Sheffield Calibration Services Ltd – Policy on the decision rule (POL 7.8.6)

Introduction

Sheffield Calibration Services Ltd is a dimensional calibration laboratory. We work to an international standard, ISO/IEC 17025:2017. This standard has a host of requirements to be fulfilled by the laboratory to ensure the laboratory can garner client confidence, operate competently and ensure the validity of results.

This Policy has been produced to provide clarity on the new requirement from Clause 7.8.6 of ISO/IEC 17025:2017 and to document policy toward the new requirements.

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 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 on the calibration certificate

Note: - 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 calibration specification details that these statements are required.

Definitions

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

Risk – the risk associated with falsely accepting or rejecting a product / item.

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

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

Level of Risk – The chances of accepting or rejecting a product and countered by applying constraints to reduce the chances of falsely accepting or rejecting a product / calibration item

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

Shared Risk - the customer and laboratory share the consequences of incorrect decisions

Laboratory Policy – Simple acceptance Shared Risk Rule

Clause 7.8.6 of ISO/IEC 17025:2017 now dictates that when a product specification instructs a decision rule must be applied then Sheffield Calibration Services Ltd must now have considered uncertainty values when applying a statement of conformity on a calibration certificate.

With that in mind the laboratory has chosen to apply the simple acceptance shared risk rule to all calibration certificates to meet the specification requirement. The rule to be applied can be found in clause 8.2.3 of the metrology guide JCGM 106 2012 – *the role of measurement uncertainty in conformity assessment.*

To meet the requirements of the Rule and prove the level of risk has been considered and accounted for, the laboratory will require an uncertainty budget for all features measured and reported on a calibration certificate. The uncertainty value must be no greater than the relevant tolerance applied from the appropriate product specification.

The Rule will replace our previous method of reporting accuracy statements which did not consider uncertainty values before the implementation of ISO/IEC 17025:2017

Scenarios and Certificate Statements

Pass - For measured values that fall within the defined limits of the product specification tolerance and the laboratory can demonstrate it has an uncertainty budget no greater than the applied tolerance, A typical statement of conformity will read, 'Pass - The laboratory has applied the simple acceptance shared risk rule for all features of this calibration and this item is within the defined limits of the specification reported in the basis of calibration section on this certificate.'

Fail - For measured values that fall outside the defined limits of the product specification tolerance and the laboratory can demonstrate it has an uncertainty budget no greater than the applied tolerance, A typical statement of conformity will read, 'Fail - The laboratory has applied the simple acceptance shared risk rule for all features of this calibration and this item has features that are outside the defined limits of the specification reported in the basis of calibration section on this certificate. Features highlighted in red denote outside defined limits.'

Other

There is a plethora of possibilities for methods to take measurement uncertainty into account when applying decision rules. These are sometimes imposed by Regulators, some are industry-based norms, others required by second party specifiers and can be agreed with the customer at the contract review stage but 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.

end of policy