Measurement Uncertainty,

Specification Compliance & Decision Rules

There are many purposes to carry out uncertainty estimations in our routine laboratory measurement activity. We know uncertainty estimates are important to the client who has provided a sample for analysis and who requires a range of values in which the true analyte concentration (i.e. true value of target analyte) should lie.

Estimation of measurement uncertainty has however, another important objective which we tend to overlook most of the time. That is, uncertainty estimates can help to demonstrate that a laboratory has the capacity to perform analyses of legal or statutory significance, or, to meet the client's product specification.

Once an uncertainty value for a particular analysis in a given laboratory is known, it is simple to interpret the results in relation to such statutory or other specification limits.

Indeed, the value of uncertainty associated with a reported test result becomes important when the analysis result is around the specification's upper or lower limit. This is because there is a specification compliance issue for consideration. It is a question of whether the sample tested is within the specification or otherwise.

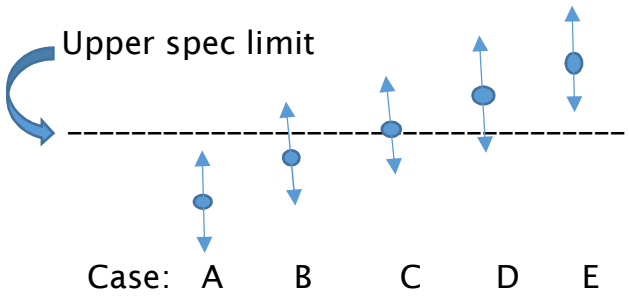
The new ISO/IEC 17025:2017 to be officially published soon has set "decision rule" as a new requirement for laboratory accreditation. The Clause 3.7 under Terms and Definitions states that it is a "*rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement*". This is in relation to Sub-clause 7.8.6 on providing "Reporting statements of conformity".

Readers are referred to the Eurachem/CITAC Guide "*Use of uncertainty information in compliance assessment"* (2007) which is a good source of reference in the subject on Decision Rule and Compliance.

There are five possible situations for us to examine if a given uncertainty estimate is in compliance with the specification limit given by the regulators or the clients, or not, as graphically illustrated in Figure 1.

The drawing below shows a requirement of upper specification limit as indicated by the horizontal line across, and has made an assumption that a coverage factor of 2 has been used to determine expanded uncertainty U at the 95% confidence level (shown by the vertical double arrows).

Figure 1 Use of uncertainty intervals to test compliance with maximum specification limit



Case A : the uncertainty interval lies completely below the specified maximum limit, so compliance with the specification has been achieved;

Case B : the 95% confidence intervals extends just beyond the upper limit, so although compliance is more likely than not, it cannot be fully verified at the 95% level;

Case C : the mean value is on the dot of the limit and there is a 50% chance that compliance is not likely. Hence, it cannot be fully verified as well;

Case D : compliance is very unlikely, though not impossible;

Case E : obviously, there is a clear failure to comply.

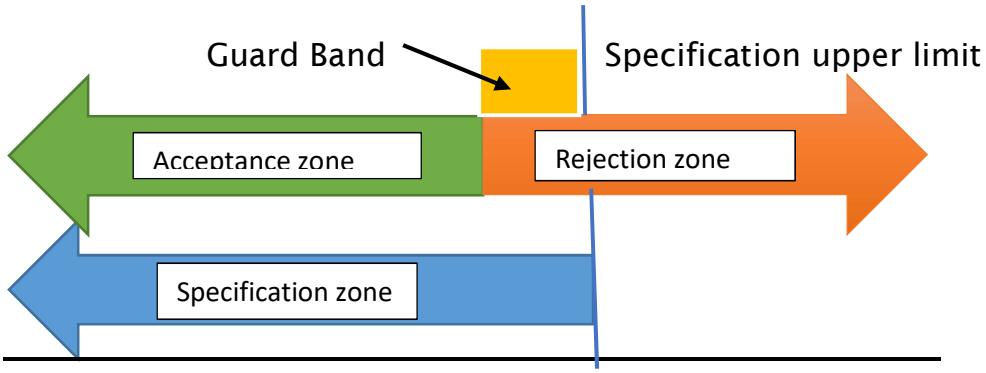
A decision rule therefore has to be taken to conclude if the reported result is in compliance with the specification, particularly in cases B, C and D. This shall be associated with some form of assessment on the minimum risk of accepting this batch of measurement results.

In the cases B and C, it is suggested to conduct additional measurement(s), or allow manufactured product be compared with an alternative specification to decide on possible sale at a different price.

A very simple decision rule is that a result equal to or above the upper limit implies noncompliance and a result below the limit implies compliance, provided that uncertainty is below a specified value. This is normally used where the uncertainty is so small compared with the limit that the risk of making a wrong decision is acceptable. To use such a rule without specifying the maximum permitted value of the uncertainty would mean that the probability of making a wrong decision would not be known.

Eurachem suggests that on the basis of the decision rules, an "Acceptance zone" and a "Rejection zone" are to be determined, such that if the measurement result lies in the acceptance zone, the product is declared compliant and if in the rejection zone, it is declared noncompliant. There is a "Guard Band" between the Acceptance zone and the Rejection zone, as shown in Figure 2.

Figure 2 A stringent Acceptance zone and a 'relaxed' Rejection zone for a specification with upper limit only



A decision rule should have a well documented method of unambiguously determining the location of acceptance and rejection zones, ideally including the minimum acceptable level of the probability that the value of the measurand lies within the specification limits.

The rule may also give the procedure for dealing with repeated measurements and outliers. The determination of the acceptance/rejection zone will normally be carried by the laboratory based on the decision rule and the information available about the uncertainty in their own measurement result.

In order to decide whether or not to accept/reject a product, given a result and its uncertainty, Eurachem recommends that there should be:

a) a specification giving the upper and/or lower permitted or acceptable limits of the characteristics (measurands) being controlled, and

b) a decision rule that describes how the measurement uncertainty will be taken into account with regard to accepting or rejecting a product according to its specification and the result of a measurement.