

Decision rule according to DIN EN ISO/IEC 17025:2018

Dear customer,

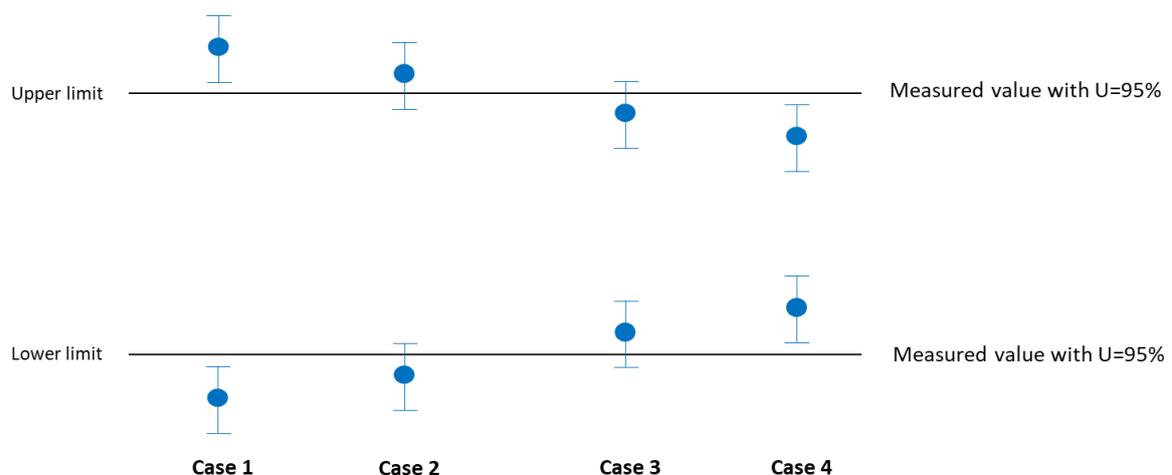
According to the standard DIN EN ISO/IEC 17025:2018 (General requirements for the competence of testing and calibration laboratories) there is a requirement to clearly define decision rules.

Decision rules are rules that describe how measurement uncertainty is taken into account when making statements about conformity with a specified requirement.

The following procedure is implemented by MPA Bremen:

1. If a client, for tests accredited according to DIN EN ISO/IEC 17025:2018, requires a statement on conformity (conformity assessment) with regard to a technical specification or standard (e.g. passed/failed, within tolerance/out of tolerance), then the following rules of clauses 2. to 4. apply for the assessment of conformity.
2. If the customer provides specifications for the decision rule to be applied, then these apply. Otherwise, 3. or 4. shall apply.
3. If the technical specification or standard specifies requirements for the decision rule to be applied, we shall apply these, unless the customer specifies other requirements for the decision rule to be applied. Otherwise, 4. applies.
4. We apply the following decision rules, if the technical specification or standard does not specify the decision rule to be applied and the customer does not provide any other information on the decision rule to be applied:

Case differentiation:



Considering a confidence interval of U=95%, the following case distinctions apply:

Case 1)

The measured value is outside the limit, also with consideration of the confidence interval.

Conformity statement: The measured value is outside the limit, including the confidence interval of U=95%, and is evaluated as **non-compliant**. The risk of a wrong evaluation is very low.

Case 2)

The measured value is outside the limit. Consideration of the confidence interval results in an overlap with the limit.

Conformity statement: the measured value is outside the limit and the sample is evaluated as **non-conforming**. Taking into account the confidence interval of U=95%, the measured value could still meet the requirements, but the risk of over/under compliance and thus a false statement is high.

Case 3)

The measured value is within the limit. When considering the confidence interval, there is an overlap with the limit.

Conformity statement: the measured value is within the limit and the sample is **evaluated as conforming**. Considering the confidence interval of U=95%, the measured value might not meet the requirements. The risk of over/under compliance and thus a false statement cannot be safely excluded.

Case 4)

The measured value is within the limit, even with consideration of the confidence interval.

Conformity statement: the measured value, including consideration of the confidence interval of U=95%, lies within the limit and the sample is **evaluated as conforming**. The risk of a false statement is very low.

The following conformity statements follow from this:

Case 1) and 2) non-compliant;
Case 3) and 4) compliant

For further questions please do not hesitate to contact us