	DECISION RULE PROCEDURE		
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Revision Status		
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	NAME / SURNAME	SIGNATURE
Prepared by	Derya Dinçer Yalçın – Quality Management Representative	
Checked by	Ayşe Gül Bal Hızlı- Laboratory Manager	
Approved by	Koralp KARADAĞ – Firm Manager	

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1. PURPOSE

The purpose is to define the rules that explain how measurement uncertainty is taken into account in conformity assessment when indicating compliance with a pre-defined requirement based on the test results performed at Kortek Test Laboratory.

2. SCOPE

It applies to all testing activities carried out in the laboratory.

3. RESPONSIBILTY

The Laboratory Manager is responsible for the execution of this procedure, and all Quality Technicians are responsible for its implementation.

4. ABBREVIATIONS

5. DEFINITIONS

Specification: These are documents such as regulations, standards, and specifications used to evaluate the conformity of test results.

Decision Rule: It is the rule that defines how measurement uncertainty is taken into account when stating compliance with a specified specification.

Protective Band: The uncertainty value calculated based on a predefined confidence level.

Decision Limit: A limit value established by adjusting the specification limit through the addition or subtraction of a guard band.

6. APPLICATION

6.1 . General Rules for Decision Rule

When test results are used to assess conformity against specifications or regulations, the measurement uncertainty must also be taken into account. In cases 1 and 4 shown in Figure I, the measurement results—considering their uncertainty range—clearly fall above or below the limit value. Therefore, the conformity assessment in these two cases is straightforward.

However, in cases 2 and 3, the conformity assessment is less clear, as the uncertainty range overlaps with the specification limit. If the method for declaring conformity is not defined by legal authorities, regulatory bodies, or mandatory regulations, a decision rule is established based on customer requirements to determine conformity or nonconformity.

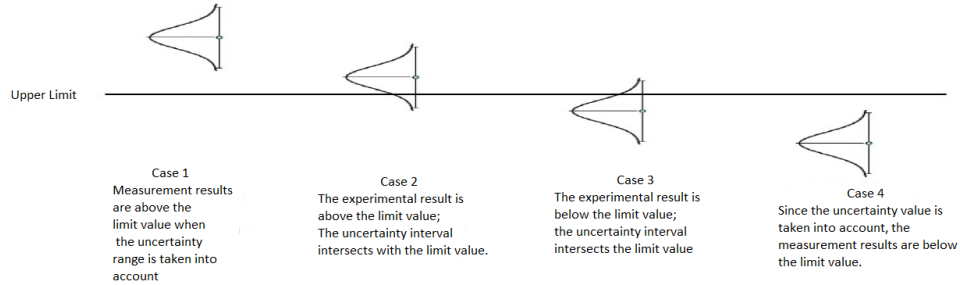| PREPARED BY	CONTROLLED BY	APPROVED BY
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Figure 1 Conformity Evaluation Based on Upper Limit

6.2. Selection of Decision Rule

Simple Acceptance Rule (Shared Risk Rule):

If the product or test standard requires a conformity statement in the laboratory report but there is no information in the relevant standards or regulations regarding the effects of confidence level and measurement uncertainty on conformity assessment, the laboratory may evaluate the test result solely based on whether it falls within the specified limits as "**conforming**" or "**non-conforming**" without considering the confidence level or measurement uncertainty. This rule is the most widely used decision rule worldwide.

This rule is often referred to as the shared risk rule because the end user assumes certain risks; namely, after testing with an agreed measurement method, the product/sample may not conform to legal regulations or specifications. In this case, there is an implicit assumption that the uncertainty of the agreed measurement method is acceptable. If the relevant legislation explicitly defines the decision rule, the defined rule must be applied.

(ISO 98-4:2012 Clause 8.2 Decision rule on Simple acceptance, TÜRKAK Decision Rule Guide Article 3.c.b)

False Rejection and False Acceptance Rule:

To decide whether the results in cases 2 and 3 in Figure I conform to the limit values, a decision rule considering the risks of incorrect decisions is required. This decision will either favor the end user (false acceptance rule) or favor the manufacturer (false rejection rule).

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Tablo 1 Decision Rule

	DECISION	
	Acceptance H_0	**Rejection H_0**
H_0 True	$(1-\alpha)$ Correct Decision	Type-I Error (Error α) (Protects the end user) **False Acceptance**
H_0 False	Type-II Error (Error β) (Protects the manufacturer/supplier) **False Rejection**	$(1-\beta)$ Correct Decision

Determination of Acceptance and Rejection Regions (Guard Band Method)

The decision rule allows for the calculation of a guard band (g). Using this guard band, acceptance and rejection regions are defined. The overlapping area between these two regions is called the decision limit.

