

ISWM Precision Balance & Scale

Metrological Traceability & Calibration Methods

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What's In It For Me?

- Be prepared for the following:
 1. ISO/IEC 17025:2015 and ILAC G8 have requirements for decision rules and conformity statements. Demonstrate competency and objective evidence during an accreditation assessment.
 2. Meet the requirements of the customer and educated to answer customer questions on the topic of decision rules and conformity statements.
 3. "Simple Acceptance" is currently allowed as a decision rule by the U.S. accreditation bodies. Prepare to meet the new policies for decision rules and acceptance statements should "simple acceptance" not be an option in the future.

Additional Reference: JCGM 106:2012, *Evaluation of measurement data – The role of measurement uncertainty in conformity assessment (GUM Supplement 6)*

Balance Tolerances:

- Outside of “legal metrology,” in which NIST Handbook 44 is applied, there are NO published Maximum Permissible Errors (MPE) (aka “Tolerance”).
- How is the laboratory balance or scale intended to be used after you perform a calibration?

Terminology

Maximum Permissible Error (of Indication):

for a measuring instrument, maximum difference, permitted by specifications or regulations, between the instrument indication and the quantity being measured

ISO GUM Supplement 6, Section 3.3.8

NOTE 1 When more than one maximum difference is specified, the term “maximum permissible errors” is used; for example, a specified maximum negative difference and a specified maximum positive difference.

NOTE 2 The error of indication can be written as $E = R - R_0$, where R is the indication and R_0 denotes the indication of an ideal measuring instrument measuring the same measurand Y . In the testing and verification of a measuring instrument, the error of indication is typically evaluated by measuring a calibrated reference standard.

Terminology

Maximum Permissible Error (of Indication):

For purposes of this discussion, we will use the terms *Tolerance* and *Maximum Permissible Error (MPE)* interchangeably though the ISO International Vocabulary of Metrology (VIM) and ISO Guide to the expression of uncertainty (GUM) defines each of these terms slightly different.

Terminology

Acceptance Limit:

Specified upper or lower bound of permissible measured quantity values. **(Not to be confused with tolerance.)**
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Terminology

Decision Rule:

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

ISO/IEC 17025:2015, Section 3.7

Documented 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.

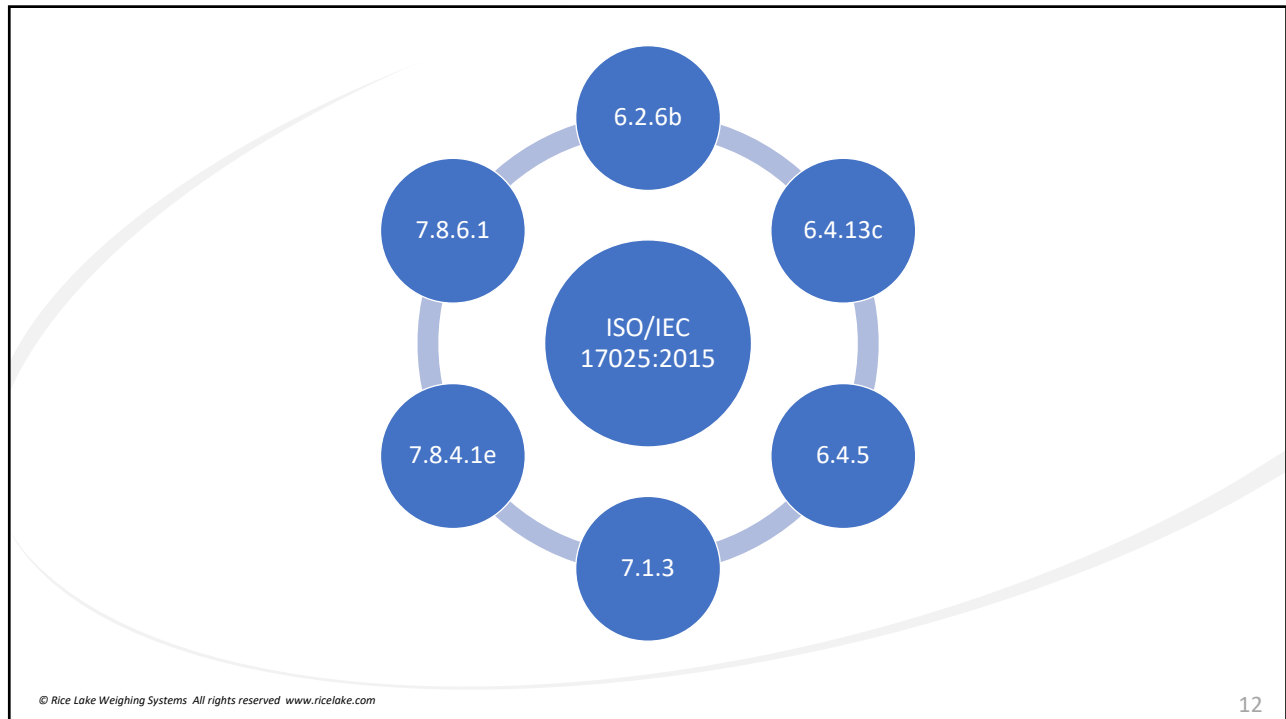
ISO GUM Supplement 6, Section 3.3.12

Terminology

Conformity Statement:

A documented statement that clearly defines whether a measurement quantity value, calibration result, or measuring system complies or does not comply with a specification (e.g., acceptance limit, tolerance, maximum permissible error (MPE), etc.). Typically expressed as “pass/fail,” “in-tolerance/out-of-tolerance,” “conforms to.../does not conform to...”

Not defined by ISO VIM, ISO GUM, ISO/IEC 17025:2015, or ILAC G8, therefore this is Mark's best attempt to define a Conformity Statement as it relates to a calibration result.



