How many shades of grey are in conformity assessment due to measurement uncertainty?

How many shades of grey are in conformity assessment due to measurement uncertainty?

How many shades of grey are in conformity assessment due to measurement uncertainty?

Ilya Kuselman[1], Francesca R Pennecchi[2], Ricardo J N B da Silva[3], D Brynn Hibbert[4]

[1] Independent Consultant on Metrology, 4/6 Yarehim St., 7176419 Modiin, Israel
[2] Istituto Nazionale di Ricerca Metrologica (INRIM), Strada delle Cacce 91, 10135 Turin, Italy
[3] Centro de Química Estrutural, Faculdade de Ciências da Universidade de Lisboa, Edifício C8, Campo Grande, 1749-016 Lisboa, Portugal
[4] School of Chemistry, UNSW Sydney, Sydney NSW 2052, Australia

Abstract: When a measured value of a property of a material or object differs from the upper or lower specification limit (actual or 'true' value) by the expanded measurement uncertainty or more, there is the clear decision on the material conformity or nonconformity - 'white' or 'black'. In the interval from the measured value to the specification limit, covered by the expanded measurement uncertainty ('grey zone'), risks of false decisions on conformity increase. Several kinds of the risks, named 'shades of grey', should be taken into account. For a multicomponent material there are four kinds of particular risks for each property value of the material (e.g. component concentration or content), and four kinds of total risks related to the material as a whole. Therefore, for $n > 1$ properties under control for the material conformity assessment one can distinguish $4(n+1)$ kinds of risks of false decisions – shades of grey.

Conformity assessment is the demonstration that specified requirements relating to a product, process, system, person or body are fulfilled [1]. Conformity of a product is assessed before it is placed on the market. The conformity assessment procedure for each product (e.g. a material) is specified in the applicable product legislation. Standard specifications for chemical composition of a multicomponent material – a medication, alloy, etc. – are tolerance limits of the actual ('true') concentration or content c_i of the i-th component, $i = 1, 2, \ldots, n$, including main components and impurities or groups of impurities. Conformity assessment of an item (material batch or lot) is based on comparing the measured concentration or content c_{im} with tolerance/specification limits. Since any c_{im} value has associated measurement uncertainty, acceptance limits for measurement results can be used in addition to tolerance limits. In these cases, the decision rules (does the test item conform or not?) are based on comparing the measured property values c_{im} with the acceptance limits [2]. The interval between a tolerance limit and corresponding acceptance limit is the 'grey zone', where probabilities of false decisions on conformity of the item are impermissible.

When tolerance limits have been defined by already taking into account measurement uncertainty, acceptance limits and tolerance limits coincide.

Several kinds of risk of a false decision on conformity of an item may be called *shades of grey*. The probability of accepting a batch of the material, when it should have been rejected, is the 'consumer's risk', whereas the probability of falsely rejecting the batch is the 'producer's risk'. For a specified batch, they are referred to as the 'specific consumer's risk' and the 'specific producer's risk' R_{ci}^{*}, respectively, for the *i*-th particular component of the material under control. The risks of incorrect conformity assessment of a batch randomly drawn from a statistical population of such batches are the 'global consumer's risk' and the 'global producer's risk' R_{ci}, as they characterize the material production globally [2]. If a tolerance limit and corresponding acceptance limit coincide, the grey zone collapses, however the risks are still above zero at any measurement result. Thus, there are four shades of grey for each property value of an item – concentration or content of *i*-th particular component of a material (consumer's and producer's risks, both are specific and global).

In general, a component-by-component evaluation of the risks of a material conformity assessment is not complete, as it does not give an answer to the question of the probability of a false decision on conformity of the material as a whole. When conformity assessment for each *i*-th component of a material is successful (i.e. the particular specific R_{ci}^{*} or global R_{ci} risks are small enough), the total probability of a false decision concerning the material as a whole (the *total* specific R_{total}^{*} or *total* global R_{total} risk) might still be significant. Evaluation of the total risks when test/measurement results are not correlated is detailed in our publications on conformity assessment of denatured alcohols [3] and total suspended particulate matter in ambient air [4]. Discussion of the cases of correlated data is available in the papers on conformity assessment of a medication [5] and an alloy [6]. These evaluations are based on the Bayesian approach [2] and performed in R programming environment. In paper [6] we have proposed also a solution of the inverse problem: the use of total specific risk values for setting multivariate acceptance limits. In papers [7, 8] tutorial and user-friendly MS Excel spreadsheets for Bayesian evaluation of total specific and global risks, respectively, are described.

Hence, there are four kinds of particular risks for each *i*-th property value (component concentration or content) of a material, and four kinds of total risks. Therefore, for $n > 1$ components under control one can distinguish $4(n+1)$ kinds of risks of false decisions – shades of grey. For example, for two components this means - 12, for three components – 16, and for four components – 20 shades of grey.

References

[1] ISO/IEC 17000:2004. Conformity assessment. Vocabulary and general principles
[2] JCGM 106:2012. Evaluation of Measurement Data – The Role of Measurement Uncertainty in Conformity Assessment
[3] Kuselman I, Pennecchi F R, da Silva R J N B and Hibbert D B 2017 Talanta **164** 189
[4] Pennecchi F R, Kuselman I, da Silva R J N B and Hibbert D B 2018 Chemosphere **202** 165
[5] Kuselman I, Pennecchi F R, da Silva R J N B and Hibbert D B 2017 Talanta **174** 789
[6] Kuselman I, Pennecchi F R, da Silva R J N B, Hibbert D B and Anchutina E 2018 Talanta **189** 666
[7] da Silva R J N B, Pennecchi F R, Hibbert D B and Kuselman I 2018 Chemometrics and Intelligent Laboratory Systems **182** 109
[8] da Silva R J N B, Lourenço F R, Pennecchi F R, Hibbert D B and Kuselman I 2019 Chemometrics and Intelligent Laboratory Systems **188** 1