Measurement Decision Risk and Decision Rules in the new ISO/IEC 17025

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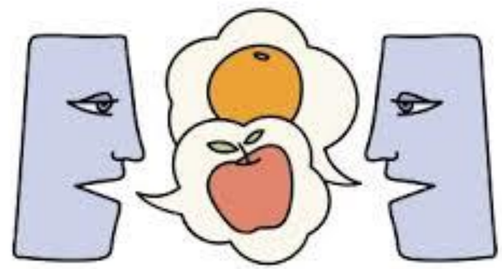
When I ask for my instrument to be calibrated…

- What do I expect to get?
- A sticker?
- Low cost (preferably free)?
- Repair?
- An adequate procedure is used?
- (Accredited) certificate of calibration?
- What does calibration Mean?
- Adjustment to nominal?
- Measurement data?
- Uncertainty?
- Measurement Traceability?
- In or out of tolerance information?
- We need to use common definitions for this important term...

Language of Metrology

- Let’s all try to use the same language, the International Vocabulary of Metrology (VIM)
- The VIM is available for free download at http://www.bipm.org/en/publications/guides/
- For ease of understanding, some of the terms used in this presentation are not always exact definitions but are consistent with the VIM definitions



Calibration Defined

- Calibration - operation that, under specified conditions, in a first step, establishes a relation between the **quantity values** with **measurement uncertainties** provided by **measurement standards** and corresponding **indications** with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a **measurement result** from an indication
- *Jeff's Translation* – calibration is a measured value with an associated uncertainty of measurement
- Calibration is not adjustment!
- Calibration is not "In Tolerance" or "Out of Tolerance"
- If you are performing calibration, you need to know about uncertainty

Statements of conformance

- Verification - provision of objective evidence that a given item fulfills specified requirements
- Review the calibration data, compare to a specified requirement (i.e. manufacturer specification) to determine In Tolerance or Out of Tolerance condition
- If you need the measurements and uncertainty, ask for calibration
- If you need a statement of conformance (in/out of tolerance info), ask for calibration and verification
- Maybe best call this “Calibration Service”

ISO/IEC 17025 Today on Conformance

- (reporting the results) 5.10.4.2 When statements of compliance are made, the uncertainty of measurement shall be taken into account

- Changed from using the term compliance to conformance
- The term compliance is used for legal requirements, conformance is used for statement of suitability

ISO/IEC 17025:2017

- (Review of requests, tenders and contracts) 7.1.3 When a customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance) the specification or standard, and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer

INTERNATIONAL STANDARD

ISO/IEC 17025

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DIS ISO/IEC 17025

- (Reporting of results) 7.8.6.1 When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account 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.

DIS ISO/IEC 17025

- **7.8.6.2** The laboratory shall report on the statement of conformity such that the statement clearly identifies:

  a) to which results the statement applies; and

  b) which specifications, standard or parts thereof are met or not met;

  c) the decision rule applied (unless it is inherent in the requested specification or standard).

- NOTE For further information see ISO/IEC Guide 98-4.
- <u>Statements of conformity are in addition to reporting measurement data and uncertainty of measurement</u>