(Internal) Requirements from ISO/IEC 17025:2017:

- **Authorize** personnel to review results and make statements of conformity. Remember to record qualifications, training, and authorizations in personnel training records. (Section 6.2.6b)

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- **Evaluate** your measurement standards to ensure the measurement accuracy and the measurement uncertainty is sufficient to provide adequate results. This includes understanding which decision rule was used during the calibration of your measurement standards and if the measurement uncertainty was included in the pass/fail evaluation of tolerance. (Section 6.4.5)

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- **Evaluate** your measurement standards to ensure the measurement accuracy and the measurement uncertainty is sufficient to provide adequate results. This includes understanding which decision rule was used during the calibration of your measurement standards and if the measurement uncertainty was included in the pass/fail evaluation of tolerance. (Section 6.4.5)
- Retain records of evidence of **verification** that equipment and measurement standards conform with specified requirements. (Section 6.4.13c)

Terminology

Verification:

provision of objective evidence that a given item (measuring system) fulfils specified requirements

Example 1: Confirmation that a target measurement uncertainty can be met.

ISO/IEC 17025:2015, Section 3.8

When the customer requests a conformity statement (Section 7.1.3):

- **Communicate** and **agree** with the customer on the decision rule to be used. (Be sure to document pertinent communication with the customer.)
- **State** the specification or standard to which the conformance is based.
- Clearly **define** the decision rule.

On the calibration report (Sections 7.8.4.1e & 7.8.6.1):

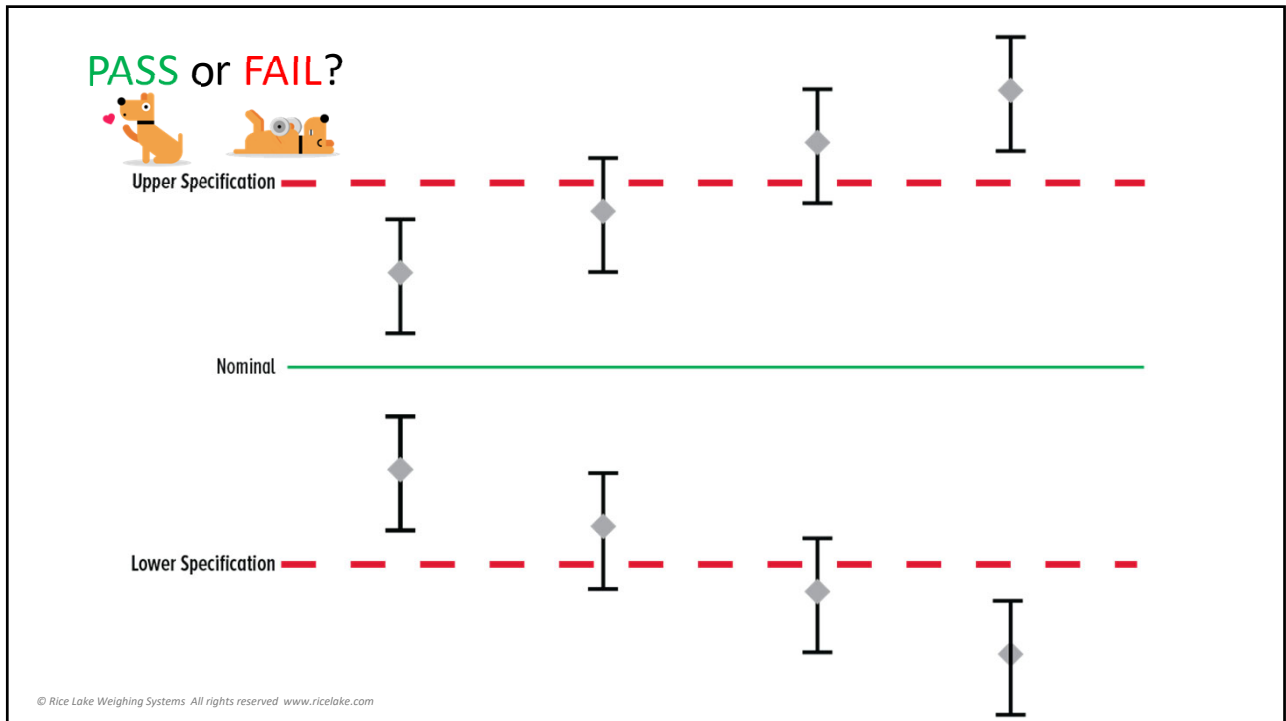
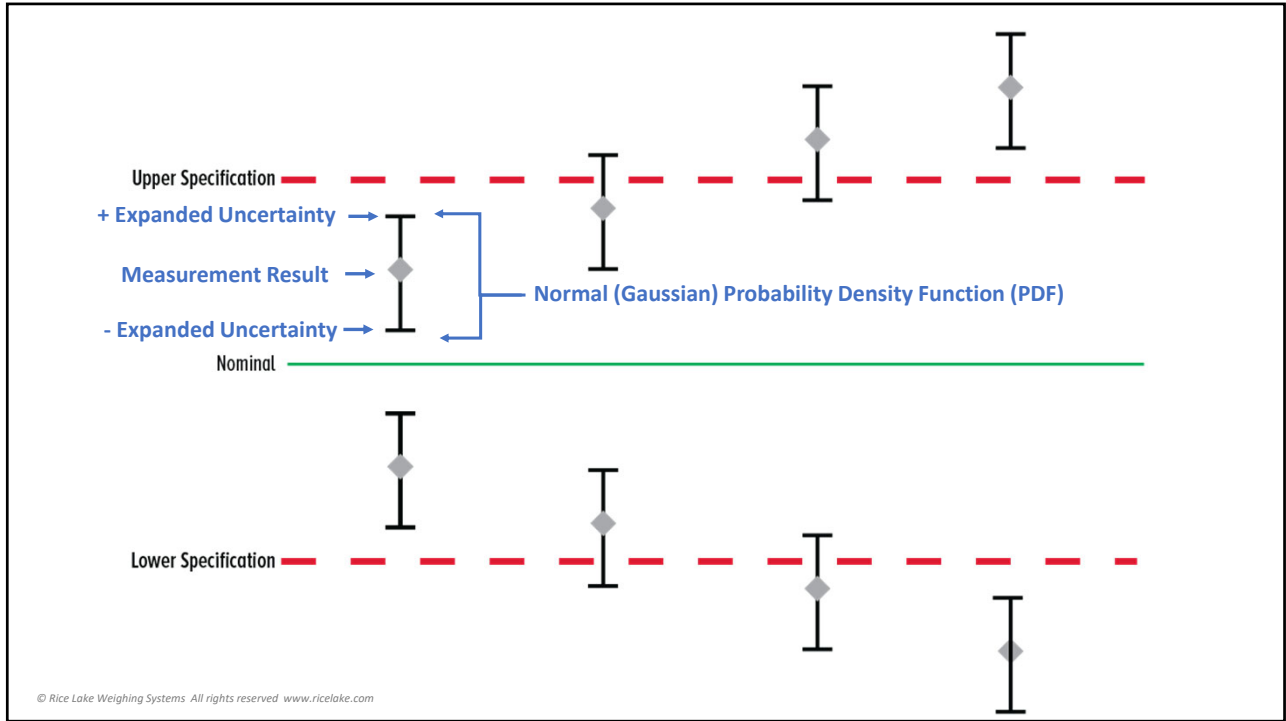
- Where relevant, a statement of conformity with the requirements or specifications (see Section 7.8.6).
- When reporting a statement of conformity:
 - a) Specify the specification or standard;
 - b) Document the decision rule used;
 - c) Account for measurement uncertainty when determining compliance (e.g., false acceptance and statistical assumptions);
 - d) If the decision rule is prescribed by the customer a risk analysis is not required.

