Decision rules at Kiwa for conformity statements – DIN EN ISO/IEC 17025:2018

Kiwa GmbH
As on: 29/02/2024

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At Kiwa GmbH, the decision rules used for statements on the conformity of test results are based on DIN EN ISO/IEC 17025:2018-03 *(General requirements for the competence of testing and calibration laboratories)* and largely follow ILAC-G8: 09/2019.

These decision rules describe how measurement uncertainty is taken into account when making statements about conformity with a specified requirement.

Variant 1: Standardised specifications for conformity testing

If the standards or specifications to be used for the measured value calibration contain precise specifications for the conformity test, these shall be applied as a decision rule for the assessment of the measurement/test results.

Variant 2: No standards or specifications with requirements for conformity testing

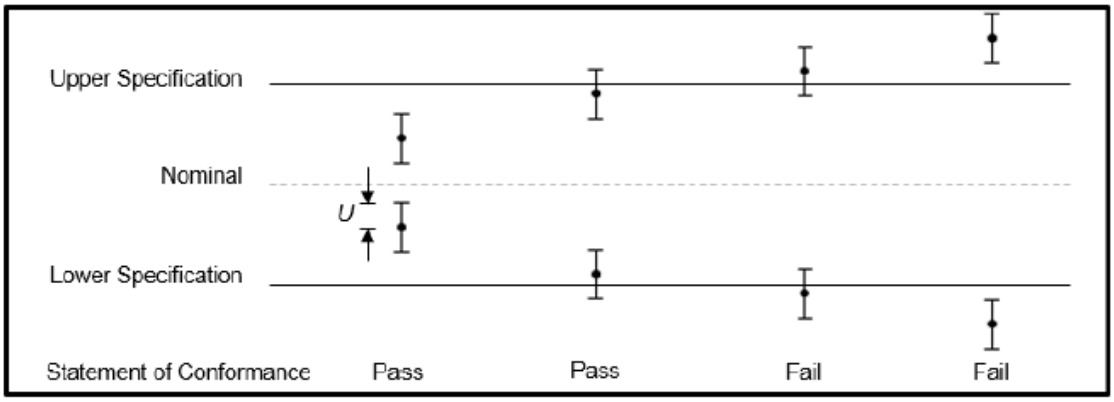
If the standards or specifications to be used for the measured value calibration do not contain precise or sufficient specifications for the conformity test, various options are available for conformity statements in test reports.

1. Binary Kiwa Decision Rules

Conformity statements can fundamentally be based on binary decision rules (fulfilled/not fulfilled), whereby Kiwa provides two decision rules. These differ in their confidence level with regard to the conformity statement and thus define the acceptance range for the determined measured values.

1.1 First Binary Kiwa Decision Rule

With the first binary Kiwa decision rule, the measurement uncertainty (U) is not taken into account in this conformity statement (Fig. 1).



U = 95% expanded measurement uncertainty

Figure 3 Graphical representation of a Binary statement - Simple Acceptance

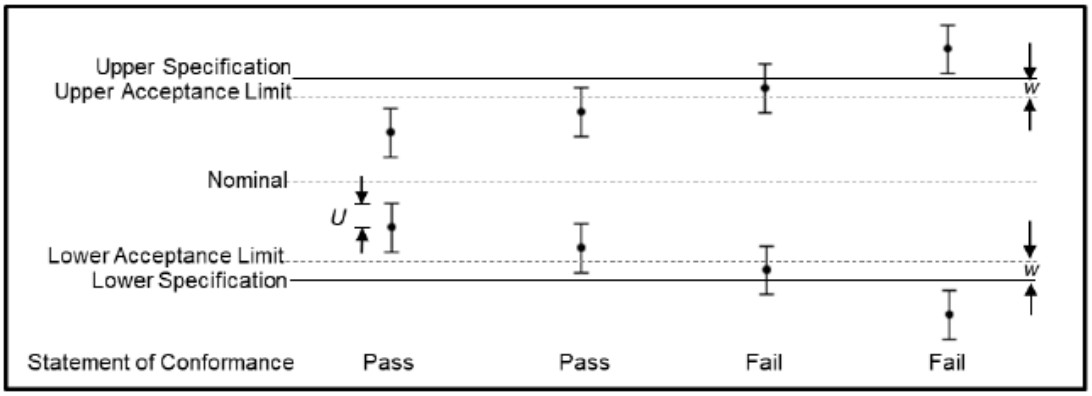
Fig. 1: Graphical representation of a binary decision rule without guard band (Source: ILAC-G8:09/2019)

