DECISION RULE PROCEDURE

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1. Purpose

This procedure aims to describe the methods of the decision rule describing how measurement uncertainty is taken into account when the results of laboratory tests are evaluated against a standard specification or national/international test standards.

2. Scope

This procedure covers all tests within the scope of TS EN ISO/IEC 17025:2017 laboratory accreditation.

3. Definitions and Abbreviations

QVV	**:** QVV Engineering UK Limited.
Test System	**:** On the specimen; It is a hydraulic system used to provide plastic deformation by applying load.
Measurement Uncertainty	**:** It is the range of values formed by the deviations of the measured magnitude from the actual value and the deviations that may be caused by various factors.
Extended Measurement Uncertainty	: It is the expression of the total standard uncertainty by confidence interval.
Decision Rule	: A rule describing how measurement uncertainty is to be taken into account when specifying conformance to a given specification.
Acceptance Area	: The area in which the measured property of the test specimen falls within the specified reference value according to the decision rule.
Rejection Area	: The area in which the measured property of the test specimen falls outside the reference value determined according to the decision rule.
Protection Area	: It is the boundary zone between the acceptance and rejection areas. In practice, this range is generally determined by measurement uncertainty.
Declaration of Conformity	: If a specification or standard specifies tolerance values, acceptance / rejection value range, it is to indicate whether the test results are appropriate according to these values.

4. Responsibility

General Manager, Marketing and Sales Manager, Quality Management Representative.

5. Procedure Detail

5.1 Decision Rule General Evaluation

When an experiment has been performed in accordance with a specified requirement and the customer or requirement requires a declaration of conformity, a statement indicating whether the results of the experiment comply with that specified requirement must be included in the report. The laboratory must state in the report to which results the declaration of conformity applies, to which requirement a conformity assessment has been performed and, if not included in the specification or standard, the decision rule applied.

There are several possible situations where uncertainty affects the statement of conformity, and these are set out below:

a) where it is clearly stated that the result of the extended test with uncertainty at a specified confidence level should not fall outside or within a limit or limits defined in the product or test standard or legislation. In these cases, the assessment of conformity or non-conformity can be easily made (Figure-1 cases 1, 5, 6 and 10).

b) However, if it is not explicitly stated that the extended test result with uncertainty at a specified confidence level should not fall outside or within a limit or limits defined in the product or test standard or legislation, the assessment of conformity or non-conformity in these cases can be carried out using the following approaches (Figure-1 case 2,3,4,7,8 and 9).

i. If the specification limits are not violated by the test result extended by half of the extended uncertainty range at the 95 % confidence level, conformity with the specification can be indicated (Cases 1 and 6 in Figure 1);

ii. Non-conformance to specification can be indicated if the test result exceeds the upper limit of the specification even after extending downwards by half the extended uncertainty range (Case 5 in Figure 1);

iii. Non-conformance to the specification can be indicated if the lower limit of the specification is violated even after the test result has been extended upwards by half the extended uncertainty range (Case 10 in Figure 1);

iv. If, without the possibility of testing other samples from the same batch of product or repeating the measurement, the single measured value falls sufficiently close to the specification limit and half of the expanded uncertainty range exceeds the limit, it is not possible to verify conformity or non-conformity at the specified level of reliability. In this case the result and the expanded uncertainty shall be reported together with a statement indicating that conformity or non-conformity at the specified level of reliability cannot be demonstrated. (Cases 2, 4, 7 and 9 in Figure 1)

Cases 2 and 7 in Figure 1 below may be indicated as conformity with the specification limit (with a lower calculated and reported reliability level) if legal requirements mandate a decision on rejection or acceptance. Cases 4 and 9 in Figure 1 below may be indicated as non-conformity with the specification (with a lower calculated and reported reliability level).

If two or more samples of a single batch can be tested or the measurement can be repeated, it is advisable to perform repeated tests or repeated measurements. After estimating the average value of all test results or repeated measurement results on the same samples and the new uncertainty value for this average value, the same comparison as described in (i) to (iv) above should be made.

