ACTA IMEKO
ISSN: 2221-870X
June 2023, Volume 12, Number 2, 1 - 3

Statements of conformity provided by laboratories

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ABSTRACT
When required to provide a statement of conformity, the laboratory shall agree with its customer on the specification and decision rule to be applied. Employing a decision rule on how to take into account measurement uncertainty carries the risk of providing an incorrect decision. To reduce this risk, the mechanism of guard banding is introduced. This technical note covers the approach presented in ILAC G8 and other relevant literature. In some cases, e.g. when assessing conformity with regulatory requirements, measurement uncertainty is taken into account indirectly. When providing statements of conformity, laboratories usually consider the risk related to a particular test item. Providing the statement of conformity is also covered by the ISO/IEC 17025 standard for the competence of laboratories.

Section: Technical note

Keywords: Statement of conformity; decision rule; laboratory; ILAC G8; ISO/IEC 17025

Citation: Ana Čop, Statements of conformity provided by laboratories, Acta IMEKO, vol. 12, no. 2, article 34, June 2023, identifier: IMEKO-ACTA-12 (2023)-02-34

Section Editor: Leonardo Iannucci, Politecnico di Torino, Italy

Received January 31, 2023; **In final form** June 11, 2023; **Published** June 2023

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1. INTRODUCTION

Laboratories are often required or expected to provide a statement of conformity to specification or standard. Specifications are usually defined in the product specification, applicable legislation, or by laboratory customer. They represent acceptable limit that (a property of) a test item shall comply with.

Because of uncertainty in measurement, when measurement results are close the specification limit, the way how the measurement uncertainty is taken into account can influence the decision on conformity of the test item. The risk of incorrect decision is taken by the side specifying the decision rule to be applied. In the context of laboratory work, this is the laboratory's customer.

This note provides information on relevant literature and practice for laboratories to extend their knowledge on statements of conformity and risks associated with decision rules. The starting point is ILAC G8 [1] and JCGM 106 [2]. For advanced statistics and calculation, the document [2] should be consulted.

2. DECISION RULE

The agreement on how to take into account measurement uncertainty is called a decision rule. The definition of decision rules in ISO/IEC 17025 [3] is "rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement". The definition in [2], "rule that describes how measurement uncertainty will be accounted for with regard to accepting or rejecting an item, given a specified requirement and the result of a measurement" is based on the consequences of the decision on the conformity of the test item. The definition in [2] also states that this rule shall be documented.

Statements of conformity can be expressed as a binary decision (conforming/nonconforming, YES/NO, PASS/FAIL) or as a non-binary decision (with more than two possible outcomes; e. g. pass, fail, and inconclusive or conditional pass/fail) [1].

In order to provide statements of conformity, a specification or tolerance limit (TL), defined as "specified upper or lower bound of permissible values of a property" [2], and an acceptance limit (AL), defined as "specified upper or lower bound of permissible measured quantity values" [2], are established. If there are both upper and lower limits, intervals are considered.

A common decision rule known as simple acceptance considers a test item as conforming if the measured value is in the tolerance interval, as shown in Figure 1. To keep the probability of incorrect decisions at an acceptable level, this decision rule is associated with the requirement for the value of related acceptable measurement uncertainty [2]. Therefore, simple acceptance should not be understood as not considering measurement uncertainty.

The risk of providing an incorrect decision of conformity is kept under control by the introduction of guard bands. A guard

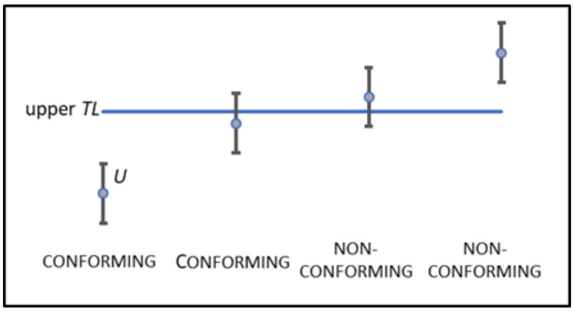

Figure 1. Illustration of the simple acceptance based on ILAC G8 [1].

band (w) is an interval between a tolerance limit and a corresponding acceptance limit where length $w = |TL - AL|$ as defined in [1]. As [1] states, guard bands are a "safety factor built into the measurement decision process".

Applying a guard band to reduce the risk of identifying a non-conforming item as conforming (or in other words reducing the probability of falsely accepting the nonconforming item) by setting the acceptance limit inside the tolerance interval is called guarded acceptance [2]. For guarded acceptance the length of the parameter w is taken to be positive [2]. The guarded acceptance is shown in Figure 2.

Guarded rejection is used to increase the probability that item identified as non-conforming item is truly nonconforming (or, in other words, reducing the probability of falsely rejecting a conforming item) [2]. Guarded rejection is commonly used "to have evidence that a limit has been exceeded prior to taking a negative action" [2].

The guard band w is usually taken to be "a multiple (r)of the expanded uncertainty U for a coverage factor $k = 2, U = 2\,u, w = r\,U$" as defined in [2].

EURACHEM/CITAC Guide [4] provides guidance and examples for determining the guard band and acceptance limit taking into account the measurement uncertainty, distribution of measurand values and required level of the probability that the measurand is within the specification limit.

The EUROLAB guide [5] provides examples where decision rules are defined based on the hypothesis testing approach.

In order to assure that the measurement uncertainty is taken into account consistently, especially in the case of assessing conformity to regulatory requirements, the measurement uncertainty is taken into account indirectly.

