Who Needs Another Tutorial on Risk or Decision Rules?

Almost everyone, the concept of evaluating measurement risk and making statements of conformance, has gotten so much debate since the ISO/IEC 17025:2017 standard came out that we see decision rules as a prevailing topic, and yet many are still confused.

SCAN ME

MHFORCE Morehouse

THE FORCE IN CALIBRATION SINCE 1925

Who Needs Another Tutorial on Risk or Decision Rules?

- Henry Zumbrun II, Morehouse Instrument Company
- 1742 Sixth Ave
- York, PA 17403
- PH: 717-843-0081   web: www.mhforce.com
- sales: hzumbrun@mhforce.com

Special Thanks to Dilip Shah at E=mc3 Solutions

Abstract

This 4-hour tutorial will help the participant eliminate much of the noise on decision rules. It will provide guidance anyone can take away and implement in their laboratory. This session aims to give guidance beyond simply requesting a 4:1 TUR or accepting a shared-risk scenario as with simple acceptance.

When a calibration report is provided by a calibration supplier, a typical concern for the customer is to know if the item calibrated is within the tolerance specified so they can continue using the device. While this traditional approach has been used by many for the last several decades, measurement science has evolved where it is not a simple binary issue of a "pass" or "fail" status to the manufacturer's specification without considering measurement uncertainty.

Abstract

Laboratory accreditation to ISO/IEC 17025 has advanced the good practices related to calibration to include more information about the process of calibrating an item and just calling it within conformance ("pass" or "fail").

This presentation educates both the consumer and supplier of calibration services on what is required of them to ensure that an "appropriate" pass or fail call is made to meet the customer's requirements when a calibration activity occurs. The presentation offers the appropriate foundational tools for the participant to evaluate what they need from their vendors and ensure their customers receive metrologically traceable calibration with an agreed-upon level of risk.

Learning Objectives

1. Are my measurements traceable? Understanding metrological traceability.
2. Understanding the decision rules for conformance.
3. Specifying the conformance requirements by the customer.
4. How measurement uncertainty impacts a decision rule.
5. How a statement of conformity should be reported.
6. Understanding the conformance decision and minimizing the risk for a safer, confident use of the calibrated item.

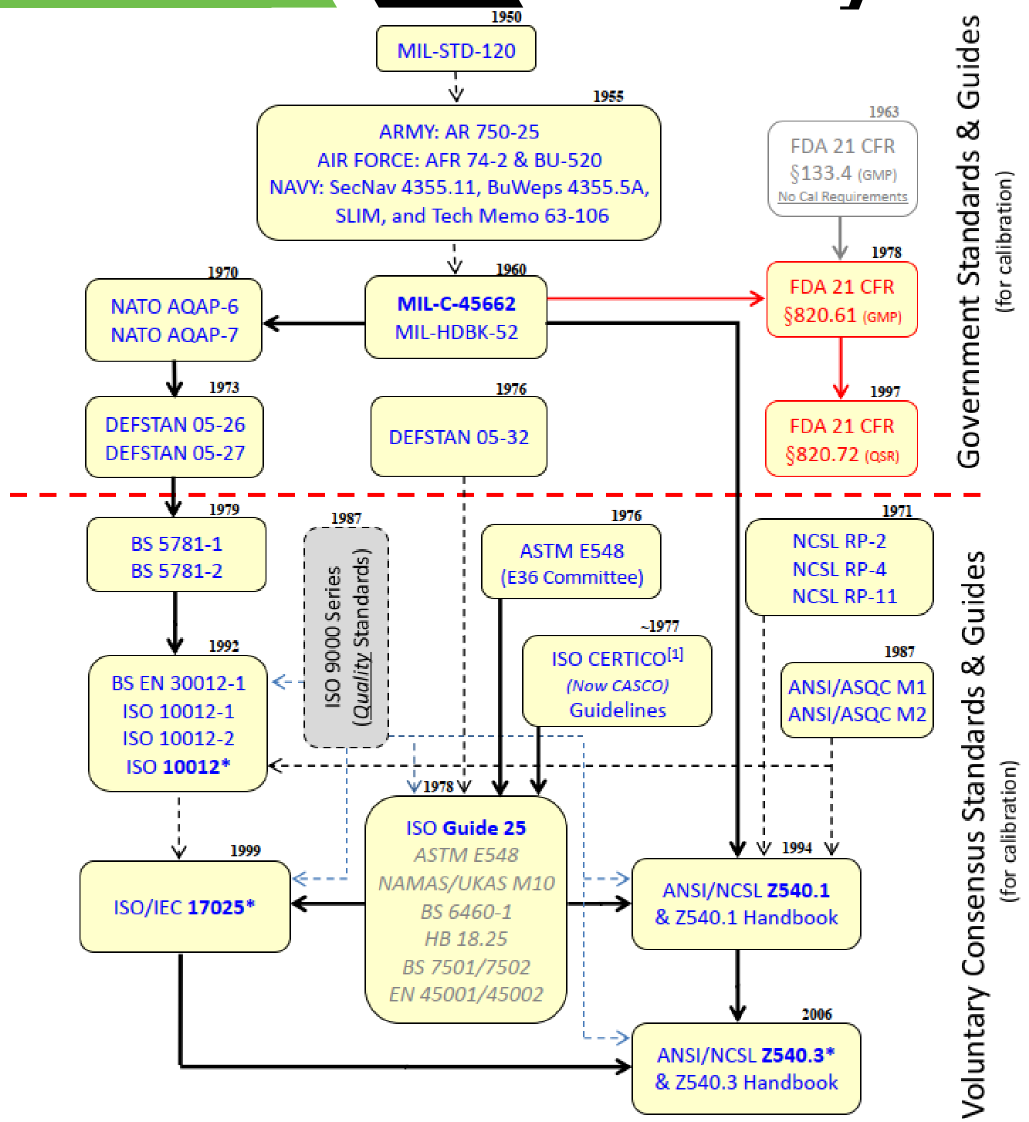
Recommended Reading – Guidance

- ILAC G8:09/2019 *Guidelines on Decision Rules and Statements of Conformity*
- JCGM 106:2012 *Evaluation of measurement data – The role of measurement uncertainty in conformity assessment*
- UKAS LAB 48: *Decision Rules and Statements of Conformity*
- ISO/IEC 17025 2017 *General requirements for the competence of testing and calibration laboratories*
- Handbook for the Application of ANSI Z540.3-2006: *Requirements for the Calibration of Measuring and Test Equipment*
- The Metrology Handbook 3rd Edition Chapter 30
- NCSLI-RP18 Estimation and Evaluation of Measurement Decision Risk
- ASME B89.7.3.1-2001 Guidelines for Decision Rules: Considering Measurement Uncertainty in Determining Conformance to Specifications
- ASME B89.7.4.1-2005 Measurement Uncertainty and Conformance Testing: Risk Analysis *
- ISO 14253-5 Part 1: Decision rules for proving conformity or nonconformity with specifications
- WADA Technical Document – TD2017DK

Recommended Reading -Papers

- Evaluation of Guardbanding Methods for Calibration and Product Acceptance – Colin J. Delker
- A STUDY OF AND RECOMMENTATIONS FOR APPLYING THE FALSE ACCEPTANCE RISK SPECIFICATION OF Z540.3 – D. Deaver J. Sompri
- Guard-banding Methods-An Overview – S. Rishi
- A Guard-Band Strategy for Managing False-Accept Risk- M. Dobbert
- Risk Mitigation Strategies for Compliance Testing – J. Harben & P. Reese
- Measurement Decision Risk – The Importance of Definitions – S. Mimbs
- Understanding Measurement Risk – M. Dobbert
- Conformance Testing: Measurement Decision Rules – S. Mimbs
- Using Reliability to Meet Z540.3's 2 % Rule – S. Mimbs
- Analytical Metrology SPC Methods for ATE Implementation – *H. Castrup*
- Calibration in Regulated Industries: Federal Agency use of ANSI Z540.3 and ISO 17025 – P. Reese

History



* Asterisk designates *active* voluntary consensus standards for calibration.
[1] CERTICO was created in 1970 as the "Committee on Certification". In 1985, it became CASCO or "Committee on Conformity Assessment".
Dates shown reflect initial publication of earliest document; see Table 1 for revision histories. Dotted lines indicate "indirect" predecessors.

Figure 1. Simplified evolution of international and national *calibration* standards and guidelines

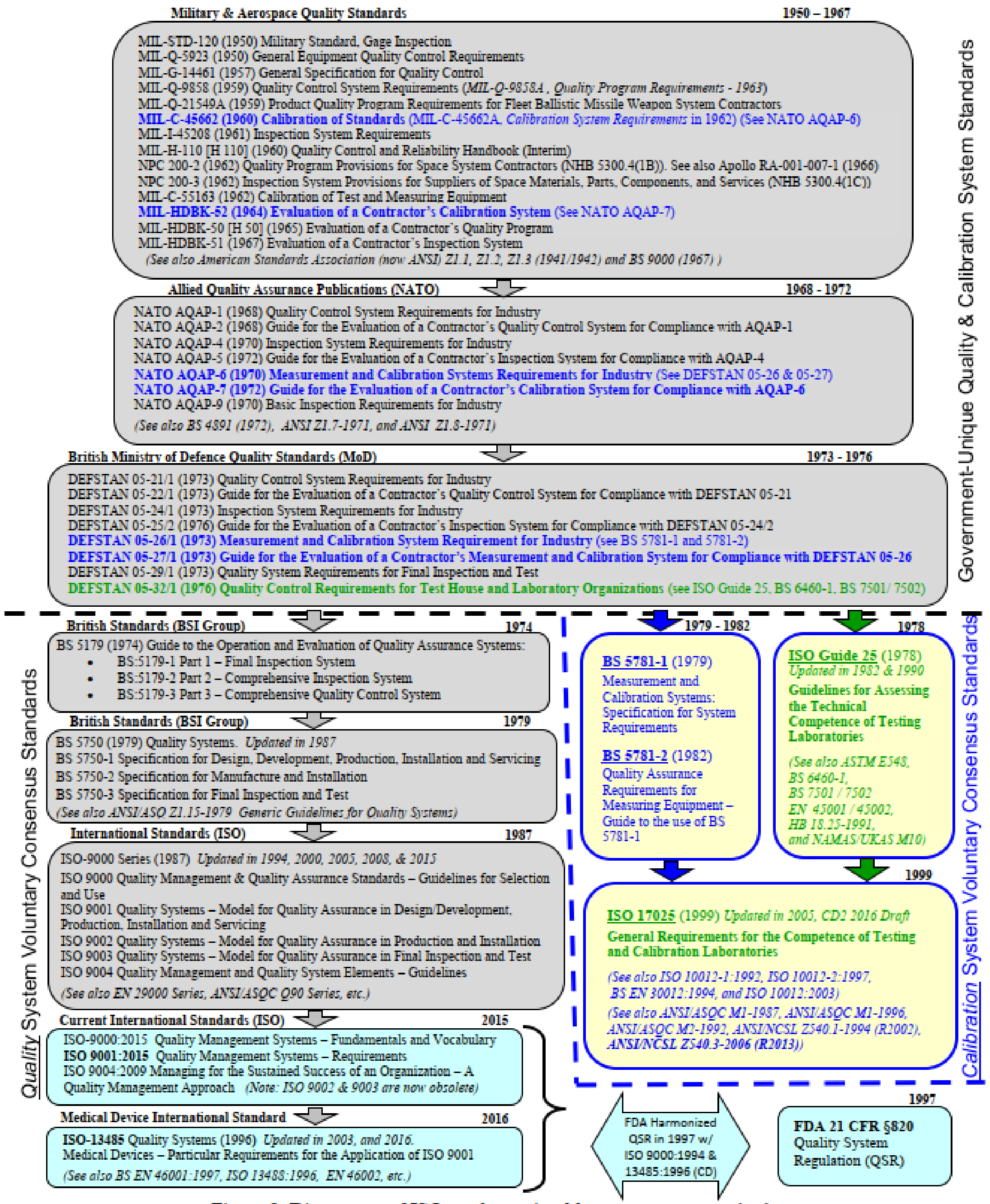


Figure 2. Divergence of ISO *quality* and *calibration* system standards

Morehouse
THE FORCE IN CALIBRATION SINCE 1925

From Calibration in Regulated Industries: Federal Agency use of ANSI Z540.3 and ISO 17025 - P.Reese

Where did the famous 4:1 Requirement Come From

- Origins of the ubiquitous 4:1 test accuracy ratio have been and attributed to Hayes and Crandon of the U.S. Navy in the 1950s. Hayes published the first known statistical analysis of calibration quality (false accept/reject) in 1955, invoking the concept of accuracy ratios, based primarily on the 1954 seminal works of Eagle and Grubbs & Coon.

A brief summary of the TAR requirements throughout the life of MIL-STD-45662A and its associated handbook is given, including its replacements ANSI Z540.1-1994 and Z540.3-2006.

- 1960: MIL-C-45662: Required a **10:1** TAR [12]
- 1962: MIL-C-45662A: No TAR specified [7]
- 1964: MIL-HDBK-52: Required **4:1** to **10:1** TAR [13]
- 1980: MIL-STD-45662: No TAR specified [30]
- 1984: MIL-HDBK-52A: *Mentions* 10:1, 4:1, 3:1, 2:1, & 1:1 TAR *examples only* [31]
- 1988: MIL-STD-45662A: Required **4:1** TAR [29] (replaced by Z540.1-1994 in 1995)
- 1989: MIL-HDBK-52B: Provided guidance on **4:1** TAR [177]
- 1994: Z540.1-1994 Required uncertainty analyses or **4:1** TAR [32]
- 1995: Z540.1 Handbook: Provided guidance on **4:1** TAR, guardbanding, etc [181A]
- 2006: Z540.3-2006 Requires **<2%** false accept risk (FAR) *or* **4:1** TUR [44]
- 2009: Z540.3 Handbook: Provides guidance on **<2%** FAR and **4:1** TUR [45]

Condon: NCSL (1966): [4]

"NASA's policy on ratio-of-accuracy as stated in NPC 200-2 requires that 'Within the state-of-the-art limitation, the standards used for calibration of inspection, measuring, and test equipment shall have a tolerance no greater than 10 % of the allowable tolerance for the equipment being calibrated.' …many measurement requirements are becoming so sophisticated that they approached the limits of the science of metrology. In such cases, it becomes impossible to maintain the 10 to 1 ratio of accuracy in the calibration of the instrument"

Russell: NCSL (1966): [5]

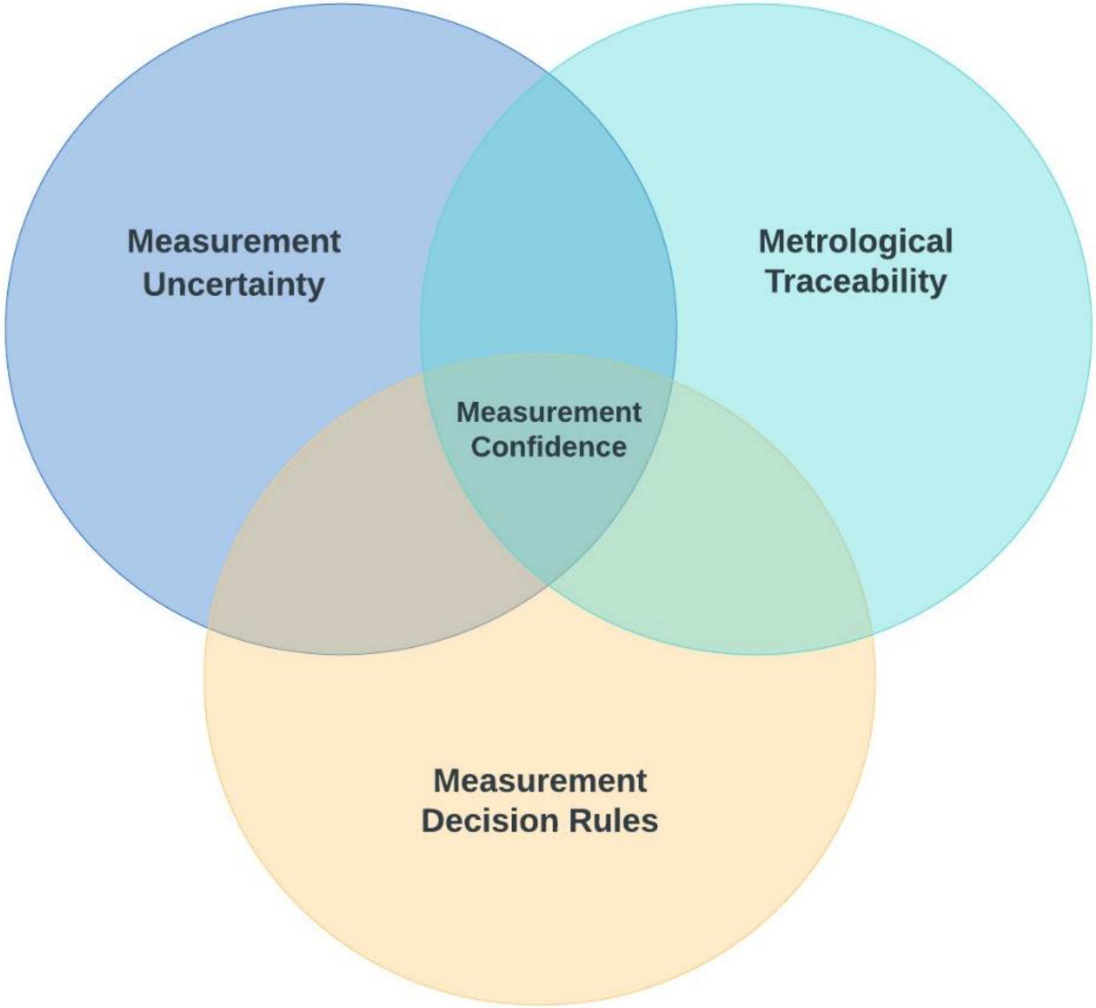
"…our discussion centered around the accuracy ratio of standard to instrument during measurement and calibration operations… Basically, the problem revolves around the actual or implied requirement that the accuracy of an instrument or standard used to measure a quantity, or to calibrate another instrument, shall be 10 times as accurate as the quantity or the instrument being calibrated.

There is also the implication that the 10-to-1 ratio of accuracy shall exist between every level or echelon in the traceability chain for product to National Standards. This requirement could create an impossible situation…

Most contractors indicated that the ratio-of-accuracy requirements imposed upon them ranged from 10:1 to 4:1, or 'state-of-the-art'. In nearly every case, they stated that the 10-to-1 requirement was considered unrealistic from an economic as well as a practical point of view…

I am of the opinion that that there are too many documents that basically state parallel requirements, the majority of which are, to a degree, unrealistic… Where 4-to-1 is maintained… the reliability of the calibrated instrument accuracy is assured…"

Measurement Confidence



Measurement Uncertainty

7.6 Evaluation of measurement uncertainty

7.6.1 Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

7.6.2 A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.

7.6.3 A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

NOTE 1 In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.

NOTE 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.

NOTE 3 For further information, see ISO/IEC Guide 98-3, ISO 21748 and the ISO 5725 series.

GUIDE 98-3

Uncertainty of measurement —

Part 3:
Guide to the expression of uncertainty in measurement (GUM:1995)

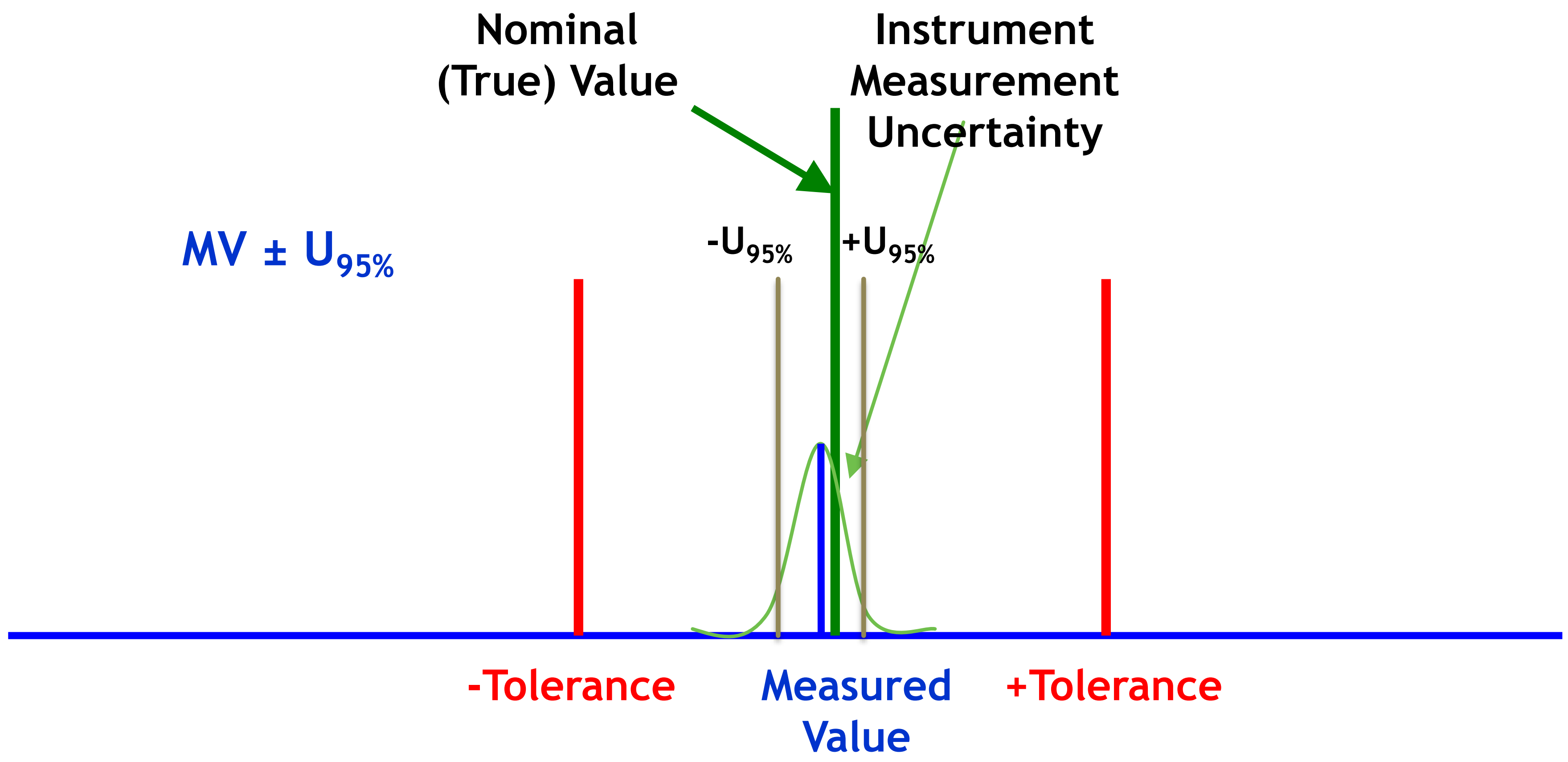
Incertitude de mesure —

Partie 3: Guide pour l'expression de l'incertitude de mesure (GUM:1995)

First edition 2008

http://www.bipm.org/
JCGM100

Measurement Uncertainty Graphically Expressed



E = mc³ Solutions

7 Steps for Evaluating Measurement Uncertainty in accordance with ISO/IEC Guide 98-3 (GUM)

Note: **Ensure that the *process of evaluating uncertainties is under statistical control before starting.***

1. ***Identify the uncertainties in the measurement process.***
2. ***Classify type of uncertainty (A or B).***
3. ***Quantify (evaluate, estimate and calculate) individual uncertainty by various methods.***
4. ***Document in an uncertainty budget.***
5. ***Combine uncertainty (Root Sum Square (RSS) method).***
6. ***Assign appropriate k factor multiplier to combined uncertainty to report expanded uncertainty.***
7. ***Document in an Uncertainty budget with the appropriate information (add notes and comments for future reference).***

Measurement Uncertainty

Assign appropriate k factor multiplier to combined uncertainty to report expanded uncertainty.

=2*NORMSDIST(Coverage Factor *k*)-1

Coverage Factor (k)	**Probability**
0.2500	19.7412651%
0.5000	38.2924923%
0.8300	59.3461216%
1.0000	68.2689492%
1.2500	78.8700453%
1.5000	86.6385597%
1.7500	91.9881686%
2.0000	95.4499736%
2.2500	97.5551055%
2.5000	98.7580669%
2.7500	99.4040474%
3.0000	99.7300204%
3.2500	99.8845950%
3.5000	99.9534742%
3.7500	99.9823165%
4.0000	99.9936658%
4.2500	99.9978623%
4.5000	99.9993205%
4.7500	99.9997966%
5.0000	99.9999427%
5.2500	99.9999848%
5.5000	99.9999962%
5.7500	99.9999991%
6.0000	99.9999998%

The TINV function in Excel does this well

=TINV((1-Probability), Effective Degrees of Freedom))

Example:

um = 5
95.45 % Probability is desired
Eff Degrees of Freedom = 1000

um	5
Probability	0.9545
Eff Degrees of Freedom	1000
Coverage Factor	2.002506

=2*NORMSDIST(Coverage Factor *k*)-1

Coverage Factor (k)	Probability
0.2500	19.7412651%
0.5000	38.2924923%
0.8300	59.3461216%
1.0000	68.2689492%
1.2500	78.8700453%
1.5000	86.6385597%
1.7500	91.9881686%
2.0000	95.4499736%
2.2500	97.5551055%
2.5000	98.7580669%
2.7500	99.4040474%
3.0000	99.7300204%
3.2500	99.8845950%
3.5000	99.9534742%
3.7500	99.9823165%
4.0000	99.9936658%
4.2500	99.9978623%
4.5000	99.9993205%
4.7500	99.9997966%
5.0000	99.9999427%
5.2500	99.9999848%
5.5000	99.9999962%
5.7500	99.9999991%
6.0000	99.9999998%

=NORM.S.INV((1+Probability)/2)

Probability & Coverage Factor	
Probability	Coverage Factor (*k*)
10.00%	0.1257
15.00%	0.1891
20.00%	0.2533
25.00%	0.3186
30.00%	0.3853
35.00%	0.4538
40.00%	0.5244
45.00%	0.5978
50.00%	0.6745
55.00%	0.7554
60.00%	0.8416
65.00%	0.9346
68.27%	1.0000
70.00%	1.0364
75.00%	1.1503
80.00%	1.2816
85.00%	1.4395
90.00%	1.6449
95.00%	1.9600
95.45%	2.0000
98.36%	2.4000
99.00%	2.5758
99.90%	3.2905
99.99%	3.8906
100.00%	4.4172

Measurement Uncertainty

CMC is defined as Calibration and Measurement Capability. It often includes the following standard uncertainty contributors:

- Repeatability
- Resolution
- Reproducibility
- Reference Standard Uncertainty
- Reference Standard Stability
- Environmental Factors

7.6.1 Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling shall be taken into account using appropriate methods of analysis.

Measurement Uncertainty

Morehouse
THE FORCE IN CALIBRATION SINCE 1925

Let us examine CMC (Calibration Measurement Capability) using a primary standard as the reference and how it affects the Expanded Uncertainty. A **Primary Standard as the Reference (CMC 0.0016 % for *k* = 2 or 0.16 lbf @ 10K)**

Measurement Uncertainty Budget Worksheet

Laboratory	Morehouse Primary Standards								
Parameter	FORCE	**Range**	10K	**Sub-Range**					
Technician	HZ	**Standards Used**							
Date									
Uncertainty Contributor	**Magnitude**	**Type**	**Distribution**	**Divisor**	**df**	**Std. Uncert**	**Variance (Std. Uncert^2)**	**% Contribution**	**u^4/df**
Reproducibiliy	000.0000E+0	A	Normal	1.000	10	000.00E+0	000.00E+0	0.00%	000.0E+0
Repeatability	57.7350E-3	A	Normal	1.000	5	57.74E-3	3.33E-3	7.51%	2.2E-6
U-7643 LLF	65.0000E-3	A	Normal	1.000	200	65.00E-3	4.23E-3	9.52%	89.3E-9
Resolution of UUT	100.0000E-3	B	Resolution	3.464	200	28.87E-3	833.33E-6	1.88%	3.5E-9
Environmental Conditions	75.0000E-3	B	Rectangular	1.732	200	43.30E-3	1.88E-3	[illegible]	[illegible]
Stability of Ref Standard	288.0000E-3	B	Rectangular	1.732	200	166.28E-3	27.65E-3	[illegible]	[illegible]
Ref Standard Resolution	24.0000E-3	B	Resolution	3.464	200	6.93E-3	48.00E-6	[illegible]	[illegible]
			None	0.000					
Morehouse CMC	160.0000E-3	B	Expanded (95.45% k=2)	2.000	200	80.00E-3	6.40E-3	14.43%	204.8E-9
			Combined Uncertainty (u_c)=			**210.62E-3**	**44.36E-3**	**100.00%**	**6.4E-6**
			Effective Degrees of Freedom			**309**			
			Coverage Factor (k) =			**1.97**			
			Expanded Uncertainty (U) K =			**0.41**	**0.00414%**		

14.43 % Contribution

Measurement Uncertainty

Let's examine CMC (Calibration Measurement Capability) using a secondary standard as the reference and how it affects the Expanded Uncertainty. **Accredited Calibration Supplier with Secondary Standards as the Reference (CMC 0.04 % for *k* =2 or 4 lbf)**

Measurement Uncertainty Budget Worksheet									
Laboratory	Morehouse Primary Standards								
Parameter	FORCE	Range	10K	Sub-Range					
Technician	HZ	Standards Used							
Date									
Uncertainty Contributor	**Magnitude**	**Type**	**Distribution**	**Divisor**	**df**	**Std. Uncert**	**Variance (Std. Uncert^2)**	**% Contribution**	**u^4/df**
Reproducibiliy	000.0000E+0	A	Normal	1.000	10	000.00E+0	000.00E+0	0.00%	000.0E+0
Repeatability	378.5939E-3	A	Normal	1.000	5	378.59E-3	143.33E-3	3.43%	4.1E-3
U-7643 LLF	65.0000E-3	A	Normal	1.000	200	65.00E-3	4.23E-3	0.10%	89.3E-9
Resolution of UUT	100.0000E-3	B	Resolution	3.464	200	28.87E-3	833.33E-6	0.02%	3.5E-9
Environmental Conditions	75.0000E-3	B	Rectangular	1.732	200	43.30E-3	1.88E-3	[illegible]	[illegible]
Stability of Ref Standard	288.0000E-3	B	Rectangular	1.732	200	166.28E-3	27.65E-3	[illegible]	[illegible]
Ref Standard Resolution	24.0000E-3	B	Resolution	3.464	200	6.93E-3	48.00E-6	[illegible]	[illegible]
			None	0.000				[illegible]	[illegible]
Accredited Cal Supplier CMC	4.0000E+0	B	Expanded (95.45% k=2)	2.000	200	2.00E+0	4.00E+0	95.74%	80.0E-3
			Combined Uncertainty (u_c)=			**2.04E+0**	**4.18E+0**	**100.00%**	**84.1E-3**
			Effective Degrees of Freedom			**207**			
			Coverage Factor (k) =			**1.97**			
			Expanded Uncertainty (U) K =			**4.03**	**0.04030%**		

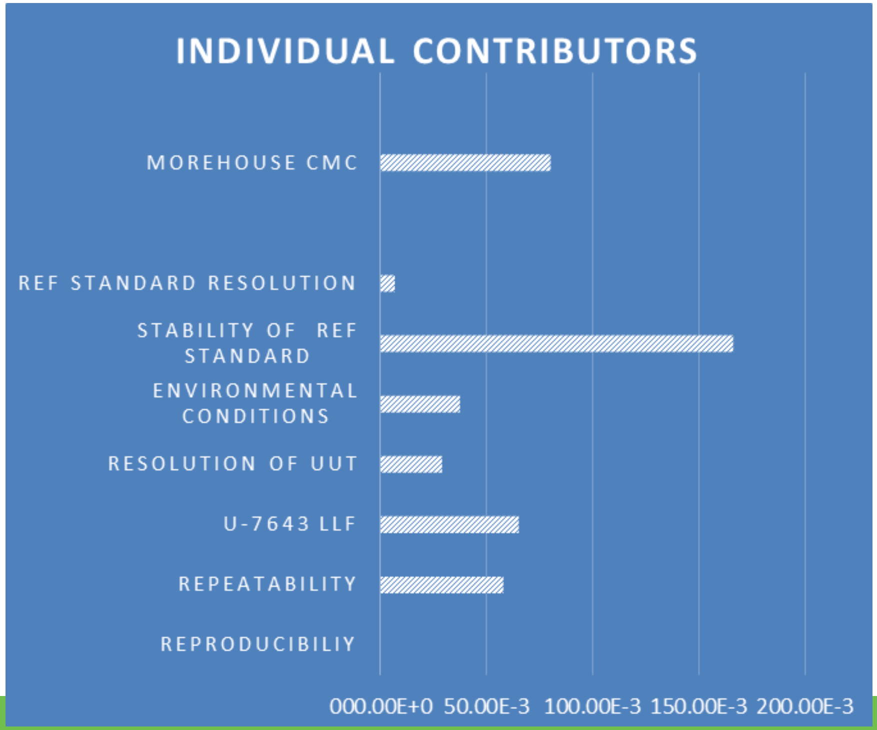
95.74 % Contribution

Measurement Uncertainty

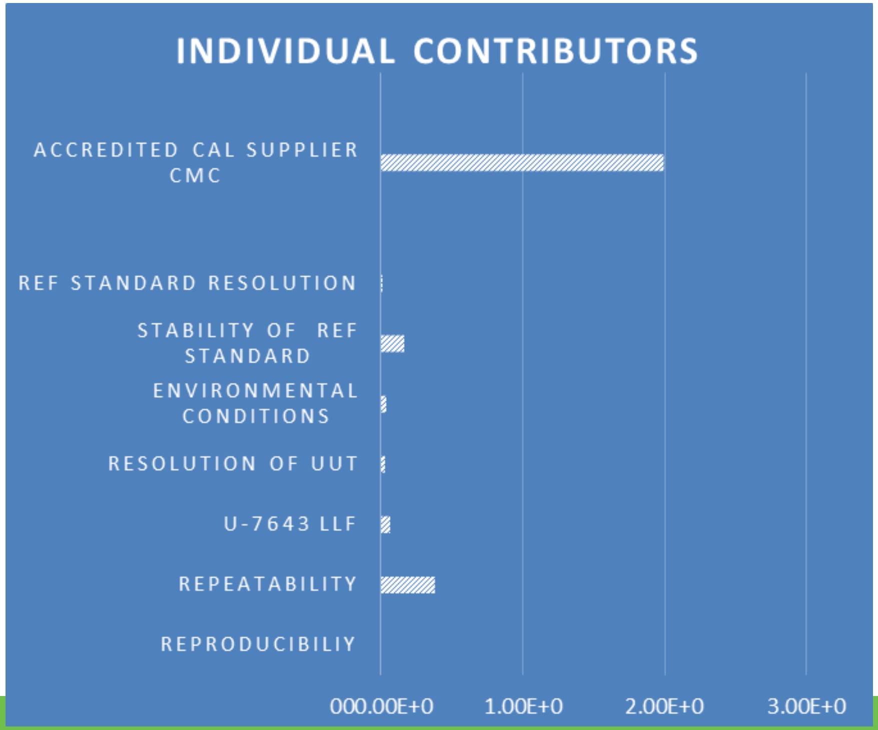
Let’s examine CMC (Calibration Measurement Capability) and what the Reference CMC does to the calibration results. Deadweight Primary Standard Versus Secondary Standards

Expanded Uncertainty when calibrated with Primary Standards is approximately 10 times lower than using secondary standards

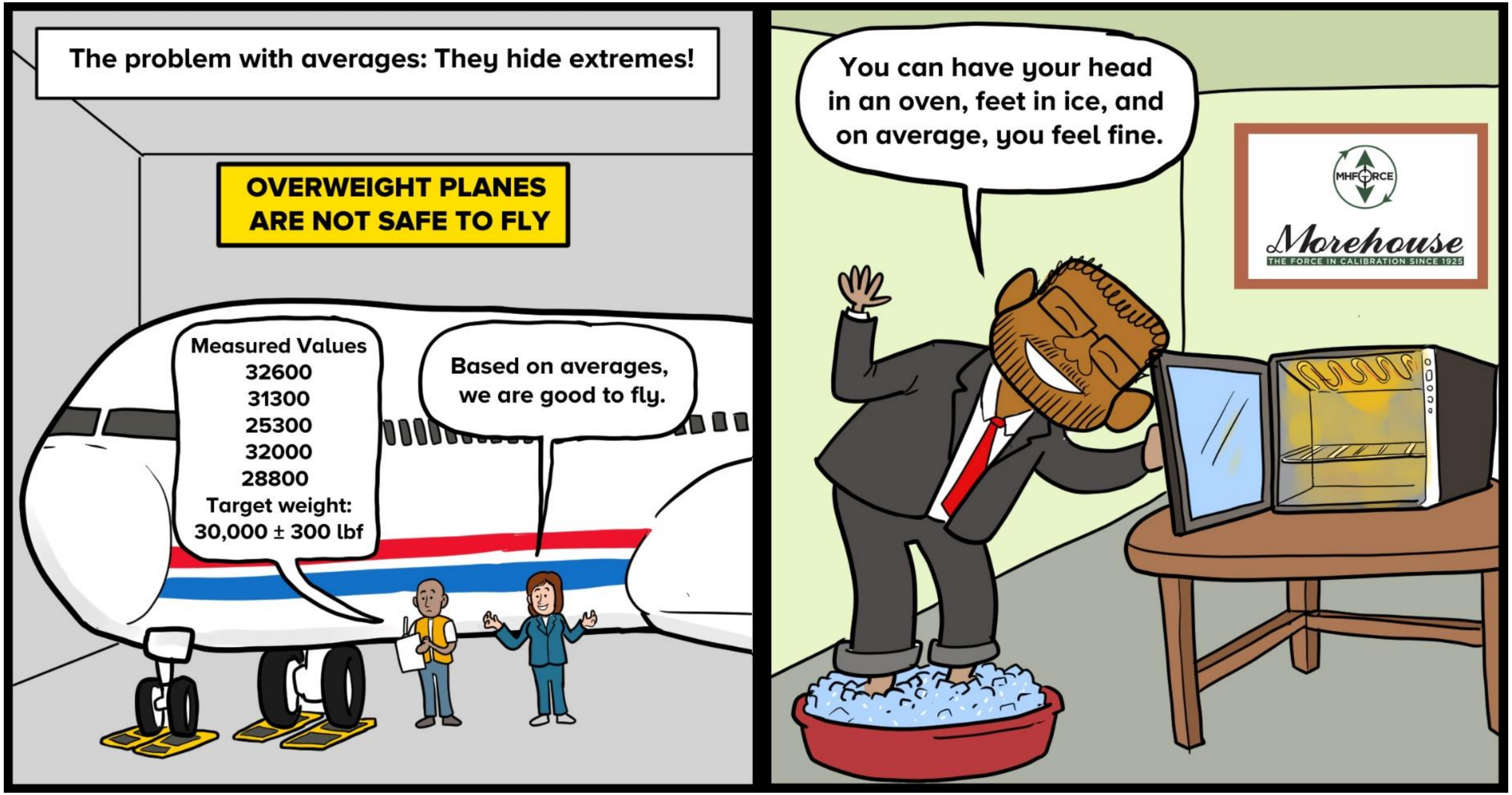
Expanded Uncertainty @ 10K = 0.41 lbf
Morehouse CMC = 0.16 lbf
Repeatability = 0.057 lbf



Expanded Uncertainty @ 10K = 4.03 lbf
Accredited Cal Supplier CMC = 4.00 lbf
Repeatability = 0.379 lbf



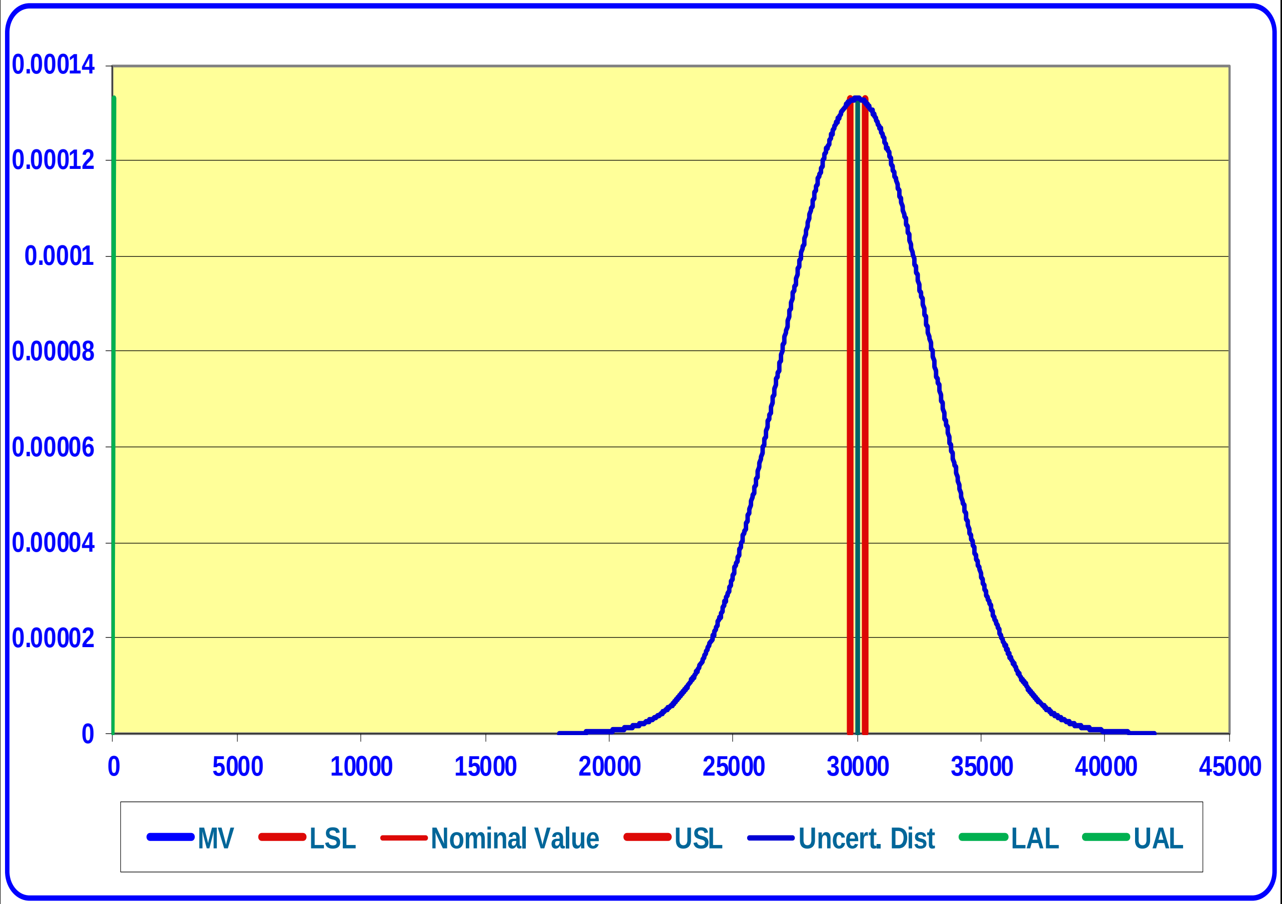
The Problem with Averages



The Problem with Averages

A1	B	C	D
2	E = mc3 Solutions	Reported Result	Acceptance Limit
3	Nominal Value	30000	
4	Lower Specification Limit	29700	INDETERMINATE
5	Upper Specification Limit	30300	INDETERMINATE
6	Measured Value	30000.0000	30000.00
7	Std. Uncert. (k=1)	3.00E+3	
8	Total Risk	92.032%	
9	Upper Limit Risk	46.016%	
10	Lower Limit Risk	46.016%	
11	Test Uncertainty Ratio (TUR) =	0.05	
12	Process Capability (C_{pk})	0.033	
Area below for calculations			
	Sample	Measurement	
	1	32600.0	
	2	31300.0	
	3	25300.0	
	4	32000.0	
	5	28800.0	
	Sample Mean	30000.00	
	Sample Standard Deviation	2999.17	

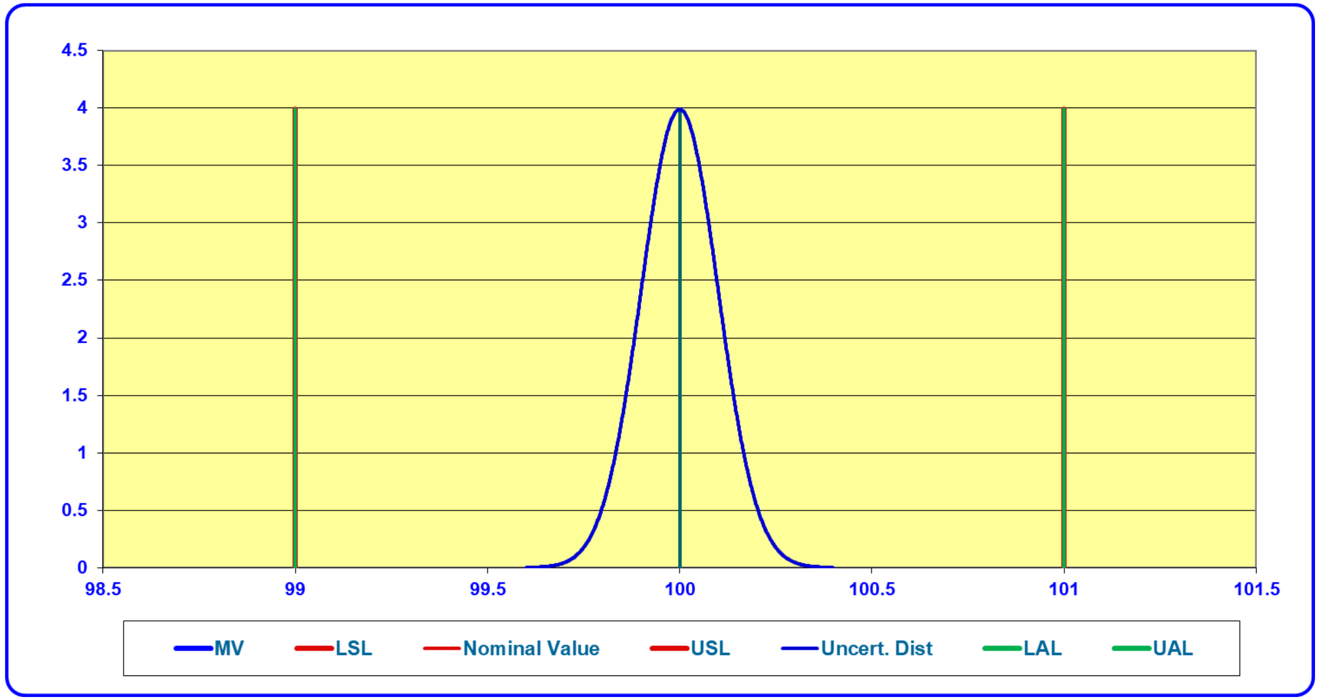
SELECTION OF GUARDBAND METHOD				
Choose Decision Rule >>>>>>>	LAC G8:2009 Decision Rule(95%	#########	Custom Acceptance Limit	2



Tolerances

- Z540.3 Definition of Tolerance - Extreme values of an error permitted by specifications, regulations, etc., for a given measuring instrument, test, or measurement application.

