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.

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)
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.

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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

Decision Rule

- Report measured value + Uncertainty
- Follow applicable legal or regulatory standard (OML R 79, R117, etc.), or OML G 19 for general guidance
- Follow conformity rule per ISO/ASTM/EURAMET Standard. Example: ISO 8503, ISO 8506, etc.
- Use Zero-gaurd band and TUR ≥ N1
- Use whU guard band
- Use guard band producing ≤ 2% PFA
- Other

Start
Conformity decision required?
Yes
Legal, regulatory
restricted?
No
Yes
Applicable Standard that
includes a decision
process?
No
Yes
Choice a
Choice b
Choice c
Choice d

Choose the decision rule that best takes into
account both false accept and false reject risk for your application.

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Figure 7: Pen Fold Conformity Decision Rule selection Flow chart.