1. PURPOSE AND SCOPE

This document describes the decision-making procedure to be applied when evaluating analysis results at the Reksoil Testing Laboratory according to a standard specification.

2. DEFINITIONS AND ABBREVIATIONS

2.1. Decision Rule: A rule that explains how measurement uncertainty should be taken into account when specifying compliance with a defined requirement.

2.2. Declaration of Conformity: Assessment of conformity according to a standard/specification or regulation.

3. RESPONSIBILITY AND AUTHORITY

3.1. General Manager

3.2. Laboratory Manager

3.3. Management Representative

4. APPLICATION

4.1. There are several possible situations where uncertainty affects the reporting of experimental/analysis results, and these are listed below:

a) This is the case where it is explicitly stated that the test result, extended with uncertainty at a defined confidence level, should not fall outside or inside 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 carried out (Figure-1 Cases 1, 5, 6 and 10).

b) However, unless it is explicitly stated that the test result, extended with a defined level of uncertainty, should not fall outside or inside a limit or limits defined in the product or test standard or legislation, the assessment of conformity or non-conformity may be carried out using the following approaches (Figure-1 Cases 2, 3, 4 , 7, 8 and 9).

i . Conformity to specification can be stated if the specification limits are not violated by the extended test result with half of the extended uncertainty range at a 95% confidence level (Cases 1 and 6 in Figure 1);

of the specification is still violated even after the test result has been extended downwards by half the extended uncertainty range , non-compliance with the specification may be indicated (Case 5 in Figure 1);

of the specification is still violated even after the test result has been extended upwards by half the extended uncertainty range , non-conformity to the specification may be indicated (Case 10 in Figure 1);

iv . If, without the possibility of testing other samples from the same batch or repeating the measurement, the single measured value falls sufficiently close to the specification limit and exceeds half of the extended uncertainty range, it is not possible to

verify conformity or non-conformity at the specified confidence level. In this case, the result and the extended uncertainty should be reported together with a statement indicating that conformity or non-conformity cannot be demonstrated at the specified confidence level (Figure 1, cases 2, 4, 7 and 9).

If legal requirements necessitate a decision of rejection or acceptance, situations 2 and 7 in Figure 1 below may be indicated as conformity to the specification limit (with a lower calculated and reported confidence level). Situations 4 and 9 in Figure 1 below may be indicated as non-conformity to the specification (with a lower calculated and reported confidence level).

If two or more samples from a single batch can be tested, or if the measurement is repeatable, 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 described in (i) to (iv) above should be performed.

Note: Results for (i) to (iv) are based on the assumption that the uncertainty distribution curve of the measured value is symmetrical 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 the uncertainty, or when a dominant uncertainty component known to have an asymmetric distribution is combined with another uncertainty component as if it had a normal distribution. In such a case, a more accurate calculation for the measured value and the measurement uncertainty may allow for a clearer conclusion.

v . If the result is above the full specification limit, it is not possible to declare conformity or nonconformity at the stated confidence level. In this case, the result and the extended uncertainty should be reported together with a statement indicating that conformity or nonconformity is not demonstrated at the stated confidence level (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, the laboratory may assess conformity or non-conformity based solely on whether the obtained result is within the specified limits, without considering the confidence level and measurement uncertainty.

Note: This is often referred to as shared risk because the end-user assumes some risk; namely, the product may not conform to specification after being tested using an agreed-upon measurement method . In this case, there is an implicit assumption that the uncertainty of the agreed-upon measurement method is acceptable and can be calculated if necessary. Relevant legislation or legal requirements may override the shared risk principle and shift the risk of uncertainty onto one party.

d) The agreement or rule of agreement between the customer and the laboratory may include provisions relating to the evaluation of test results. These provisions may include the effects of confidence level and measurement uncertainty in assessing conformity or non-conformity, the evaluation of the test result according to the limits specified by the product or test standard or the customer, and even the calculation of the confidence level at which the test result is conforming or not.

