DETERMINATION OF CONFORMANCE WITH SPECIFICATIONS USING MEASUREMENT UNCERTAINTIES – POSSIBLE STRATEGIES

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, legal frameworks and contract agreements, 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.

In the evaluation of compliance based on quantitative results different cases can occur, configuring 4 possible options (cases A to D found in Figure 1). In this, the cases A and D are unambiguous as the decisions are not influenced by measurement uncertainties. However, the cases B and C where the measurement uncertainty interval is overlapping the limit value, implies a careful analysis that should establish objective criteria (decision rule) to accept the measurement having part of the uncertainty interval outside the tolerance.

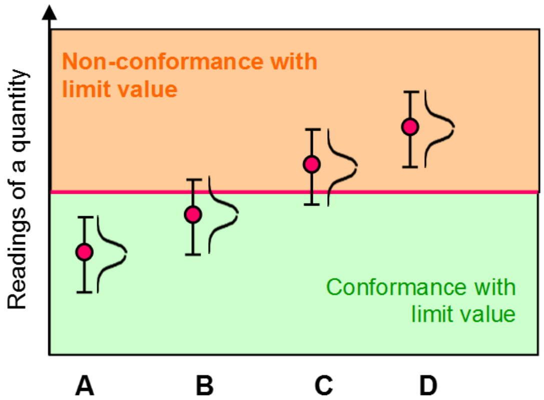

Fig. 1: Test results and their measurement uncertainties in relation to an upper limit value

A general approach to conformity assessment

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 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.

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 adopted is described in known references, namely, [EURACHEM Guide:2007], [ASME B89.7.3.1:2001] and [EUROLAB Technical Report 1/2017]. Two of them are particularly relevant.

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

Establishing the decision rule

In case regulations and normative standards contain provisions on meeting specifications or limit values taking measurement uncertainties into account, these provisions have to be applied. If such provisions are missing, rules have to be determined before testing meeting market and safety requirements.

The international standard ISO 14253:2016 part 1: *Decision rules for proving conformance or non-conformance with specifications* makes a differentiation whether conformance or non-conformance shall be determined with a high probability. The expanded measurement uncertainty U and a confidence level of approx. 95% (expansion factor k = 2) will generally be considered to be adequate. Only in exceptional cases will a higher confidence level of e.g. 99% (expansion factor k = 3) be chosen.

The definition of criteria for decision should take into account if the specification is an interval or a limit (upper or lower), if guard bands should be considered and, in this case, if they will reduce or enlarge the acceptance interval. The following Figures illustrates different possibilities (being T_U – tolerance upper limit; G_U – guard band upper limit, T_L – tolerance lower limit, G_L – guard band lower limit, $U(y)$ – expanded uncertainty of the measurement.

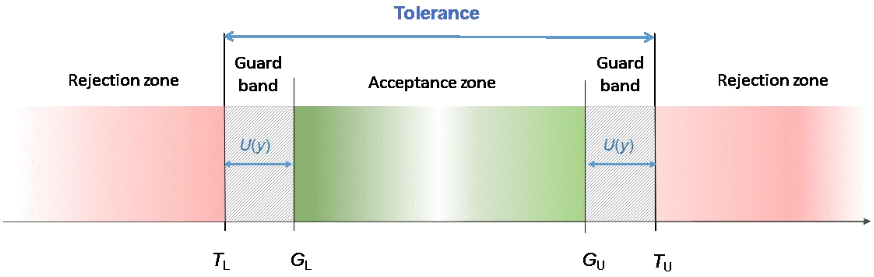

Figure 2 – Example of areas defined for a tolerance interval in order to minimise the consumer's risk

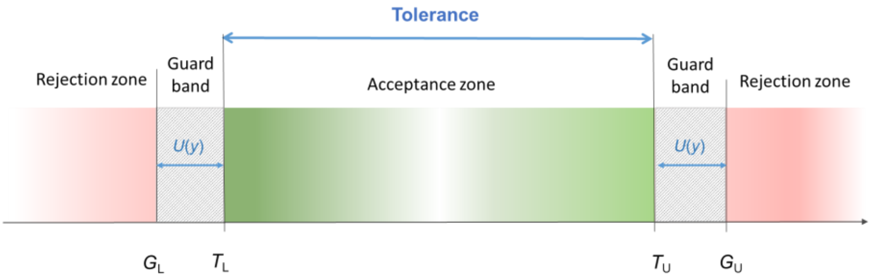

Figure 3 – Example of areas for the tolerance interval in order to minimise the supplier's risk

