Risk-aware decisions: taking into account admissible risk and measurement uncertainty in setting the acceptance limits

Alessandro Ferrero [1], *Harsha Vardhana* Jetti[2], *Sina* Ronaghi[1*], and *Simona* Salicone[1]

[1]Dipartimento di Elettronica, Informazione e Bioingegneria (DEIB), Politecnico di Milano, Italy
[2]Department of Engineering, University of Perugia, Italy

Abstract. Document JCGM 106:2012, encompassed in the ISO-IEC Guide 98-4, provides guidelines for comparing a measurement result with a tolerance interval, considering that, according to the Guide to the Expression of Uncertainty in Measurement (GUM), a measurement result is not a single value but rather a distribution of values. Therefore, the comparison does not always lead to a fully certain decision. In fact, when the distribution crosses the tolerance limits, there is a risk of making an incorrect decision. JCGM 106:2012 offers general recommendations about setting acceptance or rejection limits, without providing details on how to compute them under practical situations. This paper addresses most practical situations, considering cases of normal and non-normal distributions and cases where the distribution of values that can be reasonably be attributed to the measurand are obtained through Monte Carlo simulations. Additionally, it allows for considering any desired level of decision risk, which can be set based on the specific situation or application.

1 Introduction

Measurement results are generally used as input elements in decision-making processes, which are crucial for conformity assessment. This task is critical in many fields, ranging from industrial applications [1], where product features must meet given specifications, to environmental protection, healthcare, legal, and forensic domains [2], where decisions typically involve verifying that the amount of a substance (such as a pollutant or drug) or the error of an instrument does not exceed a specified maximum admissible limit.

Ensuring compliance requires that the measurand value lies within a range of admissible values. If the measurand is measured with negligible uncertainty, this can be easily assessed by directly comparing two numerical values: the measured value and the tolerance limits of the admissible range. In such cases, the decision appears to be made with no risk of error.

However, when measurement uncertainty is not negligible - as is often the case in practice - the Guide to the Expression of Uncertainty in Measurement (GUM) [3] states that a (coverage) interval should be provided around the measurement result. This interval encompasses a large fraction of the distribution of values that can be reasonably attributed to the measured quantity. Consequently, the decision-making process involves comparing an interval, with a given coverage probability, against the tolerance limits, which introduces a risk of false decisions (false acceptance or false rejection).

This issue is addressed in document JCGM 106:2012 [4], encompassed in the ISO-IEC Std. Guide 98-4 [5], which specifically deals with the problem of determining whether a measured quantity falls within a given tolerance interval - defined as the permissible range of values for a property. The tolerance interval can be either two-sided or one-sided. The document defines acceptance limits, stating that, given a certain measurement uncertainty, the measurand is considered conforming if the measured value falls within these limits and non-conforming if it falls outside them. It also explores different decision rules and methods for evaluating the risk of incorrect assessments based on measurement uncertainty.

It can be readily observed that the risk of a false decision, given a tolerance limit and an acceptance limit, depends on the probability distribution associated with the set of values that can be attributed to the measurand, and not just on the expanded uncertainty. Moreover, in many cases, particularly in industrial applications as well as in environmental protection, healthcare, and forensics, it is more practical to define a maximum admissible risk [6-9]. This allows for the proper adjustment of acceptance limits based on the estimated measurement uncertainty, ensuring that the risk of exceeding the tolerance limits remains below the desired maximum admissible risk.

This paper presents a method that, given:

- the distribution of values that can be attributed to the measurand (whether assumed, estimated, or obtained via Monte Carlo simulation),
- the tolerance limits,
- and the desired maximum admissible risk,

* Corresponding author: sina.ronaghi@polimi.it

determines the corresponding acceptance limits. The defined method has been also included into a general-purpose tool developed in Python, making it freely available to the Readers across multiple platforms.

2 Background: the problem

When a measured value x_m (without considering its uncertainty) is compared with a given threshold, it is immediate to take a decision, as shown in Fig. 1 [10]. On the other hand, the decision-making procedure becomes quite cumbersome when an uncertainty interval is associated to the measured value x_m [10], as shown in Figs. 2-3, in particular in the case of Fig. 3, where the uncertainty interval crosses the threshold.

