

1.0 PURPOSE

The purpose of this guide is to define the requirements for the decision rule that describes how the measurement uncertainty will be taken into account when specifying the conformity of the test result to a specified requirement (specification) when conformity assessment is requested by customers for the tests performed by the Laboratory within USB Certification within the scope of the decision rule of the TS EN ISO / IEC 17025: 2017 standard.

2.0 SCOPE

This guide covers all tests within the scope of TS EN ISO/IEC 17025 accreditation for which a declaration of conformity is requested by customers.

3.0 RESPONSIBILITY

The Laboratory Manager, Quality Manager and all personnel involved in laboratory processes are responsible for the operation of this guideline.

4.0 PROCEDURE

4.1 Definitions

Specifications: Documents such as legislation, standards, specifications, etc. where the conformity of the test results is evaluated.

Decision Rule: A rule that determines how measurement uncertainty is taken into account when specifying conformance to a given specification.

Guard Band (w): The limit value created by adding or subtracting the guard band to the specification limit.

Declaration of Conformity: The assessment of conformity to a standard or specification or legislation.

Measurement Uncertainty: It is the estimated value that characterizes the range of values that covers the true value of the measured quantity.

Extended Measurement Uncertainty: Defined as the range that contains the majority of the values of the measurement result. The combined standard is obtained by multiplying the uncertainty by a certain safety factor (coverage factor = k).

Acceptance Area: The area of permissible measured values.

Rejection Area The area where the measured property of a product falls outside the reference value set according to the decision-making rule.

Special Risk: The possibility that an accepted condition may not be suitable or that a rejected product may be suitable. This risk is based on measurements of a single sample.

Overall Risk: The average probability of not meeting an accepted condition or meeting a rejected condition. It does not directly address the possibility of incorrect acceptance of any single sample, individual measurement result or individual workpiece.

4.2 Application

4.2.1 General

When the customer requests a declaration of conformity to a specification or standard for the experiment (e.g. pass/fail, within tolerance/out of tolerance), the specification or standard and the decision rule must be clearly defined. If the selected decision rule is not already included in the requested specification or standard, the customer must be informed and this must be agreed with the customer.

If legal regulations, relevant standards, etc. do not require conformity assessment notification or if there is no customer demand, there is no need for conformity assessment.

When a declaration of conformity with a specification or standard is requested, the specification, standard and decision rule should be clearly defined. If the selected decision rule is not included in the specification or standard to be used or in the legislation, the customer must be informed and the decision rule must be agreed upon. Otherwise, the experiment should not be started. The agreed decision rule and what it is based on must be stated on the report.

If the decision rule is not included in the specification or standard, the decision rule applied is stated in the report content.

If the result after taking into account the uncertainty values does not exceed the specified limit values, "conformity" with the legal authority is declared.

In the absence of any specification, legislation / table limit value etc. standard; a range is given by taking into account the measurement uncertainty, and the results are left to the customer's evaluation.

The customer should familiarize themselves with how to apply the decision rule based on this guide. The customer must submit his/her preference on how to apply the decision rule in writing to USB Certification Laboratory with the analysis request form and make his/her decision rule preference as determined by his/her reputation.

In the absence of any request from the Client, **the Simple Acceptance Rule** applies.

4.2.2 Decision Rule Selection

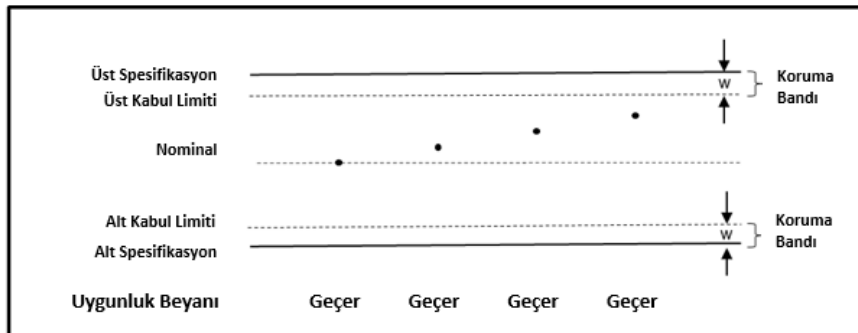
If the legislation, customer or test standard requires a declaration of conformity, but there is no rule specified in the relevant standards or legislation or by the customer, the Simple Acceptance Rule is applied. Without taking into account the confidence level and measurement uncertainty, the test result obtained is evaluated as "suitable" or "not suitable".

If the legislation, customer or test standard requires a declaration of conformity and there is a measurement uncertainty limit value specified in the relevant standards or legislation or by the customer, the test result obtained is evaluated as "appropriate" or "not appropriate", taking into account the confidence level and measurement uncertainty.

Unless required by any legal requirement or relevant standard, the decision rule set out in this guidance applies to all test request types.

4.2.3 Simple Admission Rule Election Dual Declaration

In the conformity assessment in the USB Certification Laboratory, the "Dual Declaration for Simple Acceptance Rule" rule is applied. The result is characterized as "Conforms / Passes" or "Not Conforms / Fails". Accordingly, the measurement result is interpreted by reflecting the measurement uncertainty at $k=2$ 95% confidence interval. The application and interpretation of the decision rule is performed by Analysts, Laboratory Unit Supervisor and Laboratory Manager.



4.2.4 Simple Acceptance Rule Selection Special Risk

Depending on the customer application, different shielding tape samples can be used to achieve certain specific risk levels. Accordingly, different protective tape samples and specific risk factors for protective tape and risk assessment according to ILAC-G8:09/2019 are given in Table-1.