A measurement quantity of 100 Volts has a tolerance of ±1 Volt. The measurement process used for calibration has an estimated 95 % expanded uncertainty of 0.2 Volts.



Tension Links – Tolerance?
PROPER PIN DIAMETER

Pin B (2.0030 to 2.0060)	Pin A (2.0005 to 2.0045)
50,070	50,010
50,050	50,020
50,040	50,010
50,070	50,020
50,090	50,020
50,060	50,030
50,080	50,010
50,070	50,030
50,090	50,020
50,090	50,070
50,080	50,060
50,100	50,070
17.81640375	22.74696117
Out of 24 tests 13 did not meet spec ± 50	

Standard Deviation of the Mean
Standard Error of the Mean
Experimental Standard Deviation of the Mean

This is an estimate of the Standard Deviation of the Mean. This is an estimate of the precision of the sample mean. It is calculated by dividing the corresponding Standard Deviation value by the square root of **m**.

$$s_{\bar{x}} = \frac{\sqrt{\dfrac{\sum_{i=1}^{i=n}(\bar{x}-x_i)^2}{n-1}}}{\sqrt{m}}$$

OFTEN MISUSED! The GUM shows this function for Type A Data but does not explain well.

E = mc³ Solutions

Type A data

	January	February	March	April	May	June	July	August	September	October	November	December
1	49.989	49.983	49.995	50.018	49.980	50.001	49.982	49.988	49.988	49.985	49.995	49.993
2	50.013	50.001	49.995	50.014	50.003	50.001	50.010	50.010	49.983	50.004	50.009	49.989
3	50.008	49.991	50.016	49.986	49.989	50.018	50.006	50.011	50.010	50.002	50.015	49.998
4	49.991	50.012	50.010	49.992	50.011	50.018	50.019	50.001	49.987	49.991	50.020	49.981
5	50.015	50.013	49.984	49.991	50.002	50.014	50.007	49.995	49.994	49.982	49.983	49.987
6	50.008	50.018	50.014	49.988	50.015	49.991	50.013	49.989	50.019	50.002	50.007	50.017
7	49.996	49.988	50.007	50.005	50.016	49.984	50.000	50.002	50.011	50.003	50.013	49.982
8	49.991	49.992	49.980	49.981	50.005	50.005	49.992	50.000	49.986	49.999	49.989	49.997
9	50.013	49.994	50.014	50.020	49.984	50.009	50.002	49.997	50.013	50.004	50.015	50.013
10	49.998	50.015	50.002	49.988	49.991	50.000	49.992	50.008	49.998	50.008	49.989	49.998
Average	50.0021	50.0000	50.0001	50.0000	49.9971	50.0103	50.0047	50.0009	49.9926	49.9927	50.0044	49.9896
Sample Std. Dev.	12.4E-3	13.2E-3	12.6E-3	14.6E-3	12.2E-3	8.7E-3	13.7E-3	9.7E-3	10.7E-3	9.9E-3	15.0E-3	6.3E-3
Sample Variance	103.9E-6	174.6E-6	159.7E-6	214.5E-6	149.9E-6	75.0E-6	188.0E-6	93.6E-6	114.7E-6	97.4E-6	225.2E-6	39.4E-6
Reproducibility	5.8E-3											
Repeatability	11.7E-3											

Type A data

	January
1	49.989
2	50.013
3	50.008
4	49.991
5	50.015
6	50.008
7	49.996
8	49.991
9	50.013
10	49.998
Average	50.0021
Sample Std. Dev.	12.4E-3

	January
1	49.989
2	50.013
3	50.008
4	49.991
5	50.015
6	50.008
7	49.996
8	49.991
9	50.013
10	49.998
Average	50.0021
Sample Std. Dev.	12.4E-3
Sample Variance	103.9E-6
Std. Deviation of the Mean	3.9E-3

$$s_{\bar{x}} = \frac{\sqrt{\frac{\sum_{i=1}^{i=n} (\bar{x} - x_i)^2}{n-1}}}{\sqrt{m}}$$

Type A data

	January	February	March	April	May	June
1	49.989	49.983	49.995	50.018	49.980	50.001
2	50.013	50.001	49.995	50.014	50.003	50.001
3	50.008	49.991	50.016	49.986	49.989	50.018
4	49.991	50.012	50.010	49.992	50.011	50.018
5	50.015	50.013	49.984	49.991	50.002	50.014
6	50.008	50.018	50.014	49.988	50.015	49.991
7	49.996	49.988	50.007	50.005	50.016	49.984
8	49.991	49.992	49.980	49.981	50.005	50.005
9	50.013	49.994	50.014	50.020	49.984	50.009
10	49.998	50.015	50.002	49.988	49.991	50.000
Average	50.0021	50.0000	50.0001	50.0000	49.9971	50.0103
Sample Std. Dev.	12.4E-3	13.2E-3	12.6E-3	14.6E-3	12.2E-3	8.7E-3
Sample Variance	103.9E-6	174.6E-6	159.7E-6	214.5E-6	149.9E-6	75.0E-6

Type A data

$$s_{\bar{x}} = \frac{\sqrt{\dfrac{\sum_{i=1}^{i=n}(\bar{x} - x_i)^2}{n-1}}}{\sqrt{m}}$$

Average	50.0021	50.0000	50.0001	50.0000	49.9971	50.0103
Sample Std. Dev.	12.4E-3	13.2E-3	12.6E-3	14.6E-3	12.2E-3	8.7E-3

Std. Deviation of the Mean	1.9E-3	Std. Dev. Divided by sqrt(6)
Std. Deviation of the Mean	1.4E-3	Std. Dev. Divided by sqrt(10)

Calculation of Repeatability and Reproducibility

Sub Groups	1	2	3	4	5
1	0.9956	1.0087	1.0069	0.9927	1.0029
2	1.0092	1.0000	0.9938	1.0047	0.9908
3	1.0073	1.0014	0.9943	0.9913	1.0053
4	1.0049	0.9926	0.9921	0.9919	0.9956
5	0.9940	0.9986	0.9953	1.0070	0.9940
Sum	5.01100	5.00130	4.98240	4.98760	4.98860
Mean	1.00220	1.00026	0.99648	0.99752	0.99772
Range	0.01520	0.01610	0.01480	0.01570	0.01450
Standard Deviation	0.00695	0.00579	0.00594	0.00766	0.00613
Variance	0.000048	0.000034	0.000035	0.000059	0.000038
Repeatability (s_r)	0.006533	=SQRT(AVERAGE(B11:F11))			0.020
Reproducibility (s_R)	0.002338	=STDEV(B8:F8)			
$s_r^2 + s_R^2 =$	0.000048	$SQRT(s_r^2 + s_R^2) =$	0.006939084		
$s_L^2 =$	-0.000003	$s_L =$	0.000000	$s_R = SQRT(s_r + s_L^2) =$	0.006533

$s_L^2 = s_{X\text{-}Bar}^2 - s_r^2/n$

if s_L^2 is negative, set $s_L^2 = 0$ and $s_L = 0$

Documented Measurement Uncertainty Budget.

Contributors	Magnitude	Type	Distribution	Divisor	df	Std. Uncert.	Variance	% Contribution	u^4/df
Repeatability	19.950E-6	A	Normal	1	20	19.950E-6	398.000E-12	56.4%	7.920E-21
Reproducibility	16.793E-6	A	Normal	1	4	16.793E-6	282.000E-12	40.0%	19.881E-21
Resolution	10.000E-6	B	Resolution	3.464101615	100	2.887E-6	8.333E-12	1.2%	694.444E-27
Reference Standard Uncertainty	5.00E-06	B	k=2	2	100	2.500E-6	6.250E-12	0.9%	390.625E-27
Reference Standard Stability	3.00E-06	B	Rectangular	1.732050808	100	1.732E-6	3.000E-12	0.4%	90.000E-27
Environmental Factors	4.00E-06	B	U-Shaped	1.414213562	100	2.828E-6	8.000E-12	1.1%	640.000E-27
			Combined Uncertainty			**26.563E-6**	**705.583E-12**	**100.0%**	**27.803E-21**
			Effective Degrees of Freedom			**17**			
			k=			**2.11**			
			Expanded Uncertainty			**56.043E-6**			

	1	2	3	4	5
1	**1.00003**	**0.99997**	**1.00000**	**0.99997**	**0.99997**
2	**1.00002**	**0.99999**	**1.00002**	**1.00001**	**1.00002**
3	**1.00003**	**0.99998**	**1.00003**	**0.99998**	**1.00003**
4	**1.00000**	**1.00001**	**1.00003**	**0.99999**	**1.00003**
5	**0.99999**	**0.99998**	**1.00003**	**0.99997**	**0.99997**
Sum	**5.0001**	**4.9999**	**5.0001**	**4.9999**	**5.0000**
Average	**1.0000**	**1.0000**	**1.0000**	**1.0000**	**1.0000**
Std. Dev.	**18.166E-6**	**15.166E-6**	**13.038E-6**	**16.733E-6**	**31.305E-6**
Variance	**330.000E-12**	**230.000E-12**	**170.000E-12**	**280.000E-12**	**980.000E-12**
Repeatability	**19.950E-6**				
Reproducibility	**16.793E-6**				

ISO/IEC 17025:2017 Requirement

6.5 Metrological traceability

6.5.1 The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

NOTE 1 In ISO/IEC Guide 99, metrological traceability is defined as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty".

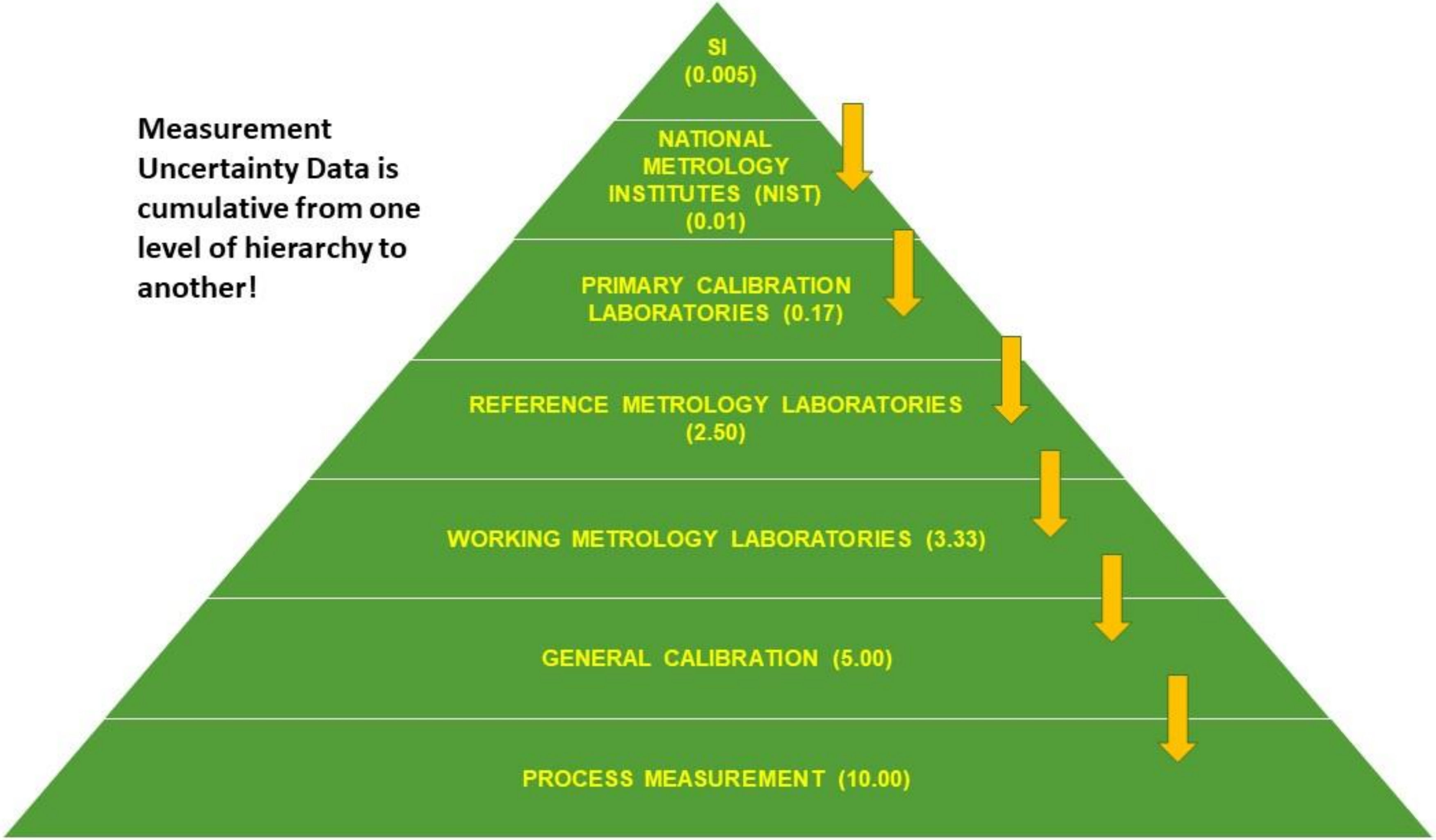
NOTE 2 See Annex A for additional information on metrological traceability.

Measurement Related Terms

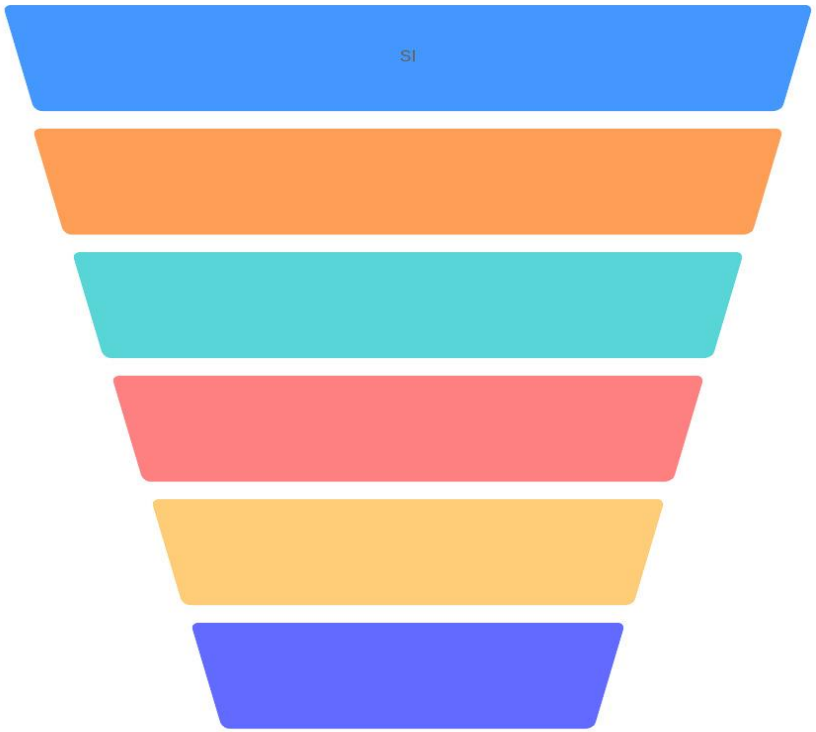
- **Metrological Traceability:** Property of a measurement result whereby the result can be related to a reference through a ***documented unbroken chain of calibrations, each contributing to the measurement uncertainty.***
  - NOTE 1 For this definition, a 'reference' can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.
  - NOTE 2 Metrological traceability requires an established calibration hierarchy.
  - NOTE 3 Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.
  - NOTE 4 For measurements with more than one input quantity in the measurement model, each of the input quantity values should be metrologically traceable.

Measurement Traceability

Measurement Uncertainty Data is cumulative from one level of hierarchy to another!



Metrological Traceability



SI

NMI

Accredited Laboratory

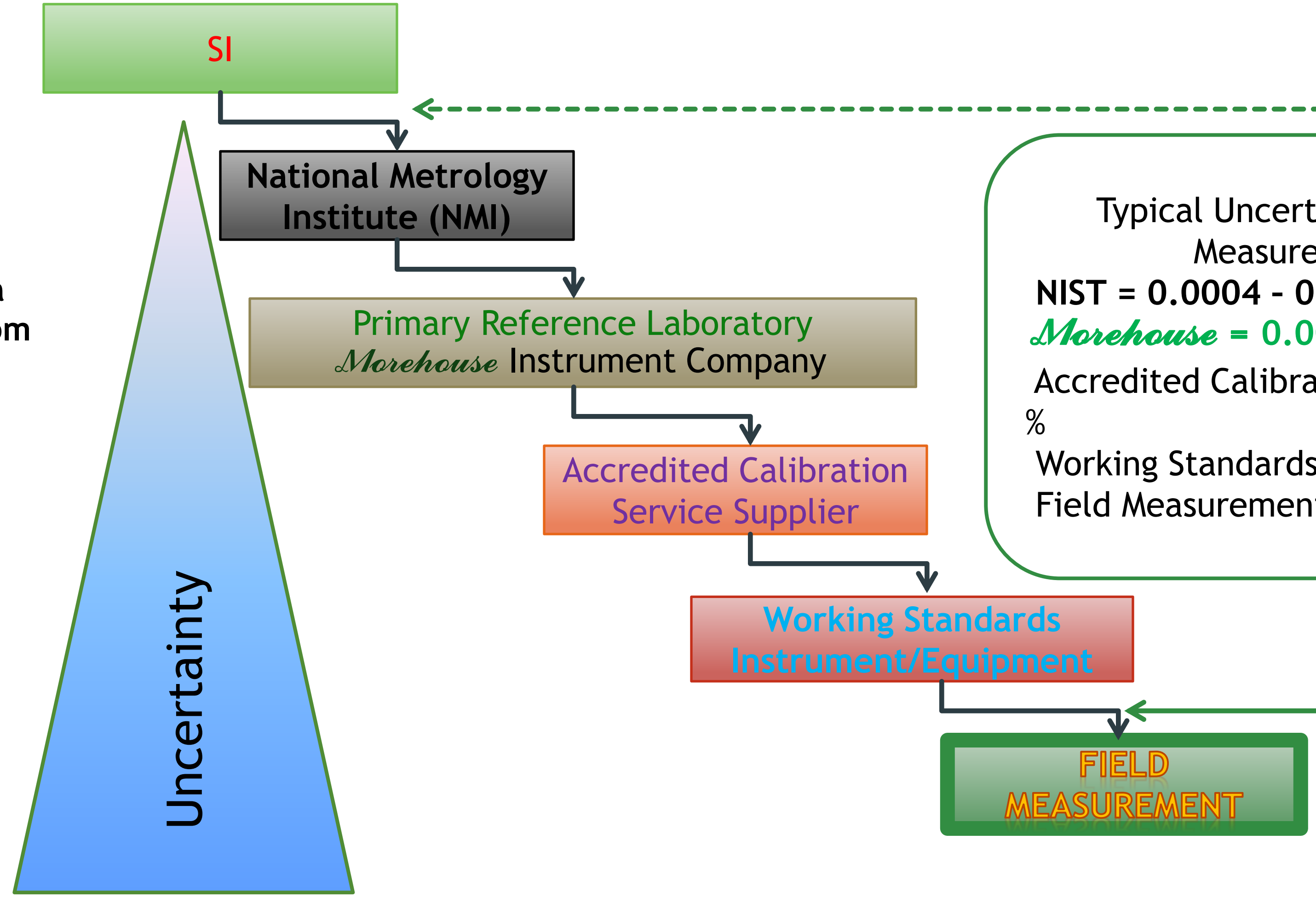
Primary Standard

Secondary Standard

Unit Under Test

Measurement Uncertainty's Relation to Measurement Hierarchy

Measurement Uncertainty Data is cumulative from one level of hierarchy to another!



Typical Uncertainties for Force Measurement *k* =1

NIST = 0.0004 - 0.0005 %

Morehouse = 0.0008 %

Accredited Calibration Supplier = 0.02 %

Working Standards = 0.1 %

Field Measurement = 0.5 %

Measurement Decision Rules

7.8.6 Reporting statements of conformity

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.

NOTE Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

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 of conformity applies;

b) which specifications, standards 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.

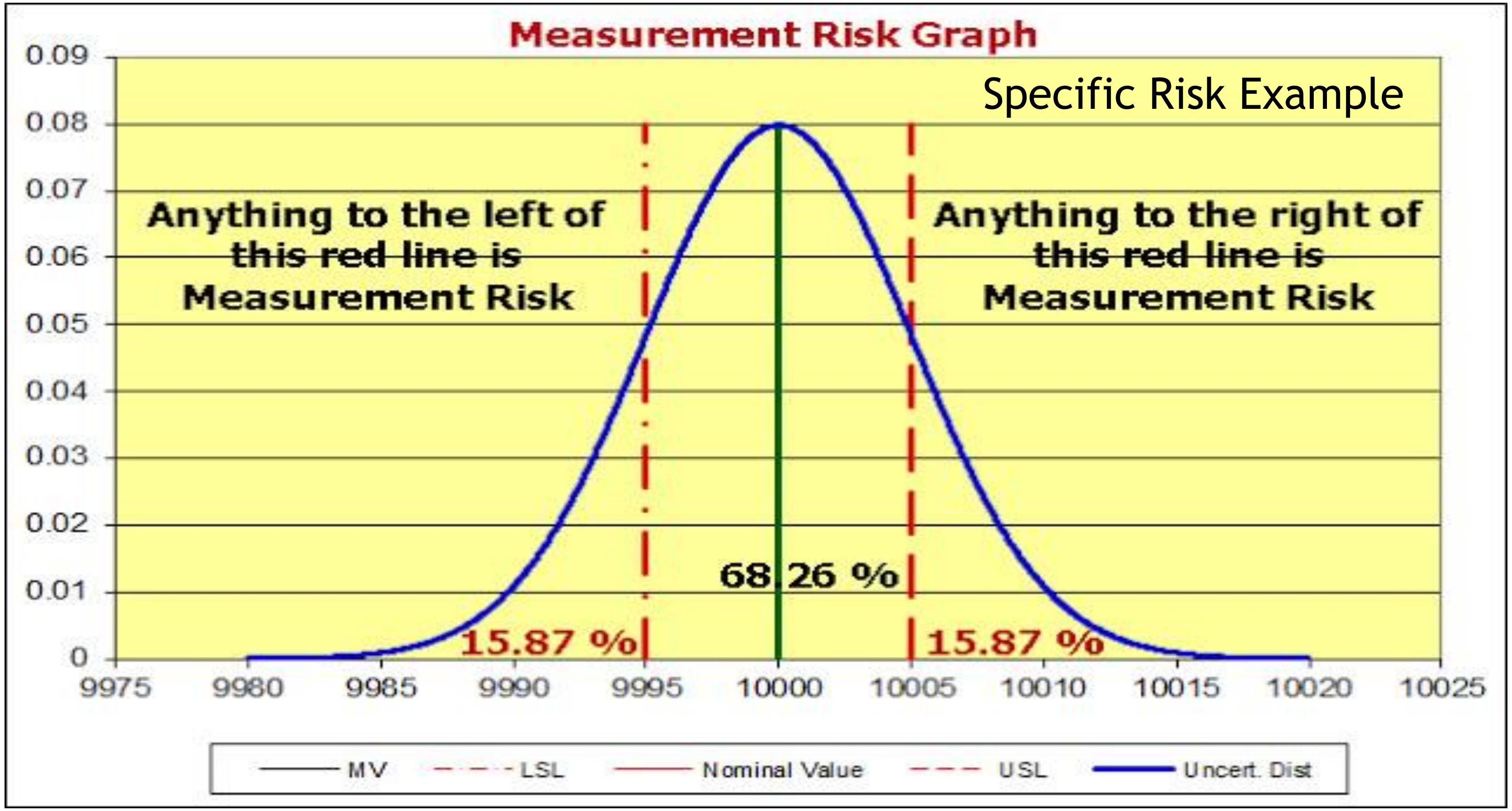
Why is Measurement Uncertainty Important?

ISO/IEC 17025: 2017 Section 7.8.6.1

If you want to say something is “in-tolerance” or passes calibration with measurement risk of less than X, you need to figure out what decision rule applies and how measurement uncertainty is accounted for.

ISO/IEC 17025: 2005 Section 5.10.4.2 When statements of compliance are made, the uncertainty of measurement shall be taken into account.

Measurement Decision Risk



ISO/IEC 17025: 2017 Section 3.7 defines a decision rule as a rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

A calibration laboratory cannot make a statement of conformity or "Pass" an instrument without violating ISO/IEC 17025:2017, as section 3.7 defines a Decision Rule as a rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement. Some may argue that you can take it into account by ignoring it.

To that end, can we all decide to take all red stop lights into account and start ignoring them?

Risk Through the Decades

- Since we are going to make measurement errors in testing a product for acceptability, we should perhaps place test limits somewhat different from the specification limits in order to guard against accepting too much bad material and also against rejecting too much good material. - 1954

- *Because of uncertainty in measurement, there is always the **risk** of incorrectly deciding whether or not an item conforms to a specified requirement based on the measured value of a property of the item. Such incorrect decisions are of two types: an item **accepted as conforming may actually be non-conforming**, and an item **rejected as non-conforming may actually be conforming**. -2012*

Types of Risk (Errors)

Type I - Type II Error			
		Calibration	
		In Tolerance (GOOD)	Out Of Tolerance (BAD)
Decision Made	Called In Tolerance - ACCEPT	(1-α) *Calibration Lab's Confidence (Probability of Correct Accept - PCA)*	β *Type II Error (Probability of False Accept - PFA)*
	Called Out of Tolerance - REJECT	α *Type I Error (Probability of False Reject - PFR)*	(1- β) *End User's Confidence (Probability of Correct Reject - PCR)*

Types of Risk (Errors)

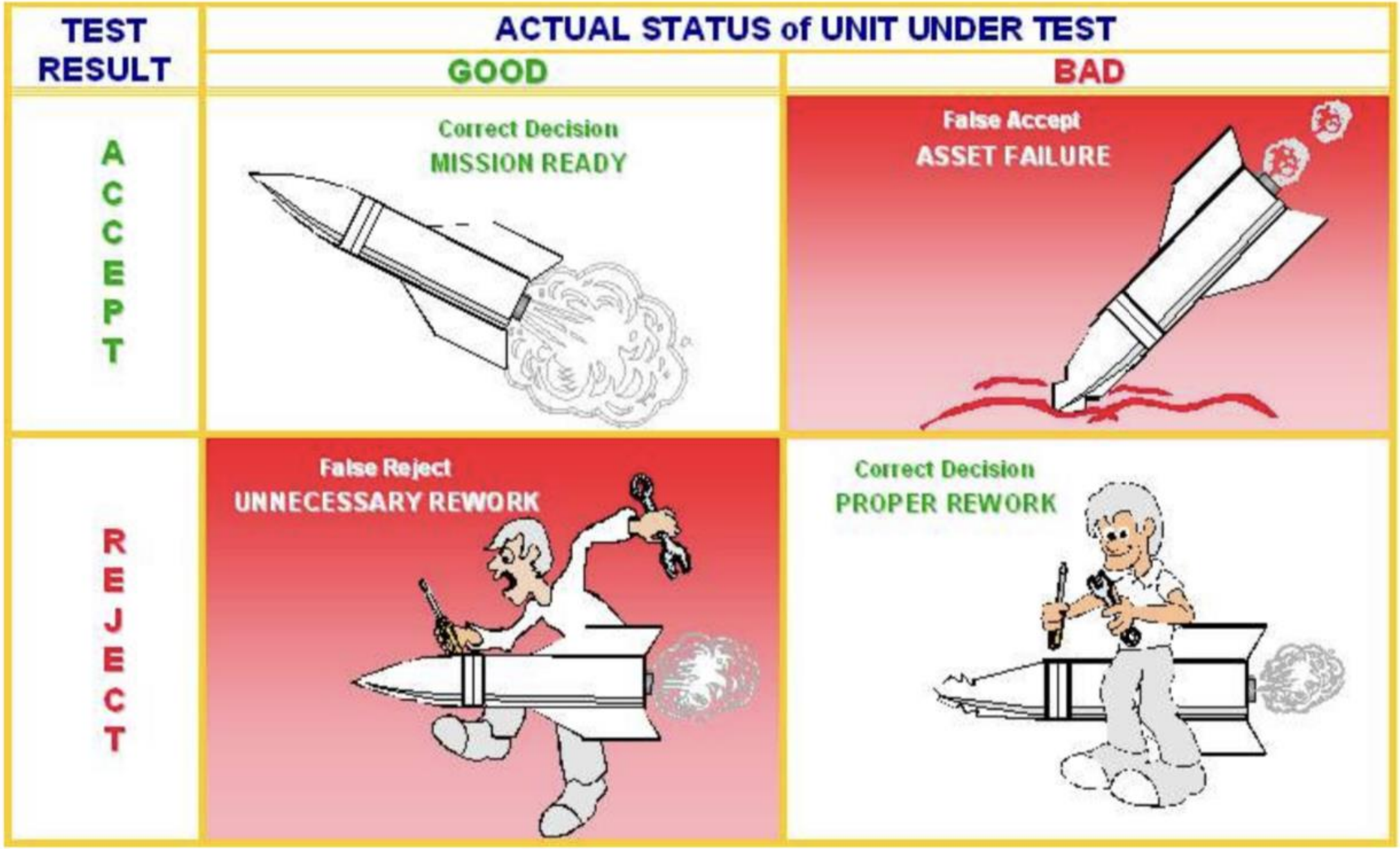


Image from NAVSEA (asq711.org)

(PFA)

PFA – Probability of False Accept (Consumers Risk, False-Accept Risk, Type *II error*)

- There are two types of False-Accept risks- “unconditional” & “conditional” risks.
- An Unconditional False (Global)-Accept Risk is the average risk for a population of calibrated devices (appropriate for managing many instruments)
- A Conditional (Specific) False-Accept Risk is appropriate when dealing with a specific instrument – typically a recalibration scenario.

PFR – Probability of False Reject (Producers Risk, False-Reject Risk, Type *I error*)

- One must note that increasing Guard-band for reducing the False-Accept risk (Consumer’s risk) disproportionately increases the False-Reject risk (Producer’s risk)

(PFA)

Probability of False Acceptance (PFA) could be altered by fine-tuning of calibration system control tools like:

- Measurement reliability
- Calibration intervals
- Calibration process uncertainty
- Calibration adjustments
- Guard-bands

From: Guard-banding Methods-An Overview

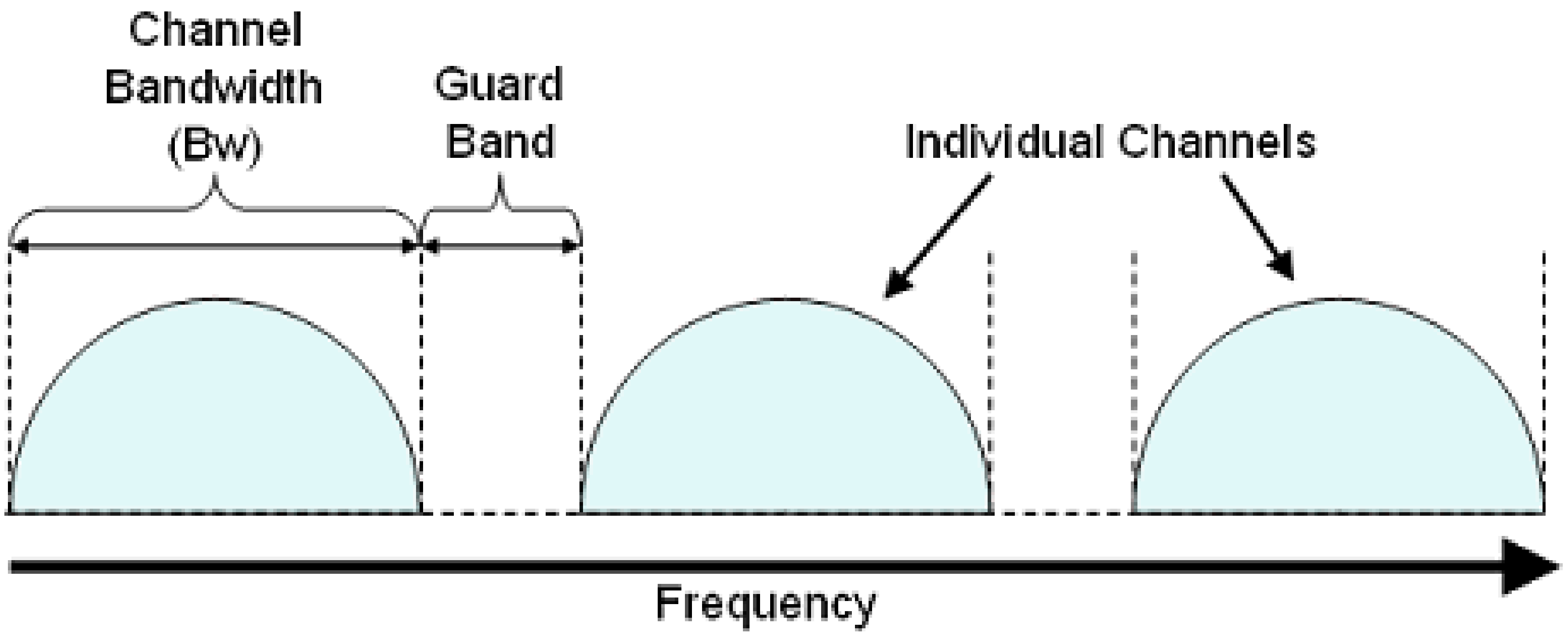
Guidelines on Decision Rules and Statements of Conformity

ILAC-G8:09/2019

Common Definitions ILAC G8

- **Tolerance Limit (*TL*) (Specification Limit)** specified upper or lower bound of permissible values of a property.
- **Measured Quantity Value** quantity value represents a measured result.
- **Acceptance Limit (*AL*)** specified upper or lower bound of permissible measured quantity values.
  - LSL – Lower Specification Limit
  - USL – Upper Specification Limit
- **Guard Band (*w*)** interval between a tolerance limit and a corresponding acceptance limit where length $w=|TL-AL|$.
- **Decision Rule** that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement. *(ISO/IEC 17025:2017 3.7 a rule that describes how measurement uncertainty will be accounted for when stating conformity with a specified requirement).*
- **Test Uncertainty Ratio (*TUR*)** the ratio of the tolerance, *TL*, of a measurement quantity divided by the 95% expanded measurement uncertainty of the measurement process where $TUR=TL/U$.

Guard banding



Bandwidth (Bw) = 2 / Symbol Rate (Rs)

Guard banding /PFA

- As used in the National Standard, a guard band is used to change the criteria for making a measurement decision, such as pass or fail, from some tolerance or specification limits to achieve a defined objective, such as a 2 % (Actually 2.275 %) probability of false accept.
- The offset may either be added to or subtracted from the decision value to achieve this objective.

Guard banding/PFA

- False accepts can result in "reduced end-item function or capacity, mission loss or compromise, loss of life, damaged corporate reputation, warranty expenses, shipping and associated costs for returned items, loss of future sales, punitive damages, legal fees, etc." (NASA Reference Publication 1342, Metrology – Calibration and Measurement Processes Guidelines).

Types of Risk Scenarios

- It is important to evaluate your decision rules based on the appropriate type of risk.
- This means if we have enough data from a population of like or similar instruments, we might consider using a global risk-based method.
- If we do not have population data or only meager information, some might argue that we can only use a more conservative bench level or specific risk approach

Types of Risk Scenarios

ASME B89.7.4.1-2005 describes both risk levels well

- Specific Risk or Bench Level risk mitigation can be thought of as “controlling the quality of the workpieces,” while program level risk strategies are described as “controlling the average quality of work pieces.”
- Bench level being instantaneous liability at the time of the measurement and program level is more about the average probability that incorrect acceptance decisions will be made based on historical data

Specific Risk

Specific Risk (also called bench-level risk) is based on a specific measurement result.

- It triggers a response based on measurement data gathered at the time of the test.
- It may be characterized by one or two probability distributions, depending on the method.
- Any representation with only one probability distribution is always a specific risk method.

Specific Risk is that we are testing an instrument when we do not have a high enough sample size or information other than where the result is located in relation to the tolerance requested and calculate our uncertainty correctly to calculate the false accept risk.

Specific Risk

From ILAC G8 section 5.3 If the laboratory only measures a single instrument and has no history of calibration results for that serial number, or if it has no information on the behaviour of that model as a population, that can be considered to be a situation with “meagre prior information” (see 7.2.2 of JCGM 106 [2]). Some take the view that when a laboratory receives an instrument for calibration (and subsequent verification to manufacturer’s tolerance) with meagre prior information, that the laboratory can only provide specific risks.