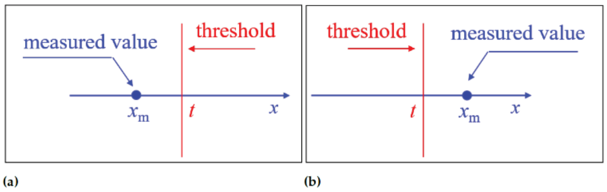

Fig. 1. Comparison of a single measured value with a threshold, when the measured value x_m is lower (a) and greater (b) than threshold t.

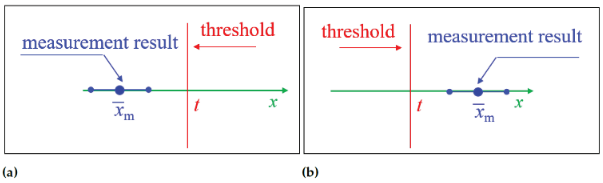

Fig. 2. Comparison of an uncertainty interval with a threshold t, when the uncertainty interval is completely below (a) or above (b) the threshold.

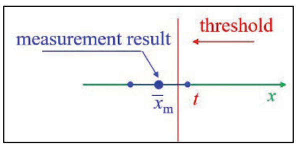

Fig. 3. Comparison of an uncertainty interval with a threshold t, when the threshold falls within the interval.

However, it is important to underline that in all the above situations there is a risk of taking a wrong decision.

In the case of Fig.1, where the decision is simply taken by considering whether $x_m < t$ or $x_m > t$, the risk can reach 50% when $x_m = t$, [10]. In fact, the decision is simply taken by considering the measured value x_m and its position with respect to t, but it is known that, because of uncertainty contributions, a probability distribution is always associated to x_m [3]. Therefore, supposing this distribution is symmetric, half distribution will be above t and half distribution will be below t, when $x_m = t$, thus giving a probability of 50% of a wrong decision.

In the case of Fig. 2, where the uncertainty interval is considered, a risk of a wrong decision could be still present, since the width of the interval is strictly related to the probability distribution and the considered coverage factor [3]. In Fig. 3 the risk of a wrong decision is even more evident.

To consider this problem in decision making procedures and in conformity assessment, document JCGM 106:2012 [4], encompassed in the ISO-IEC Std. Guide 98-4 [5], proposes a more precautionary approach, as described in Fig. 4 and reported in [10].

In short, when acceptance or rejection decisions need to be made based on measured values, the threshold is increased or decreased in order to widen or narrow the interval, in the direction of making a more precautionary decision.

As an example, in Fig. 4, the measured value must be lower than an upper threshold T_U (up) and therefore the resulting decision will be considered positive (accepted) only if the measured value satisfies $x_m < A_U$, where $A_U < T_U$ and the width w of the guard band is determined as a multiple of the expanded uncertainty associated to x_m; or it must be included between a lower and an upper threshold T_L and T_U (down), and therefore the decision will be positive (accepted) only if the measured value satisfies $A_L < x_m < A_U$.

This approach represents an improvement with respect to the case that does not consider measurement uncertainty but does not yet provide step-by-step guidance on how to evaluate w in practical cases. This paper aims to provide an answer to this problem.

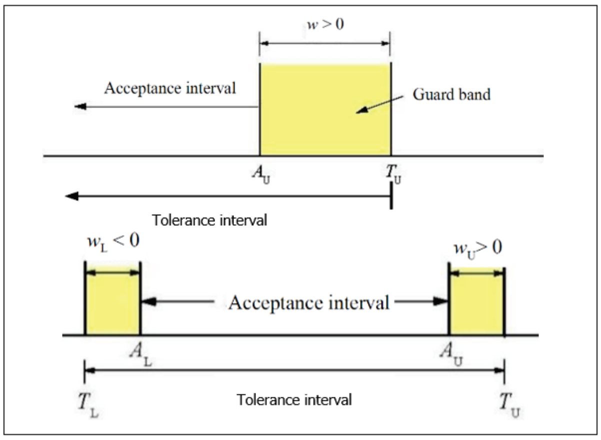

Fig. 4. Decision rule based on guarded acceptance. Up: a one-sided tolerance interval upper limited by T_U. Down: two-sided tolerance interval between lower and upper limits T_L and T_U.

3 Decision rule based on the maximum admissible risk

The GUM [3] states that a probability distribution is always associated to a measurement result. Furthermore, documents JCGM 106:2012 [4] and ISO-IEC Std. Guide 98-4 [5] state that such distribution is always obtained from two components: the one available before performing the measurement (called *prior* information) and the additional information supplied by the measurement, combined through the well-known Bayes' theorem.

