1st Edition 2024-04

DECISION RULE GUIDANCE

Written by

Henry Zumbrun, Morehouse Instrument Company
Greg Cenker, Indysoft
Dilip Shah, E=mc³ Solutions

Morehouse
THE FORCE IN CALIBRATION SINCE 1925

IndySoft

E = mc³ Solutions

Decision Rule Guidance

We created this guidance document to help anyone struggling with decision rules and measurement risk.

Please feel free to share it with anyone. The information is not proprietary and is given in the hope that we, as a metrology community, can stop bad practices and start making better measurements.

To quote the late and great Neil Peart, "If you choose not to decide, you still have made a choice." However, we hope you will read this document and implement its contents.

Image Courtesy of imgflip.com

Decision Rule Guidance

Table of Contents

Introduction

There are numerous documents on decision rules; however, the authors have found that many of these guidance documents are hard for most people to understand. Thus, we wrote this guidance document to provide the foundational requirements for good metrology and to simplify the calculation of measurement decision risk. The goal is to simplify the topic, making it accessible for anyone to implement decision rules that account for measurement uncertainty.

The basis for good metrology can be summarized by the three pillars of measurement.
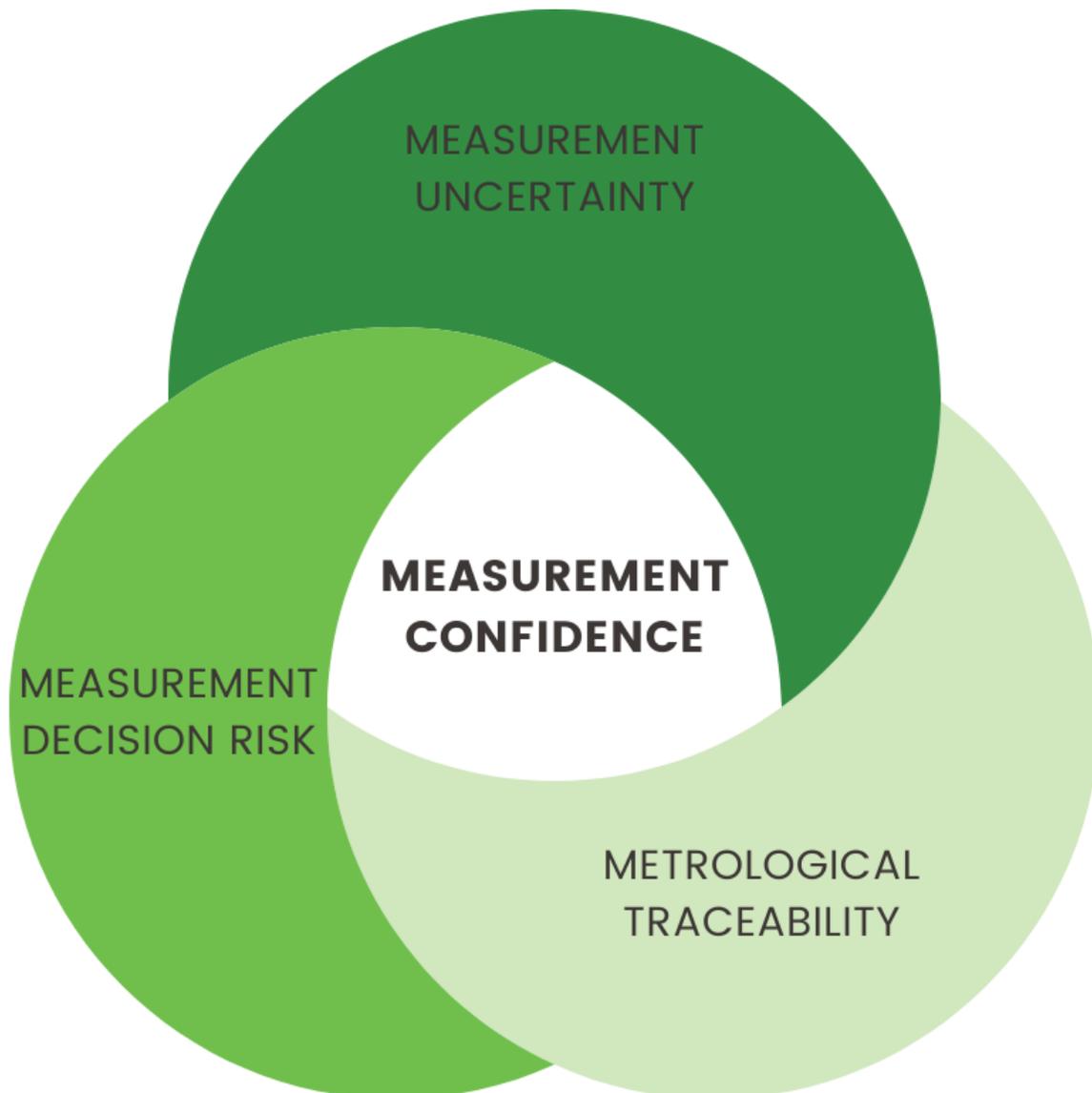

Figure 1 Achieving Measurement Confidence Requires all Three Circles to be Understood.

Three Pillars of Measurement:

1. Measurement Uncertainty: This involves how robust (thorough) the evaluation of measurement uncertainty is, as it helps support the next two pillars of measurement. It refers to the extent to which measurements can vary and estimates the confidence in a measurement result. It's crucial for decision-making, as it helps users understand the reliability of a measurement.

   Note: Many decision rules involve taking the measurement uncertainty into account, specifically by decreasing the tolerance (sometimes called accuracy). This results in an acceptance zone that is less than the tolerance. Over-evaluating measurement uncertainty results in a smaller acceptance zone in which the property's measured value could be considered nonconforming when it is conforming. Under-evaluating measurement uncertainty results in a larger acceptance zone where the property's measured value could be considered conforming when it is non-conforming.

2. Metrological Traceability: This involves ensuring that measurements are traceable to the International System of Units (SI), creating a documented, unbroken chain of calibrations, each contributing to the measurement uncertainty. In some cases, metrological traceability is indirectly traceable to the SI (e.g., test measurement uncertainty).

Note: The attainment of metrological traceability in your measurements is contingent on the proper calculation and statement of measurement uncertainty at every preceding tier leading up to the specific measurements being made. The testing laboratory example might involve mixing compounds.

3. Measurement Decision Rules: Decision rules determine whether a measurement result is fit for its intended purpose, taking measurement uncertainty into consideration (more justification for robust evaluation of measurement uncertainty). These rules should consider acceptable risks (depending on the application) and ensure that measurement results are used to make conformity decisions.

Note: Taking measurement uncertainty into account does not necessarily require numerical propagation into a probability calculation; it may also be addressed through predefined acceptance criteria, customer-agreed decision rules, or qualitative consideration of risk.

When these pillars are addressed properly, it ensures high confidence in measurement results.

Inaccurate, ill-defined conformity decisions can have serious consequences, such as engineering disasters, financial losses, and potential loss of life.

Measurements play a critical role in decision-making across various industries. When measurements are accurate, traceable, and have well-defined decision rules, it instills confidence in the results, leading to safer products and services and reducing risks for consumers and suppliers alike.

Both consumers and suppliers of measurement services should be aware of measurement risk and the importance of adhering to consensus standards and guidance documents for better decision-making. When measurement results ensure confidence, it reduces risks and ensures the quality and safety of products and services.

This document is intended to provide guidance and examples for implementing decision rules under ISO/IEC 17025. It does not introduce additional requirements beyond those specified in the standard. Where advanced methods are discussed, they are presented to illustrate possible approaches and risk trade-offs, not to establish mandatory practices.

Definitions

ILAC G8:2019/2019 definitions: [1]

Tolerance Limit (TL or L) (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.

> LAL – Lower Acceptance Limit
>
> UAL – Upper Acceptance Limit

Guard band (w): the interval between a tolerance limit and a corresponding acceptance limit where length $w=|TL-AL|$.

Decision Rule: is a rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement. (ISO/IEC 17025:2017 3.7 "rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement).

TUR - the ratio of the tolerance, TL, of a measurement quantity, divided by the 95 % expanded measurement uncertainty of the measurement process where $TUR = TL/U$. (Please note that this definition is slightly different than the one cited in ANSI/NCSLI Z540.3: 2006).

JCGM 106:2012 definitions: [2]

Measurement Capability Index: Tolerance divided by a multiple of the standard measurement uncertainty associated with the measured value of a property of an item.

Specific consumer's risk: probability that a particular **accepted** item **is non-conforming.**

Specific producer's risk: probability that a particular **rejected** item **is conforming.**

Global consumer's risk: probability that a **non-conforming** item **will be accepted** based on future measurement result.

Global producer's risk: probability that a **conforming** item **will be rejected** based on future measurement result.

*Note: Looking at the math for **global risk**, End of Period Reliability (**EOPR**) is not well explained with these definitions. EOPR covers endless measurements from the past to the future. Historical data is crucial for **global risk**, except when starting a new manufacturing line.*

ASME B89.7.3.1-2001 definitions: [3]

Binary decision rule: a decision rule with only two possible outcomes, either acceptance or rejection.

(A non-binary decision rule can add conditional acceptance and rejection)

N:1 decision rule: a situation where the width of the specification zone is at least N times larger than the uncertainty interval for the measurement result.

*Note: The inclusion of this rule is prompted by its presence in certain standards and its potential for misinterpretation. It is crucial to highlight that if the N:1 ratio is primarily intended for **Global Risk** assessment, in most cases the decision rule must consistently be complemented by EOPR (End of Period Reliability) data. In cases involving **Specific Risk**, this serves more as a prerequisite for conducting measurements within a straightforward acceptance or shared risk framework. In practical terms, those employing N:1 could potentially transfer up to 50% of the risk to the subsequent measurement tier.*

Guard band: the magnitude of the offset from the specification limit to the acceptance or rejection zone boundary.

Specification zone (of an instrument or workpiece): the set of values of a characteristic between, and including, the specification limits.

Acceptance zone: the set of values of a characteristic, for a specified measurement process and decision rule, that results in product acceptance when a measurement result is within this zone.

Transition zone: the set of values of a characteristic, for a specified measurement process and decision rule, that is neither in the acceptance zone nor rejection zone.

Other Definitions:

Measurement Uncertainty:

Measurement uncertainty quantifies the doubt about the measured value. This value is derived through a systematic process that evaluates various contributing factors, including the uncertainty inherent in the measurement standards and the uncertainty introduced by the measurement process.

This comprehensive approach ensures that the measurement uncertainty evaluates all significant sources of error, providing a more reliable representation of the measured value's possible range.

Note: This definition of Measurement Uncertainty can be found from various sources.

End of Period Reliability (EOPR) is the number of calibrations resulting in as-received IN – Tolerance Results divided by the total number of calibrations.

*Note: You may notice the term "guardband" spelled differently, such as "guard band." The correct spelling is **guardband** as a single word. However, when quoting other documents, we retain the original spelling used in those sources for consistency. In its simplest form, a **guardband** is often used as part of a **decision rule** as a buffer or margin applied to specification limits to account for **measurement uncertainty**.*

The concept of **decision rules** is a key component of ISO/IEC 17025:2017, emphasizing the importance of accounting for **measurement uncertainty** when determining conformity with specified requirements.

ISO/IEC 17025 References to Decision Rules

Sections and text from ISO/IEC 17025:2017 mentioning decisions rule(s)[4]

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

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

NOTE: For further guidance on statements of conformity, see ISO/IEC Guide 98-4 (JGCM 106:2012).

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.

A.2.3 Measurement standards that have reported information from a competent laboratory that includes only a statement of conformity to a specification (omitting the measurement results and associated uncertainties) are sometimes used to disseminate metrological traceability. This approach, in which the specification limits are imported as the source of uncertainty, is dependent upon:

— the use of an appropriate decision rule to establish conformity;

— the specification limits subsequently being treated in a technically appropriate way in the uncertainty budget.

The technical basis for this approach is that the declared conformance to a specification defines a range of measurement values, within which the true value is expected to lie, at a specified level of confidence, which considers both any bias from the true value, as well as the measurement uncertainty.

EXAMPLE The use of OIML R 111 class weights to calibrate a balance.

NOTE: Further Clarification of ISO/IEC 17025

ISO/IEC 17025 requires that, when a statement of conformity is made, the laboratory define and apply a decision rule that accounts for measurement uncertainty and considers the level of risk associated with the conformity decision.

The standard **does not require** the use of probability calculations, probability of false accept or reject, guardbands, or any other specific mathematical or statistical risk model. ISO/IEC 17025 intentionally allows flexibility in how decision rules are implemented, provided the decision rule is defined, applied, and agreed with the customer when required.

The methods described in this document—such as probability-based decision rules, guardbanding approaches, and specific or global risk models—are **optional tools** that may be used to satisfy the requirements of ISO/IEC 17025. These methods represent best-practice techniques for managing and quantifying risk, but they are **not mandated** by the standard.

Metrological Traceability and Measurement Uncertainty

Figure 2 SI Pyramid Example courtesy of Morehouse.

Metrological traceability relies on tracing the measurement chain back to SI units. The proper way to claim metrological traceability is to trace each calibration back to the SI through a documented, unbroken chain of calibrations, each contributing to the measurement uncertainty. The chain will often end with a National Metrology Institute (NMI), such as NIST, which is recognized under the Committee International de Poids et Mesures (CIPM) Mutual Recognition Arrangement (MRA).

To meet the metrological traceability requirements, measurement uncertainty must be properly evaluated, taking into consideration the minimum number of contributors.

Measurement uncertainty is the doubt about the true value of the measurand that remains after making a measurement. Expanded Uncertainty of the Measurement Process is the non-bias uncertainty ascribed to the result of a measurement at a particular test point.

When you are accredited to **ISO/IEC 17025:2017**, it is mandatory to report **measurement uncertainty** on a **certificate of calibration**. This is essential because your customer may want you to make a statement of conformance on whether the device or artifact is in tolerance. When that conformity assessment happens, measurement uncertainty must be considered.

Measurement uncertainty is required to establish your metrological traceability. It is crucial because you want to know that the laboratory calibrating your device or artifact can perform the calibration. If you need a device with less than 0.02 % measurement uncertainty, then you must use a calibration provider that gives you the best chance of achieving that result. If the calibration provider has a stated measurement uncertainty of 0.04 %, then mathematically, they are not the right calibration lab to calibrate or verify your device or artifact.

Knowing the Measurement Uncertainty is crucial for calculating the Test Uncertainty Ratio (TUR) or Measurement Capability Index (Cm), which is often used to determine measurement risk. More information on the [calculation of measurement uncertainty](#) is found later in this document.

Note: Because of the confusion over the definition of TUR throughout the years, many documents use the term Measurement Capability Index (C_m).

Measurement Risk

Inaccurate measurements can result in catastrophic consequences. Consider several notable disasters where poor measurement practices and faulty decision-making played a critical role: the BP oil refinery explosion in Texas, the Hubble Telescope's focus issue, the Space Shuttle Challenger disaster, a Stealth Bomber crash, Cox Health's overdose of 152 cancer patients, the Paris train platform misalignment, and yet another BP oil rig disaster. These tragedies highlight the importance of ensuring accurate, reliable measurements to prevent costly mistakes and, more importantly, save lives.

The 2016 film *Deepwater Horizon* vividly illustrates how a critical and avoidable decision error triggered a blowout, leading to a catastrophic explosion that claimed 11 lives and caused an environmental disaster through a massive oil spill.

Note: While several examples are extreme and represent worst-case scenarios, it's essential to recognize that numerous practical situations exist where effective decision rules prevent product recalls, enhance safety, and can result in substantial cost savings for companies that employ them judiciously.

The essence of decision risk and conformity assessment lies in ensuring the final product's quality, accuracy, and durability. A quality where both the likelihood and consequences of a failure are evaluated, often using a risk matrix. In many cases, the measurement that is made can be thought of as the "likelihood," and this document deals primarily with tools to help minimize that "likelihood." The consequences happen after the measurement and can be severe when these tools are not used properly.

Proper application of decision risk analysis can lead to significant economic benefits for both manufacturers and consumers. By prioritizing the production of durable, high-quality goods, companies

can potentially save or earn millions to billions of dollars over time. This approach results in products that maintain functionality for years rather than those that fail prematurely after only a few months or years of use. Ultimately, this strategy benefits society by reducing waste, improving consumer satisfaction, and fostering long-term economic growth.
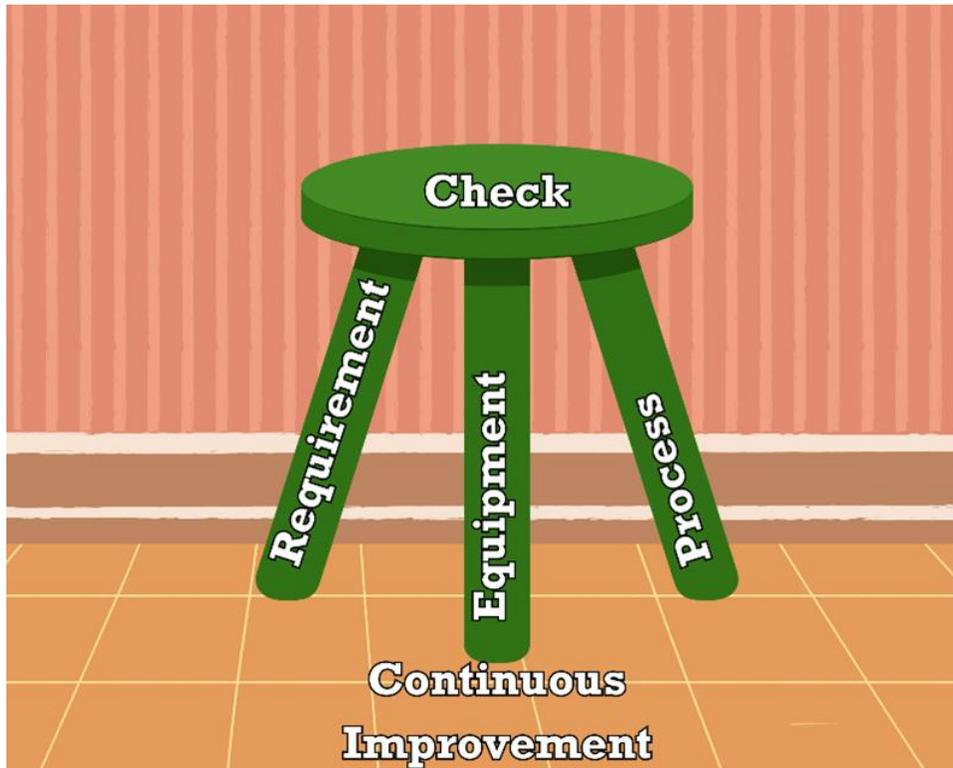
Figure 3 Five Rules to Reduce Measurement Risk courtesy of Morehouse.

So, how can we avoid these issues? Here are five simple rules to reduce your measurement risk:

1. **Understanding the Right Requirements**: This first rule involves knowing what is needed to accomplish the task. The more accurate the system, the higher the costs to procure and calibrate the equipment. Buying the wrong equipment will often lead to more frequent calibrations, often costing more and reducing availability. The recommendation before any purchase is to discuss the intended purchase with those calibrating it. The results of procuring the wrong equipment can be extremely costly. Most of these wrong choices could easily be remedied if metrology were consulted before the actual procurement. Technicians often will know what equipment frequently fails calibration.

2. **Purchasing the Right Equipment**: Not all tools are created equal. Make sure you're using the right equipment for the job. This includes the appropriate measurement uncertainty and metrological traceability criteria using qualified calibration providers. Using the wrong equipment or calibration provider can lead to inaccurate measurements and more significant problems. Continually evaluate externally provided products and services to minimize the risks involved.

Note: The authors have collectively observed a recurring issue where incorrect equipment purchases are made, leaving teams stuck with suboptimal measurement tools. This problem is widely recognized, yet management often fails to address it, despite awareness of the frequent occurrence and its negative impact. One author noted that switching to the correct equipment resulted in over one million USD in annual savings, highlighting the significant financial consequences of such errors.

3. **Have the Right Processes:** This rule requires a training program and proof of training (records) to validate the individuals calibrating or using the equipment. A process should be in place that ensures all aspects of the standards are being carefully satisfied in the calibration process, such as the use of the proper auxiliary equipment (test adapters, leads, etc.). The robustness of the process should include good practices such as control chart implementation and calibration interval evaluation.

4. **Check Your Work:** Technicians are human, and humans make mistakes. Always double-check your measurements to make sure they're accurate. It's easy to overlook a small error, but that small error can have big consequences. So, take the time to verify your work. A good verification and validation process will aid, as well as a good checklist.

5. **Stay Vigilant/Continuous Improvement:** Don't let success lead to complacency. Always stay vigilant for potential risks and take proactive measures to mitigate them. Implementing control chart monitoring is an effective way to track and manage deviations in your processes. It's easy to become complacent when things seem to be running smoothly, yet that's often when mistakes occur. By establishing a reliable system that collects the right data and using control charts to monitor that data, you can reduce risks and maintain process stability over time.

The first three requirements are the legs of the stool. If one is neglected, it will be hard to sit on the stool. Checking the work helps ensure accuracy. The floor or support structure is continually improving to keep everything in place.

A tremendous foundational tool is a measurement assurance program based on control charts and a well-laid-out Proficiency Test or an Inter Laboratory Comparison plan.

Following these rules can help reduce your measurement risk and prevent avoidable potential disasters. It's all about being proactive and taking the necessary steps to ensure accuracy and safety.

After all, the ultimate objective is to develop products that function effectively and are safe for use. Those adhering to established guidelines will clearly understand the necessary equipment—in terms of physical tools and the calibration standards required in a laboratory setting—to validate the accuracy of reported measurement uncertainty. This comprehensive approach ensures not only the functionality and safety of the products but also builds credibility by providing clear and defendable measurement data.

It is often said that an error overlooked in one stage of a process can multiply the effort required to fix it in the next stage by a factor of ten. Implementing additional checks and safeguards early on can significantly reduce the risk of such costly mistakes. Ignoring established process protocols often results in higher expenses, whether through the need to develop custom solutions that are difficult to validate

or by choosing off-the-shelf equipment that fails to mitigate critical risks. For example, a company might save $15,000 on its initial equipment purchase but later face a staggering $1,000,000 scrap costs due to a preventable oversight. Therefore, managing risk effectively requires a thorough understanding of how **Uncertainty**, **Specifications**, and **Decisions** are interconnected in the measurement process, ensuring accurate conformity assessments and maintaining quality standards.

Uncertainty, Specifications, and Decisions

Measurement Uncertainty: The doubt about the true value of the measurand that remains after making a measurement.

- Every measurement—even the most careful—always has a margin of doubt.

- Uncertainty is the inherent limitation of a measurement process due to instrumentation and process variation.

- Measurement uncertainty does not include mistakes (e.g., oversights, omissions, miscalculations).

- Quantifies the error associated with the measurement process.
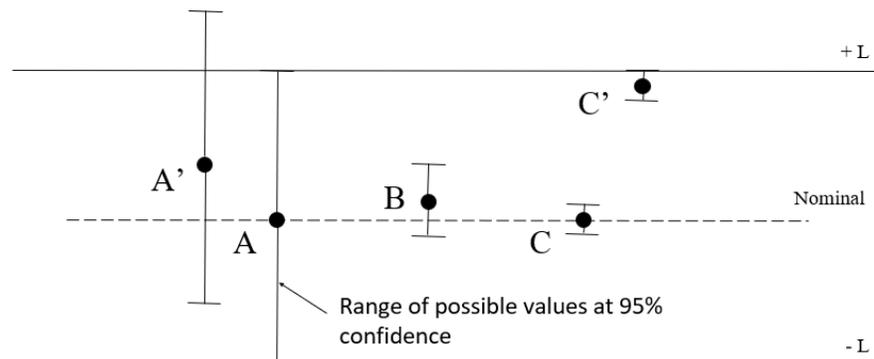
Figure 4 Image Courtesy of Scott Mimbs

Demonstration of conformity requires a correct decision. Making a correct decision requires a robust evaluation of measurement uncertainty.

The probability of whether a decision is "good" or "bad" can be determined by:

- The amount of uncertainty in the measurement process that is based on a robust evaluation.

- Where the measurement result lies with respect to the tolerance limit (e.g., ± *TL*)

- Knowledge acquired from previous measurements of similar items (i.e., *a priori* distribution)
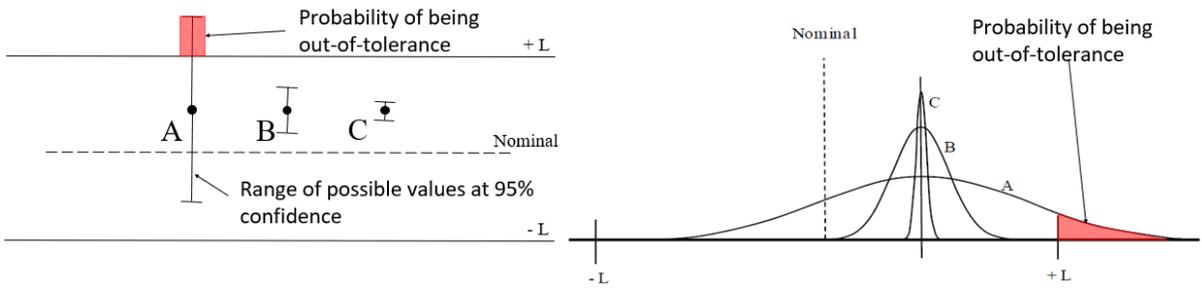
Figure 5 Image Courtesy of Scott Mimbs.

