DECISION RULE APPLICATION INSTRUCTIONS

1. PURPOSE AND RESPONSIBILITY

The purpose of this instruction is to describe how to apply the decision rule chosen by the Customer. The Quality Management Officer is responsible for the preparation of this instruction, and the Chief of Laboratories and those assigned responsibility for its implementation.

2. DEFINITIONS

Decision Rule: Rule that describes how measurement uncertainty is to be taken into account when stating compliance with a specified requirement.
Tolerance Limit (TL): A specified upper or lower limit of the allowed values of a property
Tolerance Range (TA): Range of allowed values for the property
Acceptance Limit (KL): Specified upper or lower limit of permissible measured values
Acceptance Range (KA): Range of permissible measured values
Protection Band (w): Difference between tolerance limit and corresponding acceptance limit $w=|TL-KL|$
Simple Acceptance: A decision rule K where the acceptance limit is the same as the tolerance limit$L=TL$
Specific Risk: It is the probability that an accepted situation is not suitable or a rejected product is suitable. This risk is based on measurements of a single sample.
Global Risk: The average probability of not complying with an accepted situation or complying with a rejected situation is the average probability. It does not directly address the possibility of incorrect admission to any single sample, individual measurement result, or individual workpiece.

3. APPLICATION

When the customer requests a declaration of conformity according to a specification or standard for the test result (e.g. within/ out of limit values, pass/fail), the specification/standard and the applied decision rule are clearly defined in the report.

If the selected decision rule is not already included in the requested specification or standard, it must be communicated to the customer and agreed upon with the customer.

Legal legislation, relevant standards, etc. If conformity assessment notification is not made mandatory or there is no customer request, there is no need to carry out conformity assessment.

When the customer requests a declaration of conformity to a specification or standard for testing, the specification, standard and decision rule must be clearly defined. If the selected decision rule is not included in the agreed upon specification or standard or legislation, it must be notified to the customer and agreed upon with the customer.

Unless required by any legal requirement or relevant standard, the decision rule specified in this instruction applies to all types of test requests. This instruction is published on BUTEKOM's website, accessible to everyone, and kept up to date.

For test requests, agreement with the customer is achieved by signing the (Test/Analysis Inspection Request Form); If the customer has a request different from this instruction, he must notify BUTEKOM in writing based on the relevant request form. If no notification is made, it is assumed that he/she accepts this procedure. The customer's demands cannot conflict with legal requirements.

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When an experiment is carried out on samples arriving at the laboratory according to a specified requirement and requested by the customer or in cases where the requirement requires the declaration of conformity, the test results and the conformity assessment declaration are given in the report together with the measurement uncertainty values.

If the relevant sources do not require conformity notification, the result obtained from the test is written directly in the test report without any conformity assessment notification. If the relevant sources require the declaration of conformity but do not take into account the measurement uncertainty values (at the 95% confidence level), opinions and comments can be expressed in the test report based only on whether the analysis results obtained are within the specified limit values.

The decision rule regarding the declaration of conformity and the specification or standard or legal regulation according to which the declaration of conformity was made and which test result was subjected to this conformity evaluation are stated in the test report.

The declaration of conformity is based on a 95% probability of coverage for expanded uncertainty in test reports.
Test results are not given below the 95% confidence level.

The requirement by which the experimental result to be decided will be evaluated is defined. This requirement may be a lower or upper limit or range of error (defect) associated with the value. Sources on which this definition is based;

a-) A requirement determined by legal legislation,

b-) A requirement determined by the standard or

c-) In case of a requirement determined according to non-standard methods, it may be a requirement or requirement determined at the request of the customer.

4. REQUIREMENTS

No conformity assessment is made if the relevant sources (specification, standard or legal regulations) do not require conformity notification or are not requested by the customer.

When a test is carried out in accordance with a specified requirement and the customer requests it or the requirement obliges a declaration of conformity, a statement indicating whether the test results comply with the specified requirement is given in the report content.