The confidence level of the correct decision is at least 50%. The risk of making the wrong decision is also equal to 50%. For this binary Kiwa decision rule, the acceptance range is equal

to the tolerance range and thus larger than for the second binary Kiwa decision rule. For measured values in the tolerance range and on the respective tolerance limit, conformity is fulfilled (ILAC-G8: 09/2019 para. 4.1 and 4.2.1). Consequently, the confidence level of this conformity statement is not as high as for the second binary Kiwa decision rule listed below under 1.2.

1.2 Second binary Kiwa decision rule

In the second binary Kiwa decision rule, a “particularly high confidence level” is aimed for; the confidence level of the correct decision is usually 97.5%. The risk of a wrong decision is less than 2.5%. The measurement uncertainty (U) is taken into account in this conformity statement (Fig. 2).



U = 95% expanded measurement uncertainty

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

Fig. 2: Graphical representation of a binary decision rule with guard band (w). (Source: ILAC-G8:09/2019)

The acceptance range is limited compared to the tolerance range specified in the standard, as any measurement uncertainties are taken into account in this procedure. The measurement uncertainties thus determine the width of the safety/guard band w between the tolerated limit specified in the standard and the acceptable limit according to this decision rule (Fig. 3).

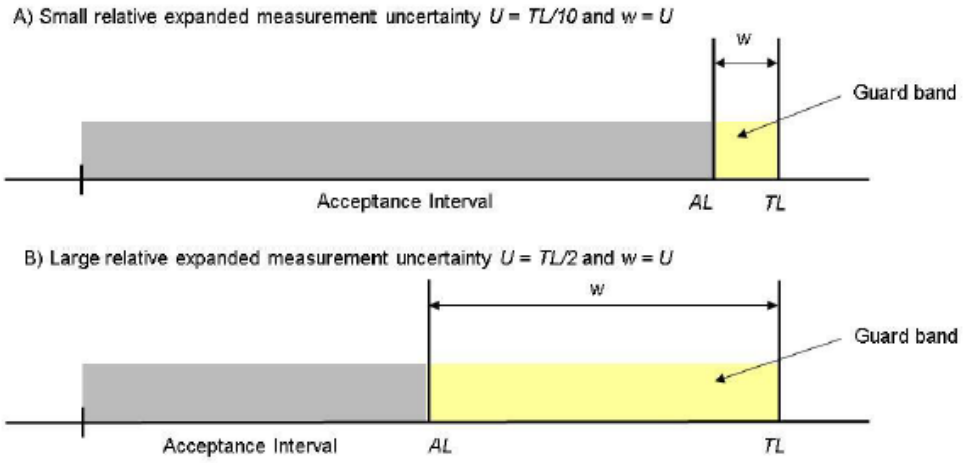


Figure 6 Acceptance interval for a case where expanded measurement uncertainty is small compared to tolerance A) and large B) for the same tolerance limit *TL*. A large guard band narrows the distribution function of accepted items.

Fig. 3: Graphical representation of acceptance range and guard band (Source: ILAC-G8:09/2019)

For measured values in the acceptance range and on the respective acceptance limit, conformity is fulfilled (ILAC-G8: 09/2019 para. 4.1 and 4.2.2).

2. Conformity statement on multiple rules

Conformity statements can also be based on multiple rules (fulfilled/conditionally fulfilled/conditionally not fulfilled/not fulfilled).

3. Customised decision rules

In addition to the two binary Kiwa decision rules and other multiple rules, customised decision rules and associated conformity statements can also be applied and reported in the test report.

Selection from the above options for variant 2:

If the standards or specifications to be used for the calibration of measured values do not contain precise or sufficient specifications for the conformity test (variant 2), the specification of a conformity statement according to the above options depends on the agreement to be reached with the customer. If no agreement has been reached, either no conformity statement is made in the test report or the first binary Kiwa decision rule is applied.