

Risks of false decisions in conformity assessment

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The ISO/IEC 17025:2017 prescribes that "when a statement of conformity to 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 assumption) associated with the decision rule". A relevant note indicates ISO/IEC Guide 98-4:2012 (which is the JCGM 106) for further information. This document "provides guidance and procedures for assessing conformity of an item (entity, object or system) with a specified requirement". Such requirement typically takes the form of a tolerance interval, i.e. an interval of permissible/conforming values of a measurable property of the item. Beside tolerance intervals, also an acceptance zone can be applied, depending on the measurement uncertainty and the requirements of the decision rule. "Because of uncertainty in measurement, there is always the risk of incorrectly deciding whether or not an item conforms to a specified requirement based on the measured value of a property of the item". In this framework, the 'consumer's risk' is the probability of accepting the item when it should have been rejected, that is, the probability that the measured value falls within the acceptance interval whereas the true value of the measurand is outside the tolerance interval (the 'producer's risk' being defined the other way round.)

In order to calculate such risks, the basic idea underlying the ISO/IEC Guide 98-4:2012 is to resort to probability theory: the knowledge about the measurand can be expressed in terms of a probability density function (pdf), which, according to the Bayes theorem, combines prior information on the measurand and new knowledge (including the uncertainty term) acquired during the measurement. In this vein, a guide for investigating out-of-specification test results of chemical composition was published and several works were developed in the context of a IUPAC project devoted to the evaluation of probability of false decisions in conformity assessment of multicomponent materials or objects.