Decision risks in conformance testing – Part II

In this note, we shall look at the decision risks on measuring instrument compliance. In the later series of articles, we shall discuss the compliant decision risks and rules on laboratory measurement process. The logics for these two subjects are fairly similar.

How to determine conformity testing decisions on measuring instrument?

Practically all instrument manufacturers would establish appropriate maximum permissible errors (MPEs) for their measuring instruments. The cost to the consumer, vendor or manufacturer associated with the use of MPEs which are unnecessarily large or small can be reduced through taking likely measurement uncertainties into account when first establishing the MPEs.

Setting very small MPEs, though seemingly a good precision, can be costly to the instrument manufacturer who will likely pass the additional cost on to the consumer because he must build a more costly and sophisticated instrument to meet the tighter requirements.

Therefore, by considering likely levels of measurement uncertainty for different uses of measuring instruments, more optimal MPEs can be set such as to yield acceptable levels of risk and to be fit for purpose.

Approaches to make a decision on compliance

OIML (International Organization of Legal Metrology) Guide G19 (2017) "*The role of measurement uncertainty in conformity assessment decisions in legal metrology*" proposes two approaches to make a decision on measuring instrument compliance, namely (1) *the classical method* and (2) *the probabilistic method* which formally incorporates measurement uncertainty of the error of indication, when the instrument is used.

What is the error of indication? This error value E_I is typically defined as the difference between the indicated value Y_I of the measuring instrument or process system obtained when measuring the measurand, and the "true" value of that measurand, Y_S, as determined when using a measurement standard. We can express their relationship mathematically as follows:

$$E_I = Y_I - Y_S \quad (1)$$

This error of indication E_I from the measuring instrument is used to compare with the MPEs that is specified for the particular application.

Although a single measured error of indication is allowed for individual conformity decisions, it is better to obtain two or more errors of indication and use the average value $\bar{E}_I$ as the basis of the conformity decision in order to account for random variations in measured values.

We have to stress here that the term "true value" normally used in metrology is not of the same sense used in this context. In here, the true value means the value associated with a *measurement standard* that is used in the process of testing a measuring instrument.

In general, Y_S can be determined through use of a series of measurements with values (x_i), so Y_S depends on, or is a function (f) of the values x_i:

$$Y_S = f(x_1, x_2, \ldots, x_n) \quad (2)$$

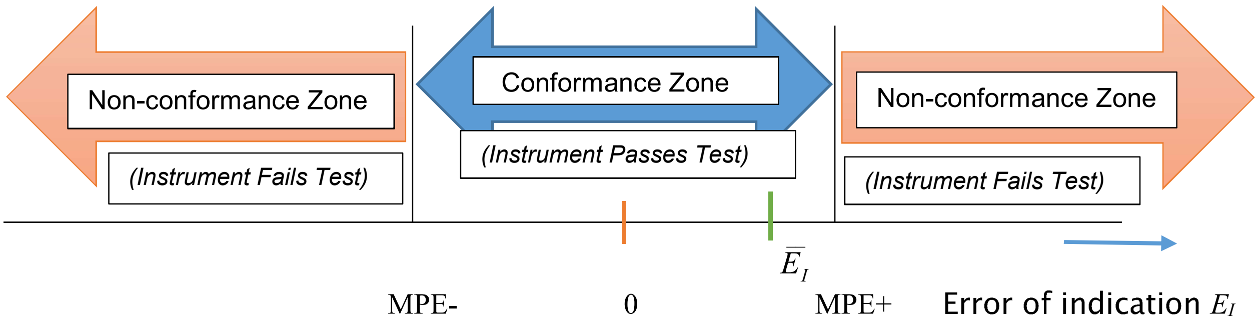
These measurements also bound to have variations. Amongst these variations, the number of individual errors of indication through repeated measurements of the standard would have been included.

(1) The classical method

In this approach, common to all of the categories of tests, conformity decisions are ultimately made based on the results of one or more tests that compare measured errors of indication with MPEs. It makes use of random variations in measured values when two or more repeated measurements are performed.

The concept of comparing a measured error of indication with a set of MPEs (upper and lower), for purposes of making a conformity decision, is shown schematically in Figure 1.

Figure 1: Using error of indication E_I and MPE for making a conformity decision



As illustrated in Figure 1, the test would be considered to pass since $\bar{E}_I$ lies in the conformance (or acceptance) zone. On the other hand, if the mean error of indication, $\bar{E}_I$ lies in the non-conformance (or rejection) zone, the test would be decided as failed.