In this case, the assessment of conformity or non-conformity must be carried out according to these provisions of the agreement. The provisions of the agreement must not conflict with legal requirements. Furthermore, assessments related to 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 stated confidence level. In this case, the result and the extended uncertainty must be reported together with a statement indicating that conformity or non-conformity cannot be demonstrated at the stated confidence level.

If legal requirements mandate a notification of compliance or non-compliance regardless of the level of confidence, the notification must 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, the discrepancy is indicated.

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

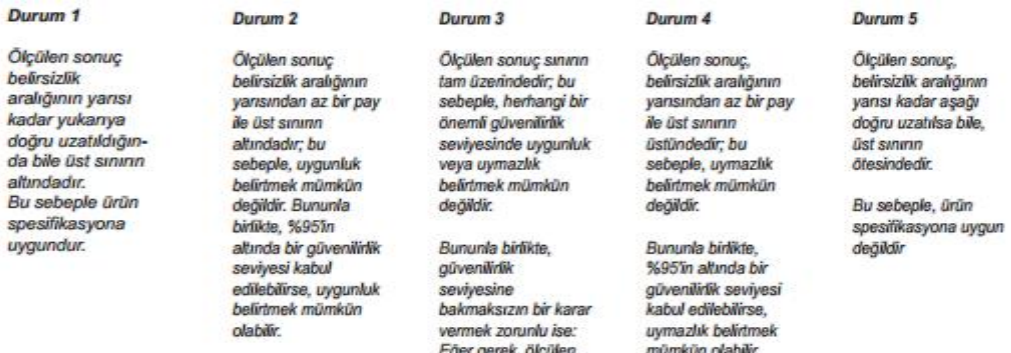

Figure 1: Cases Related to the Decision Rule

4.2. If no decision rule regarding the issuance of a declaration of conformity is defined in the analysis standard or legal regulation, and the customer requests a declaration of conformity, the following information must be provided by the customer. (Requests, Offers and Contracts Review Procedure (PRS.09))

- ❖ Request for Declaration of Conformity
- ❖ Specification (Standard/Regulation/Specification) that specifies the lower and/or upper limits.
- ❖ Decision Rule (One of the following can be selected)

□False Rejection, □False Acceptance, □Measurement Uncertainty Will Not Be Included.

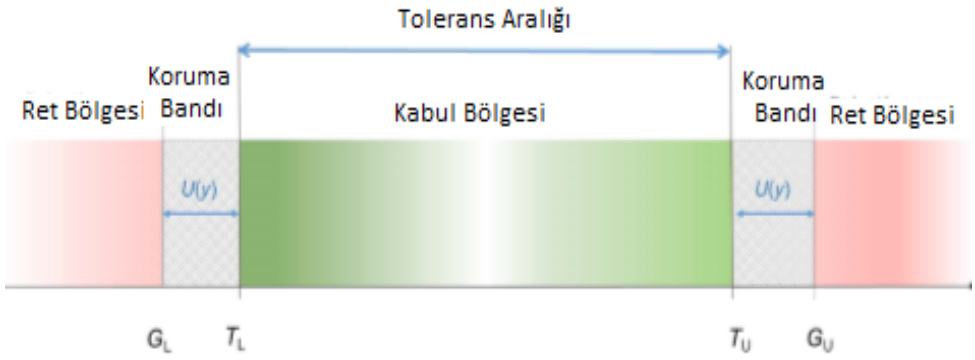

Figure 2 - Acceptance and Rejection Zone Based on Lower and Upper Limits (False Rejection)

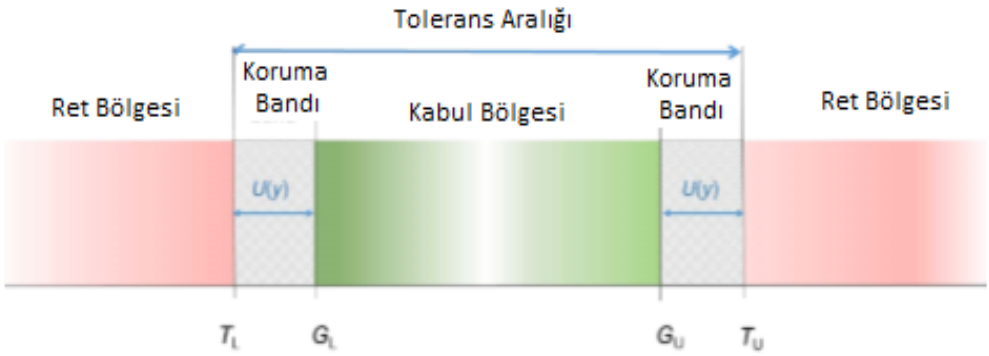

Figure 3 - Acceptance and Rejection Zone Based on Lower and Upper Limits (False Acceptance)

