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1.0 AIM

The aim of this instruction is to explain the decision rule that will apply in cases where test results for the test conducted within MFI are evaluated in accordance with standards, legislation or a specification.

2.0 SCOPE

It covers all tests conducted in the laboratory within the scope of accreditation

3.0 APPLICATION**3.1 Definitions - Explanations**

- **Test:** Determination of one or more characteristics in accordance with a procedure.
- **Declaration of Conformity:** Evaluation of conformity to a standard or specification or legislation.
- **Decision Rule:** The rule that specifies how uncertainty of measurement will be included when defining a specified requirement.
- **Requirement:** When client requests declaration of conformity to a standard or legislation or specification for analysis, standard or legislation or specification and selected decision rule shall be clearly identified.
- **Expanded Measurement Uncertainty:** Uncertainty obtained by multiplying joint standard uncertainty with reliability coefficient.
- **Acceptance Area:** The area where the measured property of a product is within the reference range defined according to the decision rule.
- **Rejection Area:** The area where the measured property of a product is outside the reference range defined according to the decision rule.
- **Confidence Interval:** Uncertainty value calculated at predetermined reliability level.

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- **Decision Limit:** Limit value obtained by adding or deducting safety range to or from specification limit.
- **Type 1 Error (α):** Probability of evaluating the tested sample being acceptable even though the obtained measurement result is not in conformity (FN). (Producer Rule-Accepting Unacceptable Product)

FN=False Negative =Type 1 error i.e.: α = False Rejection (Situation where Supplier Risk is Reduced)
- **Type 2 Error (β):** Probability of evaluating the tested sample being unacceptable even though the obtained measurement result is in conformity (FP). (Producer Rule-Rejecting Acceptable Product)

FP=False Positive = Type 2 error i.e.: β =False Acceptance (Situation where Consumer Risk is Reduced)
- **Supplier Risk:** Causing reprocessing or discarding costs by evaluating an acceptable product as unacceptable.
- **Consumer Risk:** Evaluating a nonconforming product positively and delivering it to the consumer and being subject to a penal clause.
- **Simple Acceptance:** Rule that the acceptance limit is the same as the tolerance limit (where measurement uncertainty is ignored). (Shared Risk)

3.2 RESPONSIBILITY AND AUTHORITY

- Laboratory Director / Vice Director
- Laboratory Test Supervisor

3.3 APPLICATION

3.3.1 General

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Bu dokümanın tüm baskıları kontrolsüz kopyadır. Yalnızca sistemde bulunan yürürlükteki soft versiyonunun güncelliği garanti altına alınmıştır.

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There are certain situations where uncertainty affects the notification of the evaluation of analysis results and these are defined below:

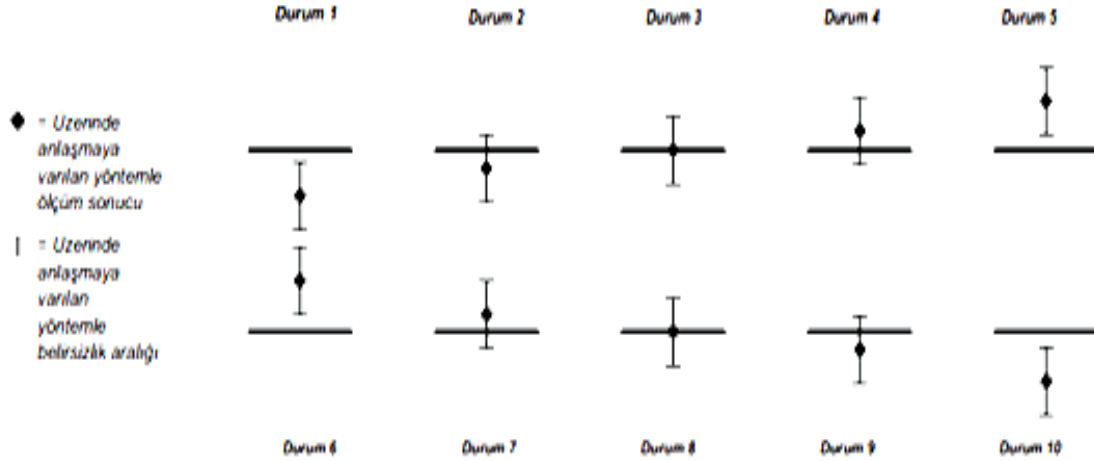


Figure 1: Situations regarding decision rule

Conformity decision for situations 1 and 6 and nonconformity decision for situations 5 and 10 can be given easily. However, in situations 2, 3, 4, 7, 8 and 9 Decision Rule shall be defined to decide between conformity and nonconformity.

In cases where the product or the test standard necessitates declaration of conformity in the laboratory report but the relevant standard does not clarify the impact of reliability level and measurement uncertainty in evaluation of conformity, laboratory can evaluate conformity or nonconformity by only considering whether the obtained result is within the specified limits without regarding reliability level and measurement uncertainty.

This is generally named shared risk because end user takes some risks; such that the product may fail to conform to the standard after being tested with an agreed upon measurement method. Relevant legislation or legal conditions may override shared risk principle and may lay the burden of uncertainty to one party.

If legal conditions necessitate a declaration of evaluation in form of conformity or nonconformity, without regards to reliability level, the declaration shall be made in

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accordance with the limit (criteria) stipulated by the legislation:

- (i) If the limit is defined as “<” or “>” and the analysis results is equal to the limit nonconformity is declared,
- (ii) If the limit is defined as “≤” or “≥” and the analysis results is equal to the limit conformity is declared

In cases where the terms maximum and minimum are used the conditions laid out in (ii) applies.

3.3.2 Evaluating Conformity and Selecting Decision Rule

If declaration of conformity is determined in test standart or legal regulations or specification, it is not issued. Otherwise, laboratory is responsible for issuance of declaration of conformtiy. Referring to customer request, declaration of conformity can e issued in a state of out of scope of accreditation or deviation from method. Declaration of conformtiy and decision rula is applied according to customer requests.

Unless stated in the test standard or the legislation or the specifications or if the request form/letter sent by the client does not request declaration of conformity, declaration of conformity will not be given.

In issuance of Declaration of Conformity, below terms will be used.

- Conformity=Positive
- Nonconformity=Negative (Noncompliance)

If there are no decision rules defined on issuance of declaration of conformity in the test standard or legislation or the specifications and the client has requested issuance of declaration of conformity, below information shall be provided by the client. (Instruction on Review of Requests, Quotes and Contracts (S17-P1T8))

- Declaration of Conformity Request
- Specification stipulating lower and/or upper limits
(Standard/Legislation/Specification)

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➤ Decision Rule (any of the below can be selected if not stipulated in Standard/Legislation/Specification.)

Measurement Uncertainty will be included Measurement Uncertainty will be excluded.

() False Rejection () False Acceptance (Simple Acceptance)

Unless client request otherwise, safety range method will be used. Safety range will be calculated by multiplying standard uncertainty (68% confidence interval k=1) with one sided k value. One sided k value for 95% confidence interval is 95%. For cases where sample is taken by the client, data excluding measurement uncertainty arising from sampling will be used. Our laboratory does not engage in sampling. Measurement uncertainties are calculated in accordance with Measurement Uncertainty Calculation Instructions (S17-P1T26).

In cases where the client requests issuance of declaration of conformity but the decision rule is not specified in product/analysis standard or legislation or the specifications or not selected by the client; MFI opts to decide without including measurement uncertainty (Simple Acceptance) when evaluating conformity. In cases where the client does not define decision rule in request form/letter, it is assumed that they agree to this condition. In cases where the client requests, TUR (Test Uncertainty Ratio) is also evaluated. General rule of $U \leq 1/3$ MPE can be used. Any specific conditions shall be defined in test instructions.