It is stated in the report content that the decision rule regarding the declaration of conformity and the results to which the declaration of conformity is applied, according to which requirement a conformity assessment is made, and if it is not included in the specification or standard, what the decision rule is applied.

Compliance evaluation of the tested samples with the specification or the relevant legislation is made by the laboratory unit performing the experiment and the technical personnel performing the experiment. Therefore, the personnel performing the test must be provided with access to the specification, standard or legal regulation subject to evaluation.

There may be three possible outcomes when assessing the conformity of tested samples (e.g. within/out of limit values, pass/fail). Evaluation is made by applying different approaches in case A, acceptance in case C, rejection in case C, and different approaches in case B in Figure 1.

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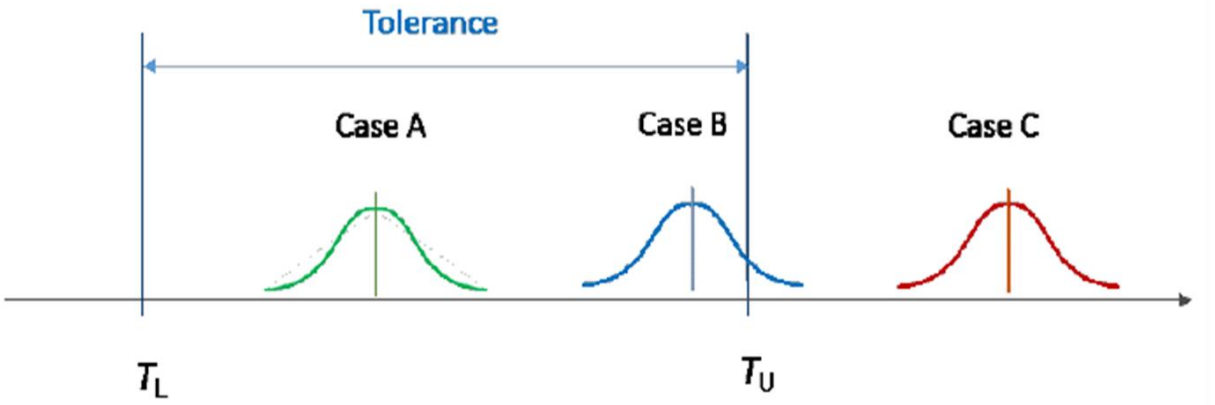

Figure 1:*Rejection/acceptance situations according to the limit values of the conformity assessment result.*

TS EN ISO / IEC 17025 requires laboratories to evaluate measurement uncertainty and apply a documented decision rule when making conformity declarations. The approach taken for the decision rule can vary significantly depending on the situation and different guard bands (w) may be applied. While it is common to use the w=U (Extended Measurement Uncertainty) guard band, there may be cases where a multiplier other than one is more appropriate. Table 1 provides examples of different protective tapes to achieve certain specific risk levels depending on the customer application.

Table 1: *YKO- False Acceptance Probability and YRO- False Rejection Probability*

Decision Rule	**Protection Band (w)**	**Specific Risk**
6 Sigma	3U	<1ppm YKO
3 Sigma	1.5U	<0.16% NCR
ILAC G8:2009	u	<2.5% NCR
ISO 14253-1:2017	0.83U	<5% NCR
Simple Acceptance	0	<50% NCR
Non-critical	-U	The item is worth more than KL = TL + U rejected for large measured value <2.5%YRO
Customer Defined	rU	Customers can optionally define multiple r to apply as security band.

While determining the BUTEKOM Decision Rule, the guard band was not used and w = 0. Therefore, for Figure 2, Cases 2, 3, 4, 7, 8, 9, the probability of false acceptance or false rejection is considered <50%.