In practical applications, information about the measurement result is provided either in terms of a known probability distribution function (PDF) or as a set of measurements belonging to an unknown PDF. In this section, it is shown how to evaluate values A_U and A_L, according to the available information of the measurement result and to the maximum admissible risk (*MAR*), that is, the maximum risk that can be accepted in the specific application domain. In particular, Sec. 3.1 covers the case where the PDF of the measurement result is known, while Sec. 3.2 covers the case where the shape of the PDF is not known, and multiple measurements are available.

3.1 Known PDF

The width of the guard bands must be determined in relation to both the probability density function (PDF) of the measurement result and the Maximum Allowable Risk (*MAR*). In this section, several common PDFs are examined to formulate relationships for A_U and A_L (which represent the upper and lower acceptance limits in the context of guarded acceptance), as well as for R_U and R_L (which denote the upper and lower rejection limits in the context of guarded rejection). It is also important to note that, these relationships are expressed as a function of *MAR*.

The reported equations (the readers are addressed to [10] for the details) are evaluated starting from the following simple considerations.

Given PDF $p(x)$ associated to the measurement result, the cumulative distribution function (CDF)

$$F_X(x) = \int_{-\infty}^{x} p(t)dt \tag{1}$$

represents the probability that variable X is lower than x; similarly, $1 - F_X(x)$ represents the probability that variable X is greater than x. Therefore, if the tolerance limits T_U or T_L shall not be exceeded and the *MAR* is given, the following inequalities shall be satisfied:

$$\begin{cases} F_X(T_U) \geq 1 - MAR & \text{when } x < T_U \text{ is required} \\ F_X(T_L) \leq MAR & \text{when } x > T_L \text{ is required} \end{cases} \tag{2}$$

The acceptance or rejection limits are hence evaluated by considering the specific measured value (which is also the mode of the considered PDF) for which, in equation (2), the equalities hold.

3.1.1 Normal PDF

Let's suppose $p(x)$ is normal, with standard deviation σ. Then, it follows [10, 11]:

$$A_U = T_U - \sqrt{2}\sigma \cdot \text{erfinv}(1 - 2 \cdot MAR) \tag{3}$$
$$A_L = T_L + \sqrt{2}\sigma \cdot \text{erfinv}(1 - 2 \cdot MAR) \tag{4}$$
$$R_U = T_U + \sqrt{2}\sigma \cdot \text{erfinv}(1 - 2 \cdot MAR) \tag{5}$$
$$R_L = T_L - \sqrt{2}\sigma \cdot \text{erfinv}(1 - 2 \cdot MAR) \tag{6}$$

where erfinv is the *inverse error function*.

Figs. 5 and 6 show an example where a resistor with nominal resistance $R_n = 100\ \Omega$ is considered and its conformity to a ±2% tolerance must be assessed. It is assumed that a normal PDF is associated with the measured value, with a standard deviation $\sigma = 0.5\ \Omega$; the tolerance limits are: $T_U = 102\ \Omega$, $T_L = 98\ \Omega$, and the *MAR* is set to 0.05.

The application of equations (3)-(6) provides the following values for the acceptance and rejection limits: $A_U = 101.18\ \Omega$; $A_L = 98.82\ \Omega$; $R_U = 102.82\ \Omega$; $R_L = 97.18\ \Omega$. In Fig. 5, the pink line shows a normal PDF with the given standard deviation and centred exactly on A_U and the pink area shows the probability that this PDF exceeds the tolerance limit T_U. This area is exactly equal to the set *MAR*. Similarly, the green line shows a normal PDF with the given standard deviation and centred exactly on A_L and the green area shows the probability that this PDF exceeds the tolerance limit T_L. This area is exactly equal to the set *MAR*. Similar considerations can be done for Fig. 6, where the PDFs are centred on the rejection limits R_L and R_U.

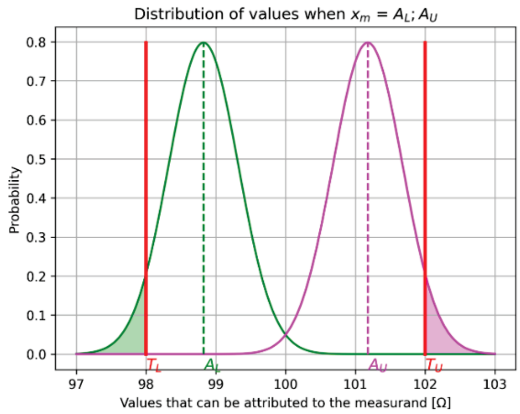

Fig. 5. Example of evaluation of A_U and A_L (guarded acceptance) with a normal distribution.