JCGM 106:2012 states:[5]

*If the **true value** of the property lies within the tolerance interval, it is said to be conforming, and non-conforming otherwise.*

JCGM 106:2012 states:[6]

*Accepting or rejecting an item when the measured value of its property is close to a tolerance limit may result in an **incorrect decision** and lead to **undesirable consequences**.*
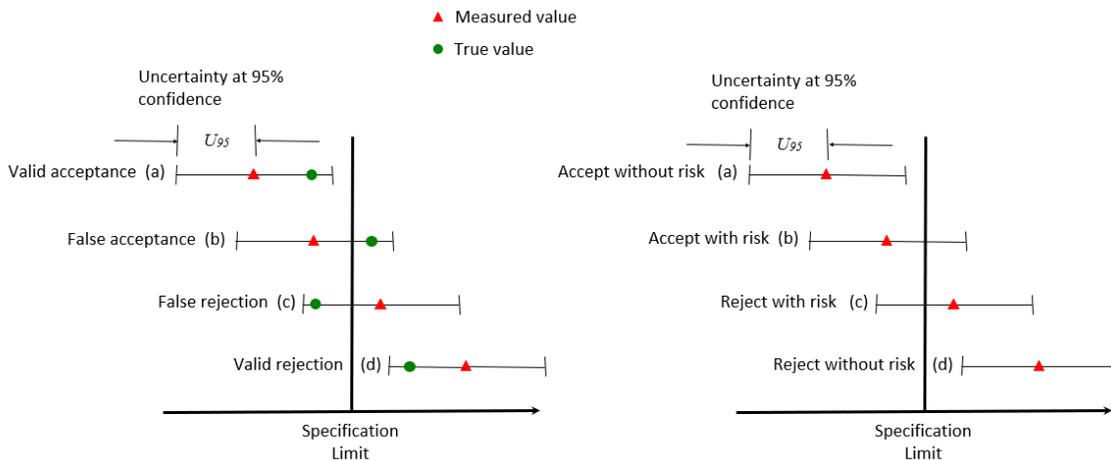
Figure 6 Image adapted from JCGM 106 Example.

Note: A graphic indicating "accept" or "reject" without risk implies that while there might still be a minimal level of risk, it is considered negligible. The expectation is that there is a close to 100 % certainty that the measurement outcome will result in either acceptance or rejection with a very high level of confidence.

JCGM 106:2012 states:[7]

*Choosing the **tolerance limits** and **acceptance limits** are **business or policy decisions** that depend upon the consequences associated with deviations from intended product quality.*

The guiding principle for <u>default decision rules</u> is that *the measurement uncertainty always counts against the party who is verifying conformity or nonconformity…*
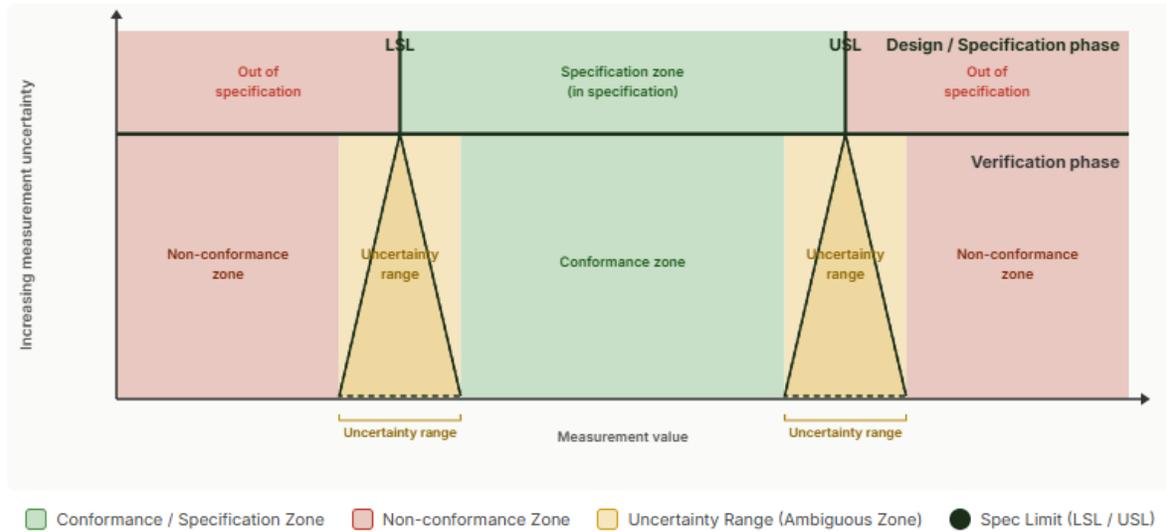
Figure 7 Adopted from ISO 14253-1:2017, Decision rules for verifying conformity or nonconformity with specifications. [8]

Measurement uncertainty influences the zones where conformity or nonconformity can be verified.

The above figure demonstrates the concept of measurement uncertainty and how it can impact the conformance zone. Measurement process uncertainty is directly proportional to consumer and producer risk. As measurement process uncertainty decreases, the risk decreases.

The conformance or acceptance zone shown is an example of a **Specific Risk** model.

When the **measurement uncertainty** and **tolerance limits** are known, **conditional probability**—the likelihood of an event occurring given that another event has already occurred—helps quantify **Specific Risk** by determining error probabilities, such as the Probability of False Accept (PFA) or the **Probability of False Reject (PFR)**. By applying conditional probabilities, calibration providers can set **guardbands** to manage **Specific Risk** and reduce the likelihood of making incorrect **conformity decisions**.

Several other examples of decision rules can be used to set the acceptance limits and control the measurement risk. The three basic decision rules from which most others are derived are found in the next section.

Some Acceptable Examples of Decision Rules (3 Methods of Guardbanding)

We will focus on three specific decision rules that address most applications to avoid unnecessary complexity. These rules are discussed in more detail in subsequent sections of this document.

Specific Risk (typically a single probability distribution) is <u>described in the next section</u>. This provides conservative acceptance limits where meager historical data is unavailable or unobtainable.

Managed Guardbands —This method, often referred to as Method 6, was developed by Michael Dobbert. It aims to achieve the Z540.3 requirement of a PFA of less than 2 % for all combinations of TUR and OOT rates.

Method 1, Unconditional PFA Estimation – Test Point Population Data.

The third method, which is the most flexible, is the most complex method to implement in a metrology laboratory system.

Method 1 provides an unconditional PFA estimate applied to a **population** of "<u>like calibration processes</u>" at the **test point level**. This means that the population or average PFA is estimated for each test point of the same M&TE model and manufacturer and evaluated for compliance prior to measurement.

Specific Risk

Specific Risk in Metrology mainly focuses on the Probability of False Accept (PFA) and Probability of False Reject (PFR).

These concepts are crucial in the decision-making process based on measurement results.

Specific Risk, as the term suggests, is a risk specific to a given test measurement result.

It is often thought of as **controlling the quality of individual workpieces** or examining the individual measured values on the test, measurement, and diagnostic equipment (TMDE).

It is the probability that a test measurement result indicates a product is within specifications when it is truly outside specifications.

Specific Risk can be invaluable to the decision-making process. First, it proves useful when there is a lack of historical data or prior information about the population of devices being evaluated. Second, it becomes relevant when a more cautious approach to **false accepts** is required. In both cases, this metric provides a more conservative estimate, helping to mitigate potential risks associated with device acceptance when uncertainty is high or when the consequences of false acceptance are particularly significant.

Risk Calculator		
Upper Tolerance T_U	10010.0000	
Lower Tolerance T_L	9990.0000	
Nominal Value	10000.0000	
Measurement Unc um	5.0000	
Measured Value xm	10000.0000	
Tolerance T	20.00	Area Outside of USL
Z Upper	2.00	2.275%
		Area Outside of LSL
Z Lower	-2.00	2.275%

Setting the Guard Band Upper and Lower p_c	
Select Desired Conformance Probability	95.00%
Maximum Risk if within G_U & G_L	5.00%
h U (GB Multiplier)	0.8224
Guard Band Upper G_U	10001.7757
Guard Band Lower G_L	9998.2243
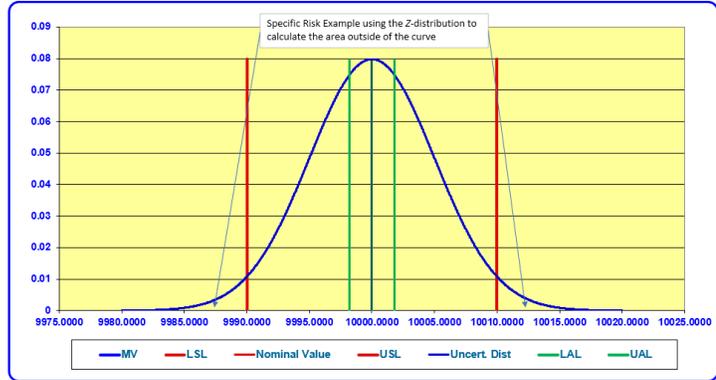
Figure 8 Specific Risk Image Courtesy of Morehouse Instrument Company.

To visualize this, consider the test measurement uncertainty's Probability Density Function (PDF).

The **Specific Risk** is illustrated by the upper tail of the probability curve falling above the upper specification limit and the lower tail falling below the lower specification limit.

The area under this curve represents the probability (**Specific Risk**) of incorrectly accepting a product given this measurement result.

The above example uses an extreme scenario where the expanded measurement uncertainty of **5** (U$_{95.45\%}$) equals the tolerance limit.

The Guardband multiplier is calculated for the desired conformance probability. In this case, that is 95 %. Setting the maximum risk to 95 % limits the maximum risk to 5 %. The total risk shown is the area outside of the curve. That area is 2.275 % for the Upper Specification Limit (USL) and Lower Specification Limit (LSL) for a total risk of 4.55 %. Since the maximum allowable risk is 5 %, this measurement would meet the criteria to issue a "pass."

Risk Calculator		
Upper Tolerance T_U	10010.0000	
Lower Tolerance T_L	9990.0000	
Nominal Value	10000.0000	
Measurement Unc um	1.0000	
Measured Value xm	10008.0000	
Tolerance T	20.00	Area Outside of USL
Z Upper	2.00	2.275%
		Area Outside of LSL
Z Lower	-18.00	0.000%

Setting the Guard Band Upper and Lower p_c	
Select Desired Conformance Probability	95.00%
Maximum Risk if within G_U & G_L	5.00%
h U (GB Multiplier)	0.8224
Guard Band Upper G_U	10008.3551
Guard Band Lower G_L	9991.6449
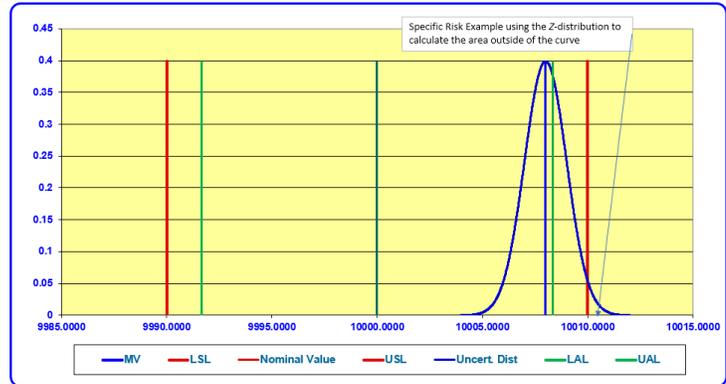
Figure 9 Specific Risk Image Courtesy of Morehouse Instrument Company.

In our second example above, we have changed the 95.45 % Expanded Measurement Uncertainty to **1**; this time, we have a 5:1 ratio of the measurement uncertainty to the tolerance. We also changed the location of the measurement from 10000 to 10008, which resulted in a total risk of 2.275 %. When we compare this to our first example, the difference in the measurement uncertainty allows for the USL and LSL to be larger. Notice that the size of the curve is considerably smaller. That is the impact of measurement uncertainty. The smaller the measurement uncertainty, the larger the acceptance limits become.

We used a Guardband multiplier to set our acceptance limits in these two examples.

Some might be saying, what is a Guardband multiplier?

Several examples in **ILAC G8, JCGM 106, UKAS LAB 48, ISO 14253-5,** and **ASME B89.7.4.1** explain Guardband multipliers.

Specific Risk Example using the *Z*-distribution to calculate the area outside of the curve (PFA)

10000.0000   10005.0000   10010.0000   10015.0000
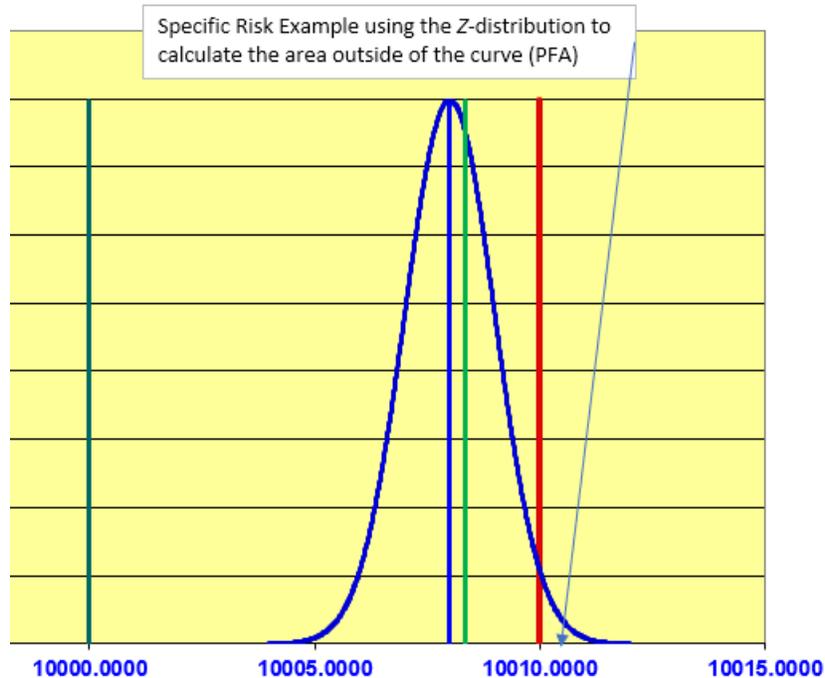
Figure 10 Specific Risk Image Courtesy of Morehouse Instrument Company.

The simplest explanation comes from **ASME B89.7.4.1**, which discusses setting a Guardband multiplier to assure conformance probability. ASME refers to gauging (or test) limits and guardbands. The gauging limits define a reduced acceptance zone.

The Guardband is chosen to set the maximum limit to achieve a desired conformance probability.

When the measured value is at the upper acceptance limit (the upper gauging limit above), the area outside the curve will equal the desired maximum risk. In contrast, the rest of the curve inside of the Tolerance Limit will be the probability of conformance to the specification. [9]

Note: More information on the Guardband multiplier and how to calculate it is in the Specific Risk calculation section.

Simple Acceptance (Shared Risk) may not meet your risk requirements.
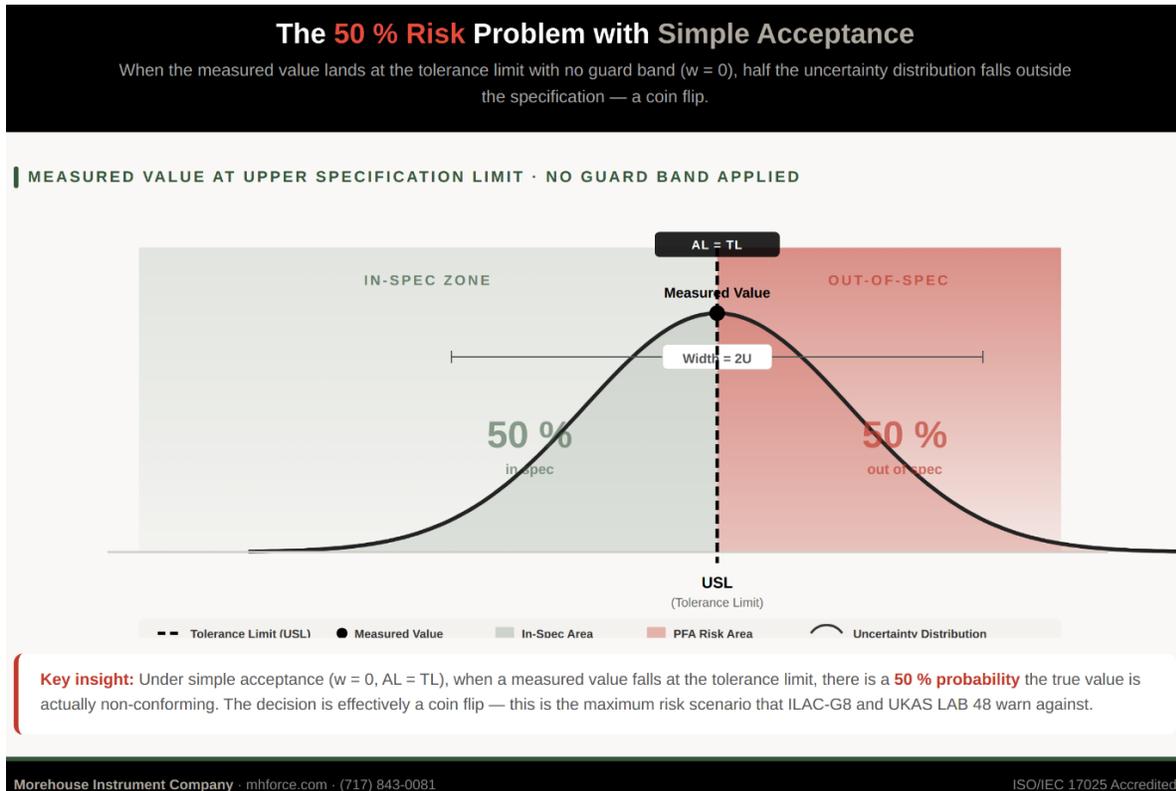
Figure 11 Specific Risk Image Showing 50 % PFA Courtesy of Morehouse Instrument Company.

Several in the industry often take a "shared risk" approach, and some disguise this by stating a Guardband of **w=0** has been applied. What that phrase means is that **NO Guardband** has been applied.

What "shared risk" means is as long as the measured value is less than or equal to the tolerance, the value is reported. It is agreed upon as being in conformance, though many are not applying a Guardband (**w=0**) and taking the approach that the end-user can decide if it is *in or out of conformance*.

ISO/IEC 17025:2017 Clause 7.1.3 dictates that the customer must agree upon the decision rule when a statement of conformity is to be made.

The customer shall specify the acceptance criteria for conformity. The decision rule(s) requirement is unnecessary if no conformance criteria is specified. [10]

Simply put, regarding decision rules, if you choose not to decide, you still have made a choice (Shared Risk).

ISO/IEC 17025 Clarification
Simple acceptance (acceptance based solely on the measured value relative to specification limits) is permitted under ISO/IEC 17025 **when it is explicitly defined as the decision rule and agreed with the customer**.

In such cases, the associated risk—potentially up to 50 % Probability of False Acceptance at the tolerance limit—is accepted by the customer. ISO/IEC 17025 does not prescribe acceptable risk levels; it requires that risk be understood and documented.

Specific Risk Versus Global Risk Under Simple Acceptance

It is important to distinguish between **specific risk**, which applies to an individual conformity decision, and **global risk**, which applies to populations of measurements over time.

In the context of simple acceptance, the conformity decision is governed by a **specific risk model**: each measurement result is evaluated independently, and the Probability of False Accept (PFA) at the tolerance limit may approach 50 %, as shown in the above figure. This risk is inherent to the decision rule and is accepted by the customer when simple acceptance is explicitly agreed upon.

In contrast, specifying a **Test Uncertainty Ratio (TUR) does not change the specific risk associated with an individual (specific risk) conformity decision.** Instead, a stated TUR is a **global risk control**, intended to limit overall risk across a population of measurements by ensuring adequate measurement capability. TUR functions as a screening or capability criterion, reducing the likelihood of excessive false acceptances *in aggregate*, rather than controlling the probability associated with any single decision.

Therefore:

- **Specific risk** governs the correctness of an individual pass/fail decision.

- **Global risk**, such as that implied by a stated TUR, governs long-term performance, population behavior, and overall exposure to risk.

Specification of a Test Uncertainty Ratio (TUR) is typically a customer- or program-level requirement and does not alter the laboratory's responsibility to apply the agreed decision rule for conformity.

Under simple acceptance, specifying a minimum TUR (e.g., TUR ≥ 3:1 or 4:1) does **not** transform the decision rule into a guarded or probability-based rule. Rather, it represents an **additional global-risk constraint** that helps mitigate the cumulative consequences of shared risk over time. For organizations concerned with long-term yield, cost, or reliability, global risk methods may be supplemented with End-of-Period Reliability (EOPR) or process capability analysis.

ISO/IEC 17025 requires that the decision rule be defined and agreed with the customer and that the associated risk be understood. It does not require laboratories to implement global risk models; however, such tools may be applied by end users as part of a broader quality or asset management strategy. Ultimately, decisions regarding risk reflect business considerations involving likelihood, consequence, and detectability.

Type I - Type II Error			
Statement of Conformity		**Consequence**	
		Actually in Conformance (ACCEPT)	**Actually out of Conformance (REJECT)**
Decision Made: (Based on Decision Rule)	**Called In Conformance: ACCEPT**	(1-α) *Calibration Lab's Confidence (Probability of Correct Accept - PCA)*	β: *Type II Error (Probability of False Accept - PFA) CONSUMER'S RISK*
	Called Out of Conformance: REJECT	α: *Type I Error (Probability of False Reject - PFR) PRODUCER'S RISK*	(1- β) *End User's Confidence (Probability of Correct Reject - PCR)*

Figure 12 Image courtesy of Dilip Shah at E= mc³ Solutions.

The probability of false acceptance (PFA), also known as Consumer's Risk or Type II error, is the probability that a test measurement on any product results in an incorrect pass determination.

On the other hand, the Probability of False Reject (PFR), also known as Producer's Risk, Type I error, is the probability that a measurement result indicates a product is outside the limits when its actual value is within the acceptance criteria.

Both PFA and PFR are integral to understanding and managing **Specific Risk**.

They provide a quantitative measure of the risk associated with a particular measurement result, guiding the decision-making process.

Risk Calculator		
Upper Tolerance T_U	10010.0000	
Lower Tolerance T_L	9990.0000	
Nominal Value	10000.0000	
Measurement Unc um	1.0000	
Measured Value xm	10010.0000	
Tolerance T	20.00	Area Outside of USL
Z Upper	0.00	50.000%
		Area Outside of LSL
Z Lower	-20.00	0.000%

Setting the Guard Band Upper and Lower p_c	
Select Desired Conformance Probability	98.00%
Maximum Risk if within G_U & G_L	2.00%
hU (GB Multiplier)	1.0269
Guard Band Upper G_u	10007.9463
Guard Band Lower G_L	9992.0537
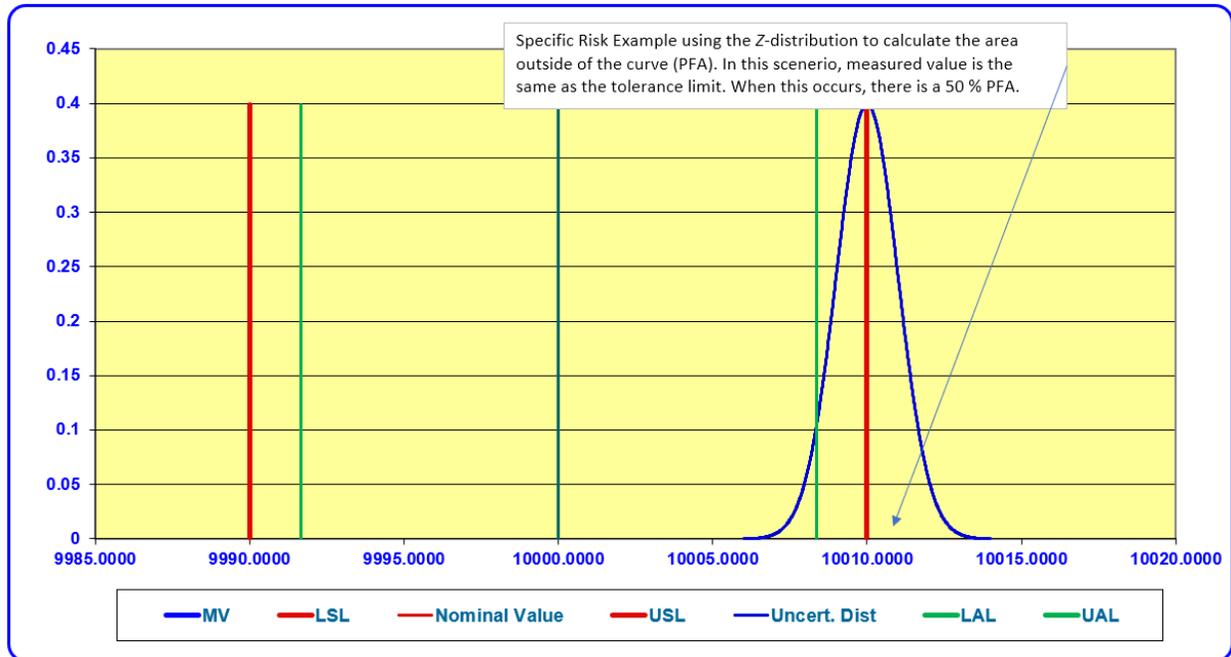
Figure 13 Specific Risk Image Courtesy of Morehouse Instrument Company.

For instance, a high PFA indicates a high risk of incorrectly accepting a product that is out of acceptance criteria.

This could lead to potential issues, such as product failures, impacting safety, or customer dissatisfaction.

On the other hand, a high PFR indicates a high risk of incorrectly rejecting a product that is within acceptance criteria.

This could lead to unnecessary rework when it is not required.

In the case of shared risk, when the measured value is exactly at the tolerance limit, the Conditional Probability of False Reject (PFR) is 50 %, meaning there is an equal chance of incorrectly rejecting a product that meets the specified tolerance.

This is the worst scenario, as it is a compilation of PFA and PFR. This could lead to any of these:

- Unnecessary rework (cost!!)
- Product safety
- Liability issues
- Loss of reputation

By understanding and managing Probability of False Accept (PFA) and Probability of False Reject (PFR), laboratories and their personnel can make more informed decisions about whether to accept or reject equipment based on the measurement results.

This practice enhances the reliability and accuracy of measurements, ultimately improving the quality of both the measuring equipment and the services provided.

By conducting a robust evaluation of measurement uncertainty and using that information to formulate an appropriate level of risk, one can implement the decision rule that considers both the PFA and PFR to make a conformity decision.

