PPC TESTING, INSPECTION & CERTIFICATION SINGLE MEMBER S.A.
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Decision rule and statement of conformity factsheet

On the basis of the **ISO/IEC 17025:2017** requirements, the Quality Management System of PPC Inspectra laboratories mandates an *a priori* agreement on the Decision Rule to be applied in assessing whether any measured attributes of the specimens/equipment to be calibrated conforms to predetermined conformance zones in accordance with existing law, relevant standards, specifications, and reference documents. The same requirement for an *a priori* agreement on the decision rule applies, if the customer wishes that a declaration of conformity be included in the Testing/Calibration Report.

Please be aware that in all cases, the decision rule selected for all testing/calibration services requested must be in accordance with the requirements and directives of existing legislation and with the standards implemented for each specific method. If there is a lack of any information regarding the decision rule in the existing legislation and relevant standards, all parameters of the decision rule must be prearranged between PPC Inspectra and the customer. The Decision rule must be agreed upon, described, and presented in the application form, prior to any review of the form by PPC Inspectra and, in any case, before the execution of the testing/calibration service requested.

Relevant Terminology:

- **Statement of Conformity:** A clear declaration on the Testing/Calibration Report regarding the conformity or non-conformity of the material/product tested/calibrated to a predetermined specification, standard, or requirement.
- **Decision Rule:** A documented rule that describes how measurement uncertainty is accounted for in accepting or rejecting a product, when stating conformity with a predetermined requirement.
- **Combined Measurement Uncertainty $u_c(y)$:** A parameter associated with a measurement result (y) of the actual value (Y) of a measurand and expresses the laboratory's estimation of the dispersion of the values that could be reasonably attributed to the measurand, considering several factors possibly responsible for error contribution.
- **Expanded Measurement Uncertainty (U):** The Expanded Uncertainty (U) of a measurement (y) of the actual value (Y) of a measurand, calculated by multiplying the combined standard uncertainty $u_c(y)$ by a coverage factor k, so that: $U=k\,u_c(y)$. The result of the measurement (y) is expressed as $y\pm U$, where y is considered as the best estimate of the actual value (Y), whereas the interval from y − U to y + U is expected to encompass a large fraction of the distribution of values that could be reasonably attributed to Y. The term "measurement" includes all processes leading to the final result (e.g., method of measuring, raw data manipulations, etc.).
- **Tolerance/Specification Limit:** The upper or lower value limit for a measurand, according to the product's specification.
- **Tolerance interval:** the interval delimited by the tolerance/specification limits.
- **Conformance Limit:** The limiting upper or lower value determining the conformance of a material/product.
- **Conformance Zone:** The interval of limiting quantity values measured, within which a specimen is accepted on the basis of a given method of measurement and decision rule.
- **Non-Conformance Zone:** The interval of limiting quantity values measured, within which a specimen is rejected on the basis of a given method of measurement and decision rule.
- **Guard Band:** The offset from tolerance/specification limits to conformance limits. Using a Guard Band (w) on the decision rule may render the conformance zone wider or narrower than the tolerance interval. A conformance zone wider than the tolerance interval leads to an easier acceptance of the material/product. Conversely, a conformance zone narrower than the tolerance interval leads to a more difficult acceptance of the material/product. Using a Guard Band aims at minimising possible risks of false acceptance or rejection of the material/product.
- **Probability of false acceptance/rejection:** The probability of falsely accepting or rejecting a product based on the result of the testing/calibration.
- **TUR (Test Uncertainty Ratio):** The ratio of the difference between the upper and lower tolerance/specification limits (T_u-T_L) of a measurand to the expanded measurement uncertainty(U): TUR= (T_u-T_L)/U.

