# POLICY FOR MAKING STATEMENTS OF CONFORMITY IN CALIBRATION CERTIFICATES

**Purpose:** This policy is intended to proactively communicate the decision rules used by Fluke calibration laboratories regarding how the expanded uncertainty in a calibration is taken into account to make statements of conformity to a specification.

**Application:** This policy is for calibrations where the resultant measurement error, i.e. the difference between the measured quantity value and the reference quantity value, is evaluated for verification to a product specification. There are many calibrations where the result of a measurement and its associated uncertainty are all that is reported. This policy is not applicable to those calibrations.

**Policy:** When making statements of conformity, Fluke uses methodologies based upon a 2% false accept risk estimate. This is accomplished by the following methods assuming a worst-case end of period reliability of 85%. The methods used to control this are as follows:

1. Maintenance of no less than 4:1 test uncertainty ratio. Fluke's goal is to always provide a calibration with an expanded uncertainty that is at least four times less than the specification. In this case 2% probability of false accept is assured, and there is no need to guardband.

2. Use of a Guardband. In cases where it is not possible to ensure an expanded uncertainty to be four times less than the specification Fluke uses guardband methods that ensure there is a maximum false accept risk of 2%. In this case there is some possibility that there may be a conditional pass result. This is where the measurement error is less than the specification (i.e. in tolerance or pass), but because of expanded uncertainty the false accept risk may exceed 2%. Note that it is extremely rare, even with TURs approaching 1:1 to have a false accept risk greater than 10%. The possible guardband methods used are:

    a. Root-difference-square (RDS) guardband (G) ILAC-G8:09/2019, APPX B, example 3. The square root of the square of the specification (S) minus the square of the expanded uncertainty (U) at a 95% confidence level.

    $$G = \sqrt{S^2 - U^2_{95\%}}$$

    b. ILAC-G8:09/2019, APPX B, example 2. Specification minus the expanded uncertainty at a 95% confidence level.

    $$G = S - U_{95\%}$$

    c. Dobbert method. Based on the paper "A Guard-Band Strategy for Managing False-Accept Risk", Michael Dobbert, Keysight Technologies Inc., 2008 NCSL International Workshop and Symposium.

    d. Calculated using RiskGuard™ software, Integrated Sciences Group. By entering 2% as false accept limit, uncertainty and confidence, the appropriate end of period reliability and using the resultant guardband.

Please understand that these methods are not available options for every calibration but are possibilities based on the laboratory location and the product being calibrated. The calibration certificate may only describe the method used by referencing this policy and applicable paragraph such as "FCM 7008.1, paragraph 2a".

If the methods described above are not acceptable to you, it must be indicated at the time your request is submitted to Fluke. This may be done through a purchase order, in the RMA request, or by communicating directly to one of our call center personnel. Though we always want to comply to our customer's request, it is possible we may not be able to accommodate a different decision rule depending on the complexity or laboratory restraints.