Statement of Conformity

When performing a measurement and subsequently making a statement of conformity, for example, in or out-of-tolerance to the manufacturer's specifications or Pass/Fail to a particular requirement, there are two possible outcomes:

a. The result is reported as conforming with the specification

b. The result is reported as not conforming with the specification

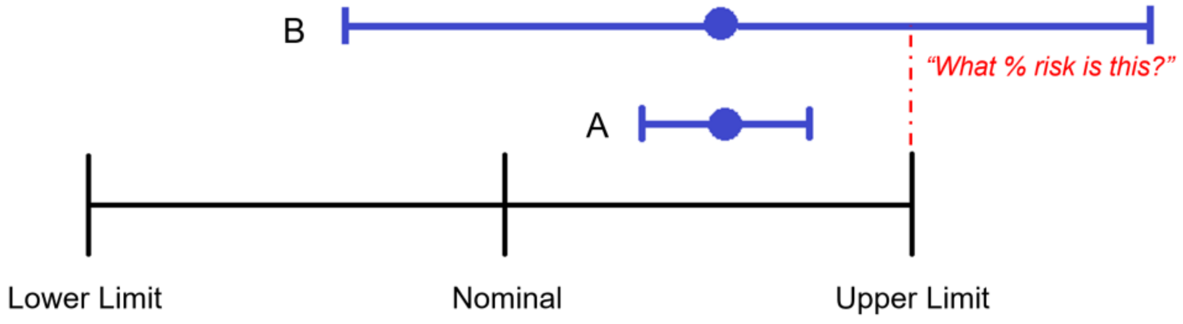
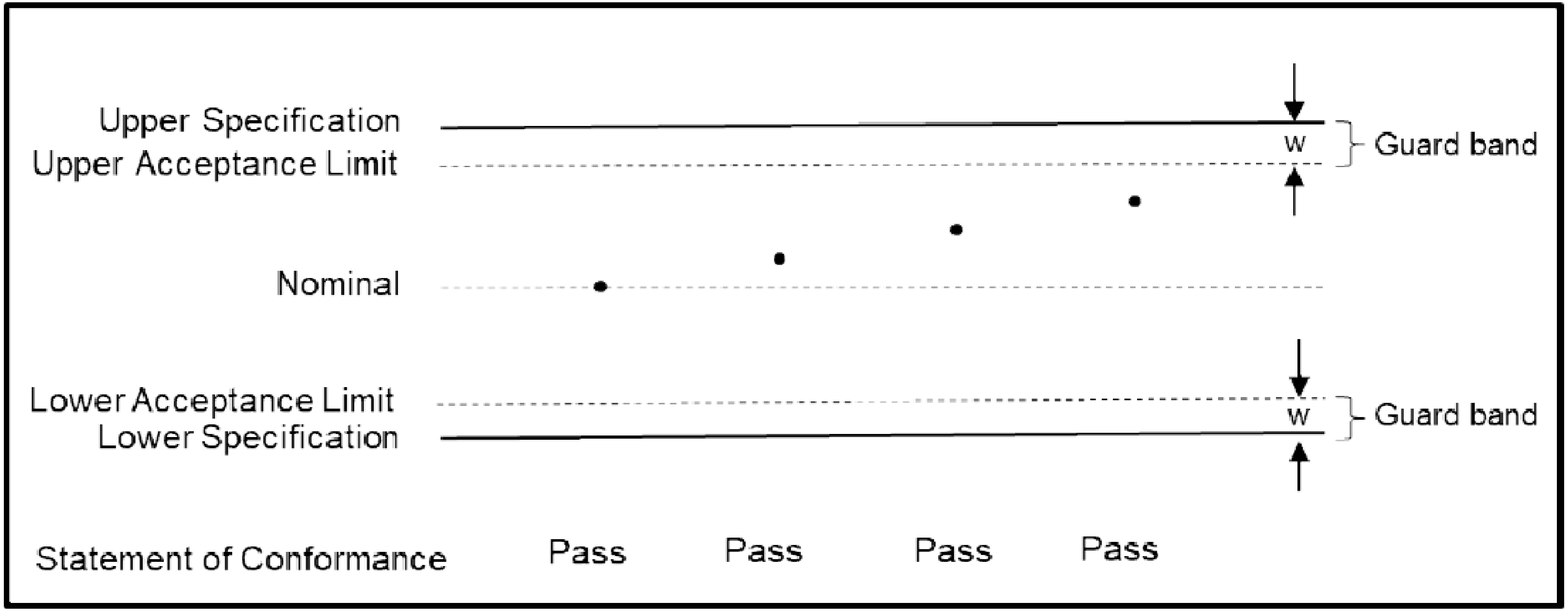


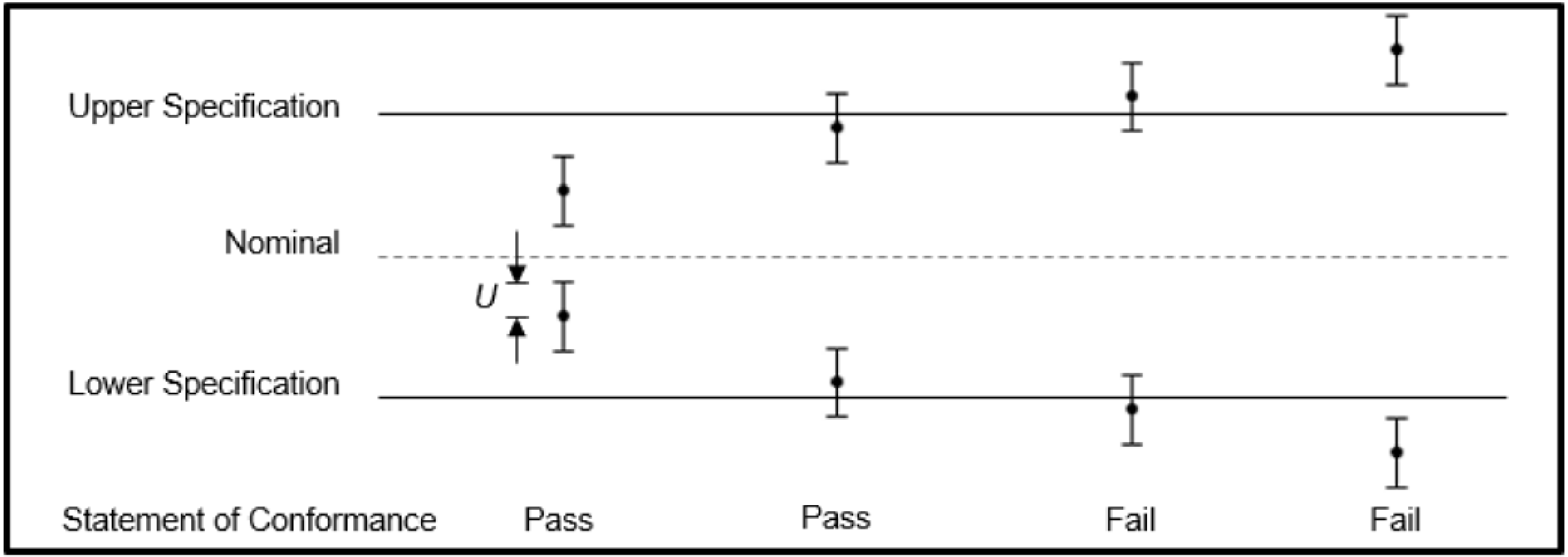
Illustration of Measurement Decision Risk

Guard Band



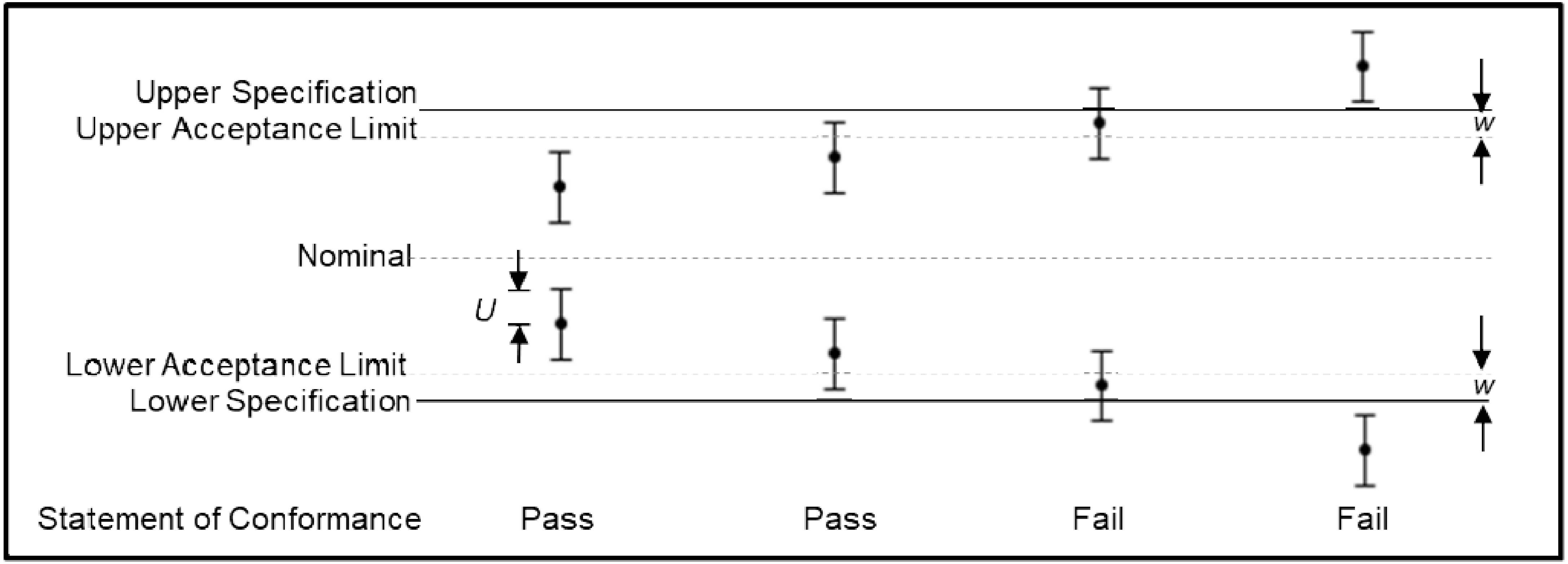
Upper Specification
Upper Acceptance Limit
W
Guard band
Nominal
Lower Acceptance Limit
Lower Specification
W
Guard band
Statement of Conformance
Pass
Pass
Pass
Pass

Simple Binary Acceptance



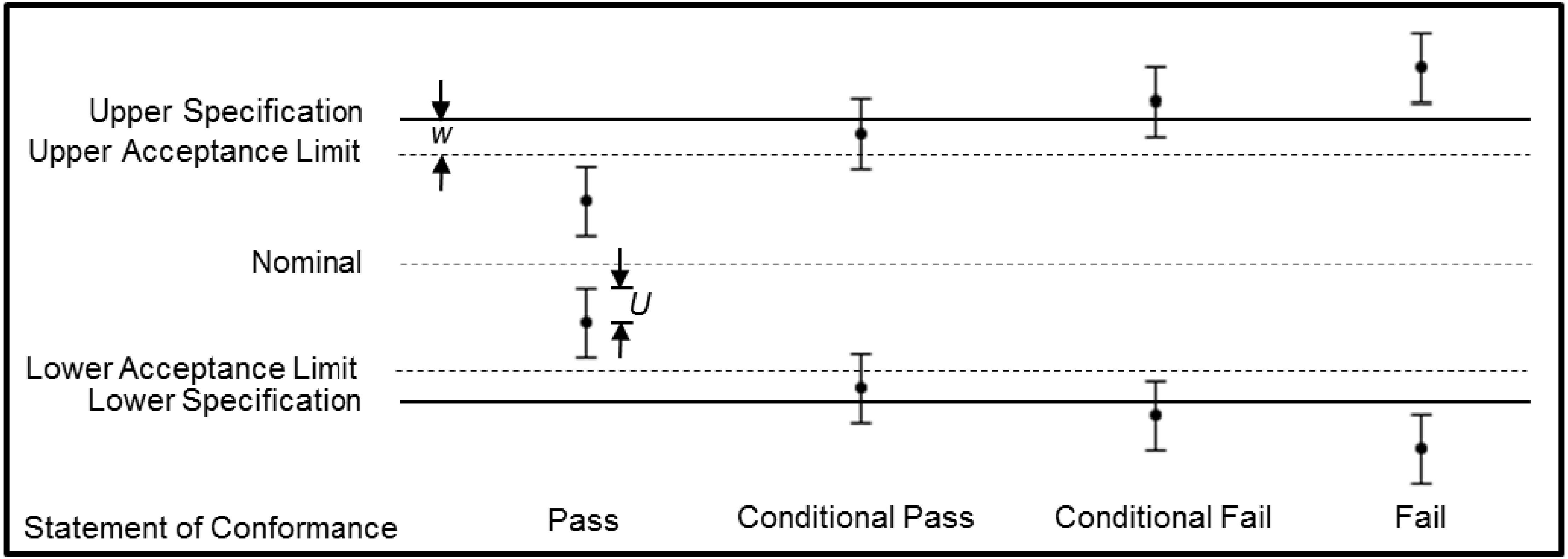
U = 95% expanded measurement uncertainty

Binary Statement with Guard Band



U = 95% expanded measurement uncertainty

Non-Binary Statement with Guard Band



U = 95% expanded measurement uncertainty


Can you calibrate my device and tell me if it's good to use for another year?
CAL LAB 1 DOES THE CALIBRATION AND ISSUES REPORT
The instrument may be in tolerance, but we're not sure
Calibrations R Us
CAL LAB 2 DOES THE CALIBRATION AND ISSUES REPORT
The instrument is out of tolerance, but it may still be ok for your application
Malarkey Cal
ELIMINATE THE GUESSWORK
We will meet your needs per ISO/IEC 17025, adjust the device if requested, and take measurement uncertainty into account.
Morehouse
THE FORCE IN CALIBRATION SINCE 1925

ASME B89.7.3.1-2001 – Specific Risk

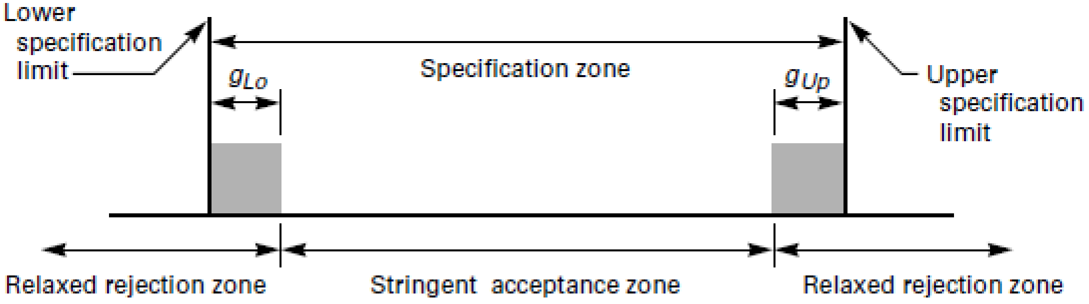
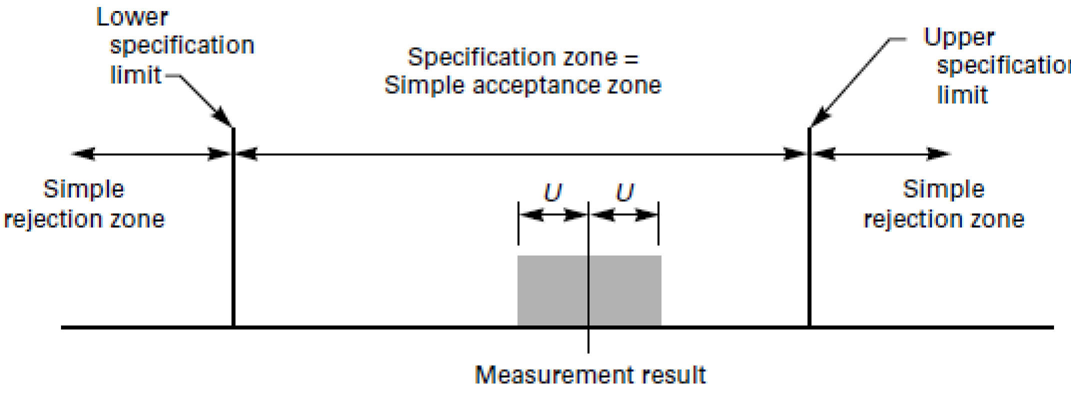
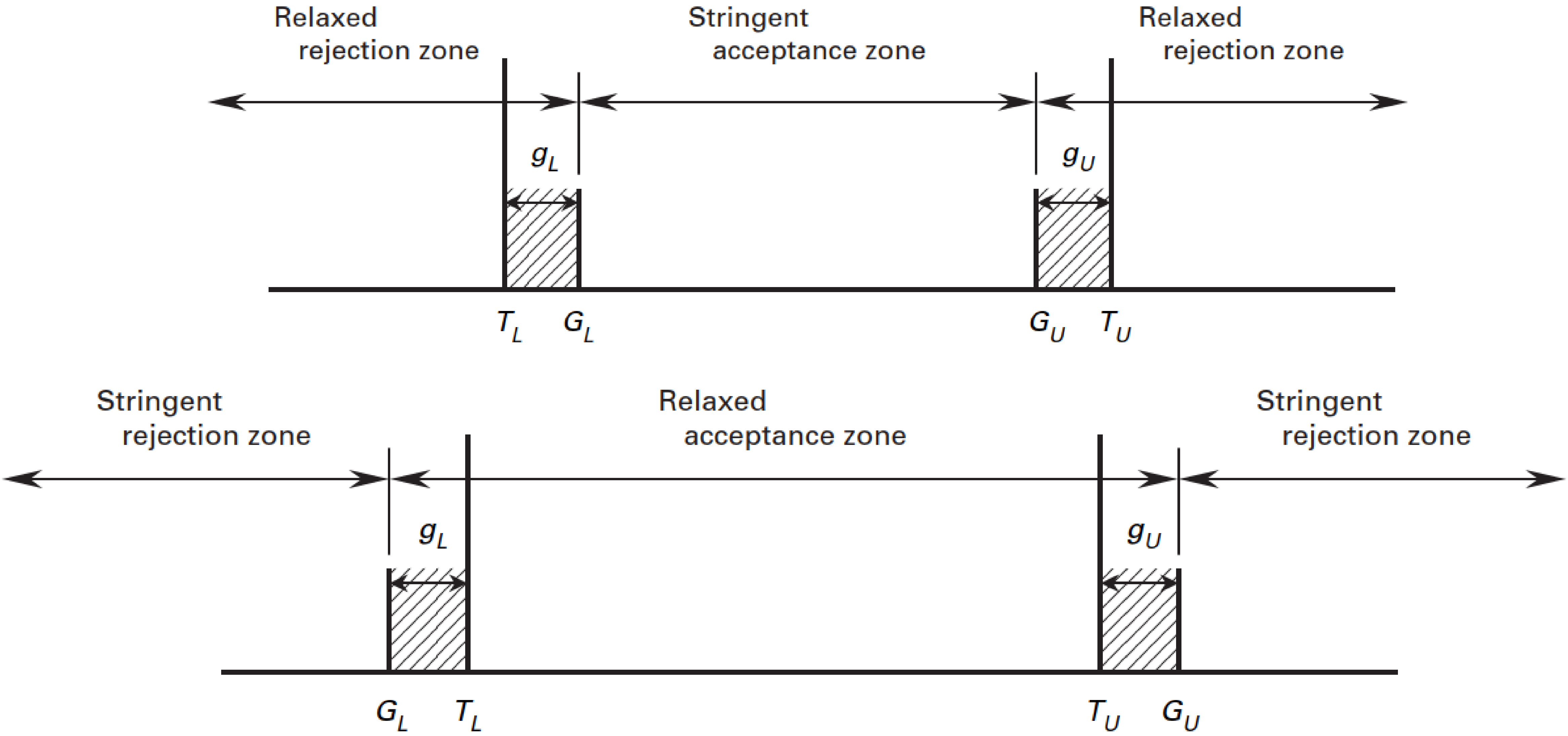


FIG. 1 AN EXAMPLE OF GUARD BANDS USED FOR CREATING A BINARY DECISION RULE WITH STRINGENT ACCEPTANCE AND RELAXED REJECTION ZONES

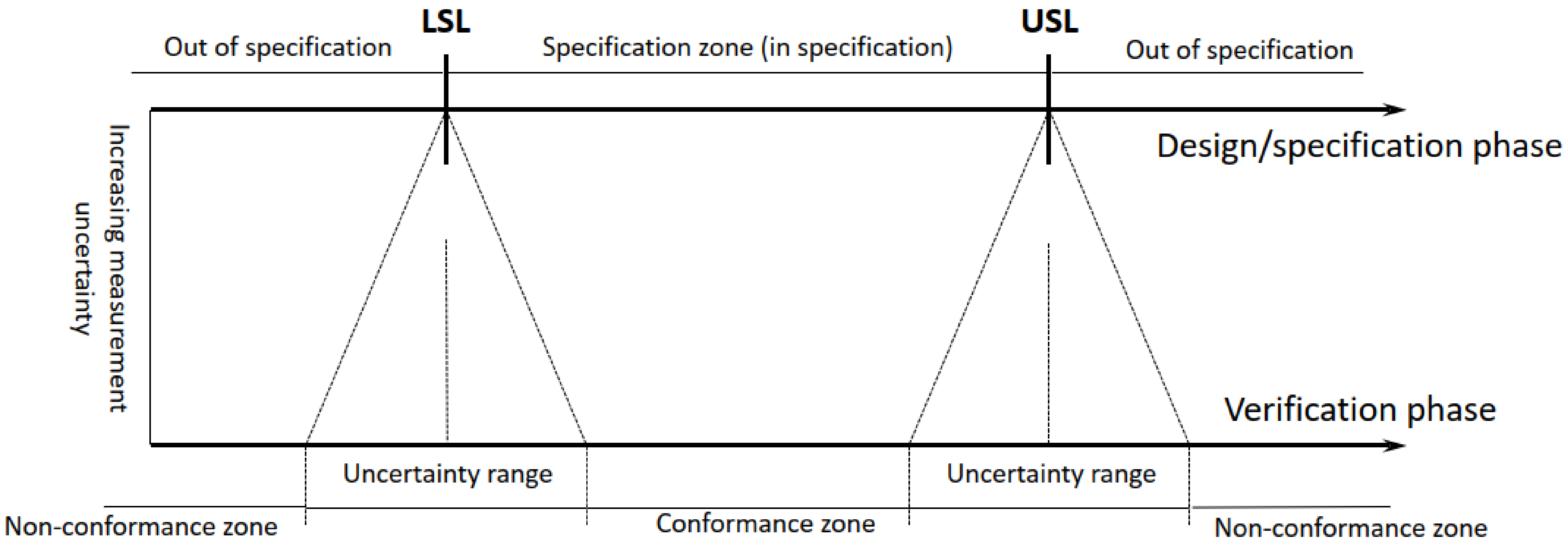


GENERAL NOTE: The measurement uncertainty interval is of width $2U$, where U is the expanded uncertainty, and the uncertainty interval is no larger than one-fourth the product's specification zone. The measurement result shown verifies product acceptance.

ASME B89.7.4.1-2005 – Specific Risk



The Size of Acceptance limits is Determined by the Measurement Uncertainty and Desired Risk Level.



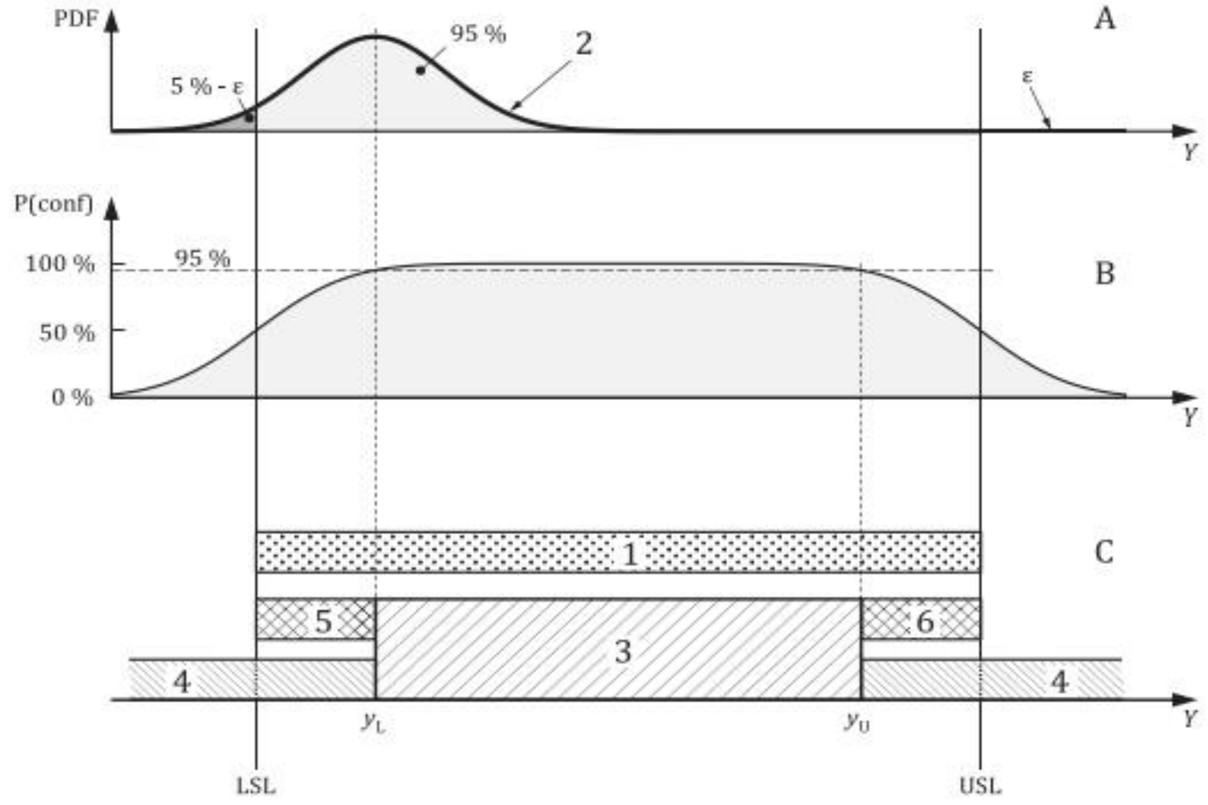
ISO 14253-1:2017

ISO 14253-1:2017

From ISO 14253-1:2017

If the probability density function of the measured values is normally distributed with a standard deviation significantly smaller than the size of the specification zone, the default conformance probability limit of 95 % corresponds to a guard band factor of 1,65, equivalent to a guard band width 1,65 times the combined standard uncertainty.

Note: This equates to 0.825 if using two times the standard uncertainty



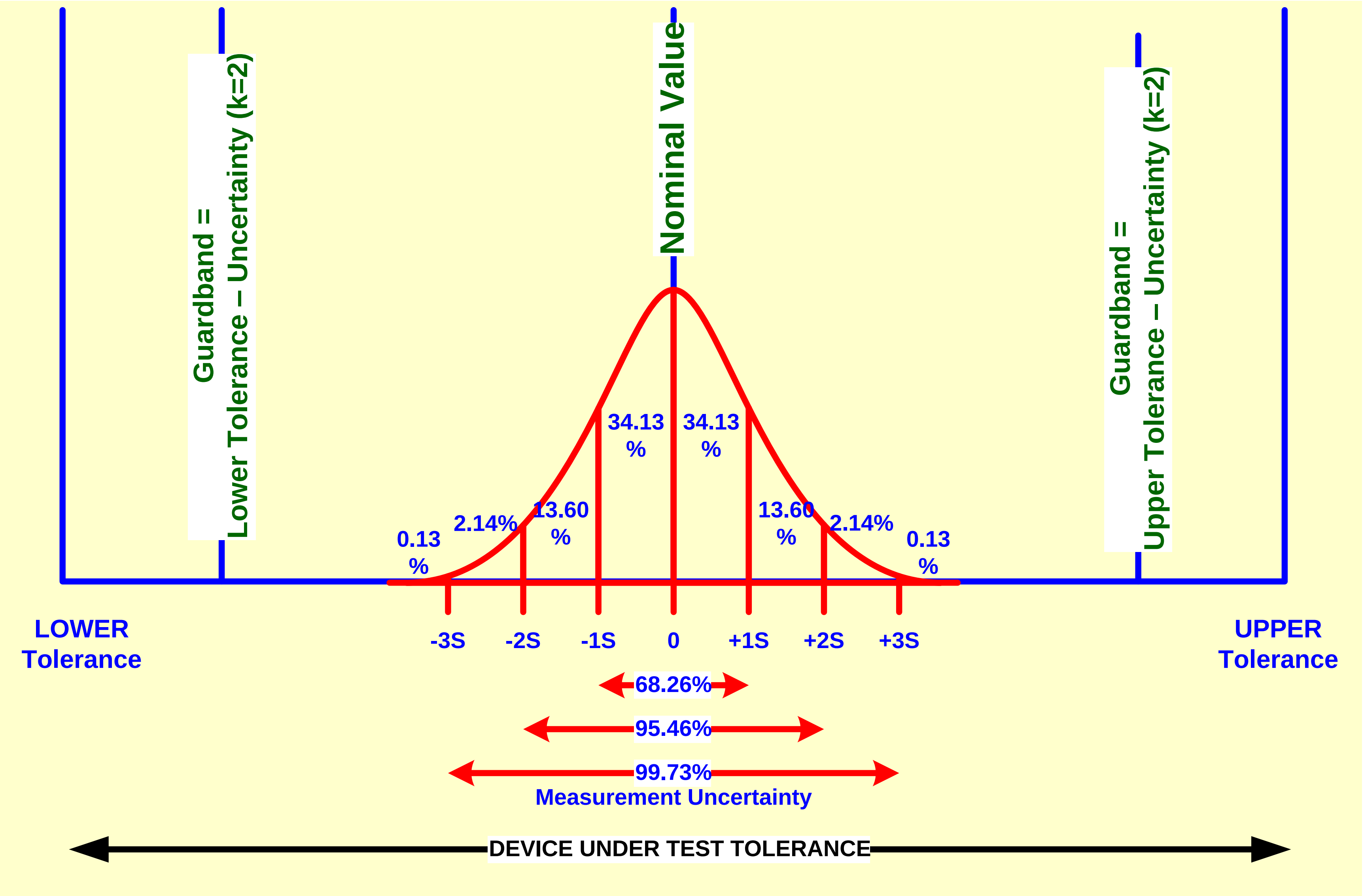
Key

A PDF of measured value y_L = LSL + g_{LA}
B conformance probability
C acceptance zone when verifying conformity
1 specification zone
2 probability density function of a measured value at LSL + g_{LA}
3 default acceptance zone
4 default rejection zone
5 guard band g_{LA} at lower specification limit
6 guard band g_{UA} at upper specification limit
y_L smallest measured value for which conformity can be verified
y_U largest measured value for which conformity can be verified
Y measured values
LSL lower specification limit
USL upper specification limit
ε infinitesimal rest

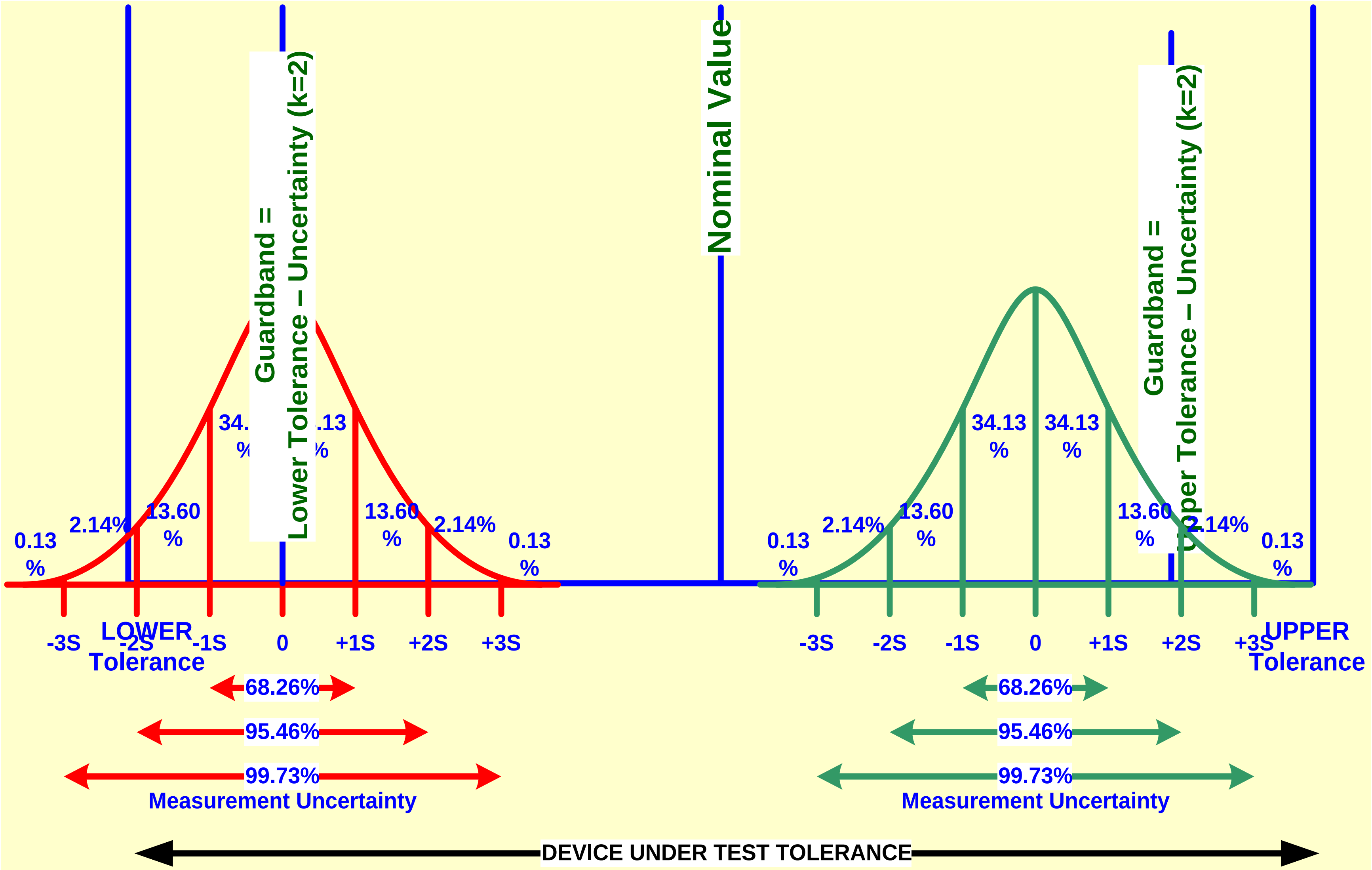
Decision Rule Examples – Specific Risk (ILAC G8)

Decision rule	**Guard band w**	**Specific Risk**
6 sigma	3 U	< 1 ppm PFA
3 sigma	1,5 U	< 0.16% PFA
ILAC G8:2009 rule	1 U	< 2.5% PFA
ISO 14253-1:2017 [5]	0,83 U	< 5% PFA
Simple acceptance	0	< 50% PFA
Uncritical	$-U$	Item rejected for measured value greater than $AL = TL + U$ < 2.5% PFR
Customer defined	$r\,U$	Customers may define arbitrary multiple of r to have applied as guard band.

Instrument Measurement Uncertainty Guard Banding



Instrument Measurement Uncertainty Guard Banding



MHFORCE Morehouse
THE FORCE IN CALIBRATION SINCE 1925

z Distribution Table

$$z = \frac{x - \mu}{\sigma}$$

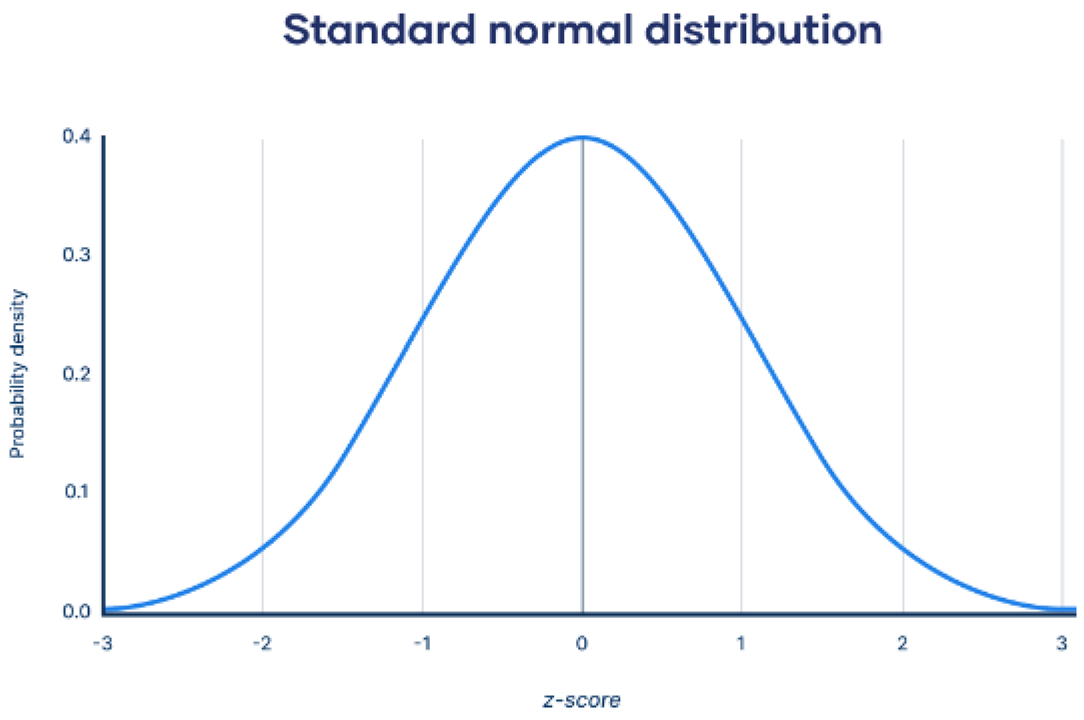
Areas Under the Normal Curve
z - Table

z	0.00	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09
0.0	0.00000	0.00399	0.00798	0.01197	0.01595	0.01994	0.02392	0.02790	0.03188	0.03586
0.1	0.03983	0.04380	0.04776	0.05172	0.05567	0.05962	0.06356	0.06749	0.07142	0.07535
0.2	0.07926	0.08317	0.08706	0.09095	0.09483	0.09871	0.10257	0.10642	0.11026	0.11409
0.3	0.11791	0.12172	0.12552	0.12930	0.13307	0.13683	0.14058	0.14431	0.14803	0.15173
0.4	0.15542	0.15910	0.16276	0.16640	0.17003	0.17364	0.17724	0.18082	0.18439	0.18793
0.5	0.19146	0.19497	0.19847	0.20194	0.20540	0.20884	0.21226	0.21566	0.21904	0.22240
0.6	0.22575	0.22907	0.23237	0.23565	0.23891	0.24215	0.24537	0.24857	0.25175	0.25490
0.7	0.25804	0.26115	0.26424	0.26730	0.27035	0.27337	0.27637	0.27935	0.28230	0.28524
0.8	0.28814	0.29103	0.29389	0.29673	0.29955	0.30234	0.30511	0.30785	0.31057	0.31327
0.9	0.31594	0.31859	0.32121	0.32381	0.32639	0.32894	0.33147	0.33398	0.33646	0.33891
1.0	0.34134	0.34375	0.34614	0.34849	0.35083	0.35314	0.35543	0.35769	0.35993	0.36214
1.1	0.36433	0.36650	0.36864	0.37076	0.37286	0.37493	0.37698	0.37900	0.38100	0.38298
1.2	0.38493	0.38686	0.38877	0.39065	0.39251	0.39435	0.39617	0.39796	0.39973	0.40147
1.3	0.40320	0.40490	0.40658	0.40824	0.40988	0.41149	0.41309	0.41466	0.41621	0.41774
1.4	0.41924	0.42073	0.42220	0.42364	0.42507	0.42647	0.42785	0.42922	0.43056	0.43189
1.5	0.43319	0.43448	0.43574	0.43699	0.43822	0.43943	0.44062	0.44179	0.44295	0.44408
1.6	0.44520	0.44630	0.44738	0.44845	0.44950	0.45053	0.45154	0.45254	0.45352	0.45449
1.7	0.45543	0.45637	0.45728	0.45818	0.45907	0.45994	0.46080	0.46164	0.46246	0.46327
1.8	0.46407	0.46485	0.46562	0.46638	0.46712	0.46784	0.46856	0.46926	0.46995	0.47062
1.9	0.47128	0.47193	0.47257	0.47320	0.47381	0.47441	0.47500	0.47558	0.47615	0.47670
2.0	0.47725	0.47778	0.47831	0.47882	0.47932	0.47982	0.48030	0.48077	0.48124	0.48169
2.1	0.48214	0.48257	0.48300	0.48341	0.48382	0.48422	0.48461	0.48500	0.48537	0.48574
2.2	0.48610	0.48645	0.48679	0.48713	0.48745	0.48778	0.48809	0.48840	0.48870	0.48899
2.3	0.48928	0.48956	0.48983	0.49010	0.49036	0.49061	0.49086	0.49111	0.49134	0.49158
2.4	0.49180	0.49202	0.49224	0.49245	0.49266	0.49286	0.49305	0.49324	0.49343	0.49361
2.5	0.49379	0.49396	0.49413	0.49430	0.49446	0.49461	0.49477	0.49492	0.49506	0.49520
2.6	0.49534	0.49547	0.49560	0.49573	0.49585	0.49598	0.49609	0.49621	0.49632	0.49643
2.7	0.49653	0.49664	0.49674	0.49683	0.49693	0.49702	0.49711	0.49720	0.49728	0.49736
2.8	0.49744	0.49752	0.49760	0.49767	0.49774	0.49781	0.49788	0.49795	0.49801	0.49807
2.9	0.49813	0.49819	0.49825	0.49831	0.49836	0.49841	0.49846	0.49851	0.49856	0.49861
3.0	0.49865	0.49869	0.49874	0.49878	0.49882	0.49886	0.49889	0.49893	0.49896	0.49900
3.5	0.49977	0.49978	0.49978	0.49979	0.49980	0.49981	0.49981	0.49982	0.49983	0.49983
4.0	0.49997	0.49997	0.49997	0.49997	0.49997	0.49997	0.49998	0.49998	0.49998	0.49998
4.5	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000
5.0	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000
5.5	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000
6.0	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000	0.50000
z	0.00	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09

z Distribution

z-distribution is a standardized version of the normal distribution with a mean of 0 and a standard deviation of 1. It allows us to compare values and assess the significance of statistical results.

- The shape of the z-distribution is bell-shaped, with most values clustered around the mean of 0. The distribution is symmetric, meaning that the probabilities of obtaining values to the left and right of the mean are equal.
- The z-distribution is useful because it allows us to standardize and compare different values in a dataset. By converting individual values into z-scores, we can determine how many standard deviations a particular value is away from the mean. A positive z-score indicates a value above the mean, while a negative z-score indicates a value below the mean.

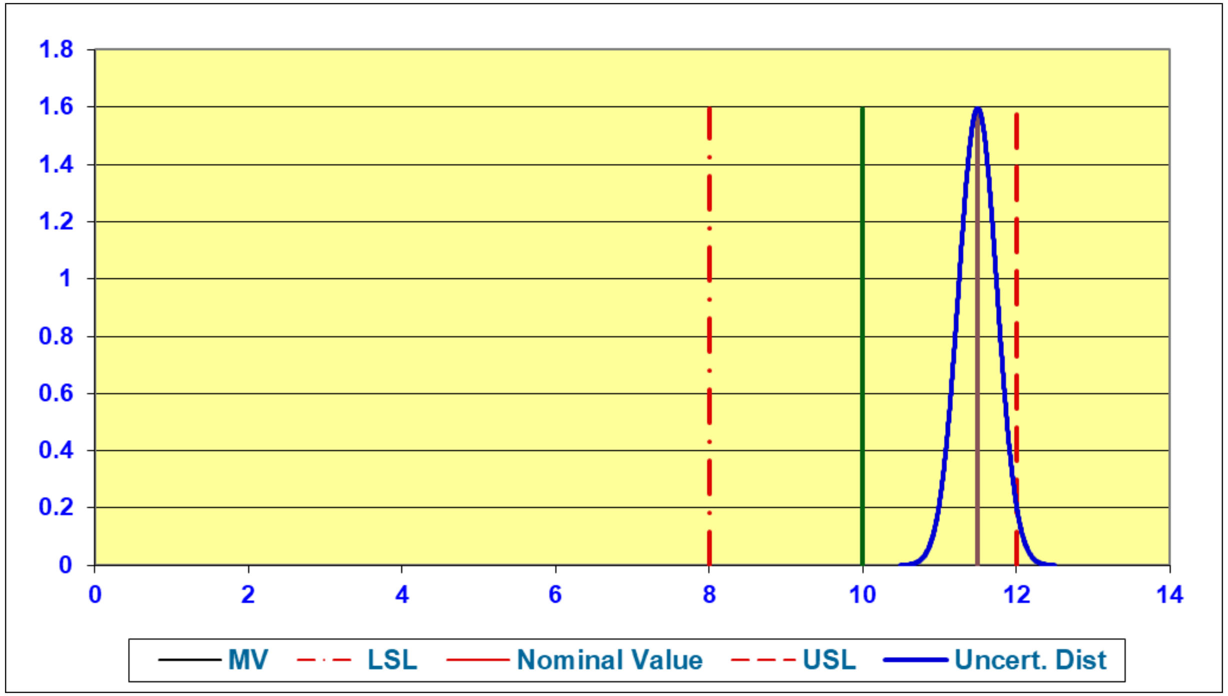


$z = \frac{x - \mu}{\sigma}$

Risk Calculation Exercise

(Using z – Distribution Table)

Nominal Value	10
Lower Specification Limit	8
Upper Specification Limit	12
Measured Value	11.5000
Std. Uncert. (k =1)	250.00E-3



$$z = \frac{x - \mu}{\sigma}$$

$\mu =$ Mean

$\sigma =$ Standard Deviation

x = Upper Specification Limit

μ = Measured Value

σ = standard uncertainty

$z = \frac{x - \mu}{\sigma}$

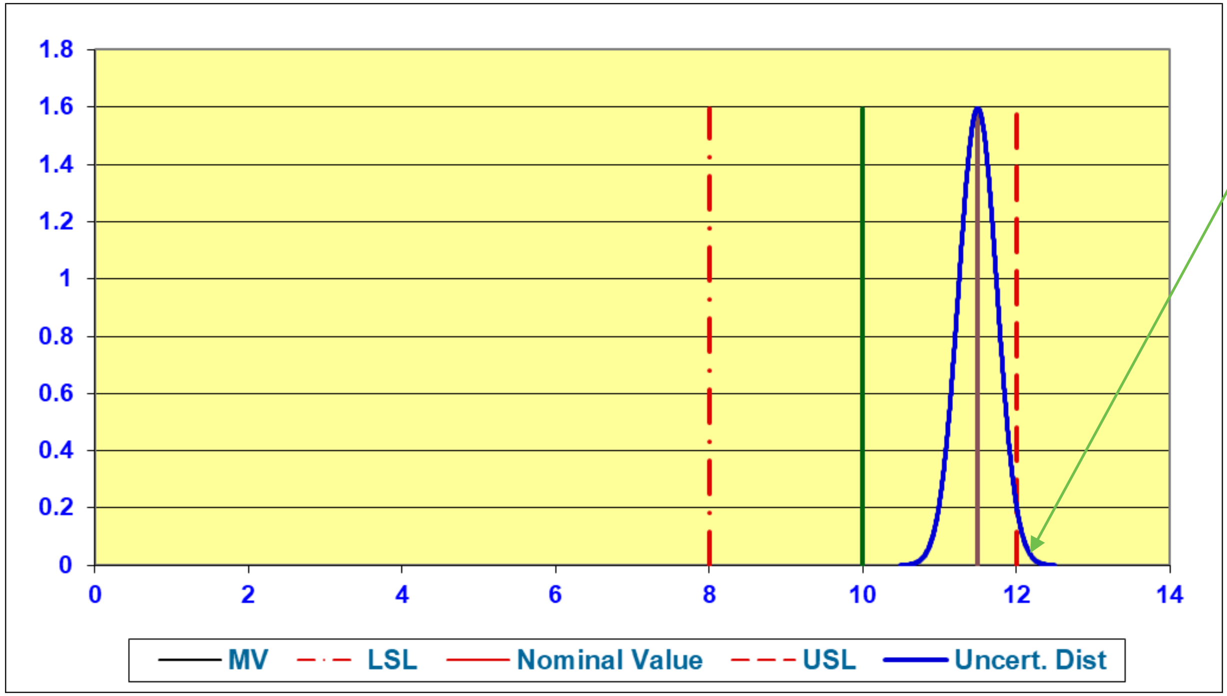
MHFORCE Morehouse THE FORCE IN CALIBRATION SINCE 1925

Risk Calculation Exercise

(Using z – Distribution Table)

Nominal Value	10
Lower Specification Limit	8
Upper Specification Limit	12
Measured Value	11.5000
Std. Uncert. (k =1)	250.00E-3

1. z = (12 - 11.5)/0.25 = 2.00
2. $z_{2.00}$ = 0.47725
3. (12-11.5)- 0.47725 = 0.02775 (2.775 %)



Areas Under the Normal Curve z - Table							
z	0.00	0.01	0.02	0.03	0.04	0.05	0.06
0.0	0.00000	0.00399	0.00798	0.01197	0.01595	0.01994	0.02392
0.1	0.03983	0.04380	0.04776	0.05172	0.05567	0.05962	0.06356
0.2	0.07926	0.08317	0.08706	0.09095	0.09483	0.09871	0.10257
0.3	0.11791	0.12172	0.12552	0.12930	0.13307	0.13683	0.14058
0.4	0.15542	0.15910	0.16276	0.16640	0.17003	0.17364	0.17724
0.5	0.19146	0.19497	0.19847	0.20194	0.20540	0.20884	0.21226
0.6	0.22575	0.22907	0.23237	0.23565	0.23891	0.24215	0.24537
0.7	0.25804	0.26115	0.26424	0.26730	0.27035	0.27337	0.27637
0.8	0.28814	0.29103	0.29389	0.29673	0.29955	0.30234	0.30511
0.9	0.31594	0.31859	0.32121	0.32381	0.32639	0.32894	0.33147
1.0	0.34134	0.34375	0.34614	0.34849	0.35083	0.35314	0.35543
1.1	0.36433	0.36650	0.36864	0.37076	0.37286	0.37493	0.37698
1.2	0.38493	0.38686	0.38877	0.39065	0.39251	0.39435	0.39617
1.3	0.40320	0.40490	0.40658	0.40824	0.40988	0.41149	0.41309
1.4	0.41924	0.42073	0.42220	0.42364	0.42507	0.42647	0.42785
1.5	0.43319	0.43448	0.43574	0.43699	0.43822	0.43943	0.44062
1.6	0.44520	0.44630	0.44738	0.44845	0.44950	0.45053	0.45154
1.7	0.45543	0.45637	0.45728	0.45818	0.45907	0.45994	0.46080
1.8	0.46407	0.46485	0.46562	0.46638	0.46712	0.46784	0.46856
1.9	0.47128	0.47193	0.47257	0.47320	0.47381	0.47441	0.47500
2.0	0.47725	0.47778	0.47831	0.47882	0.47932	0.47982	0.48030
2.1	0.48214	0.48257	0.48300	0.48341	0.48382	0.48422	0.48461

Risk Calculation Exercise (Using z – Distribution Table)

Risk Calculator	
Uppper Tolerance T_U	12.0000
Lower Tolerance T_L	8.0000
Nominal Value	10.0000
Measurement Unc um	0.2500
Measured Value xm	11.5000
Tolerance T	4.00
Z Upper	2.00
Z Lower	-14.00

$$z = \frac{x - \mu}{\sigma}$$

$\mu =$ Mean

$\sigma =$ Standard Deviation

Area Outside of USL
2.275%
Area Outside of LSL
0.000%

Risk Calculator			
K4	Uppper Tolerance T_U	12	
K5	Lower Tolerance T_L	8	
K6	Nominal Value	10	
K7	Measurement Unc um	0.25	
K8	Measured Value xm	11.5	
	Tolerance T	=K4-K5	Area Outside of USL
	Z Upper	=(K4-K8)/K7	=1-NORM.S.DIST(K10,TRUE)
			Area Outside of LSL
	Z Lower	=(K5-K8)/K7	=NORM.S.DIST(K12,TRUE)

Example – Radar Gun

EXAMPLE 1 Speed limit enforcement
In highway law enforcement, the speed of motorists is measured by police using devices such as radars and laser guns. A decision to issue a speeding ticket, which may potentially lead to an appearance in court, must be made with a high degree of Confidence that the speed limit has been exceeded.