An example may be: Accept when PFA is less than or equal to 10 %. Otherwise, Reject.

The application of decision rules stating the acceptable level of risk by the customer (stakeholder) to make statements of conformity (or nonconformity) provides more confidence in the decision-making.

Therefore, the customer (stakeholder) takes the **Specific Risk** associated with statements of conformity, i.e., PFA & PFR.

Specific Risk – Calculating PFA

To Calculate PFA, the Excel function is NORM.DIST.

To calculate the PFA for the Upper Tolerance Limit (PFA Risk Upper):

Risk Upper = NORM.DIST(Measured value, Upper Tolerance Limit, Standard Uncertainty, TRUE)

To calculate the PFA for the Lower Tolerance Limit (PFA Risk Lower):

Risk Lower = 1- NORM.DIST(Measured value, Lower Tolerance Limit, Standard Uncertainty, TRUE)

Total PFA = Risk Upper + Risk Lower

Example PFA Calculations

A 10,000 N load cell has a tolerance of ± 0.1 % of full scale.

The measured value is 10,000 N.

The Expanded Measurement Uncertainty is 10N for a coverage factor of *k* = 2.

Upper Tolerance = 10,010 N

Lower Tolerance = 9,990 N

Measured Value = 10,000 N

Standard Uncertainty = 5 N

Risk Upper = NORM.DIST(10000, 10010, 5, TRUE) = 2.275 %

Risk Lower = 1- NORM.DIST(10000, 9990, 5, TRUE)) = 2.275 %

Total Risk = 4.550 %

Specific Risk Calculations – Two-Sided

There are numerous methods for calculating acceptance limits. The method presented below works for any level of risk. If the stakeholder says they want 10 % risk, it works; if they want 1 % risk, it works. Therefore, we believe this is the de facto method for calculating risk.

ASME B89.7.4.1-2005 provides an explicit method of setting the width of the acceptance zone for a specified probability of conformance.

The Guardband is a multiple of the expanded uncertainty of the measurement process, $g=hU$, where the Guardbands are the same size, $g_L = g_U = g$. The guardband multiplier (h) is given by:

$$h = \frac{1}{2}\phi^{-1}(P_C)$$

Formula to Calculate Specific Risk.

Where:

Φ^{-1} ( ) is the inverse standard normal distribution function. The Excel function to calculate Φ^{-1} ( ) is NORMSINV (). (or NORM.S.INV() for Excel version 2010 or higher)

h is the guardband multiplier

U is the Expanded Uncertainty

P_c is the probability of conformance

G_U is $T_U - hU$

T_U is the Upper Tolerance Limit
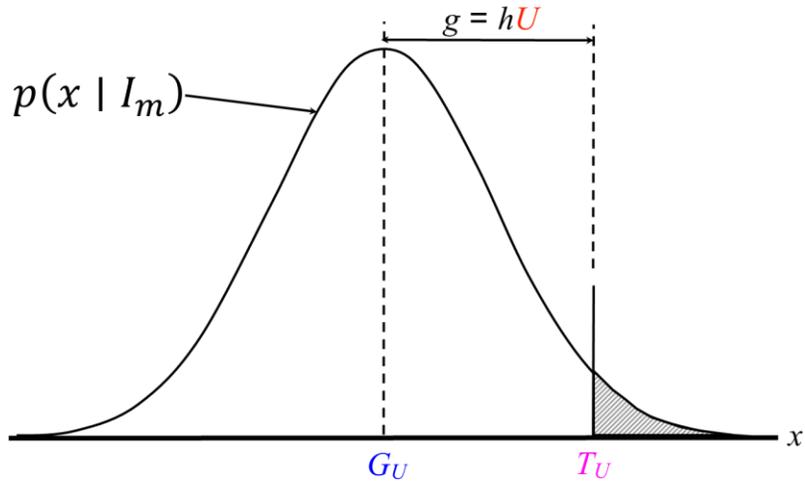
Figure 14 Image Adopted from ASME B89.7.4.1-2005.

The Guard Band is chosen so that a desired portion of the probability of conformance area under the curve lies inside the tolerance zone. [11]

Example Specific Risk Calculations – Two-Sided

We are trying to calculate the acceptance zone using a Guardband to limit our risk to a 2.5 % limit between **– 1 (Lower Tolerance Limit)** and **+ 1 (Upper Tolerance Limit)** units with a standard measurement uncertainty of 0.125 units.

Conformance Probability Table	
Conformance Probability , P_c	Guard Band Multiplier, 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
0.9750	0.980
0.9800	1.027
0.9900	1.163
0.9990	1.545

Figure 15 Conformance Probability Table Courtesy Morehouse Instrument Company.

Our Standard Measurement Uncertainty **($k=1$) is 0.125** units.

This Standard Measurement Uncertainty is applied as Expanded Measurement Uncertainty at a Coverage Factor of 2 to express at a 95.45 % Confidence Interval, assuming infinite degrees of freedom.

The customer has told us to fail anything with more than **2.5 %** risk per side.

Thus, we are calculating our **Conformance Probability** for **97.50 % (100 % - 2.5 %)** confidence for a symmetrical tolerance. We calculate the Guardband Multiplier using the Excel formula of **NORM.S.INV(0.975)/2,** resulting in **0.980.**

We then use this value of **0.980** as our GB Multiplier as follows.

For the Guardband upper limit, we have 1 – (GB Multiplier * Expanded Measurement Uncertainty)

$$1 – (0.980 * (2 * 0.125)) = 0.7550$$

For the Guardband lower limit, we have -1 + (GB Multiplier * Expanded Measurement Uncertainty)

$$-1 + (0.980 * (2 * 0.125)) = -0.7550$$

Our Acceptance Zone is to pass any measured value between *-0.7550 and + 0.7550*.

The formula can be simplified to:

 Acceptance Limit = Tolerance Limit ± Guardband multiplier * Expanded Measurement Uncertainty.

ILAC-G8:09/2019 states, "Often the Guard band is based on a multiple **r** of the expanded measurement uncertainty **U** where $w = rU.$ For a binary decision rule, a measured value below the acceptance limit

AL = TL − w is accepted." [12]

Specific Risk Calculations – One-Sided

We are trying to calculate the acceptance zone using a Guardband to limit our risk to 2.5 % between the lower and upper tolerances. In this example, we use either **-1 (Lower Tolerance Limit)** or **+ 1 (Upper Tolerance Limit)** units with a standard measurement uncertainty of **0.125 units**.

Conformance Probability Table	
Conformance Probability , P_c	Guard Band Multiplier, r Single - Sided
0.0668	-1.500
0.1590	-0.999
0.3085	-0.500
0.5000	0.000
0.6914	0.500
0.8000	0.842
0.8500	1.036
0.9000	1.282
0.9500	1.645
0.9545	1.690
0.9750	1.960
0.9800	2.054
0.9900	2.326
0.9990	3.090

Figure 16 Conformance Probability Table Courtesy Morehouse Instrument Company.

We are calculating our Conformance probability for 97.50 % Confidence using a single-sided tolerance. We calculate the Guardband Multiplier using the Excel formula of **NORM.S.INV(0.975)/2**.

Our Standard Measurement Uncertainty **(k=1) is 0.125** units.

This Standard Measurement Uncertainty is applied as Expanded Measurement Uncertainty at a Coverage Factor of 2 to express at a 95.45 % Confidence Interval, assuming infinite degrees of freedom.

Thus, we are calculating our **Conformance Probability** for **97.50 % (100 % - 2.5 %)** confidence. We calculate the Guardband Multiplier using the Excel formula of **NORM.S.INV(0.975)/2**, which results in **0.980.**

We then use this value of **0.980** as our GB Multiplier as follows.

If the single-sided tolerance is an upper tolerance:

For the Guardband upper limit, we have 1 – (GB Multiplier * Expanded Measurement Uncertainty)

1 – (0.980 * 0.250) = 0.755

If the single-sided tolerance is a lower tolerance:

For the Guardband lower limit, we have -1 + (GB Multiplier * Expanded Measurement Uncertainty)

-1 + (0.980 * 0.250) = -0.755

Note: For a one-sided tolerance at 2.5 % risk, the guardband multiplier is the same as for a two-sided tolerance at 2.5 % per side, because each side is treated independently. The multiplier differs only when the desired risk level differs.

The formula can be simplified to:

Acceptance Limit = Tolerance Limit ± Guardband multiplier * Expanded Measurement Uncertainty.

Guarded Rejection

It is crucial to have a high degree of confidence in the decision to assess a product or service's conformity to a specified requirement.

This is especially true when the consequence of a false rejection (**PFR**) or false acceptance (**PFA**) is high.

Guarded rejection is a decision rule that can reduce the risk of false rejection.

A Guarded Rejection decision rule is often employed when one wants clear evidence that the limit has been exceeded.

It is a way of setting the rejection criteria so that there is a high degree of confidence that a rejected product or service is out of tolerance.

The rejection criteria are typically set wider than the tolerance to implement guarded rejection.

This creates a "Guardband" between the tolerance and rejection criteria. As a result, a product or service will only be rejected if it falls outside the Guardband.

The Guardband would determine the appropriate risk level when rejecting or specifying non-conformance.
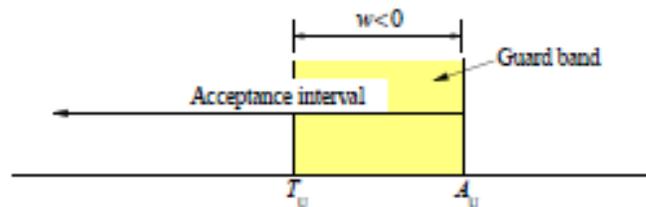
Figure 17 Image found in JCGM 106 Figure 11. [13]

The width of the Guardband is determined based on the uncertainty of the measurement and the desired level of confidence in the decision.

JCGM 106:2012 section 8.3.3.1 states the following concerning guarded rejection, ***"An acceptance limit outside a tolerance interval, as shown in figure 11, can be chosen so as to increase the probability that a rejected item is truly non-conforming. Such a guarded rejection decision rule is often employed when one wants clear evidence that a limit has been exceeded prior to taking a negative action."*** [14]

Some examples of guarded rejection include:

- Enforcing the Speed Limit where the officer wants to know without a doubt or, say, 99.9 % confidence that someone was speeding.
- Finding the Blood Alcohol or other substances present is within an x % confidence to remove doubt.
- Anti-Doping for Athletes (WADA)

- With DNA, if there is a 20 % chance that the DNA is not a match, is that enough of a chance to get a conviction? If we use guarded rejection, we can set the level to less than a 0.1 % chance, or even less.

The formula to calculate the Z value for a probability of 95 % as 0.95 can be calculated using the Excel function, which would then be used with the Excel **NORM.S.INV(0.95)**.

Guarded rejection can also be used in manufacturing, quality control, and environmental testing.

It is a valuable tool for reducing the Risk of false rejection and ensuring that only products and services that are genuinely out of tolerance are rejected.

However, it can significantly reduce the risk, especially when the uncertainty of the measurement is significant compared to the tolerance.

Benefits of using guarded rejection

- There are several benefits to using guarded rejection, including:
- Reduced Risk of false rejection: Guarded rejection can significantly reduce the risk of false rejection, especially when the uncertainty of the measurement is significant compared to the tolerance.
- Improved quality: By reducing the Risk of false rejection, guarded rejection can help improve the overall quality of products and services.
- Reduced costs: False rejection can lead to unnecessary costs, such as the expense of rework or scrap. By reducing the Risk of false rejection, guarded rejection can help reduce these costs.
- Improved customer satisfaction: False rejection can lead to dissatisfied customers. By reducing the Risk of false rejection, guarded rejection can help improve customer satisfaction.

How to implement guarded rejection

To implement guarded rejection, the following steps should be taken:

1. Perform a robust evaluation of the measurement uncertainty of the process.
2. Select a desired level of confidence in the decision.
3. Calculate the width of the Guardband often using the probability and the NORM.S.INV(Probability) Excel function.
4. Set the rejection criteria based on the probability needed.

It is important to note that the Guardband should be set wide enough to reduce the risk of false rejection to an acceptable level.

Guarded Rejection Example:

JCGM 106:2012 uses a speed limit enforcement example for issuing a ticket.

In highway law enforcement, police use devices such as radars and laser guns to measure motorists' speeds.

A decision to issue a speeding ticket, which may lead to an appearance in court, must be made with a high degree of confidence that the speed limit has been exceeded.

Using a particular Doppler radar, speed measurements in the field can be performed with a relative standard uncertainty **u(v)=v** of **2 %** in the interval **50 km/h** to **150 km/h**. Knowledge of a measured speed **v** in this interval is assumed to be characterized by a normal PDF with expectation v and standard deviation **0.02v**.

Under these conditions one can ask, for a speed limit of $v_0 = 100$ km/h, what threshold speed $v_{\max}$ (acceptance limit) should be set so that for a measured speed $v \geq v_{\max}$ the probability that $v \geq v_0$ is a least 99.9 %?

This mathematical problem is equivalent to the calculation of a conformance probability for a one-sided tolerance interval (see clause 7.3). Here a value of $z = (v_{\max} - v_0)/(0.02v_{\max})$ is needed for which 99.9 % of the probability lies in the region $V \geq v_0$. From table 1 on page 15 it is seen that $z = 3.09$, so that

$$v_{\max} = \frac{v_0}{1 - 0.02z} = \frac{100}{1 - 0.02 \times 3.09} \text{ km/h} \approx 107 \text{ km/h}.$$

The interval [100 km/h $\leq v \leq$ 107 km/h] is a guard band that ensures a probability of at least 99.9 % that the speed limit has been exceeded for a measured speed of 107 km/h or greater.

Figure 18 Equation 1 from JCGM 106. [15]

JCGM 106 Example:

This example differs from several others using the guarded rejection formula as the standard measurement uncertainty is of the indicated value. Thus, any solution will account for the standard uncertainty associated with the indicated value.

$$T_U = 100 km/h$$

$$u_m = 2\% v_{max}$$

$$P_c = \Phi(z) = 99.9\,\%$$

$$z = \Phi^{-1}(0.999) = 3.09$$

$\Phi^{-1}(\,)$ is the inverse standard normal distribution function. The Excel function is NORMSINV ()

99.9 % of the probability lies in the region $v_{max} \geq T_U$, therefore: $z = \frac{v_{max} - T_U}{u_m}$

$$z = \frac{v_{max} - T_U}{0.02 \cdot v_{max}} \Rightarrow 0.02z = 1 - \frac{T_U}{v_{max}} \Rightarrow v_{max} = \frac{T_U}{1 - 0.02z}$$

$$v_{max} = \frac{T_U}{1 - 0.02z} = \frac{100}{1 - 0.02 \cdot 3.09} \approx 107 km/h \,(Actual\ Value\ of\ 106.5876095\ km/h)$$

	A	B	C	D	E
1	Probability	Z Value	Speed Limit (km/h)	Threshold (99.9 %)	Threshold (95 %)
2	0.95	1.644853627	80	85.27008759	82.72128822
3	0.999	3.090232306	90	95.92884854	93.06144925
4			100	106.5876095	103.4016103
5			110	117.2463704	113.7417713
6			120	127.9051314	124.0819323
7	Excel functions used to calculate the above table values				
8		=NORM.S.INV(A2)		=C2/(1-0.02*B3)	=C2/(1-0.02*B2)
9		=NORM.S.INV(A3)		=C3/(1-0.02*B3)	=C3/(1-0.02*B2)
10				=C4/(1-0.02*B3)	=C4/(1-0.02*B2)
11				=C5/(1-0.02*B3)	=C5/(1-0.02*B2)
12				=C6/(1-0.02*B3)	=C6/(1-0.02*B2)

Figure 19 Excel Example of Guarded Rejection Courtesy of E=mc3 Solutions and Morehouse Instrument Company.

Above are Excel formulas, and the corresponding answers match the JCGM 106:2012 value of **106.587 (107 rounded) km/h** for anyone wanting to implement Guarded Rejection.

If one wanted to reverse solve the equation (i.e., verify the guarded rejection value does indeed back-calculate to 99.9 %), we would have to solve for the standard uncertainty of Vmax **= 106.587 609 5** by multiplying V_{max} **by 2 %.**

NORM.DIST(V_{max},Mean,Std Dev * V_{max},TRUE)

NORM.DIST(106.587,100,(2 % *106.587 609 5),TRUE)=0.99900 =99.9 %

Specific Versus Global Risk Field Goal Example:

A SIMPLE EXAMPLE: THE FIELD GOAL KICKER

In American football, a field goal kicker either kicks the ball between the goal posts or does not.

SPECIFIC RISK
This kick, right now
Did it go through?

VS.

GLOBAL RISK
All kicks from this distance
What's the historical success rate?
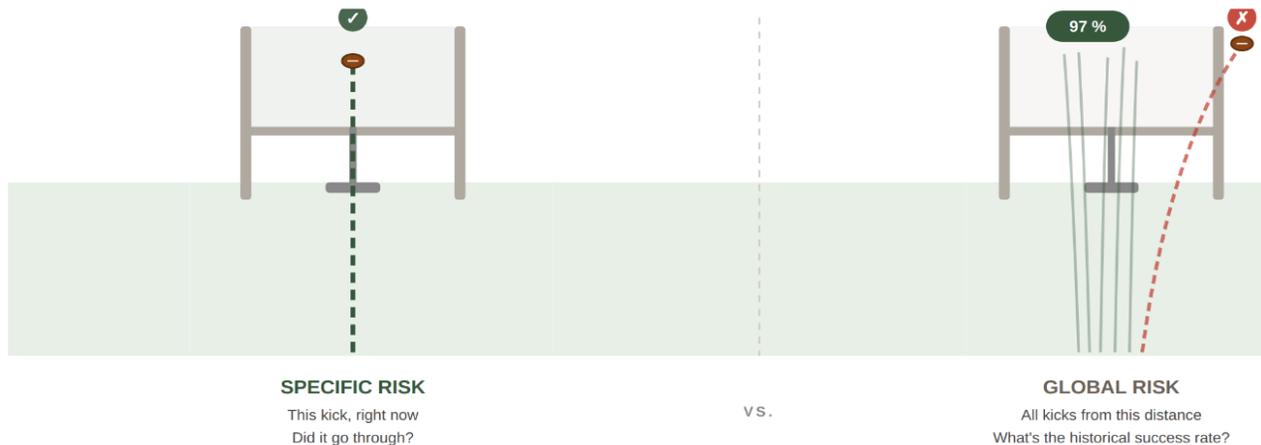
Figure 20 Field Goal Example Courtesy of Morehouse Instrument Company.

Specific (Conditional) Vs Global (Unconditional) Risk, A Simple Example: The Field Goal Kicker

In American football, a field goal kicker either kicks the ball between the goal posts or does not.

Specific risk is the single kick in front of you right now. The ball either traveled between the goal posts or it didn't. Pass and points or fail and no points for your team (sorry, Ravens fans). When we make a measurement and record the observed value, it is either between the acceptance limits or it is not. One kick, one result, one decision.

Global (average) risk steps back and looks at all the kicks. Say the Steelers kicker makes 97 % of his field goals from the 35-yard line. This kick is from the 35-yard line, yet it didn't go in. Based on population data alone, you would say it is likely that it did go in. And the Steelers won the game, hooray!

That is exactly the tension between the two approaches. Global risk uses historical population data to assess the probability of an incorrect decision, such as a false accept or false reject, across a population. Specific risk evaluates the single result in front of you. One tells you how reliable the process is over time. The other tells you what happened right now.

Now shift your focus from the kick to the goal posts themselves. The distance between them represents your tolerance. A kicker with a tight, repeatable trajectory effectively has more room to succeed because their variability is low. In contrast, a kicker with inconsistent performance needs nearly perfect alignment every time. The same principle applies to measurement: as uncertainty decreases, the "usable" portion of the tolerance increases, and confidence in the result improves.

With that perspective in mind, Global Risk methods attempt to answer the population question, what the overall reliability of the measurement process across all the kicks is, while Specific Risk methods answer the individual question at each measurement point. The following section addresses Global Risk in detail.

Global Risk

Global Risk is mathematically based on the entire measurement result (for an infinite number of measurements). **Global Risk** depends on two probabilities to evaluate the overall probability of incorrect conformance decisions.

Measurement uncertainty, u_m.

Product/process a priori uncertainty, u_p.

The risks now depend on the measurement process and the production process.

When a production process consistently produces items within their tolerance limits, the risk of making incorrect decisions typically decreases.
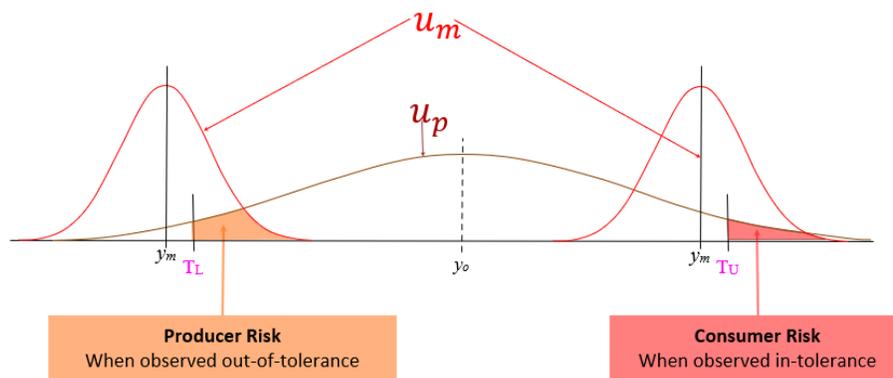
Figure 21 Image Courtesy of Scott Mimbs.

Global Consumer Risk refers to the probability that a test measurement on any product results in an incorrect pass determination, which means someone says something is good when it is not.

This is also known as *Unconditional PFA or Consumer Risk*.

In contrast to **Unconditional PFA,** conditional risk, particularly the **Conditional Probability of False Accept** (**CPFA**), tends to be higher. Consider a scenario where a laboratory employs a criterion to pass equipment when the PFA does not exceed 2 %. This unconditional risk is determined at the time of calibration. However, when the equipment is put into actual use, the **Conditional PFA (CPFA)** will always exceed whatever the **Unconditional PFA** was.

The rise signifies more uncertainties and factors that occur in practical applications, which weren't accounted for in the initial controlled calibration. Conditional PFA can be viewed as the risk the user or equipment owner assumes when placing the item into service. From this angle, the pivotal risk is the likelihood that attributes deemed acceptable will be out of tolerance (OOT). Given that the risk of accepting a faulty test or calibrated item under this perception is contingent on its initial approval, it's termed "conditional probability of false accept risk," or CPFA.

The formula to calculate CPFA is as follows:

$$CPFA = 1 - \frac{\textbf{Probability}(\textbf{\textit{In Tolerance}}, \textbf{\textit{Accepted}})}{\textbf{Probality}(\textbf{\textit{Accepted}})}$$

Note: CPFA is typically associated with large-scale calibration processes, such as those used in manufacturing where high volumes of identical products are involved. For general calibration scenarios involving a small number of similar devices, CPFA is usually not a significant concern.

Global Risk also refers to the probability that a test measurement on any product results in an incorrect failure determination, which means someone says something is bad when it is good.

This is also known as the *Unconditional PFR or Producer Risk*.

Global Risk considers the test measurement probability distribution and the probability of encountering a product at that measured value.

It's important to note that **Global Risk** cannot be calculated without specifying a distribution of values for the product, which is obtained from a priori knowledge that changes with every new measurement made and the current measurements being made.

<u>*Note:*</u> *When dealing with Global Risk, if you currently have a desired EOPR, and a week later, your EOPR changes to lower than your threshold value, you need to come back and look at the measurements/calibrations performed during the past week. This means the Global Risk's EOPR reliability is fundamentally related to both the past and future.*

In simple terms, most people worry more about the probability that their equipment will not maintain the required tolerance during the calibration cycle since **Global Risk** relies on past measurement history at the time of calibration.

This can be a significant issue when safety is crucial.

One example might be the potential consequences if an aircraft's weight is miscalculated due to inaccurate measurements, causing the center of gravity to be off.

When labs don't correctly calculate this Risk or loosen their restrictions/requirements, they create a potential danger wherever this equipment is utilized in subsequent processes.

A good example would be not looking at the overall reliability of their equipment, which means not adjusting calibration/maintenance intervals or widening specifications to meet their reliability targets.

Global Risk Example: A calibration lab tracks its PFA and PFR rates across thousands of calibrations. By managing global risk, the lab ensures that its overall false decision rate remains within an acceptable limit, even if some individual calibrations carry a slightly higher risk.

Global risk tools, such as End-of-Period Reliability (EOPR) or population-based risk analysis, are generally applied by the customer or end user as part of broader quality or asset management strategies, rather than as laboratory conformity decision requirements.

Reliability/End of Period Reliability

The Estimate of Reliability can be calculated using the formula below.

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

Reliability is defined as the number of calibrations resulting in as-received IN – Tolerance Results divided by the total number of calibrations.

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 decreases with time after calibration.

Reliability Analysis of M&TE should be based on similar instrumentation, manufacturer, model #, and calibration intervals. What should be avoided is intermixing different M&TE with different calibration intervals, environments, and conditions (applications).

The example above estimates the EOPR by simple division, which provides "a number" but disguises the confidence associated (it is not "the number"). For example, if a particular make/model instrument were calibrated 100 times with no "Out of Tolerance" (OOT) noted, using simple math, we discover the EOPR is 100%. While technically correct according to the equation above, this statement is also dangerously misleading. Here is why: Although 100 out of 100 items were found "In-Tolerance," the true reliability is somewhere between two reliability confidence bounds. If the servicing lab has an EOPR target of 99% with 90% confidence and zero failures, the worst-case EOPR is assumed to be the lower calculated confidence bound.