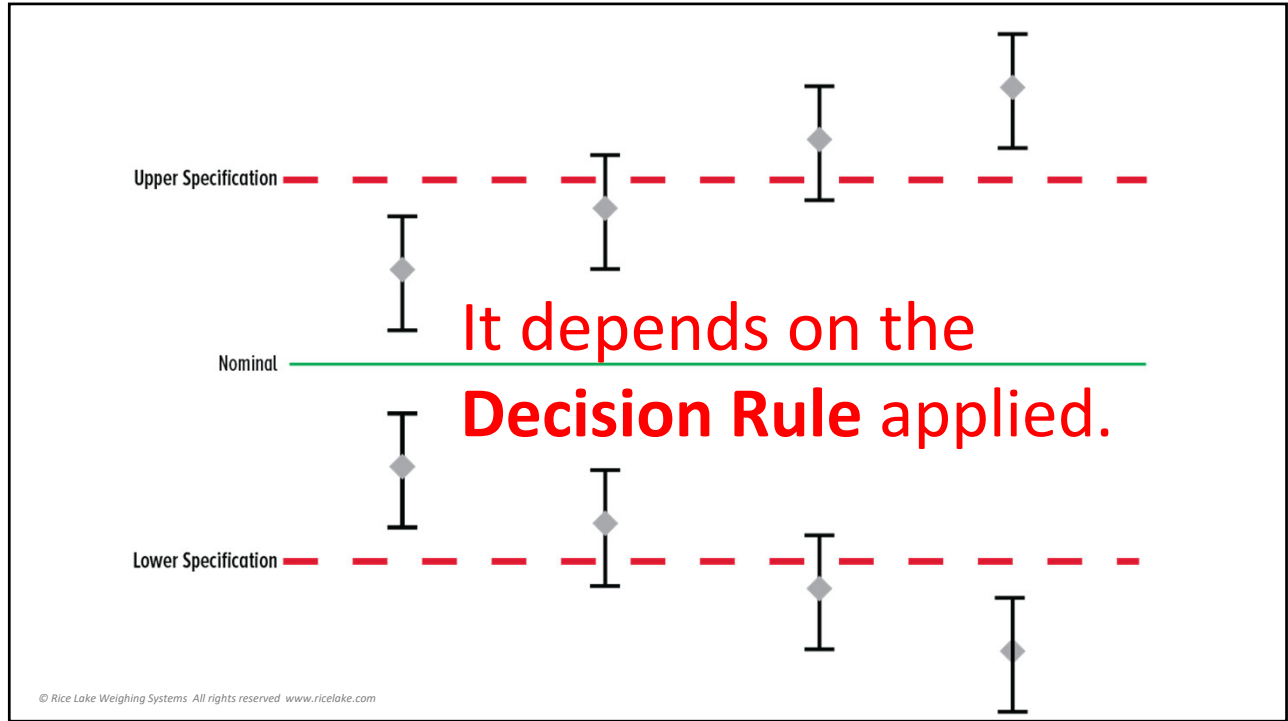
On the calibration report clearly identify (Section 7.8.6.2):

- a) To which results the statement of conformity applies
- b) Which specifications, standards or parts thereof are met or not met;
- c) The decision rule applied
(unless inherent in the requested specification or standard).

- Note: ISO/IEC Guide 98-4 gives further guidance and terminology.