Note: The results for (i) to (iv) are based on the assumption that the uncertainty distribution curve of the measured value is symmetric above the mean value. In some cases, this may not be true, e.g. when no significant correction is made to a measured value and it is considered as a contribution to uncertainty, or when a dominant uncertainty component i, known to have a non-symmetric distribution, is combined with another uncertainty component i as if it had a normal distribution. In such a case, a more accurate calculation of the measured value and measurement uncertainty may allow a clear conclusion to be drawn.

v. If the result is above the full specification limit, it is not possible to declare conformity or non-conformity at the specified reliability level. In this case the result and the extended uncertainty shall be reported together with a statement indicating that conformity or non-conformity cannot be demonstrated at the specified level of reliability. (cases 3 and 8 in Figure 1)

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

Note: This is often referred to as shared risk because the end user takes some of the risk, i.e. the product may not conform to the specification after testing with an agreed measurement method. In this case, there is an implicit assumption that the uncertainty of the agreed measurement method is acceptable and can be calculated if necessary. Relevant regulatory or legal requirements may override the principle of shared risk and place the risk of uncertainty on one party.

d) The agreement or decision rule between the customer and the laboratory may contain provisions on the evaluation of test results. The provisions of the agreement may include the effects of confidence level and measurement uncertainty in the assessment of conformity or non-conformity, the assessment of the test result against the limits specified by the product or test standard or by the customer, or even the calculation of the confidence level at which the test result conforms or does not conform. In this case, the assessment of conformity or non-conformity must be made according to these provisions of the agreement. The terms of the agreement should not conflict with legal requirements. In addition, assessments of shared risk also apply here.

e) If the result is above the full specification limit, it is not possible to declare conformity or non-conformity at the specified reliability level. In this case the result and the extended uncertainty shall be reported together with a statement indicating that conformity or non-conformity cannot be demonstrated at the specified level of confidence.

If legal requirements require the declaration of an assessment of conformity or non-conformity regardless of the level of confidence, the declaration shall be made according to the limit (criterion) specified by the legislation:

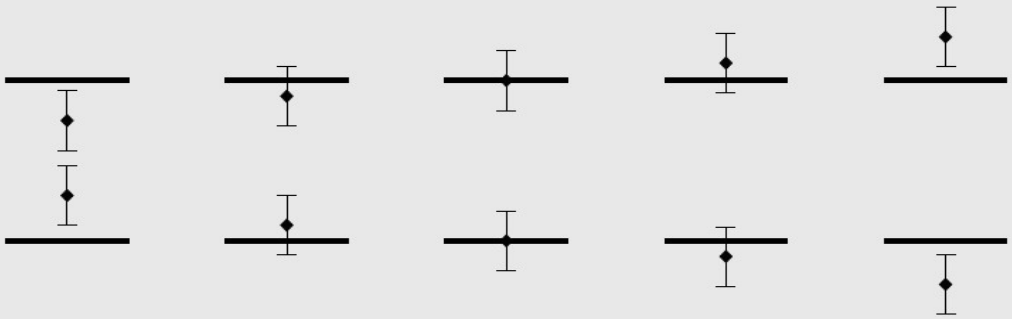
(i) If the limit is defined as "<" or ">" and the test result is equal to the limit, non-conformity is indicated,

(ii) If the limit is defined as "≤" or "≥" and the test result is equal to the limit, compliance is indicated.

Şekil-1: Karar kuralına ilişkin durumlar

◆ = Üzerinde anlaşmaya varılan yöntemle ölçüm sonucu

| = Üzerinde anlaşmaya varılan yöntemle belirsizlik aralığı



Durum 1

Ölçülen sonuç belirsizlik aralığının yarısı kadar yukarıya doğru uzatıldığında bile üst sınırın altındadır. Bu sebeple ürün spesifikasyona uygundur.

Durum 2

Ölçülen sonuç belirsizlik aralığının yarısından az bir pay ile üst sınırın altındadır; bu sebeple, uygunluk belirtmek mümkün değildir. Bununla birlikte, %95'in altında bir güvenilirlik seviyesi kabul edilebilirse, uygunluk belirtmek mümkün olabilir.

Durum 3

Ölçülen sonuç sınırın tam üzerindedir; bu sebeple, herhangi bir önemli güvenilirlik seviyesinde uygunluk veya uymazlık belirtmek mümkün değildir.

Bununla birlikte, güvenilirlik seviyesine bakmaksızın bir karar vermek zorunlu ise: Eğer gerek, ölçülen değer ≤ üst sınır ise, bir uygunluk belirtmek mümkün olabilir. Eğer gerek, ölçülen değer <üst sınır ise, bir uymazlık belirtmek mümkün olabilir.

Durum 4

Ölçülen sonuç, belirsizlik aralığının yarısından az bir pay ile üst sınırın üstündedir; bu sebeple, uymazlık belirtmek mümkün değildir.

Bununla birlikte, %95'in altında bir güvenilirlik seviyesi kabul edilebilirse, uymazlık belirtmek mümkün olabilir.

