Decision risks in conformance testing – Part I

Introduction

Following up from our previous discussion on type I and type II errors in significance testing (*https://consultglp.com/wp-content/uploads/2017/12/Type-I-and-type-II-errors-in-significance-tests.pdf*) , let's turn to the important subject of decision risks involved in providing a compliance statement for a specification or regulatory limit. The decision risks cover the chance (or probability) for false pass/acceptance and false fail/rejection.

The new ISO/IEC 17025:2017 introduces a new concept, i.e., "risk-based thinking" which requires the accredited laboratory to plan and implement actions to address possible risks and opportunities associated with the laboratory activities. The laboratory is responsible for deciding which risks and opportunities need to be addressed. The aims are:

a) to give assurance that the management system achieves its intended results;

b) to enhance opportunities to achieve the purpose and objectives of the laboratory, and,

c) to prevent, or minimize, undesired or interfering elements

The word of '*risk*' can be found in the following clauses of this international standards:

Clause 4.1.4:

Identifying *risk* to impartiality

Clause 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."

Clause 7.10:

Actions taken for nonconforming work based upon *risk* levels established by the laboratory

Clause 8.5:

Actions to address *risks* and opportunities

Clause 8.7:

Updated *risk* and opportunities when corrective action is taken

Clause 8.9:

Management review agenda to include results of *risk* identification

In this article, we shall only discuss the clause 7.8.6.1 on giving "pass-or-fail" decision risk for measurements when one has to issue a statement of conformance after testing or calibration.

What is conformance testing?

Conformity assessments are normally made after a product development, testing or calibration. They are usually applied in forensic, pharmaceutical, medical and manufacturing fields.

The Decision Rules

ISO/IEC 17025:2017 defines the "*decision rule*" as a "rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement." The decision rules thus give us a prescription for the acceptance or rejection of a product based on the measurement result, its uncertainty associated, and the specification limit or limits. Where product testing and calibration provide for reporting measured values, levels of measurement decision risk acceptable to both the customer and supplier must be prepared.

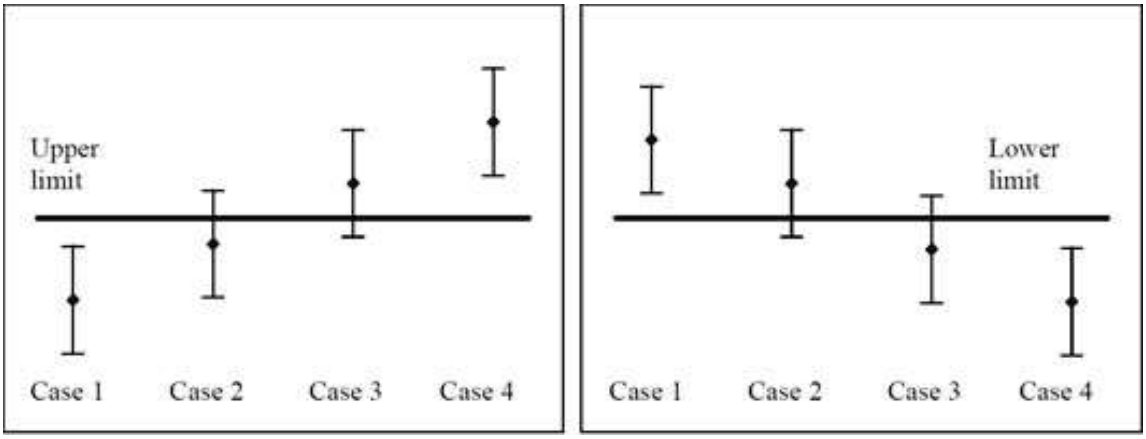
The basis of the decision rules is to determine an "Acceptance zone" and a "Rejection zone", such that if the measurement result lies in the acceptance zone, the product is declared compliant, and, if in the rejection zone, it is declared non-compliant.

Hence, a decision rule should document the method of determining the location of acceptance and rejection zones, ideally including the minimum acceptable level of the probability that the value of the targeted analyte lies within the specification limits.

A straight forward decision rule that is widely used today is in a situation where a measurement implies non-compliance with an upper or lower specification limit if the measured value exceeds the limit by its expanded uncertainty.

This is quite an obvious decision and we can never get it wrong. This situation refers to both Case (4) in upper and lower limits in Figure 1. But Cases (2) and (3) for conformity considerations are not obvious, and decision rules on compliance have to be made.