As mentioned, an estimate of reliability can be calculated using binomial confidence bounds. What is a binomial confidence bound? It is the statistical equivalent of putting a "tolerance" around the target reliability. Like a typical specification, it might be read as **1 VDC ±0.1 VDC at 95 % confidence**. In this example, the **Value of 1 VDC is bound by 0.9 to 1.1 VDC**. If the measured value is +1.015 VDC, the measurement is considered "In-Tolerance." The true value, however, is unknown. It is unknown because of the measurement uncertainty involved. The true value lies within the measured value and the associated uncertainty. This is the case for any measurement, as uncertainty is unavoidable.
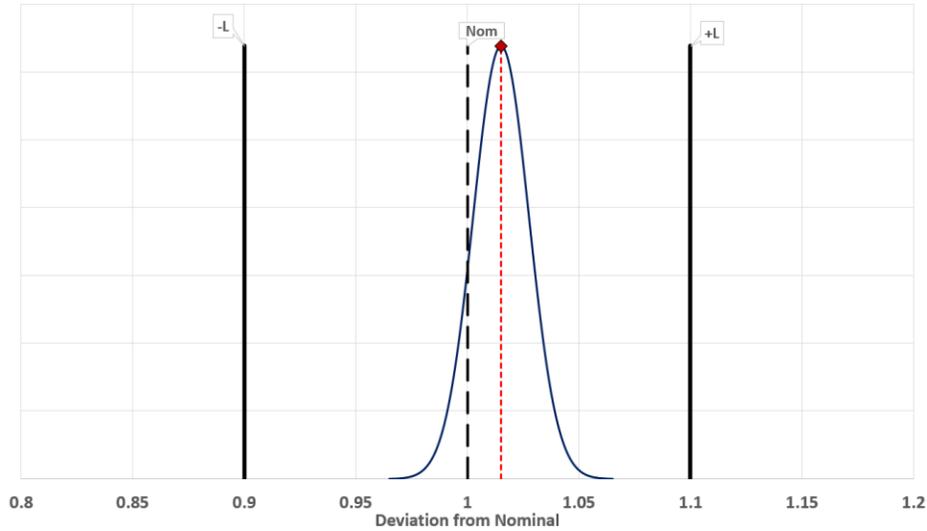
Figure 22 Confidence Bounds Image Courtesy of Greg Cenker & Indysoft.

Using the Binomial as a tolerance bound concerning reliability makes the similarity between acceptance/rejection criteria obvious. Instead of the deviation from nominal, the question becomes "Is the reliability in tolerance?"

Let's revisit the initial example of 100 items calibrated with zero failures. It was stated the reliability target was 99 % with 90 % confidence around that estimate. We will substitute using the binomial confidence bound and borrow the A3 methodology from RP-1, Establishment, and Adjustment of Calibration Intervals (2010). The graph below shows the upper confidence bound (pU), reliability target (Rtarg), and the lower confidence bound (pL). The true reliability is between pU and pL. Since we don't know the true reliability, we take a conservative path and label the lower confidence bound as the estimated EOPR. It is, therefore, assumed the worst-case EOPR becomes 97.72 %
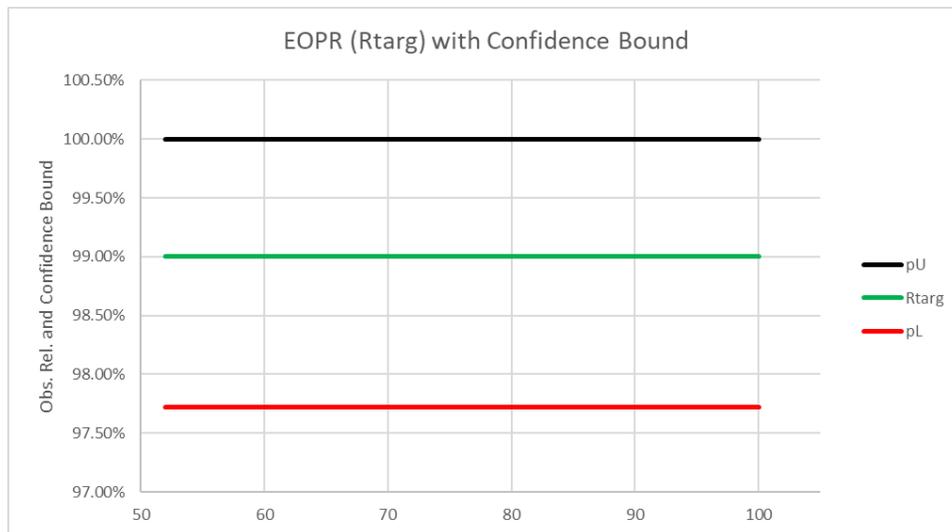
Figure 23 Confidence Bounds Image Courtesy of Greg Cenker & Indysoft.

The upper and lower binomial confidence bounds are easily calculated using Excel and the inverse beta function.

BETA.INV = (Probability, Alpha, Beta, A, B) the values for A and B are left blank as they are optional and not applicable to this example.

Using the sample size of 100 trials and 100 successes, with a desired confidence of **90 %**, we write a function.

<u>Note:</u> in the event of zero failures, which is true in this example, the result will produce an error in excel displayed as #NUM! To avoid seeing this error, write the formula as described below. The IFERROR function translation reads "if there is an error, return the value of 1, otherwise calculate the formula."

P_U = IFERROR(1 – (BETA.INV ((1 – confidence) * 0.5, trials – successes, successes + 1)),1)

   = IFERROR(1 – (BETA.INV ((1 – 90 %) * 0.5, 100 – 100, 100 + 1)),1)

   = IFERROR(1 – BETA.INV ((1 – 90 %), 0, 101),1) * there is an error, therefore the result is 1

P_U = 100 % or 1

Calculating the lower limit uses the same function but the input parameters are arranged differently. The error trapping, in this case, guards against the event of zero successes.

P_L = IFERROR(1 - (BETA.INV (confidence, trials - successes + 1, successes)),0)

   = IFERROR(1 - (BETA.INV (90 %, 100 - 100 + 1, 100)),0) *<u>note the order of execution, 100 – 100 + 1 is the correct input while 100-(100+1) is incorrect and will produce an error</u>*

   = IFERROR(1 – (BETA.INV (90 %, 1, 100)),0)

   = IFERROR(1 – 0.02276)),0)

   =IFERROR(0.9772)),0)

P_L = 97.72 % or 0.9772

In closing, we see our true reliability is between **100 and 97.72 %**. To protect all downstream customers, act conservatively by reporting the **EOPR is therefore ~97.7 %**

In the manufacturing realm, this is known as the OC curve (Operator Characteristics), where a sample size is drawn determining acceptance/rejection of a product run.

How much testing is required to demonstrate reliability with confidence?

The formula used in determining the appropriate sample size for a given reliability target is very simple to replicate in Excel or virtually any calculator. The formula is as follows:

Sample Size = ln(1-Confidence)/ln(Target $_{Reliability}$)

Reliability target = 95 %

Confidence of the reliability target = 90 %

Sample Size = ln(1-90 %)/ln(95 %)

Sample Size = -2.302 585 093/-0.051 293 294

Sample Size = 45 (rounded up from ~44.89)

It is worth stating that this number, consisting of 45 samples, is necessary to demonstrate 95 % EOPR with 90 % confidence and assume zero failures. If the very next data point is a failure, the EOPR drops from 95 % to 91.8 % and would require 32 additional samples to bring it back to 95 %. Maintaining a high EOPR matched with an equally high level of confidence easily impacts the number of samples required to meet overly ambitious goals.

The mathematics utilized to recalculate the revised sample size is not a closed-form solution. The value required is an iterative function represented by a "Do Until" loop. For readers interested in this solution, it can be found in the appendix as a VBA function add-in.

So, what is the best way to calculate EOPR for my organization?

This question has a variety of answers. The correct answer depends on the criticality of the measurement results and the risk penalty the company may be exposed to in the event of a false acceptance. If your company manufactures implantable cardioverter-defibrillators, the false accept risk level will likely be quite low, and therefore, maintaining a high level of EOPR is not only desirable but mandatory. However, if the product is a paper notepad, an acceptable EOPR might be 85 % or less, with a higher tolerance for false acceptance. The possibilities are nearly endless; therefore, each laboratory must arrive at its own conclusion of acceptable EOPR and risk.

Calculating Global Risk

A step-by-step guide on how to calculate **Global Risk**:

1. Understand the Concept: One part of **Global Risk** is the probability that a test measurement on any product results in an incorrect pass determination. It's also known as the PFA or consumer risk. The other part is that an incorrect failure is reported (Probability of False Reject), also known as producer risk.
2. Identify the Test Measurement Probability Distribution: This is the likelihood of different outcomes in a measurement. This distribution is a fundamental part of calculating **Global** Risk.
3. Identify the Probability of Encountering a Product at that Measured Value: This is another crucial factor in calculating **Global Risk**. It's the likelihood of coming across a product with a specific measured value.
4. Specify a Distribution of Values for the Product: **Global Risk** cannot be calculated without this. This distribution is obtained from prior knowledge and measurements of the product.
5. Integrate the Joint PDF: This is the joint Probability Density Function of the test measurement and the PDF of the unit under test. This integration is a mathematical process that combines these two factors to calculate **Global Risk**.
6. Make sure there is enough EOPR data to use the Global Risk formulas confidently.
7. Apply the Formula: The formula for calculating global consumer and producer risk is found in JCGM 106 section 9.5.2.2: "For a measured value in the acceptance interval and a value of Y outside the tolerance interval, the global consumer's Risk is

$$R_C = \int_{\widetilde{C}} \int_A g_0(\eta) \, h(\eta_m|\eta) \, \mathrm{d}\eta_m \mathrm{d}\eta.$$

Figure 24 The formula for Global Risk is found in JCGM 106. [(16)]

Global Risk: For a measured value outside the acceptance interval and a value of Y within the tolerance interval, the global producer's Risk is:

$$R_P = \int_{C} \int_{\widetilde{A}} g_0(\eta) \, h(\eta_m|\eta) \, \mathrm{d}\eta_m \mathrm{d}\eta.$$

Figure 25 The formula for Global Risk is found in JCGM 106. [(17)]

Note: Please refer to JCGM 106, as there is a lot more than just this formula. In a real-world scenario, the desired level of Risk will likely be chosen based on acceptance limits, cost analysis, and uncertainty.

8. Interpret the Result: The resulting Value is the **Global Risk**, which represents the likelihood of incorrectly accepting a product based on the test measurement.
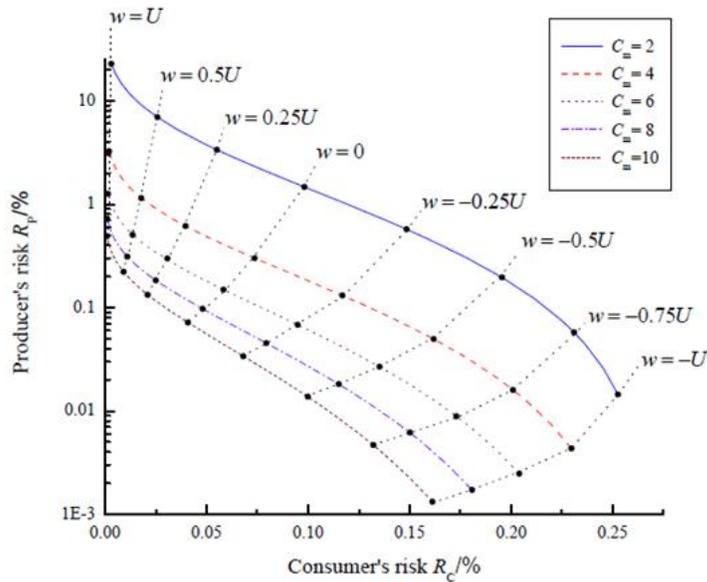
Figure 26 JCGM 106 Figure 17 Global Risk versus Consumer Risk. [18]

9. To reduce the probability of an incorrect, accept/reject decision, you should invest in better equipment to reduce the uncertainty. The above figure shows varying levels of measurement uncertainty and how Risk is lower with higher measurement capability index ratios (the Measurement Capability Index is analogous to TUR).

Ensure you have the correct data and understand the process before calculating **Global Risk**. Much of this has to do with calculating TUR or Measurement Capability Index Correctly.

Calculating **Global Risk** requires solving a double-integral, which doesn't have analytical solutions because of the exponential function. Tools and software are available to make calculating **Global Risk** easier than following those nine steps above.

Some free software, such as SunCal, can be found at https://sandiapsl.github.io/.

There are also many excellent reading references listed in our recommended reading section.

Other software, such as Mathcad, can be used as well. Mathcad examples are included in the appendix.

Calculating TUR and Measurement Capability Index

$$\mathbf{TUR} = \frac{\mathbf{Span\ of\ the\ \pm\ UUT\ Tolerance}}{\mathbf{2\ x\ k_{95\%}(Expanded\ Uncertainty\ of\ the\ Measurement\ Process})}$$

TUR is a ratio of the calibrated item tolerance divided by the uncertainty of the entire calibration process. Evaluation of the TUR is a rigorous process that includes additional contributors to the uncertainty beyond just the uncertainty of the calibration standard. ANSI/NCSLI Z540.3 and the Handbook published in 2006 completely define TUR. It relies on knowing how to calculate uncertainty following a calibration hierarchy, including metrological traceability. There is a lot of confusion in the industry on how to calculate Test Uncertainty Ratio.

Rightfully so, the definition has taken different shapes and forms over the decades. Sometimes, it is even confused with the Test Accuracy Ratio (TAR).

$$\mathbf{TAR} = \frac{\mathbf{Accuracy\ of\ the\ Unit\ Under\ Test}}{\mathbf{Accuracy\ of\ the\ Reference\ Standard}}$$

TAR is a ratio comparing the Unit Under Test's Accuracy with the Reference Standard's accuracy. Its origins date back to the 1950s.

The roots of measurement decision risk can be traced back to early work done by Alan Eagle, Frank Grubbs, and Helen Coon, which include papers published around 1950. These measurement decision risks concepts were complex for many and gained little traction.

About five years later, Jerry Hayes of the United States Navy established accuracy ratios versus decision risks for the calibration program. TAR was introduced because it simplified much of the measurement decision risk. First, a consumer risk of 1 % was accepted, which would be a Probability of False Accept (PFA) today. This means that about a 3:1 accuracy ratio would be required.

Then, working with Stan Crandon, Hayes decided to add this ratio to account for some uncertainty in the reliability of tolerances. Thus, 3:1 became 4:1, and the US Navy adopted a policy many in the metrological community adopted. More details about this history are found in "Measurement Decision Risk – The Importance of Definitions" by Scott Mimbs. [19]

Since there was limited computing power, the 4:1 TAR ratio was an easy-to-follow rule that solved a problem. The TAR is a ratio of the tolerance of the item being calibrated divided by the accuracy of the calibration standard. Thus, if I have a device that needs to be accurate to 1 %, I need a calibration standard that is four times better or 0.25 %. Since the concept was so simple, many followed it and continued to follow it. Initially, TAR was supposed to be a placeholder until more computing power became available.

$$\text{TUR} = \cfrac{\textbf{Span of the } \pm \textbf{ Tolerance}}{2 \text{ x } \textbf{k}_{95\%} \sqrt{\left(\cfrac{\textbf{CMC}}{\textbf{k}_{\textbf{CMC}}}\right)^2 + \left(\cfrac{\textbf{Resolution}_{\textbf{UUT}}}{\sqrt{12}}\right)^2 + \left(\cfrac{\textbf{Repeatability}_{\textbf{UUT}}}{1}\right)^2 + \cdots (\textbf{u}_{Other})^2}}$$

The TUR formula is an adaptation with the denominator clarified for current practices from Handbook for the Application of ANSI/NCSLI ANSI 540.3 -2006. Some may contend that resolution is accounted for with repeatability studies. However, the UUT's resolution must be considered if repeatability equals zero.

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 using the approved procedure to calibrate the M&TE. Therefore, the estimate includes all components of error that influence the calibration measurement results, including 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." [20]

This definition of the TUR denominator aligns very closely with ILAC P14:09/2020, which states, "Contributions to the uncertainty stated on the calibration certificate shall include relevant short-term contributions during calibration and contributions that can reasonably be attributed to the customer's device. Where applicable, the uncertainty shall cover the same contributions to uncertainty that were included in evaluation of the CMC uncertainty component, except that uncertainty components evaluated for the best existing device shall be replaced with those of the customer's device. Therefore, reported uncertainties tend to be larger than the uncertainty covered by the CMC." [21]

An Alternative Formula (ANSI Z540.3 Method 6, aka Mike Dobbert Method) that Controls PFA to Less than 2 %.
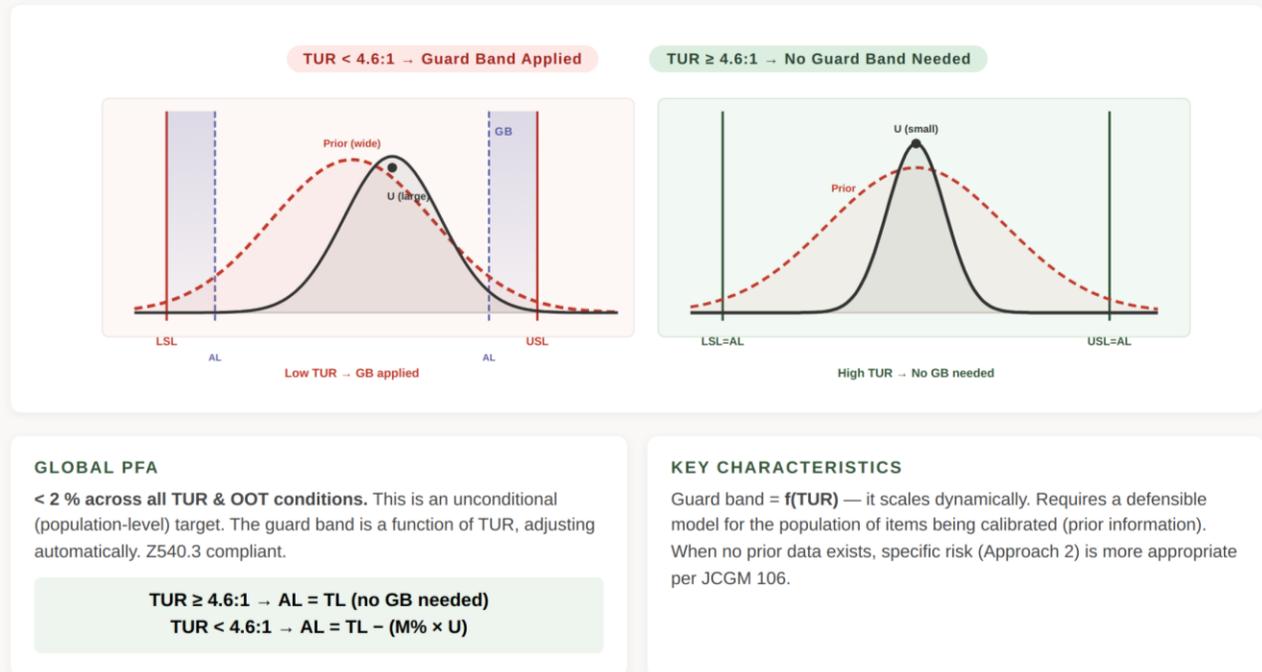
Figure 27: Managed Guard Bands to limit PFA < 2 %.

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 the reliability data (EOPR) needed for **Global Risk** models.

In response, Michael Dobbert developed a **Managed Risk Guardband** that does not require EOPR.

Paul Reese and John Harben wrote a paper titled Risk Mitigation Strategies for Compliance Testing, which proved that for the worst-case EOPR if the TUR was 4.6:1 or greater, the false accept risk would always be below 2 %.

Max Risk vs TUR

(Assumes Worst-Case EOPR for a given TUR)
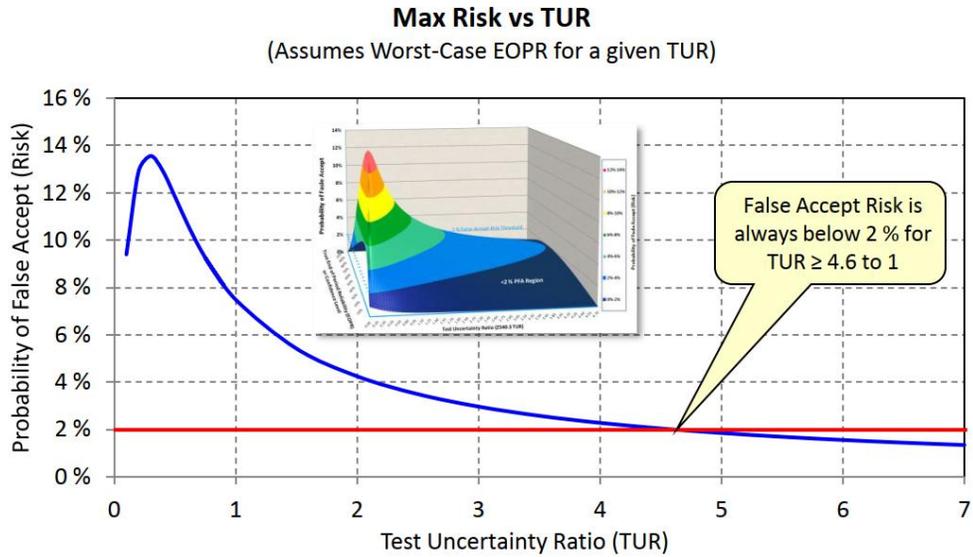
Figure 28: Max Risk Vs. TUR from Implementing Strategies for Risk Mitigation. [22]

The Managed Risk Guardband is based on the fact that for a given **measurement capability index (Cₘ),** there is a maximum consumer risk for all product/process uncertainty values. The reader may notice some peculiar behavior in the PFA graph dropping off for a TUR (Cm) less than 1:1. This is because the difference between the reference standard and the M&TE is the same, accuracy-wise; the problem of falsely accepting products drops off significantly where nearly everything tested is falsely rejected.

Max Risk vs EOPR

(Assumes Worst-Case TUR for a given EOPR)
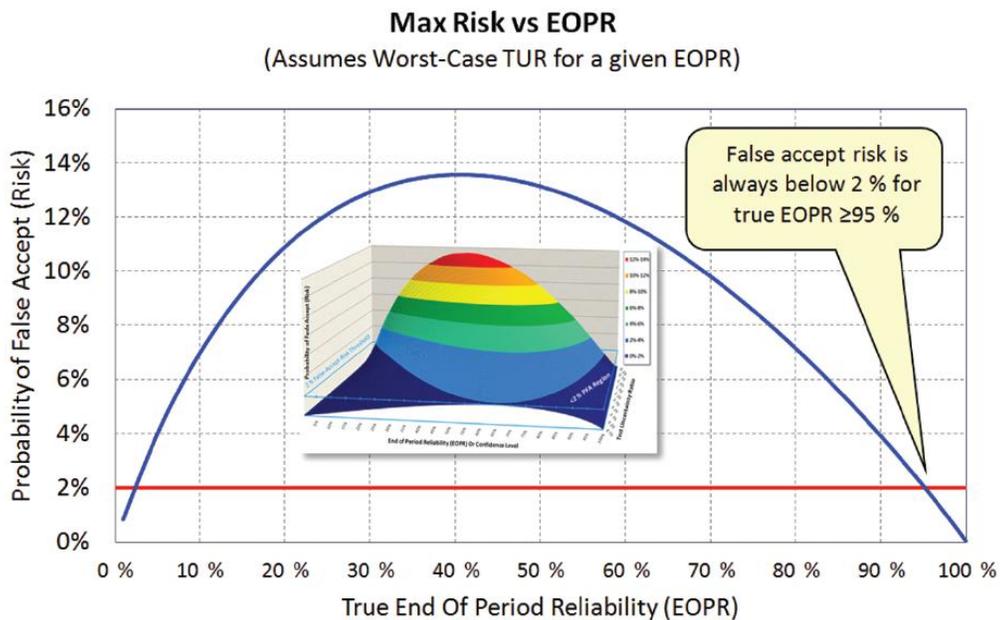
Figure 29: Max Risk vs EOPR from Implementing Strategies for Risk Mitigation. [23]

Figure 27 assumes a worst-case TUR. When both True EOPR and TUR are low, most measurements lie outside of the tolerance, and the risk of falsely accepting an item is low. The false accept risk is low when EOPR is near 100 %.

Therefore, for a given **measurement capability index C_m**, applying just enough of a guardband to lower the maximum risk below a desired level is possible.

Thus, Dobbert calculated a multiplier that adjusts the guardband for a specified **measurement capability index C_m** to meet the 2% consumer risk requirement of Z540.3.

This method ensures that the consumer risk is in control while minimizing the producer risk.

Applying a guardband to manage maximum false-accept risk results in a guardband that is always less than the 95% expanded uncertainty. Accordingly, the acceptance limits can be expressed as follows,

$$A = T - U95 \text{ \% } \times M$$

Where:

A = acceptance limit

T = tolerance limit

U95 % = calibration process 95% expanded uncertainty

M = multiplier: the fraction of the 95% expanded uncertainty for which the acceptance limits provide the desired false-accept risk.

$$M_{2\,\%} = 1.04 - e^{(0.38\,\ln(C_m) - 0.54)}$$
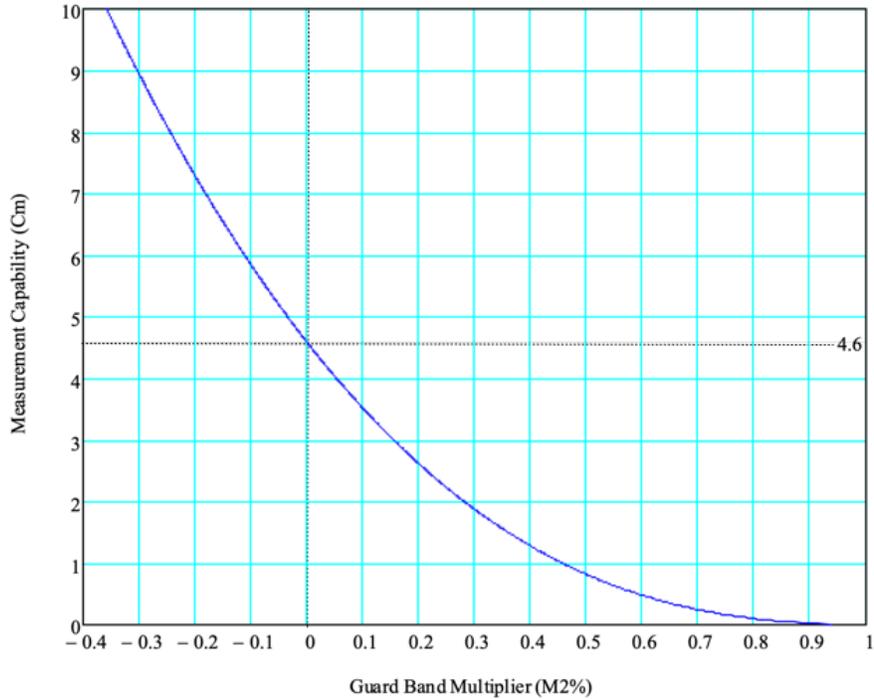
Figure 30: Image Courtesy of Scott Mimbs.