Durum 5

Ölçülen sonuç, belirsizlik aralığının yarısı kadar aşağı doğru uzatılsa bile, üst sınırın ötesindedir.

Bu sebeple, ürün spesifikasyona uygun değildir

Durum 6

Ölçülen sonuç belirsizlik aralığının yarısı kadar aşağıya doğru uzatıldığında bile alt sınırın üstündedir. Bu sebeple ürün spesifikasyona uygundur.

Durum 7

Ölçülen sonuç belirsizlik aralığının yarısından az bir pay ile alt sınırın üstündedir; bu sebeple, uygunluk belirtmek mümkün değildir. Bununla birlikte, %95'in altında bir güvenilirlik seviyesi kabul edilebilirse, uygunluk belirtmek mümkün olabilir.

Durum 8

Ölçülen sonuç sınırın tam üzerindedir; bu sebeple, herhangi bir önemli güvenilirlik seviyesinde uygunluk veya uymazlık belirtmek mümkün değildir.

Bununla birlikte, güvenilirlik seviyesine bakmaksızın bir karar vermek zorunlu ise: Eğer gerek, ölçülen değer ≥ alt sınır ise, bir uygunluk belirtmek mümkün olabilir. Eğer gerek, ölçülen değer > üst sınır ise, bir uymazlık belirtmek mümkün olabilir.

Durum 9

Ölçülen sonuç, belirsizlik aralığının yarısından az bir pay ile alt sınırın altındadır; bu sebeple, uymazlık belirtmek mümkün değildir. Bununla birlikte, %95'in altında bir güvenilirlik seviyesi kabul edilebilirse, uymazlık belirtmek mümkün olabilir.

Durum 10

Ölçülen sonuç, belirsizlik aralığının yarısı kadar yukarı doğru uzatılsa bile, alt sınırın ötesindedir. Bu sebeple, ürün spesifikasyona uygun değildir.

5.2 Terms of Application of the Decision Rule

TS EN ISO / IEC 17025:2017 Standard Revision TÜRKAK Information Guide - Test results are evaluated according to the legal legislation as specified in the following article 3.c of the Decision Rule;

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

In the article 7.1.3 of the TS EN ISO / IEC 17025: 2017 Standard;

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

In accordance with the statement, the decision rule is applied when necessary upon customer request.

Decision rule measurement uncertainty; reporting is made by evaluating the confidence interval (k = 2, 95%) determined by the laboratory for the relevant parameter.

5.2.1 Decision Rule Application:

If requested by the Client;

a. Evaluation : If the decision rule is not specified in the relevant test standard or legal regulations or specifications or if it is not selected by the customer, when the evaluation is requested; the relevant standard tolerance values are added to the report. No conformity/non-conformity is declared.
b. Decision Rule: When a decision rule is requested, the simple acceptance decision rule is applied (Figure.1). The measurement uncertainty value is calculated at 95% confidence interval and added to the relevant results. According to the tolerance values; "... The sample numbered ... meets / does not meet the standard values." It is declared with the statement.
c. If not requested by the client and/or if the decision rule is not mandatory in the legal regulations and specifications, the decision rule is not applied and not specified in the reports.

The relevant assessment standard is indicated in the "Assessment Standard" section of the report. If the customer does not request a declaration of conformity in the test report, the Declaration of Conformity decision rule is not applied to the results and is not specified in the report.