If we know that we can only win a court case if there is a 99.9 % probability that our speed limit has been exceeded, when can we write a ticket?

Example – Radar Gun

Speed Limit is 65 mph with an
u_m of 2 %
u_m = 0.02
Probability = 99.9 %
T_U = 65

Guarded Rejection	
Probability (%)	99.90%
Nominal Value	75.0000
Measurement Unc um	0.0200
99.9 % Acceptence Threshold	79.941
Probability of Making a Wrong Decision	0.10%

What is V_{max} or the speed someone has to be going to receive a speeding ticket with 99.9 % probability of actually speeding?
Vmax = T_U / 1 – 0.02 z

ANSWER?

What about 75 mph?
Vmax = 65 / 1 -0.02 (3.090) = 69.28 mph

Vmax = 75 / 1 -0.02 (3.090) = 79.94 mph

$$P_c = \Phi(z) = 99.9\,\%$$
$$z = \Phi^{-1}(0.999) = 3.09$$

=NORMSINV(Probability)/1

Probability Table (single sided)	
Probability	Z-Value
0.5000	0.000
0.7000	0.524
0.7500	0.674
0.8500	1.036
0.9000	1.282
0.9500	1.645
0.9545	1.690
0.9773	2.000
0.9800	2.054
0.9900	2.326
0.9990	3.090
1.0000	5.998

Excel Function

NORMDIST function

Returns the normal distribution for the specified mean and standard deviation. This function has a very wide range of applications in statistics, including hypothesis testing.

Syntax

NORMDIST(x,mean,standard_dev,cumulative)

The NORMDIST function syntax has the following arguments:

- **X** Required. The value for which you want the distribution.
- **Mean** Required. The arithmetic mean of the distribution.
- **Standard_dev** Required. The standard deviation of the distribution.
- **Cumulative** Required. A logical value that determines the form of the function. If cumulative is TRUE, NORMDIST returns the cumulative distribution function; if FALSE, it returns the probability mass function.

Excel Function

Remarks

- If mean or standard_dev is nonnumeric, NORM.DIST returns the #VALUE! error value.
- If standard_dev ≤ 0, NORM.DIST returns the #NUM! error value.
- If mean = 0, standard_dev = 1, and cumulative = TRUE, NORM.DIST returns the standard normal distribution, NORM.S.DIST.
- The equation for the normal density function (cumulative = FALSE) is:

$$f(x;\mu,\sigma) = \frac{1}{\sqrt{2\pi}\sigma} e^{-\left(\frac{(x-\mu)^2}{2\sigma^2}\right)}$$

- When cumulative = TRUE, the formula is the integral from negative infinity to x of the given formula.

Building the Specific Risk Spreadsheet

	B	C
2		No Guard Band
3	Nominal Value	10
4	Lower Specification Limit	8
5	Upper Specification Limit	12
6	Measured Value	10
7	Std. Uncert. (k=1)	0.25
8	Total Risk	0.000%
9	Upper Limit Risk	0.000%
10	Lower Limit Risk	0.000%

W = 0

Total Risk	=SUM(C9:C10)
Upper Limit Risk	=NORMDIST(C6,C5,C7,1)
Lower Limit Risk	=1-NORMDIST(C6,C4,C7,1)

Calculating a Guard Band (w)

$w = r * U_{95}$

Risk Calculator	
Uppper Tolerance T_U	1500.2000
Lower Tolerance T_L	1499.8000
Nominal Value	1500.1800
Measurement Unc um	0.0400
Measured Value xm	1500.1069
Tolerance T	0.40
Probability of Conformance (p_c)	99.003%
Probability of NonConformance ($1 - p_c$)	0.997%
Setting the Guard Band Upper and Lower p_c	
Select Desired Conformance Probability	0.990
Risk if within G_U & G_L	1.00%
h U (GB Multiplier)	1.1632
Guard Band Upper G_u	1500.1069
Guard Band Lower G_L	1499.8931

Conformance Probability Table	
Conformance Probability , P_c	Guard Band Multipier, *r* Two Sided
0.0668	-0.750
0.1590	-0.499
0.3085	-0.250
0.5000	0.000
0.6914	0.250
0.8000	0.421
0.8500	0.518
0.9000	0.641
0.9500	0.822
0.9545	0.845
0.9773	1.000
0.9800	1.027
0.9900	1.163
0.9990	3.090
1.0000	5.998

Look up the appropriate r value for the Conformance Probability (P_C)

Calculating a Guard Band (w)

w = r * U_{95}

Risk Calculator	
Uppper Tolerance T_U	1500.2000
Lower Tolerance T_L	1499.8000
Nominal Value	1500.1800
Measurement Unc um	0.0400
Measured Value xm	1500.1069
Tolerance T	0.40

Probability of Conformance (p_c)	99.003%
Probability of NonConformance (1 - p_c)	0.997%

Setting the Guard Band Upper and Lower p_c	
Select Desired Conformance Probability	0.990
Risk if within G_U & G_L	1.00%
h U (GB Multiplier)	1.1632
Guard Band Upper G_u	1500.1069
Guard Band Lower G_L	1499.8931

Conformance Probability Table	
Conformance Probability , P_c	Guard Band Multipier, *r* Two Sided
0.0668	-0.750
0.1590	-0.499
0.3085	-0.250
0.5000	0.000
0.6914	0.250
0.8000	0.421
0.8500	0.518
0.9000	0.641
0.9500	0.822
0.9545	0.845
0.9773	1.000
0.9800	1.027
0.9900	1.163
0.9990	3.090
1.0000	5.998

w = 1.163 * (2 * MU)
= 1.1632 *(0.08) = **0.09304**

G_U = T_U – w
1500.2 – 0.09304 = 1500.1069
G_L = T_L + w
1499.8 + 0.09304 = 1499.8931

Instrument Measurement Uncertainty Guard Banding

Risk Calculator	
Upper Tolerance T_U	1500.2000
Lower Tolerance T_L	1499.8000
Nominal Value	1500.0000
Measurement Unc um	0.0400
Measured Value xm	1500.1069
Tolerance T	0.40

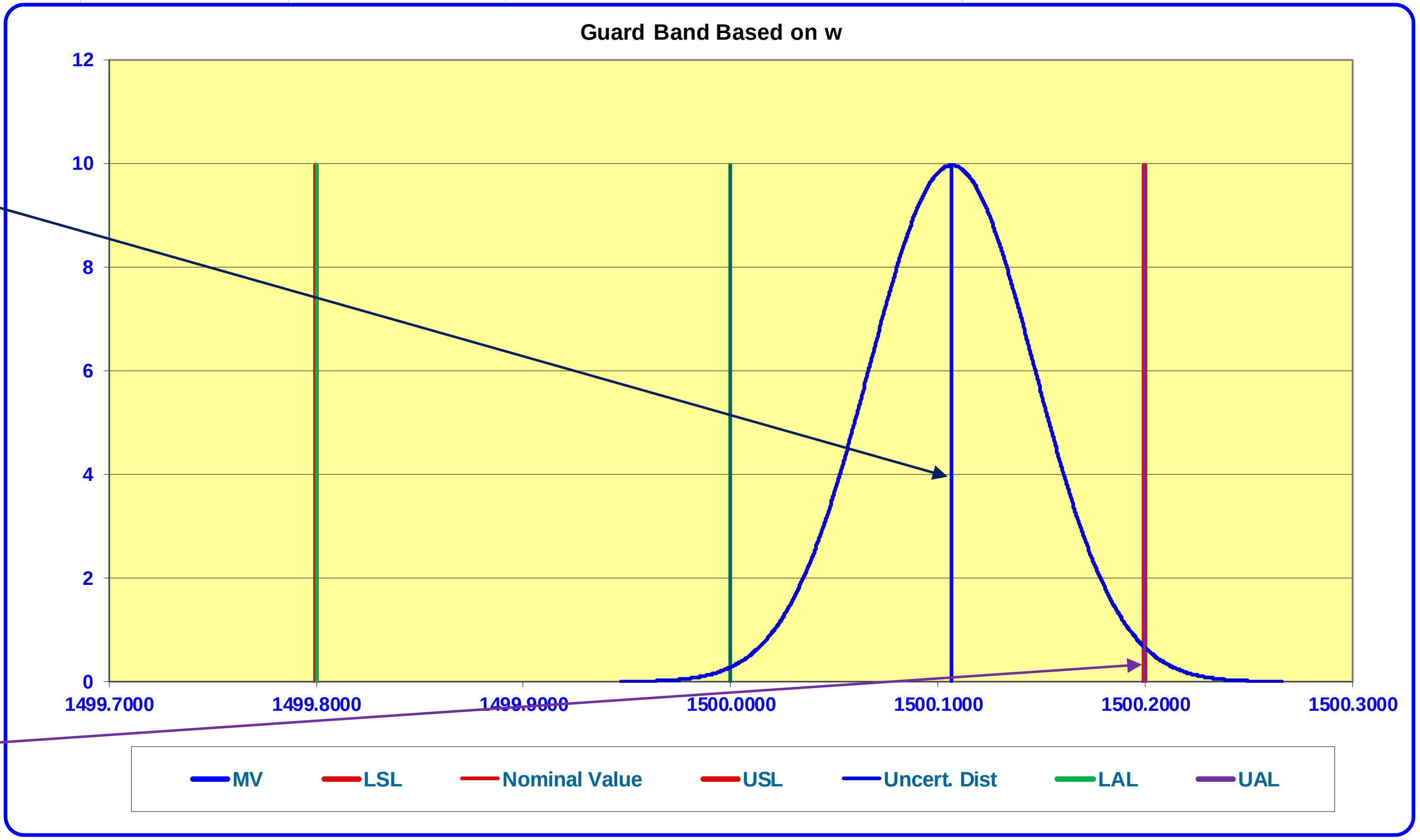
Probability of Conformance (p_c)	99.003%
Probability of NonConformance (1 - p_c)	0.997%

Setting the Guard Band Upper and Lower AL	
Guard Band Upper G_u (AL= TL - w)	1500.2000
Guard Band Lower G_L (AL = TL + w)	1499.8000

Setting AL based on Guard Band	
r	0.0000
$w = U_{95} * r$	0.00000
C_m	2.50000

Setting AL based on Guard Band w	
Upper Acceptance Limit	PASS
Lower Acceptance Limit	PASS

Area of Curve Outside of the AL	0.997%



Guard Band of w = 0 MV = 1500.1069 < 1500.2

Classic 50 % risk scenario with "Simple Acceptance" at the bench level (w = 0).

Risk Calculator	
Upper Tolerance T_U	1500.2000
Lower Tolerance T_L	1499.8000
Nominal Value	1500.0000
Measurement Unc um	0.0400
Measured Value xm	1500.2000
Tolerance T	0.40

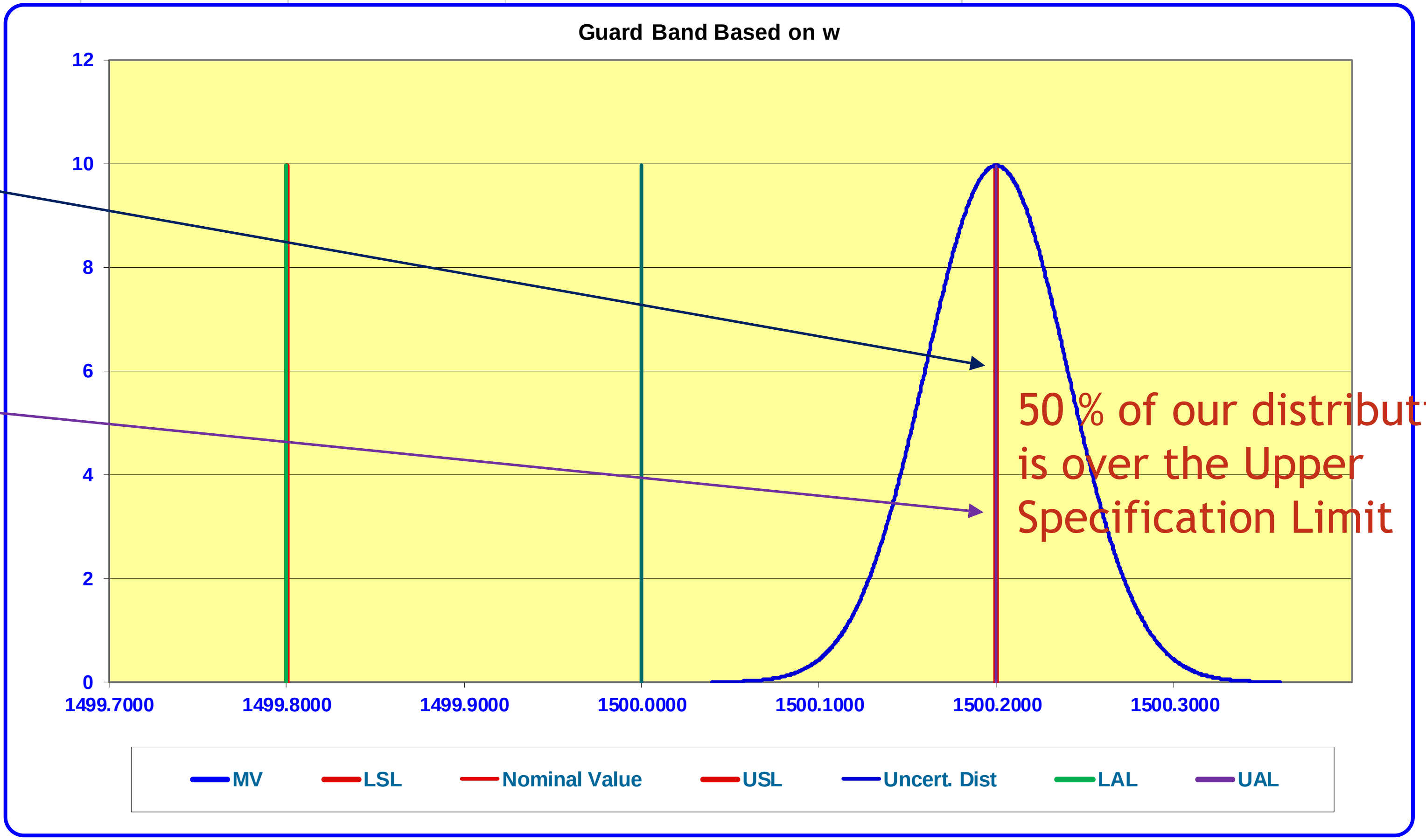
Probability of Conformance (p_c)	50.000%
Probability of NonConformance (1 - p_c)	50.000%

Setting the Guard Band Upper and Lower AL	
Guard Band Upper G_u (AL= TL - w)	1500.2000
Guard Band Lower G_L (AL = TL + w)	1499.8000

Setting AL based on Guard Band	
r	0.0000
w = U_{95} * *r*	0.00000
C_m	2.50000

Setting AL based on Guard Band w	
Upper Acceptance Limit	PASS
Lower Acceptance Limit	PASS

Area of Curve Outside of the AL	50.000%



50 % of our distribution is over the Upper Specification Limit

Instrument Measurement Uncertainty Guard Banding

Risk Calculator	
Upper Tolerance T_U	1500.2000
Lower Tolerance T_L	1499.8000
Nominal Value	1500.0000
Measurement Unc um	0.0400
Measured Value xm	1500.2000
Tolerance T	0.40

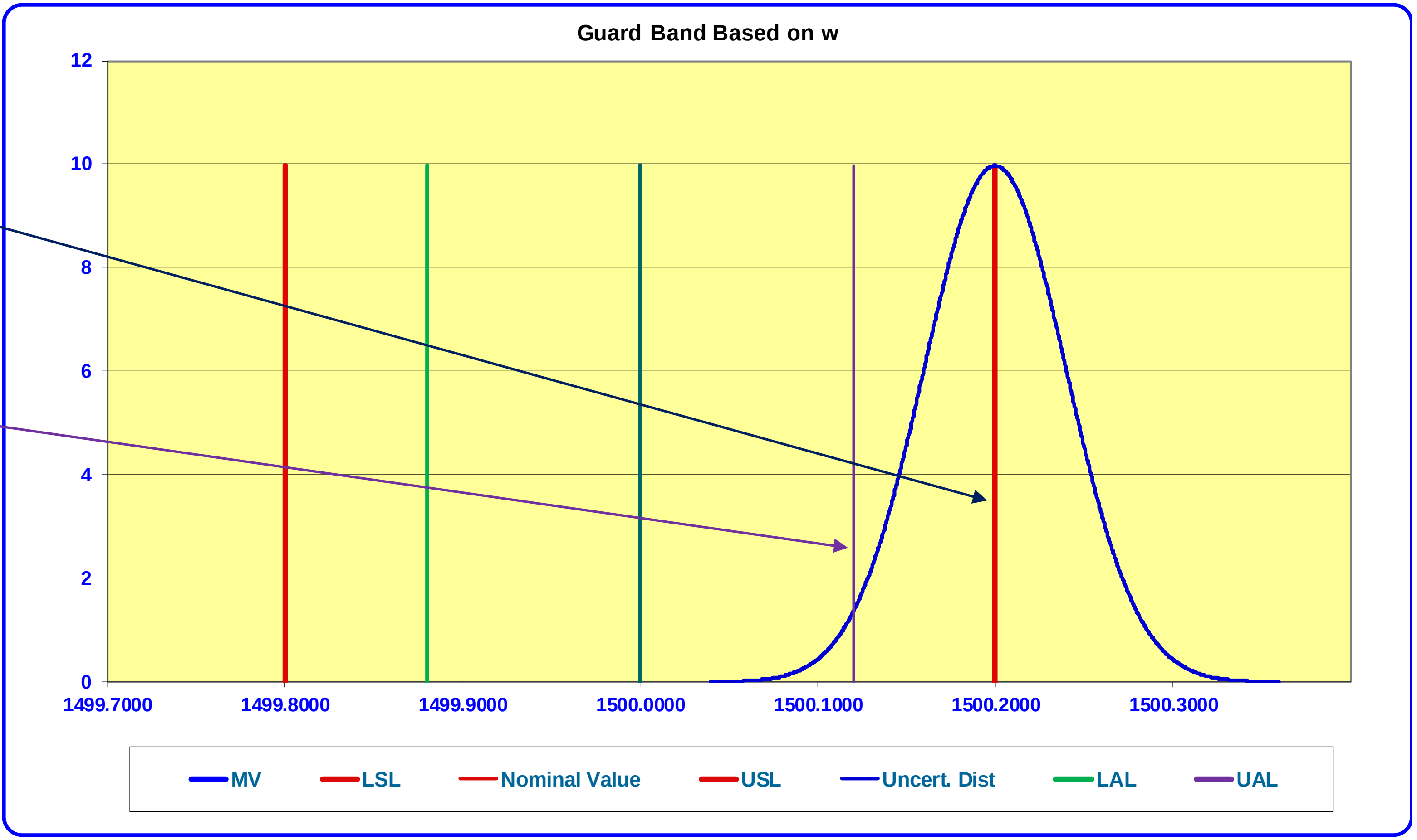
Probability of Conformance (p_c)	50.000%
Probability of NonConformance (1 - p_c)	50.000%

Setting the Guard Band Upper and Lower AL	
Guard Band Upper G_u (AL= TL - w)	1500.1200
Guard Band Lower G_L (AL = TL + w)	1499.8800

Setting AL based on Guard Band	
r	1.0000
w = U_{95} * *r*	0.08000
C_m	2.50000

Setting AL based on Guard Band w	
Upper Acceptance Limit	FAIL
Lower Acceptance Limit	PASS

Area of Curve Outside of the AL	97.725%



Guard Band of w = 1 MV = 1500.2 > 1500.12

Instrument Measurement Uncertainty Guard Banding

Risk Calculator	
Upper Tolerance T_U	1500.2000
Lower Tolerance T_L	1499.8000
Nominal Value	1500.0000
Measurement Unc um	0.0400
Measured Value xm	1500.1069
Tolerance T	0.40

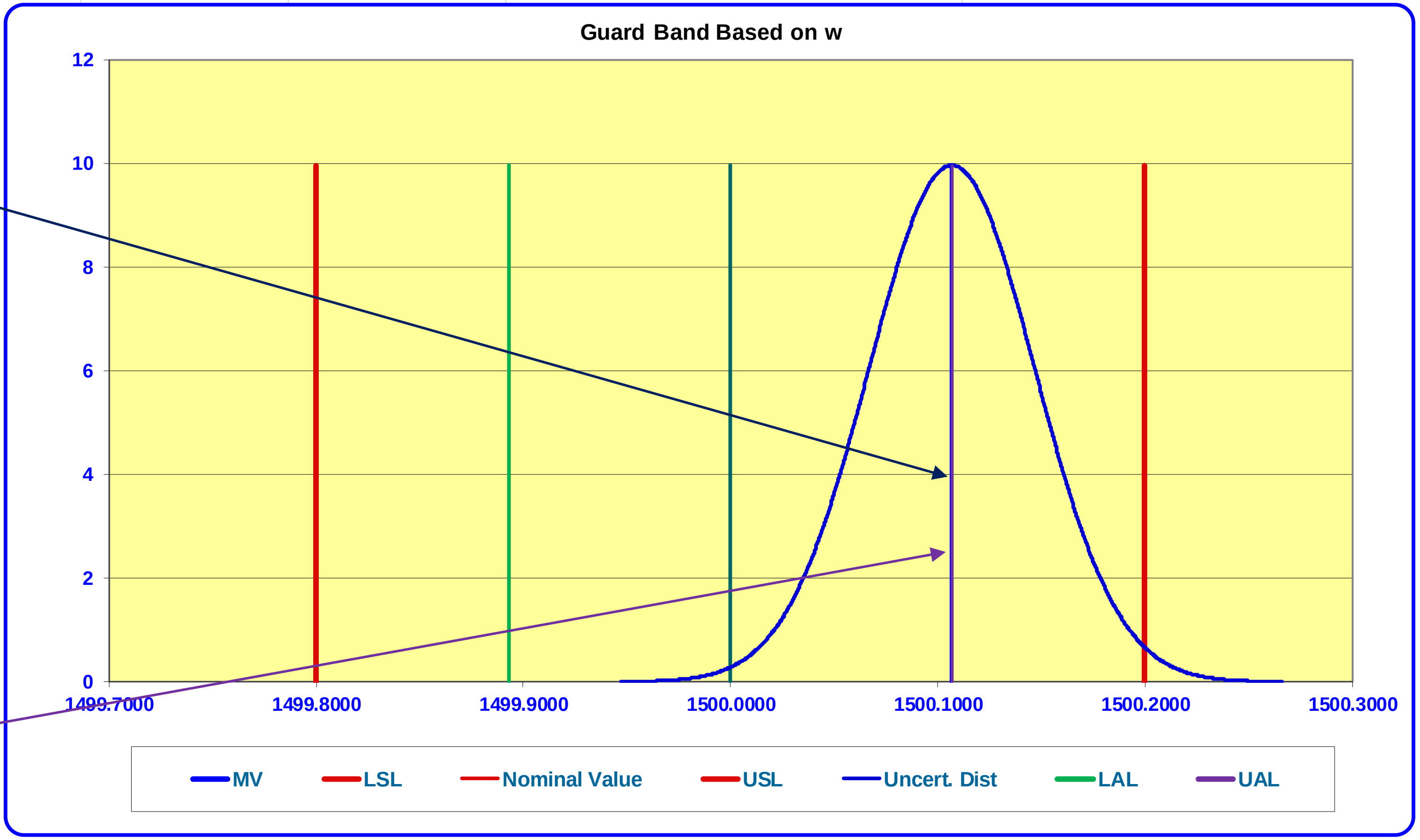
Probability of Conformance (p_c)	99.003%
Probability of NonConformance (1 - p_c)	0.997%

Setting the Guard Band Upper and Lower AL	
Guard Band Upper G_u (AL= TL - w)	1500.1069
Guard Band Lower G_L (AL = TL + w)	1499.8931

Setting AL based on Guard Band	
r	1.1632
$w = U_{95} * r$	0.09305
C_m	2.50000

Setting AL based on Guard Band w	
Upper Acceptance Limit	PASS
Lower Acceptance Limit	PASS

Area of Curve Outside of the AL	49.954%



Guard Band of w = 0.09305 MV = 1500.1069 = 1500.1069

Instrument Measurement Uncertainty Guard Banding

Total Risk	=IF(Q16="SR",SUM(C9:C10),"Global Risk")
Upper Limit Risk	=IF(Q16="SR",(NORMDIST(C6,C5,C7,1)),"Global Risk")
Lower Limit Risk	=IF(Q16="SR",1-NORMDIST(C6,C4,C7,1),"Global Risk")
Test Uncertainty Ratio (TUR) =	=((C5-C4))/(4*C7)
Measurement Capability Index (C_m)=	=((C5-C4))/(4*C7)
Process Capability (C_{pk})	=MIN(((C5-C6)/(3*C7)),((C6-C4)/(3*C7)))
Probability of Conformance (p_c)	=NORM.DIST(C5,C6,C7,TRUE)-NORM.DIST(C3,C6,C7,TRUE)
Probability of NonConformance (1 - p_c)	=1-C14

$$P_c = \Phi\left(\frac{T_U - y_m}{u_m}\right) - \Phi\left(\frac{T_L - y_m}{u_m}\right)$$

Φ is the standard normal distribution function.
In Excel, this function is NORMSDIST().

Probability of non-conformance: $\bar{P}_c = 1 - P_c$

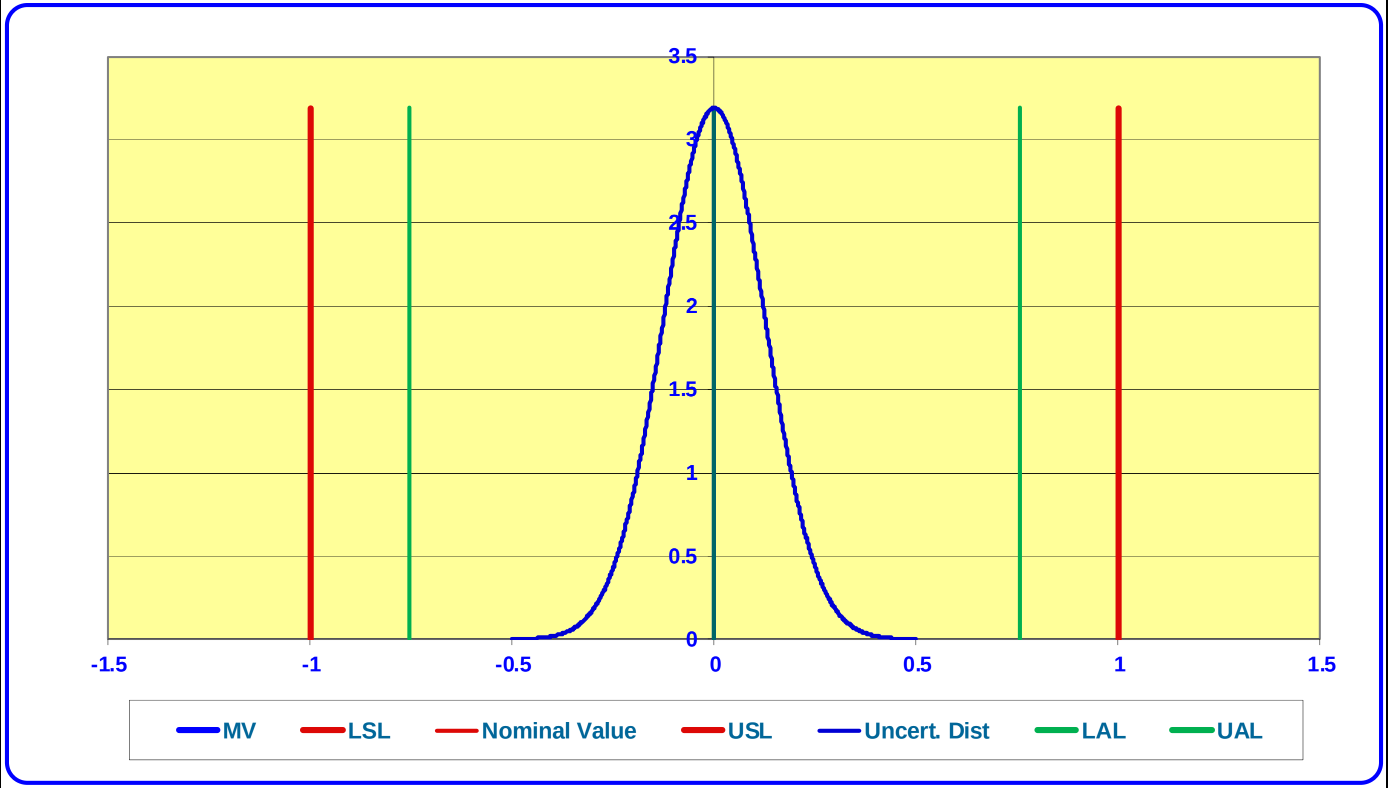
Star Wars Example

With a 2-meter hole and a 0.5-meter Photon Torpedo.

What would be the acceptance limits using a specific risk example?

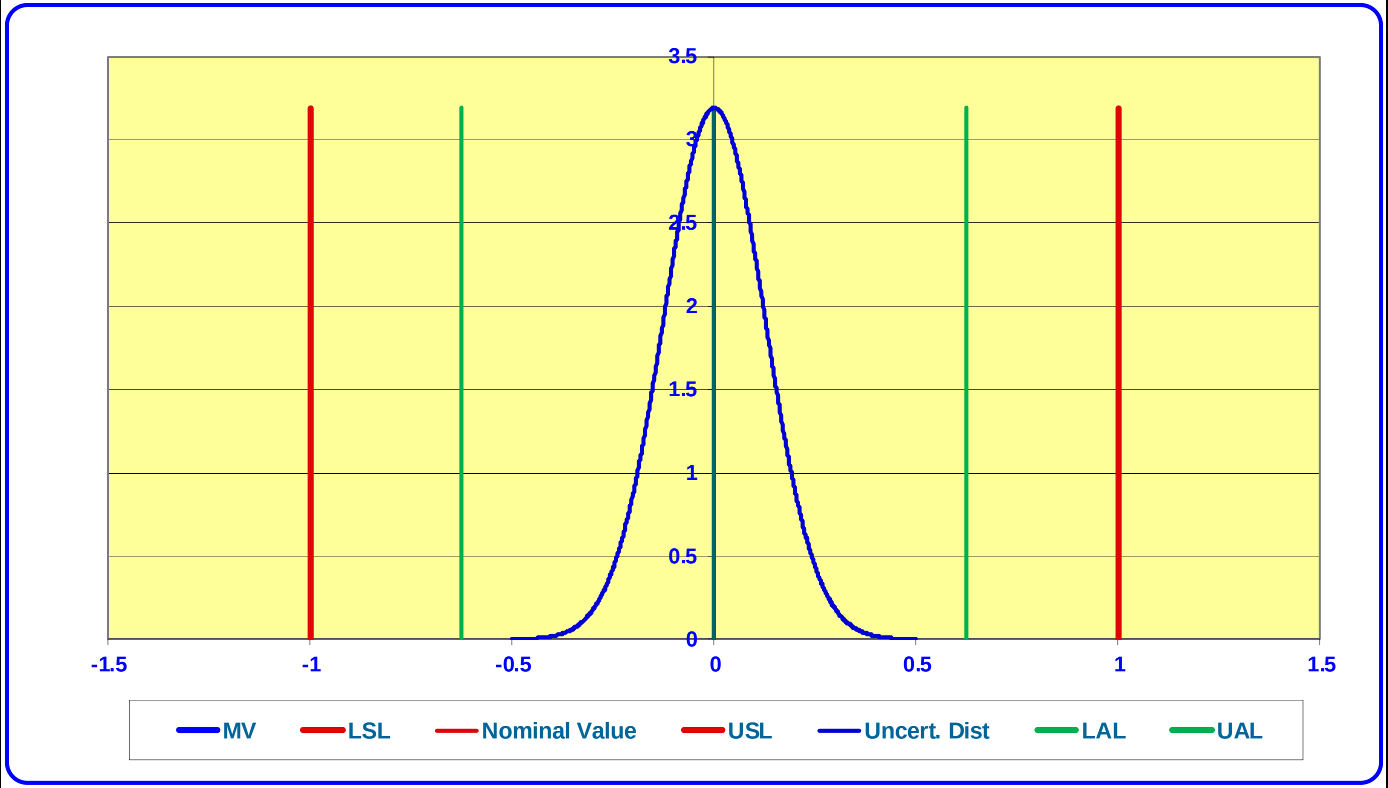
Star Wars Example – 95 % Confidence

3	Nominal Value	0	
4	Lower Specification Limit	-1	-0.755
5	Upper Specification Limit	1	0.755
6	Measured Value	0.0000	0.000
7	Std. Uncert. (k =1)	125.00E-3	
8	Total Risk	0.000%	
9	Upper Limit Risk	0.000%	
10	Lower Limit Risk	0.000%	
11	Test Uncertainty Ratio (TUR) =	4.00	
12	Measurement Capability Index (C_m)=	4.00	
13	Process Capability (C_{pk})	2.667	
14	Probability of Conformance (p_c)	100.000%	
15	Probability of NonConformance (1 - p_c)	0.000%	
	Area below for calculations		
	Sample	Measurement	
	1	0.000	
	2	0.000	
	3	0.000	
	4	0.000	
	5	0.000	
	Sample Mean	0.000	
	Sample Standard Deviation	0.000	



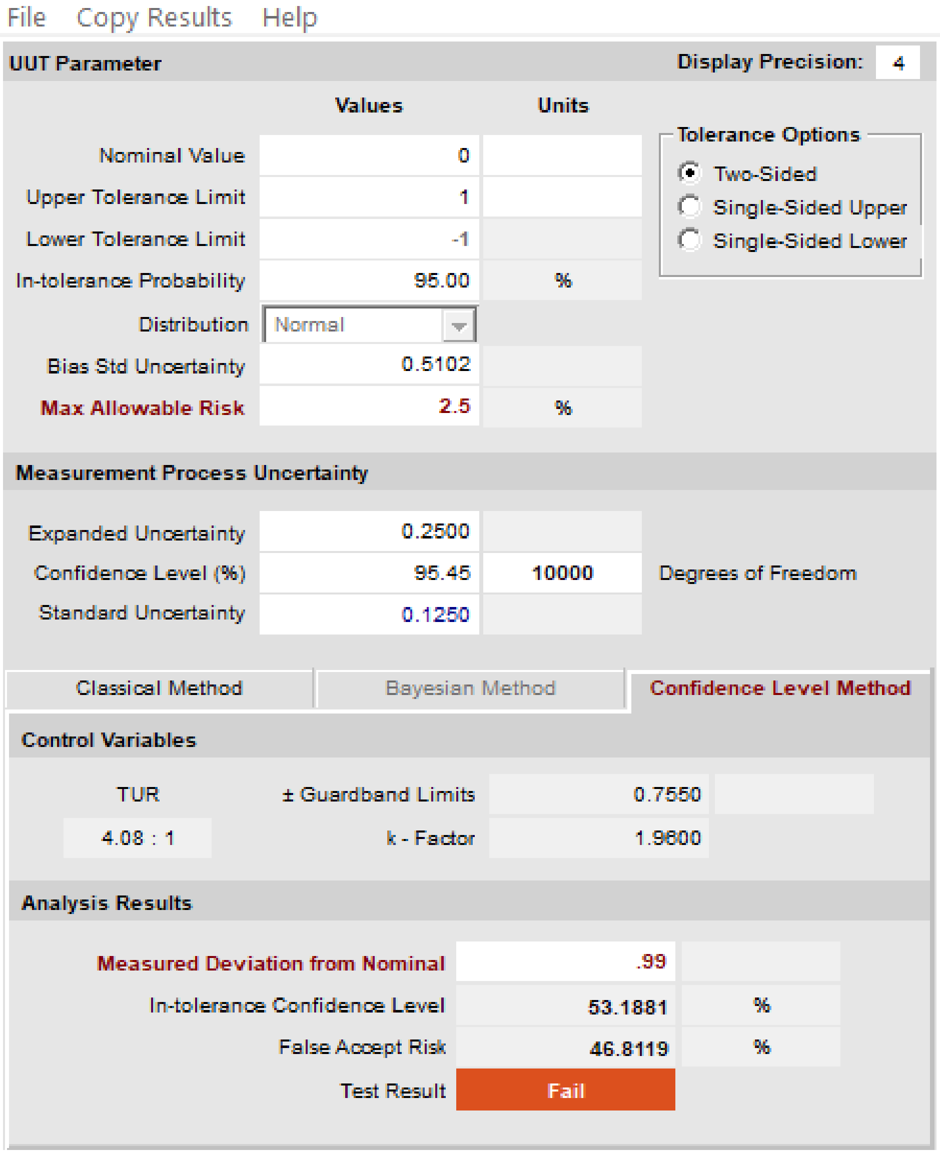
Star Wars Example – 99 % Confidence

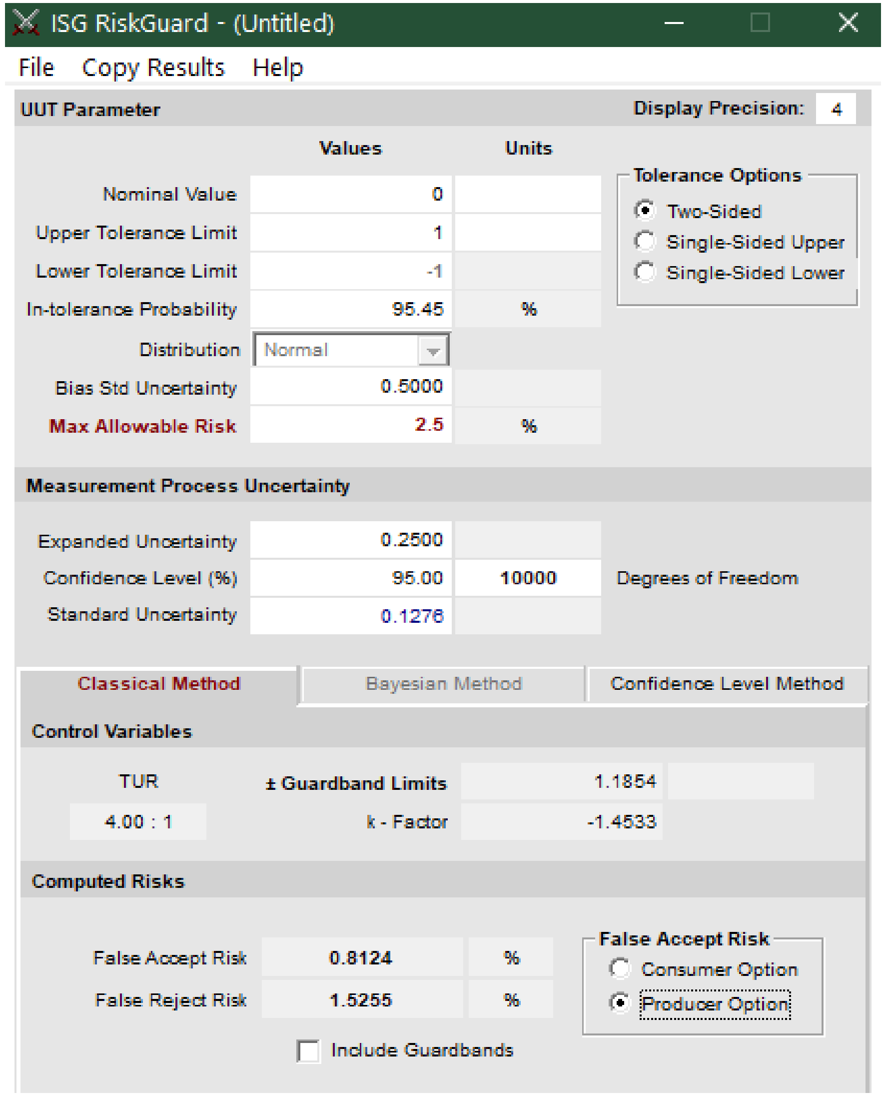
3	Nominal Value	0	
4	Lower Specification Limit	-1	-0.625
5	Upper Specification Limit	1	0.625
6	Measured Value	0.0000	0.000
7	Std. Uncert. (k =1)	125.00E-3	
8	Total Risk	0.000%	
9	Upper Limit Risk	0.000%	
10	Lower Limit Risk	0.000%	
11	Test Uncertainty Ratio (TUR) =	4.00	
12	Measurement Capability Index (C_m)=	4.00	
13	Process Capability (C_{pk})	2.667	
14	Probability of Conformance (p_c)	100.000%	
15	Probability of NonConformance (1 - p_c)	0.000%	
	Area below for calculations		
	Sample	Measurement	
	1	0.000	
	2	0.000	
	3	0.000	
	4	0.000	
	5	0.000	
	Sample Mean	0.000	
	Sample Standard Deviation	0.000	



