

New ISO/IEC 17025:2017 and Decision Rule

The current version of ISO/IEC 17025:2005 has the following clauses:

Clause 5.10.3.1b for testing laboratories: “the test report shall, where necessary for the interpretation of the test results include..., where relevant, a statement of compliance/non-compliance with requirements and/or specification”.

Clause 5.10.4.2 states that “When statements of conformance are made, the uncertainty of measurement shall be taken into account.”.

These statements have been commented to be rather vague as they leave open to a wide range of interpretations on how to decide conformity when the test result is at the borderline of the stipulated regulatory or product specification limits with its measurement uncertainty taken into consideration.

Since then, few learned organizations have tried to address this issue, such as:

1. The Eurachem/CITAC published a Guide “*Use of uncertainty information in compliance assessment*” in 2007 on the subject on Decision Rule and Compliance;
2. ILAC G-8:03/2009 “*Guidelines on the reporting of compliance to specification*” attempts to provide some clarity by writing a guide on how to look at making a “pass/fail” conformity assessment, and how to present the “conformance/non-conformance” statements;
3. The JCGM 106:2012 “*Evaluation of Measurement Data- the Role of measurement uncertainty in conformance assessment*” is another guideline on how to deal with this problem with more details and suggestions on different ways of interpreting results.

Now, the newly revised ISO/IEC FDIS 17025:2017 to be implemented before the end of this year is addressing this issue by adding a new term “Decision rule” under its Terms and Definitions Clause 3.7 which states that it is a “*rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement*”. This is in relation to Sub-clause 7.8.6 on providing “*Reporting statements of conformity*”.

The new ISO standard gives further directives:

“7.8.6 Reporting statements of conformity

7.8.6.1 When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule.

NOTE Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

7.8.6.2 The laboratory shall report on the statement of conformity, such that the statement clearly identifies:

- a) to which results the statement of conformity applies;*
- b) which specifications, standards or parts thereof are met or not met;*
- c) the decision rule applied (unless it is inherent in the requested specification or standard)*

NOTE For further information see ISO/IEC Guide 98-4.”

In this issue of conformity, one therefore must make an educated discussion with his principals (customers or regulators) during the negotiation of a job contract or a contract review, It is a risk to both parties concerned, which must be duly assessed and decided upon when the reported measurement is found not within or below/above specification stipulated.

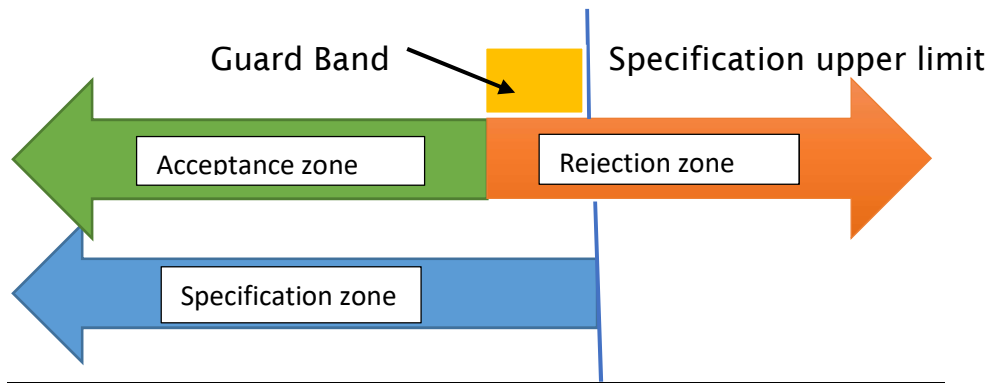
If we were to look at the Sub-clause 7.8.6.1 again carefully, we could make the following interpretations:

- a. The statement “When a statement of conformity to a specification or standard is provided, the laboratory shall document ...” implies that the specification or standard is provided by the principals;
- b. This follows that a “contract review” on this issue must take place. The laboratory is to enter an educated discussion with mutual understanding and agreement with the principals (commercial customers or regulators) about its standard or negotiated decision rule on making a statement of compliance, (i.e. the probability of “*false accept*” when a product or

material should fail and “*false reject*” when this product or material should pass) before taking up the job.

The laboratory may have to discuss with the principals regarding a “Guard Band” (see Figure 1) that will be comfortable to both parties, and also ensure that its test procedure employed can meet the specification limit required. It may even need to change or modify its test procedure (e.g. by lowering its method detection limit) to cater for its decision rule to be applied.

Figure 1 Graphic presentation on a stringent Acceptance zone and a ‘relaxed’ Rejection zone for a specification with an upper limit



A decision rule ultimately relies on the outcome of the ever popular hypothesis or significance testing based on the distribution(s) of test statistic and sets a risk level that is mutually acceptable.

It is obvious that an accredited laboratory migrated to this new ISO/IEC 17025:2017 version will need to be formally trained on how to make decision rules by studying the level of risk associated and making a decision on “false accept” and “false reject”, based on statistical assumptions made.

Our national accreditation body on the other hand is also encouraged to prepare a technical guide on this challenging topic: Decision Rule.

