

### **Application of the decision rules DIN EN ISO/IEC 17025:2018-03**

If the client requires a statement on conformity with regard to a specification or standard (for example pass/fail, within tolerance/out of tolerance), the specification or standard as well as the decision rule.

As a rule, the contractor makes a statement of conformity without taking the measurement uncertainty into account. If the selected decision rule for the measurement uncertainty is not included in the requested specification or standard, it must be unambiguous, communicated to the client or agreed between the client and the contractor. In the case of statements on conformity to a specification or standard, the laboratory must document the decision rule applied. A decision rule describes how the measurement uncertainty is taken into account in the conformity assessment.

Simple steps to select the decision rule according to ILAC-G8:09/2019:

1. Is a conformity decision necessary?  
No: Specify measured value and uncertainty  
Yes: Then continue with 2.
2. Are there legal/regulatory standards?  
Yes: follow applicable legal or regulatory standard as general guidance.  
No: Then continue with 3.
3. Is there a standard that contains the decision-making process?  
Yes: Follow conformity rule according to ISO (ASTM/EURAMET), Ex. DIN EN ISO 6508  
No: Then continue with 4.
4. Choose the decision rule that best accounts for both the risk of false acceptance and false rejection for the application situation.

### **Decision rule without consideration of measurement uncertainty:**

If a test standard or specification stipulates that the measurement uncertainty may not be used in conformity assessments, then only a comparison of the measured values with the limit values in the tolerance interval is made. If not required by the customer, no additional safety band, i.e. no additional safety factor of the limit values is taken into account. Using the example of the graphical representation (Fig. 1), cases I to III would be compliant, since the measured value is within the limits. Cases IV and V are non-compliant; the measured value has fallen below or exceeded a limit value. The specific risk (probability of false rejection or acceptance) of cases II, III and IV is equal to the measurement uncertainty.

Decision rule with consideration of measurement uncertainty:

For the expanded uncertainty of measurement, a confidence level of 95 % with a coverage factor  $k = 2$  is specified in the laboratory. Other agreements are to be designated in advance.

- Case I compliant, measured value and measurement uncertainty is within the limits.  
The specific risk of the result in this case is very low.
- Case II/III not reliably compliant, measured value is within the limit values, measurement uncertainty is partly outside the limit values  
The risk of incorrect evaluation due to the inclusion of measurement uncertainty cannot be ruled out with certainty.
- Case IV not reliably compliant, measured value is outside the limit values, measurement uncertainty is partly within the limit values  
Measured value is outside the limit values and is evaluated as non-compliant, but when the measurement uncertainty is included, the result may be within the limit values.  
If the measurement uncertainty is taken into account, there is a possibility that the value will meet the requirements. The risk for exceeding and thus non-compliance is high.
- Case V non-compliant, measured value and measurement uncertainty are outside the limits  
The risk of a wrong evaluation is low in that case.

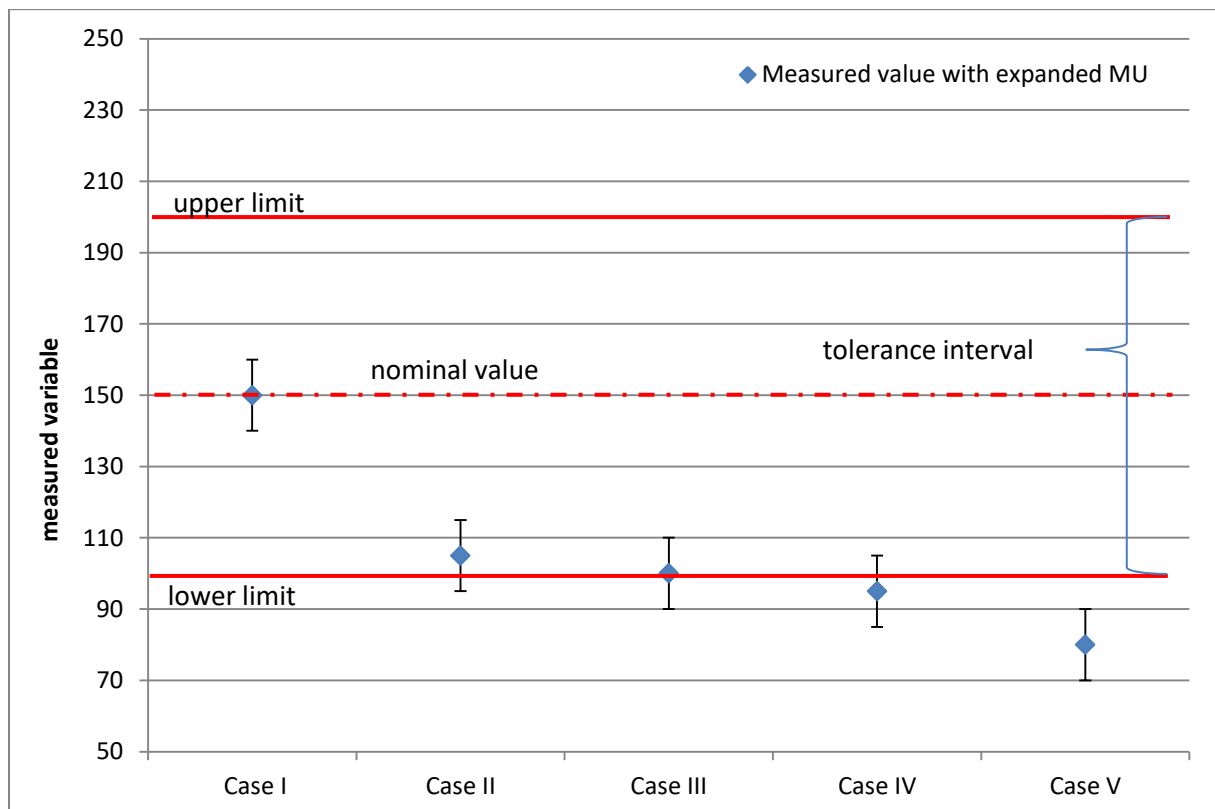


Figure 1: Graphical representation of the decision rules