Technical note ForMEQ (NT 8/2024)

Decision rules: use of measurement uncertainty in conformity assessment

(English version)

1 Contextualization

Many decisions are made based on measurement results. In such situations, the way in which measurement uncertainty will be considered for decision-making should be expressed in an appropriate decision rule.

Decision rules are guidelines that specify how measurement results should be interpreted against established limits, taking into account measurement uncertainty. In contexts where it is necessary to verify the compliance of products or processes with regulatory or quality specifications, decision rules help determine whether an item is compliant (acceptable) or not (rejectable).

2 Main decision rules

The main decision rules include decision rules with: a) simple acceptance; b) use of a guard band; c) conditional or inconclusive results; and d) two-stage procedure.

2.1 Simple acceptance decision rule

In this rule, compliance is determined by the direct comparison between the measured value and the specification limit, without taking into account the information about its uncertainty. If the measured value is within the limit, the tested item or batch is considered compliant. Otherwise, it is not compliant.

The simple acceptance decision rule is also called the shared risk decision rule, since both the risks of incorrect acceptance (consumer's risk) or incorrect rejection (producer's risk) can have a value up to 50%.

2.2 Decision rule with use of a guard band

In this approach, a guard band (g) is added or subtracted from the specification limit, in order to reduce a certain risk of incorrect decision. The guard band is usually a multiple of the standard uncertainty of the measurement, u ($g = ku$).

When the risk of incorrect acceptance (consumer's risk) is to be controlled, the guard band is added to the lower specification limit ($L_i + g$) and/or subtracted from the upper limit ($L_s - g$), making the control more restrictive.

On the other hand, when the objective is to control the risk of an incorrect rejection (producer's risk), the guard band is subtracted from the lower specification limit ($L_i - g$) and/or added to the upper specification limit ($L_s + g$), making the control more permissive. Figure 1 illustrates the definition of acceptance limits for producer risk (or low false rejection) and for consumer risk (or low false acceptance).

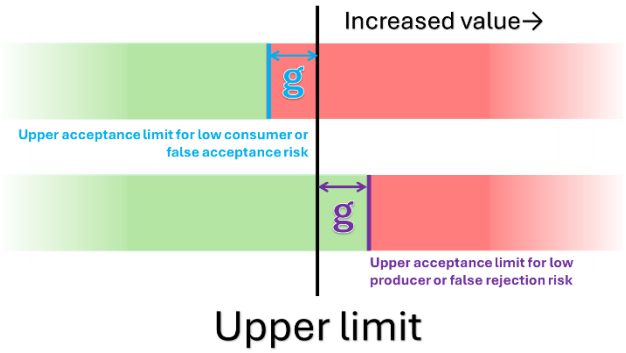

Figure 1 – Decision rule with use of a guard band.

2.3 Decision rule with conditional or inconclusive results

This decision rule includes the possibility of conditional decisions or inconclusive results, when measurement uncertainty overlaps the specification limit. In these cases, a tested item or lot can be considered compliant, non-compliant, or with an inconclusive result, depending on what is defined in the decision rule.

In some situations, additional measurements or a more detailed decision process may be required to determine final compliance.

2.4 Decision rule with two-step procedure

In some cases, a two-step decision procedure may be employed to reduce the risk of false acceptance or false rejection. In this rule, if the initial result is inconclusive, a second measurement can be performed, employing a different analytical procedure than the first measurement.

3 Application of the rules of decisions

Consider that an analytical laboratory has been hired to determine the concentration of a contaminant in water samples, with the aim of verifying compliance with drinking water quality standards. The maximum permissible limit for this contaminant is 50 µg L^{-1}, as established by regulation.

The laboratory measures the concentration of (48 ± 3) µg L^{-1}, with expanded uncertainty with approximately 95 % confidence level and coverage factor k= 2.

3.1 Simple acceptance decision rule

Considering the simple acceptance rule, the measured value is directly compared to the limit. In this case, the sample is declared compliant, as the measured value (48 µg L^{-1}) is below the maximum specification limit (50 µg L^{-1}).

3.2 Decision rule with use of a guard band

Considering that one wishes to minimize a false acceptance, an acceptance limit of 47.5 µg L^{-1} was adopted, based on the uncertainty information ($L_s - g = 50 - (1.64 \times 3/2)$ = 47.5 µg L^{-1}, considering a maximum risk of 5 %). The expanded uncertainty is converted into standard uncertainty ($u = U/K =$ 3/2) and then multiplied by an appropriate coverage factor (usually, 1.64 to 95% confidence or 5% risk). In this case, the sample is declared non-compliant, as the measured value (48 µg L^{-1}) is above the maximum acceptance limit (47.5 µg L^{-1}). This means that the risk of the consumer receiving water with a concentration of the contaminant above the maximum limit established by the regulation is greater than 5%.

3.3 Decision rule with conditional or inconclusive results

Considering that the 95% confidence interval for the concentration of the contaminant (45 µg L^{-1} to 51 µg L^{-1}) overlaps the maximum limit established by the regulation (50 µg L^{-1}), the comparison of the result with the limit is considered inconclusive. Alternatively, the decision rule can describe in which situation conditional acceptance (or conditional rejection) of the sample may occur.

3.4 Decision rule with two-step procedure

Considering that the result was inconclusive, the sample can be submitted to a confirmatory analysis (second measurement), with an analytical procedure that leads to a measurement uncertainty lower than that obtained in the screening analysis (first measurement), in order to ensure greater confidence in the final decision.

3.5 Decision rule in testing accreditation

Laboratories accredited by the ISO/IEC 17025 Standard must evidence the discussion with customers and the presentation in the test report of decision rules not specified in the regulation, by the customer or in the test standard used. A laboratory may only include conformity assessment of a result in a test or calibration report if it has been requested by the customer.

4 Conclusion

Decision rules allow laboratories, or regulatory bodies, to make decisions about the conformity (or not) of a tested item or lot, based on information about the uncertainty of its results, in a clear and objective way. The most appropriate decision rule must be chosen according to the intended purpose, in order to protect the most relevant interests (of the consumer, producer or both indistinctly).

5 References

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