Star Wars Example

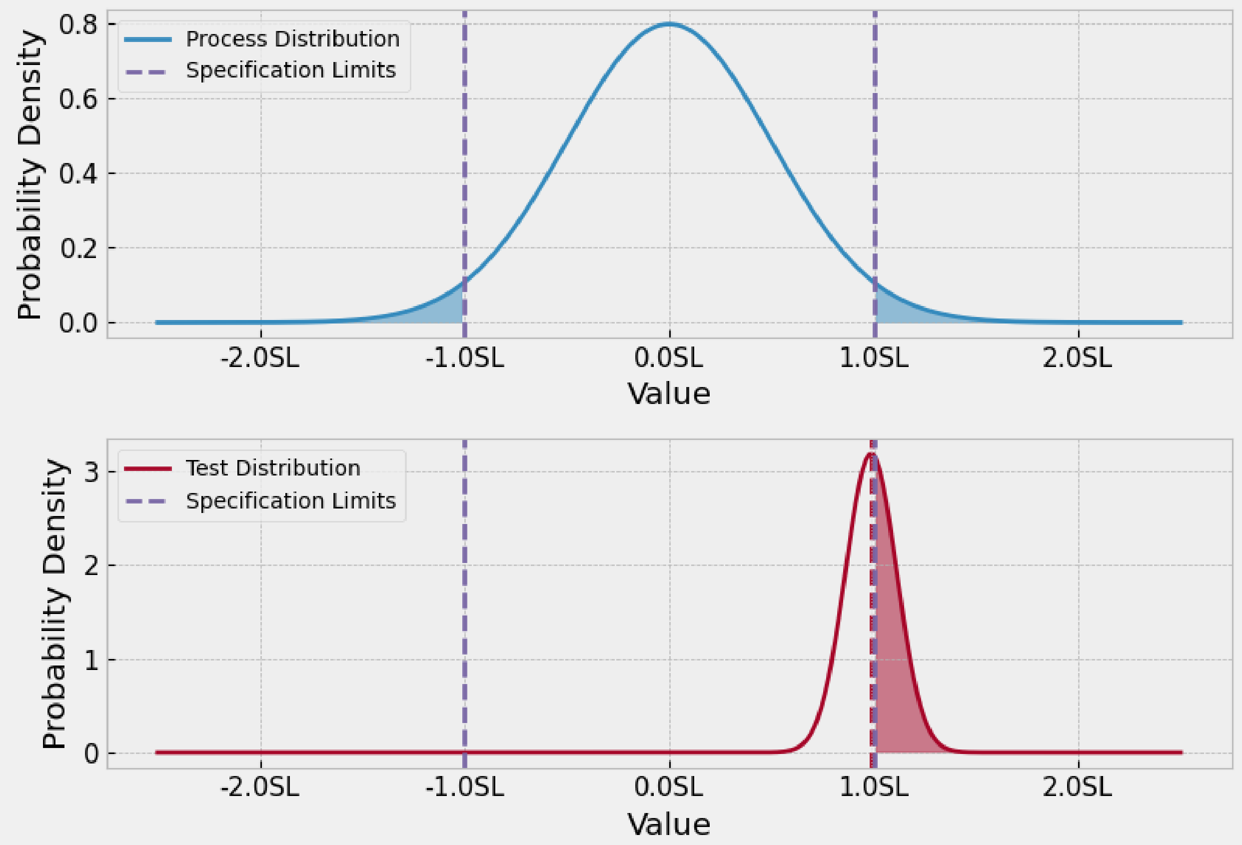
Morehouse
THE FORCE IN CALIBRATION SINCE 1925



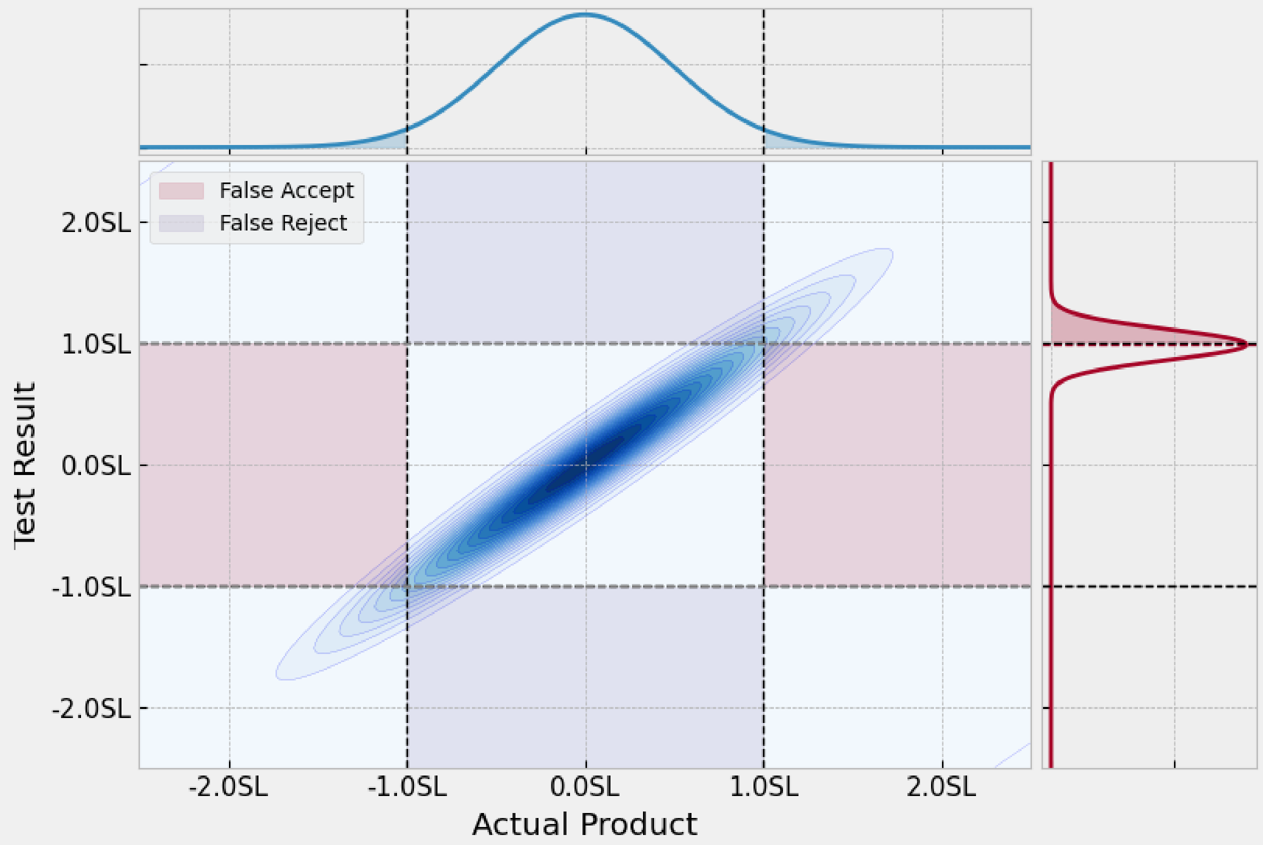


http://www.isgmax.com/risk_freeware.htm

Star Wars Example



Process Risk	Specific Measurement Risk	Global Risk
Process Risk: 4.6%	TUR: 4.0	Total PFA: 0.79%
Upper limit risk: 2.3%	Measured value: 0.99	Total PFR: 1.5%
Lower limit risk: 2.3%	Result: ACCEPT	-
Process capability index (Cpk): 0.67	Specific FA Risk: 46%	-



Process Risk	Specific Measurement Risk	Global Risk
Process Risk: 4.6%	TUR: 4.0	Total PFA: 0.79%
Upper limit risk: 2.3%	Measured value: 0.99	Total PFR: 1.5%
Lower limit risk: 2.3%	Result: ACCEPT	-
Process capability index (Cpk): 0.67	Specific FA Risk: 46%	-

Cpk

Std Unc

k =1	CpK	TUR	Pcent	Lower Limit	Upper Limit	Measured Value	P(In-Tol)	P(OOT)	LL Risk	UL Risk	Total Risk
0.005 000	0.666 667	1	No Solution								
0.004 000	0.666 667	1.25	20.00%	99.998	100.002	100.002	97.59%	2.41%	0.13%	2.27%	2.41%
0.003 333	0.666 667	1.5	33.33%	99.997	100.003	100.003	97.72%	2.28%	0.00%	2.27%	2.28%
0.002 500	0.666 667	2	50.00%	99.995	100.005	100.005	97.72%	2.28%	0.00%	2.27%	2.28%
0.002 000	0.666 667	2.5	60.00%	99.994	100.006	100.006	97.73%	2.27%	0.00%	2.27%	2.27%
0.001 667	0.666 667	3	66.67%	99.993	100.007	100.007	97.73%	2.27%	0.00%	2.27%	2.27%
0.001 429	0.666 667	3.5	71.43%	99.993	100.007	100.007	97.73%	2.27%	0.00%	2.27%	2.27%
0.001 250	0.666 667	4	75.00%	99.993	100.007	100.007	97.73%	2.27%	0.00%	2.27%	2.27%
0.001 111	0.666 667	4.5	77.78%	99.992	100.008	100.008	97.73%	2.27%	0.00%	2.27%	2.27%
0.001 000	0.666 667	5	80.00%	99.992	100.008	100.008	97.72%	2.28%	0.00%	2.28%	2.28%
0.000 833	0.666 667	6	83.33%	99.992	100.008	100.008	97.73%	2.27%	0.00%	2.27%	2.27%
0.000 714	0.666 667	7	85.71%	99.991	100.009	100.009	97.72%	2.28%	0.00%	2.28%	2.28%
0.000 625	0.666 667	8	87.50%	99.991	100.009	100.009	97.73%	2.27%	0.00%	2.27%	2.27%
0.000 556	0.666 667	9	88.89%	99.991	100.009	100.009	97.73%	2.27%	0.00%	2.27%	2.27%
0.000 500	0.666 667	10	90.00%	99.991	100.009	100.009	97.73%	2.27%	0.00%	2.27%	2.27%
0.000 200	0.666 667	25	96.00%	99.990	100.010	100.010	97.73%	2.27%	0.00%	2.27%	2.27%
0.000 050	0.666 667	100	99.00%	99.990	100.010	100.010	97.72%	2.28%	0.00%	2.28%	2.28%
0.000 025	0.666 667	200	99.50%	99.990	100.010	100.010	97.72%	2.28%	0.00%	2.28%	2.28%

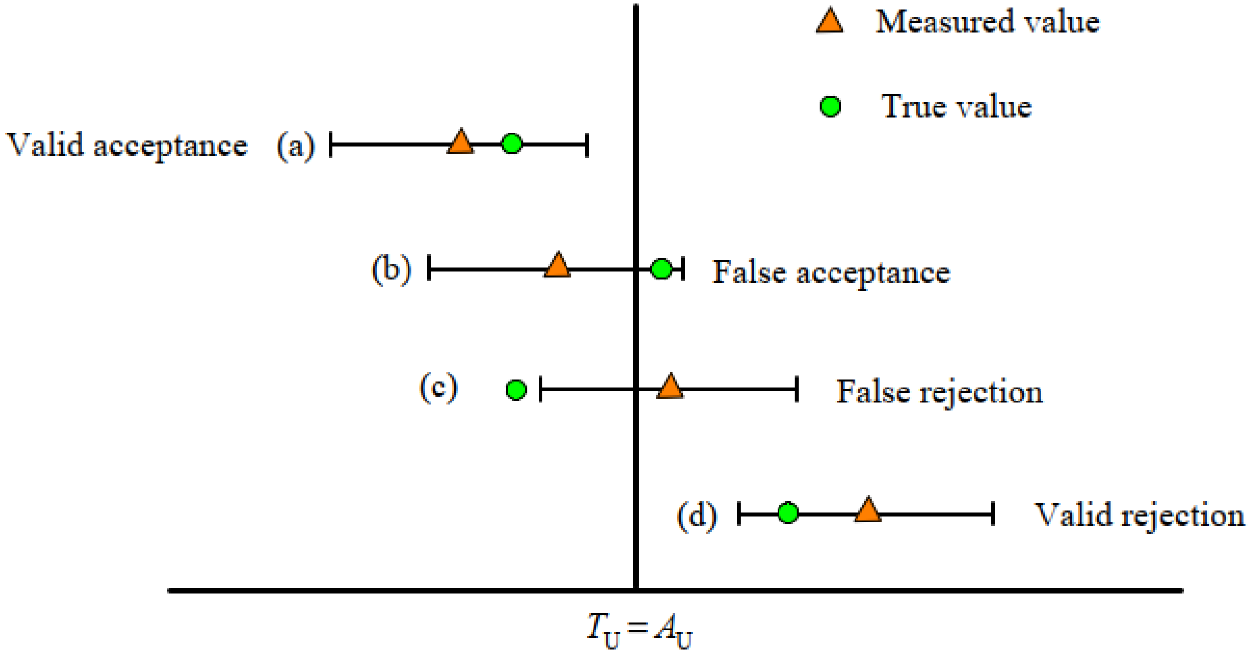
CpK or Process Capability Index is a quantifiable comparison of the expectations of the customer and the control limits.

For example, in the production world, a CpK value of 1.33 would mean that if we made one million parts, 63 of them would fail.

When used in metrology, CpK is a statistical tool designed to produce an objective measure of the capability of a process to produce output within tolerance specification limits often set from a confidence level such as 1.96 σ (95 %), 2 σ (95.45%), or 3 σ (99 %).

Using a coverage factor of 3 for 3 σ, a CpK of 0.667 would equate to 95.45 % confidence or 2.275 % maximum measurement risk (Specific Risk).

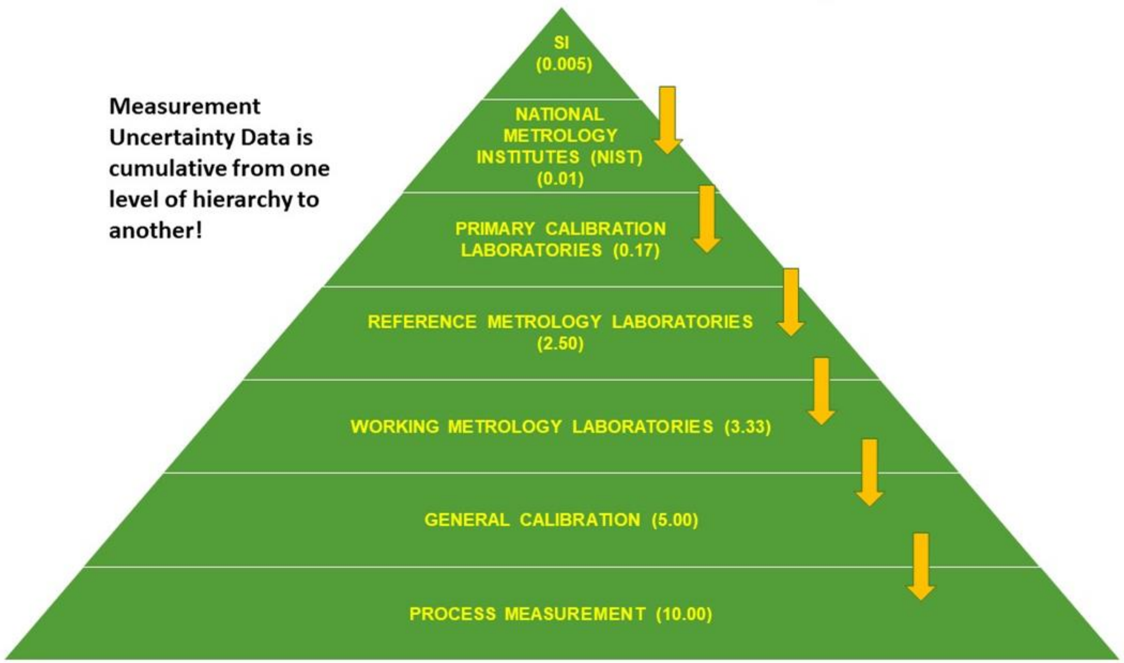
Acceptance Limits Reduce the Decision Risk when Verifying Specifications.



JCGM 106 Simple acceptance decision rule near an upper tolerance limit TU, with four 95 % coverage intervals. For such a decision rule, the acceptance limit AU coincides with the tolerance limit. Decisions to accept or reject inspected items are based on measured values (triangles); the true values (circles) cannot be known. Cases (b) and (c) lead to incorrect decisions called false acceptance and false rejection, respectively (see clause 9.3.2). In case ©, the true value of the measurand lies (unknowingly) outside the 95 % coverage interval.

Global Consumers' Risk in Evaluation of Decision Rules

Global Consumers' risk is defined in JCGM 106:2012. The role of CPU in conformity assessment is defined as "the probability that a non-conforming item will be accepted based on a future measurement result."



If only one tier of the calibration chain cares about the measurement decision risk, then the whole process is at risk. When this risk is propagated throughout succeeding tiers, can we expect the process to work properly?

Global Risk

Global Risk (also called process-level risk) is based on a future measurement result.

- It is used to ensure the acceptability of a documented measurement process.
- It is based on expected or historical information and is usually characterized by two probability distributions.

The term TUR (Test Uncertainty Ratio) is commonly used as a simplified approach to evaluating global risk. When we know the tolerance, we are working to, we have a high enough sample size to know the shape and the distribution of the calibration results.

We can then use TUR with End of Period reliability, or even by itself, to calculate the appropriate uncertainty that corresponds to the maximum amount of false accept risk we are okay with.

Global Risk

From ILAC G8 section 5.3, Some customers take steps to actively reduce the probability that instruments submitted for calibration and verification will be returned “Failed”. They do so by operating a “Calibration system” (See 5.3.4 of Z540.3 [7]) such that calibration records (measurement reliability) are monitored by model number, and calibration intervals are actively managed to achieve a desired target reliability (See 5.4.1 of Z540.3 [7]), where target reliability refers to the percentage of instruments that “Pass” calibration. The end result is a process by which the instrument submitted is part of a customer device population. If that process “rarely results in an instrument whose property of interest is near the tolerance limits, there is less opportunity for incorrect decisions to be made”.

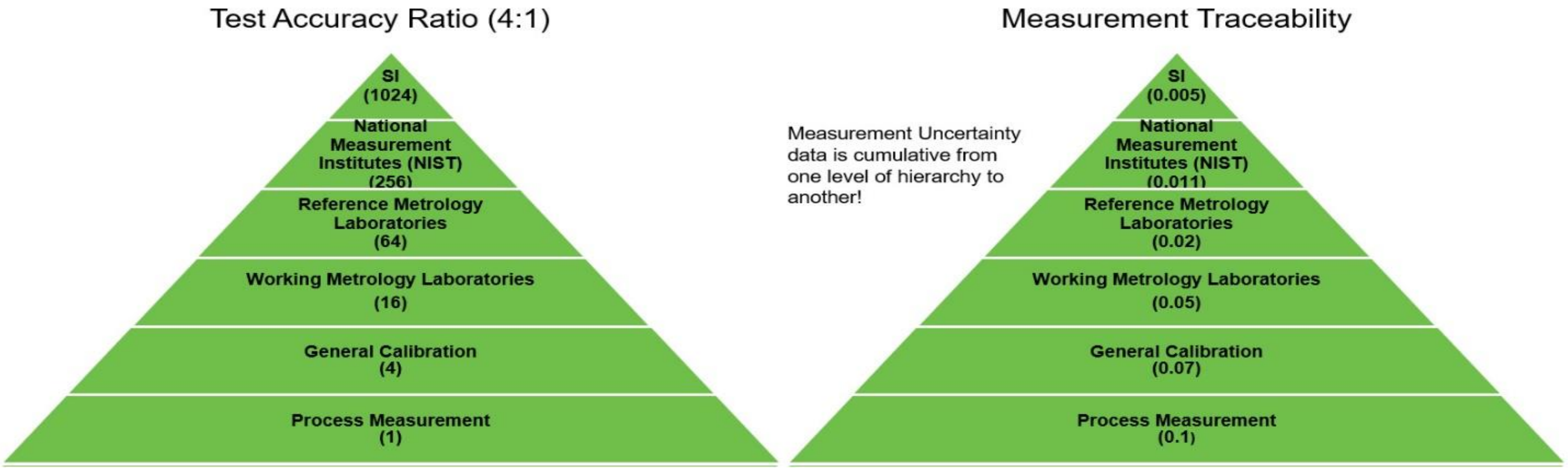
(See 9.1.4 of JCGM 106 [2]).

Global Risk Continued

Thus, the average probability of false accept and false reject (global risk) can be applied by evaluation of the joint probability density consisting of customer-managed device population and laboratory-managed calibration process uncertainty (See equations 17 and 19 of JCGM 106 [2]). References [8] and [9] provide simple techniques for estimating global risk.

When a customer actively manages calibration intervals, as mentioned here, during contract negotiation with laboratories for services compliant with ISO/IEC 17025:2017, they can direct the laboratory to use the average global risk associated with decision rules when reporting results per clause 7.8.2.2. As already clarified in definition 1.15, an instrument passing a global risk criteria e.g. 2% probability for false acceptance (2% PFA), may not pass a specific risk with a guard band equal to the expanded measurement uncertainty and may have a specific risk for false acceptance that can be as high as close to 50%. This is similar to the criteria for approval of instruments mostly utilized in legal metrology. Generally, the output from decision rules based on OIML principles (e.g. $TUR > 3:1$ or 5:1) and global risk with approximately 2% PFA may provide the same results in terms of the number of falsely rejected instruments.

Outdated Practices Can Lead to Higher Risk

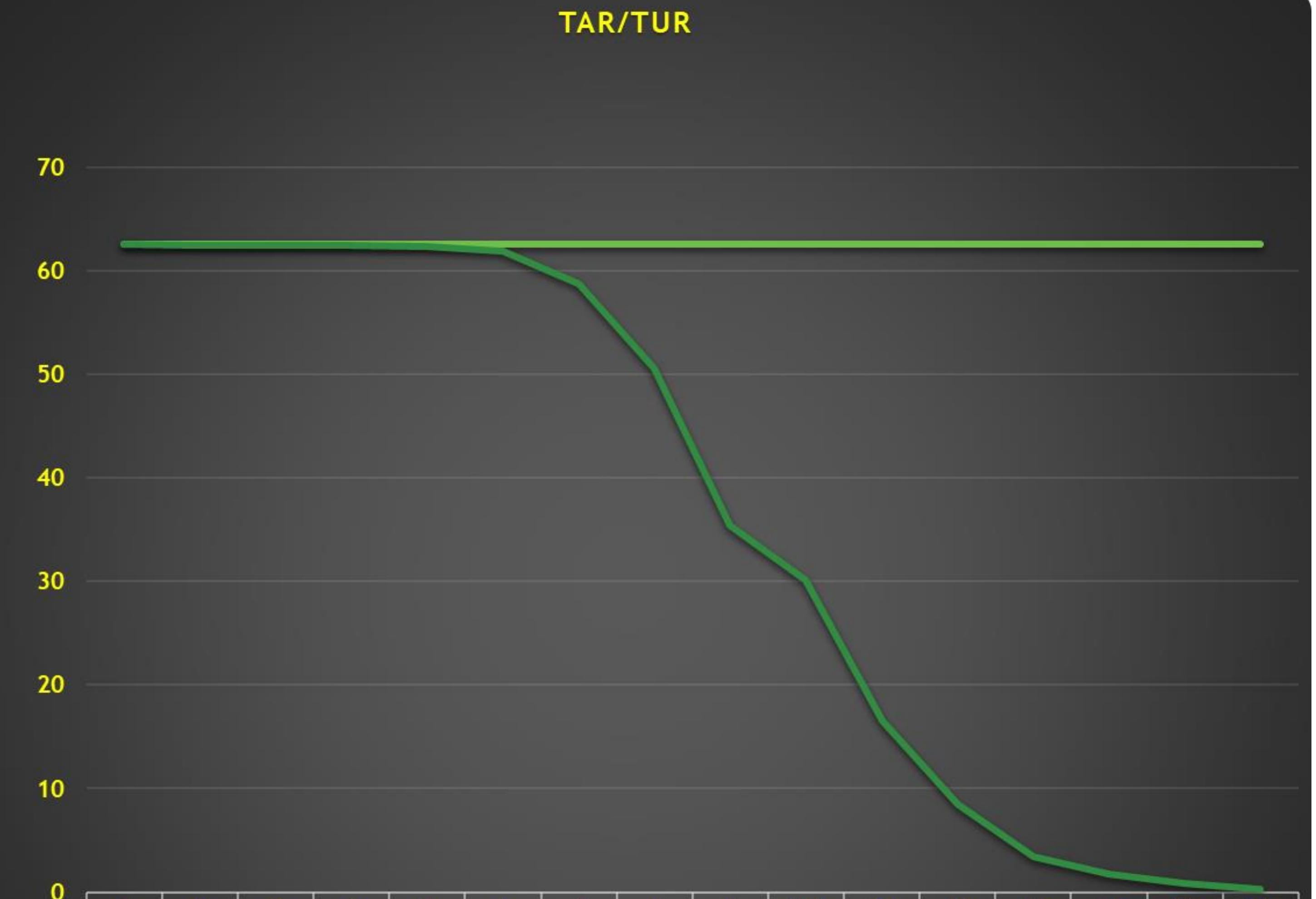


In *Measurement Decision Risk – The Importance of Definitions*, Scott M. Mimbs provides an example of a digital micrometer using a TAR 25:1 ratio. Comparing this example with the definition of TUR found in the ANSI/NCSL Z540.3 Handbook produces a 1.5:1 ratio for the same measurement.

Outdated Practices Lead to Higher Risk

Capacity	Req Tolerance	LSL	USL	Res UUT	Rep UUT	CMC	Std Unc	Exp Unc	TUR	TAR
1000	0.100%	999.0	1001.0	0.0001	0.000	0.0016%	0.01	0.02	62.500	62.5
1000	0.100%	999.0	1001.0	0.0002	0.000	0.0016%	0.01	0.02	62.498	62.5
1000	0.100%	999.0	1001.0	0.0004	0.000	0.0016%	0.01	0.02	62.493	62.5
1000	0.100%	999.0	1001.0	0.001	0.000	0.0016%	0.01	0.02	62.459	62.5
1000	0.100%	999.0	1001.0	0.002	0.000	0.0016%	0.01	0.02	62.335	62.5
1000	0.100%	999.0	1001.0	0.004	0.000	0.0016%	0.01	0.02	61.849	62.5
1000	0.100%	999.0	1001.0	0.01	0.000	0.0016%	0.01	0.02	58.737	62.5
1000	0.100%	999.0	1001.0	0.02	0.001	0.0016%	0.01	0.02	50.546	62.5
1000	0.100%	999.0	1001.0	0.04	0.001	0.0016%	0.01	0.03	35.409	62.5
1000	0.100%	999.0	1001.0	0.05	0.002	0.0016%	0.02	0.03	30.120	62.5
1000	0.100%	999.0	1001.0	0.1	0.004	0.0016%	0.03	0.06	16.573	62.5
1000	0.100%	999.0	1001.0	0.2	0.007	0.0016%	0.06	0.12	8.514	62.5
1000	0.100%	999.0	1001.0	0.5	0.018	0.0016%	0.15	0.29	3.432	62.5
1000	0.100%	999.0	1001.0	1	0.036	0.0016%	0.29	0.58	1.718	62.5
1000	0.100%	999.0	1001.0	2	0.072	0.0016%	0.58	1.16	0.859	62.5
1000	0.100%	999.0	1001.0	5	0.179	0.0016%	1.45	2.91	0.344	62.5

In this table we are only varying resolution and repeatability of the UUT.



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
TAR	62.5	62.5	62.5	62.5	62.5	62.5	62.5	62.5	62.5	62.5	62.5	62.5	62.5	62.5	62.5	62.5
TUR	62.50	62.49	62.49	62.45	62.33	61.84	58.73	50.54	35.40	30.12	16.57	8.514	3.432	1.718	0.859	0.344

Test Uncertainty Ratio (TUR)

- **Test Uncertainty Ratio:** The ratio of the span of the tolerance of a measurement quantity subject to calibration to twice the 95% expanded uncertainty of the measurement process used for calibration.
  - NOTE: This applies to two-sided tolerances.

ANSI/NCSL Z540.3 – 2006 Definition

UUT – Unit Under Test

$$\text{T.U.R.} = \frac{\text{U.U.T. Tolerance}}{\text{Calibration Process Uncertainty}}$$

The Correct Definition and Calculation of TUR

$$\text{TUR} = \frac{\text{Span of the } \pm \text{Tolerance}}{2 \text{ x } k_{95\%}\left(\sqrt[2]{\left(\frac{\text{CMC}}{k_{\text{CMC}}}\right)^2 + \left(\frac{\text{Resolution}_{\text{UUT}}}{\sqrt[2]{12}}\right)^2 + \left(\frac{\text{Repeatability}_{\text{UUT}}}{1}\right)^2 + \cdots (u_{Other})^2}\right)}$$

Example of a TUR Formula (Adapted from the ANSI/NCSL Z540.3 Handbook)

In most cases, the numerator is the UUT Accuracy Tolerance. The denominator is slightly more complicated. Per the ANSI/NCSL Z540.3 Handbook, "For the denominator, the 95 % expanded uncertainty of the measurement process used for calibration following the calibration procedure is to be used to calculate TUR. The value of this uncertainty estimate should reflect the results that are reasonably expected from the use of the approved procedure to calibrate the M&TE. Therefore, the estimate includes all components of error that influence the calibration measurement results, which would also include the influences of the item being calibrated except for the bias of the M&TE. The calibration process error, therefore, includes temporary and non-correctable influences incurred during the calibration such as **repeatability**, **resolution**, error in the measurement source, operator error, error in correction factors, environmental influences, etc."

TUR (Test Uncertainty Ratio)

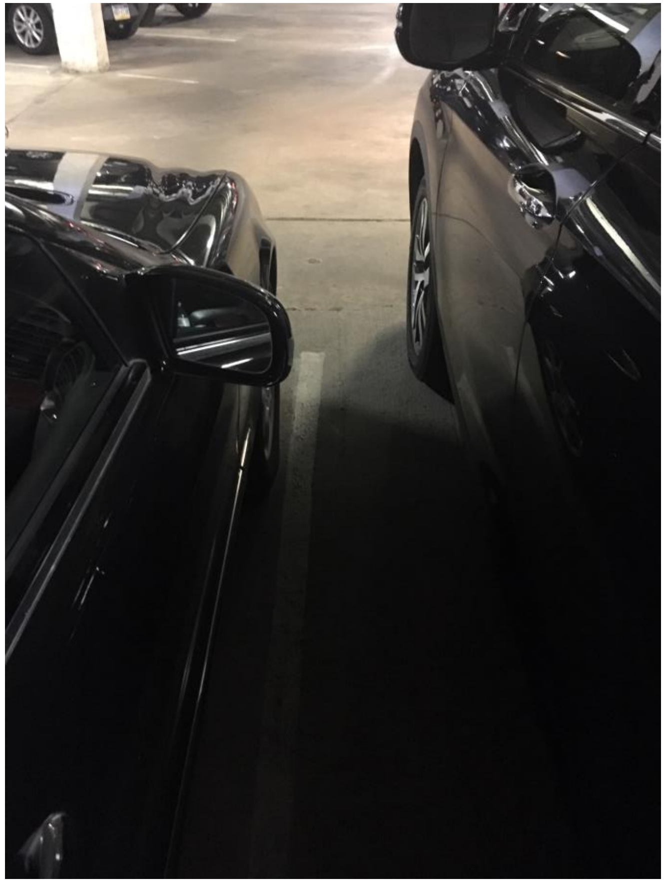
$$\text{T.U.R.} = \frac{\text{U.U.T. Tolerance}}{\text{Calibratio n Process Uncertain ty}}$$

$$\mathbf{TUR} = \frac{\textbf{Span of the } \pm \textbf{ Tolerance}}{\mathbf{2\ x\ k_{95\%}} \left(\sqrt[2]{\left(\frac{\mathbf{CMC}}{\mathbf{k_{CMC}}}\right)^2 + \left(\frac{\mathbf{Resolution_{UUT}}}{\sqrt[2]{\mathbf{12}}}\right)^2 + \left(\frac{\mathbf{Repeatability_{UUT}}}{\mathbf{1}}\right)^2 + \cdots (\mathbf{u}_{Other})^2} \right)}$$

UUT Tolerance = (USL-LSL)/2
CMC = Reference labs Calibration and Measurement Capability
k = coverage factor

The lab with the smaller uncertainties will typically produce larger TURs, giving you more space to be in tolerance!

The lab with the larger uncertainties will typically produce smaller TURs, giving you less space to be in tolerance!



ANSI/NCSLI Z540.3 Section 5.3(b) requirements

b) Where calibrations provide for verification that measurement quantities are within specified tolerances, the probability that incorrect acceptance decisions (false accept) will result from calibration tests shall not exceed 2% and shall be documented. Where it is not practicable to estimate this probability, the test uncertainty ratio shall be equal to or greater than 4:1.

Requesting a 4:1 TUR

- The origins of 4:1 TUR assume a 95 % in-tolerance probability for both the measuring device and the UUT.
- If one does the math, a 4:1 TUR with a coverage probability of $k = 2$ for the measurement uncertainty and a 95 % End of Period reliability can equate to less than 1 % false accept and slightly over 1.5 % false reject.

EOPR

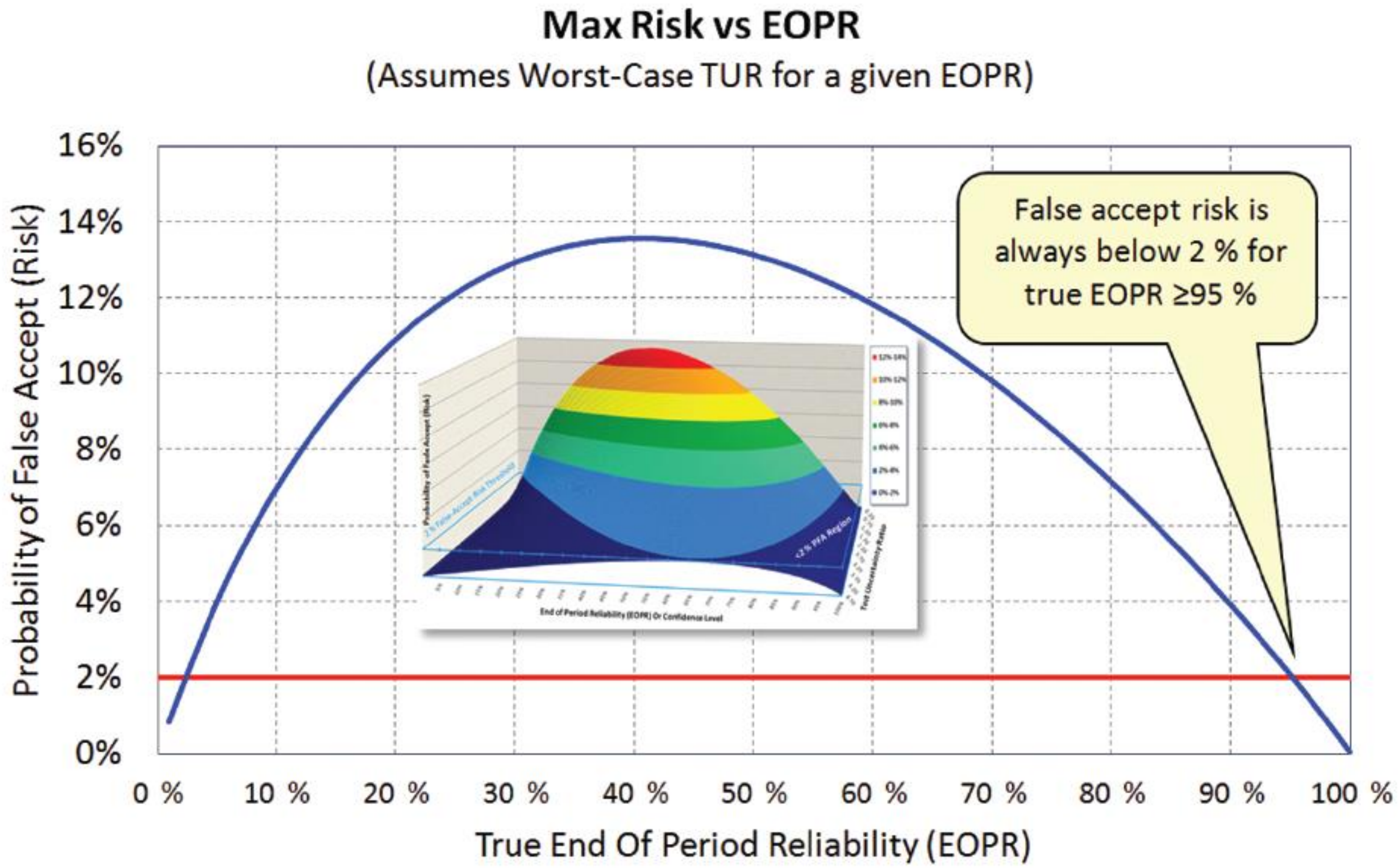
$$EOPR = \frac{\text{Number of in-tolerance results}}{\text{Total number of calibrations}}$$

- In simplistic terms, End of Period Reliability is defined as the number of calibrations resulting in acceptance criteria being met divided by the total number of calibrations. This formula to determine "In-Tolerance" Reliability from historical data is easy to replicate in Excel. The formula is **Sample Size = ln(1-Confidence)/ln(Target Reliability)**

- If we use the formula for Sample Size above, we will need over 59 (58.4) samples to use a joint probability distribution associated with many TUR-based methods.

- There is more with EOPR as the rules to establish EOPR can be subjective. Things such as how many first-time calibrations are counted, are broken instruments included, are calibrations with different due dates, or calibrations that are extended included, what about post-dating, and so on.

EOPR



From Risk Mitigation Strategies for Compliance Testing by Jonathan Harben and Paul Reese

EOPR

Reliability Considerations may include:

- Reliability decreases with time after calibration
- How much testing is required to demonstrate reliability with confidence?
- *A priori* knowledge of the M&TE

Reliability Analysis of M&TE should be based on similar instrumentation manufacture, model #, calibration intervals. What should be avoided is intermixing different M&TE with different calibration intervals.

Reliability Analysis

$$1 - \text{Confidence} = \sum_{r=0}^{r=f} \binom{n}{r} \times pr \times (1-p)^{n-r}$$

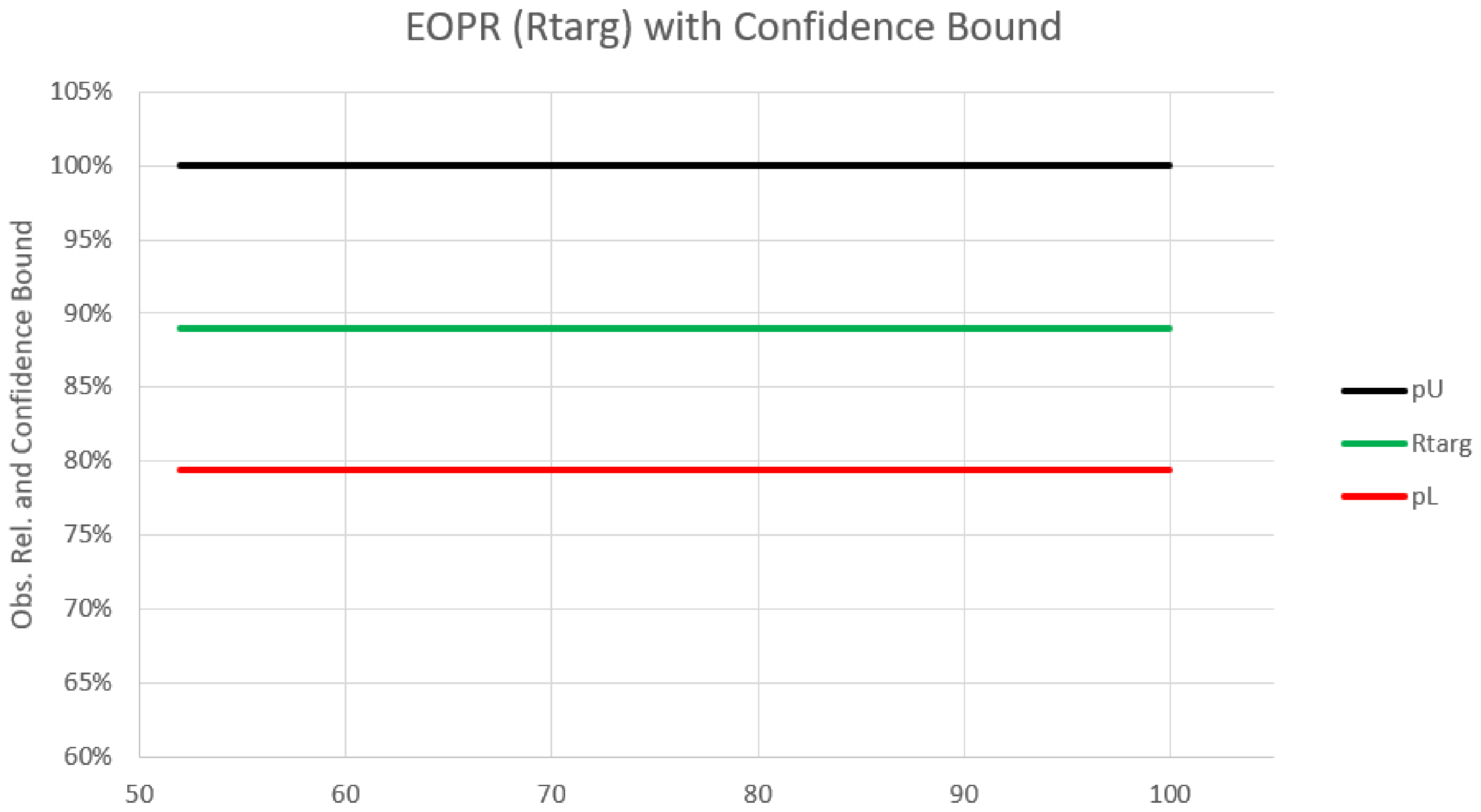
$$1 - 0.1 = (1-p)^{n-0} = r^{n}$$

$$0.10 = r^{100} = \exp\left(\frac{\ln(0.1)}{100}\right)$$

$$r = 0.977$$

Note: the interval is the estimate, that is, 0.977 is not a reliability estimate, but merely a lower bound of a confidence interval estimate

EOPR



When trying for a particular EOPR at a specific confidence interval, what you are doing is creating a tolerance around your EOPR.

So, for 89 % EOPR at 95 % confidence with 26 samples, the (conservative) EOPR is ~89 % (89 % to 100 %). One should always take the calculated lower binomial bound as the worst case EOPR.

