a tolerance interval*

For guarded rejection the guard bands can be calculated according:

$$G_\mathrm{U} = T_\mathrm{U} + U(y)$$

$$G_\mathrm{L} = T_\mathrm{L} - U(y)$$

8 – References and further readings

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