The graph above illustrates the size of the Managed Risk Guardband multiplier over a range of **measurement capability indices (C_m).**

A = T −U95 % × M

C_m = Measurement Capability Index (TUR)

M = 1.04-EXP(0.38 x In(C_m)-0.54)

T = Required Tolerance

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

Note: The formula here shows that this decision rule does not apply to a single-sided tolerance.

It is mathematically described as:

Method 6 Example:

$$M_{2\%} = 1.04 - exp(0.38 \times ln\,(TUR) - 0.54)$$

$$+Acceptance = Upper\;Test\;Limit - Uc95\,\% \times M_{2\%}$$

$$-Acceptance = Lower\;Test\;Limit + Uc95\,\% \times M_{2\%}$$

Test Limit (TL)= ±1

Expanded Measurement Uncertainty (Uc95 %) = ±0.5

TUR = 1/ 0.5 = 2.0

$M_{2\%}$ =0.281 645 308

+Acceptance Limit = Upper TL - $Uc95\,\% \times M_{2\%}$= 0.859 177 346

-Acceptance Limit = Lower TL + $Uc95\,\% \times M_{2\%}$= -0.859 177 346

The M 2% expression was empirically fit to achieve a worst-case PFA of 2 %. This is a very easily implemented option.

Method 1 Unconditional PFA Estimation – Test Point Population Data.

Method 1, which is the most flexible, is the most complex method to implement in a metrology laboratory system. The functions are given in this document's appendix, making them truly copy-and-paste. The difficulty arises in understanding their proper use.

Method 1 provides an unconditional PFA estimate applied to a **population** of "like calibration processes" at the **test point level**. This means that the **population or average PFA** is estimated for each test point of the **same M&TE model and manufacturer** and evaluated for compliance prior to a measurement. The estimated PFA is compared with the requirement to determine whether the test point is compliant. This unconditional PFA estimation approach can also be used to develop test point level guardbands. Method 1 allows for directly determining compliance to a global risk requirement that may be _any_ value required by the customer. This is a primary advantage over **Managed Guardbands (M6)** as the overall PFA, in that method (**M6**), is hard coded and limited to ~2%. The **Method 1** algorithm is listed in the full VBA code in the appendix.

This section discusses the meaning of numerical search methods and provides an algorithm appropriate for determining acceptance limits.

In general, numerical search methods solve complex mathematical expressions that cannot be solved in closed form. These search methods are often based on derivatives of the formulas used in the expressions. This is the case with iterative methods such as the "Newton" method, which is generally included in calculus texts. The Newton Method is utilized in **Method 1** for asymmetrical tolerance calculations.

Numerical bisection provides a numerical search method that does not require derivatives. This algorithm is simple to understand and implement, making it appropriate for determining guardbands and acceptance limits.

As applied to acceptance limits, numerical bisection starts by setting the acceptance limit equal to the tolerance limit and estimating PFA using one of the estimation methods provided in **Method 1**. If the estimated PFA is greater than the requirement, the acceptance limit is lowered until it is less than or equal to the requirement.

At this point, the algorithm tries to find an acceptance limit closer to the tolerance limit. When the estimated PFA is lower than the requirement, an acceptance limit is increased using a bisection between the current acceptance limit and the tolerance limit. When the estimated PFA is greater than the requirement, an acceptance limit is decreased using bisection between the current acceptance limit and the previously tried acceptance limit.

This bisection process continues until the estimated PFA is found to be between the PFA requirement and the PFA requirement minus some small precision factor (0.000 000 001).

Although **Method 1** is complicated, we can demonstrate how it can be configured to provide the same results as the **Managed Guardband Method**. Using the same basic inputs demonstrated in the Managed Guardband Method, we will add 2 variables: the estimated End of Period Reliability for the UUT (designated in the function as "R") and the maximum level of risk required (designated as "Req"). Since we know nothing about our UUT, we will assume an EOPR value of 68.27 %.

For reference, by reverse solving for EOPR using the **Managed Guardband** method, this EOPR value was calculated to 69.674 %, but we will use 68.27 % (1-sigma) to keep things simple.

Test Limit (TL) = ±1

R (UUT's assumed End of Period Reliability since we know nothing about it) = 68.27 %

Expanded Measurement Uncertainty (Uc95 %) = ±0.5

TUR = 1/ 0.5 = 2.0

Function uutUnc(68.27 %, Uc95 % / 2, Lower TL, Upper TL)

     =uutUnc(68.27 %, 0.25, -1, 1) = ~ 1

Function PFAGBMult(Req, uutUnc(68.27 %, 0.25, -1, 1), Uc95 % / 2, Lower TL, Upper TL)

     = PFAGBMult(2 %, 1, 0.25, -1, 1)

     = 86.834 %

     +A = Upper TL x 86.834 % = 0.86834

     -A = Lower TL x 86.834 % = -0.86834

Verify newly calculated tolerances limit the PFA to 2 %

PFA = (uUUT, Uc95 % /2, Lower TL, Upper TL, Lower AL, Upper AL)

PFA = (1, 0.25, -1, 1, -0.86834, 0.86834)

PFA = 2.000 %

By substituting the **Managed Guardband** results into the PFA equation, we can see they agree within reason.

PFA = (1, 0.25, -1, 1, -0.859177346, 0.859177346)

PFA = 1.890 %

*Note: the slight difference in PFA between both methods is due to the **Managed Guardband** methodology utilizing a curve fit to ensure all EOPRs with all TUR combinations, yielding a PFA of <2 %. To the end user, you will not know what the "actual" PFA is because the results simply limit the PFA to a value <2 %. Method 1 uses a direct calculation **specific** to the individual test point. **Method 1** offers much more flexibility because it allows for the entry of true EOPR estimates for both the UUT and the reference standard at the test point level to be added if this information is available.*

Decision Rule Tree

Below is a modified version of the Decision Rule Selection Guide in ILAC G8. The modification was done to ensure there is enough historical data to use different **Global Risk** decision rules that rely on End of Period Reliability. (***Not all methods mentioned in the flow chart are discussed in this paper***)
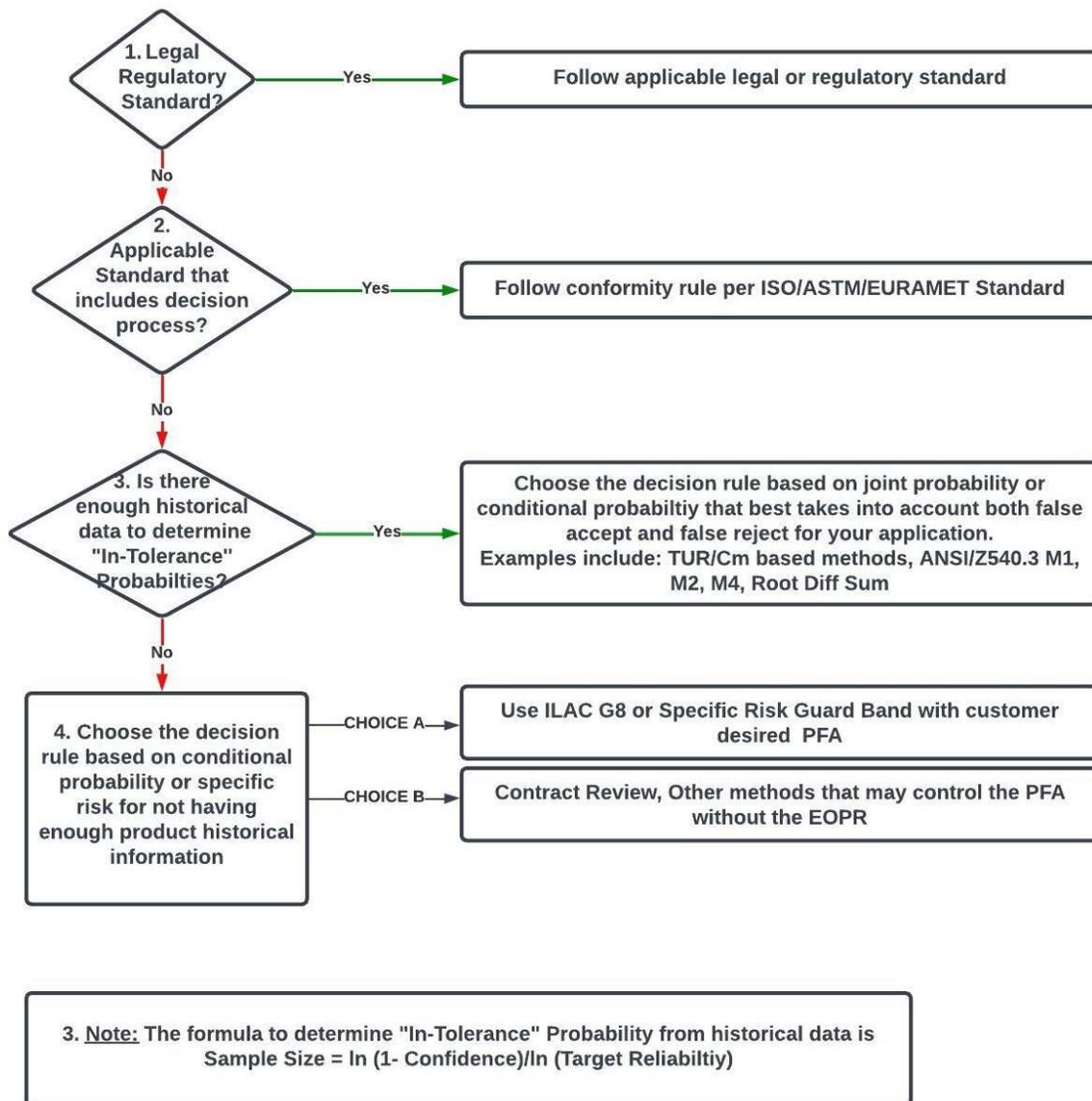
Figure 31: This is a modified version of the ILAC G8:09/2019 table.

We modified the ILAC G8 table because we believe that the ILAC G8 table does not fully elaborate on the additional requirements for using some **Global Risk** methods that require EOPR analysis.

How to Use Global Risk: Costing Formulas That Save Big on Equipment

Imagine your company is making a product and having to reject 10 % of everything produced. What if you could reduce the reject rate to under 1 %? What would you save by doing so? Whatever your present failure rate, there is likely a solution involving better-measuring equipment and process improvements that can lower the risk of false rejections.

We tend to observe companies that have purchased something; someone wants to validate their purchase by continuing to use that equipment (drowning without asking for help). Measuring and testing equipment can be a large expense, and once something is purchased for whatever reason, the determination to continue using it can be large. Management will often provide too much friction to justify purchasing something better when a cheaper alternative seems good enough.

Let's examine this hypothetical case study inspired by the JCGM resistor example to prove our point. Unfortunately, this represents a common issue impacting numerous companies globally, potentially leading to billions in lost revenue.

Case Study: Cost Cutting Leads to Quality Issues in Resistor Manufacturing

Background:

This case study describes a scenario where a manufacturer of resistors faced challenges due to prioritizing cost-cutting measures over ensuring accurate measurement processes using the appropriate measurement capability index (C_m), also known as Test Uncertainty Ratio (TUR).

Problem:

The company needed to manufacture resistors with a tolerance of 1,500 ohms ± 0.2 ohms (approximately ± 0.013%). To minimize costs, they opted for a mid-tier digital multimeter with a resolution of 7 ½ digits, assuming it would be sufficient for their needs.

Using Global Risk Calculations to Solve the Problem:

Being cost-efficient while providing the highest manufacturing yield is not mutually exclusive. Both are within reach if the process is appropriately vetted while still in the planning stages. We will take a hypothetical look at the potential rejection/scrap rate of manufacturing a simple resistor. This resistor isn't particularly interesting and has rather unimpressive specifications:

Nominal value = 1500 Ω

Specification = ±0.2 Ω (±0.0133 %)

Expected in-tolerance probability (itp) = ~90 % (assumes roughly 10% will fail)

Expected process uncertainty = ±0.12 Ω

Measurement Capability, Cm (a.k.a TUR) = 2.5 (±0.04 Ω measurement uncertainty)

The manufacturer has a high-speed Digital Multimeter (DMM) previously purchased, and a decision was made to utilize this instrument instead of making a new purchase. The monthly yield is expected to be

about 100,000 pieces. Instead of purchasing new equipment, the manufacturer decided to reduce the acceptance criteria specifications from **±0.2 to ±0.18** utilizing a Guardband to keep the Probability of False Accept (PFA) to 1 % or less, as seen by the consumer. Without reducing the acceptance specifications to ±0.18, the consumer would likely see ~10 % field failures.

The cost to manufacture **and test** each one of these resistors is $13.50, while the cost to retest before scrapping is $35. Before going further, the reader may wonder why the cost of retesting the failed production item is significantly higher.

There are several reasons for the cost increase: the time taken to remove the failed item from the line, filling out the retest tag, transporting it to the higher-level lab, technician time/salary performing the additional measurement, the final disposition of the item (did it indeed pass/fail), and the return to production or scrap.

This is where Global Risk calculations can shine, shedding light on the production process and justifying the purchase of higher-quality processes and/or instrumentation. Taking what we know, stated above (specs, tolerances, and cost), the failure/scrap rate can be accurately predicted. If the manufacturer continues with the plan to build these resistors as-is, with a total process uncertainty of **±0.12 Ω**, the metrics will likely be:

New GB Limit =	90.17%	Probability the item passes
New GB Limit =	± 0.18	
Correct Accept 83.604%	Consumer Risk (False Accept) 1.000%	**84.60%**
Producer Risk (False Reject) 6.838%	Correct Reject 8.558%	Probability the item fails 15.396%
Probability the item conforms	90.44%	
Probability of non-conformance	9.56%	

Figure 32 PFA & PFR Matrix Courtesy of Greg Cenker & Indysoft.

So, how does this translate into lost profit? From the chart above, we see the following:

Resistors Produced =	100,000		Correctly Accepted =	83,604
(Prod)Cost per item =	$13.50		Falsely Accepted =	1,000
Cost to retest =	$35.00		Total Accepted =	84,604
	(1) Initial Build + Testing Production Cost (100,000 x 13.5) =			$1,350,000
Falsely Rejected =	6,838			
Correctly Rejected =	8,558			
Total Rejections =	15,396	(2) Cost due to False & True Rejections =		$207,846.48

The number of true rejections and false rejections is all-inclusive. Therefore, all rejections are scrutinized by retesting all of them at a secondary inspection station.

(3) Cost to retest (15,396 x 35) =	$538,876.81
False reject + retest cost (additional cost) =	$746,729.29
Total cost for (1) + (2) + (3) =	$2,096,723

Making matters worse, retesting found 8,857 (55.58%) that initially failed, passed secondary inspection costing ~$310,000 needlessly. We can partially offset this cost by selling newly passed items @ an unknown price.

A very large part of this equation is the reduced **C$_m$ of 2.5**. Although the actual build process of the resistor alone may contribute significantly to the rework cost (**itp ~90 %**), how could selecting better test equipment help identify true problems? As stated, the itp (In Tolerance Probability) was expected to be **~90 %,** but this number may be completely underreported due to poor instrumentation. The graph below illustrates our baseline assumptions.
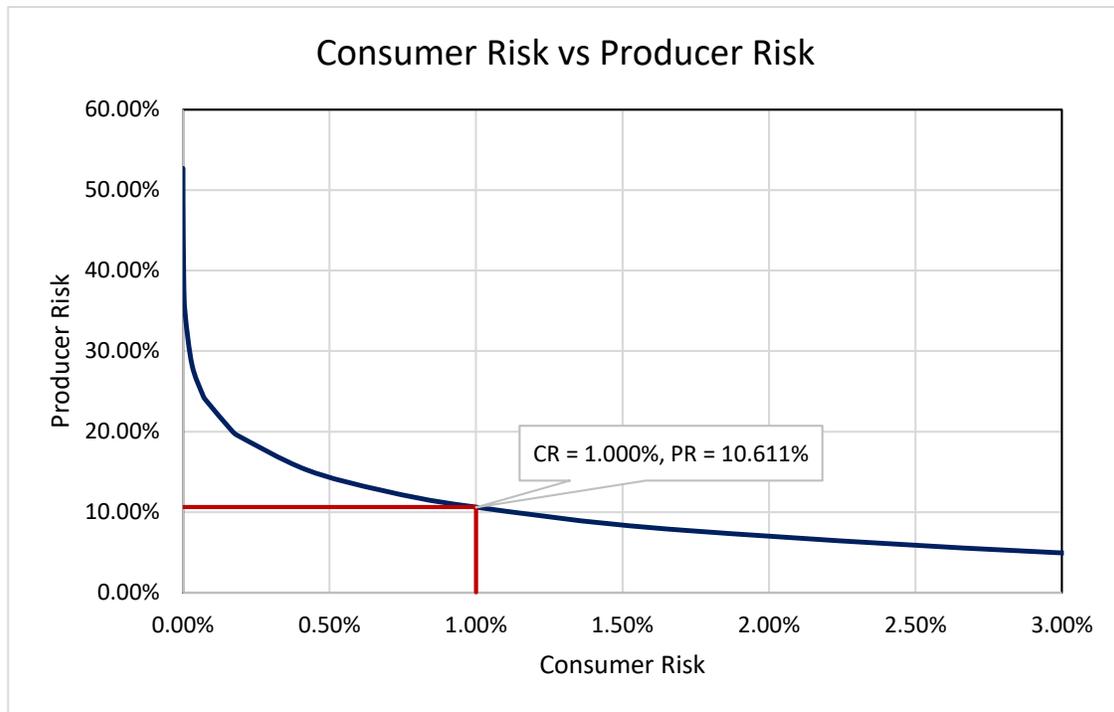
Figure 33: Consumer Risk vs Producer Risk Courtesy of Greg Cenker & Indysoft.

Available DMM choices	Low Buck	Acme Standard	Acme Bronze	Acme Silver	Acme Gold
Estimated Acquisition Cost	$4,405.00	$6,000.00	$13,481.00	$14,315.00	$19,429.00
Measurement Uncertainty (1-sigma)	0.06939	0.04000	0.01038	0.00711	0.00677
UUT Specification	0.2	0.2	0.2	0.2	0.2
C_m	1.44	2.5	9.63	14.06	14.78
Falsely Accepted	1,000	1,000	970	671	639
Falsely Rejected	23,970	9,611	65	31	28
Production Cost	$1,350,000.00	$1,350,000.00	$1,350,000.00	$1,350,000.00	$1,350,000.00
Cost due to false rejection	$323,598.52	$129,751.63	$879.36	$412.60	$373.69
Cost to retest	$838,959.14	$336,393.12	$2,279.82	$1,069.71	$968.84
Production, False Rej. & Retesting =>	$2,512,557.66	$1,816,144.75	$1,353,159.18	$1,351,482.31	$1,351,342.53
Increased cost as % of budgeted	86.12%	34.53%	0.23%	0.11%	0.10%
Likely Yield, 99% confidence	76.03%	90.39%	99.94%	99.97%	99.97%
Likely Product Rejection Rate	23.97%	9.61%	0.07%	0.03%	0.03%

Figure 34: Example Showing the High Cost of False Rejection Courtesy of Greg Cenker & Indysoft.
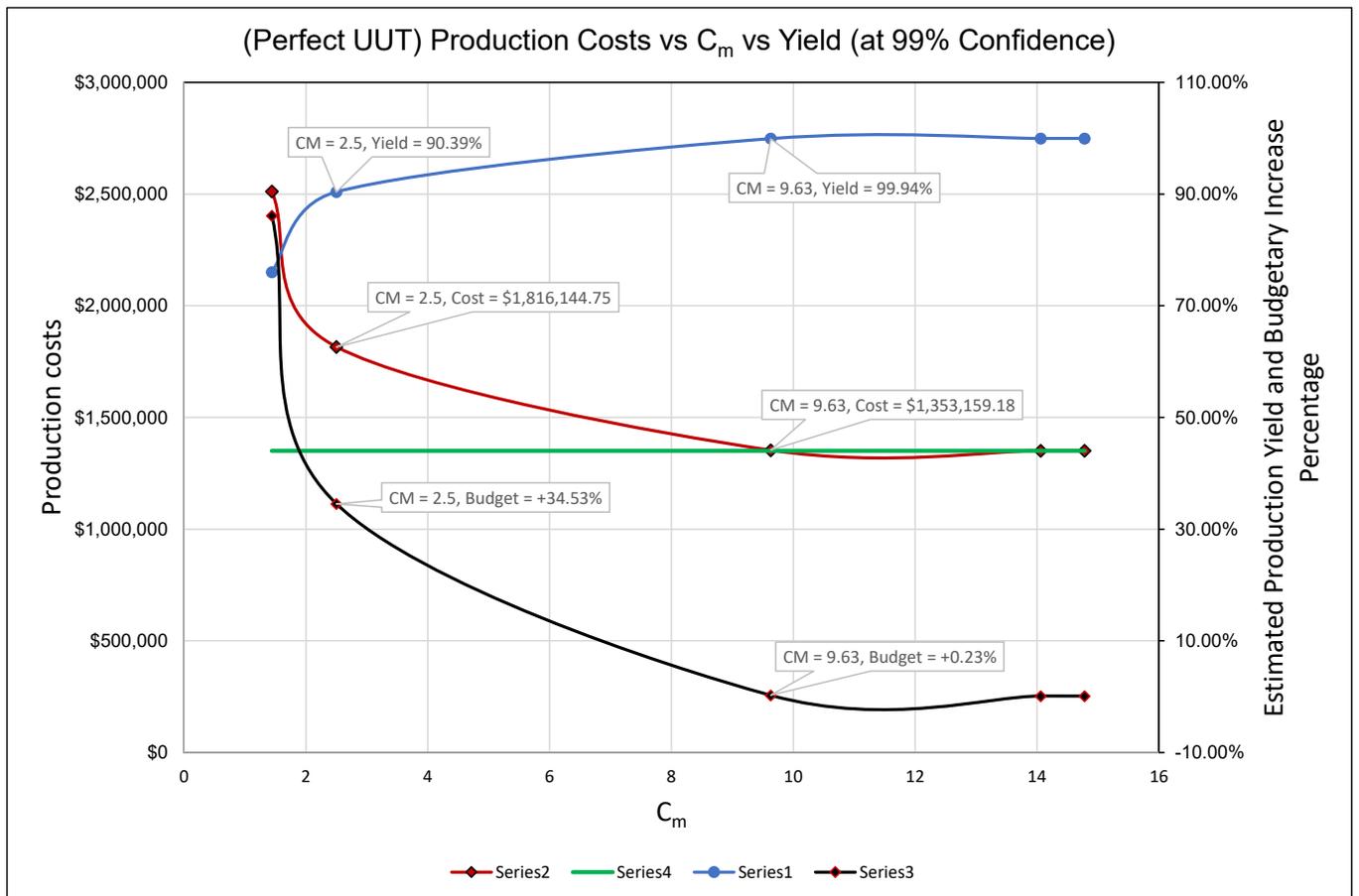
Figure 35: Production Cost vs C_m vs Yield at 99 % Confidence Courtesy of Greg Cenker & Indysoft.

The higher the C_m **(9.63)**, the higher the expected yield **(99.91 %)**, with minimum capital going over the base budget **(+0.23 %)**. Going the other way, the lower the C_m **(2.5)**, the lower the expected yield **(90.39 %)** and the increase over the base budget **(34.53 %)**.

There is more going on than simply changing out DMMs. Perhaps there is a throughput (speed) issue or concerns about the overall maintenance of a higher echelon reference DMM.

This demonstrates that by taking the uncertainty of the reference equipment into account before the decision is made to put some test system into operation, virtually all new sources of error will likely be due to the UUT itself because the process would still need to be established. Taking the uncertainty of the reference system into account will likely save hundreds of thousands of dollars once the decision to produce is greenlighted. This is because as we use Decision Rules to shrink the uncertainty of the process measurement system by buying the right equipment, we automatically expand our view of the other sources of production cost variability, which are still reducing our profits.

These calculations are based on the manufacturer's specifications and do not consider EOPR.

Miscalculation:

The company calculated a Measurement Capability Index (Cm) of 1.44:1, indicating that their measurement process might not reliably distinguish between conforming and non-conforming products.

However, they disregarded this concern and assumed a narrower acceptance zone of ± 0.12 ohms instead of the specified ± 0.2 ohms. This significantly reduced the probability of products falling within the acceptable range.

Consequences:

High rejection rate: During production, around 30% of resistors failed the global tolerance test of ± 0.12 ohms.

False rejections: Upon further investigation, the metrology lab confirmed that less than 0.2% of the rejected products were outside the specified tolerance. This signifies many unnecessary rejections due to an overly stringent internal acceptance zone.

Root Cause:

The primary cause of this issue was prioritizing cost savings over ensuring accurate measurement capabilities. Choosing an inadequate measuring instrument and implementing an unrealistic acceptance zone led to unreliable quality control and excessive product rejections.

Lessons Learned:

• Prioritize measurement accuracy: Selecting appropriate measuring equipment based on the required precision is crucial for reliable quality control.

• Understand measurement uncertainties: Calculating and interpreting the Measurement Capability Index helps assess the process capability and identify potential issues.

• Set realistic acceptance criteria: Acceptance zones should be established based on actual measurement capabilities and industry standards, not solely on cost-cutting efforts.