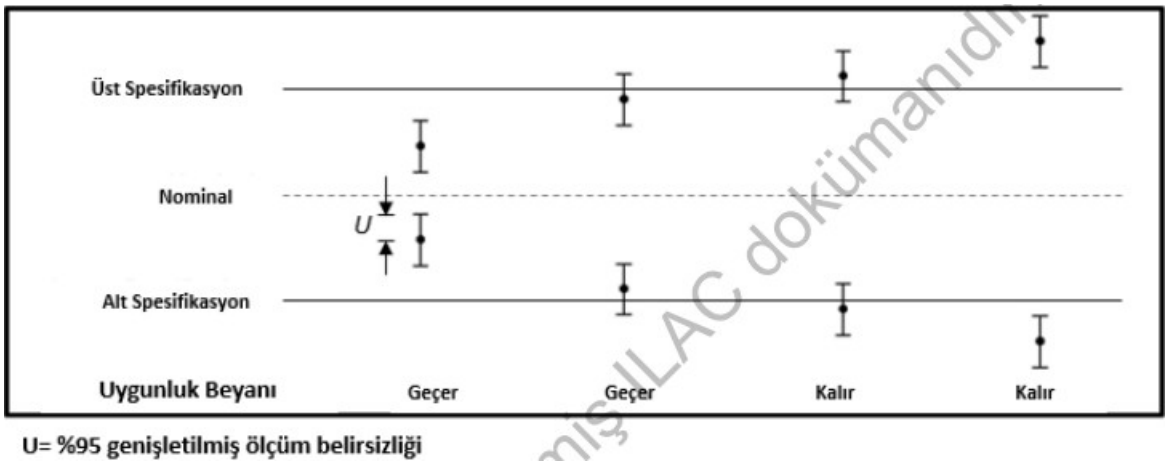


Fig.1 Simple Acceptance Rule

5.2.2 Determination of Acceptance and Rejection Zones (Guard Band Method) :

The decision rule allows the calculation of a guard band (g). This guard band defines acceptance and rejection zones. The intersection of these two zones is called the decision limit.

The information needed to make a decision:

- Measured magnitude (Unit)
- Experiment result
- Uncertainty - k factor and confidence interval for Extended Uncertainty
- Specification indicating lower and/or upper limits
- Decision rule

Measurement uncertainties are calculated at 95% confidence interval for all parameters analyzed in the laboratory.

Acceptance and rejection zones are created by adding and/or subtracting the guard bands to the limit value and the analysis results are evaluated according to the decision rule selected by considering the measurement uncertainty.

5.2.2.1 False Rejection Inappropriate Test Result Acceptance (Guard Band Method)

Fig.2 Acceptance and Rejection Zone Based on Lower and Upper Limit (False Rejection)

Example 1 : Protective Band Based on Lower Limit-False Rejection

The measured value of the S355 quality sample with a minimum limit value of 355 MPa is 354 MPa and the expanded uncertainty at k=2 and 95% Confidence Interval is 5 MPa. The calculated protection band is 4.1 MPa and the new lower acceptance limit calculated according to the "False Rejection" rule is 350.9 MPa and since the result is within this range, the result is given as CONFORMITY.

Protective Band Based on Lower Limit-False Rejection					
X	:	354	MPa	**Measured Value**	
$Lower_{Limit}$	:	355	MPa	**Lower Limit**	
U	:	5,0	MPa	95% G.A.	
u	:	2,5	MPa	68% G.A.	
k	:	1,64		Single Ended	
Protection Tape	:	4,1	MPa		
New Lower Acceptance Limit	:	350,9	MPa		**G.A. %**
Evaluation	:	CONFORMITY			95

Example 2: Protective Band Based on Upper Limit - False Rejection

The measured value of the S355 quality sample with a maximum limit value of 630 MPa is 632 MPa and the expanded uncertainty at k=2 and 95% Confidence Interval is 7.2 MPa. The calculated protection band is 5.9 MPa and the new upper acceptance limit calculated according to the "False Rejection" rule is 635.9 MPa and since the result is within this range, the result is given as CONFORMITY.

Protective Band Based on Upper Limit-False Rejection					
X	:	632	MPa	**Measured Value**	
$Upper_{Limit}$	:	630	MPa	**Upper Limit**	
U	:	7,2	MPa	95% G.A.	
u	:	3,6	MPa	68% G.A.	
k	:	1,64		Single Ended	
Protection Tape	:	5,9	MPa		
New Upper Acceptance Limit	:	635,9	MPa		**G.A. %**
Evaluation	:	CONFORMITY			95

Example 3: Guard Band Based on a Tolerance Range - Incorrect Rejection

The measured value of the S355 quality sample with a Minimum Limit Value of 470 MPa and a Maximum Limit Value of 630 MPa is 465 MPa and the expanded uncertainty at k=2 and 95% Confidence Interval is 6.5. The calculated protection band is 5.3 and the new lower acceptance limit calculated according to the "False Rejection" rule is 464.7 and the upper acceptance limit is 635.3, and since the result is within this range, the result is given as CONFORMITY.

Guard Band Based on a Tolerance Range-False Rejection					
X	:	465	MPa	**Measured Value**	
$Lower_{Limit}$	:	470	MPa	**Lower Limit**	
$Upper_{Limit}$	:	630	MPa	**Upper Limit**	
U	:	6,5	MPa	95% G.A.	
u	:	3,3	MPa	68% G.A.	
k	:	1,64		Single Ended	
Protection Tape	:	5,3	MPa		
New Lower Acceptance Limit	:	464,7	MPa		