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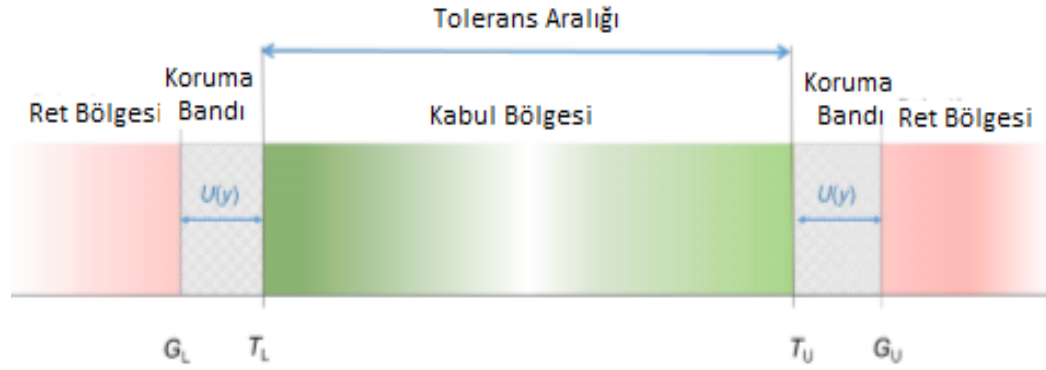
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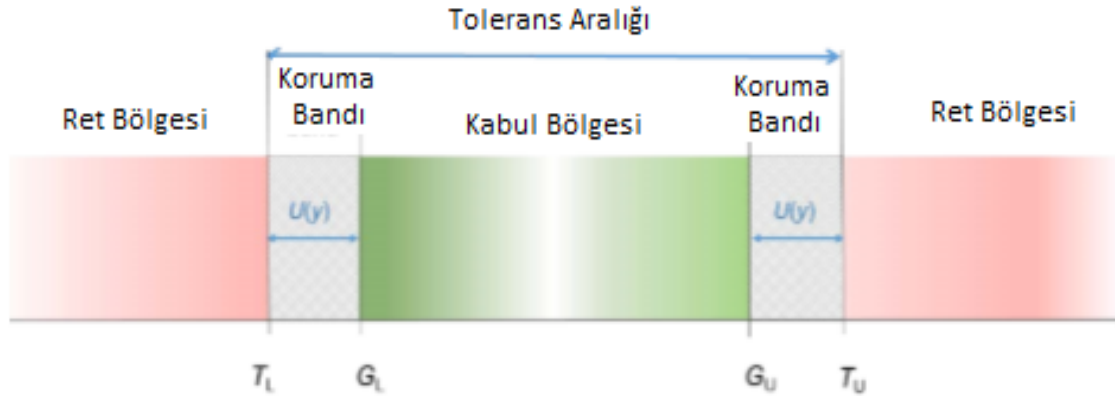
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**Figure 2-Acceptance and Rejection Areas Depending on Upper and Lower Limits
(False Rejection)**



**Figure 3- Acceptance and Rejection Areas Depending on Upper and Lower Limits
(False Acceptance)**

Decision rule is checked for each test with S17-P1T28F1 Conformity Evaluation Form.

3.3.3 Conformity Evaluation for Qualitative Tests

These are issue as CONFORMITY where the qualitative results yield the results specified in the standard method and NONCONFORMITY otherwise.

4.0. RELATED DOCUMENTS

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- 4.1** S17-P1T8 Instruction on Review of Requests Quotes and Contracts
- 4.2** S17-P1T26 Measurement Uncertainty Calculation Instruction
- 4.3** S17-P1T28F1 Conformity Evaluation Form
- 4.4** ILAC G8 Guide of Decision Rules and Declarations of Conformity
- 4.5** EUROLAB Technical Report No.1-2017
- 4.6** ISO/IEC GUIDE 98-4 Uncertainty of measurement — Part 4: Role Of Measurement
Uncertainty in Conformity Assessment
- 4.7** EURACEM / CITAC Guide Use of Uncertainty Information in Compliance Assessment

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