But for the same EOPR with only 13 samples, EOPR is 79.42 % (79 % to 100 % as shown above)

A Critique of the 4:1 TUR

NCSLI RP-18, in section 3.5.2 A Critique of the 4:1 Requirement discusses some Z540.3 TUR requirements that deserve mention. These are:

- The requirement is merely a ratio of UUT tolerance limits relative to the expanded uncertainty of the measurement process. It is, at best, a crude risk control tool, i.e., one that does not control risks to any specified level. Moreover, in some cases, it may be superfluous. For instance, what if all UUT attributes of a given manufacturer/model are in-tolerance prior to testing or calibration? In this case, the false accept risk is zero regardless of the TUR.
- The requirement is not applicable when UUT tolerances are single-sided.
- The requirement is only approximately applicable when tolerances are two-sided but asymmetric, and the UUT bias is distributed such that its mode value is zero.

Bias – Centered Measurement

- Page 92 Section 5.2 Introduction to Statistics in Metrology

5.2.1.5 Risk with Biased Measurements

While the 4:1 TUR requirement is commonly used to ensure a measurement is adequate for making an accept/reject determination, this metric assumes that the process distribution is centered between the specification limits, that is $\mu_p = (SL_U + SL_L)/2$. If this is not the case, TUR cannot be reliably used as an indicator of risk, however, the PFA and PFR equations are still valid assuming the correct μ_p is used.

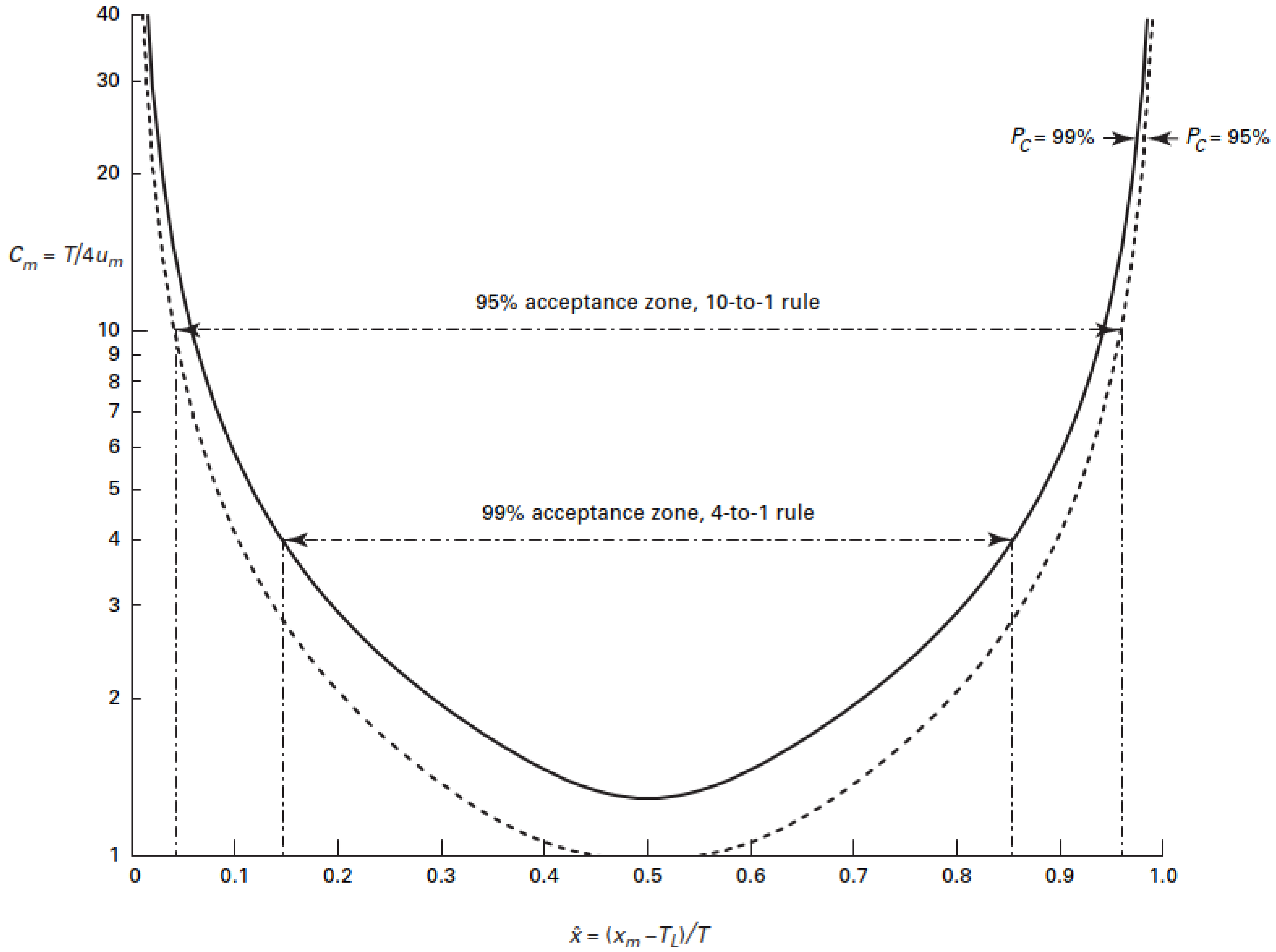
The measurement uncertainty distribution is also assumed to be centered about the actual value t when calculating TUR. The measurement process is said to be biased if it is not centered about t and systematically overstates or understates the true value of the measurement. Properly accounting for measurement bias provides a more accurate risk evaluation. If bias is ignored, the risk might be understated, perhaps significantly.

In the presence of bias, the distribution of the measurement y, given the actual value t, shifts from a $N\left(t, \sigma_m^2\right)$ distribution to a $N\left(t - b_m, \sigma_m^2\right)$ distribution, where b_m is the measurement bias.

With bias b_m, the expressions for the PFA and PFR (without guardbanding) become

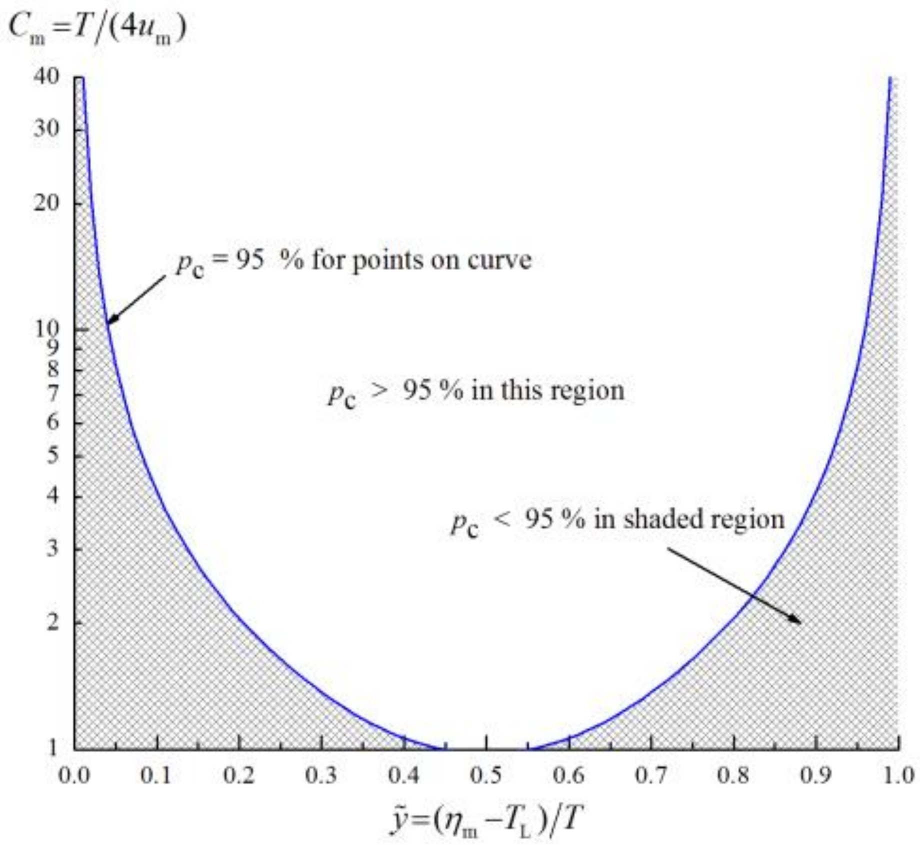
$$\begin{aligned} \text{PFA} = & \int_{-\infty}^{SL_L} \left(\int_{SL_L}^{SL_U} \frac{1}{\sigma_m \sqrt{2\pi}} e^{-\frac{1}{2\sigma_m^2}(y-(t-b_m))^2} dy \right) \frac{1}{\sigma_p \sqrt{2\pi}} e^{-\frac{1}{2\sigma_p^2}(t-\mu_p)^2} dt \\ & + \int_{SL_U}^{+\infty} \left(\int_{SL_L}^{SL_U} \frac{1}{\sigma_m \sqrt{2\pi}} e^{-\frac{1}{2\sigma_m^2}(y-(t-b_m))^2} dy \right) \frac{1}{\sigma_p \sqrt{2\pi}} e^{-\frac{1}{2\sigma_p^2}(t-\mu_p)^2} dt. \end{aligned} \tag{5.18}$$

Measurement Capability Index



ASME B89.7.4.1-2005

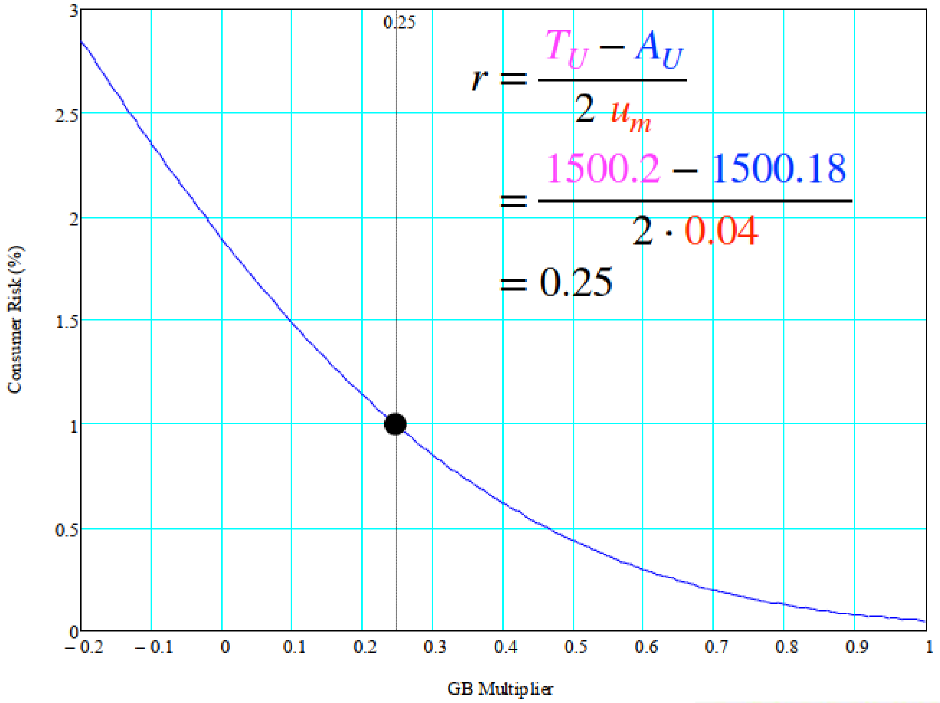
Measurement Capability Index



Measurement capability index Cm = T/(4um) versus y = (ηm − TL)/T, showing the locus of constant 95 % conformance probability pc. The curve separates regions of conformity and non-conformity at a 95 % level of confidence. The post-measurement distribution for the measurand Y is taken to be the normal PDF ϕ η; ηm, um2.

Setting acceptance limits for Global Risk is more complex, requiring iterative numerical integration to find the acceptance limits for a desired level of risk. Many times, graphical solutions can be used to set the acceptance limits.

Guard Band Multiplier, **r** = **Norm.s.inv(0.6827)/2 = 0.2376**



$$r = \frac{T_U - A_U}{2\ u_m} = \frac{1500.2 - 1500.18}{2 \cdot 0.04} = 0.25$$

$$A_U = T_U - r \cdot 2\ u_m = 1500.18$$

$$C_m = \frac{0.4}{4 \cdot 0.04} = 2.5$$

$$C_p = \frac{0.4}{6 \cdot 0.12} = 0.556$$

Conformance Probability, P_C	Guard Band Multiplier, r
0.80	0.42
0.85	0.52
0.90	0.64
0.95	0.82
0.977	1.00
0.99	1.16
0.999	1.55

ASME B89.7.4.1-2005 numerical example. T=0.4 mm, TU=1500.2 mm, TL=1499.8 mm, um=0.04 mm, xm=1500.16 mm

$$P_c(0.4, 1500.2, 1499.8, 0.04, 1500.16) = 84.134\%$$

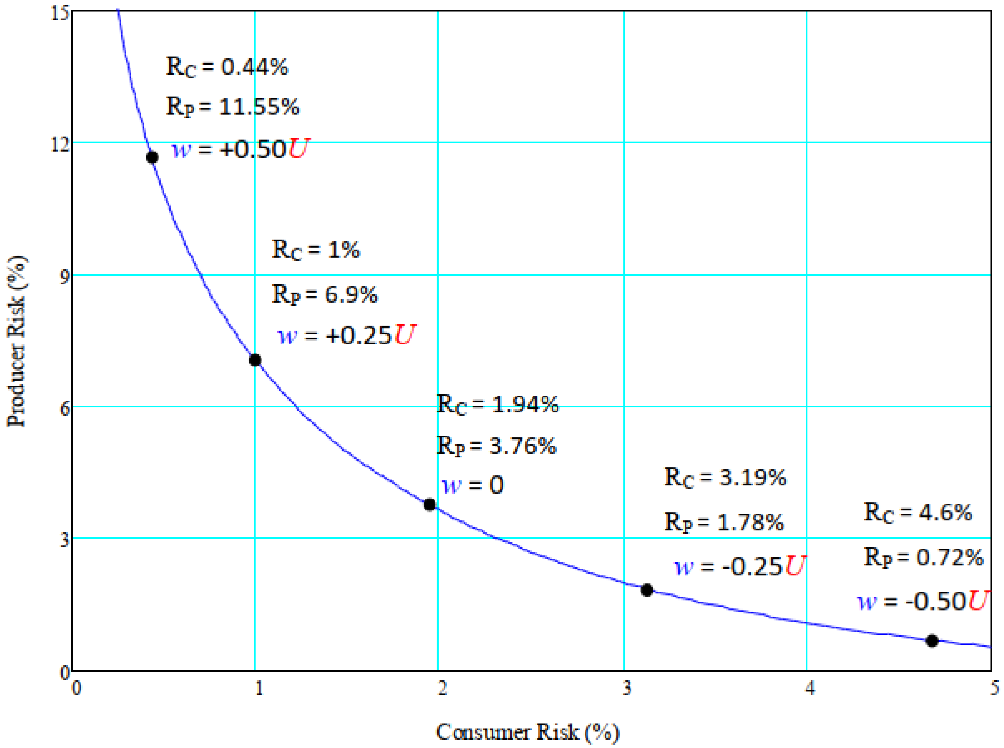
$$1 - P_c(0.4, 1500.2, 1499.8, 0.04, 1500.16) = 15.866\%$$

Using the information from the previous numerical example, several values of guard band magnitude w are shown to illustrate the influence acceptance limits have on consumer and producer risk.

$$C_p = \frac{0.4}{6 \cdot 0.12} = 0.556$$

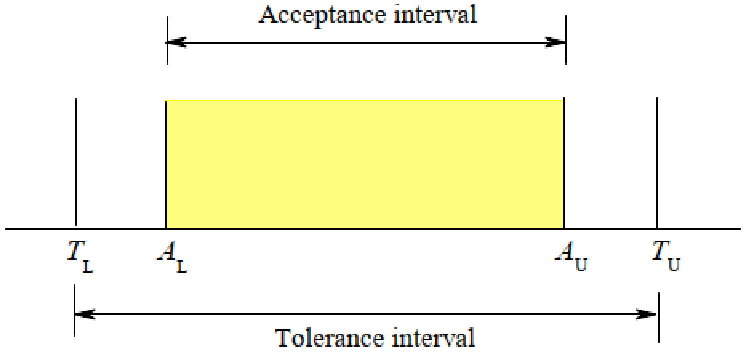
$$C_m = \frac{0.4}{4 \cdot 0.04} = 2.5$$

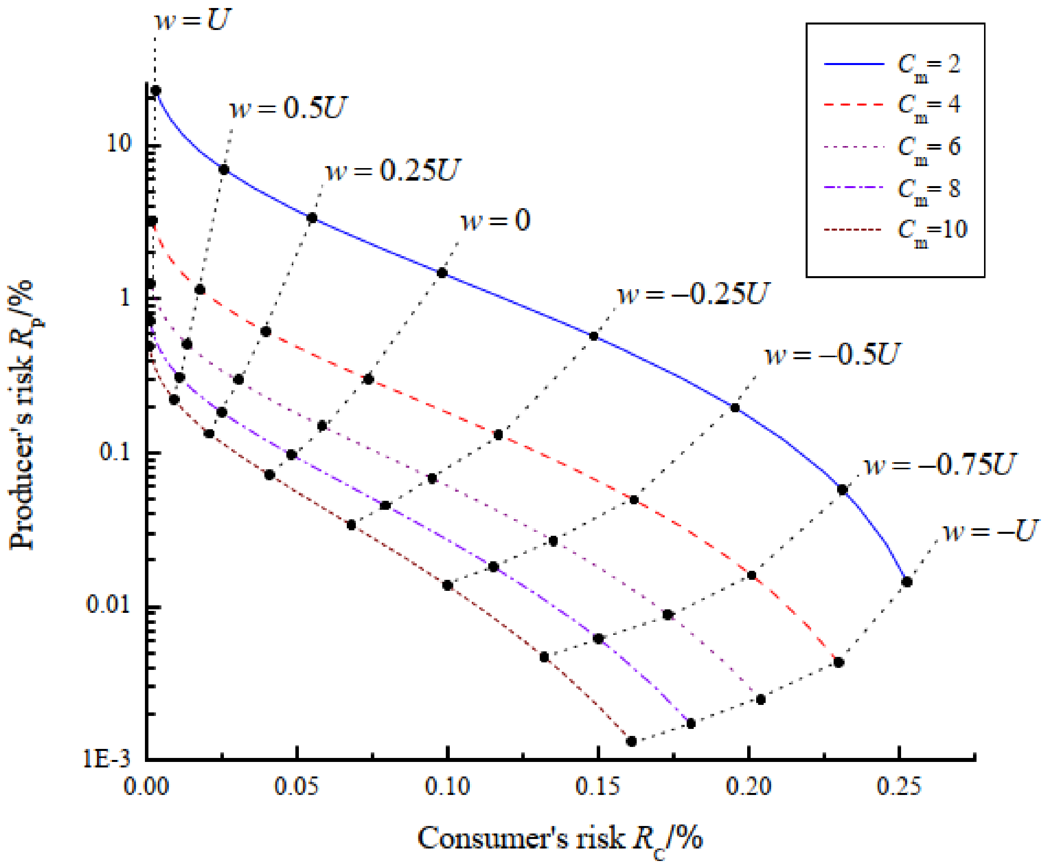
$$w = r \cdot U_{95} \qquad r = \frac{T_U - A_U}{2\ u_m}$$



JCGM 106:2012, Section 9.5.3.2, Example.

Global Risk





Global risks RP versus RC for a binary conformity assessment with prior standard uncertainty u0 = T/6. The five curves correspond to values of the measurement capability index Cm = T/(4um) in an interval from 2 to 10. The solid points locate guard bands with length parameters from w = −U to w = U, with U = 2u. Positive values of w correspond to guarded acceptance, with acceptance limits inside the tolerance limits as shown left.

Global Risk

- Scott Mimbs wrote a paper on EOPR at 89 % and how the 2 % PFA rule could be met by analyzing a population of instruments with years of history.
- If one cannot gather all of the information, then further analysis would be needed, and TUR must be determined at each test point. If the analysis reveals the TUR is greater than 4.6:1, then the PFA will be less than 2 %. (From Risk Mitigation Strategies for Compliance Testing)
- If neither the EOPR nor TUR threshold is met, one could choose to use Specific Risk methods or use another method.

Calculating Global Risk without Process Uncertainty

- In late 2006, ANSI/NCSL Z540.3 added a Global consumer risk requirement of 2% or less for calibrations requiring a conformance decision
- Many calibration labs did not have reliability data (EOPR) needed for global risk models
- In response, Michael Dobbert, developed a Managed Risk guard band that does not require EOPR.
- The Managed Risk guard band for a given measurement capability (Cm) there is a maximum consumer risk for all product/process uncertainty values.
- Therefore, for a given Cm, it is possible to apply just enough of a guard band to lower the maximum risk below a desired level.
- This is known as Method 6 in the Z540.3 Handbook

Dobbert's Method

$$A_{2\%} = T - U_{95} \cdot M_{2\%} \qquad M_{2\%} = 1.04 - e^{(0.38 \cdot \log(TUR) - 0.54)}$$

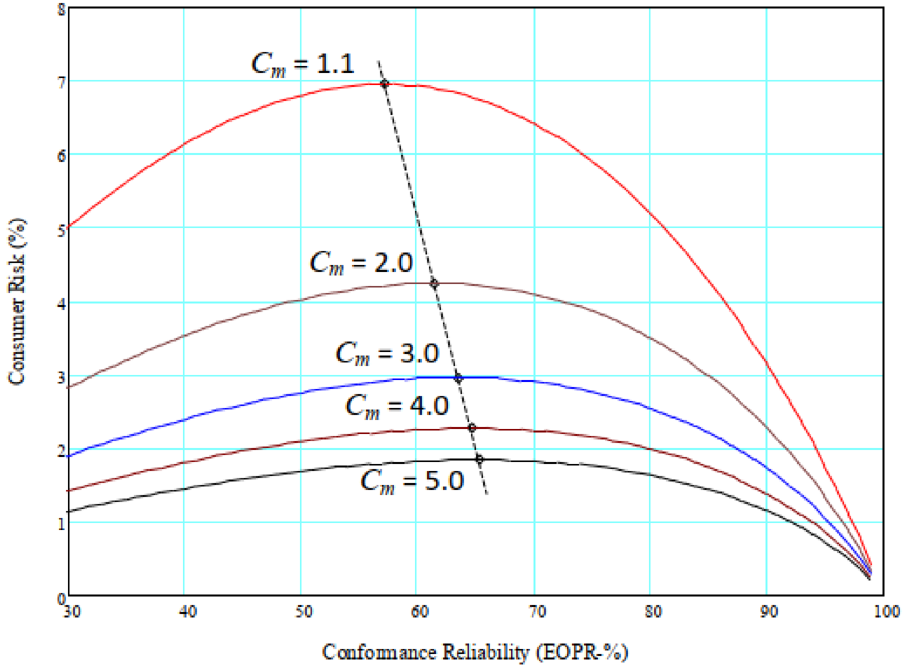
Log( ) is a natural logarithm.
In Excel the function is LN()

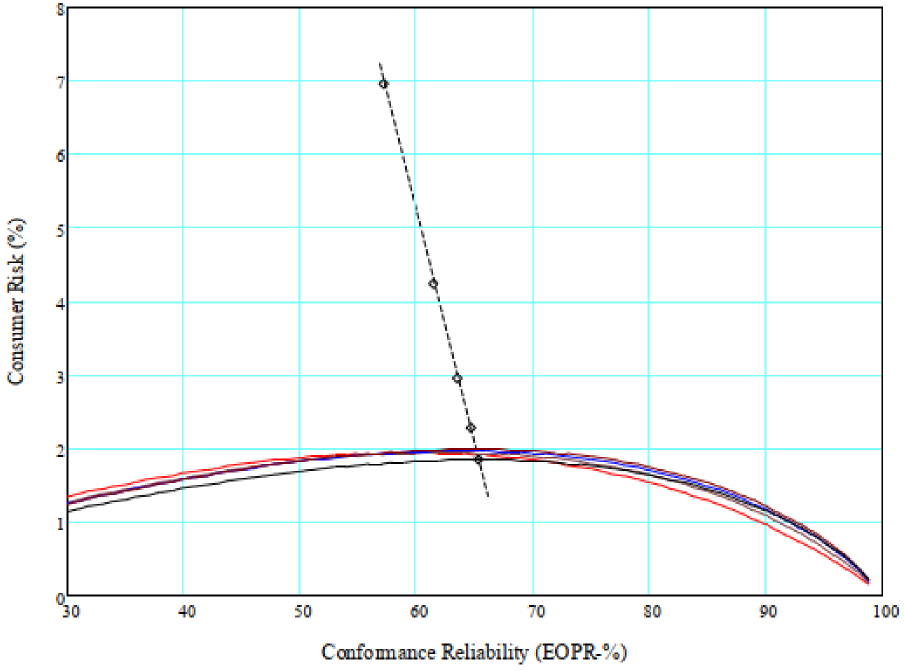
$A_{2\%}$ acceptance limit magnitude used to achieve a maximum of 2% PFA

T tolerance limits

$U_{95\%}$ 95-percent expanded uncertainty of the calibration measurement process

$M_{2\%}$ multiplier to the expanded uncertainty that provides acceptance limits for the desired consumer risk.





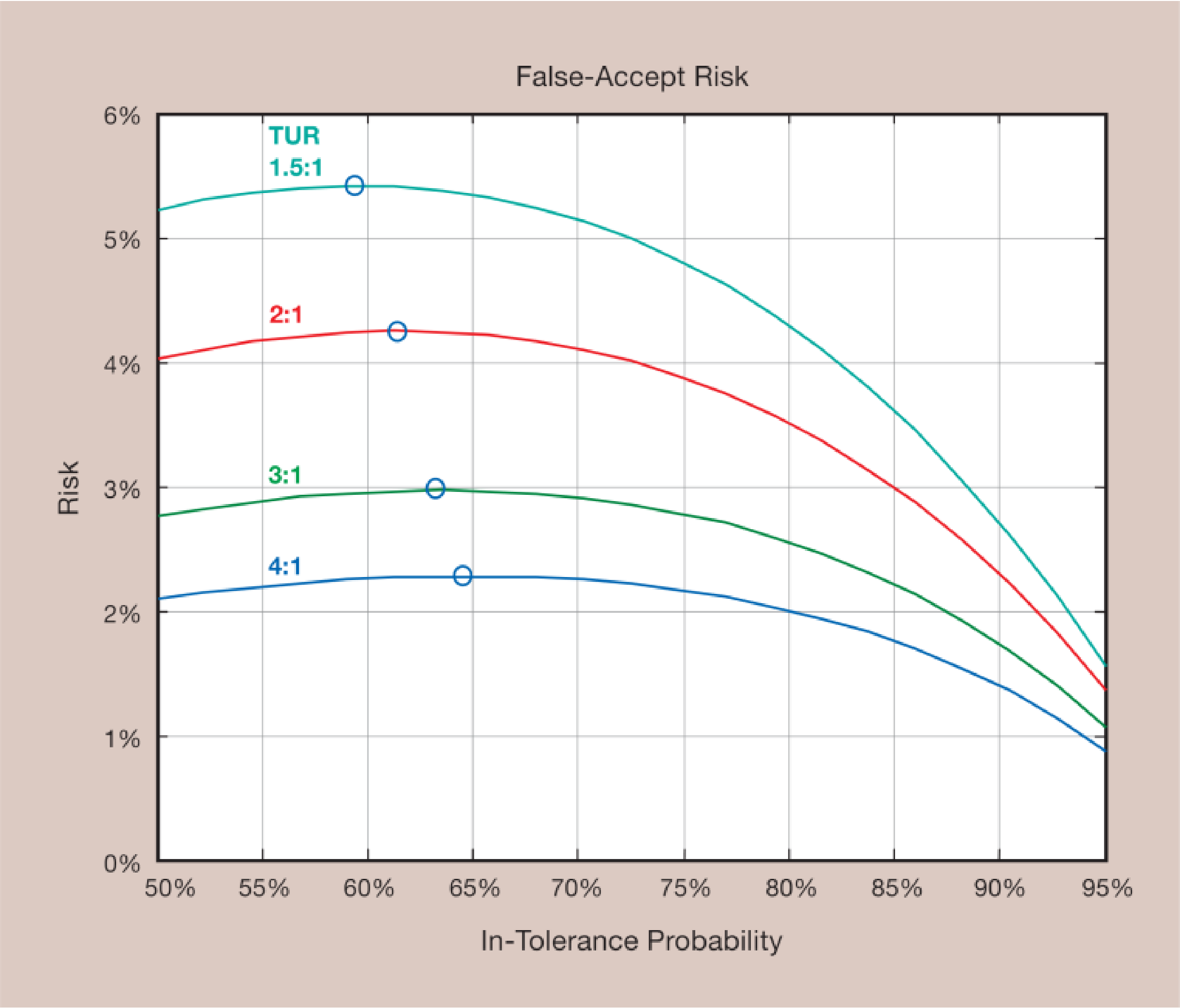
Dobbert, Michael: *A Guard-Band Strategy for Managing False-Accept Risk*. 2008 NCSL International Workshop and Symposium, Orlando, FL, August 2008

Dobbert's Method

False-accept risk can be determined by evaluating a joint probability density function that models a calibration measurement.

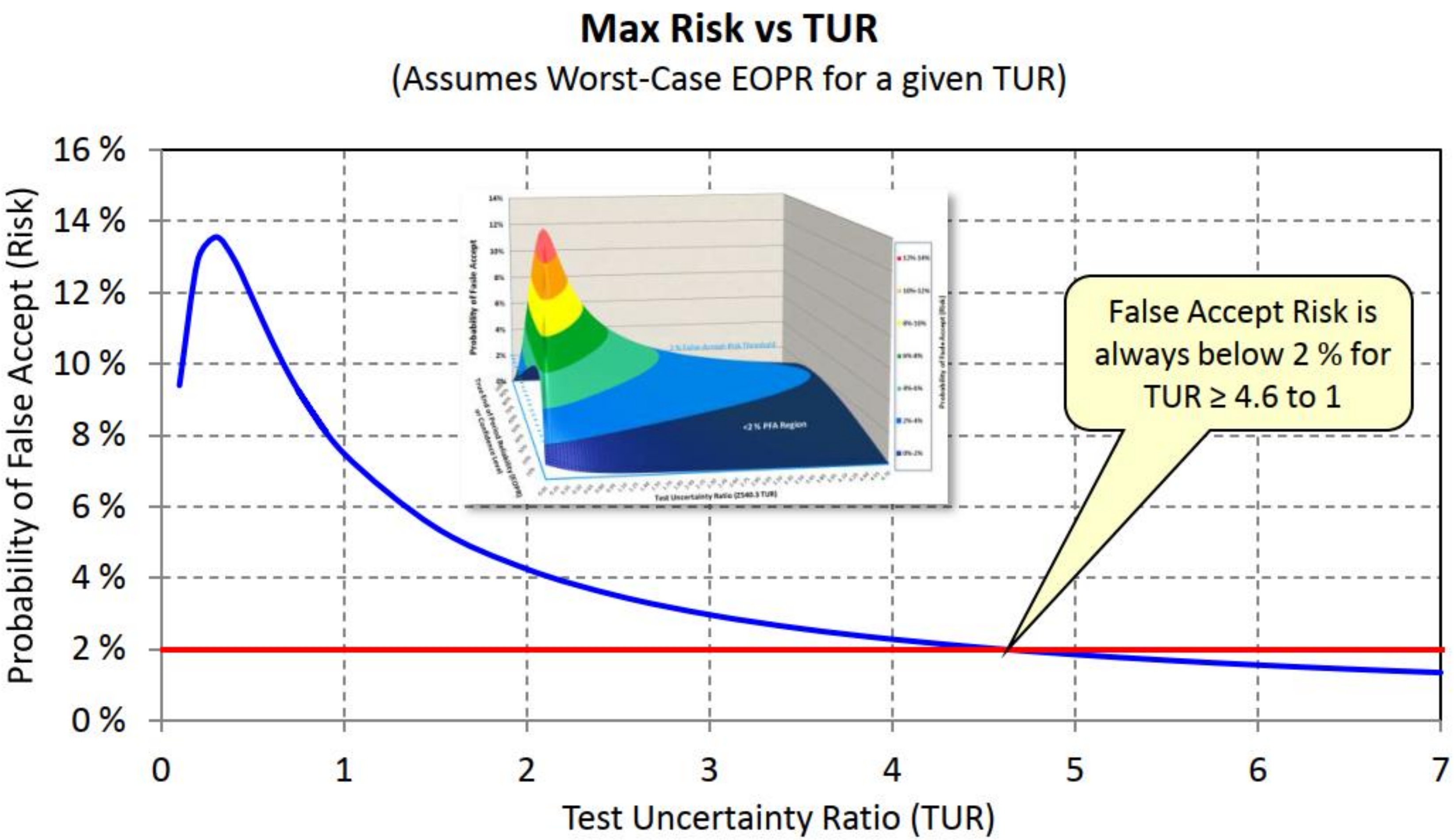
Dobbert calculated a multiplier based on Tolerance Limits, Guard-Band, Calibration Process Uncertainty, & a Reasonable estimate of *a piori* probability that the device is in-tolerance.

This method adjusts the guard band for a specified Cm to meet the 2% consumer risk requirement of Z540.3.



From A Guard-Band Strategy for Managing False-Accept Risk

Global Risk



The image is taken from Implementing Strategies for Risk Mitigation In the Modern Calibration Laboratory

ANSI/NCSL Z540.3 Method 5 Versus Method 6

Raw Data measurements. A 10,000 lbf device with a tolerance of 0.05 % and a resolution of 0.1 lbf.

Force or Torque Applied	Instrument Reading 1	Instrument Reading 2	Instrument Reading 3	Avg Instrument Reading
1000	1001	1000	1001	1000.67
2000	2001	2000	2001	2000.67
3000	3002	3001	3002	3001.67
4000	4002	4002	4001	4001.67
5000	5002	5001	5002	5001.67
6000	6002	6002	6002	6002.00
7000	7002	7003	7002	7002.33
8000	8002	8004	8002	8002.67
9000	9002	9005	9002	9003.00
10000	10002	10005	10002	10003.00

ANSI/NCSL Z540.3 Method 5 Versus Method 6

Instrument Capacity	10,000	
Resolution UUT	0.10	
Tol UUT	0.050%	Full Scale
Plus 1 Count	no	
CMC	0.0016%	
K = for CMC	2	

What happens if we change the CMC to 0.05 %, which is what most secondary laboratories have for a CMC?

DIFFERENCE IN ACCEPTANCE LIMITS METHOD 5 VS METHOD 6

Force or Torque Applied	Avg Instrument Reading	**Method 6 AL**	PASS/FAIL	**Method 5 AL**	PASS/FAIL	**% Diff in AL**
1000	1000.67	**4.94**	PASS	**3.80**	PASS	**23.16%**
2000	2000.67	**4.94**	PASS	**3.74**	PASS	**24.16%**
3000	3001.67	**4.92**	PASS	**3.66**	PASS	**25.59%**
4000	4001.67	**4.88**	PASS	**3.56**	PASS	**27.09%**
5000	5001.67	**4.82**	PASS	**3.43**	PASS	**28.86%**
6000	6002.00	**4.94**	PASS	**3.77**	PASS	**23.72%**
7000	7002.33	**4.68**	PASS	**3.14**	PASS	**33.07%**
8000	8002.67	**4.15**	PASS	**2.11**	FAIL	**49.04%**
9000	9003.00	**3.49**	PASS	**0.99**	FAIL	**71.60%**
10000	10003.00	**3.43**	PASS	**0.89**	FAIL	**73.98%**

ANSI/NCSL Z540.3 Method 5 Versus Method 6

Instrument Capacity	10,000	
Resolution UUT	0.10	
Tol UUT	0.050%	Full Scale
Plus 1 Count	no	
CMC	0.0500%	**Changed The CMC**
K = for CMC	2	

Tolerance of 0.05 %

DIFFERENCE IN ACCEPTANCE LIMITS METHOD 5 VS METHOD 6

Force or Torque Applied	Avg Instrument Reading	**Method 6 AL**	PASS/FAIL	**Method 5 AL**	PASS/FAIL	**% Diff in AL**
1000	1000.67	**4.93**	PASS	**3.71**	PASS	**24.88%**
2000	2000.67	**4.82**	PASS	**3.43**	PASS	**28.86%**
3000	3001.67	**4.65**	PASS	**3.06**	PASS	**34.24%**
4000	4001.67	**4.43**	PASS	**2.63**	PASS	**40.66%**
5000	5001.67	**4.18**	PASS	**2.17**	PASS	**48.06%**
6000	6002.00	**4.04**	PASS	**1.92**	FAIL	**52.49%**
7000	7002.33	**3.63**	PASS	**1.21**	FAIL	**66.49%**
8000	8002.67	**3.03**	PASS	**0.26**	FAIL	**91.53%**
9000	9003.00	**2.33**	FAIL	**-0.83**	FAIL	**135.77%**
10000	10003.00	**2.05**	FAIL	**-1.25**	FAIL	**160.82%**

ANSI/NCSL Z540.3 Method 5 Versus Method 6

Instrument Capacity	10,000	
Resolution UUT	0.10	
Tol UUT	0.100%	Full Scale
Plus 1 Count	no	
CMC	0.0016%	
K = for CMC	2	

What happens if we change the tolerance to 0.1 %

DIFFERENCE IN ACCEPTANCE LIMITS METHOD 5 VS METHOD 6

Force or Torque Applied	Avg Instrument Reading	Method 6 AL	PASS/FAIL	Method 5 AL	PASS/FAIL	% Diff in AL
1000	1000.67	9.94	PASS	8.81	PASS	11.34%
2000	2000.67	9.94	PASS	8.81	PASS	11.34%
3000	3001.67	9.94	PASS	8.81	PASS	11.35%
4000	4001.67	9.94	PASS	8.81	PASS	11.36%
5000	5001.67	9.94	PASS	8.81	PASS	11.37%
6000	6002.00	9.99	PASS	9.88	PASS	1.09%
7000	7002.33	9.94	PASS	8.81	PASS	11.39%
8000	8002.67	9.88	PASS	7.62	PASS	22.83%
9000	9003.00	9.45	PASS	6.44	PASS	31.86%
10000	10003.00	9.45	PASS	6.44	PASS	31.87%

Global Versus Specific Risk Summary

- Specific Risk is dependent on a single probability function and can be referred to as Probability of Conformance from the customer's point of view.
- Global Risk is dependent on two probabilities, the second being the a priori knowledge, which could be taken as the process or instrument reliability.
- Typically, when we talk about TUR, we are talking about Global Risk.
- Though TUR is also a ratio that can be useful at the bench level as higher TUR's increase our acceptance zone.

Other Methods

From Evaluation of Guardbanding Methods for Calibration and Product Acceptance.

The recommendation from this document is to use the Root Sum Square

Note: The calculated *gbf* is then multiplied by the tolerance and then added or subtracted from the USL or SLS

2. GUARDBAND METHODS

Common guardbanding methods are described here. In all these methods, the TUR is defined as

$$TUR = \frac{\pm\, Specification\ Limit}{\pm\, Measurement\ Uncertainty}$$

Where the measurement uncertainty is reported at a 95% level of confidence (k=2).

2.1. Root Sum Squares

The RSS method is recommended in the PSLM [4] and is one of two options allowed by General Requirements Document 9900000 [5].

$$gbf = \sqrt{1 - \frac{1}{TUR^2}}$$

2.2. 95% Measurement Uncertainty (U95)

The 95% Measurement Uncertainty method subtracts the expanded measurement uncertainty U^{95} from the specification limit ($AL = SL - U^{95}$). This method is the second option allowed by 9900000, and is the only available option for one-sided product requirements where the TUR cannot be calculated. In terms of TUR, it is equivalent to

$$gbf = 1 - \frac{1}{TUR}.$$

RDS Method

- **RDS** method was developed in the early/mid-1990s

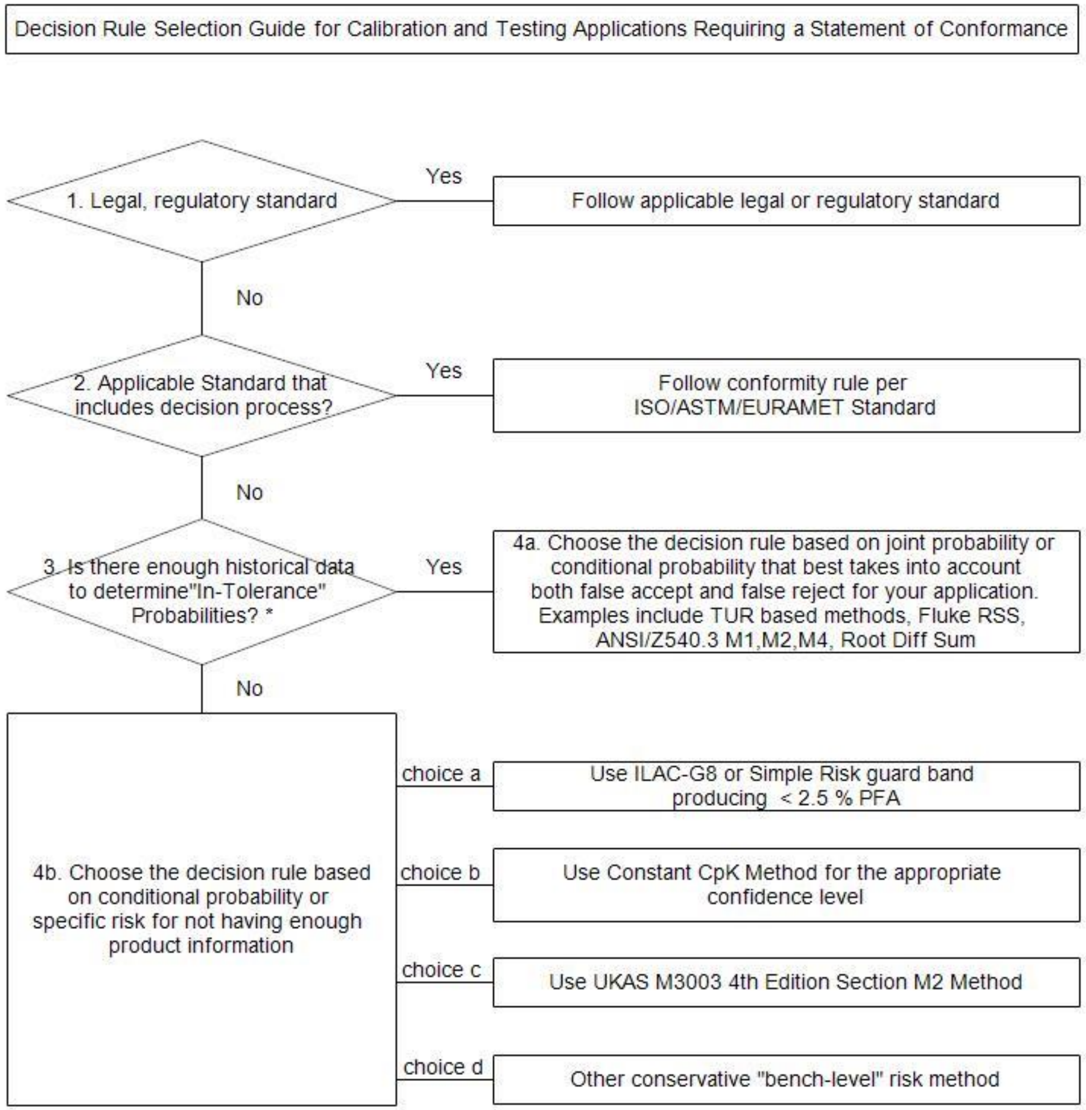
- **It was based on 0.8 %** Global False Accept Risk (PFA) and occurred anytime you had a 4:1 TUR, with a 95 % EOPR for the UUT.

- Most guard banding methods back then (at least, those widely accepted by the NCSL) tried to achieve false accept risk equivalent to that alluded to in MIL-STD-45662A (i.e., **<0.8 %** risk, assuming 4:1 TUR and 95 % EOPR for the UUT).

- It is interesting that the Dobbert guard band appears to be approximated very closely by the RSS, or root difference-of-squares (RDS) method.