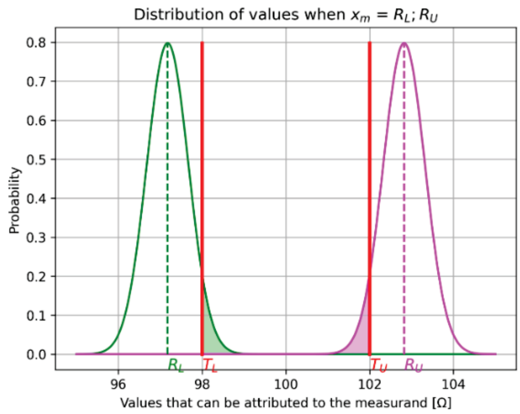

Fig. 6. Example of evaluation of R_U and R_L (guarded rejection) with a normal distribution.

3.1.2 Uniform PDF

Let's suppose $p(x)$ is uniform, with support $2a$. Then, it follows [10, 11]:

$$A_U = T_U - a \cdot (1 - 2 \cdot MAR) \tag{7}$$
$$A_L = T_L + a \cdot (1 - 2 \cdot MAR) \tag{8}$$
$$R_U = T_U + a \cdot (1 - 2 \cdot MAR) \tag{9}$$
$$R_L = T_L - a \cdot (1 - 2 \cdot MAR) \tag{10}$$

Figs. 7 and 8 show the results obtained considering the same example as in section 3.1.1, where it is now assumed that the considered PDF is uniform with $a = 1\ \Omega$, the tolerance limits are still $T_U = 102\ \Omega$, $T_L = 98\ \Omega$, and the *MAR* is set again to 0.05. Equations (7)-(10) leads to the following values for the acceptance and rejection limits: $A_U = 101.10\ \Omega$, $A_L = 98.90\ \Omega$; $R_U = 102.90\ \Omega$; $R_L = 97.10\ \Omega$. Similar considerations as those reported for Figs. 5 and 6 apply to these figures too.

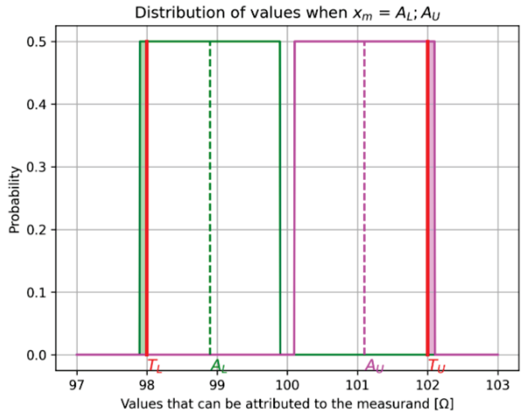

Fig. 7. Example of evaluation of A_U and A_L (guarded acceptance) with a uniform distribution.

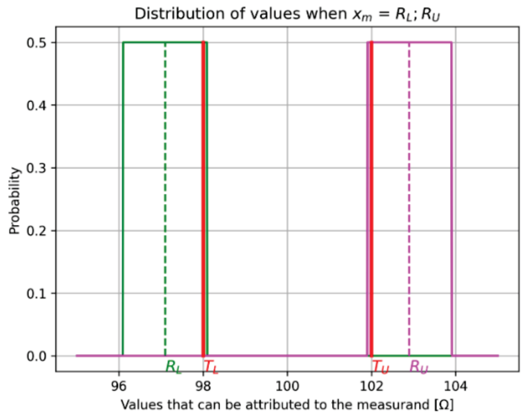

Fig. 8. Example of evaluation of R_U and R_L (guarded rejection) with a uniform distribution.