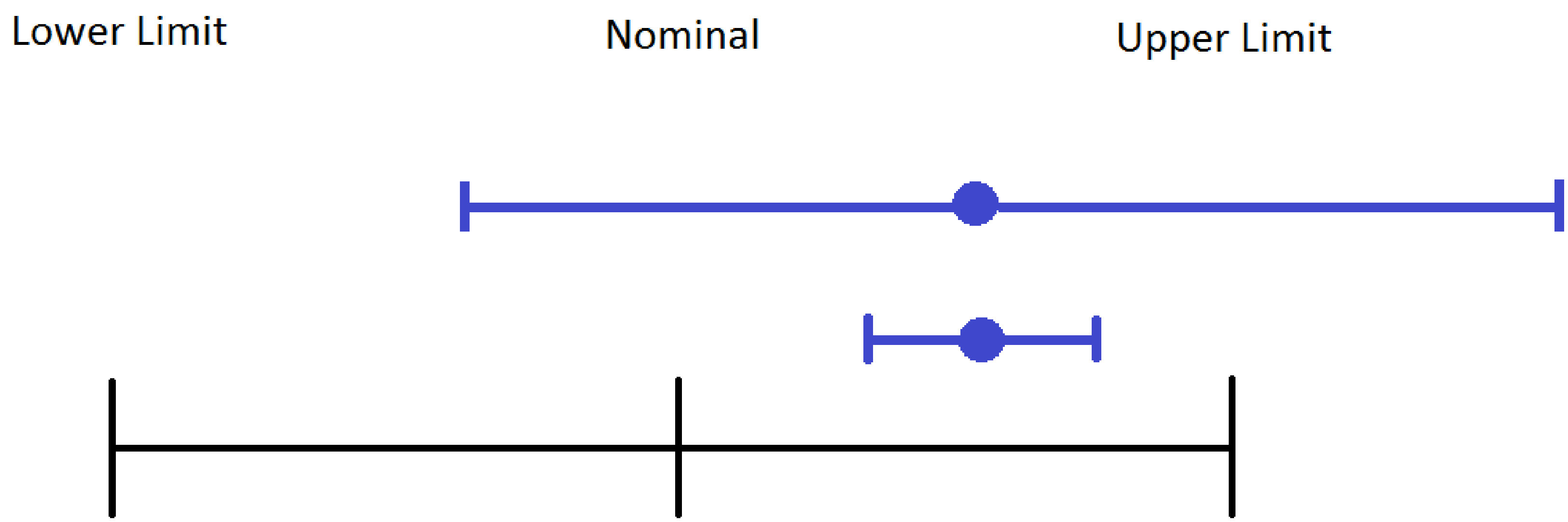
What's a decision rule?

- (Terms and Definitions) 3.7 – Decision rule: a rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

Why are decision rules important?

- When performing a calibration and subsequently making a statement of conformance with an identified metrological specification (such as in or out of tolerance to manufacturer's specifications) there are two possible outcomes
- You are right
- You are wrong
- Each measurement has an associated uncertainty, and it is the uncertainty that can affect your chance of being right or wrong

Measurement Decision Risk



- If your uncertainty is large compared to the specified requirement, how confident are you in your declaration of In Tolerance or Out of Tolerance?

Measurement Decisions

- When an instrument is declared in tolerance but the instrument is actually out of tolerance, it is referred to as a false accept
- When an instrument is declared out of tolerance, but the instrument is actually in tolerance, it is referred to as a false reject
- False rejects cost money by requiring unnecessary adjustment, repair or replacement
- False accepts cost everybody money by putting out of tolerance test equipment in the field
    - Insert horror story here….

Measurement Decisions Involve Risk

- The chance of making a false accept or false reject can be understood as a probability, which is usually expressed as a percentage
- When a customer requests a calibration they
  - Usually don’t worry about false reject risk
  - May specify a maximum acceptable false accept risk
- How much false accept risk is too much?
  - 1%?
  - 5%?
  - 10%?
  - 33%?

Controlling risk

- Measurement decision risk can be controlled through the application of Decision rules
- Two types of Decision Rules
- Rules that control risk by specifying a minimum uncertainty (3:1 or 4:1 rule)
- Rules that controls (consumer) risk by testing to a value that is smaller than the specification (guardbanding)

N:1 rules

- Evaluate the specification you are calibrating to
- Evaluate the uncertainty associated with the measurement (calibration)
- Determine the Test Uncertainty Ratio

