




Level of risk associated with standard decision regulation

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1. Aim

The purpose of this procedure is to define the level of risk associated with the standard decision rule used by RTM Breda.

2. Applicabilità (campo di applicazione)

This procedure applies to conformity assessments carried out by RTM Breda on accredited tests.

3. References

- ISO 9000: "Quality management systems — Fundamentals and vocabulary";
- ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories"
- ILAC-G8:09: "Guidelines on Decision Rules and Statements of Conformity"

4. Operative modality

If requested by the customer, Rtm Breda can provide in the test report a declaration of conformity to a specification/standard/defined requirement; for this purpose the laboratory must agree in the contract with the customer the decision rule used, taking into account the level of risk associated with it, and apply this rule.

Note: When the decision rule is imposed by the customer, by regulations or normative documents, no further considerations on the level of risk are necessary.

The decision on whether or not a component or instrument complies with the specifications may take into account the uncertainty affecting the measurement. Such decisions are generally based on comparing the measured characteristics with limits specified by regulations, when applicable, or agreements between Supplier and Customer.

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The internal procedure PI001 "Procedure for the calculation/Estimation of Uncertainty" gives some examples of applicable decision rule.

On the basis of the historical nature of RTM Breda's laboratory activities, unless otherwise agreed with the customer, the applied rule is not to consider the contribution of uncertainty and to carry out the assessment of conformity by comparing the result of the measurement alone with the limits of acceptability by standards and/or specified by the customer. This rule is communicated to the Customer and described in the general terms and conditions,

La procedura interna PI001 "Procedura per il calcolo /Stima dell'incertezza" riporta alcuni esempi di regola decisionale applicabile.

Sulla base della storicità delle attività di laboratorio di RTM Breda , se non diversamente concordato con il committente, la regola applicata è quella di non considerare il contributo di incertezza ed eseguire la valutazione della conformità confrontando il solo risultato della misurazione coi limiti di accettabilità da standard e/o specificati dal cliente (Accettazione semplice – Simple Acceptance). Tale regola viene comunicata al cliente e descritta nelle condizioni contrattuali generali, possibly with a reference to this document.

In this case, there is the risk of making incorrect conformity assessments from a theoretical point of view (for example, incorrect acceptance and/or rejection); this is typically accepted by the customer as it is considered that during the design phase of components, safety coefficients are applied that take this situation abundantly into account and that allow a simplified conformity assessment but appropriate to the purpose of the test.

The standard ILAC-G8:09: Guidelines on Decision Rules and Statements of Conformity is a general guide about the selection of the more suitable decisional rules and for the identification of the required elements from the decisional rules when there are not applicable standards.

In particular the document gives useful definitions and clarifications for the risk level, identifying the modality of probability evaluation of False Acceptances (PFA) and False Reject (PFR).

The following table identifies the risk level for simple acceptance:

Decisional Rule	Guard Band w	Risk Level
Simple acceptance	0	< 50% PFA

If the customer agrees on a different decision rule during the contractual definition, the risk level must be redefined and communicated to the customer using the ILAC-G8: 09 standard as a reference.