Information required for making a decision:

- Measured quantity (unit)

- Test result

- Uncertainty — coverage factor (k) for expanded uncertainty and confidence interval

- Specification indicating lower and/or upper limits

- Decision rule

For all parameters analyzed in the laboratory, relative measurement uncertainties at a 95% confidence interval have been calculated. An Excel-based Decision Rule Limit Values Table has been created, where guard bands are calculated by applying the measurement uncertainty value to the specification limit value (using k=1.65 for a one-tailed t-value at 95% confidence level). In cases where the sample is taken by the customer, data excluding the measurement uncertainty caused by sampling are used. This situation is indicated in the Decision Rule Limit Values Table.
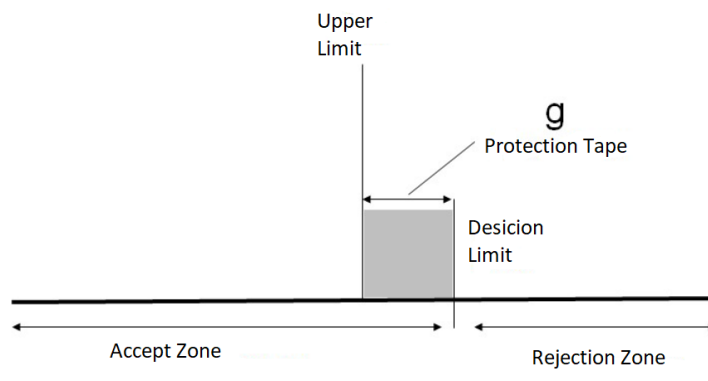
Acceptance and rejection regions are created by adding and/or subtracting the guard bands from the limit values.

"Acceptance of Nonconforming Product" - False Rejection Rule:

The acceptance and rejection regions have been defined as shown in Figures II, III, and IV to implement the "acceptance of nonconforming product" (false rejection) rule.
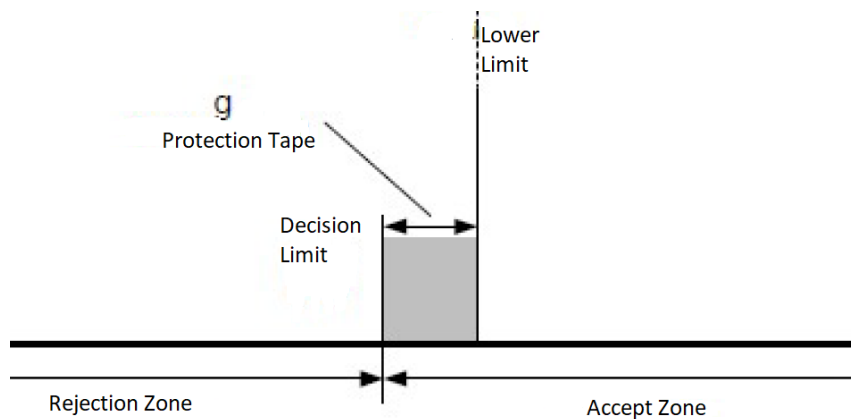
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If the measurement result is equal to or less than the decision limit, it is considered complian.

Figure II: Acceptance and Rejection Regions Based on the Upper Limit

If the measurement result is equal to or greater than the decision limit, it is considered compliant.

Figure III: Acceptance and Rejection Regions Based on the Lower Limit
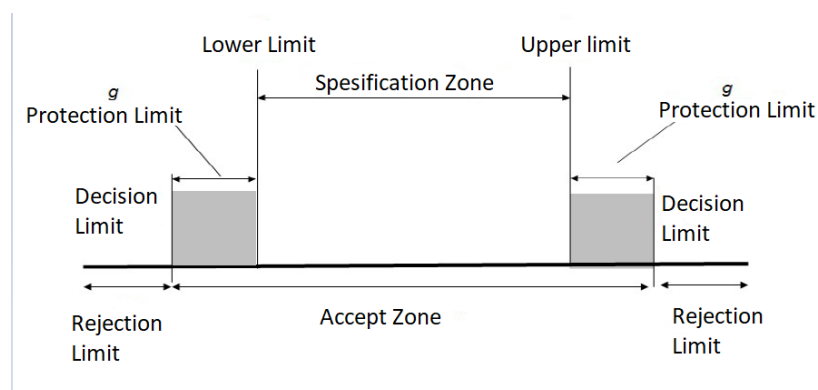
If the measurement result is equal to or within the range of the decision limits, it is considered compliant.
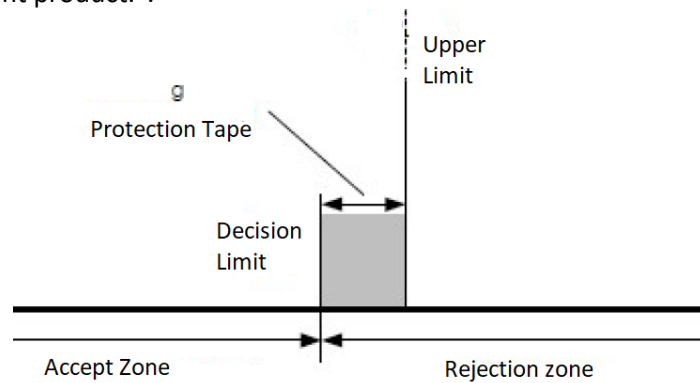
Figure IV: Acceptance and Rejection Regions Based on Both Lower and Upper Limits