1:1 TUR ≈ 2.1% FA, 13.4% FR*

2:1 TUR ≈ 1.5% FA, 4.3% FR

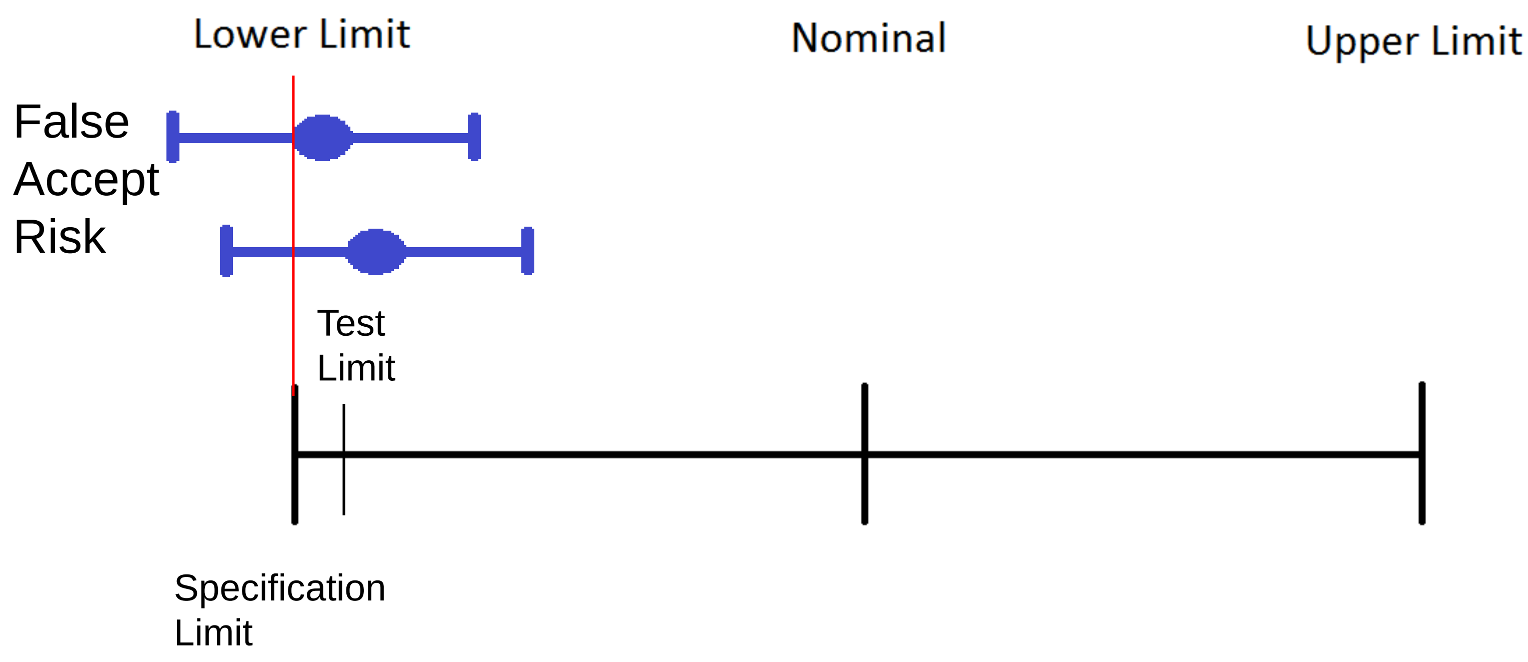
3:1 TUR ≈ 1.1% FA, 2.3% FR

4:1 TUR ≈ 0.9 % FA, 1.6 % FR

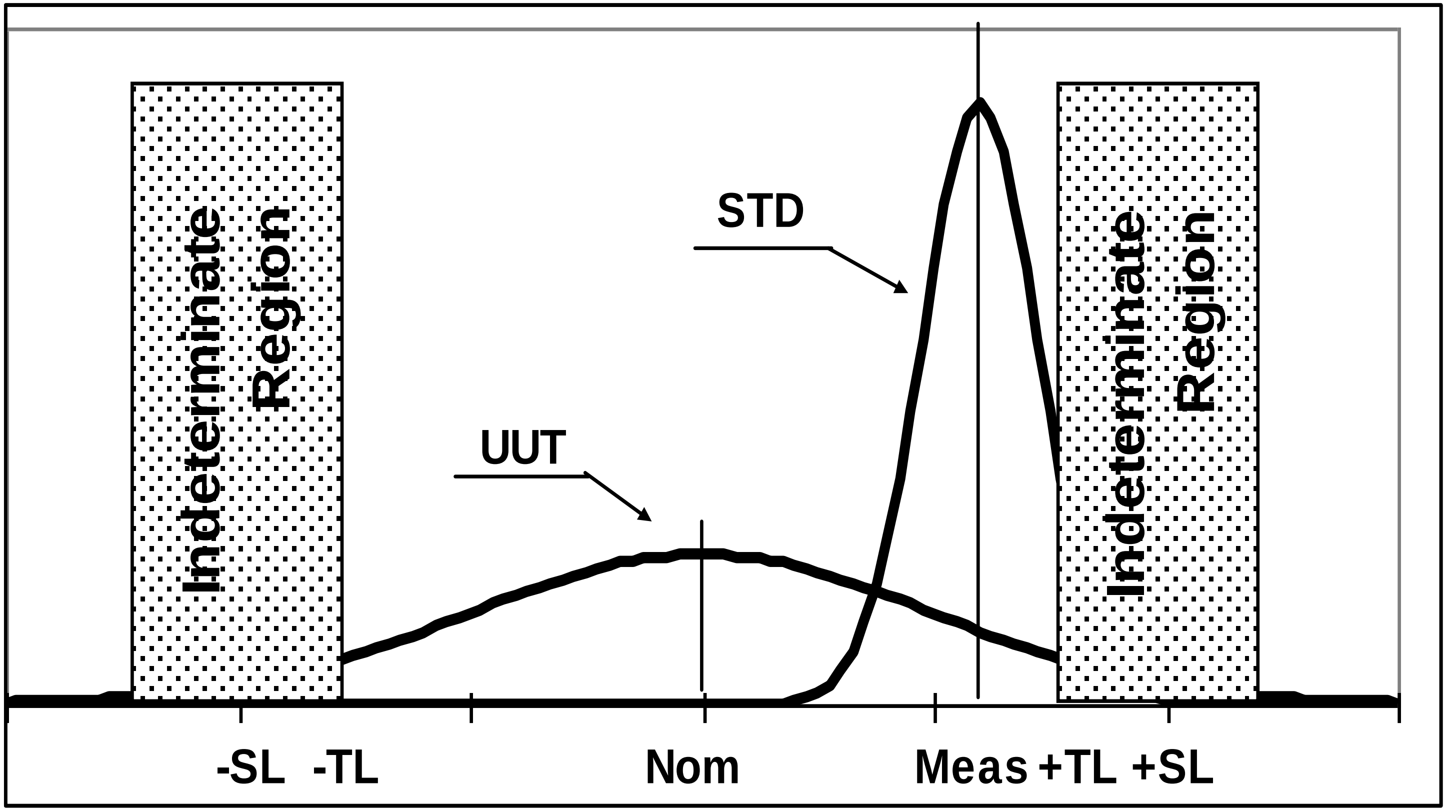
*Evaluated using joint probability

Guardbanding

- Decreases False accept risk by developing a “test limit” that is less than the specification limit



Guardbanding



Guardband Selection Methods

- For a 2:1 TUR
- Root difference of Squares
  - ≈ 0.6 % FA, 8.2 % FR

$$TL = \sqrt{SL^2 - U^2_{95\%}}$$

- ISO 14253-1 (U95)
  - ≈ 0.1 % FA, 35 % FR

$$TL = SL - U_{95\%}$$

- Dobbert method
  - ≈ 2 % FA, 10 % FR

$$TL = SL - U_{95\%} \times M$$

- Zero Guardband
  - ≈ 4 % FA, 5 % FR

$$TL = SL$$

Conclusions

FLUKE Calibration

- The customer and the calibration lab need to communicate in order to understand what is provided by the calibration service
- Clarify if a statement of conformance is needed or not
- Agree on a decision rule and communicate the level of risk associated with it
- Report the information on the certificate of calibration
- Lots of NCSLI conference papers available on the subject
- 173 (Metrology Practices) committee has lots of experts that can help