

Decision rules for Statements of Conformity

Every result of an analysis is subject to a measurement uncertainty, because the measured value only represents an estimate of the true (unknown) value due to limitations such as display accuracy, signal noise, or environmental influences.

If a measured value is used to make a statement regarding compliance with a specified tolerance limit (statement of conformity), this decision can be made either with or without consideration of the measurement uncertainty.

ISO/IEC 17025:2018 requires accredited testing laboratories to make statements of conformity based on a defined decision rule. This rule must be communicated to the customer and is applied unless the standard or technical specification on which the statement of conformity is based specifies a different decision rule.

RMS Foundation reports an extended measurement uncertainty $U_{k=2}$ for a confidence interval of 95% for all measurement results. In some cases, the information can be provided on request. Unless otherwise specified or agreed, statements of conformity are made by RMS Foundation on the basis of a **simple decision rule**. This means that the measurement uncertainty is **not** taken into account in the decision. Measurement results are rounded to the number of decimal places specified in the standard or technical specification before conformity is assessed. As illustrated in the following graph, only the measured value, or the mean value of a multiple measurement, must be within the acceptance interval (A-B) to pass the conformity assessment. Measured values outside the acceptance interval fail the assessment (D-E). If a measured value lies exactly on the tolerance limit (C), it passes the assessment if the tolerance limit represents an acceptable minimum or maximum value, or if the acceptance interval includes the tolerance limit (\geq or \leq). Otherwise, the measured value fails the conformity assessment. Without a clear indication of the role of the tolerance limit, measured values in case C pass the conformity assessment.

The probabilities for false positive declarations of conformity (error probability) arising from these decision rules are tabulated below for the 5 different cases A-E. On test certificates with a statement of conformity, RMS Foundation notes the applied decision rule in each case.

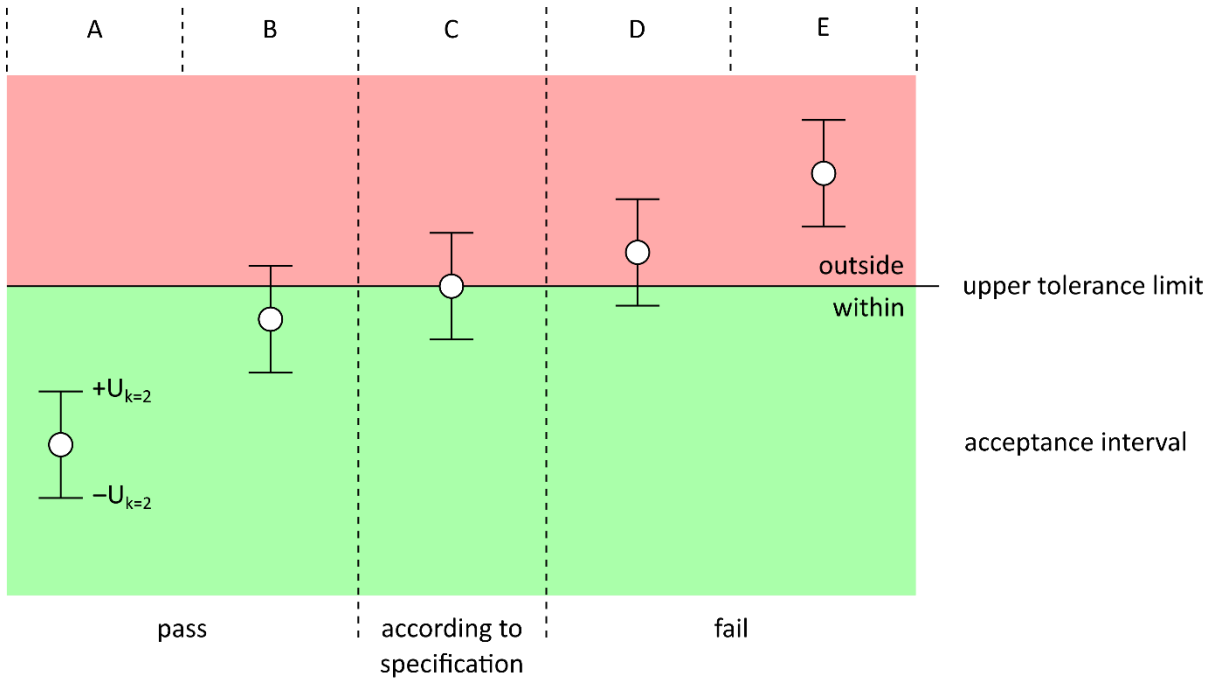


Figure: Binary statement of conformity for simple acceptance.

Table: Decisions for cases A to E and associated probabilities of false declaration of conformity.

Case	Decision	Error probability
A	Pass	< 2.5%
B	Pass	2.5% bis < 50%
C	According to specification*	50%
D	Fail	2.5% bis < 50 %
E	Fail	< 2.5%

* If the acceptance interval includes the tolerance limit (acceptable minimum or maximum value, or \geq or \leq), the measured value passes the conformity assessment. Otherwise, it fails. If the rule of the tolerance limit is undefined, it passes.