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Rejection of a Compliant Product (False Rejection)

Acceptance and rejection regions are determined as shown in Figures V, VI, and VII to apply the rule for "rejection of a compliant product.".

If the measurement result is equal to or less than the decision limit, it is considered compliant.

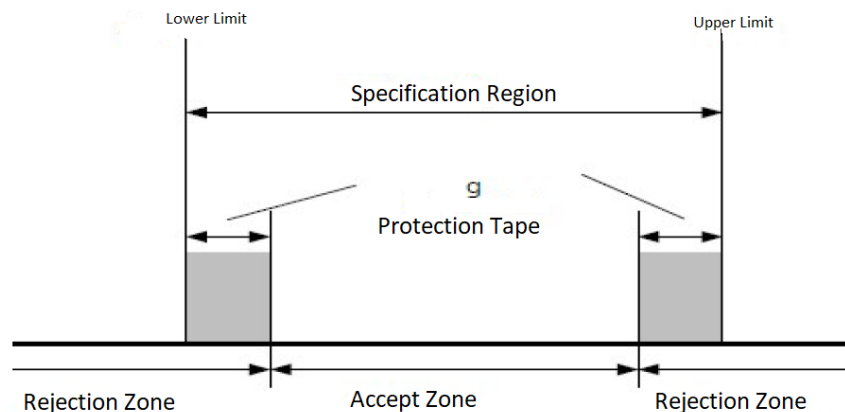*Figure V: Acceptance and Rejection Regions Based on the Upper Limit*
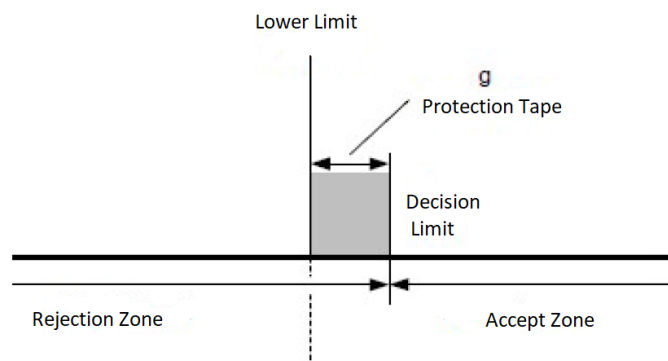
If the measurement result is equal to or greater than the decision limit, it is considered compliant.

Figure VI: Acceptance and Rejection Regions Based on the Lower Limiti

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If the measurement result is equal to or within the range of the decision limits, it is considered compliant.

Figure VII: Acceptance and Rejection Regions Based on Both Lower and Upper Limits

The declaration of conformity in the Analysis Report is carried out according to the Report Management Procedure.

6.3. If there is any statement regarding which decision rule to use in regulations, directives, standards, specifications, contracts, or similar documents, this statement is taken into account when determining the decision rule.

When providing conformity assessment related to test results, the decision rule specified in the relevant regulation, directive, standard, specification, contract, or similar document is applied. If there is no decision rule specified in the legislation, the decision rule agreed upon with the customer during the request, offer, and contract process is applied.

Our laboratory's decision rule policy is as follows:

If a valid decision rule exists in the legislation, that decision rule is applied. If there is no valid decision rule in the legislation, the measurement uncertainty value is evaluated according to the "Simple Acceptance Rule," and the results are reported as is, without adding or subtracting the confidence level and measurement uncertainty.

If the customer requests a different decision rule, and notifies the laboratory with an official letter and the laboratory accepts it, any of the mutually agreed rules specified in this instruction can be applied..

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7. RELATED DOCUMENTS

P12 Report Management Procedure

P07 Review of Requests Procedure

P10 Measurement Uncertainty Procedure

EUROLAB Technical Report No. 01/2017: Decision Rules Applied to Conformity Assessment

Eurochem/CITAC Guide: Use of Uncertainty Information in Compliance Assessment

ISO 98-4 Standard

ILAC G8 Guide on Decision Rules and Statements of Conformity

TÜRKAK Decision Rule Guide

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