Unless otherwise requested by the customer, the protection band method will be used. The protection band will be calculated by multiplying the standard uncertainty (68% confidence interval k=1) by the one-way k value. At a 95% confidence interval, the one-way k value is 1.64. In cases where the sample is taken by the customer, data excluding the measurement uncertainty resulting from sampling will be used. Sampling is not performed in our laboratory.

Examples:

Example: 1

the specification with a minimum limit value of 7.10 %C, the value found in the sample is 6.70 %C, and with k=2 and a 95% confidence interval, the extended uncertainty is 0.60 % C. The calculated protection band is 0.49 %C, and according to the "False Rejection" rule, the new lower acceptance limit is 6.61 %C. Since the result is within this range, a CONFORMITY result is given.

=NORMTERS(0,95;0;1)=1.64

X	**:**	6.70	%C	**Measured Value**	
Lower Limit	**:**	7.10	%C	**Lower Limit**	
U	**:**	0.60	%C	95% GA	
u	**:**	0.30	%C	68% GA	
k	**:**	1.64		Single-ended	
Protective Tape	**:**	0.49	%C		
Lower Acceptance Limit	**:**	6.61	%C		**GA %**
Evaluation	**:**	SUITABILITY			95

Figure 4 - Acceptance and Rejection Zone Based on Lower Limit (False Rejection)

Example 2

the specification with a maximum limit value of 15.00 %S, the value found in the sample is 14.55 %S, and the extended uncertainty at k=2 and a 95% confidence interval is 0.60 %S . The calculated protection band is 0.49 %S, and the new upper acceptance limit calculated according to the "False Acceptance" rule is 14.51 %S. Since the result is outside this range, a NON-CONFORMITY result is given.

X	**:**	14.55	%S	**Measured Value**	
Upper Limit	**:**	15.00	%S	**Upper Limit**	
U	**:**	0.60	%S	95% GA	
u	**:**	0.30	%S	68% GA	
k	**:**	1.64		Single-ended	
Protective Tape	**:**	0.49	%S		
Upper Acceptance Limit	**:**	14.51	%S		**GA %**
Evaluation	**:**	DISAGREEMENT			95

Figure 5 - Acceptance and Rejection Zone Based on the Upper Limit (False Acceptance)

Example 3:

the specification with a maximum limit value of 15.00 %S, the value found in the sample is 14.55 %S, k=2, and the expanded uncertainty at a 95% confidence interval is 0.60 % S . Since the result falls within this range according to the "Measurement Uncertainty Not Included" rule, a CONFORMITY result is given.

X	**:**	14.55	%S	**Measured Value**	

Upper Limit	**:**	15.00	%S	**Upper Limit**	
U	**:**	0.60	%S	95% GA	
u	**:**	0.30	%S	68% GA	
					GA %
Evaluation	**:**	SUITABILITY			95

Figure 6 - Acceptance and Rejection Region Based on the Upper Limit (Excluding Measurement Uncertainty)

5. RECORDS

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6. REFERENCES

6.1. Laboratory Measurement Uncertainty Estimation Procedure (AK-P-25)

6.2. Procedure for Reviewing Offers and Contracts (AK-P-3)

6.3. ISO/IEC 17025 STANDARD REVISION INFORMATION GUIDE - Decision Rule

6.4. EUROLAB Technical Report No.1-2017 Decision rules applied to conformity assessment

7th REVISION HISTORY

Revision No.	Revision Date	Nature of Revision
00	July 29, 2019	First Publication
01	July 13, 2023	Example 2 protection band value was corrected to 0.49.