Decision rule	Protection tape w	Special Risk
6 sigma	3 U	< 1 ppm PFA
3 sigma	1,5 U	< 0.16% PFA
ILAC G8:2009 rule	1 U	< 2.5% PFA
ISO 14253-1:2017 [5]	0,83 U	< 5% PFA
Simple acceptance	0	< 50% PFA
Not critical	-U	Item rejected due to measured value greater than $AL = TL + U$ < 2.5% PFR
Customer defined	$r U$	Customers can optionally define <i>multiple r's</i> to be used as guard bands.

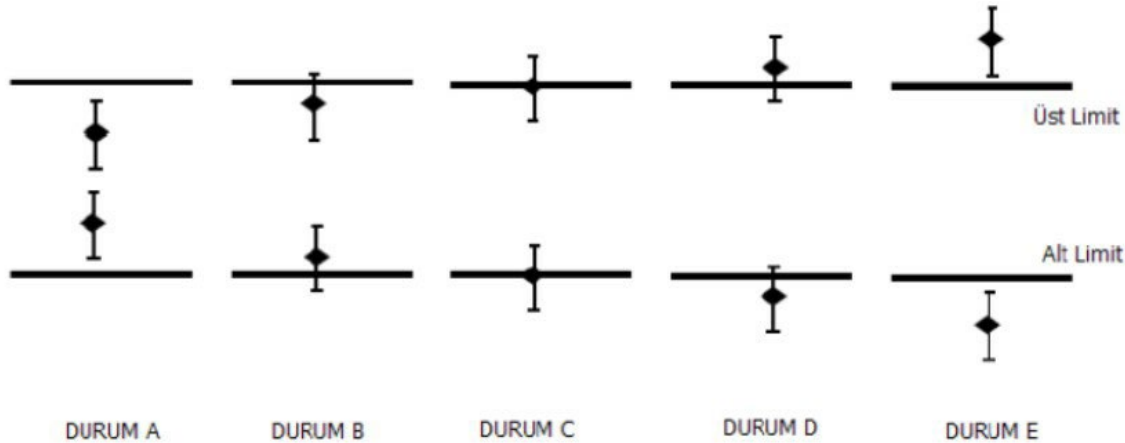
Table 1. PFA - Probability of False Acceptance and PFR - Probability of False Rejection

*PFA - Probability of False Acceptance

**PFR - Probability of False Rejection

In addition to the decision rule risk factor, analyzers and laboratory personnel perform risk assessment and apply the assessment on an ongoing basis to ensure that problems related to the evaluation of experimental results are eliminated before they arise.

4.2.5 Measurement Interpretation of uncertainty



State A: The measurement result is within limits (below the upper limit or above the lower limit) even when expanded by uncertainty. In this case the product **meets** the specification.

Condition B: The limits coincide halfway with the limit when the experimental result is below the upper limit but the measurement result is expanded with uncertainty, or above the lower limit but the measurement result is expanded with uncertainty

when the limits coincide halfway with the limit. In this case, "conformity" can be stated when the measurement uncertainty is reflected in the result so that $k=2$ is within the 95% confidence interval. However, if the uncertainty is reflected in the uncertainty confidence interval that does not meet the $k=2$ 95% confidence interval, conformity cannot be given. The result is characterized as "not conform".

C status: The measurement result is just above the limit. In this case it is not possible to indicate conformity or non-conformity at any significant level of reliability. In this case, the test result and measurement

uncertainty are given in the test report. In addition, the test report states "No assessment of conformity or non-conformity can be made based on the measurement uncertainty of the experiment and the targeted confidence level (95%)". However, if it is mandatory to make a decision regardless of the reliability level: (a) If the limit is defined as " \leq " or " \geq " and the test result is equal to the limit, **"conform"** (b) If the limit is defined as " $<$ " or " $>$ " and the test result is equal to the limit, **"not conform"**.

D state: The experimental result is above the upper limit, but the limits coincide halfway with the limit when the measurement result is expanded with uncertainty, or below the lower limit, but the limits coincide halfway with the limit when the measurement result is expanded with uncertainty. It is not possible to specify non-conformity for the results. However, if a reliability level below 95% is acceptable, it may be possible to indicate non-conformity.

Case E: The measurement result exceeds the limits even when expanded with uncertainty. In this case the product **does not meet** the specification.

4.2.6 Measurement Where uncertainty is not taken into account

If the declaration of conformity is mandatory or required, but the relevant legislation, product or test standard does not provide information on the effects of confidence level and measurement uncertainty in the assessment of conformity, the laboratory can make an assessment of conformity or non-conformity based on whether the test result obtained without taking into account the confidence level and measurement uncertainty is only within the specified limits.

According to this;

- a) **"Nonconformity"** is given when the test result does not comply with the specification limit or specification range value.
- b) **"Conformity"** is given when the test result complies with the specification limit or specification range value.
- c) If the specification, limit or specification range value is defined as less than ($<$) or greater than ($>$) and the test result is equal to this value, **"nonconformity"** is indicated.
- d) If the specification limit or specification range value is defined as less than or equal to (\leq) or greater than or equal to (\geq) and the test result is equal to this value, **"conformity"** is indicated.

5.0 RELATED DOCUMENTS AND RECORDS

Document Number	Title or Description
ISO GUIDE 98-4	Uncertainty of measurement - Part 4: Role of measurement uncertainty in conformity assessment
ILAC G8	Guidance on Decision Rules and Declarations of Conformity