Experimental results have a binary decision rule when the outcome is limited to two options (pass-fail, suitable-inappropriate, etc.). BUTEKOM Laboratories has determined the Decision Rule based on the Simple Acceptance Rule specified in the ILAC G8 (2019) document. (w=0)

If the product or test standard requires a declaration of conformity in the laboratory report, but does not provide any information regarding the effects of confidence level and measurement uncertainty in the assessment of conformity in the relevant standards, the laboratory will rely only on whether the test result obtained is within the specified limits, without taking into account the confidence level and measurement uncertainty, may evaluate suitability or non-conformity.

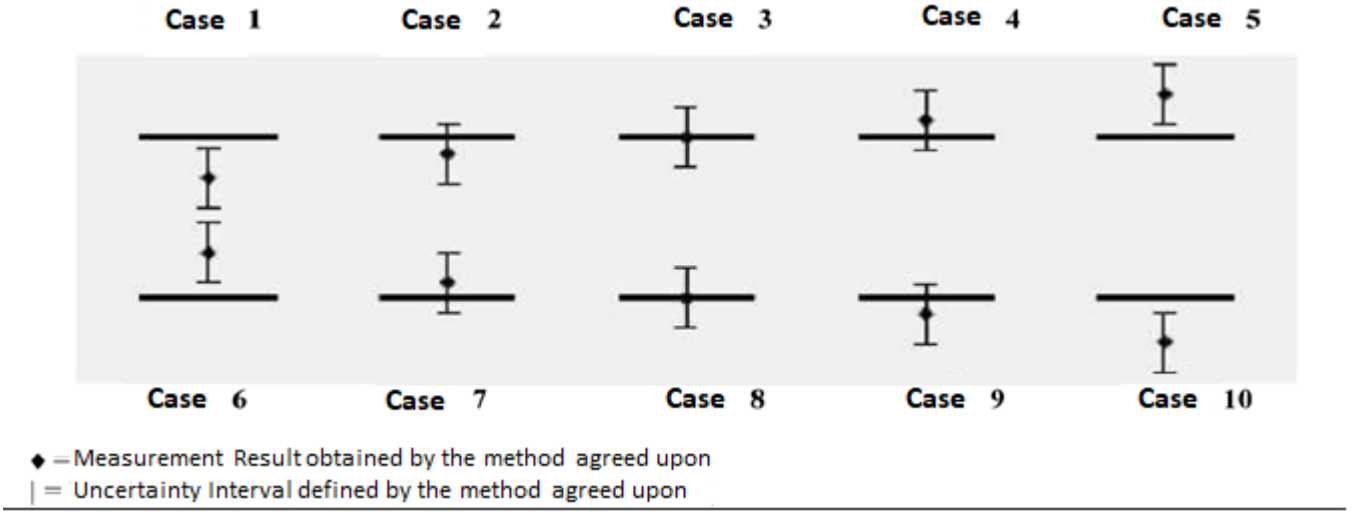

Figure 2: *Analysis result and measurement uncertainty according to compliance limits.*

5. CONCLUSION

In Figure 2, Case 1 and Case 6, the suitability decision is made. Figure 2,

Case 5 and Case 1. In those cases, a decision of non-conformity is made.

In Figure 2, Cases 2 and 7, the eligibility decision is made.

In Figure 2, Cases 4 and 9, a nonconformity decision is made.

In Figure 2, Case 3, if the desired value is ":S" upper limit in requirements such as standards, specifications or legal conditions, a decision of conformity is made, and if the upper limit is "<", non-conformity is decided.

In Figure 2, Case 8, if the desired value is "2:" lower limit for requirements such as standards, specifications or legal requirements, a decision of conformity is made, and if the lower limit is ">", a decision of non-conformity is made.

7. RECORDS

Relevant Test/Analysis Result Report

8. REFERENCES and RELATED DOCUMENTS

EUROLAB Technical Report No.1/2017 - Decision Rules Applied to Conformity Assessment,
ISO/IEC 17025 STANDARD REVISION TO INFORM Decision rule GUIDE
ISO/IEC GUIDE 98-4
ILAC-G8:09/2019 Guidelines on Decision Rules and Statements of Conformity About ILAC

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