TPS 72

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UKAS Policy on Decision Rules - Pass/Fail Criteria, taking Uncertainty of Measurement into Account

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Changes since last edition

New document.

1. Introduction

1.1 The international standard ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* was revised in November 2017. This edition included a new requirement on the reporting of statements of conformity and on the decision rules required to produce them. This Technical Policy Statement has been produced to provide clarity on this new requirement, and to document UKAS policy toward the new requirements.

1.2 Clause 7.8.6 of ISO/IEC 17025:2017 requires that when a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, considering the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule. Furthermore, this decision rule must be agreed with the customer and also reported with the results.

1.3 There are many different ways in which measurement uncertainty can be evaluated and considered, with many reference documents available, including JCGM 106:2012 (ISO/IEC Guide 98-4), ILAC G8 and OIML G19. These documents have been considered during the production of this technical policy statement

1.4 ISO/IEC 17025:2017 Cl 7.8.1.2 refers to the reporting of all information necessary for the interpretation of results and Cl 7.8.3.1 c) refers explicitly to the inclusion of measurement uncertainty when it affects conformity to a specification.

2. Scope

2.1 This document relates to applicant and accredited testing and calibration laboratories that produce statements of conformity under the requirements of ISO /IEC 17025:2017.

Note that it is not mandatory for laboratories to report statements of conformity. These rules apply when a laboratory has agreed with a customer that such statements will be reported, or when the testing specification details that these statements are required.

3. Terminology

3.1 *Decision rule* – a rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

3.2 *Probability of false acceptance* (PFA) – a quantitative evaluation of the risk of falsely accepting a non-conforming item.

3.3 *Probability of false rejection* (PFR) – a quantitative evaluation of the risk of falsely rejecting a conforming item.

3.4 *Simple Acceptance* – A result is accepted when its value falls within the defined limit(s) of tolerance/specification.

3.5 *Constrained Simple Acceptance* – Simple Acceptance with the added constraint that uncertainty of measurement is somehow taken into account. For example, a result is accepted when its value falls within defined limits of risk, using techniques such as guard banding or by setting a maximum percentage of false accept/reject using uncertainty of measurement to inform that process.

3.6 *Unconstrained Simple Acceptance* – Simple Acceptance with no account taken for uncertainty of measurement for the reported quantity, or for the uncertainty associated with other measurement conditions.

4. Policy

4.1 It is UKAS policy that when a statement of conformity is required this shall be clearly reported by the laboratory, including reference to the decision rule(s) employed. Requirements to report such statements shall be discussed and agreed with the customer during the contract review process and may be as a result of regulation or normative document as well as customer request.

4.2 ISO/IEC 17025:2017 requires test reports and calibration certificates to include the measurement uncertainty where this affects conformity to a specification limit. When agreeing decision rules for statements of conformity, measurement uncertainty must therefore be taken into account.

4.3 In cases where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk will not normally be necessary provided that the measurement uncertainty is accounted for in the decision rules that are agreed.

4.4 Where decision rules proposed by the customer are not considered appropriate or applicable to the results being reported, then the laboratory will need to discuss this with their customer to ensure that the outcome is fit for purpose. It is also important in these instances that the agreed decision rule employed for this customer is clearly detailed in the contract review and in the report or certificate produced following testing / calibration. If a simplified report is requested, then the decision rule

applied will still need to be fully recorded in the laboratory documentation for the testing / calibration that has been performed. The Laboratory shall not agree any decision rule that will have a detrimental impact on the integrity and outcome of the test or calibration.

4.5 ISO/IEC 17025:2017 allows decision rules to be based around normative documents and regulations. In these instances, such documents must make it clear exactly what the decision rule is. Some documents may simply state a specification that must be met and may, or may not, give an indication of the expected uncertainties. In situations where uncertainty requirements are not stated the method would have to be very prescriptive with regard to instrumentation, environment, calibration etc to allow a simple acceptance rule to be put in place.

5. Decision Rules

5.1 Unconstrained Simple Acceptance

5.1.1 A simple acceptance rule would be that a result is accepted when its value falls within the defined limits of tolerance / specification, or alternatively, below or above a single sided specification.

5.1.2 If uncertainty of measurement is not taken into account, the risk of false acceptance (PFA), or false rejection (PFR) against specified criteria for the produced result cannot be quantified. In summary, it will be extremely difficult for the accredited laboratory to demonstrate that the decision rule was acceptable to either the producer or the customer of the product being tested / calibrated for the following reasons:

i. The Uncertainty of measurement has not been taken into account
ii. The level of risk has not been evaluated as described in section 7.8.6.1 of the standard.

5.1.3 It would not be appropriate for a laboratory to make a conformity decision and state that uncertainty of measurement is not taken into account, particularly if the uncertainty is not declared.

5.1.4 In the above context, attention is drawn to the principle that all information relevant to the validity of the results is reported (refer to section 1.3).

5.2 Constrained Simple Acceptance

5.2.1 There are methods that allow for the use of simple acceptance decision rules with some constraints imposed that can be easily agreed and implemented with the customers of the laboratory.

5.2.2 Guard banding is a valid technique used such that a pass or fail mark is offset by a value defined in terms of the uncertainty of measurement.

5.2.3 Using an agreed PFA/PFR is a similar valid technique that allows a customer to appreciate the level of risk involved in the decision.

5.3 Standard Methods

5.3.1 Where a standard method is used, the levels of risk do not need to be further considered when the standard method being employed is very explicit with regards to how statements of conformity are made. However, it must be very clear in the standard what the rules are. If the standard only stipulates a specification / tolerance interval, then this is not a decision rule. If uncertainty of measurement is not considered nor limited, it is unlikely that that such a rule would comply with ISO/IEC 17025:2017.

5.3.2 Where the specification being used is very prescriptive with regard to all the possible variables, as in the case of a validated standard analytical method (e.g. quality of instrumentation used, calibration levels, environmental conditions, defined procedure etc), and the possible variables can be demonstrated to be well controlled for all users of the standard method, it can be argued that account for uncertainty of measurement has been embedded within the method by the designers of the standard. In these instances, there is a case for constrained simple acceptance criteria to be agreed that will be consistent across all testing/calibration laboratories using that specification.

5.3.3 Where the standard method has a specification / tolerance interval and also indicates that the measurement uncertainty achievable should be within a certain value then the laboratory shall establish that their uncertainty of measurement is within that limit and that they are using any method specified by the test specification.

5.4 Other Forms of Decision Rules

5.4.1 There is a plethora of possibilities for methods to take measurement uncertainty into account when making decision rules. These are sometimes imposed by Regulators, some are industry-based norms, others required by second party specifiers, etc. Guidance on the calculations required are to be found in the relevant requirements, and JCGM 106 is a useful reference tool.

6. References

6.1 ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*

6.2 Joint Committee for Guides in Metrology (JCGM) 106 *Evaluation of measurement data – The role of uncertainty in conformity assessment*

6.3 ILAC G8:03 *Guidelines on the Reporting of Compliance with Specification*

6.4 International Organisation of Legal Metrology (OIML) G19 *The role of measurement uncertainty in conformity assessment decisions in legal metrology*

6.5 ISO 14253-1 Geometrical product specifications (GPS) – *Inspection by measurement of workpieces and measuring equipment*