Practices in legal metrology [6] include the approach of accounting for plausible measurement uncertainty in maximum permissible errors (MPEs), by "establishing conservative (in-service) maximum permissible errors in order to draw "safe" conclusions concerning whether measured errors of indication are within acceptable limits" or "specifying s a fraction, like 1/3 or 1/5, for the maximum allowed ratio of the error (uncertainty) of the standard (reference) measuring instrument to the MPE".

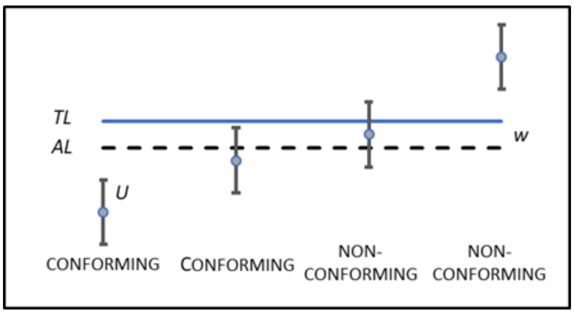

Figure 2. Illustration of the guarded acceptance based on ILAC G8 [1].

The example where acceptable measurement uncertainty is included in acceptance limit is the WADA technical document [7]. This document provides a detailed explanation of defining the decision limit with the guard band defined with maximum acceptable measurement uncertainty obtained from the external quality assessment scheme and k factor corresponding to 95% coverage range for one tailed normal distribution. It is also required that the measurement uncertainty of particular laboratory is lower than this maximum acceptable measurement uncertainty. The document also provides instructions on how to report.

An example from law enforcement practice is reduction of the measured speed value by a certain amount (guard band) when calculating a fine for speeding violation, which ensures that the decision to impose a fine for a speeding violation is made with significant confidence that the speed limit has been exceeded.

In some cases, like water legislation [8], the performance criteria, limit of detection and acceptable measurement uncertainty are defined, and if ensured, the obtained measurement result is directly compared to the specification limit.

The decision rule can also be explicitly stated in regulation or standards. As defined in [9] supporting European official food control, "compliance with the maximal residue level (MRL) is checked by assuming that the MRL is exceeded if the measured value exceeds the MRL by more than the expanded uncertainty ($x - U > MRL$). With this decision rule, the value of the measurand should be above the MRL with at least 97.5% confidence".

3. RISK CONSIDERATION

When laboratory considers, the risk of falsely accepting a non-conforming item or falsely rejecting a conforming item is commonly based on the measurement of a particular item.

As already mentioned, the risk arising from a measurement decision is on the side that specifies the decision rule to be applied. Since the decision rule is specified, or at least accepted, by laboratory customers, it is up to them to cope with the risk of incorrect decisions. Laboratory customers also take the responsibility for the consequences of non-conforming items.

As [4] points out, there is a need to balance resources to be invested in reducing measure uncertainty against the costs arising from a higher number of incorrect decisions in case of higher measurement uncertainty.

As described in [1], different guard bands correspond to different levels of risk. In case of simple acceptance and assuming normal distribution of measurement results, the probability of false accept is up to 50 %. In case of guarded acceptance with a guard band equal to extended measurement uncertainty and assuming the normal distribution of measurement results, the probability of false accept is up to 2.5 %. For larger guard bands, the probability of false accept is additionally reduced.

It is up to the laboratory to consider other laboratory risks. A laboratory should invest effort in ensuring that measurement uncertainty is monitored, that it is estimated realistically, fit for purpose and stable in time. With respect to laboratory personnel competence, skills and knowledge should include understanding the context and purpose of measurement requested by the laboratory customer, standard or legislation, if applicable; and the risks associated with decision rules.

4. ISO/IEC 17025 REQUIREMENTS

The ISO/IEC 17025 [3] standard includes requirements related to providing statements of conformity by laboratories.

Personnel responsible shall be authorised for this activity (ISO/IEC 17025, §6.2.6) based on the competence criteria set. Monitoring of laboratory personnel competence shall also cover competence for providing statements of conformity.

In the request review phase, it is up to the laboratory to assure that the customer requesting a statement of conformity is aware and agrees with the decision rule in the request review stage (ISO/IEC 17025, §7.1.3).

When a statement of conformity is provided, the employed decision rule shall be documented and applied. The decision rule shall take into account risks of an incorrect decision, unless it is specified by the customer, legislation, or standard. (ISO/IEC 17025, §7.8.6.1)

The report shall contain both the specification and decision rule applied. (ISO/IEC 17025, §7.8.6.1).

The extent of what the statement of conformity shall identify is prescribed by ISO/IEC 17025, §8.6.2; and includes “to which results the statement of conformity applies; which specifications, standards or parts thereof are met or not met; and which decision rule is applied (unless it is inherent in the requested specification or standard)”, [3].

5. CONCLUSIONS

The risk associated with the applied decision rule is to be taken by laboratory customer. To assist the customers who are sometimes not even aware of the risk of incorrect decision, the laboratory shall understand the purpose of the measurement and the level of risk associated with the decision rule applied.

To ensure consistent understanding and application, it is necessary that both decision rule and specification are defined and documented in the request review stage, and that the resulting report includes information on both.

In order to make a reliable decision on the conformity of the test item, it is an important task of the laboratory to realistically estimate and monitor measurement uncertainty.

Special care shall be taken in cases where there are several properties measured in the same sample. Providing a general statement that the sample is conforming can be misleading. As described in ISO/IEC 17025, §8.6.2, a statement of conformity shall identify “to which results it applies”, [3].

When sampling activity, as one of laboratory activities recognised by ISO/IEC 17025, is included in laboratory services, sampling measurement uncertainty contribution to overall measurement uncertainty shall also be considered when providing statements of conformity.

ACKNOWLEDGEMENT

I wish to thank Višnja Gašljević for numerous fruitful discussions on measurement uncertainty and decision rules.

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