3.1.3 Triangular PDF

Let's suppose $p(x)$ is triangular, with support $2a$. Then, it follows [10, 11]:

$$A_U = T_U - a \cdot \left(1 - \sqrt{2 \cdot MAR}\right) \tag{11}$$

$$A_L = T_L + a \cdot \left(1 - \sqrt{2 \cdot MAR}\right) \tag{12}$$

$$R_U = T_U + a \cdot \left(1 - \sqrt{2 \cdot MAR}\right) \tag{13}$$

$$R_L = T_L - a \cdot \left(1 - \sqrt{2 \cdot MAR}\right) \tag{14}$$

Figs. 9 and 10 show the results obtained considering the same example as in section 3.1.1, where it is now assumed that the considered PDF is triangular with $a = 1\ \Omega$, $T_U = 102\ \Omega$, $T_L = 98\ \Omega$, and the MAR is set to 0.05 again. Equations (11)-(14) lead to the following values for the acceptance and rejection limits: $A_U = 101.32\ \Omega$; $A_L = 98.68\ \Omega$; $R_U = 102.68\ \Omega$; $R_L = 97.32\ \Omega$. Similar considerations as those reported for Figs. 5 and 6 apply to these figures too.

3.1.4 Trapezoidal PDF

Let's suppose $p(x)$ is trapezoidal, with major base $2a$ and ratio of the minor base to the major base β. Then, it follows [10, 11]:

$$A_U = T_U - a \cdot \left(1 - \sqrt{2 \cdot MAR \cdot (1 - \beta^2)}\right) \tag{15}$$

$$A_L = T_L + a \cdot \left(1 - \sqrt{2 \cdot MAR \cdot (1 - \beta^2)}\right) \tag{16}$$

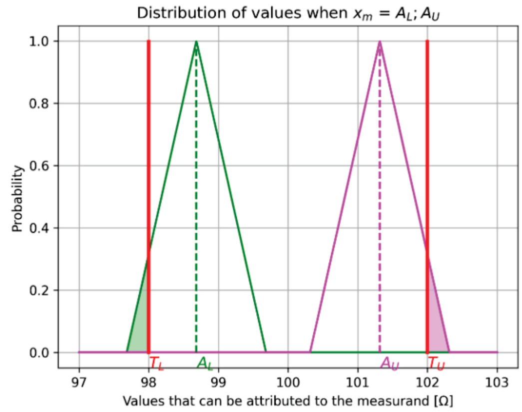

Fig. 9. Example of evaluation of A_U and A_L (guarded acceptance) with a triangular distribution.

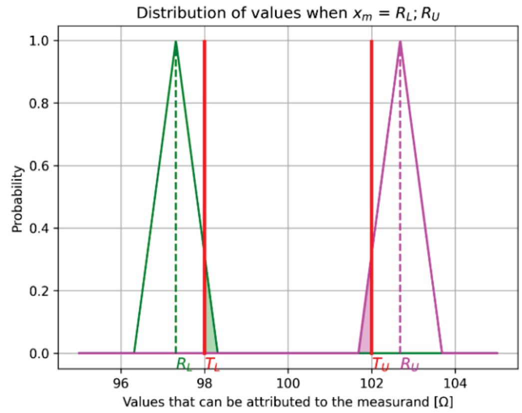

Fig. 10. Example of evaluation of R_U and R_L (guarded rejection) with a triangular distribution.

$$R_U = T_U + a \cdot \left(1 - \sqrt{2 \cdot MAR \cdot (1 - \beta^2)}\right) \tag{17}$$

$$R_L = T_L - a \cdot \left(1 - \sqrt{2 \cdot MAR \cdot (1 - \beta^2)}\right) \tag{18}$$

Figs. 11 and 12 show the results obtained considering the same example as in section 3.1.1, where it is now assumed that the considered PDF is trapezoidal with $a = 1\ \Omega$, $\beta = 0.75$, $T_U = 102\ \Omega$, $T_L = 98\ \Omega$, and the MAR is set to 0.05 again. Equations (15)-(18) lead to the following values for the acceptance and rejection limits: $A_U = 101.21\Omega$; $A_L = 98.79\ \Omega$; $R_U = 102.79\ \Omega$; $R_L = 97.21\ \Omega$. Similar considerations as those reported for Figs. 5 and 6 apply to these figures too.

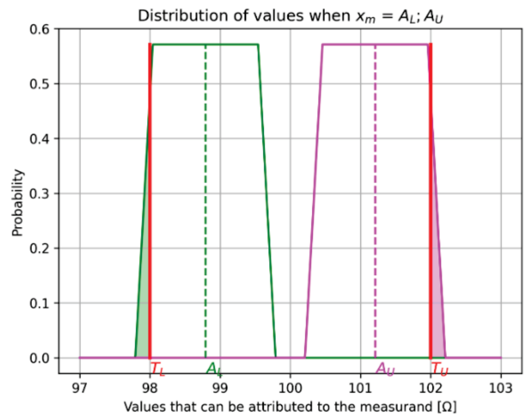

Fig. 11. Example of evaluation of A_U and A_L (guarded acceptance) with a trapezoidal distribution.

