

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

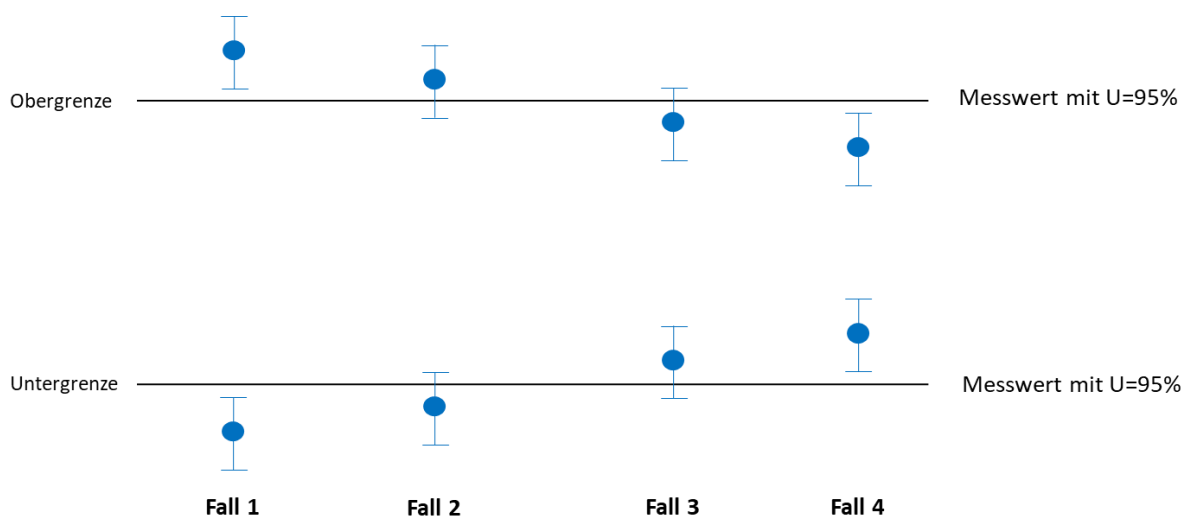
Dear customer,

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 the 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/outside 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, provided that the customer does not specify any other requirements for the decision rule to be applied. Otherwise, 4. applies.
4. We shall apply the following decision rules, if the technical specification or standard does not specify any requirements for the decision rule to be applied and the customer does not provide any other requirements for the decision rule to be applied:

Case distinction:



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

Case 1)

The measured value is outside the limit, even with consideration of the measurement uncertainty.

Conformity statement: The measured value is outside the limit and is evaluated as **non-compliant**. The risk of a wrong evaluation is very low, because the measurement uncertainty is included in the decision.

Case 2)

The measured value is outside the limit. When considering the MU, there is an overlap with the limit.

Conformity statement: The measured value is outside the limit and the sample is evaluated as **non-compliant**. Taking into account the measurement uncertainty, the measured value could still meet the requirements, but the risk of exceeding/falling below the limit and thus of a false statement is high.

Case 3)

The measured value is within the limit. When considering the measurement uncertainty, there is an overlap with the limit.

Conformity statement: The measured value is within the limit and the sample is **evaluated as compliant**. Taking into account the measurement uncertainty, the measured value might not meet the requirements. The risk of an overshoot/undershoot and thus a false statement cannot be ruled out with certainty.

Case 4)

The measured value is within the limit, also with consideration of the measurement uncertainty.

Conformity statement: The measured value is within the limit, including consideration of the measurement uncertainty, and the specimen is **evaluated as compliant**. The risk of a false statement is very low, since the measurement uncertainty is included in the decision.

The following statements on conformity follow from this:

Case 1) and 2) **non-compliant**

Case 3) and 4) **compliant**

For microbiological tests, the measurement uncertainty is generally taken into account in limit values of the respective standards.

If you have any further questions, please do not hesitate to contact us