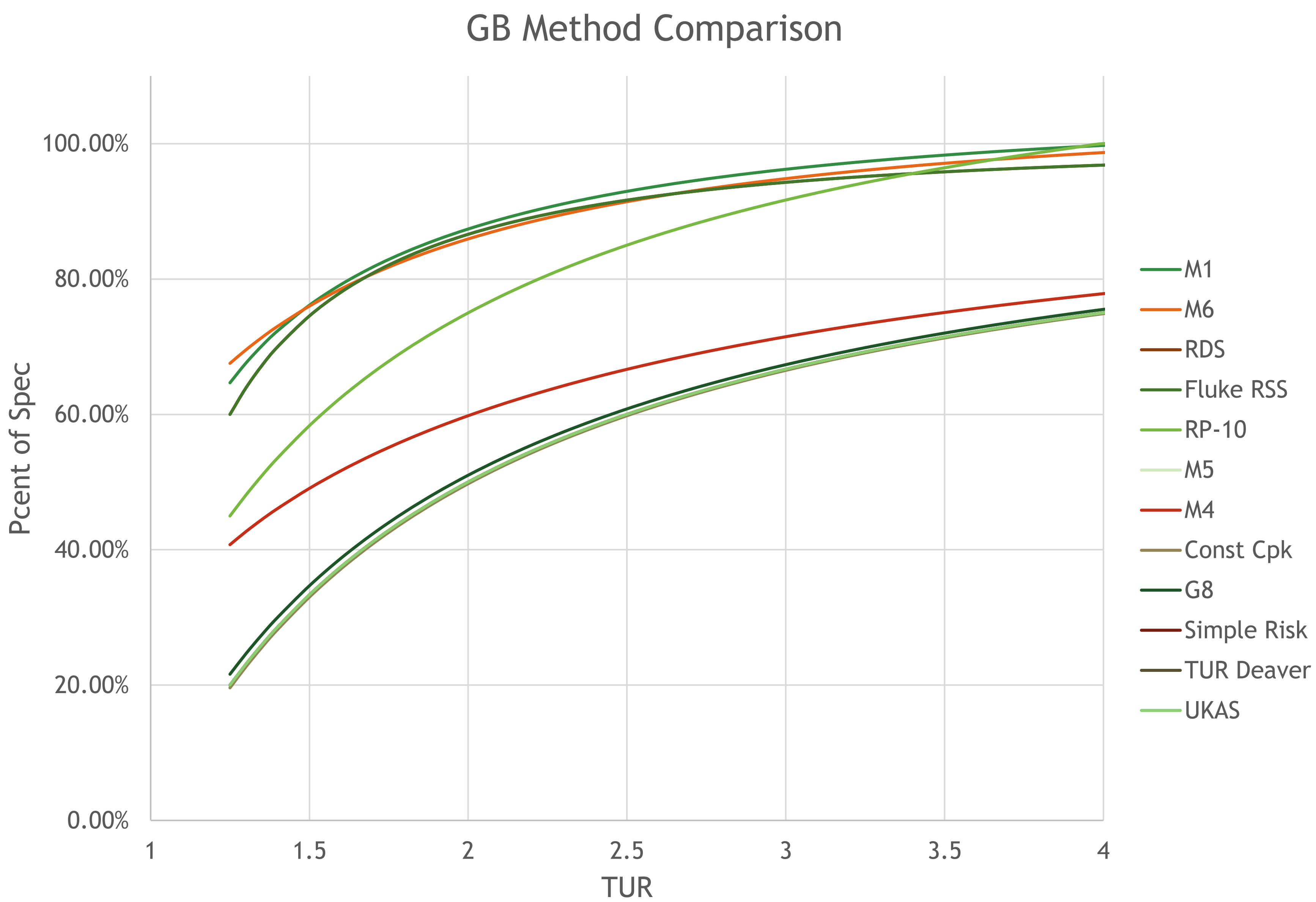
TUR	$K_{Dobbert}$	M	K_{RDS}
1.1	0.60	0.44	0.42
1.5	0.76	0.36	0.75
2.0	0.86	0.28	0.87
2.5	0.91	0.21	0.92
3.0	0.95	0.16	0.94
3.5	0.97	0.10	0.96
3.99	0.99	0.05	0.97
4.00	1.00		0.97

Selecting the Appropriate Decision Rules



*3. *Note: The formula to determine "In-Tolerance" Probability from historical data is*
SampleSize = ln(1-Confidence)/ln(Target $_{Reliability}$)

Decision Rules



Decision Rules

- When you have an instrument, or a gage calibrated you should receive a calibration certificate (and hopefully you're getting calibration data and the lab's measurement uncertainties too).
- **What do you do with the certificate if it indicates the instrument was In Tolerance? – Do you look at the report?**
- **What do you do if it is out of Tolerance? – do you perform a reverse traceability scheme and recall equipment, if needed?**

What are Some of the Things We can Control to Mitigate Our Risk?

- We can raise our tolerance if we do not need what the manufacturer states.
- We can decrease the time between calibrations
- Maybe it is a matter of a too coarse resolution where a different indicator would help.

If we want to observe high in-tolerance probability, we will need to have one of these conditions met

- An extremely good UUT, and an acceptable Reference Standard, providing a miniscule PFA (e.g., 0.01 %), or
- A relatively good UUT, and a good Reference Standard, providing an acceptable PFA (e.g. < 2.0 %)

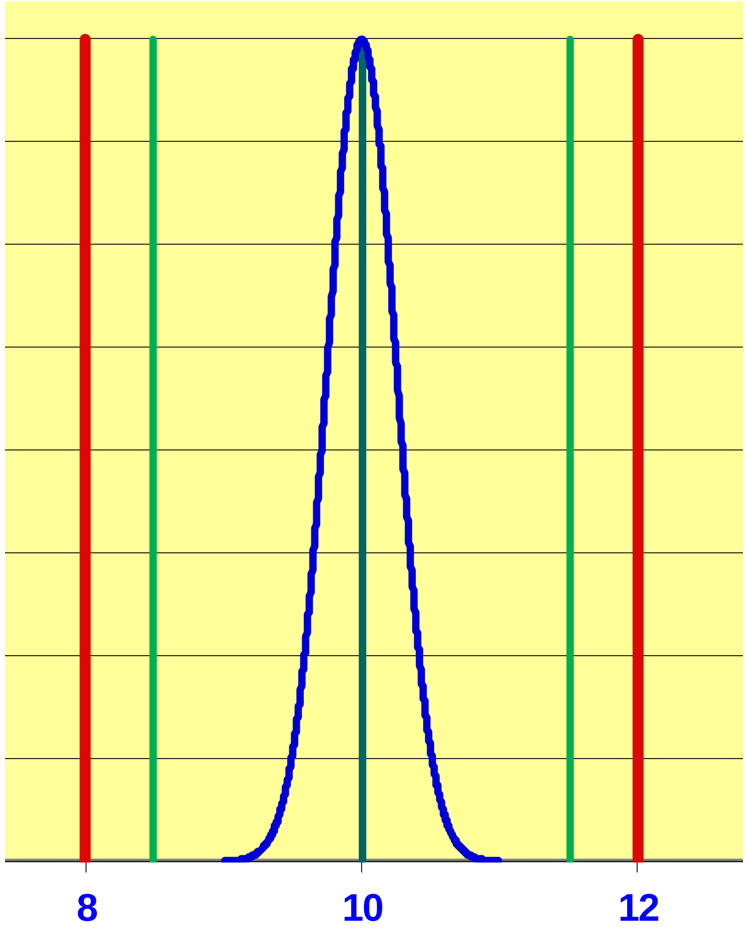
- S. Mimbs Rule of 89 paper

Additional Recommended Reading

- ASME B89.7.3.1-2001 GUIDELINES FOR DECISION RULES: CONSIDERING MEASUREMENT UNCERTAINTY IN DETERMINING CONFORMANCE TO SPECIFICATIONS
- ASME B89.7.4.1-2005 Measurement Uncertainty and Conformance Testing: Risk Analysis
- ISO 14253-1:2017 Geometrical product specifications (GPS) — Inspection by measurement of workpieces and measuring equipment — Part 1: Decision rules for verifying conformity or nonconformity with specifications
- JCGM 106: 2012 Evaluation of measurement data – The role of measurement uncertainty in conformity assessment
- **UKAS LAB 48: Decision Rules and Statements of Conformity**
- **ILAC G8:09/2019 Guidelines on Decision Rules and Statements of Conformity**

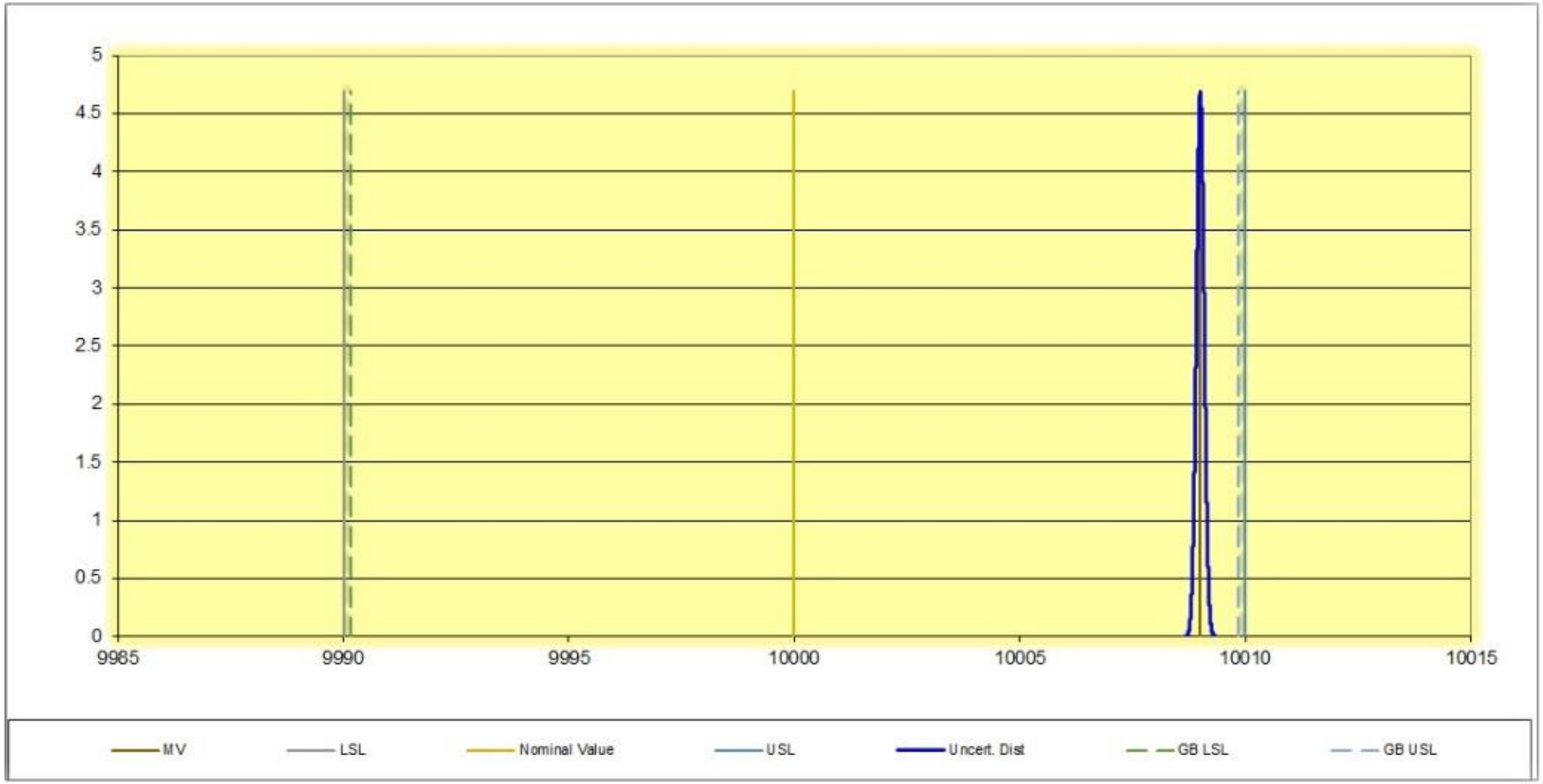
Instrument Measurement Uncertainty Guard Banding

There are, important assumptions associated with using TUR as a metric and the requirement of a TUR of 4:1 or better. Using a TUR assumes that all measurement biases have been removed from the measurement process and the measurements involved follow a normal distribution. If there are significant biases that cannot be removed, the TUR may not account for the increased risk.



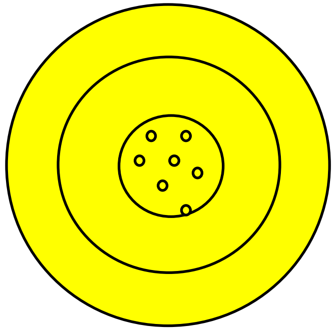
Instrument Measurement Uncertainty Guard Banding

Nominal Value	10000.0
Lower specification Limit	9990.0
Upper Specification Limit	10010.0
Measured Value	10009.0
Measurement Error	9.0
Std. Uncert. (k=1)	0.085
Total Risk	0.00%
Upper Limit Risk	0.000%
Lower Limit Risk	0.000%
TUR =	58.78943644
Cpk=	5.999032319
TAR=	62.5
Simple Guard Band (Subtract Uncertainty)	
Guard Band LSL	9990.170
Guard Band USL	10009.8299
Percent of Spec	98.30%
Guard Band Limits for Risk of	2.500%
Guard Band LSL	9990.167
Guard Band USL	10009.833
Percent of Spec	98.33%

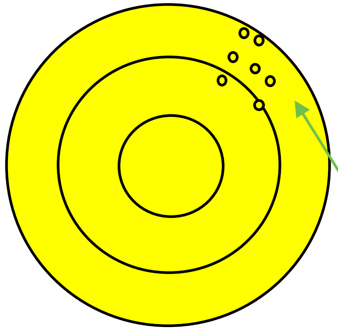


In this example, we are making a conformity assessment based on Specific Risk of “Pass” if the measured value is between 9 990.167 and 10 009.833.

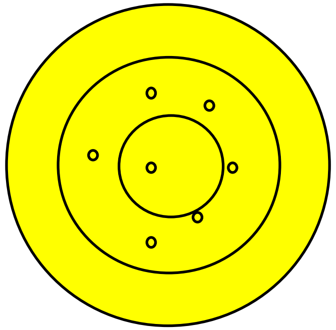
Accuracy and Precision



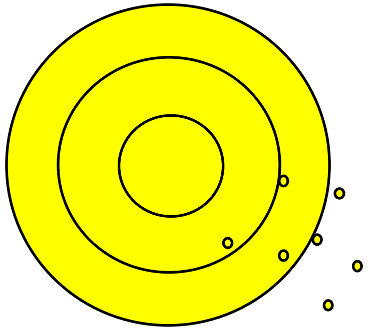
High Precision (Small Random Error)
High Accuracy (Low Bias)



High Precision
Low Accuracy (High Bias)



Low Precision (Large Random Error)
High Accuracy (Low Bias)



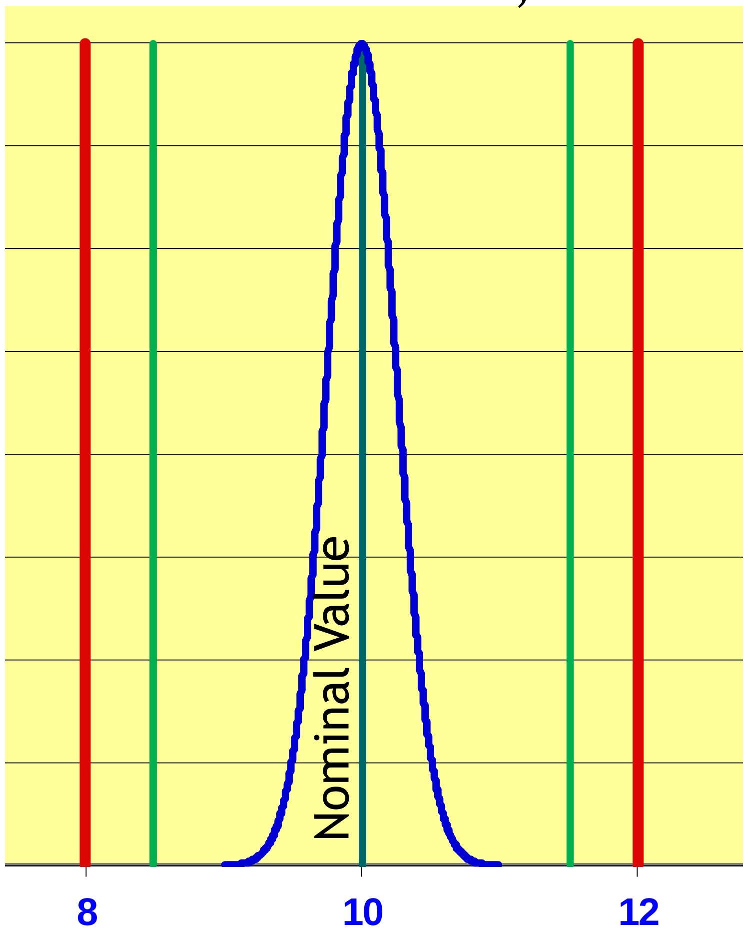
Low Precision
Low Accuracy (High Bias)

This is what we see happening a lot and the reason for this discussion.

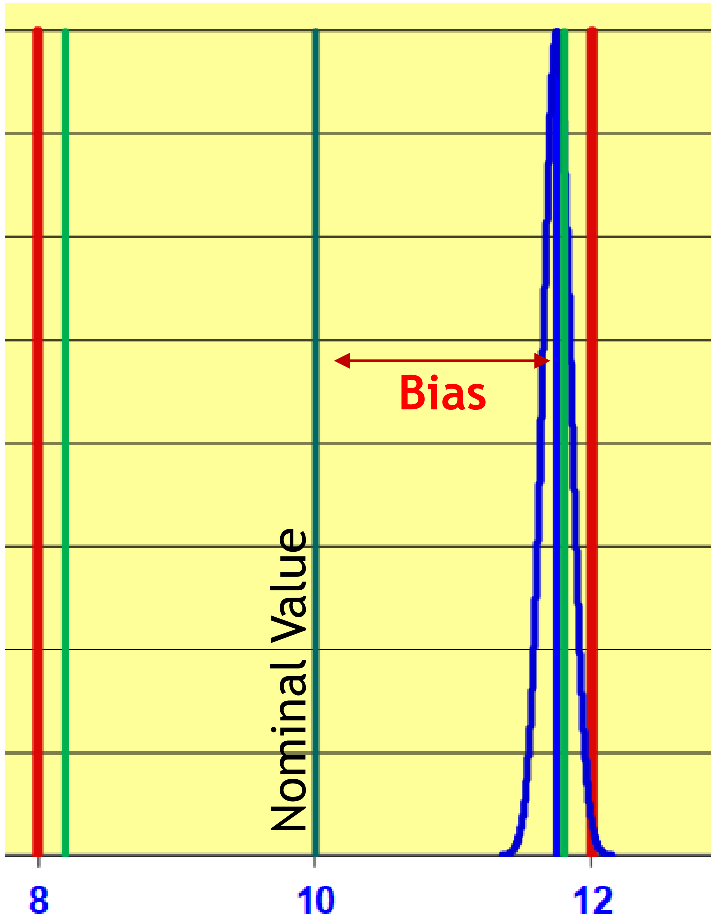
A precise instrument with a known Systematic Error

Instrument Measurement Uncertainty Guard Banding

Nominal Value of **10**
Measured Value of **10**, **No Bias**

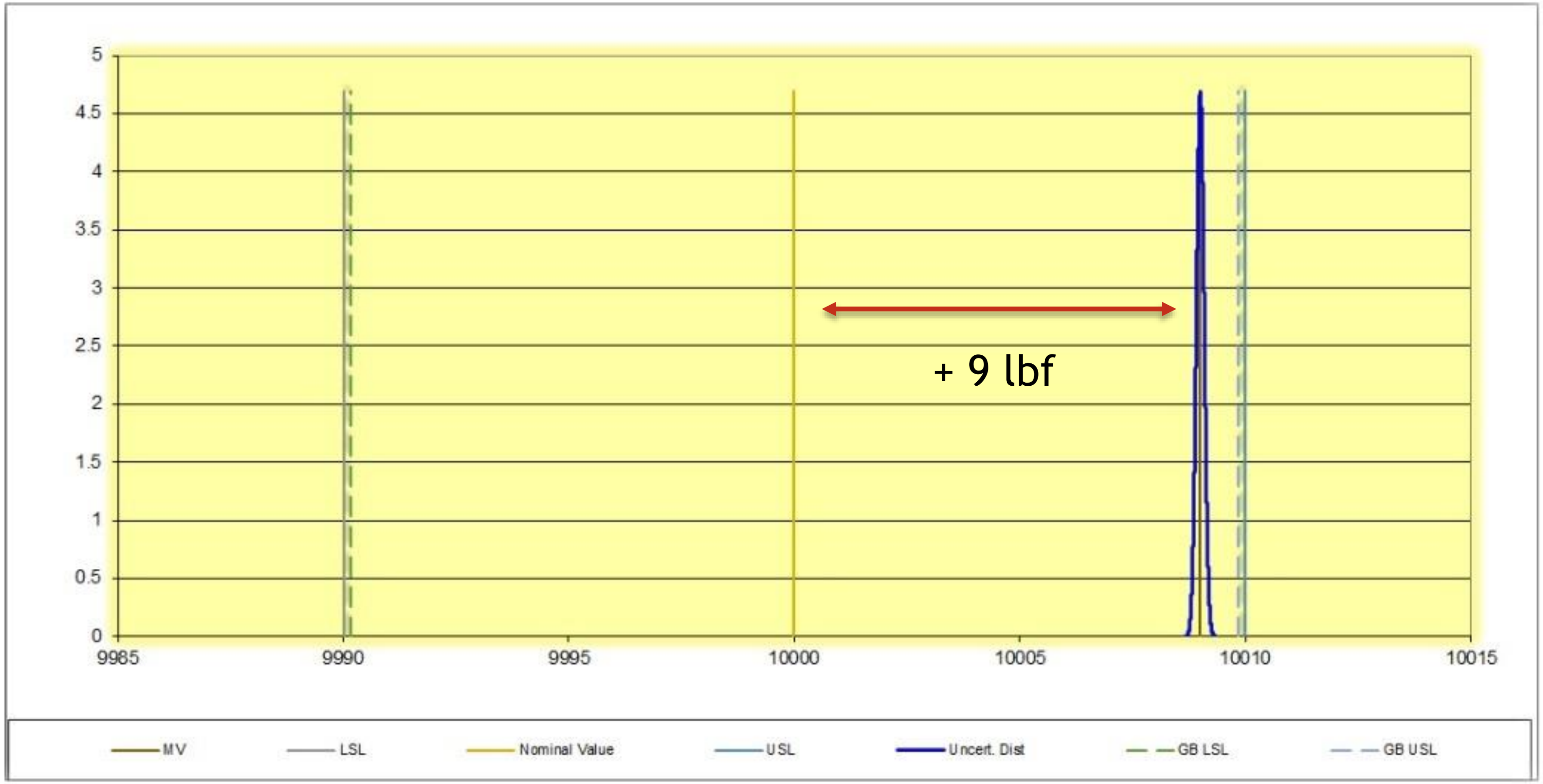


Nominal Value of **10**
Measured Value of **11.75**, **Bias**



Instrument Measurement + 9 lbf Bias

Nominal Value	10000.0
Lower specification Limit	9990.0
Upper Specification Limit	10010.0
Measured Value	10009.0
Measurement Error	9.0
Std. Uncert. (k=1)	0.085
Total Risk	0.00%
Upper Limit Risk	0.000%
Lower Limit Risk	0.000%
TUR =	58.78943644
Cpk=	5.999032319
TAR=	62.5
Simple Guard Band (Subtract Uncertainty)	
Guard Band LSL	9990.170
Guard Band USL	10009.8299
Percent of Spec	98.30%
Guard Band Limits for Risk of	2.500%
Guard Band LSL	9990.167
Guard Band USL	10009.833
Percent of Spec	98.33%



Graph Showing 10 009.0 as the measured value with a 58.789:1 TUR, which is achieved by using a lab with low uncertainties (Morehouse actual example) There is a bias of + 9 lbf in this example.

Instrument Measurement
+ 9 Bias

Force Applied	Measurement Value	Offset, Bias ,Systemic Measurement Error
10 000.00	10 009.00	+ 9
10 000.00	10 009.00	+ 9

When we make repeated measurements or have enough history on the device to know that replicate measurements will produce the same result, we have a known systematic error.

Systemic Measurement Error

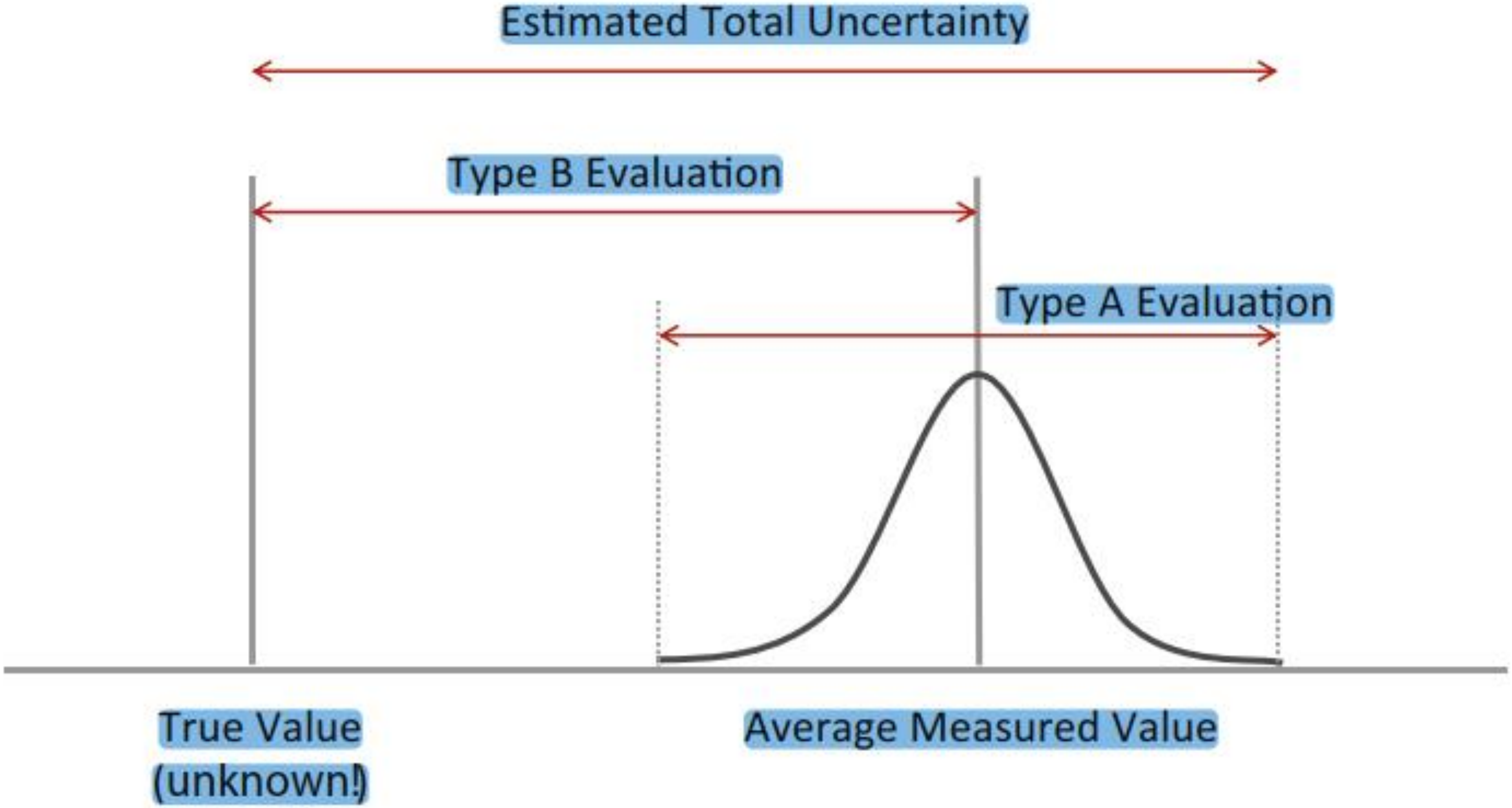
“Systematic error” is an error that, when fully quantified, is predictable.

Systematic error can be **a bias or offset in the measurement** or an error based on an independent parameter, such as a known temperature dependency. **If the systematic error is known, a correction should be applied to the measurement result.**

Again, since the true value can never be known, the use of the term “systematic error” is discouraged unless referring to a quantitative, known offset that can be corrected.

- Section 2.2.2.2 Introduction to Statistics in Metrology

When We Correct For a Known Bias



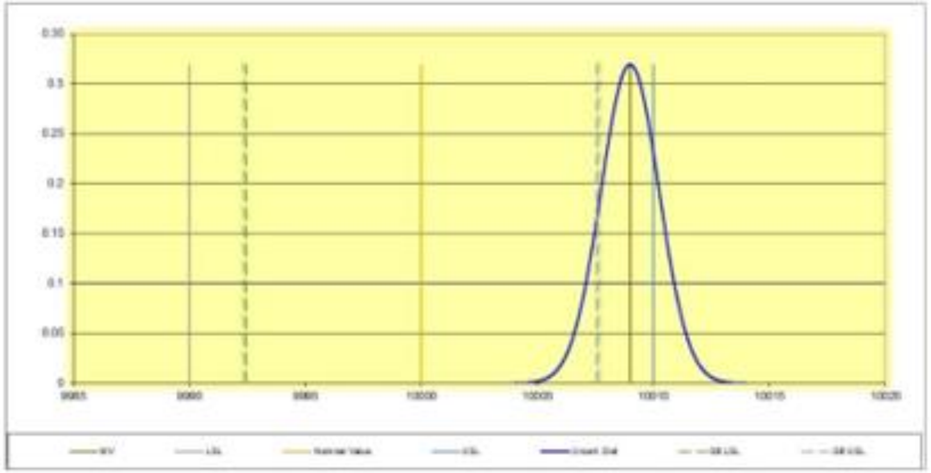
Comparing two different MU values

Low-Risk Scenario

Nominal Value	10000.0
Lower specification Limit	9990.0
Upper Specification Limit	10010.0
Measured Value	10009.0
Measurement Error	9.0
Std. Uncert. (k=1)	0.085
Total Risk	0.00%
Upper Limit Risk	0.000%
Lower Limit Risk	0.000%
TUR =	58.78943644
Cpk=	5.999032319
TAR=	62.5
Simple Guard Band (Subtract Uncertainty)	
Guard Band LSL	9990.170
Guard Band USL	10009.8299
Percent of Spec	98.30%
Guard Band Limits for Risk of	2.500%
Guard Band LSL	9990.167
Guard Band USL	10009.833
Percent of Spec	98.33%

High-Risk Scenario

Nominal Value	10000.0
Lower specification Limit	9990.0
Upper Specification Limit	10010.0
Measured Value	10009.0
Measurement Error	9.0
Std. Uncert. (k=1)	1.250
Total Risk	21.19%
Upper Limit Risk	21.192%
Lower Limit Risk	0.000%
TUR =	3.998933697
Cpk=	0.408061957
TAR=	4
Simple Guard Band (Subtract Uncertainty)	
Guard Band LSL	9992.501
Guard Band USL	10007.4993
Percent of Spec	74.99%
Guard Band Limits for Risk of	2.500%
Guard Band LSL	9992.451
Guard Band USL	10007.549
Percent of Spec	75.49%



Graph Showing 10 009.0 as the measured value comparing two different MU values

Force Applied	Measurement Value	Offset, Bias ,Systemic Measurement Error
10 000.00	10 009.00	+ 9
10 000.00	10 009.00	+ 9

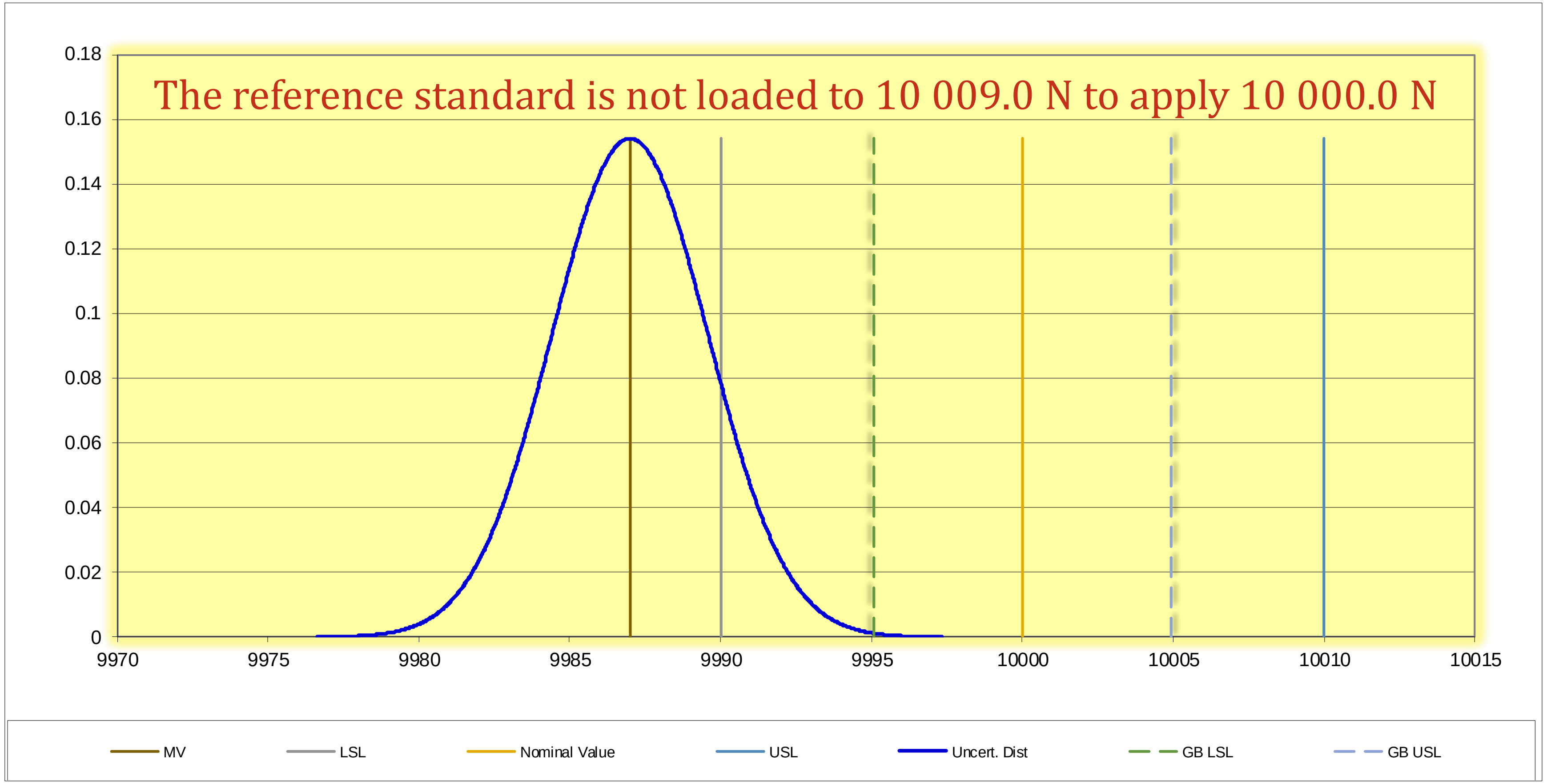
When you know the value to generate 10 000.0 N is 10 0009.0 N.

The right thing for the end-user to do is to load the device to 10 009.0 N to apply 10 000.0 N of force.

What Happens When We Do Not Correct the Bias?

Let us assume they do not do that and use this device to calibrate another 10,000 N instrument.

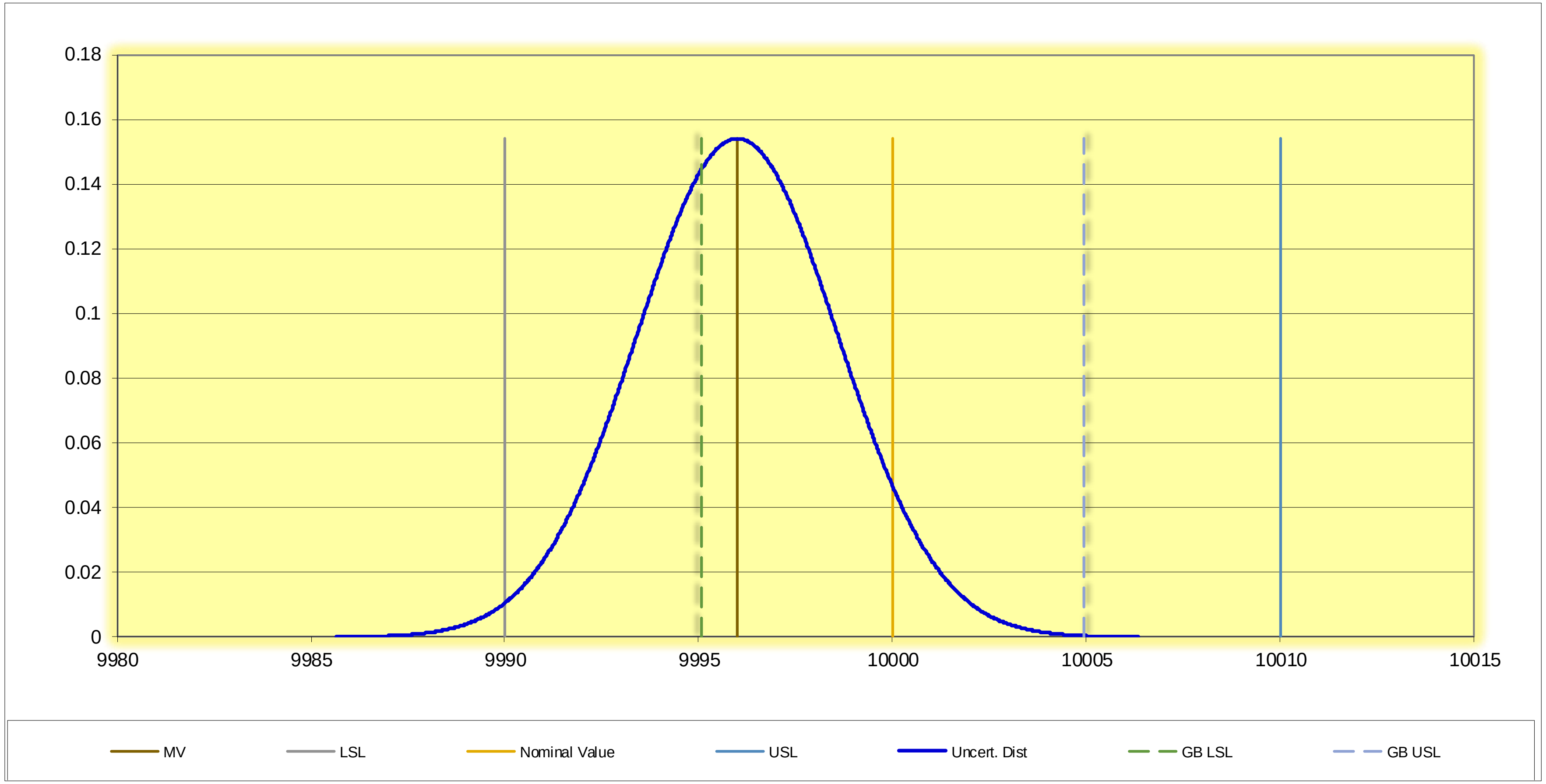
Nominal Value	**10000.0**
Lower specification Limit	9990.0
Upper Specification Limit	10010.0
Measured Value	**9987.0**
Measurement Error	-13.0
Std. Uncert. (k=1)	**2.589**
Total Risk	**87.67%**
Upper Limit Risk	0.000%
Lower Limit Risk	87.672%
TUR =	**1.931223436**
Cpk=	**-0.59120171**
TAR=	**3.99840064**
Simple Guard Band (Subtract Uncertainty)	
Guard Band LSL	**9995.178**
Guard Band USL	**10004.8219**
Percent of Spec	**48.22%**
Guard Band Limits for Risk of	**2.500%**
Guard Band LSL	**9995.074**
Guard Band USL	**10004.926**
Percent of Spec	**49.26%**



What Happens When We Correct the Bias?

The right thing for the end-user to do is to load the device to 10 009.0 N to apply 10 000.0 N of force. When this practice is followed, the DUT is now in specification.

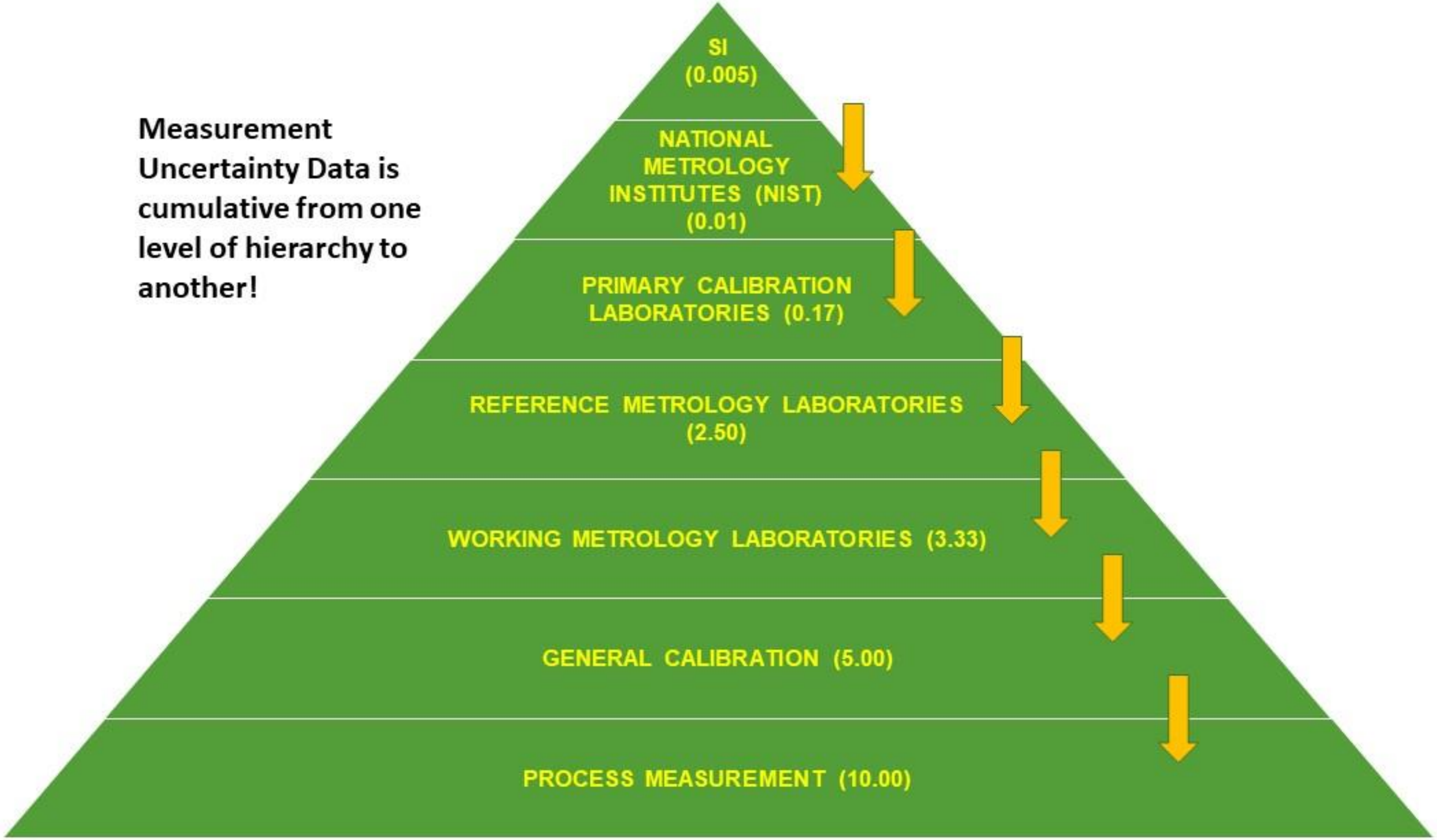
Nominal Value	**10000.0**
Lower specification Limit	9990.0
Upper Specification Limit	10010.0
Measured Value	**9996.0**
Measurement Error	-4.0
Std. Uncert. (k=1)	**2.589**
Total Risk	**1.02%**
Upper Limit Risk	0.000%
Lower Limit Risk	1.024%
TUR =	**1.931223436**
Cpk=	**1.182403422**
TAR=	**3.99840064**
Simple Guard Band (Subtract Uncertainty)	
Guard Band LSL	**9995.178**
Guard Band USL	**10004.8219**
Percent of Spec	**48.22%**
Guard Band Limits for Risk of	**2.500%**
Guard Band LSL	**9995.074**
Guard Band USL	**10004.926**
Percent of Spec	**49.26%**



Morehouse
THE FORCE IN CALIBRATION SINCE 1925

Measurement Traceability

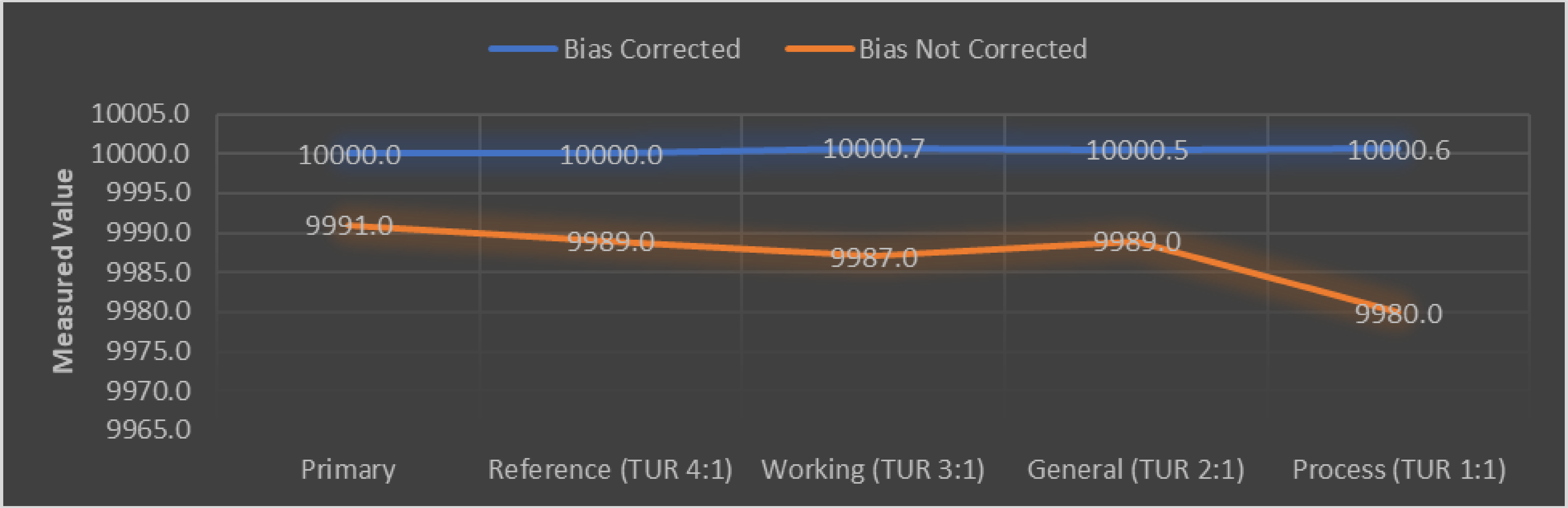
Measurement Uncertainty Data is cumulative from one level of hierarchy to another!



