ILAC-G8: 2019 - Guidelines on Decision Rules and Statements of Conformity – A summary

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Berlin, 20 November 2019

Guidelines on Decision Rules and Statements of Conformity

http://mechem.rd.ciencias.ulisboa.pt/

1. Aim of the guide

Developed to assist laboratories in the use of decision rules for conformity assessment. The guidance was prepared for assessors, laboratories, regulators, and customers.

» Different decision rules will be used in different scenarios

Provide guidance on:

1) Selecting appropriate rules

2) Defining a decision rule §

» Based on the JCGM 106: 2012, Evaluation of measurement data – The role of measurement uncertainty in conformity assessment.

[G8: does not describe the associated statistics and mathematics]

§ "…how measurement uncertainty will be accounted for when stating conformity with a specified requirement."

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2. Requirements of the ISO 17025: 2017

The standard mentions decision rules in:

Personnel (6.2): Identification of personnel that performs conformity assessments;

Contract review (7.1):If customer request a statement of conformity, the decision rule should be clearly defined, communicated and agreed with the customer (if not regulated);

Reporting (7.8): Reporting of the measurement uncertainty if relevant for the conformity assessment.

Rules for reporting the conformity assessment:

1) to which results applies;

2) which specifications are considered;

3) the decision rule applied.

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3. Guard band and decision rules

Describes the used of guard bands to define acceptance limits in order to reduce the risk of wrong decisions.

Examples refer to:

» Specific consumer's risk based on a single maximum limit;

Mentions conformity assessment based on guard band zero, designated "shared risk" approach. In this case, the risk of wrong decision can reach up to 50 %.

Discuss cases where binary (pass/fail) of non-binary statements are considered (pass/ conditional pass/ conditional fail/ fail)

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4. Taking measurement uncertainty into account

Mentions that some regulators define a target measurement uncertainty and also set a decision rule.

Other regulators define a very low maximum consumer's risk.

Determination of the guard band, *w*, for defining acceptance limits:

$$w = r \cdot U$$

r – multiple of the expanded measurement uncertainty.

5. Types of risks

Specific vs. Global Risk:

The specific and global risk concepts are only described in section 5.3 for the wrong acceptance of equipment calibration.

Mentions that the inclusion of prior information has a major impact on conformity assessment.

[the guide is not very clear about the difference between these types of risk]

Consumer's and producer's risk:

In section 5.4, it is mentioned that risk assessment can be referenced to producer's and/or consumer's risk.

6. Decision rule selection flow chart

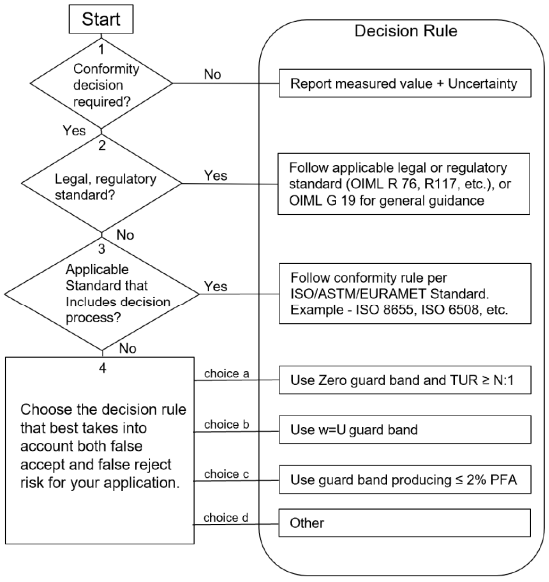

Figure 7. Pass/Fail Conformity Decision Rule selection flow chart.

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