Most Common Examples of Implementation for Balance Calibration

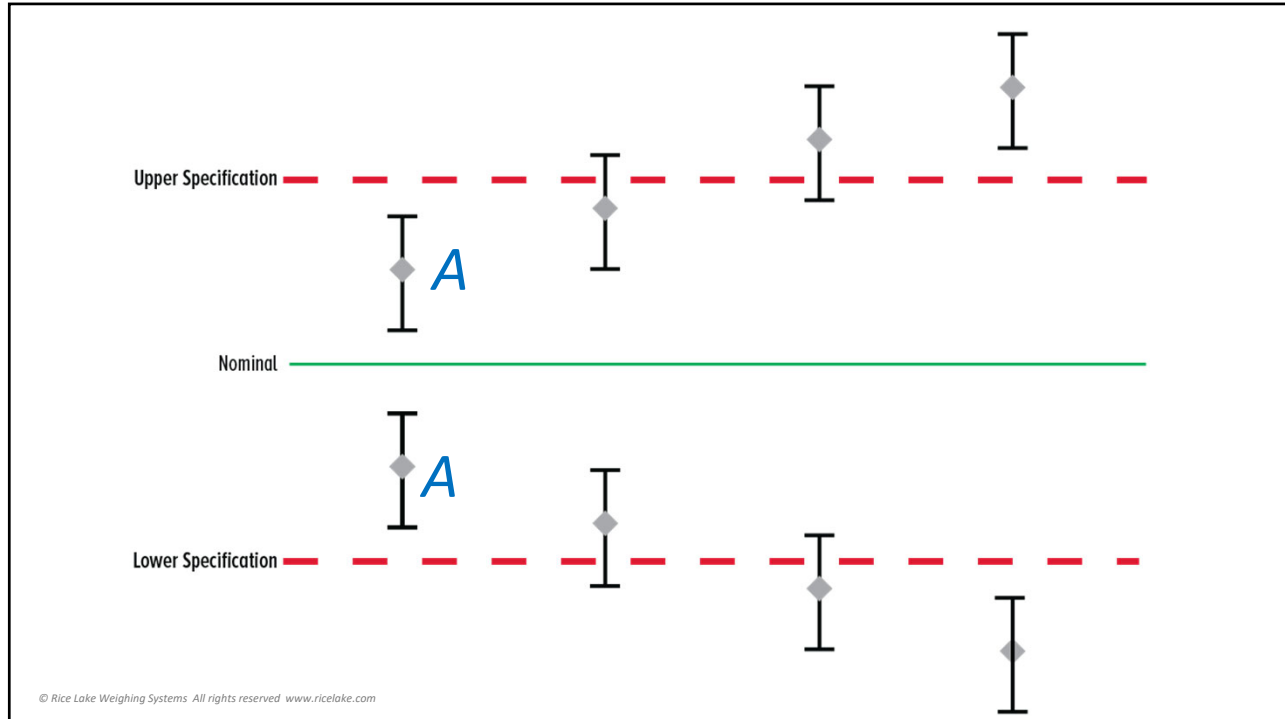




Decision Rules Have Implications and Outcomes

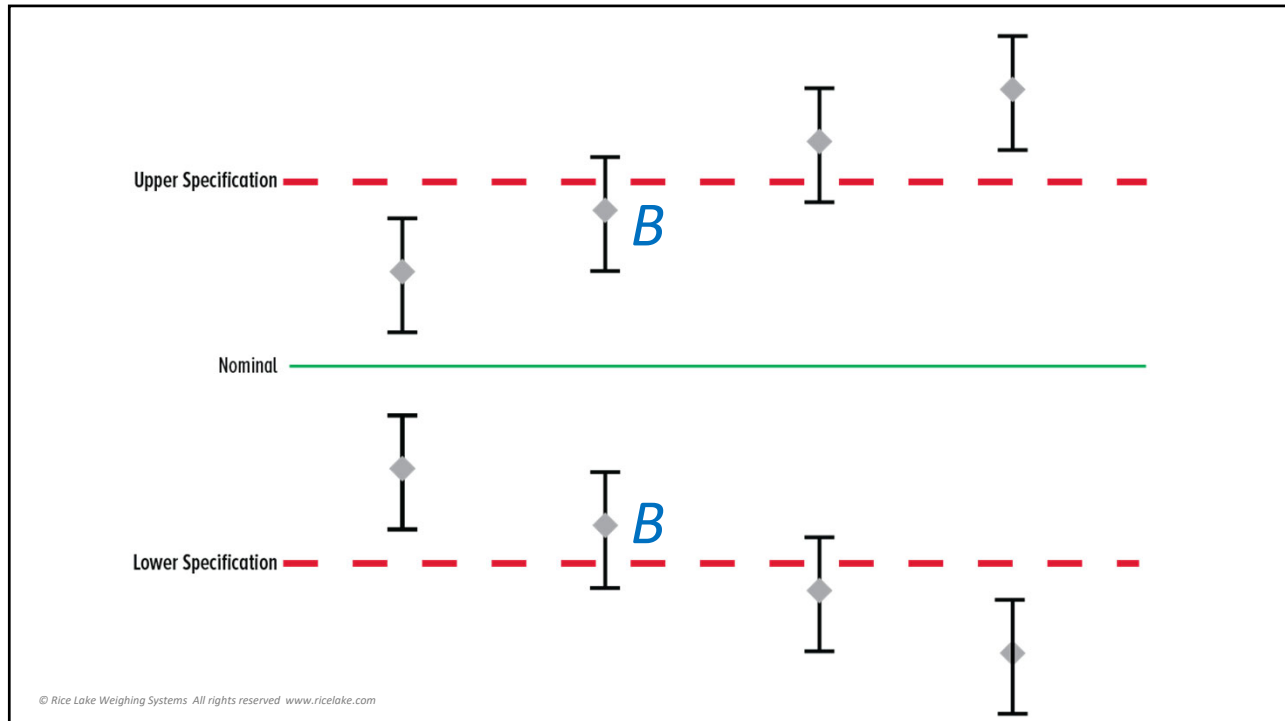
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Risks?