- Invest in proper calibration: Regularly calibrating measuring instruments ensures accuracy and reliability.

Note: See Production Yield Example on Calculating Cost Associated with PFA and PFR in the Appendix

Additional Information on Measurement Uncertainty

The **JCGM 200 (VIM) in section 2.26** defines measurement uncertainty as a non-negative parameter characterizing the dispersion of the quantity values attributed to a measurand based on the information used. [24]

Measurement uncertainty is the value assigned to "doubt" about the validity of an assigned calibration value.

Documented measurement uncertainties are required on a calibration certificate to support metrological traceability. Uncertainty is more than any accuracy statement. Accuracy usually has one type A evaluation (typically repeatability) and one type B (typically bias). Contributors to the measurement process are included in the evaluation of Measurement uncertainty. Of these contributors, uncertainty is often divided into Type A and Type B evaluations.

Type A is derived from statistical data or uncertainty evaluation by the statistical analysis of a series of observations. Type B is an evaluation of uncertainty by means other than the statistical analysis of a series of observations. Examples of both types are below.

Type A Uncertainty Contributions

The GUM states that all data analyzed statistically is treated as a Type A contribution with a normal statistical distribution. Typical examples are:

- Repeatability (required by the GUM and Accreditation bodies)
- Reproducibility
- Stability / Drift
- Others (These would include ASTM E74 Lower Limit Factor (LLF), non-linearity, hysteresis, or SEB for commercial calibrations)

Note: Stability can be treated as Type B if values are taken over a range using previous measurement data. Stability data may be treated as Type A if an evaluation is made using statistical methods over several calibration data sets (i.e., Control Charts).

Type B Uncertainty Contributions

Per section 4.3 of the JCGM 100 (GUM)[25], Type B evaluation of standard uncertainty may include:

- Previous measurement data
- Experience with or general knowledge of the behavior and properties of relevant materials and instruments.
- Manufacturer's specifications.
- Data provided in calibration and other certificates.
- Uncertainties assigned to reference data taken from handbooks.
- Bias (systemic error) if not corrected*

Additional Type B considerations are provided below.

- •   Resolution of the reference standard.
- •   Resolution of the best existing force-measuring instrument or the force-measuring instrument used for repeatability studies.
- •   Reference standard uncertainty.
- •   Reference standard stability.
- •   Environmental factors.
- •   Other error sources.

*Note on bias: The GUM requires that corrections be applied for all recognized and significant systematic effects and potential errors. Where a correction is applied based on a bias, an estimate of the associated Uncertainty must be included in the uncertainty analysis. If corrections are not applied, bias must be added to the expanded uncertainty (U + bias).

Note: A full Measurement Uncertainty Budget must be completed for any decision rule. The budget is often represented by the nomenclature CMC (Calibration and Measurement Capability). Failure to include all significant sources of measurement uncertainty can result in an incorrect conformity decision.

Additional Guidance on Measurement Uncertainty Recommendations.

In our recommended reading, we referenced **Introduction to Statistics in Metrology, 1st Edition**. This is a fantastic read for those wanting help creating and understanding measurement uncertainty budgets.

Morehouse has created many documents for help with force uncertainty budgets that can be found [here](#).

A great book to help with common measurement uncertainty problems and solutions is *Practical Numerical Methods for Chemical Engineers Using Excel with VBA, 5th Edition*.

JCGM 106:2012 Evaluation of measurement data – The role of measurement uncertainty in conformity assessment.

How to Specify Requirements on Purchase Orders

The first thing the customer of Measurement Services should do is evaluate the supplier's capability. This may be conducted by reviewing the supplier's ISO/IEC 17025 (or equivalent, e.g., ISO/IEC 17034) Scope of Accreditation (SoA).

The Checklist:

- ISO/IEC 17025 accredited (ISO/IEC 17034 if purchasing Reference Materials)?
- Supplier evaluation (ISO/IEC 17025 Clause 6.6)
- Metrological Traceability (ISO/IEC 17025 Clause 6.5)
- Uncertainties sufficient for the intended use (ISO/IEC 17025 Clause 7.6)?
- Measurement Uncertainty is less than the requirements (specifications) per ILAC P14:09/2020.
- If a conformity decision is required, can they implement appropriate decision rule suitable to your risk appetite (ILAC G8:09/2019)?
- Contract Review (ISO/IEC 17025 Clause 7.1).
- Communicating requirements to the calibration supplier:
    - ✓ ISO/IEC 17025 (or equivalent) accredited calibration is required.
    - ✓ Actual Measurement uncertainty per data point, range specified per ILAC P14 requirements.
    - ✓ Conformity decision with the decision rule specified (or decision rule utilized by the supplier is appropriate for use). - See example language in this section.
- Review of received product and services ((ISO/IEC 17025 Clause 6.6.2)
    - ✓ Utilize tools provided in this document to verify conformance requirements to ensure the risk criteria are satisfied.

Many of us have observed various purchase orders with very vague instructions. One of our favorites is the phrase, "Please Calibrate."

There's also "Calibrate to Manufacture's Specifications" or a vague request to ensure a 4:1 TAR or 4:1 TUR has been met and to only report measurement uncertainty if the condition cannot be met.

Many of these give very little guidance for the laboratory performing the calibration to make a conformity decision of "pass "or "fail" without further instruction.

Many requests do not specifically deal with the acceptable level of risk required to make the binary conformity decision of pass or fail.

The best conformity guidance comes directly from the equipment's end-user and clearly states when to "Pass" or "Fail" the calibration.

When someone wants to limit their measurement risk, they can specify acceptance criteria. These criteria can use either a simpler acceptance method or a guardband.

An example of a rule based on Simple Acceptance with a limit on expanded uncertainty would assume the end-user has calculated the appropriate maximum risk.

The language for Simple Acceptance might look something like this:

Please calibrate "As Found" Manufacturer 10,000 N Load cell S/N XXXX with indicator Manufacturer Readout XXXX to 10,000 N in Compression only and issue a "Pass" when the measured value is within ± 10 N of the force applied and the expanded uncertainty U $_{95\%}$ ≤ 2 N, otherwise "Fail" and adjust to within ± 10N and issue an "As Left" report after adjustment.

Several examples exist of specifying a guardband to limit risk. For this example, we will assume that the user wants their PFA to be less than 2 % and wants a binary conformity assessment.

Please calibrate "As Found" Manufacturer 10,000 N Load cell S/N XXXX with indicator Manufacturer Readout XXXX to 10,000 N in Compression only and issue a "Pass" when the PFA using Specific Risk is ≤ 2 %; otherwise, Fail.

The above example can be rewritten with a multi-state decision rule.

Please calibrate "As Found" Manufacturer 10,000 N Load cell S/N XXXX with indicator Manufacturer Readout XXXX to 10,000 N in Compression only and issue a "Pass" when the PFA using Specific Risk is ≤ 2 %, "Fail" when PFA > 50 %, otherwise issue a "Possible Pass."

Example of Simple Acceptance with TUR (C_m)

PASS when the measured value is between the Tolerance Limits and TUR (C_m) is greater than 4:1; otherwise, Fail.

Decision Rule Selection Examples for Suppliers of Measurement Services

A supplier of Measurement Services may provide different options for a customer to select. The following is provided as an example:

For the LABORATORY (quotation, reporting, and Web Site):

ISO/IEC 17025:2017, Clause 7.8.6 requires that when statements of conformance (PASS/FAIL, GO/NO GO) to a specification or a standard are made, the LABORATORY is required to take the measurement uncertainty into account when making PASS/FAIL decisions on a calibration. This may mean that a measurement point on a calibration that may PASS with OPTION 1 may fail with OPTIONS 2 and 3 depending on the customer requirements (specifications).

If a conformance (PASS/FAIL) decision on a calibration is required, the customer shall provide the associated specifications for the measurement (The customer may specify the manufacturer's specifications).

By default, LABORATORY shall utilize OPTION (3 or 4) in reporting measurement results on the ISO/IEC 17025 accredited calibration and test reports.

OPTION 1: PASS/FAIL compliance decision against the specification without taking the uncertainty into account (traditional approach-**SIMPLE ACCEPTANCE**) with other criteria such as acceptable TUR or Capability Index.

OPTION 2: PASS/FAIL compliance decision taking the uncertainty into account (conservative, tighter guardband approach, deducting the measurement uncertainty from the upper and lower specification-**ILAC G8:2009 Rule**).

OPTION 3: PASS/FAIL compliance decision taking the measurement uncertainty into account using the ANSI/NCSL Z540.3 Handbook Method 6 with a Probability of False Accept (PFA) of less than 2%. (A more aggressive approach with a defined risk)

OPTION 4: Measurement Result and associated Measurement Uncertainty (Customer evaluates the suitability of Measurement data or when no specification is provided).

Note: No option presented should be interpreted as inherently superior. The suitability of any decision rule depends on customer needs, applicable regulatory or contractual requirements, and the level of risk deemed acceptable.

Language for the certificate:

Only the measurement result and its associated uncertainty are stated in the report (OPTION 4).

A statement of Conformance is based on the customer option chosen. By default, LABORATORY does not make any claims on the conformance as it cannot ascertain every individual customer's requirement unless expressly specified in the customer requisition. When a specification (requirement) is provided by the customer, **OPTION 3** is used by default to make a statement of conformance unless otherwise stated. Please refer to the LABORATORY website (http://Laboratoryxxxxxx.com/) for further explanation on statements of compliance to **OPTIONS 1 to 4**.

Summary of Key Points

ISO/IEC 17025 does not mandate probability-based decision rules.

Simple acceptance is permitted when the decision rule is defined and agreed upon with the customer.

Guardbands, probability calculations, and TUR are tools, not requirements.

Decision-rule risk applies to individual conformity statements.

Global risk tools address population-level or program-level risk considerations.

Measurement Decision Risk is a business decision that involves likelihood and consequences. Failure to make the right decision may lead to outcomes that do not align with the organization's risk tolerance or the intended use of the measurement result.

Conclusion

This document serves as a comprehensive guide to decision rules and measurement risk, covering foundational requirements and calculations for implementing decision rules in the context of measurement uncertainty. It addresses the three critical pillars of measurement – uncertainty, metrological traceability, and decision rules – ensuring confidence in results. It explores **Specific Risk**, **Global Risk**, and guarded rejection and emphasizes adherence to standards for effective decision-making. By enabling informed decisions, this document helps develop safer products and services, reduces risks for consumers and suppliers, and elevates the quality of measuring equipment and services.

Current Decision Rule materials seem tailored almost exclusively to those with advanced statistical backgrounds. Through our collaborative effort, we have tried to make these topics accessible to a much broader slice of our community. We hope this leads to more robust measurement decision risk programs and yields savings for organizations in reputation and tangible costs.

Recommended Reading

We have reviewed numerous published documents on decision rules. While this list highlights valuable resources, it's important to acknowledge that there are countless other relevant documents we may have missed.

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*
- **https://www.eurolab.org/pubs-cookbooks** **"Cook Book" – Doc No. 8**
- 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*
- ASQ 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.
- Introduction to Statistics in Metrology 1st ed.
- WADA Technical Document – TD2017DK

Papers:

- Evaluation of Guardbanding Methods for Calibration and Product Acceptance – Colin J. Delker
- Whose Risk is it Anyway? Considerations for Risk-based Decision Rules - Delker
- A STUDY OF AND RECOMMENDATIONS 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*
- The Force of Decision Rules: Applying Specific and **Global Risk** to Star Wars – H. Zumbrun & G. Cenker
- Unraveling the Tom Brady Deflate Gate – G. Cenker, & H. Zumbrun
- The Definition of a Fool is a Drowning Man Who Tries to Keep It a Secret – G. Cenker, & H, Zumbrun
- Calibration in Regulated Industries: Federal Agency use of ANSI Z540.3 and ISO 17025 – P. Reese
- Ensuring Data Integrity – G. Cenker

Appendix A: Examples

UKAS LAB Shared Risk Example

UKAS LAB 48 has several great examples of decision rules, and we highly recommend that anyone wanting more examples than are covered in this document refer to this excellent document. The example we present here is a common one in the calibration industry that should never happen. That is an example of simple acceptance where only the measured value is said to "pass" when inside of the tolerance limits.

The problem with allowing decision rules that do not consider measurement uncertainty.

Conformity statements under ISO/IEC 17025:2017 require a Decision Rule (3.7) that takes account of measurement uncertainty. Some might argue that it is possible to 'take account' by ignoring it if that is what the customer requests; however, this seems to require a rather contradictory belief that you can be 'doing something' by 'not doing something' (is it possible to 'obey a red stop light' by 'not obeying a red stop light'?) [26]

Despite the grammatical and logical inconsistency in this approach, others also argue that it is allowable because 'the customer accepts the risk associated with ignoring uncertainty.' This too is a flawed argument, as will be shown by a simple example…

Suppose that for some reason, Simple Acceptance with no account of measurement uncertainty was defined to be an acceptable Decision Rule i.e. PASS when the measured value is within the stated tolerance interval and uncertainty plays no part in the decision process…

Also, suppose that, for a particular measurement there is a tolerance of ±1 and the measured value equals 0.5.

As the value is within the tolerance interval the result is therefore declared to be a PASS regardless of the measurement uncertainty (**Figure 34**).

In such a scenario, further evaluation is required to assess the conformity acceptance by the end-user. Simple acceptance may be specified with *additional accompanying TUR or C_m requirements*.
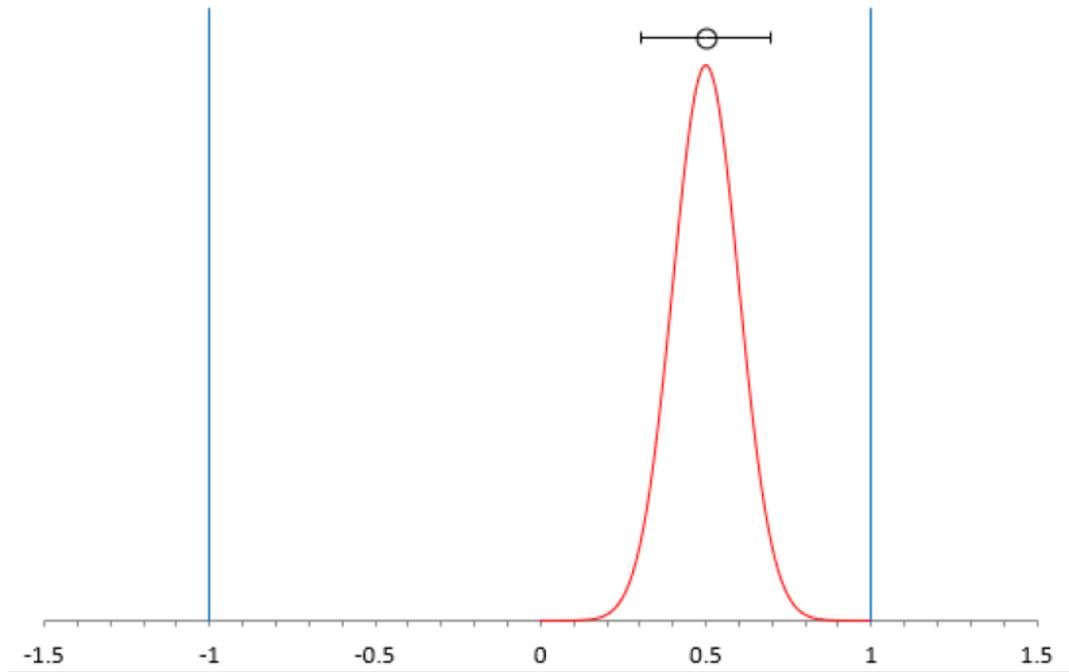
$u = 0.1, p_c = 100\%$: PASS according to Simple Acceptance rule with no account for u

Figure 36: One of Several Great Examples in UKAS LAB 48.

In fact, all of the following measurement scenarios will result in a PASS according to this rule... [27]

In this example from UKAS, it's emphasized that failing to consider measurement uncertainty means any measured value might appear to fall within the tolerance limits and be deemed conforming. However, ignoring measurement uncertainty increases the likelihood that the measurement is non-conforming. This oversight can lead to product failures; if the product is consumer-related, it could jeopardize public safety. For critical applications like missiles, this might result in failing to hit the intended target, among other consequences. Thus, disregarding measurement uncertainty can have severe implications, potentially leading to loss of life.

How to Implement Decision Rules:

Specific Risk Examples

Specific Risk Calculations for two-sided tolerances

We are calculating our Conformance probability for 97.50 % Confidence for symmetrical tolerances. We calculate the Guardband Multiplier using the Excel formula **NORM.S.INV (0.975)/2.**

We then use this value of 0.980 as our GB Multiplier as follows.

For the Guardband upper limit, we have

*1 – (GB Multiplier * **Coverage Factor * Standard Measurement Uncertainty**)*

$$1 – (0.980 * (2 * 0.125)) = 0.7550$$

For the Guardband lower limit, we have -1 + (GB Multiplier * Expanded Measurement Uncertainty)

$$-1 + (0.980 * (2 * 0.125)) = -0.7550$$

The formula can be simplified to Acceptance Limit = Tolerance Limit ± Guardband multiplier * Expanded Measurement Uncertainty.

Specific Risk Calculations for one-sided tolerances

We are calculating our Conformance probability for 97.50 % Confidence using a single-sided tolerance. We calculate the Guardband Multiplier using the Excel formula of **NORM.S.INV(0.975)/2.**

Our Standard Measurement Uncertainty is 0.125 units.

We then use this value of 0.980 as our GB Multiplier as follows.

If the single-sided tolerance is an upper tolerance:

For the Guardband upper limit, we have 1 – (GB Multiplier * Coverage Factor * Standard Measurement Uncertainty)

1 – (0.980 * 0.250) = 0.755

If the single-sided tolerance is a lower tolerance:

For the Guardband lower limit, we have -1 + (GB Multiplier * Coverage Factor *Standard Measurement Uncertainty)

-1 + (0.980 * 0.250) = -0.755

The formula can be simplified to Acceptance Limit = Tolerance Limit ± Guardband multiplier * Expanded Measurement Uncertainty.

Morehouse Load Cell Example - Specific Risk

What would the risk document be without a force example for **Specific Risk**?

A customer sent their 10,000 N load cell in for calibration. The purchase order indicates calibration to the manufacturer's specification.

Since the purchase order is incomplete regarding pass/fail criteria and how measurement uncertainty is taken into account, the customer is contacted and presented with several options based on their risk requirements.

The customer decides to rewrite the order. The new purchase order reads calibrate using a tolerance of 0.1 % of full scale (± 10 N), taking measurement uncertainty ($U_{95.45\%}$) into account using specific risk calculations. Fail if the PFA for either side > 2.5 %; otherwise, pass.

Step 1 Calibrate the equipment that we will need to determine the Standard Uncertainty (k =1) of the Measurement Process for this calibration.

For simplistic sake, we will look at the 10,000 N point.

10,000 N force was applied three times, and the instrument read 10,000 10,002 10,001.

Taking the standard deviation of these numbers =stdev(10,000 10,002 10,001) we get 1

The resolution of the equipment is 1 N.

The CMC of the reference standard is 0.2 N.

$$\sqrt{\left(\frac{\textbf{CMC}}{\textbf{k}_{\textbf{CMC}}}\right)^2 + \left(\frac{\textbf{Resolution}_{\textbf{UUT}}}{\sqrt{\textbf{12}}}\right)^2 + \left(\frac{\textbf{Repeatability}_{\textbf{UUT}}}{\textbf{1}}\right)^2 + \cdots (\textbf{u}_{Other})^2}$$

Thus, the formula for Standard Uncertainty of the Measurement Process becomes.

$$\sqrt{\left(\frac{0.2}{2}\right)^2 + \left(\frac{1}{\sqrt{12}}\right)^2 + \left(\frac{1}{1}\right)^2} = 1.04563 \text{ N}$$

We now have everything we need to calculate Guardbanded Acceptance Limits and PFA.

A 10,000 N load cell has a tolerance of ± 0.1 % of full scale.

Measured Value = 10,000 N.

Upper Tolerance = 10,010 N.

Lower Tolerance = 9,990 N.

Resolution$_{UUT}$ = 1 N.

Repeatability$_{UUT}$ = 1 N

Measured Value = 10,001 N.

Standard Uncertainty = 1.04563 N.

Step 2 Calculate Acceptance Limits

We are calculating our Conformance probability for 97.50 % Confidence for symmetrical tolerances. We calculate the Guardband Multiplier by using the formula in Excel of **NORM.S.INV (0.975)/2.**

We then use this number of 0.98 as our GB Multiplier as follows.

*For the Guardband upper limit, we have 10010 – (GB Multiplier * Coverage Factor * Standard Measurement Uncertainty)*

*10010 – (0.980 * (2 *1.04563)) = 10007.9506*

*For the Guardband lower limit, we have 9990 + (GB Multiplier * Coverage Factor *Standard Measurement Uncertainty)*

*9990 + (0.980 * (2 * 1.04563)) = 9992.0494*
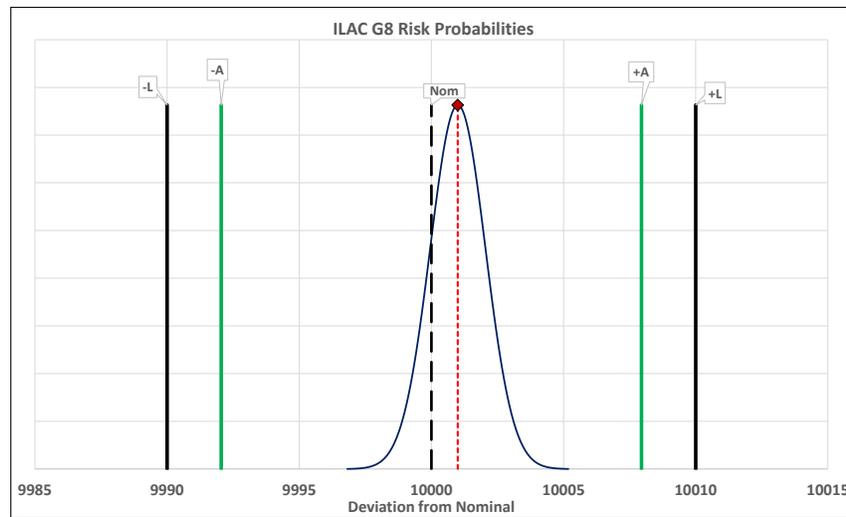
Figure 37: Graph showing the GB Acceptance Limits to limit PFA to 2.5 %

Thus, our acceptance limit is between *9992.0494 and 10007.9506, as any measured value between these two values will have less than 2.5 % PFA.*

Step 3 Calculate PFA

Risk Upper = NORM.DIST(10001, 10010, 1.04563, TRUE) = 0 %

Risk Lower = 1- NORM.DIST(10001, 9990, 1.04563, TRUE)) = 0 %

Total Risk = 0 %

Additional Proof

One can use the Upper or Lower GB Acceptance Limit to verify the GB acceptance limits.

Risk Upper = NORM.DIST(10007.950603, 10010, 1.04563, TRUE) = 2.5 %

Scale Example Where the Resolution is the Same as the Accuracy - Specific Risk

In this simple example, we have a common kitchen scale with an accuracy of ±1g with a resolution of 1g. Without giving this much thought, the initial assumption would be that the scale can accurately measure typical cooking/baking ingredients to ±1g.

The model shown is a MyWeigh KD-7000.

We are baking a cake, and since baking is chemistry, the recipe calls for 3,100 grams of flour ±5g (~6.8 pounds). During the weighing process, we were able to dispense exactly 3,103 grams of flour per our recipe accurately, and we were confident that it was accurate to ±1g.

Weighing Modes

Mode	Capacity	Resolution
Kilograms	7.000 kg	0.001 kg
Grams	7000 g	1 g
Pounds : Ounces	15 lbs : 7 oz	0.1 oz
Pounds	15.450 lbs	0.002 lb
Ounces	246.9 oz	0.05 oz

Let's do a quick risk assessment to ensure an in-tolerance probability of 98 % (2 % risk). Since we know nothing about the distribution concerning the scale, we default to a conservative estimate of 1g divided by SQRT(3) to yield ~91.6 % confidence for a 1-sigma value of 0.5774g and insert that value into our risk calculator. This is all the information available.

Risk Calculator	
Upper Tolerance T_U	3105
Lower Tolerance T_L	3095
Nominal Value (NV)	3100
Measured Value xm	3103.0000
Measurement Unc um	0.5774
Maximum Allowable Risk (PFA)	2.0000%
Guarded Rejection Certainty	95.00%
Use guarded rejection as relaxed acceptance limits?	☐
Tolerance T±	5.00

Probability of Conformance (p_c)	99.973%
Probability of NonConformance (1 - p_c)	0.027%
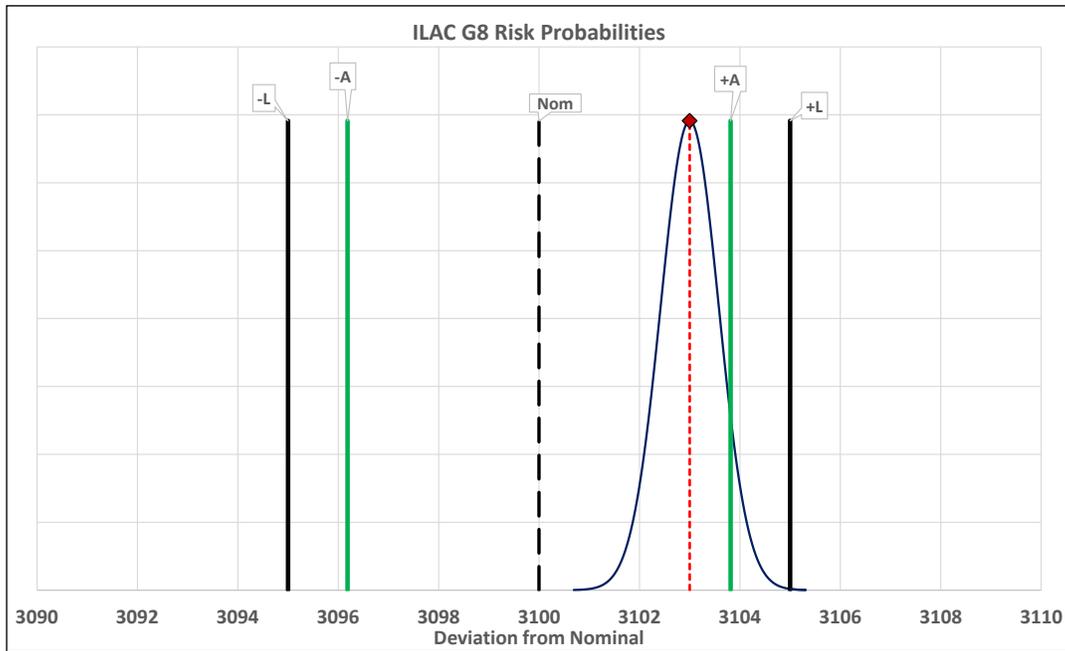
Figure 36 Graph showing the GB Acceptance Limits to limit PFA to 2.0 %

It appears our in-tolerance probability is 99.973 % (we wanted at least 98 %), and we are within our guarded acceptance limits with a probability of non-conformance at 0.027 %.