New Upper Acceptance Limit	:	635,3	MPa		**G.A. %**
Evaluation	:	CONFORMITY			95

5.2.2.2 Incorrect Acceptance Rejection of an Appropriate Test Result (Guard Band Method) :

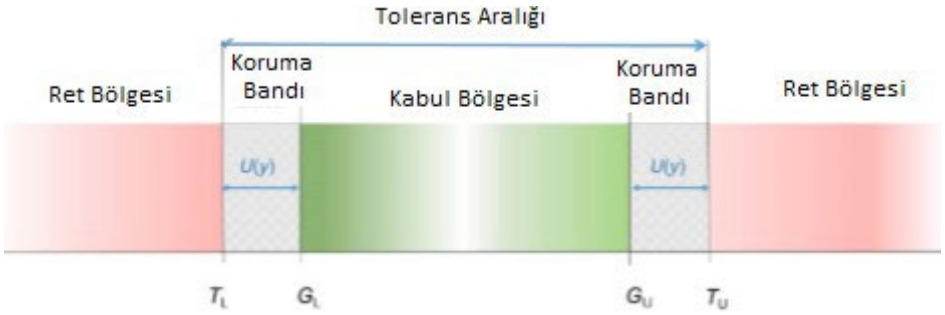


Fig.3 Acceptance and Rejection Zone Based on Lower and Upper Limit (False Acceptance)

Example 1: Protection Band Based on Lower Limit - Incorrect Acceptance

The measured value of the S355 grade sample with a minimum limit value of 355 MPa is 354 MPa and the expanded uncertainty at k=2 and 95% Confidence Interval is 5 MPa. The calculated protection band is 4.1 MPa and the new lower acceptance limit calculated according to the "False Rejection" rule is 359.1 MPa, and since the result is within this range, the result of DISCONFORMITY is given.

Protection Band Based on Lower Limit - Incorrect Acceptance					
X	:	354	MPa	**Measured Value**	
$Lower_{Limit}$	:	355	MPa	**Lower Limit**	
U	:	5	MPa	95% G.A.	
u	:	2,5	MPa	68% G.A.	
k	:	1,64		Single Ended	
Protection Tape	:	4,1	MPa		
New Upper Acceptance Limit	:	359,1	MPa		**G.A. %**
Evaluation	:	DISCONFORMITY			95

Example 2: Protection Band Based on Upper Limit - Incorrect Acceptance

The measured value of the S355 specimen with a maximum limit value of 630 MPa is 632 MPa and the expanded uncertainty at k=2 and 95% Confidence Interval is 7.2 MPa. The calculated protection band is 5.9 MPa and the new upper acceptance limit calculated according to the "False Rejection" rule is 624.1 MPa, and since the result is within this range, the result of DISCONFORMITY is given.

Protection Band Based on Upper Limit - Incorrect Acceptance					
X	:	632	MPa	**Measured Value**	
$Upper_{Limit}$	:	630	MPa	**Upper Limit**	
U	:	7,2	MPa	95% G.A.	
u	:	3,6	MPa	68% G.A.	
k	:	1,64		Single Ended	
Protection Tape	:	5,9	MPa		
New Upper Acceptance Limit	:	624,1	MPa		**G.A. %**
Evaluation	:	DISCONFORMITY			95

Example 3: Guard Band Based on a Tolerance Range - Incorrect Acceptance

The measured value of the S355 quality sample with a Minimum Limit Value of 470 MPa and a Maximum Limit Value of 630 MPa is 465 MPa and the expanded uncertainty at k=2 and 95% Confidence Interval is 6.5. The calculated protection band is 5.3 and the new lower acceptance limit calculated according to the "False Rejection" rule is 475.3 and the upper acceptance limit is 624.7, and since the result is within this range, the result of DISCONFORMITY is given.

Protection Band Based on a Tolerance Range - Incorrect Acceptance					
X	:	465	MPa	**Measured Value**	
$Lower_{Limit}$	:	470	MPa	**Lower Limit**	
$Upper_{Limit}$	:	630	MPa	**Upper Limit**	
U	:	6,5	MPa	95% G.A.	
u	:	3,3	MPa	68% G.A.	
k	:	1,64		Single Ended	
Protection Band	:	5,3	MPa		
New Lower Acceptance Limit	:	475,3	MPa		
New Upper Acceptance Limit	:	624,7	MPa		**G.A. %**
Evaluation	:	DISCONFORMITY			95

6. Related Documents

- TS EN ISO 17025: 2017 General Requirements for the Competence of Testing and Calibration Laboratories

- Measurement Uncertainty Estimation Procedure (QVV-PRO-017)

- ILAC G8 Decision Rules and Guidance on Declarations of Conformity

- TURKLAB Decision Rule Training Notes

7. Amendments

Amendments to this procedure are made by the Quality Management Representative.