<u>Figures 1 and 2 present cases in which the Conformance Zone is either narrower or wider than the Tolerance Interval.</u>

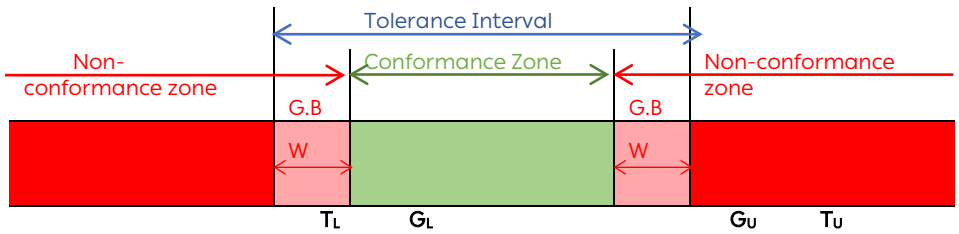

Figure 1: Example of narrower Conformance Zone (stricter acceptance; reduced risk for the consumers)

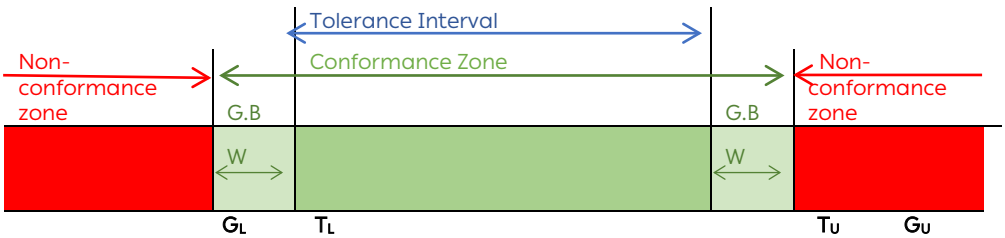

Figure 2: Example of wider Conformance Zone (easier acceptance; reduced risk for the producer)

<u>Legend:</u> **T_u**: Upper Tolerance/Specification Limit, **G_u**: Upper Conformance limit, **T_L**: Lower Tolerance/Specification Limit, **G_L**: Lower Conformance Limit, **w or G.B.**: Guard Band

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How to select the appropriate decision rule:
Please note that the decision rule on the basis of which any statements of conformity will be made is agreed upon by both parties signing the application form and is mentioned on the Testing/Calibration Report/Certificate. All decision rules described below, and any relevant statements of conformity refer exclusively to the samples, specimens, or equipment on which any requested testing or calibration service will be performed.

K1. No statement of conformity required on the Testing/Calibration Report/Certificate
K1 is used in cases in which a statement of conformity is not required by law or a standard, or if the customer has not ticked the "Statement of Conformity" field on the application form. The results of the measurements are stated on the Report/Certificate alongside the measurement uncertainty for a known confidence level (e.g., 95%). No statement of conformity is included in the Report/Certificate.

K2. A statement of conformity on the Testing/Calibration Report/Certificate is required
A Statement of Conformity will be included in the Report/Certificate, **provided that** the customer has marked the "Statement of Conformity" box on the application form. The following decision rules K2.1, K2.2 and K2.3 – or alternatively K2.4 – will be followed in order of priority.

K2.1 The Decision rule to be used is determined by National or EU Law or other regulatory documents:
It is mandatory that K2.1 be followed when National Law, EU Law, or other official regulatory documents determine the Decision Rule to be applied to the requested testing/calibration service. This applies regardless of the definition of any other decision rules in standards, specifications or reference documents and regardless of the customer's wish to select an alternative rule. The customer must, to the best of their knowledge, mention any relevant regulatory documents in the application form.

K2.2 Decision rule determined by standards, specifications, or reference documents of measuring equipment:
When the decision rule for the requested testing/calibration service is determined by standards, specifications, or reference documents of measuring equipment, K.2.2 is followed. The customer must mention all relevant documents in the application form.

K2.3 Application of the General Decision Rule adopted by PPC Inspectra:
K2.3 is followed for any testing/calibration, regardless of whether they fall under the OSA of PPC Inspectra, when there is no requirement in place for the application of a specific decision rule based on law (in which case K2.1 applies), standard, and reference document (in which case K2.2 applies), or when the customer does not wish to define their own rule (in which case K2.4 applies). The General Decision Rule that PPC Inspectra applies in assessing the conformity of the specimens measured is as follows:
Binary Statement for Simple Acceptance: Guard Band (w)=0; the Acceptance and Tolerance intervals overlap.
Acceptance of the Specimen: the value measured lies within the conformance zone (see conformance zone in figure 3 below)
Rejection of the Specimen: the value measured lies outside the conformance zone (see non-conformance zone in figure 3 below)
The probability of a false acceptance or rejection increases the closer the value measured approximates the Conformance Limit within the range of measurement uncertainty. For example, the probability of a false acceptance or rejection can be up to 50% high, when the result of the measurement is very close to the Conformance limit.
For all testing and calibration that fall under the OSA of PPC Inspectra:

1. the expanded uncertainty of the measurement (U) is mentioned for a known level of confidence (e.g., 95%). This expanded uncertainty does not affect the decision but might affect the probability of a false acceptance or rejection of the specimen.
2. In case of a two-sided tolerance interval, K2.3 can only be applied when TUR≥ 5:1, namely only when the ratio of the tolerance interval (T_U-T_L) to the expanded uncertainty (U) is greater than or equal to 5. If TUR < 5:1, K2.3 cannot be applied, and the Testing/Calibration Report/Certificate will not include a statement of conformity. The TUR <5:1 limitation does not apply to one-sided tolerance limits (upper or lower), as a TUR cannot be defined.

For any testing/calibration outside the scope of the OSA of PPC Inspectra the limitation TUR ≥ 5:1 is at play only when there is an estimate for the measurement uncertainty.

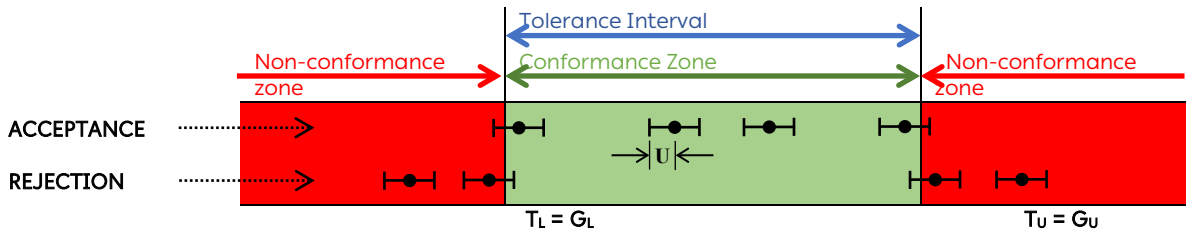

Figure 3: Example of the Binary Statement for Simple Acceptance (Guard Band w=0)

K2.4. Customer defined decision rule:
Wherever K2.1 and K2.2 are not applicable, rule K2.4 may be selected by the customer instead of K2.3. The table and examples below provide guidance on how to choose the appropriate subcategory of K.2.4 depending on the width of the Guard Band and taking into consideration the need for decreasing the probability of a false acceptance (consumer risk) or rejection (producer risk). The probability of false acceptance/rejection is calculated assuming a single-sided specification limit and a normal distribution of measurements and differs in cases of two-sided intervals or of another type of distribution. A relevant statement will be made on the Testing/Calibration Report/Certificate.

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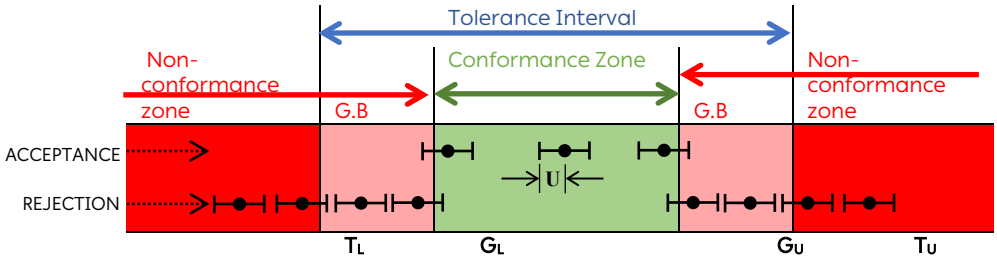
RULE K2.4 SUBCODES		
Decrease of probability of False Acceptance (Reduces consumer risk)		
Subcode	**Guard Band *w***	**Probability of False Acceptance ***
K2.4.1	1,5·U	<0,16%
K2.4.2	1·U	<2,5%
K2.4.3	0,83·U	<5%
Decrease of probability of False Rejection (Reduces producer risk)		
Subcode	**Guard Band *w***	**Probability of False Rejection ***
K2.4.4	-1,5·U	<0,16%
K2.4.5	-1·U	<2,5%
K2.4.6	-0,83·U	<5%

*Assumes a one-sided specification limit and normal distribution of measurement results

EXAMPLE: Decrease of the Probability of False Acceptance



EXAMPLE: Decrease of the Probability of False Rejection