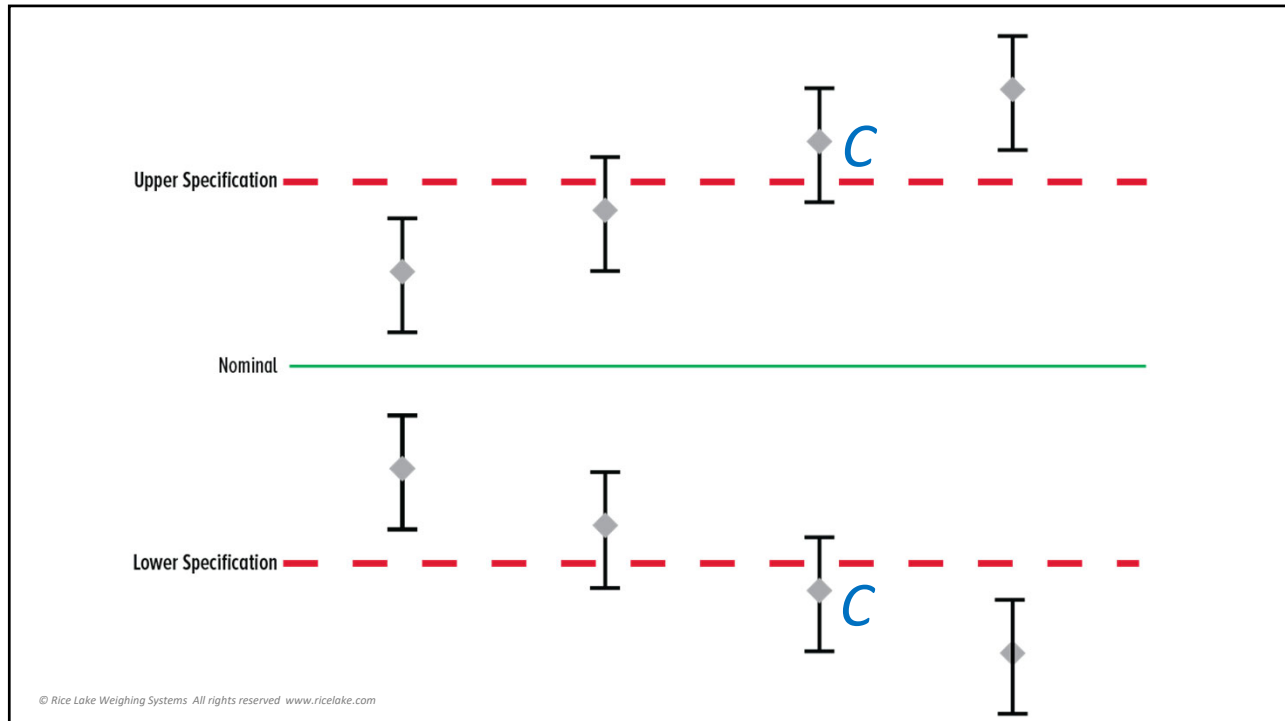
Example of Decision Rules and how they are used to make conformity statements:

- A. Pass: Measurement Results \pm Expanded Uncertainty are within the MPE (tolerance/spec)



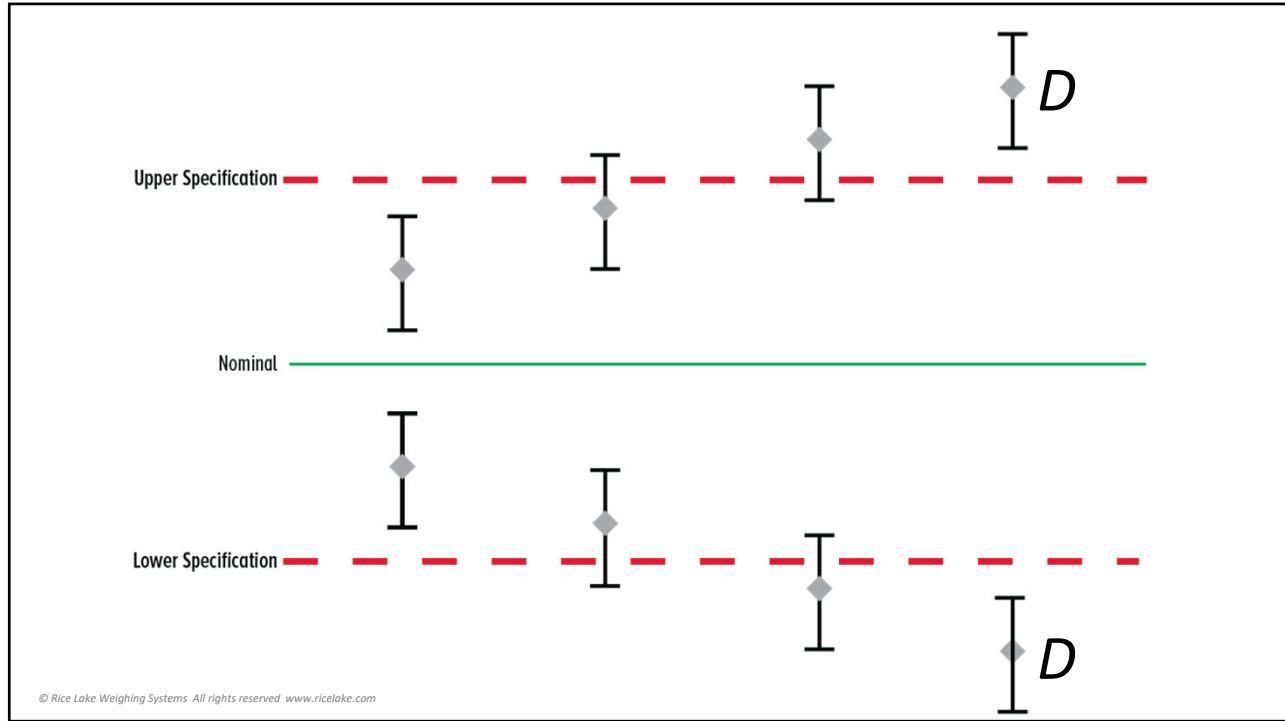
Example of Decision Rules and how they are used to make conformity statements:

- B. Pass: The Measurement Result is within the MPE (tolerance/spec.); however, the Measurement Results \pm Expanded Uncertainty exceeds the MPE (tolerance/spec.).