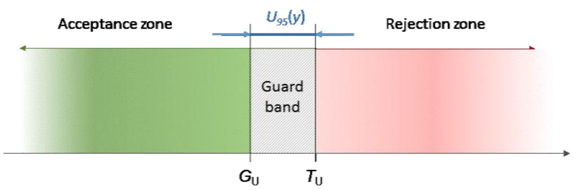

Figure 4 – Guard band for upper tolerance and guarded acceptance defined with an expanded uncertainty of 95%

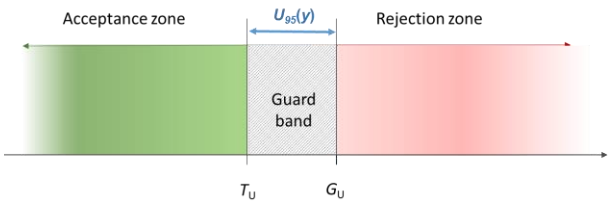

Figure 5 – Guard band for upper limit and guarded rejection

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.

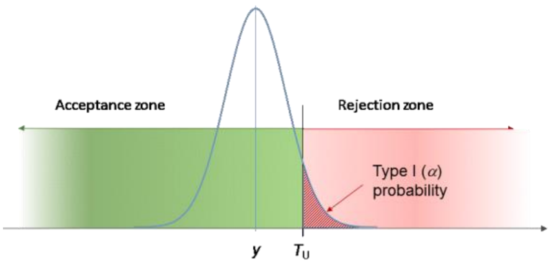

Figure 6 – Example with single upper tolerance

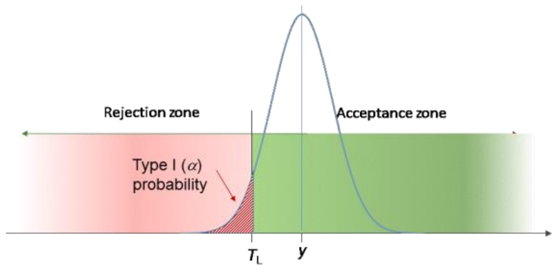

Figure 7 – Example with single lower tolerance

In these cases, the criteria can be established performing a test of hypothesis in which fulfilment of H_0 condition implies the decision of acceptance and otherwise implies the decision of rejection. Therefore, assuming a probability of type I error (α), the decision rule can be expressed as:

Decision rule

Acceptance if the hypothesis H_0: $P(Y \leq \mathrm{T}_U) \geq (1-\alpha)$ is true;

Rejection if the hypothesis H_0 is false, $P(Y \leq \mathrm{T}_U) < (1-\alpha)$.

Expression to test: $P_\mathrm{C} = P(\eta \leq T_\mathrm{U}) = \Phi\left(\frac{\mathrm{T}_\mathrm{U}-y}{u(y)}\right)$

A pratical example of application is the following:

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 normal PDF (Probability Distribution function), the decision rule will be:

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

Rejection if the hypothesis H_0: $P(Y \leq 3{,}0\ \mathrm{mm}) \geq 0{,}95$ is false

To estimate probabilities related with the example given, the conformance probability (P_c) need to be calculated using the general expression for normal PDF's:

$$P_\mathrm{C} = P(\eta \leq T_\mathrm{U}) = \Phi\left(\frac{\mathrm{T}_\mathrm{U}-y}{u(y)}\right)$$
$$P_\mathrm{C} = \Phi\left(\frac{3{,}0-2{,}7}{0{,}2}\right) = \Phi(1{,}5) \approx 0{,}933 \text{ (93,3 \%)} < 0{,}95$$

Then, the hypothesis H_0 is false and the decision to take is of rejection (non-compliant).

Note:
The value of $\Phi(z)$ can be obtained using tables of standard Gaussian PDF or software having functions to perform this type of calculations, e.g.:

MS Excel function NORMDIST(x, mean, standard deviation, cumulative), for the above case, NORMDIST(3,0;2,7;0,2;TRUE) would calculate the result (0,933).

More details and a list of references can be found in the EUROLAB Technical Report 1/2017.