Measurement Uncertainty and Conformity Assessment in Analytical Measurement—Considerations for the University Curriculum [†]

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Many analytical measurements are made in order to check a system or product for conformity with a requirement. Requirements can be, for example, manufacturing tolerances, customer specifications, regulatory limits for environmental or safety reasons, or limits for tax and revenue purposes. In the great majority of these cases, an analytical result, or an average of several results, is compared with a limit. Often, the laboratory is expected to give an indication of compliance or non-compliance when reporting their results. Further, with the publication of ISO/IEC 17025:2017 [1], laboratories are additionally expected to provide information on the procedure they use to come to a compliance conclusion—that is, the ‘decision rule’ used—and in particular to provide information on how measurement uncertainty was taken into account. To assist in this, ILAC offer general guidance on decision rules and on statements of conformity [2]. Eurachem also provides guidance more closely aligned to analytical measurement [3].

The effective specification and use of decision rules does, however, require an understanding of a surprising range of concepts. For the routine use of typical simple rules, a technician may need only understand the basic ideas of limits, and understand simple decision rules for comparing a result with a limit. The idea of uncertainty, expressed as a range, is also increasingly important. They may also need to understand that some procedures involve follow-up measurements to confirm a borderline or noncompliant finding, and the general issues around use of repeated measurement in compliance assessment.

At a more advanced level, for example at the level of implementing ILAC G8 for a range of problems, laboratory staff need substantially deeper understanding. ILAC G8 and the Eurachem guidance both use the concept of ‘guard bands’ to provide higher confidence of compliance. These can provide simple rules but demand some understanding of measurement uncertainty and the idea of ‘expanded uncertainty’. The idea of test uncertainty ratio (TUR) is another important concept used in practice; choice of the ratio, however, requires some understanding of false acceptance and false rejection rates. Yet to understand and estimate false acceptance rates even for a simple case requires an understanding of probability and of probability distributions. To estimate what is called the ‘global risk’—the chance of a false acceptance or rejection averaged over a large number of test items—requires the combination of a process distribution (describing the distribution of true values for different test items) with the distribution of possible values inferred from measurement and expressed as a measurement uncertainty; a basic understanding of the principle is important when choosing a test uncertainty ratio, for example.

Finally, although beyond the scope of any current guidance for accredited laboratories, some authors (e.g., in [4,5]) have suggested that fitness-for-purpose be based on the eventual economic

risks of false responses, which requires a still broader understanding of the economic and regulatory environment for analytical work.

This presentation will accordingly review the process of compliance assessment against limits with consideration of measurement uncertainty. The aim is not to give a comprehensive description, but to identify some of the underpinning concepts needed for a good understanding of the topic.

References

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