Example of Decision Rules and how they are used to make conformity statements:

- C. Fail: The Measurement Result exceeds the MPE (tolerance/spec.); however, Measurement Results \pm Expanded Uncertainty overlaps the MPE (tolerance/spec.).



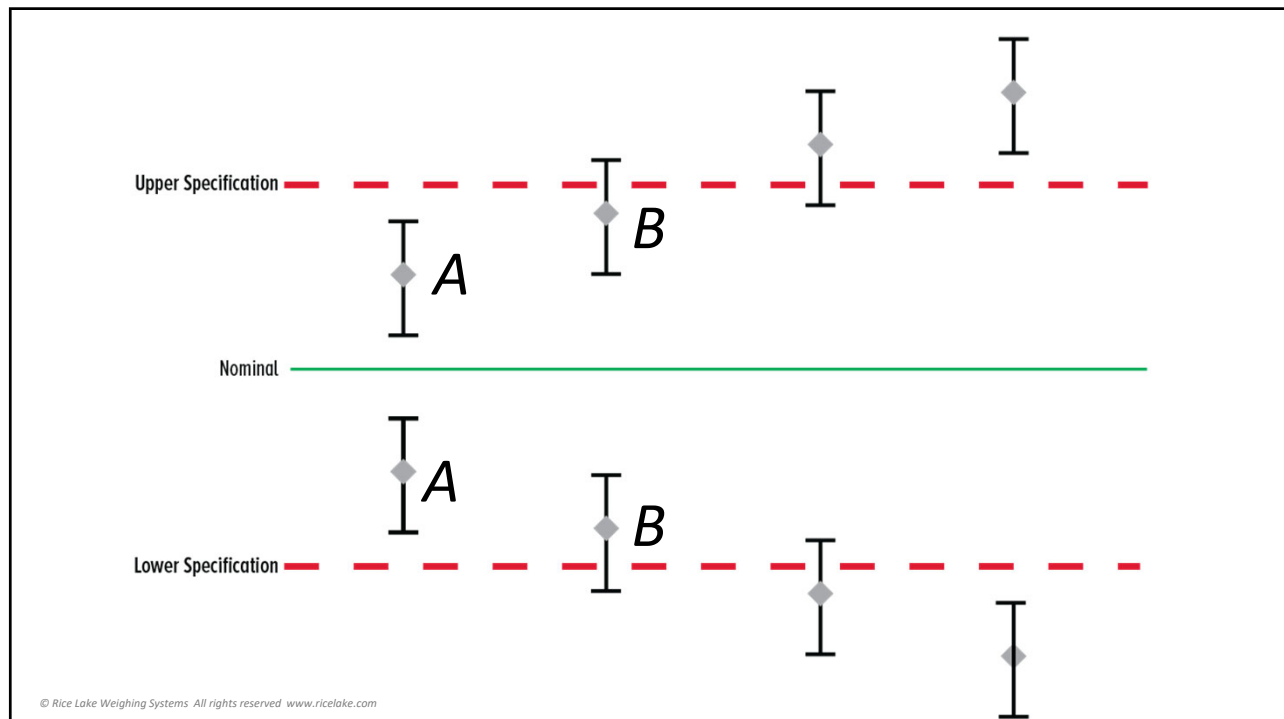
Example of Decision Rules and how they are used to make conformity statements:

D. Fail: Measurement Results \pm Expanded Uncertainty exceed the MPE (tolerance/spec.).

Simple Acceptance (Shared Risk) Example:

- The calibration uncertainty is not considered in the decision rule or subsequent conformity statement. The acceptance limit is the same as the MPE (tolerance, spec.).
- Pass: If the Measurement Result is within the MPE (tolerance/spec.).
- Fail: If the Measurement Result exceeds the MPE (tolerance/spec.).
- Risk Analysis: The probability of accepting a Measurement Result that exceeds the MPE (tolerance/spec.) OR rejection a Measurement Result that is within the MPE (tolerance/spec.) can be as large as 50 percent depending how close the measurement result is to the acceptance limit (MPE/tolerance/spec.), assuming the uncertainty is based on a normal distribution. It is the responsibility of the end user to determine.

NOTE: Simple Acceptance may not be an "acceptable" decision rule by accreditation bodies outside of the U.S. Be prepared to conform to ILAC G8 if you have international customers who request conformity statements.



Terminology

Guard Band:

The interval between a *tolerance limit* and a corresponding *acceptance limit*.

ISO GUM Supplement 6, Section 3.3.11

Terminology

Acceptance Limit:

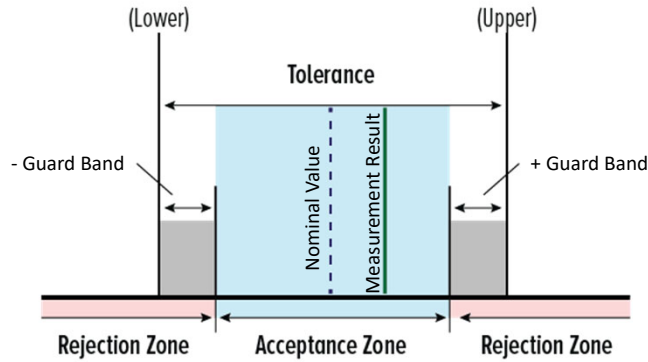
Specified upper or lower bound of permissible measured quantity values.