What happens when we do not correct the bias?

	Measurement Uncertainty $k = 2$	BIAS Measured Value With Bias	BIAS CORRECTED Measured Value Bias Removed
Primary	0.17	9991.0	10000.0
Reference (TUR 4:1)	2.5	9989.0	10000.0
Working (TUR 3:1)	3.3	9987.0	10000.7
General (TUR 2:1)	5	9989.0	10000.5
Process (TUR 1:1)	10	9980.0	10000.6

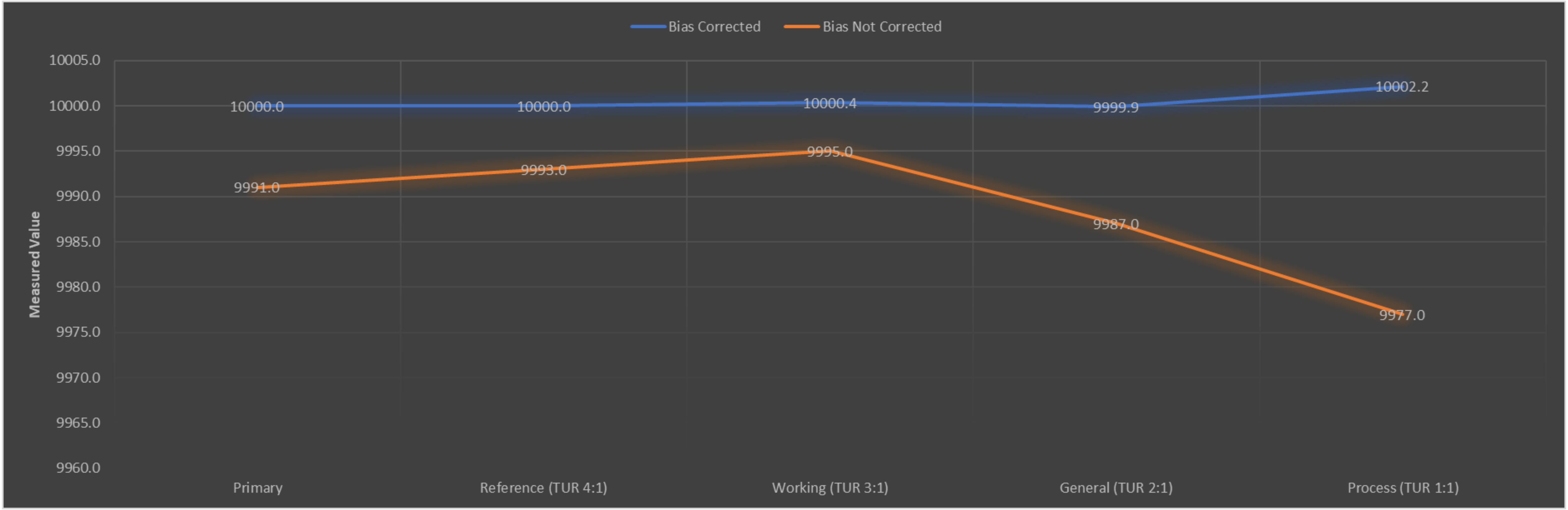
Not Correcting for Bias



The Figure above shows what happens when the reference laboratory does not correct for bias and applies 9,991.0 lbf and not 10,000 lbf.

In this scenario, instruments may have failed when they would have passed calibration.

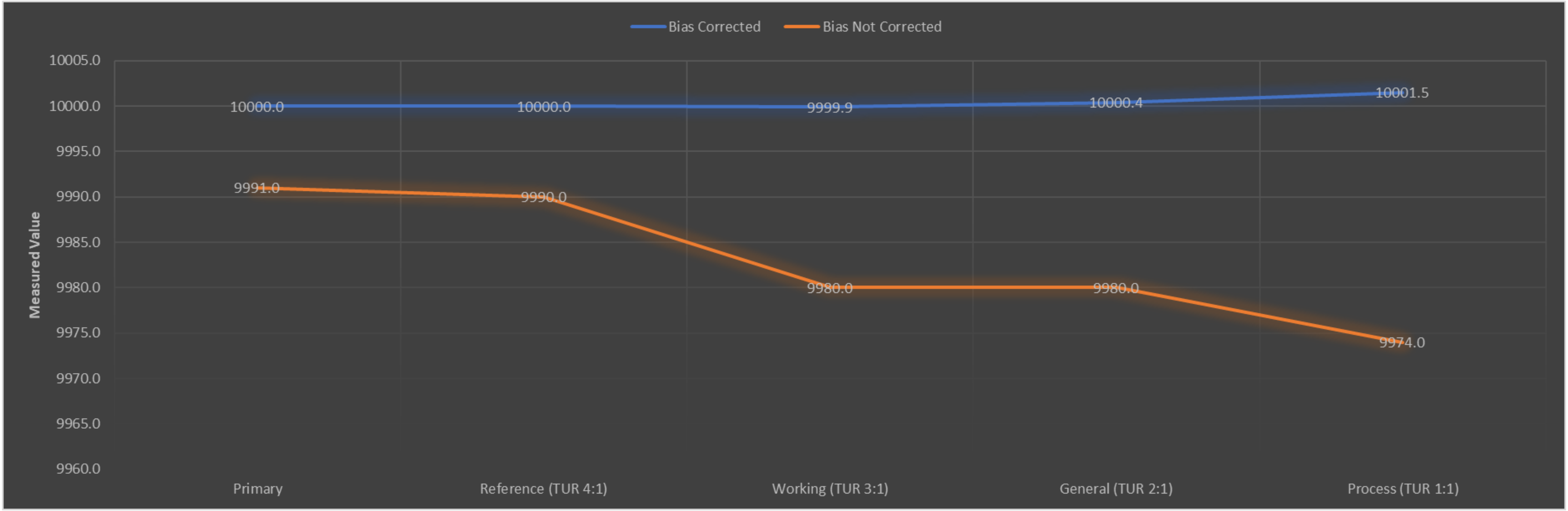
Not Correcting for Bias Simulation 2



The Figure above shows what happens when the reference laboratory does not correct for bias and applies 9,991.0 lbf and not 10,000 lbf.

In this scenario, instruments may have failed when they would have passed calibration.

Not Correcting for Bias Simulation 3



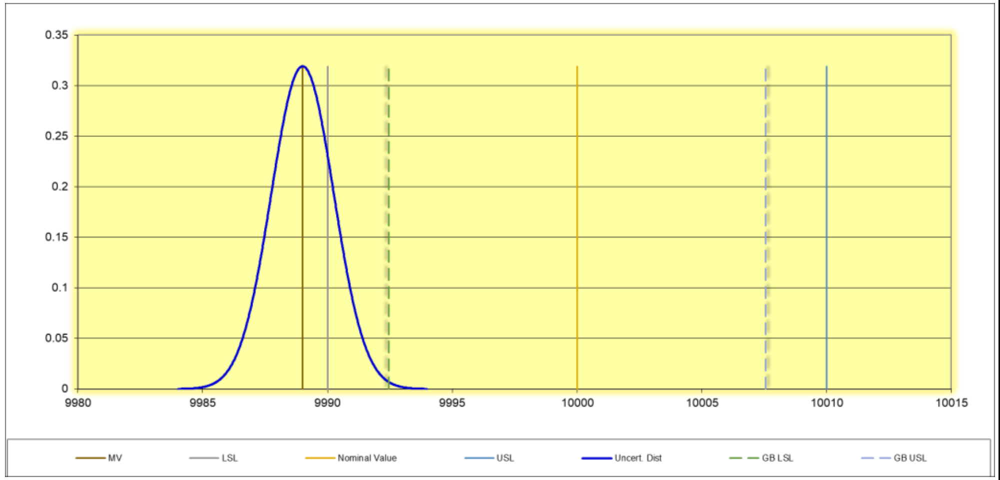
The Figure above shows what happens when the reference laboratory does not correct for bias and applies 9,991.0 lbf and not 10,000 lbf.

In this scenario, instruments may have failed when they would have passed calibration.

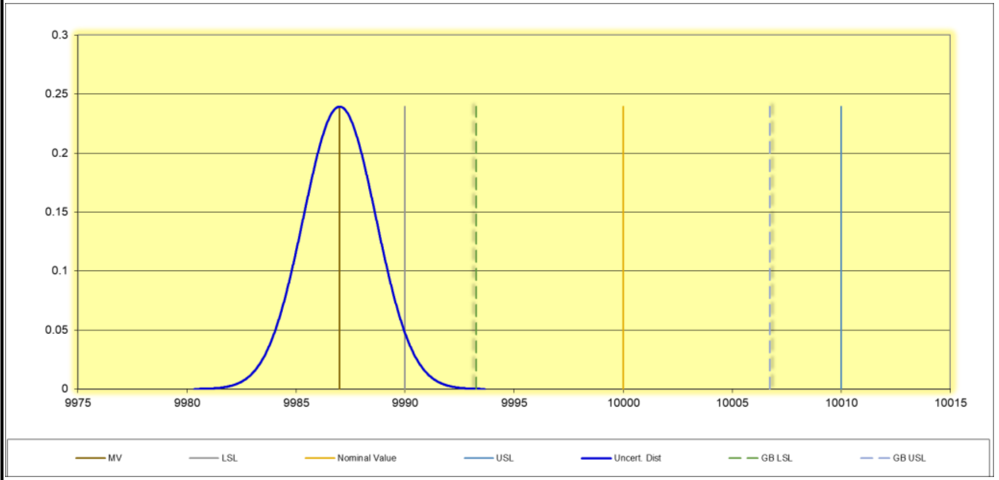
Not Correcting for Bias

Measurement Bias Not Corrected

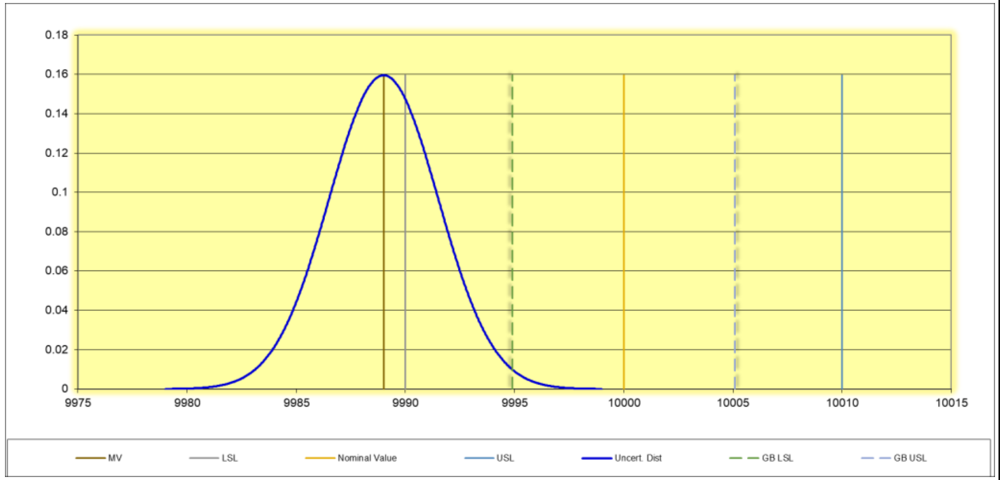
Type	TUR	Bias	Total Risk
Reference	**4:1**	**-9**	**78.81%**



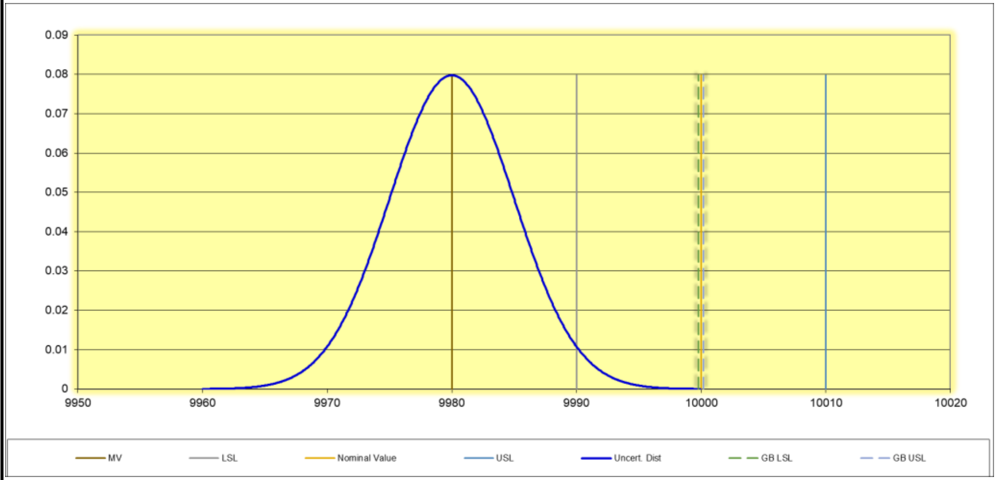
Type	TUR	Bias	Total Risk
Working	**3:1**	**-13**	**96.41%**



Type	TUR	Bias	Total Risk
General	**2:1**	**-11**	**65.54%**



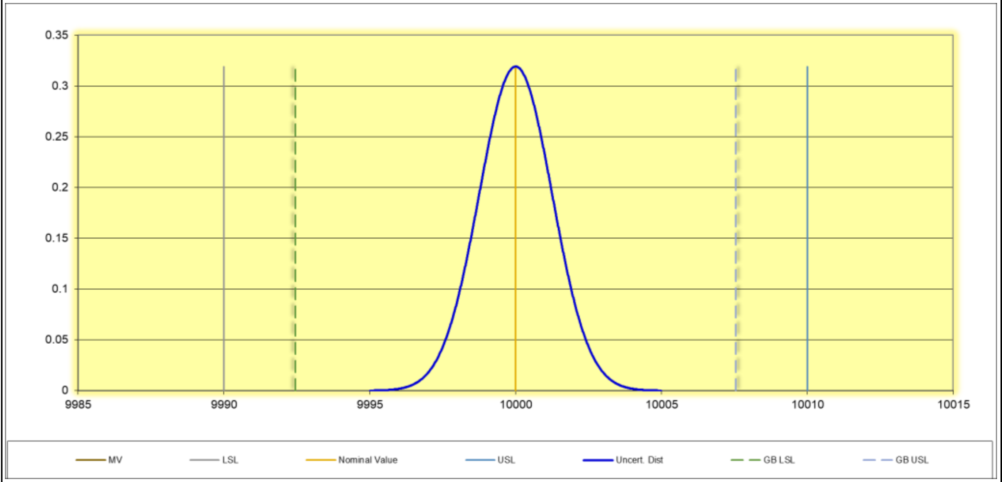
Type	TUR	Bias	Total Risk
Process	**1:1**	**-20**	**97.25%**



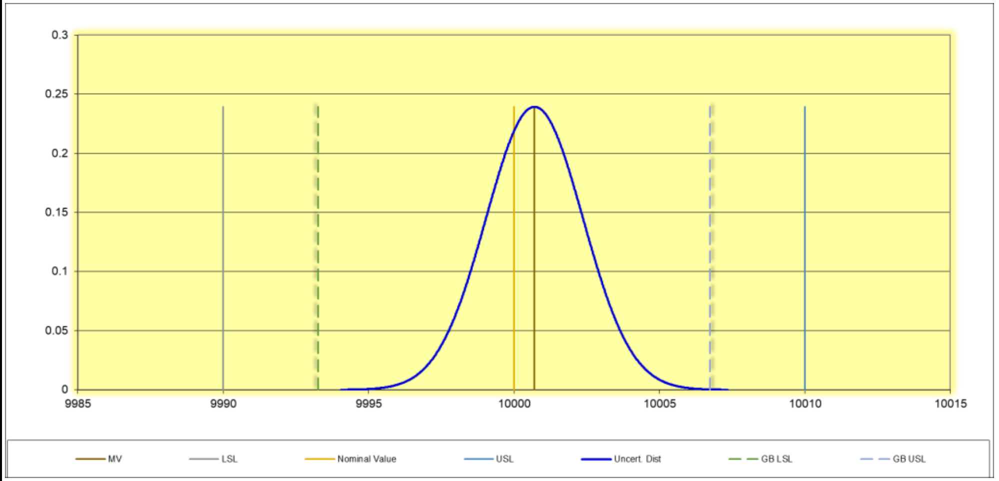
Correcting for Bias

Measurement Bias Corrected

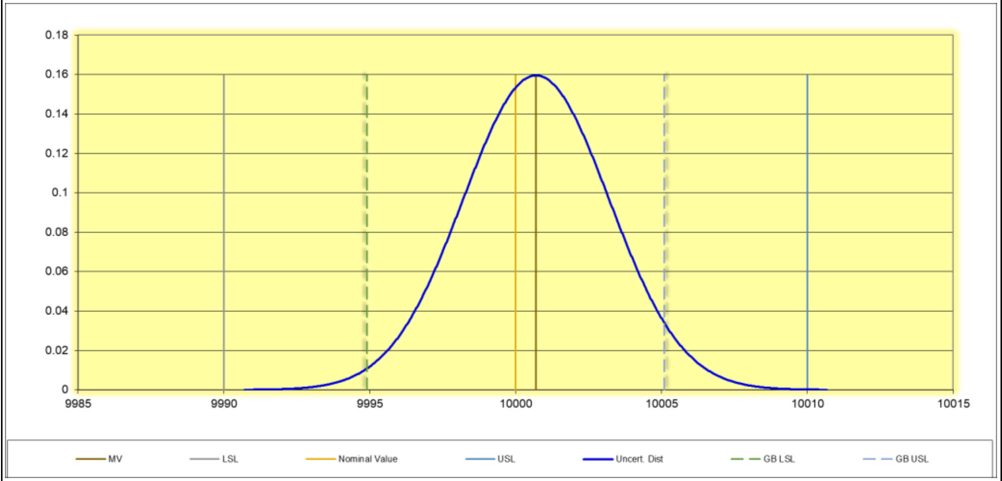
Type	TUR	Bias	Total Risk
Reference	**4:1**	**0**	**0.00%**



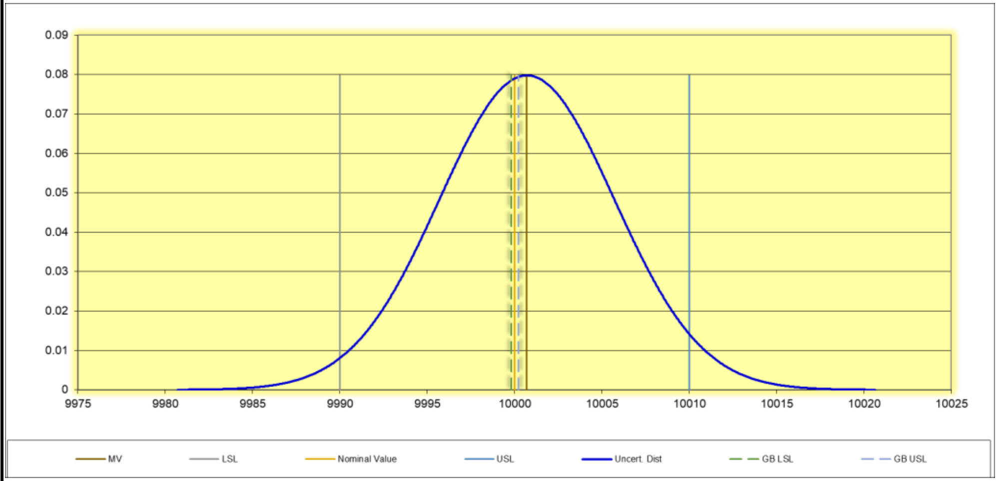
Type	TUR	Bias	Total Risk
Working	**3:1**	**0.7**	**0.00%**



Type	TUR	Bias	Total Risk
General	**2:1**	**0.5**	**0.00%**



Type	TUR	Bias	Total Risk
Process	**1:1**	**0.6**	**4.76%**



Correcting for Bias

Table for 95 % Confidence Interval 5 % Total Risk						
Std Unc	Std Unc %	TUR	Percent of Spec	In Engineering Units ±	GB LSL	GB USL
0.085 048	0.001%	58.79	98.33%	9.833	9990.167	10009.833
1.250 000	0.013%	4.00	75.50%	7.550	9992.450	10007.550
1.501 502	0.015%	3.33	70.57%	7.057	9992.943	10007.057
2.500 000	0.025%	2.00	51.00%	5.100	9994.900	10005.100
5.000 000	0.050%	1.00	2.00%	0.200	9999.800	10000.200

Guard Banded Acceptance Limiting Risk to Total Risk 5 % using ILAC G8 Decision Rule

Bias Comparison

	Measurement Uncertainty	BIAS Measured Value With Bias	BIAS CORRECTED Measured Value Bias Removed
Primary	0.17	9991.0	9999.9
Reference (TUR 4:1)	2.5	9991.3	9999.9
Working (TUR 3:1)	3.33	9989.6	10000.6
General (TUR 2:1)	5	9987.1	9995.3
Process (TUR 1:1)	10	9979.9	10001.0

When the instrument is good, it might have been adjusted to the wrong number if the bias was not corrected. If we continue to generate data randomly, we might end up with the table and graphs below.

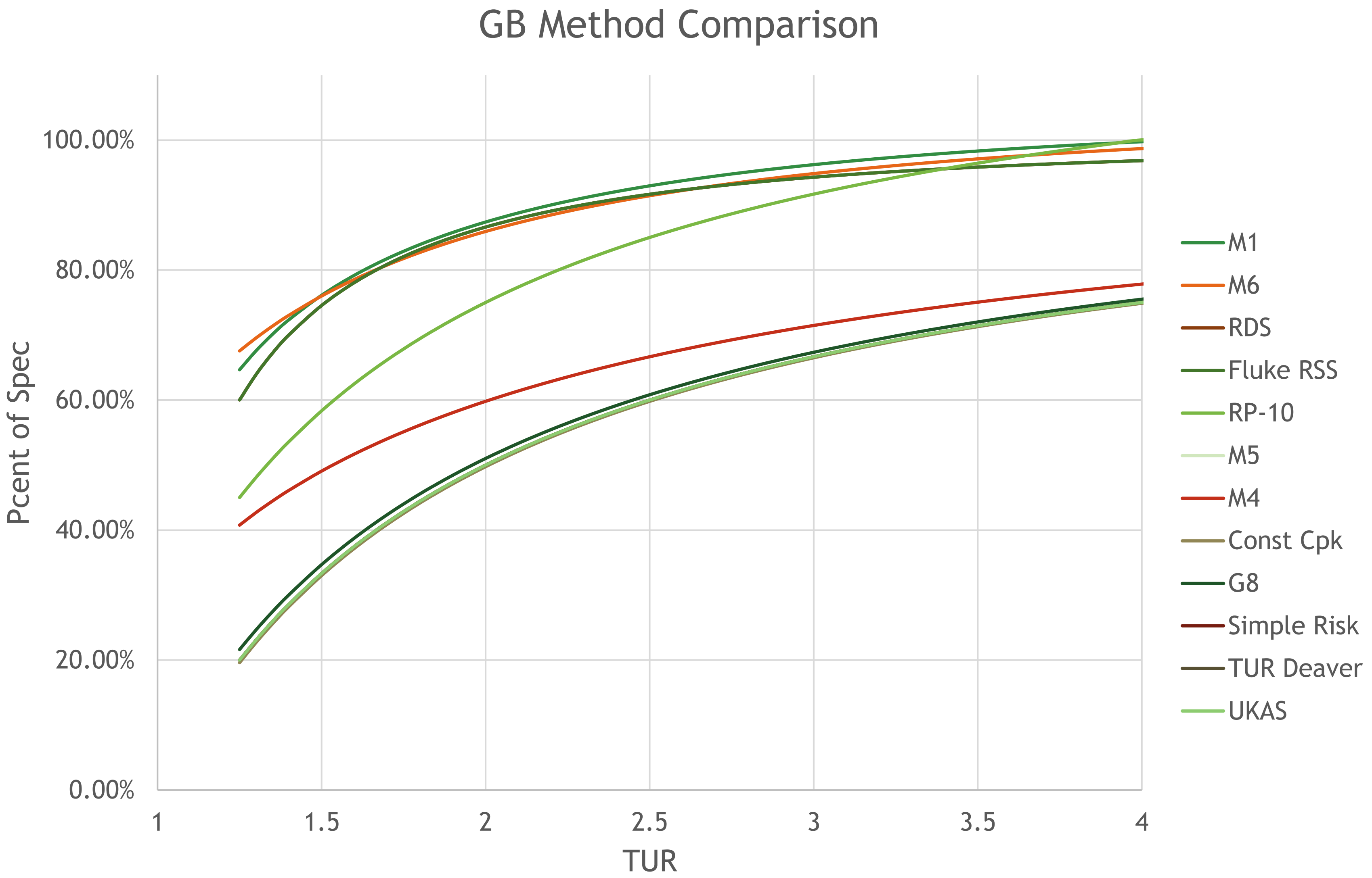
This should matter to you because when there is a bias that is ignored, meaning not corrected or not included in a lab's calibration and measurement capability uncertainty parameter, measurement traceability is not achieved, and all subsequent measurements are not traceable.

The Effect of UUT Resolution on Risk & Uncertainty

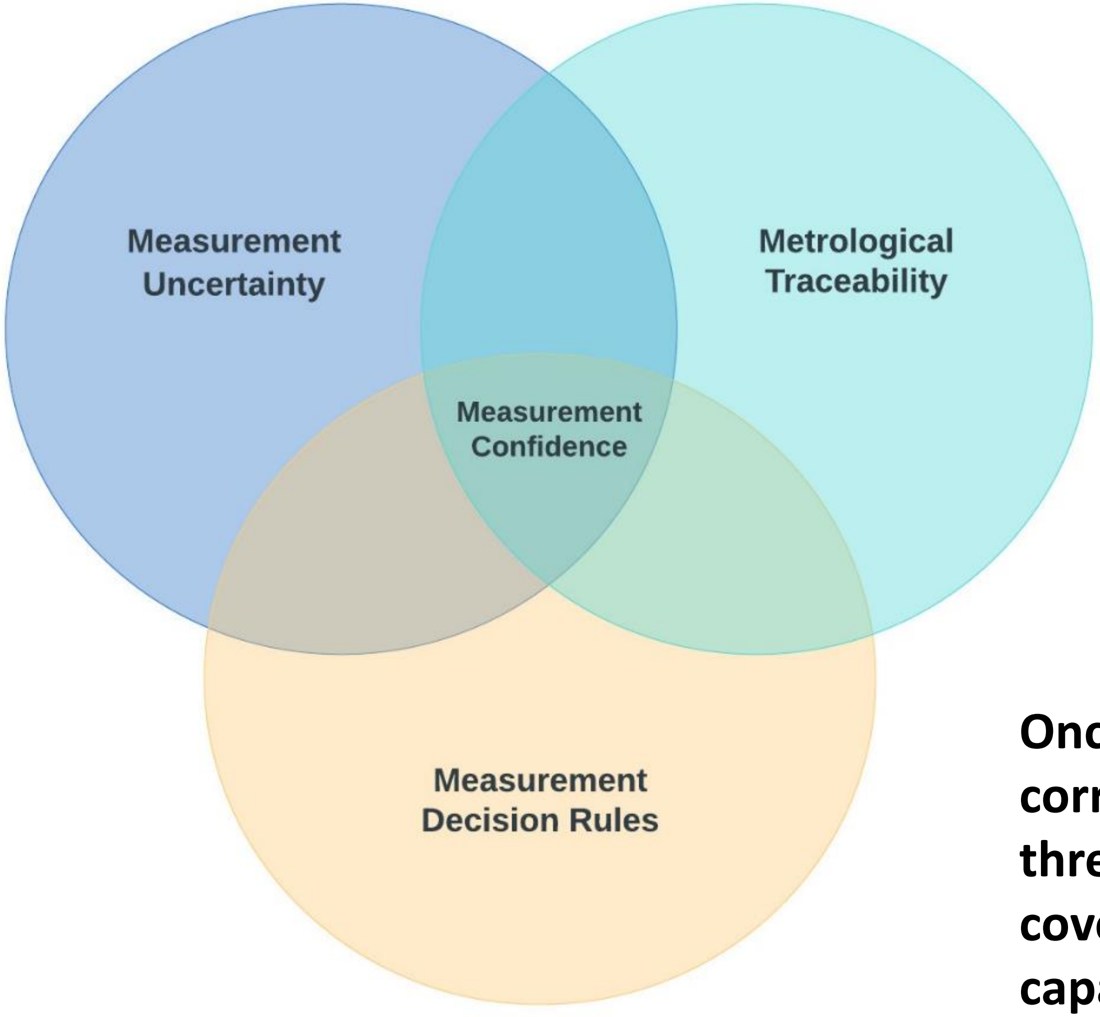
TUR cannot be the ratio of the Manufacturer's accuracy tolerance to the reference standard uncertainty, per ANSI/NCSL Z540.3 and ILAC-G8:09/2019

When the resolution is considered, the TUR starts at 6.25:1 with a UUT resolution of 0.001 kgf and then declines to 0.17:1 with a UUT resolution of 1.0 kgf. When the resolution is not accounted for, the TUR ratio stays at 6.25:1 regardless of the resolution. If a calibration laboratory uses the Test Value Uncertainty, then the UUT's resolution could be ignored in the conformity assessment.

Selecting the Appropriate Decision Rules



Measurement Confidence



Once known biases are corrected, and we have these three pillars of measurement covered, we need to prove our capability.

Interlaboratory Comparison and Proficiency Testing

Satisfy the ISO/IEC 17025:2017 Force ILC requirement for force proficiency tests & interlaboratory comparison (Force ILC), validate your CMC claims and uncover ways to improve your measurement process with the Morehouse ILC force rental kit.

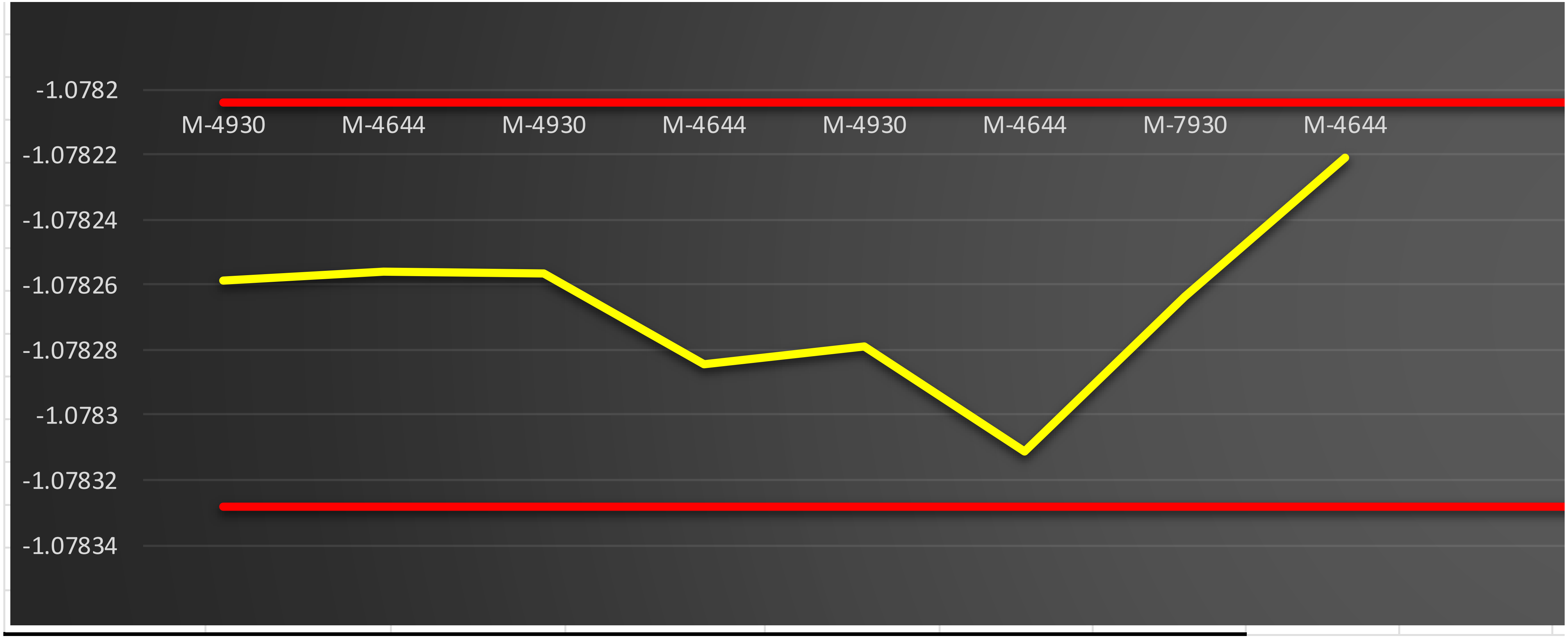
CONTACT SALES

https://mhforce.com/calibration/force-ilc-and-pt/

Measurement Assurance
SPC DATA

	2021		2021		2022		March-2023-CK	
1K Load Cell	M-4930	M-4644	M-4930	M-4644	M-4930	M-4644	M-7930	M-4644
1	-1.07826	-1.07832	-1.07827	-1.07833	-1.07826	-1.07828	-1.07826	-1.07822
2	-1.07828	-1.07827	-1.07827	-1.07832	-1.07824	-1.0783	-1.07824	-1.07821
3	-1.07822	-1.07827	-1.07827	-1.07832	-1.07826	-1.07828	-1.07826	-1.07822
4	-1.07823	-1.07827	-1.07826	-1.07831	-1.07828	-1.07832	-1.07826	-1.07823
5	-1.07828	-1.07826	-1.07823	-1.0783	-1.07828	-1.07833	-1.07826	-1.07822
6	-1.07826	-1.07826	-1.07824	-1.07829	-1.07827	-1.07832	-1.07827	-1.07823
7	-1.07833	-1.07826	-1.07825	-1.07829	-1.07826	-1.07828	-1.07827	-1.07823
8	-1.07824	-1.07824	-1.07823	-1.07828	-1.07828	-1.0783	-1.07826	-1.07822
9	-1.07822	-1.07825	-1.07825	-1.07828	-1.0783	-1.07828	-1.07827	-1.07821
10	-1.07830	-1.07825	-1.07824	-1.07827	-1.0783	-1.07832	-1.07825	-1.07821
11	-1.07822	-1.07825	-1.07824	-1.07826	-1.07829	-1.07833	-1.07827	-1.07823
12	-1.07822	-1.07824	-1.07829	-1.07826	-1.07828	-1.07834	-1.07825	-1.07821
13	-1.07828	-1.07824	-1.07828	-1.07826	-1.07831	-1.07832	-1.07827	-1.07823
14	-1.07825	-1.07823	-1.07826	-1.07825	-1.07828	-1.07834	-1.07825	-1.07822
15	-1.07829	-1.07823	-1.07827	-1.07825	-1.07829	-1.07833	-1.07826	-1.07822
Ending Zero	-0.00008	-0.00008	-0.00006	-0.00006	-0.00006	-0.00004	0	-0.000014
Range	0.00011	9E-05	6E-05	8E-05	7E-05	6E-05	3E-05	2E-05
Std. Dev.	3.4198E-05	2.2297E-05	1.83874E-05	2.669E-05	1.85E-05	2.26E-05	9.26E-06	7.99E-06
Average	-1.07825867	-1.078256	-1.078256667	-1.0782847	-1.078279	-1.078311	-1.07826	-1.078221
X-Double Bar	-1.07826583	-1.0782587	-1.078258667	-1.0782587	-1.078259	-1.078259	-1.078259	-1.078259
UCL	-1.07820362	-1.0782036	-1.078203623	-1.0782036	-1.078204	-1.078204	-1.078204	-1.078204
LCL	-1.07832804	-1.078328	-1.078328043	-1.078328	-1.078328	-1.078328	-1.078328	-1.078328
Z-Score	0.047201816		0.621147887		0.794795305		2.280684097	
							Note: Anything beyond spe	
EN Ratio	0.042865463		0.450087363		0.525101923		0.632265581	

SPC DATA GRAPHS



Conclusion

- Calculating Measurement Uncertainty correctly is essential to everything that comes after it including decision rules.
- Metrological Traceability relies on a documented unbroken chain of contributions, each contributing to the measurement uncertainty, linking them to an appropriate reference.
- A statement of conformity should take into account the measurement uncertainty.
- Using the manufacturer's accuracy specification and not correcting for bias can further increase Measurement Risk.

Conclusion

- Not correcting for bias seems to be a problem many in the calibration deal with, and their unsuspecting customers are likely getting calibrations that carry too much overall Measurement Risk.
- The habit of insisting on a 4:1 TUR assumes the measurement process is centered (measurement bias is corrected).
- When bias is not corrected, the risk of making a measurement that does not properly account for bias can result in an underestimation of measurement uncertainty and therefore disagrees with the metrologically traceability definition and undermines measurement confidence.

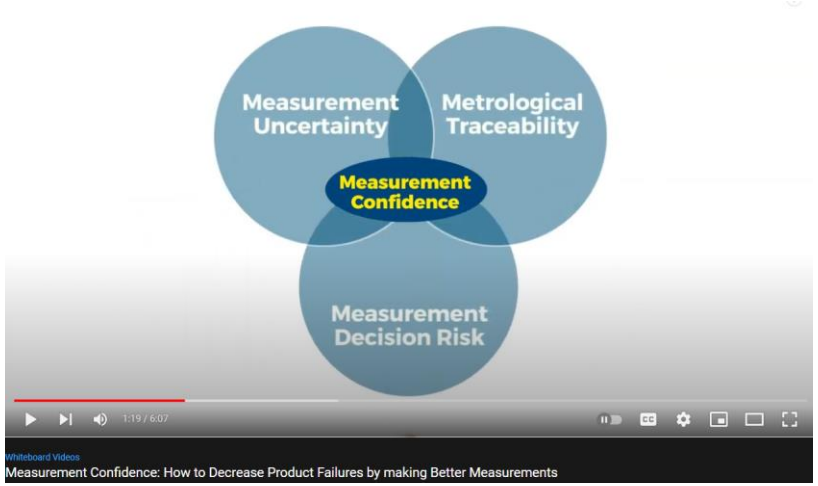
Solution for Force Measurements

Morehouse has many options with our force calibrations systems that use coefficients generated at the time of calibration. Our 4215 plus and C705P use coefficients that are programmed into the indicator to help correct and minimize measurement bias.

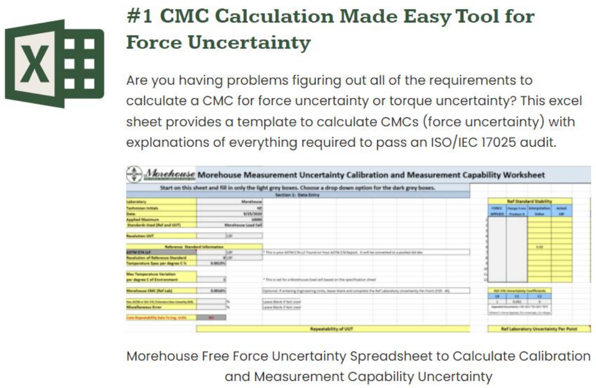
Common Issues with Laboratories Performing Measurements

1. CMC values that are unrealistic.
2. Lack of understanding the standards.
3. Not properly evaluating Measurement Risk or Probability of False Accept (PFA).
4. The lab does not replicate how the instruments are used by using the right adapters.
5. Not making the proper corrections.

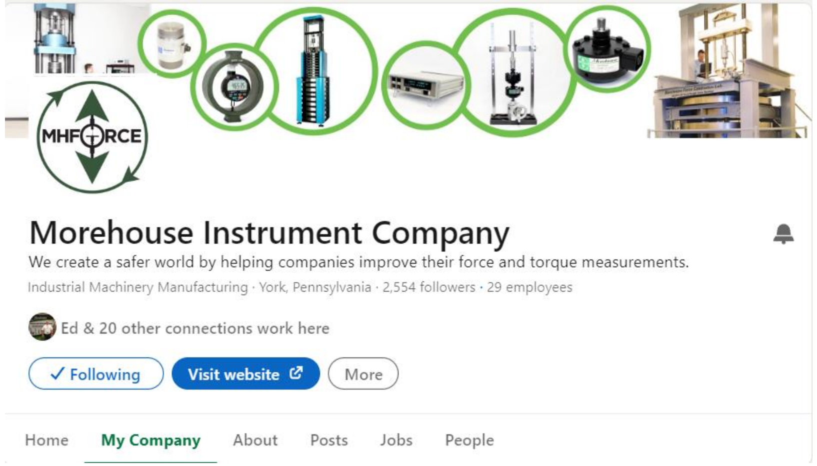
Want More Information?



[Morehouse YouTube Videos](#)



[Morehouse Free Downloads](#)



[Follow Morehouse on LinkedIn](#)

Contact us at info@mhforce.com