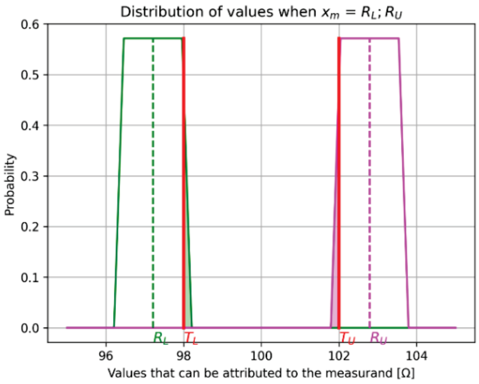

Fig. 12. Example of evaluation of R_U and R_L (guarded rejection) with a trapezoidal distribution.

3.2 Unknown PDF

In the previous section, mathematical relationships have been presented that related tolerance limits, measurement uncertainty, acceptance/rejection limits and risk of exceeding the tolerance limits, under the assumption of specific PDFs. These relationships improve the guidelines in [4, 5]. The presented relationships in (3)-(18) are significantly useful in practice, since they represent most of the practical situations for measurement results and their associated uncertainties.

However, since other scenarios cannot be excluded a priori, a generalized approach has also been developed to ensure the broad application of the proposed decision-making procedure [11].

When the mathematical equation of the PDF is not known, it is not possible to have a mathematical equation of the CDF and find closed-form formulas for the acceptance and rejection limits. Under this situation, by applying a Monte Carlo simulation (as also recommended by [12]), or by experimentally repeating the measurement procedure, if possible, N values are obtained for the measurand, and their PDF can be approximated by the histogram of the relative frequencies. This histogram is initially supposed to have a mean value exactly in either T_U or T_L. Its associated CDF can be hence numerically evaluated as:

$$F_X(x) = \sum_{-\infty}^{x} h(x) \quad (19)$$

where, for each class of the histogram, $h(x)$ represents the relative frequency of the class.

Then, according to $F_X(x)$, the value x_{MAR} can be numerically found. In particular, in case of guarded acceptance, x_{MAR} has to satisfy to:

$$x_{MAR} | F_X(x_{MAR}) = 1 - MAR \quad (20)$$

when $x < T_U$ is considered; and to:

$$x_{MAR} | F_X(x_{MAR}) = MAR \quad (21)$$

when $x > T_L$ is considered [11].

On the other hand, in case of guarded rejection, x_{MAR} has to satisfy to:

$$x_{MAR} | F_X(x_{MAR}) = MAR \quad (22)$$

when $x < T_U$ is considered; and to:

$$x_{MAR} | F_X(x_{MAR}) = 1 - MAR \quad (23)$$

when $x > T_L$ is considered [11].

The evaluation of x_{MAR} on the CDF allows us to shift the CDF on the left or right, so that the risk of exceeding the threshold becomes exactly MAR [11]. The following equations for the acceptance and rejection limits are found as [11]:

$$A_U = R_U = 2 \cdot T_U - x_{MAR} \quad (24)$$

$$A_L = R_L = 2 \cdot T_L - x_{MAR} \quad (25)$$

Let us again consider the previous example where $T_U = 102\ \Omega$, $T_L = 98\ \Omega$ and the MAR is set to 0.05. Figs. 13 shows the histogram associated to the measurement values with a mean value equal to T_U. The associated CDF is evaluated as in (19), while x_{MAR} is evaluated as in (20) or (22), when, respectively, guarded acceptance or guarded rejection are considered. The acceptance and rejection limits are then evaluated as in (24). Although the formula is the same, it will provide two different values for A_U and R_U, since equations (20) and (22) provide a different x_{MAR} value. In particular, in the considered example, it will be: $A_U = 101.15\ \Omega$ and $R_U = 102.83\ \Omega$.

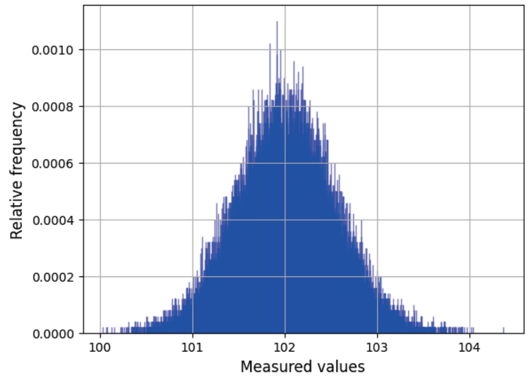

Fig. 13. Histogram of the relative frequencies associated to the measured values, centred on T_U.

