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Customer information on measurement uncertainty and decision rule

For the interpretation of analytical results and a resulting conformity assessment, knowledge and consideration of the measurement uncertainty of a test method is essential.

Laboratories accredited according to DIN EN ISO/IEC 17025:2018 are therefore obliged to determine the expanded measurement uncertainty of the test results and, if possible, to show this numerically in test reports.

What is the uncertainty of measurement?

Analytical measurement results are always associated with measurement uncertainty, since no measurement result exactly matches the true value. This fact may be of great importance when testing for compliance with guidelines and limit values or specifications and an associated conformity assessment.






The measurement uncertainty of an analytical test method is determined with a statistical certainty of 95%. Both systematic and random uncertainties of the method are included in this measurement uncertainty and it is referred to as the expanded measurement uncertainty. The measurement uncertainty can vary significantly depending on the measurement method used.

If the test results received are used to perform a conformity assessment, a decision rule shall be applied for results close to a limit value, specifying how the expanded uncertainty of measurement of the method should be taken into account.

What is the decision rule?

DIN EN ISO/IEC 17025:2018 requires the application and communication of the decision rule used in the context of a conformity assessment. The decision rule determines how the expanded measurement uncertainty is taken into account in a conformity assessment that is based on an analytical test. The probability that conformity is correctly assessed depends on this decision rule.

Basically, the following scenarios should be differentiated:

	Limit	Assessment	Probability of a non-applicable conformity decision
A		compliant	irrelevant
B		compliant*	>2,5 to <50 %
C		compliant*	50 %
D		compliant*	>50 % to <97,5 %
E		non-compliant	irrelevant

*Evaluation using the decision rule established at Eurofins WEJ Contaminants GmbH.

For the decision A and E "compliant" or "non-compliant" the measurement uncertainty is not taken into account, because the ranges in which the true values are located are certainly below or above the maximum value and therefore a reliable conformity decision is possible.

In scenarios B, C and D, there is a relevant probability that the conformity decision is wrong, since the true value of the result is close to the limit value. Therefore, it is not possible to make a reliable decision on whether the result is below or above the limit value, taking into account the measurement uncertainty.

Eurofins WEJ Contaminants GmbH has defined to consider the expanded measurement uncertainty in the conformity assessment when the analyzed result exceeds a given limit or specification value, since it cannot be assumed with certainty that the exceedance of the limit or specification value is ensured taking the measurement uncertainty into account (scenario D).

If the measured value is below or equal to the given limit or specification value, the measurement uncertainty is not taken into account in the conformity assessment, although taking the measurement uncertainty into account, it cannot be concluded that the measured value is definitely below the limit or specification value (scenarios B and C).

In scenario D, we indicate on the test report that the limit value is not definitely exceeded when the measurement uncertainty is taken into account.

In the context of the entrepreneurial obligation for self-monitoring, in scenarios B, C and D, the client has to decide how to deal with affected test results in the interest of the highest possible product safety and taking into account the decision rule applied by the responsible authorities (authorities may, under certain circumstances, apply a stricter decision rule when deciding on "compliant" or "non-compliant").

Finally, we would like to point out that we already apply the above-mentioned decision rule in this way, unless a different decision rule has been agreed with us on a customer-specific basis. If you, as the client, wish to apply a decision rule that deviates from the above, this must be actively communicated to us prior to sample submission so that we can adapt the conformity assessments to your requirements.



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