Figure 1: Cases of measurement results with their respective expanded uncertainty in making a compliance decision with an upper and lower specification limit



However, there is almost always some type of risk associated with decisions, including decisions based on measurement data. In conformity testing, we need to take into account the acceptable level of the probability of making a wrong decision.

A decision (direct risk) made at the time of measurement involves either a false acceptance risk or a false rejection risk. We have to manage the probability or "likelihood" of incorrect or "bad" measurement-based decisions.

False acceptance risk

We can evaluate the quality of work by a calibration or testing organization in terms of probability that attributes that are accepted as being in-specification tolerance of a specification are actually out-of-specification tolerance. This probability is called false acceptance risk. It is also known as "customer's risk", which is part of the "Global risk".

Depending on how critical is the measurement, this type of error can lead to serious consequences such as loss of life because of safety issues, damaged corporate reputation, warranty expenses, shipping and associated costs for product recalls, loss of future earnings, punitive damages, etc.

False rejection risk

Another Global measurement-based decision risk or measure of the quality of work by a calibration or testing organization is the probability of an in-specification tolerance item or parameter being unknowingly rejected. This probability is called false rejection risk (or "producer's risk").

Setting a tolerance limit to the nominal specification

In order to achieve acceptable risk levels within the laboratory quality system, many learned organizations [*see References section*] have suggested to evaluate tolerance limits (interval) or guard bands (say, $\pm$L) added to the nominal specification for risk decision.

The purpose of establishing such an "expanded" or "conservative" error on the specification value is to draw "safe" conclusions concerning whether measurement errors are within acceptable limits.

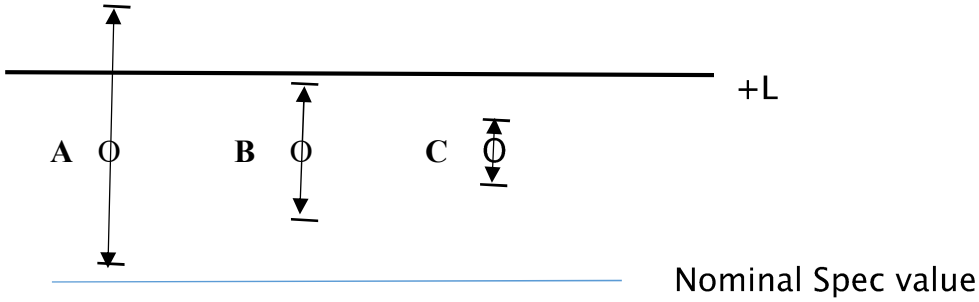
Indeed, the amount of uncertainty in the measurement process and where the measurement result lies with respect to the tolerance limit set help to determine the probability of an incorrect decision.

Figure 2 below shows an example of this key issue in proving conformity to a specification with an upper limit.

Say, we have three measurements (A, B and C) of same mean value but have three widely different expanded uncertainties associated with them and are off-nominal.

When a tolerance limit of +L which indicate the acceptable maximum allowed measurement result is added to the specification limit, as shown in Figure 2, we see that a portion of measurement A's uncertainty range extends beyond the +L limit, which means there is some probability of non-conformance, as the true value estimated by measurement A in its expanded uncertainty may be, in reality, outside of the specified limits.

Figure 2: Three different measurements verifying a nominal value with a tolerance of +L



The measurements B and C with smaller sized error distributions are however, still within the range between +L and the nominal value. Remember that an expanded uncertainty of a measurement covers the true value of the measurand with 95% confidence. This suggests that there is about 95% chance (probability) the "true" value of the measurement result lies within the tolerance limit allowed.

How to establish decision rules based on the ±L tolerance values?

For measuring instruments, the maximum permissible errors (MPEs) as the tolerance values for precision are always established by the instrument manufacturers. The users are to investigate in order to satisfy themselves that the instrument meets their performance requirements.

(*We shall discuss further in the Part II article which follows*)

References

1. Eurachem/CITAC Guide "*Use of uncertainty information in compliance assessment*" (2007)
2. "*Conformance testing: Measurement decision rules*" by Scott Mimbs, NASA, Kennedy Space Center presented at NCSL International Workshop and Symposium, 2010
3. NASA-HDBK-8739.19-4 "*Estimation and evaluation of measurement decision risk*", July 2010
4. JCGM 106:2012 "*Evaluation of measurement data – The role of measurement uncertainty in conformity assessment*"