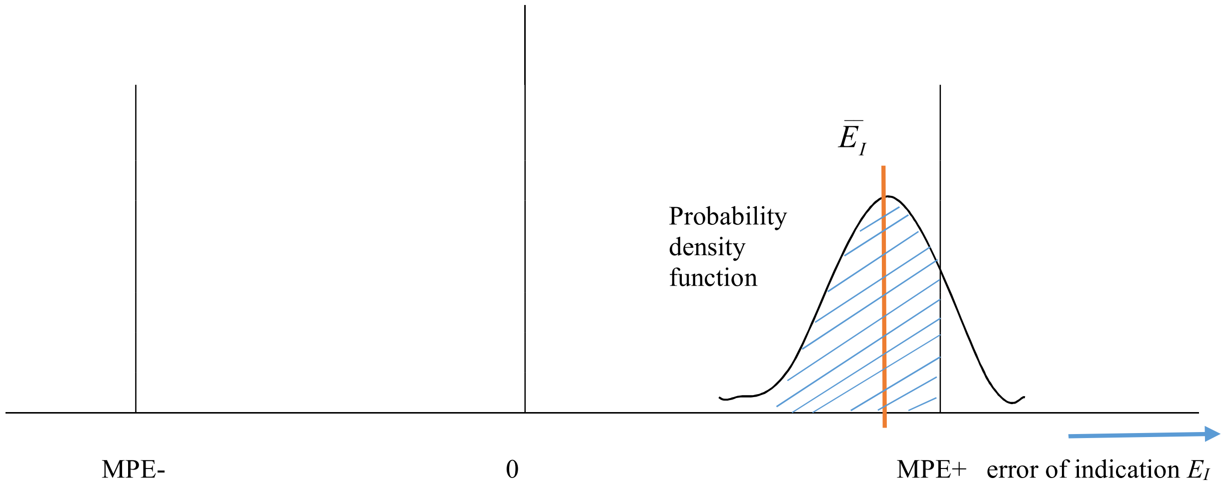
However, when formal measurement uncertainty is taken into account, the above ways of making a conformity decision disappear, because measured random variations are incorporated into measurement uncertainty, as discussed in the next section.

(2) Incorporating measurement uncertainty in conformity testing decisions

The concept of normal or Gaussian probability density function (PDF) which assumes well in chemical analysis and calibration is applied to the expanded measurement uncertainty of the mean error of indication, $\bar{E}_I$, using the probabilistic nature of the GUM uncertainty to measurement approach. As we know well, this normal PDF curve is of bell-like in shape.

Figure 2 shows schematically how this PDF which covers the 'true value' of a particular value of error of indication, with a certain degree of confidence (usually at 95%) appears on the similar situation as discussed in Figure1.

Figure 2: Normal PDF of measured value of $\bar{E}_I$ in the region of $\pm$MPE



This curve is normalized such that the total area under the curve is 1, indicating that there is a 100% probability of finding the “true” value of the error of indication somewhere along the horizontal axis.

However, we must acknowledge that if a mistake was made in performing the measurement, through a gross error, the “true” value might actually be totally outside the PDF curve.

Differences between the two approaches in making conformity decision

Since the mean value ($\bar{E}_I$) of the error of indication is within the conformance (or acceptable) zone as defined in Figure 1 by the classical approach, we would have considered that the measuring instrument has passed the particular test shown in Figure 2.

But, using the uncertainty approach and taking measurement uncertainty into account for the particular test, we note that there is a considerable area under the PDF that lies outside of the conformance zone. This means that there is a considerable probability (degree of confidence or belief) that the “true” value of the error of indication lies outside the conformance zone, even though the mean value ($\bar{E}_I$) of the error of indication is within the conformance zone.

If, on the other hand, the mean value of the error of indication ($\bar{E}_I$) is just outside of the conformance zone, there can still be a significant chance that the "true" value of the error of indication lies within the conformance zone. In this case, the classical method would have failed the particular test but a decision could still be made using the uncertainty approach that the measuring instrument passes this test, again depending upon acceptable of probability (risk) for that kind of test and it is considered to be taking the risk.

Hence, conducting a risk assessment is necessary to make a pass-fail decision due to the uncertainty approach because it might lead to a possibility (or risk) that an incorrect decision is made (e.g., either a false acceptance/pass/positive or a false rejection/fail/negative decision).

(*Part III will address the issue of risk assessment, along with rules for deciding whether a particular test is considered to pass or fail.)*