Are we confident about that measurement, and is our uncertainty information complete? Let's take a deeper look at our process.

While true, the scale is accurate to ±1 g; the accuracy is equal to the resolution of the instrument. Additionally, there is no uncertainty concerning the actual calibration of the scale or any repeatability or reproducibility studies, and the resolution isn't properly considered.

While we don't have access to the calibration uncertainty, an assumption will be made that the calibration uncertainty is ±0.25g at *k* = 2. Using a reliable mass to gauge repeatability and reproducibility (in this case, it's a granite mortar and pestle), we will add those two components, along with the scale's resolution.

Outlier Detection Confidence =	95.00%	Repeatability and Reproducibility Worksheet				
Sample	Tech 1	Tech 2	Tech 3	Tech 4	Tech 5	Tech 6
1	3,187.000	3,187.000				
2	3,187.000	3,187.000				
3	3,187.000	3,188.000				
4	3,187.000	3,187.000				
5	*3,186.000*	3,188.000				
6	3,187.000	3,187.000				
7	3,187.000	3,188.000				
8	3,187.000	3,187.000				
9	3,187.000	*3,186.000*				
10	*3,188.000*	3,187.000				
Std. Dev. =	471.405E-3	632.456E-3				
Average =	3,187.000	*3,187.200*				
Variance =	222.222E-3	400.000E-3				
Upper Tol Limit =	3101.00000	3101	#N/A	#N/A	#N/A	#N/A
IQR Upper Tol =	*3187*	*3188.965*				
IQR Lower Tol =	*3187*	*3186.035*				
Lower Tol Limit =	3099.00000	3099.00000	#N/A	#N/A	#N/A	#N/A
Grouping =	Tech 1	Tech 2				
Repeatability =	557.773E-3	F_{calc}	0.642857143	Between Groups MS		200.00E-3
Reproducibility =	141.421E-3	F_{crit}	4.4139	Within Groups MS		311.11E-3
$df_{Numerator}$	1	P-Value	*If $F_{calc} > F_{crit}$, there is significance of Reproducibility data*			
$df_{Denominator}$	18	43.31%	*Population OK, p-Value >5%*			

Uncertainty Budget								
	Error Sources (Description)	Error Limit (or Std Unc)	Error Limit Distribution (or Std Uncertainty)	Uncertainty Type (A/B)	Estimate DOF?	Degrees of Freedom	Standard Uncertainty	Uncertainty Sensitivity
1	*Repeatability (Linked to Calc.)*	0.557 773	Standard Unc.	A	*N/A*	1	0.557 773 351	33.00%
2	*Reproducibility (Linked to*	0.141 421	Standard Unc.	A	*N/A*	18	0.141 421 356	8.37%
3	Scale Accuracy	1.000 000	Rectangular √3	B			0.577 350 269	34.16%
4	Calibration Uncertainty	0.250 000	Normal (95.45% k=2)	B			0.125	7.40%
5	Scale Resolution	1.000 000	Resolution √12	B			0.288 675 135	17.08%
						Combined Uncertainty =	0.873 729 236	1.690 220 111

Combined Uncertainty Results	
Combined Uncertainty =	0.873 729 236
Uncertainty Confidence =	95.00%
Use Effective Degrees of Freedom?	☑
Effective Degrees of freedom =	6
Coverage Factor (k) =	2.447
Expanded Uncertainty =	2.137 938 422

Figure 37 Uncertainty budget for the scale

Now, with a reasonable uncertainty budget in play, we discover our expanded measurement uncertainty is ~±2.14 grams at *k* = 2 and input the 1-sigma value into our risk calculator (1.07g).

Risk Calculator	
Upper Tolerance T_U	3105
Lower Tolerance T_L	3095
Nominal Value (NV)	3100
Measured Value xm	3103.0000
Measurement Unc um	1.0700
Maximum Allowable Risk (PFA)	2.0000%
Guarded Rejection Certainty	95.00%
Use guarded rejection as relaxed acceptance limits?	☐
Tolerance T±	5.00

Probability of Conformance (p_c)	96.920%
Probability of NonConformance ($1 - p_c$)	3.080%

With most uncertainties now considered in our budget, our probability of conformance is ~96.9%, and our probability of non-conformance is now ~3.1%.

Graphically, we can see the effect it has on our risk tolerance.
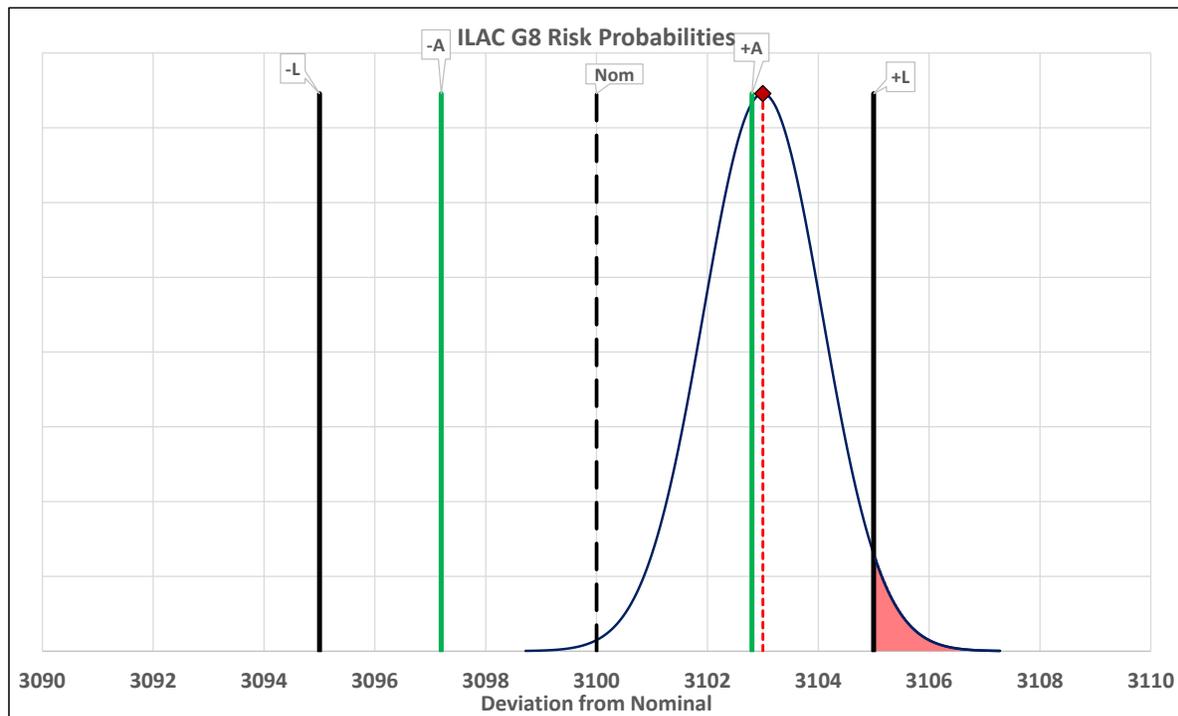
Figure 38 Graph showing the GB Acceptance Limits to limit PFA to 2.0 %

What was originally considered a "pass" is now considered a "failure" because the measured value is outside the acceptance limits, and the right tail of the distribution is outside the tolerance limits by ~3.1 % (we wanted no more than 2 %).

Note: In the case of our recipe, the risk is likely low if we are off by 3.1 %, though what if this were a mixture for a medication where too much would result in serious side effects? Though this is a simple example, it highlights what happens when measurement uncertainty is not calculated correctly.

Measurement Uncertainty Example (Omitting Resolution of the UUT)

In this example, we will take a measurement uncertainty budget of a load cell reference standard at the 10,000 lbf calibration point and compare the probability of conformance (Pass) by considering the contributors to measurement uncertainty and comparing that against ignoring contributors such as resolution.

Measurement Uncertainty Budget Worksheet									
Laboratory	Morehouse Example								
Parameter	Example Load Cel	Range	10000	Sub-Range					
Technician									
Date		Standards Used	Deadweight to Calibrate Load Cells Example						
Uncertainty Contributor	Magnitude	Type	Distribution	Divisor	df	Std. Uncert	Variance (Std. Uncert^2)	% Contribution	u^4/df
Repeatability Between Techs	0.06039087	A	Normal	1.000	27	60.39E-3	3.65E-3	3.40%	492.6E-9
Reproducibility Between Techs	0.043240245	A	Normal (68.26%, k=1)	1.000	2	43.24E-3	1.87E-3	1.74%	1.7E-6
Repeatability	14.0343E-3	A	Normal	1.000	3	14.03E-3	196.96E-6	0.18%	12.9E-9
ASTM E74 LLF	25.0000E-3	A	Normal	1.000	32	25.00E-3	625.00E-6	0.58%	12.2E-9
Resolution of UUT	25.0000E-3	B	Resolution	3.464	200	7.22E-3	52.08E-6	0.05%	13.6E-12
Environmental Conditions	150.0000E-3	B	Rectangular	1.732	200	86.60E-3	7.50E-3	6.99%	281.3E-9
Stability of Ref Standard	400.0000E-3	B	Rectangular	1.732	200	230.94E-3	53.33E-3	49.72%	14.2E-6
Miscellaneous Error	300.0000E-3	B	Rectangular	1.732	200	173.21E-3	30.00E-3	27.97%	4.5E-6
Morehouse CMC (Ref Lab)	200.0000E-3	B	Expanded (95.45% k=2)	2.000	200	100.00E-3	10.00E-3	9.32%	500.0E-9
			Combined Uncertainty (u_c)=			327.53E-3	107.28E-3	100.00%	21.8E-6
			Effective Degrees of Freedom			528			
			Coverage Factor (k), Confidence Interval =	95.45%		2.00			
			Expanded Uncertainty (U) k =			0.66	0.00657%		

Figure 38 An Example of a Load Cell Measurement Uncertainty Budget using the Welch-Satterthwaite equation.

Repeatability Between Techs	**0.06039087**
Reproducibility Between Techs	**0.043240245**
Repeatability	14.0343E-3
ASTM E74 LLF	25.0000E-3
Resolution of UUT	25.0000E-3
Environmental Conditions	150.0000E-3
Stability of Ref Standard	400.0000E-3
Miscellaneous Error	300.0000E-3
Morehouse CMC (Ref Lab)	200.0000E-3

In our example, we have these contributors to measurement uncertainty. When accounted for, the expanded measurement uncertainty is **0.66 N**.

Note: The resolution of the best existing device is used in this example. The contribution of resolution for this MU example of 0.025 N device accounts for about 0.09 % of the overall budget, and the MU contribution for repeatability of the best existing device accounts for about 0.18 % of the overall MU

budget. One would typically substitute the calibrated instrument's repeatability and resolution contribution. Since these contributors are such a small percentage, we are leaving them.

Morehouse has created documents that explain the measurement uncertainty calculation above, which can be found [here](#).

We wish to calibrate a 10,000 N device with a tolerance of ± 10 N.

The customer has stated Please calibrate "As Found" Manufacturer 10,000 N Load cell S/N XXXX with indicator Manufacturer Readout XXXX to 10,000 N in Compression only and issue a "Pass" when the PFA using Specific Risk is ≤ 5 %, Otherwise Fail.

For the sake of simplicity, we will look at the 10,000 N point.

10,000 N force was applied three times, and the instrument read 10,008 10,006 10,008.

Taking the standard deviation of these numbers =stdev(10,008 10,006 10,008) we get **Repeatability** $_{UUT}$= 1.154701 N

The resolution of the equipment is 2 N.

The CMC uncertainty of the reference standard is 0.66 N.

$$\sqrt{\left(\frac{\textbf{CMC}}{\textbf{k}_{\textbf{CMC}}}\right)^2 + \left(\frac{\textbf{Resolution}_{\textbf{UUT}}}{\sqrt{\textbf{12}}}\right)^2 + \left(\frac{\textbf{Repeatability}_{\textbf{UUT}}}{\textbf{1}}\right)^2 + \cdots (\textbf{u}_{Other})^2}$$

Thus, the formula for Standard Uncertainty of the Measurement Process becomes.

$$\sqrt{\left(\frac{0.66}{2}\right)^2 + \left(\frac{2}{\sqrt{12}}\right)^2 + \left(\frac{1.154701}{1}\right)^2} = 1.332504 \text{ N}$$

We now have everything we need to calculate Guardbanded Acceptance Limits and PFA.

A 10,000 N load cell has a tolerance of ± 0.1 % of full scale.

Measured Value = 10,008 N.

Upper Tolerance = 10,010 N.

Lower Tolerance = 9,990 N.

Measured Value = 10,008 N.

Resolution $_{UUT}$ = 2 N.

Repeatability $_{UUT}$= 1.154701 N

Standard Uncertainty = 1.332504 N
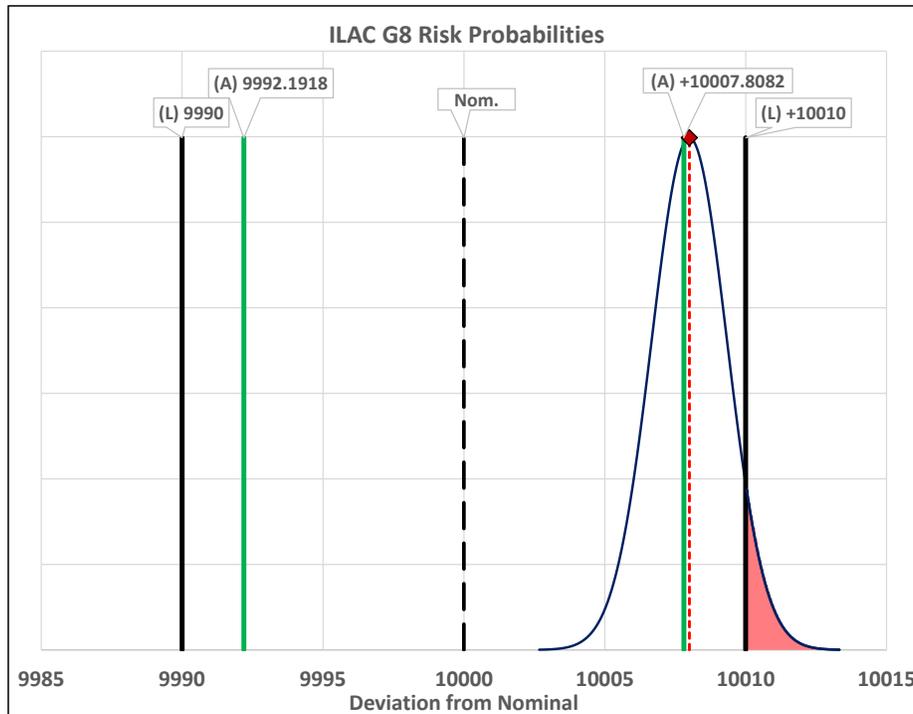
Figure 39 Load Cell Example Showing 6.669 % Probability of Nonconformance.

Risk Upper = NORM.DIST(10008, 10010,1.332504, TRUE) = 6.6686 %

Risk Lower = 1- NORM.DIST(10008, 9990,1.332504, TRUE)) = 0 %

Total Risk = **6.6686 %**

When the measurement uncertainty is properly accounted for, the device fails.

Now, let us look at what happens when we omit contributors, such as the resolution of the UUT.

$$\sqrt{\left(\frac{0.66}{2}\right)^2 + \left(\frac{1.154701}{1}\right)^2} = 1.20093 \text{ N}$$

Risk Upper = NORM.DIST(10008, 10010,1.20093, TRUE) = 4.7919 %

Risk Lower = 1- NORM.DIST(10008, 9990, 1.20093, TRUE)) = 0 %

Total Risk = **4.7919 %**

When a contributor, such as the resolution of the UUT, is not accounted for, the device will **pass.**

Mathcad JCGM Resistor Example for Calculating Global Risk

The formula for **Global Risk**, as seen from the producer and consumer, is a joint probability distribution function. It's the probability that the item produced is assumed to be in tolerance when, in fact, it is out of tolerance (OOT).

The formulas shown below were calculated using Mathcad Prime 9.0, taking the following arguments:

Upper Test Limit (T_U)	Lower Test Limit (T_L)	Upper Acceptance Limit (A_U) *Calculated with Excel*	Lower Acceptance Limit (A_L) *Calculated with Excel*
1500.20	1499.80	1500.166 816	1499.833 183

Nominal value (y_o) = 1500
1-sigma total measurement uncertainty (u_m) = 0.04

$C_m = ((T_U - T_L) / 4 \times u_m) = 2.5$

$y_o = 1500$ $\quad$ $T_U = 1500.20$ $\quad$ $T_L = 1499.80$ $\quad$ $A_U = 1500.166\ 816$ $\quad$ $A_L = 1499.833\ 183$

$$u_0 = \frac{T_U - T_L}{2}$$

$$Risk_{Consumer} := \int_{-\infty}^{\frac{T_L - y_o}{u_o}} \left(\mathrm{cnorm}\left(\frac{A_U - y_o - u_o \cdot z}{u_m}\right) - \mathrm{cnorm}\left(\frac{A_L - y_o - u_o \cdot z}{u_m}\right) \right) \cdot \frac{1}{\sqrt{2 \cdot \pi}} \cdot \exp\left(\frac{-z^2}{2}\right) dz \quad = 1.000\%$$

$$+ \int_{\frac{T_U - y_o}{u_o}}^{\infty} \left(\mathrm{cnorm}\left(\frac{A_U - y_o - u_o \cdot z}{u_m}\right) - \mathrm{cnorm}\left(\frac{A_L - y_o - u_o \cdot z}{u_m}\right) \right) \cdot \frac{1}{\sqrt{2 \cdot \pi}} \cdot \exp\left(\frac{-z^2}{2}\right) dz$$

$$Risk_{Producer} := \int_{\frac{T_L - y_o}{u_o}}^{\frac{T_U - y_o}{u_o}} \left(1 - \left(\mathrm{cnorm}\left(\frac{A_U - y_o - u_o \cdot z}{u_m}\right) - \mathrm{cnorm}\left(\frac{A_L - y_o - u_o \cdot z}{u_m}\right) \right) \right) \cdot \frac{1}{\sqrt{2 \cdot \pi}} \cdot \exp\left(\frac{-z^2}{2}\right) dz = 10.611\%$$

Where cnorm = the cumulative normal function, and z is the placeholder for the integration

Production Yield Example on Calculating Cost Associated with PFA and PFR (Do I have Measuring Equipment Capable of Limiting Costly Rework)

For the following example, we will assume the Unit Under Test (UUT) specification has no historical information regarding EOPR. The specification shall be taken at a face value of ±0.2Ω (essentially 1-sigma).

Measurement Capability Index, C_m, is defined as

$$C_m := \frac{T_{Upper} - T_{Lower}}{4 \cdot u_{meas}} = 2.5 \qquad Upper_{Limit} := 1500.2 \qquad Lower_{Limit} := 1499.8 \qquad u_{meas} := 0.04$$

The variable changing, in the examples shown, going forward, will be u_{Meas}. All other variables, apart from the calculated ±Acceptance Limits, remain constant.

Before proceeding, it should be noted there are significant mathematics going on in the background to calculate the risk values, Guardbands, and product yield values. The VBA code will be provided in the appendix to replicate these results. The functions are listed below, and the input parameters are explained.

Functions – <u>**NOTE ALL VALUES INPUT INTO THESE FUNCTIONS ARE ENTERED AS THE DEVIATION FROM AN ASSUMED NOMINAL OF ZERO**</u>! The exception is uCal. This value is a ± value determined by an uncertainty analysis.

Note: PFA, Probability of conformance, and FAR, are equivalent. PFR, Probability of non-conformance, and FRR are equivalent.

Probability of Conformance = PFA (uUUT, uCal, Llow, Lup, ALow, AUp)

> **uUUT** = The uncertainty of the Unit Under Test (UUT). This function is for symmetrical specifications only and the value can be represented in 2 distinct forms:

- (Upper Test Limit – Lower Test Limit) / 2
    - (1500.2 – 1499.8) / 2 = 0.2
- (Upper Test Limit – Lower Test Limit) / NORM.S.INV((1+itp)/2)
    - Where itp = In-Tolerance Probability (e.g. 90 %) = NORM.S.INV((1+0.9)/2)= 1.64485
    - (1500.2 – 1499.8)/1.64485 = 0.12159
        - *This applies <u>ONLY</u> if you have prior knowledge of the UUT EOPR*

> **uCal** = The 1-sigma uncertainty of the calibration process standards

- Example: Absolute DMM specification of ±0.08 at k=2 is reduced to 0.08/2 = 0.04

> **Llow** = Lower Test Limit of the UUT (e.g., -0.2)

> **Lup** = Upper Test Limit of the UUT (e.g., 0.2)

> **ALow** = Lower Acceptance Limit of the UUT (e.g., -0.2, it can be the same value as Llow)

> **AUp** = Upper Acceptance Limit of the UUT (e.g., 0.2, it can be the same value as Lup)

Probability of Non-Conformance = PFR (uUUT, uCal, Llow, Lup, ALow, AUp)

- Takes the same arguments as PFA.

Probability of Conformance Guardband Multiplier = PFAGBMult (Req, uUUT, uCal, Llow, Lup)

- Req = The level of risk desired (e.g., 1 % or 0.01)
- uUUT, uCal, Llow, Lup are the same values described in the previous functions.

Once the basic Probability of Conformance (Pc), Probability of non-Conformance (Pnc) are calculated, we will calculate the Guardband multiplier, apply the value, and *recalculate* the Pc/Pnc to validate the equipment selection parameters.

Let's revisit the previous example but this time, we will remove the UUT process uncertainty and substitute the basic accuracy specification of **±0.2 Ω**. The quantity manufactured (100,000), the cost per resistor ($13.50), the maximum risk to the consumer (1 %), and the initial **C_m** of **2.5 (±0.04 Ω** measurement uncertainty) remain the same. To test this hypothesis, we will substitute the previous itp (~90 %) by using binomial confidence bounds instead of the original analysis value.

Step 1 - Calculate the base Probability of Conformance.

Probability of Conformance = PFA (uUUT, uCal, Llow, Lup, ALow, AUp)

PFA = (0.2, 0.04, -0.2, 0.2, -0.2, 0.2) = 3.386%

Step 2 – Calculate the base Probability of Non-Conformance

Probability of Non-Conformance = PFR (uUUT, uCal, Llow, Lup, ALow, AUp)

PFR = (0.2, 0.04, -0.2, 0.2, -0.2, 0.2) = 4.335%

Step 3 – Since the Pc is >1%, we need to calculate the Probability of Conformance Guardband Multiplier.

Probability of Conformance Guardband Multiplier = PFAGBMult (**Req**, uUUT, uCal, Llow, Lup)

PFAGBMult = (**0.01**, 0.04, -0.2, 0.2) = 83.408%

Step 4 – Multiply the UUT accuracy specification by the PFAGBMult percentage. This provides the ±Acceptance limits.

Probability of Conformance = PFA (uUUT, uCal, Llow, Lup, ALow, AUp)

±A = 0.2 x 83.408% = ±0.166 816

Step 5 – Recalculate the Probability of Conformance, substituting the original estimation of ALow and AUp with the result from step 4.

Probability of Conformance = PFA (uUUT, uCal, Llow, Lup, **ALow, AUp**)

PFA = (0.2, 0.04, -0.2, 0.2, **-0.166816**, **0.166816**) = 1 %

Step 6 - Recalculate the Probability of Non-Conformance, substituting the original estimation of ALow and AUp with the result from step 4.

Probability of Non-Conformance = PFR (uUUT, uCal, Llow, Lup, ALow, AUp)

PFR = (0.2, 0.04, -0.2, 0.2, **-0.166816, 0.166816**) = 10.611 %

Step 7 – Calculate the probability the UUT will in tolerance.

Probability of pass = (1-PFR) + PFA = (0.89389) + 0.01 = 90.389 %

Step 8 – Calculate the probability the UUT will be out of tolerance.

Probability out of tolerance = 1- Probability of pass = 9.611 %

Quantity likely to be out of tolerance = 100,000 x 9.611% = 9,611

Now, we will estimate this decision's impact on actual production items using the base number of 100,000 pieces manufactured.

Step 9 – Estimate correctly accepted items.

100,000 x (1 – PFR) = 100,000 x (1- 10.611 %) = 89,389

Step 10 – Estimate falsely accepted items.

100,000 x PFA = 100,000 x 1 % = 1,000

Step 11 - Estimate falsely rejected items.

(100,000 – (Step 9 + Step 10)) x PFR = (100,000 – 90,389) x 10.611% = 1,020

Step 12 – Estimate correctly rejected items.

100,000 – (Step 9 +Step 10 + Step 11) = 100,000 – 91,409 = 8,591

Step 13 – Perform a sanity check on the items.

100,000 – (Step 9 +Step 10 + Step 11 + Step 12) = 100,000 – 100,000 = 0

Step 14 – Perform a sanity check on the probabilities.

