DECISION RULES IN PRESENTING STATEMENTS OF CONFORMITY WITH REQUIREMENTS, APPLIED AT THE LABORATORY BELONGING TO ETOS COMPANY ACCORDING TO ILAC-G8:09/2019 GUIDELINES

1. The basis for the statement of conformity is the requirement specified in accreditation standard PN-EN ISO/IEC 17025:2018-02. This standard imposes on test laboratories the requirement to include the statement of conformity of results with requirements or specifications where the client so requires in test reports. The specification or the requirement and the decision rule (the conformity/non-conformity or pass/fail result) should be clearly specified. If this is not included in the specification or requirement, the selected decision rule should be communicated to and agreed with the client. The statement of compliance of results with the specification or requirement is presented in the Test Report only at the client's request contained in Form F 24 – Analysis Request Form and in Form F 56 – Arrangements with the Client.
2. Basic terms
    a) ***Decision rule*** is a rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.
    b) ***Tolerance limit (TL)*** – permissible upper or lower limit of measurement values – it results from requirements of standards or specifications (e.g. the "highest permissible concentrations", "parametric value").
    c) ***Acceptance limit (AL)***– permissible upper or lower bound of acceptance of the measurement result.
    d) ***Guard band (w)*** – the interval between a tolerance limit (TL) and an acceptance limit (AL), where $w = |TL - AL|$
3. Each measurement result is laden with uncertainty. Where no information on the value of measurement uncertainty is provided, this may result in a wrong decision (false accept or false reject). The probability that a given accepted result is non-conforming or a rejected result is conforming is called risk. When selecting a specific decision rule (proposed by the Laboratory), the client accepts the related risk of false accept or false reject.
4. ***Rule No. 1 – the rule of simple acceptance (binary statement)***
   In this method, the guard band is not taken into consideration; TL = AL, which means that $w = 0$.

It is assumed that the estimation of the measured value has a normal distribution of probability, and **specific risk**is used for risk calculation (only for a given result). In such a case, the risk of accepted results being outside tolerance limits is up to 50%, and the risk of false reject of measurement results which are outside the tolerance limit is also up to 50%.

Upper tolerance limit
(NDS, parametric value)

Lower tolerance limit

Pass **Pass** **Fail** **Fail**

U – expanded uncertainty of measurement results at a confidence interval of approx. 95% and the expansion factor k = 2 (measurement uncertainty is provided in the Test Report)

Fig. 1 – Graphic representation of the simple acceptance rule

Statements of conformity are presented as:

- **Conformity** (pass) – the measured value is below the acceptance limit, with the false accept risk being 50%.
- **Non-conformity** (fail) – the measured value exceeds the acceptance limit, with the false reject risk being 50%.

5. ***Rule No. 2 – the rule of non-binary statement with guard band (with conditional pass/fail)***
   This rule takes the guard band "w" into consideration.
   The client agrees that decisions are based on limited bounds of acceptance. (w = U, AL = TL – w), where U is the expanded uncertainty. The statement of conformity does not have a binary nature. It is assumed that the estimation of the measured value has a normal distribution of probability, and **specific risk** is used for risk calculation (only for a given result). In such a case, the risk of acceptance of results outside the tolerance limit is < 2.5%. In the case of rejected results, the risk of them being within tolerance limits is < 2.5%. Where the measured result is near to tolerance, the risk of false accept and false reject increases to 50%.

Upper tolerance limit
(NDS, parametric value)
Upper acceptance limit
Lower acceptance limit
Lower tolerance limit

Pass **Conditional pass** **Conditional pass** **Fail** ***U*** – expanded uncertainty of measurement results at a confidence interval of approx. 95% and the expansion factor k = 2 (measurement uncertainty is provided in the Test Report)

Fig. 2 – Graphic representation of the rule of non-binary statement with the guard band "w"

Statements of conformity are presented as:

- **Conformity** (pass) – the result is within the acceptance limit, taking the guard band constituting an expanded uncertainty value (at k = 2) into consideration. The specific risk of false accept is up to 2.5%.
- **Conditional conformity** (conditional pass) – the result is within the tolerance limit – in the guard band constituting an expanded uncertainty value (at k = 2). However, the expanded uncertainty of the measurement result exceeded the tolerance limit. For a measurement result near to the tolerance limit, the specific risk of false accept increases to 50%.
- **Conditional non-conformity (**conditional fail) – the measurement result is outside the tolerance limit. However, the expanded uncertainty of the measurement result is within the tolerance limit in the guard band constituting the value of expanded uncertainty (at k = 2). For a measurement result near to the tolerance limit, the specific risk of false reject increases to 50%.
- **Non-conformity** (fail) – the measurement result, together with the expanded uncertainty of the measurement result (at k = 2), exceeded the tolerance limit. The specific risk of false reject is up to 2.5%.