ISO GUM Supplement 6, Section 3.3.8

Do not confuse Acceptance Limit with Tolerance, Tolerance Limit, or Maximum Permissible Error(s).

Guard Banding Decision Rule:

$$N - (MPE - GB) \leq MR \leq N + (MPE - GB)$$



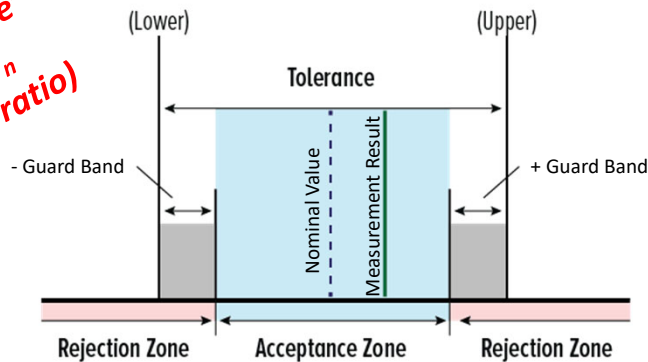
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Guard Banding Decision Rule:

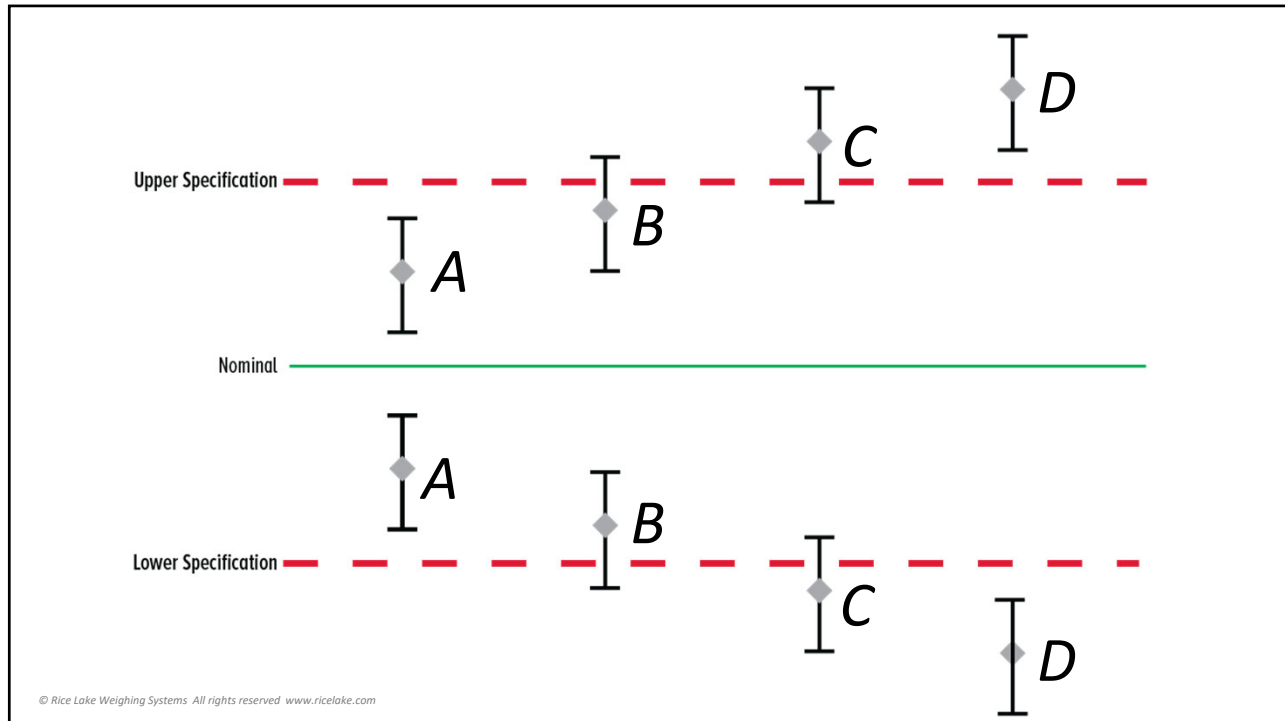
$$N - (MPE - GB) \leq MR \leq N + (MPE - GB)$$

*Must evaluate
 "fit-for-purpose"
 using the P_n
 (uncertainty ratio)*



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Uncertainty Ratio & Normalized Precision Ratio:

- A ratio of the Maximum Permissible Error vs. the Expanded Uncertainty. The maximum expanded uncertainty is some fraction or percentage of the MPE.

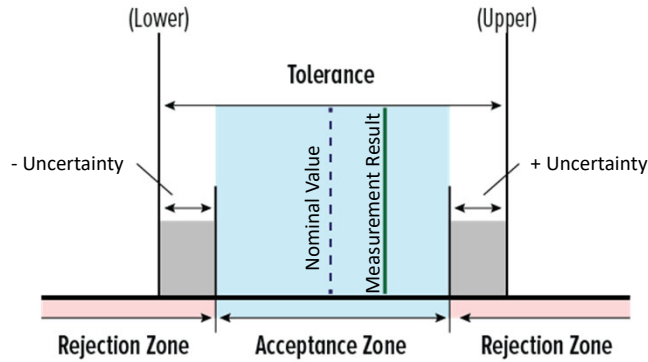
- P_n Ratio:

$$\frac{\text{Expanded Uncertainty } (U)}{(\%) \text{ MPE}}$$

- Examples
 - 10:1 Ratio
 - 4:1 Ratio
 - 3:1 Ratio
 - 1:1 Ratio

Decision Rule:

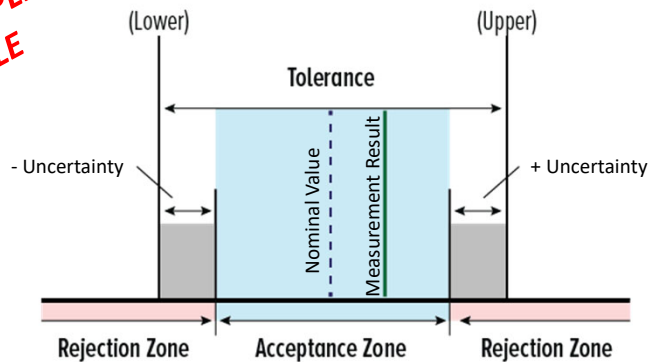
$$N - (MPE - U) \leq MR \leq N + (MPE - U)$$

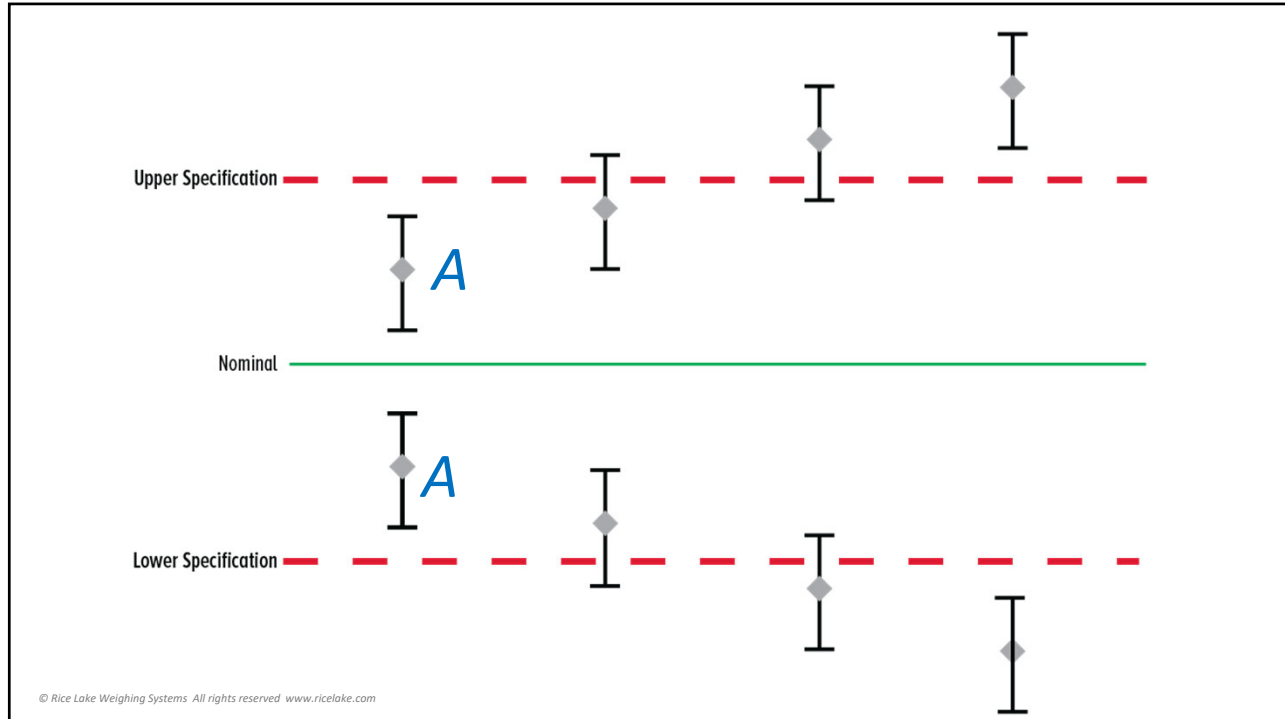


Decision Rule:

$$N - (MPE - U) \leq MR \leq N + (MPE - U)$$

**OPPOSITE OF SIMPLE
ACCEPTANCE RULE**





Option: Do Not Report Statements of Conformity:

- a) The accredited laboratory does not provide statements of conformity as a matter of practice or regulation (most frequently seen in government metrology laboratories e.g., NIST Mass & Force calibrations, State Metrology Laboratories).
- b) There is no published specification with MPE (tolerances) AND the customer does not request user-specifications.

Note 1: It is best practice to have a statement on your Calibration Report such as, "No statement of compliance to any specification is made or implied on the Calibration Report."

Warning: If your calibration report states Pass/Fail or uses any other type of language or symbol to imply pass/fail, then you are making a conformity statement and must meet all the requirements of ISO/IEC 17025:2015 and ILAC G8.

Example Conformity Statement for a Weighing Instrument

- Pass/Fail criteria has been provided by the customer for linearity, sensitivity, and eccentricity. The decision rule used is “Simple Acceptance” meaning the measurement uncertainty has not been included in the Pass/Fail determination. It is up to the end user to evaluate the calibration results and associated uncertainties to determine if this weighing instrument is fit-for-purpose.
- Because there is no national or international documentary standard with published balance tolerances (outside of legal metrology NIST HB44) this conformity statement assumes the customer provided the pass/fail criteria based on regulation or their quality management system criteria.

Best Practices:

1. Communicate your decision rules with the customer. This can be done as a statement, note, or disclaimer on quotes, proposals, contracts, or other communications.
2. Remember, some calibration specifications have inherent decision rules (e.g., ASTM E617 for mass specifications and calibrations).
3. Evaluate all of the different types of calibrations performed by your laboratory and use the appropriate communications with the customer.



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Balance Calibration & Uncertainty Seminar
October 2022
Instructor: Mark Ruefenacht

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Thank You!

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