This is shown in the left side of Figs. 14 and 15, where the pink lines represent the CDFs of the shifted, with respect to the original (in Fig. 13), histogram to the left and right respectively, in order to be centred on A_U and R_U respectively. In fact, according to equations (20) and (22), the shifted histograms have a probability of exceeding the threshold exactly equal to the set MAR, as shown by the pink lines in the figures.

Similar considerations can be done when the lower threshold T_L is considered. In this case, the initial CDF (19) is evaluated according to a histogram similar to the one shown in Fig. 13, but centred on T_L. In this case, x_{MAR} is evaluated as in (21) or (23), when, respectively, guarded acceptance or guarded rejection are considered, while the acceptance and rejection limits are evaluated as in (25). In the considered example: $A_L = 98.80\ \Omega$ and $R_L = 97.18\ \Omega$ are obtained, as shown in Figs. 14 and 15, as well as the shifted CDFs (green lines).

4 Phyton tool

A Jupyter Notebook, implemented in Python, has been developed to compute the acceptance and rejection limits given the MAR, the PDF of the values that can be reasonably attributed to the measurand, and the tolerance limits. This notebook, which is available open-source and can be accessed in [13], allows one to reproduce the presented results using the same parameters, as well as different ones.

Furthermore, in cases where the distribution of measurements at the tolerance limits are unknown and the results cannot be obtained in a closed-form solution, a Monte-Carlo simulation has been performed by generating two random sets from a normal distribution, each consisting of 5000 values. These sets are centred at 98 Ω and 102 Ω, respectively. The generated distributions are included in the repository and can be used as T_U and T_L to determine the acceptance limits (A_U, A_L), as well as the rejection limits (R_U and R_L) from (24) and (25).

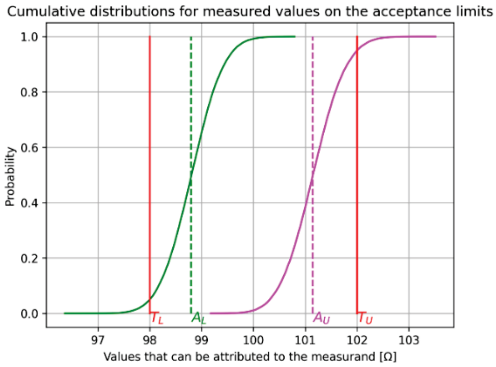

Fig. 14. Example of application of the general method when guarded acceptance is considered.

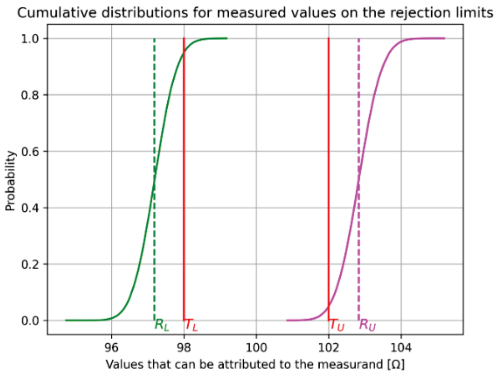

Fig. 15. Example of application of the general method when guarded rejection is considered.

5 Conclusions

The work aims to fill a gap in the JCGM 106:2012 standard regarding methods for considering measurement uncertainty in conformity assessments. The standard provides only general guidelines and does not specify a universally applicable methodology to link acceptance (or rejection) limits, uncertainty, and the risk of false decisions. The article analyses the most common probability distributions used to characterize the distribution of values reasonably attributable to the measurand and provides practical guidance for calculating one of the above parameters as a function of the other two.

In summary, this paper introduced a decision-making framework that enhances the practicality of the recommendations in JCGM 106:2012 by considering measurement uncertainty and the maximum allowable risk in real-world scenarios. The study derived equations for known unimodal probability distributions, as well as for cases where the distribution of values reasonably attributed to the measurand is obtained through Monte Carlo simulation. To ensure applicability and reproducibility, the authors also developed an open-source Python script, available in a public GitHub repository, which readers can utilize and build upon.

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