Correctly Accept = 89.389 % (89,389)

Falsely Accept = 1 % (1,000)

Falsely Rejected = 1.02 % (1,020)

Correctly Reject = 8.59 % (8,591)

Total Probability of Non-Conformance (calculated with the function) = 10.611 %

Falsely Accepted + Falsely Rejected + Correctly Rejected = 1 % + 1.02 % + 8.59 % = Probability Non-Conformance.

= 89.398 % + (Falsely Accepted + Falsely Rejected + Correctly Rejected) = 100 %

Step 15 – Create binomial confidence bounds (OC curve) validating the approximate yield using Excel.

Confidence = 99 % (needed for 1 % **Global Risk** to the consumer)

Trials = 100,000

Successes = Correct Accept + False Accept = 89,389 + 1,000 = 90,389

Upper Binomial = 1 - (BETA.INV ((1 - Confidence) * 0.5, Trials - Successes, Successes + 1))

= 90.63 %

Lower Binomial = 1 - (BETA.INV (Confidence, Trials - Successes + 1, Successes))

= 90.17 %

Note: OC Curve is the operating characteristic (OC) that indicates the probability of acceptance of the production batch versus the percentage of defective units

Step 16 – Using the lower binomial result, create a conformity statement. "There is 99% confidence the yield is at least 90.17%."

Now we will substitute ONLY the 1-sigma, total measurement uncertainty results obtained by trying different DMMs in our model. It should be noted, that the actual uncertainty analysis of each DMM substituted is outside the scope of this document. A great suggestion for learning about measurement uncertainty can be found in the UKAS document M3003.

Appendix B Code - VBA Code (copy and paste into a VBA module in Excel).

Reliability –Additional Sample Size and Binomial Confidence Bounds

Additional Sample Size

```vba
Function RevisedSample(RelTarget As Double, ConfTarget As Double, Failures As Double) As Double

'Calculates new, required sample size to achieve required reliability with failures
'RelTarget = Target Reliability
'ConfTarget = Confidence target about required reliability
'Failures = Total number of recorded failures

With Application
Dim beta As Double
Dim InitSampleSize As Double
Dim initReliability As Double
Dim x As Double
Dim y As Double
InitSampleSize = .RoundUp(Log(1 - ConfTarget) / Log(RelTarget), 0) '
Calculates the initial sample size based on reliability constraints

beta = 1 - RelTarget
initReliability = .Beta_Inv(ConfTarget, 1, InitSampleSize)

x = .Beta_Inv(ConfTarget, Failures + 1, InitSampleSize - Failures)
y = InitSampleSize

If Failures = 0 Then
    y = InitSampleSize
  Else
    Do Until x <= beta
        y = y + 1
        x = .Beta_Inv(ConfTarget, Failures + 1, y - Failures)
    Loop
End If
RevisedSample = y
      End With
End Function
```

Binomial Acceptance Bounds

Function BinomLow(Successes As Double, trials As Double, Confidence As Double) As Double

```
With Application
If Successes = 0 Then
  BinomLow = 0
Else
  BinomLow = 1 - (.Beta_Inv(Confidence, trials - Successes + 1, Successes))
End If


End With
End Function
```

Function BinomHigh(Successes As Double, trials As Double, Confidence As Double) As Double

```
With Application

If (trials - Successes) = 0 Then
  BinomHigh = 1
Else
  BinomHigh = 1 - (.Beta_Inv((1 - Confidence) * 0.5, trials - Successes,
Successes + 1))
End If


End With
End Function
```

PFA – Probability the Item may be out of tolerance but is accepted (false acceptance) – uses the function BiVar

Function PFA(uUUT As Double, uCal As Double, Llow As Double, LUp As Double, ALow As Double, AUp As Double) As Double

```
'Z540.3 Risk Software Functions
' Provides Risk probability and Guard Band calculations.
' Dependent on NormalDist module probability functions.
' Probability of False Accept
' (Probability the UUT bias is out of tolerance and the UUT is accepted by
the Calibrator.)
'
' Inputs:
'   uUUT: UUT bias std uncertainty (assume 1-sigma)
'   uCal: Calibration process std uncertainty (1-sigma)
'   LLow: Lower tolerance limit
'   LUp:  Upper tolerance limit
'   ALow: Lower acceptance limit
'   AUp:  Upper acceptance limit

    Dim a As Double
```

```
    Dim b As Double
    Dim cor As Double
    Dim uDev As Double

    uDev = Sqr(uUUT ^ 2 + uCal ^ 2)
    cor = uUUT / uDev
    a = BiVar(Llow / uUUT, AUp / uDev, cor) - BiVar(Llow / uUUT, ALow / uDev,
cor)
    b = BiVar(-LUp / uUUT, -ALow / uDev, cor) - BiVar(-LUp / uUUT, -AUp /
uDev, cor)
    PFA = a + b
End Function
```

PFR – Probability the Item be in tolerance but rejected (false rejection) – uses the function BiVar

Function PFR(uUUT As Double, uCal As Double, Llow As Double, LUp As Double, ALow As Double, AUp As Double) As Double

```
' Probability of False Reject
' (Probability the UUT bias is in tolerance and the UUT is rejected by the
Calibrator.)
'
' Inputs:
'   uUUT: UUT bias std uncertainty (assume 1-sigma)
'   uCal: Calibration process std uncertainty (1-sigma)
'   LLow: Lower tolerance limit
'   LUp:  Upper tolerance limit
'   ALow: Lower acceptance limit
'   AUp:  Upper acceptance limit
    Dim a As Double
    Dim b As Double
    Dim cor As Double
    Dim uDev As Double
    uDev = Sqr(uUUT ^ 2 + uCal ^ 2)
    cor = uUUT / uDev
    a = BiVar(LUp / uUUT, ALow / uDev, cor) - BiVar(Llow / uUUT, ALow / uDev,
cor)
    b = BiVar(-Llow / uUUT, -AUp / uDev, cor) - BiVar(-LUp / uUUT, -AUp /
uDev, cor)
   PFR = a + b
End Function
```

PFA Guardband Multiplier - The multiplier found by keeping the false acceptance risk at a constant value (e.g. 2%)

```
Function PFAGBMult(Req As Double, uUUT As Double, uCal As Double, Llow As
Double, LUp As Double) As Double
' Guardband Multiplier for PFA
' (Finds a Guardband multiplier using Bisection.)
' (Doesn't assume symmetric limits.)
'
' Inputs:
'   Req:  The PFA requirement (e.g. 2%)
'   uUUT: UUT bias standard uncertainty (assume 1-sigma)
'   uCal: Calibration process standard uncertainty (1-sigma)
'   LLow: Lower tolerance limit
'   LUp:  Upper tolerance limit

    Dim AUp As Double
    Dim ALow As Double
    Dim GBMult As Double
    Dim EstPFA As Double
    Dim Chg As Double
    Dim Prec As Double

    ' Set precision of answer
    Prec = 0.000000001

    ' Start with acceptance limit at tolerance limit.
    AUp = LUp
    ALow = Llow
    GBMult = 1

    ' If the PFA is above the requirement, start search.
    EstPFA = PFA(uUUT, uCal, Llow, LUp, ALow, AUp)
    If (EstPFA > Req) Then
        ' Find initial GBMult where PFA is below requirement
        Chg = 0.05
        Do
            GBMult = GBMult - Chg
            AUp = LUp * GBMult
            ALow = Llow * GBMult
            EstPFA = PFA(uUUT, uCal, Llow, LUp, ALow, AUp)
        Loop Until (EstPFA <= Req)

        ' Search between acceptance and tolerance limits to meet requirement
        Do Until ((EstPFA >= Req - Prec) And (EstPFA <= Req))
            Chg = Chg / 2
            If (EstPFA < Req) Then
                GBMult = GBMult + Chg
            Else
                GBMult = GBMult - Chg
            End If
            AUp = LUp * GBMult
            ALow = Llow * GBMult
```

```
                EstPFA = PFA(uUUT, uCal, Llow, LUp, ALow, AUp)
            Loop
        End If

        ' Return Guard Band Multiplier value
        PFAGBMult = GBMult
End Function
```

BiVar - The Bivariate cumulative normal distribution function – Uses the function CumNorm Function

```
Function BiVar(a As Double, b As Double, r As Double) As Double
'Normal Distribution Code
' Graeme West
' 2004
' Cumulative Bivariate Normal Distribution
' Finds Bivariate Normal integral with limits:
'   x: -inf to A
'   y: -inf to B
'   r = correlation(x,y)
' This is the Genz DW2 double precision algorithm.
    Dim i As Integer
    Dim x(5) As Double, W(5) As Double
    Dim h1 As Double, h2 As Double
    Dim LH As Double, h12 As Double
    Dim h3 As Double, h5 As Double, h6 As Double, h7 As Double
    Dim r1 As Double, R2 As Double, r3 As Double, rr As Double
    Dim AA As Double, ab As Double

    x(1) = 0.04691008
    x(2) = 0.23076534
    x(3) = 0.5
    x(4) = 0.76923466
    x(5) = 0.95308992

    W(1) = 0.018854042
    W(2) = 0.038088059
    W(3) = 0.0452707394
    W(4) = 0.038088059
    W(5) = 0.018854042

h1 = a
    h2 = b
    h12 = (h1 * h1 + h2 * h2) / 2
    LH = 0
        If Abs(r) >= 0.7 Then
            R2 = 1 - r * r
            r3 = Sqr(R2)

            If r < 0 Then
            h2 = -h2
            End If
```

```
        h3 = h1 * h2
        h7 = Exp(-h3 / 2)

        If Abs(r) < 1 Then
            h6 = Abs(h1 - h2)
            h5 = h6 * h6 / 2
            h6 = h6 / r3
            AA = 0.5 - h3 / 8
            ab = 3 - 2 * AA * h5
            LH = 0.13298076 * h6 * ab * (1 - CumNorm(h6)) - Exp(-h5 / R2) *
(ab + AA * R2) * 0.053051647
            For i = 1 To 5
                r1 = r3 * x(i)
                rr = r1 * r1
                R2 = Sqr(1 - rr)
                LH = LH - W(i) * Exp(-h5 / rr) * (Exp(-h3 / (1 + R2)) / R2 /
h7 - 1 - AA * rr)
            Next i
        End If
         BiVar = LH * r3 * h7 + CumNorm(Min(h1, h2))

        If r < 0 Then
            BiVar = CumNorm(h1) - BiVar
        End If
    Else
        h3 = h1 * h2
        If r <> 0 Then
            For i = 1 To 5
                r1 = r * x(i)
                R2 = 1 - r1 * r1
                LH = LH + W(i) * Exp((r1 * h3 - h12) / R2) / Sqr(R2)
            Next i
        End If
        BiVar = CumNorm(h1) * CumNorm(h2) + r * LH
    End If
End Function


Function CumNorm(x As Double) As Double
' Normal Distribution Code
' Graeme West
' 2004
' Normal Distribution Function
 ' Declarations.
    Dim XAbs As Double
    Dim Build As Double
    Dim Exponential As Double

    XAbs = Abs(x)
    If XAbs > 37 Then
        CumNorm = 0
    Else
```

```
        Exponential = Exp(-XAbs ^ 2 / 2)
        If XAbs < 7.07106781186547 Then
            Build = 3.52624965998911E-02 * XAbs + 0.700383064443688
            Build = Build * XAbs + 6.37396220353165
            Build = Build * XAbs + 33.912866078383
            Build = Build * XAbs + 112.079291497871
            Build = Build * XAbs + 221.213596169931
            Build = Build * XAbs + 220.206867912376
            CumNorm = Exponential * Build
            Build = 8.83883476483184E-02 * XAbs + 1.75566716318264
            Build = Build * XAbs + 16.064177579207
            Build = Build * XAbs + 86.7807322029461
            Build = Build * XAbs + 296.564248779674
            Build = Build * XAbs + 637.333633378831
            Build = Build * XAbs + 793.826512519948
            Build = Build * XAbs + 440.413735824752
            CumNorm = CumNorm / Build
        Else
            Build = XAbs + 0.65
            Build = XAbs + 4 / Build
            Build = XAbs + 3 / Build
            Build = XAbs + 2 / Build
            Build = XAbs + 1 / Build
            CumNorm = Exponential / Build / 2.506628274631
        End If
    End If
    If x > 0 Then CumNorm = 1 - CumNorm
End Function
```

Ancillary functions required (also copy into the same VB module):

- Error Function (Erf)
- Error Function Complimentary (ErfC)
- Inverse Normal Distribution (InvNormalDist)
- Minimum (Min)
- UUT Uncertainty Function (uutUnc)

```
''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''
'Cephes Math Library Release 2.8:  June, 2000
'Copyright 1984, 1987, 1988, 1992, 2000 by Stephen L. Moshier
'
'Contributors:
'    * Sergey Bochkanov (ALGLIB project). Translation from C to
'      pseudocode.
'
'See subroutines comments for additional copyrights.
'
'>>> SOURCE LICENSE >>>
'This program is free software; you can redistribute it and/or modify
'it under the terms of the GNU General Public License as published by
'the Free Software Foundation (www.fsf.org); either version 2 of the
```

```
'License, or (at your option) any later version.
'
'This program is distributed in the hope that it will be useful,
'but WITHOUT ANY WARRANTY; without even the implied warranty of
'MERCHANTABILITY or FITNESS FOR A PARTICULAR PURPOSE.  See the
'GNU General Public License for more details.
'
'A copy of the GNU General Public License is available at
'http://www.fsf.org/licensing/licenses
'
'>>> END OF LICENSE >>>
''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''
'Routines
''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''
'Error function
'
'The integral is
'
'                           x
'                            -
'                2          | |           2
'  erf(x)  =  --------      |     exp( - t  ) dt.
'             sqrt(pi)      | |
'                            -
'                           0
'
'For 0 <= |x| < 1, erf(x) = x * P4(x**2)/Q5(x**2); otherwise
'erf(x) = 1 - erfc(x).
'
'
'ACCURACY:
'
'                    Relative error:
'arithmetic   domain     # trials      peak          rms
'   IEEE      0,1          30000       3.7e-16     1.0e-16
'
'Cephes Math Library Release 2.8:   June, 2000
'Copyright 1984, 1987, 1988, 1992, 2000 by Stephen L. Moshier
'
''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''
Private Function Erf(ByVal x As Double) As Double
    Dim Result As Double
    Dim XSq As Double
    Dim s As Double
    Dim p As Double
    Dim q As Double

    s = Sgn(x)
    x = Abs(x)
    If x < 0.5 Then
        XSq = x * x
        p = 7.54772803341863E-03
        p = 0.288805137207594 + XSq * p
```

```
        p = 14.3383842191748 + XSq * p
        p = 38.0140318123903 + XSq * p
        p = 3017.82788536508 + XSq * p
        p = 7404.07142710151 + XSq * p
        p = 80437.363096084 + XSq * p
        q = 0
        q = 1 + XSq * q
        q = 38.0190713951939 + XSq * q
        q = 658.07015545924 + XSq * q
        q = 6379.60017324428 + XSq * q
        q = 34216.5257924629 + XSq * q
        q = 80437.363096084 + XSq * q
        Result = s * 1.12837916709551 * x * p / q
        Erf = Result
        Exit Function
    End If
    If x >= 10 Then
        Result = s
        Erf = Result
        Exit Function
    End If
    Result = s * (1 - ErfC(x))

    Erf = Result
End Function
'''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''
'Complementary error function
'
' 1 - erf(x) =
'
'                              inf.
'                               -
'                 2           | |           2
'  erfc(x)  =  --------       |    exp( - t  ) dt
'              sqrt(pi)     | |
'                               -
'                              x
'
'
'For small x, erfc(x) = 1 - erf(x); otherwise rational
'approximations are computed.
'
'
'ACCURACY:
'
'                  Relative error:
'arithmetic   domain     # trials     peak          rms
'    IEEE      0,26.6417   30000       5.7e-14     1.5e-14
'
'Cephes Math Library Release 2.8:  June, 2000
'Copyright 1984, 1987, 1988, 1992, 2000 by Stephen L. Moshier
'
'''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''
```

```
Private Function ErfC(ByVal x As Double) As Double
    Dim Result As Double
    Dim p As Double
    Dim q As Double

    If x < 0# Then
        Result = 2 - ErfC(-x)
        ErfC = Result
        Exit Function
    End If
    If x < 0.5 Then
        Result = 1 - Erf(x)
        ErfC = Result
        Exit Function
    End If
    If x >= 10 Then
        Result = 0
        ErfC = Result
        Exit Function
    End If
    p = 0
    p = 0.56418778255074 + x * p
    p = 9.67580788298727 + x * p
    p = 77.0816173036843 + x * p
    p = 368.519615471001 + x * p
    p = 1143.26207070389 + x * p
    p = 2320.43959025164 + x * p
    p = 2898.02932921677 + x * p
    p = 1826.33488422951 + x * p
    q = 1
    q = 17.1498094362761 + x * q
    q = 137.125596050062 + x * q
    q = 661.736120710765 + x * q
    q = 2094.38436778954 + x * q
    q = 4429.61280388368 + x * q
    q = 6089.54242327244 + x * q
    q = 4958.82756472114 + x * q
    q = 1826.33488422951 + x * q
    Result = Exp(-(x) ^ 2) * p / q

    ErfC = Result
End Function

''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''
''''
'Inverse of Normal distribution function
'
'Returns the argument, x, for which the area under the
'Gaussian probability density function (integrated from
'minus infinity to x) is equal to y.
'
'
```

```
'For small arguments 0 < y < exp(-2), the program computes
'z = sqrt( -2.0 * log(y) );  then the approximation is
'x = z - log(z)/z  - (1/z) P(1/z) / Q(1/z).
'There are two rational functions P/Q, one for 0 < y < exp(-32)
'and the other for y up to exp(-2).  For larger arguments,
'w = y - 0.5, and  x/sqrt(2pi) = w + w**3 R(w**2)/S(w**2)).
'
'ACCURACY:
'
'                      Relative error:
'arithmetic   domain        # trials       peak          rms
'   IEEE      0.125, 1        20000        7.2e-16       1.3e-16
'   IEEE      3e-308, 0.135   50000        4.6e-16       9.8e-17
'
'Cephes Math Library Release 2.8:   June, 2000
'Copyright 1984, 1987, 1988, 1992, 2000 by Stephen L. Moshier
'
'''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''''
''''
Private Function InvNormalDistribution(ByVal y0 As Double) As Double
    Dim Result As Double
    Dim Expm2 As Double
    Dim S2Pi As Double
    Dim x As Double
    Dim Y As Double
    Dim z As Double
    Dim Y2 As Double
    Dim X0 As Double
    Dim x1 As Double
    Dim code As Long
    Dim P0 As Double
    Dim Q0 As Double
    Dim P1 As Double
    Dim Q1 As Double
    Dim P2 As Double
    Dim Q2 As Double

    Expm2 = 0.135335283236613
    S2Pi = 2.506628274631
    If y0 <= 0# Then
        Result = -MaxRealNumber
        InvNormalDistribution = Result
        Exit Function
    End If

    If y0 >= 1# Then
        Result = MaxRealNumber
        InvNormalDistribution = Result
```

```
      Exit Function
   End If


   code = 1#
   Y = y0

   If Y > 1# - Expm2 Then
       Y = 1# - Y
       code = 0#
   End If


   If Y > Expm2 Then
       Y = Y - 0.5
       Y2 = Y * Y
       P0 = -59.9633501014108
       P0 = 98.0010754186 + Y2 * P0
       P0 = -56.676285746907 + Y2 * P0
       P0 = 13.931260938728 + Y2 * P0
       P0 = -1.23916583867381 + Y2 * P0
       Q0 = 1#
       Q0 = 1.95448858338142 + Y2 * Q0
       Q0 = 4.67627912898882 + Y2 * Q0
       Q0 = 86.3602421390891 + Y2 * Q0
       Q0 = -225.462687854119 + Y2 * Q0
       Q0 = 200.260212380061 + Y2 * Q0
       Q0 = -82.0372256168333 + Y2 * Q0
       Q0 = 15.9056225126212 + Y2 * Q0
       Q0 = -1.1833162112133 + Y2 * Q0
       x = Y + Y * Y2 * P0 / Q0
       x = x * S2Pi
       Result = x
       InvNormalDistribution = Result
       Exit Function
   End If


   x = Sqr(-(2# * Log(Y)))
   X0 = x - Log(x) / x
   z = 1# / x
   If x < 8# Then
       P1 = 4.05544892305962
       P1 = 31.5251094599894 + z * P1
       P1 = 57.1628192246421 + z * P1
       P1 = 44.0805073893201 + z * P1
       P1 = 14.6849561928858 + z * P1
       P1 = 2.1866330685079 + z * P1
       P1 = -(1.40256079171354 * 0.1) + z * P1
       P1 = -(3.50424626827848 * 0.01) + z * P1
       P1 = -(8.57456785154685 * 0.0001) + z * P1
```

```
        Q1 = 1#
        Q1 = 15.7799883256467 + z * Q1
        Q1 = 45.3907635128879 + z * Q1
        Q1 = 41.3172038254672 + z * Q1
        Q1 = 15.0425385692908 + z * Q1
        Q1 = 2.50464946208309 + z * Q1
        Q1 = -(1.42182922854788 * 0.1) + z * Q1
        Q1 = -(3.80806407691578 * 0.01) + z * Q1
        Q1 = -(9.33259480895457 * 0.0001) + z * Q1
        x1 = z * P1 / Q1
    Else
        P2 = 3.23774891776946
        P2 = 6.91522889068984 + z * P2
        P2 = 3.93881025292474 + z * P2
        P2 = 1.33303460815808 + z * P2
        P2 = 2.01485389549179 * 0.1 + z * P2
        P2 = 1.2371663481782 * 0.01 + z * P2
        P2 = 3.01581553508235 * 0.0001 + z * P2
        P2 = 2.65806974686738 * 0.000001 + z * P2
        P2 = 6.23974539184983 * 0.000000001 + z * P2
        Q2 = 1#
        Q2 = 6.02427039364742 + z * Q2
        Q2 = 3.67983563856161 + z * Q2
        Q2 = 1.37702099489081 + z * Q2
        Q2 = 2.16236993594497 * 0.1 + z * Q2
        Q2 = 1.34204006088543 * 0.01 + z * Q2
        Q2 = 3.28014464682128 * 0.0001 + z * Q2
        Q2 = 2.89247864745381 * 0.000001 + z * Q2
        Q2 = 6.79019408009981 * 0.000000001 + z * Q2
        x1 = z * P2 / Q2
    End If
    x = X0 - x1

    If code <> 0# Then
        x = -x
    End If

    Result = x

    InvNormalDistribution = Result
End Function

' Minimum function
Private Function Min(vFirstVal As Variant, vSecondVal As Variant) As
Variant

    If (vFirstVal < vSecondVal) Then
        Min = vFirstVal
```

```
        Else
            Min = vSecondVal
        End If

End Function
```

Function uutUnc(r As Double, uCal As Double, Llow As Double, LUp As Double, Optional AdjToTrue As Variant) As Variant
```
 ' Return the UUT bias std uncertainty
' using the end of period rel and the
' std uncertainty of the calibration process.
'
' Solves:
'
'   R = F(LUp/uDev) - F(LLow/uDev)
'   uDev^2 = uUUT^2 + uCal^2
'   F = The Normal Distribution function
'
' Inputs:
'   R = The end of period measurement reliability
'   uCal = The std uncertainty of the calibration process (1 sigma)
'   LLow = The lower tolerance limit
'   LUp = The upper tolerance limit
'
' Outputs:
'   uUUT = The standard uncertainty for the UUT

    Dim uDev As Double
    Dim uUUT As Double
    Dim uUUT2 As Double
    Dim n As Double
    Dim Rn As Double
    Dim RootTwoPiInv As Double

    ' Make sure the limits make sense.
    If (Llow > LUp Or Llow >= 0 Or LUp <= 0) Then
        n = (LUp + Llow) / 2
        LUp = Abs(LUp - n)
        Llow = -Abs(Llow - n)
    End If

    ' Get the deviation uncertainty.
    ' (the uncertainty of the difference between the
    '  UUT and the STD)

    ' Symmetric Limits
    If (LUp = -Llow) Then
        uDev = LUp / InvNormalDistribution((1 + r) / 2)
```

```
        ' Asymmetric limits
    Else
        ' Initial value
        uDev = (Abs(LUp) + Abs(Llow)) / 2 / InvNormalDistribution((1 +
r) / 2)

        ' Iteration - Newton's Method.
        RootTwoPiInv = 0.564189583547756
        Rn = CumNorm(LUp / uDev) - CumNorm(Llow / uDev)
        Do While (Abs(Rn - r) > 0.000001)
            uDev = uDev - (Rn - r) / _
                    (RootTwoPiInv / uDev ^ 2 * _
                    (Llow * Exp(-(Llow / uDev) ^ 2 / 2) - _
                     LUp * Exp(-(LUp / uDev) ^ 2 / 2)))
            Rn = CumNorm(LUp / uDev) - CumNorm(Llow / uDev)
        Loop
    End If

    '
////////////////////////////////////////////////////////////////////////
///////////////////////////
    'The following few lines of code makes a determination if the UUT
is to be adjusted to "True" EOPR or not.
    'By adjusting to "True", the equation subtracts the reference
standard uncertainty away from the UUT - this is the preferred method
    'for laboratories having much historical data on the UUT being
tested. When this action is desired, set the input variable,
    'Optional AdjToTrue As Variant to 1, Y, or any non-blank
character.

    'This is done intentionally for users who would like to verify the
risk equations using a COTS package such as IsgMax RiskGuard.
    'RiskGuard does NOT adjust the the UUT back to "true" EOPR.

    'If IsMissing(AdjToTrue) Then ' If Optional AdjToTrue As Variant
is blank, then it ignores the reference standard uncertainty
contribution and does NOT adjust the UUT back to "True" EOPR. It
leaves it as the "Observed" EOPR
    '
////////////////////////////////////////////////////////////////////////
////////////////////////
    ' Calculate the 1-sigma uncertainty of the UUT.
  If IsMissing(AdjToTrue) Then
      uUUT2 = uDev ^ 2
    Else
      uUUT2 = uDev ^ 2 - uCal ^ 2
```

```
    End If

    If (uUUT2 <= 0) Then
        uUUT = 0
    Else
        uUUT = Sqr(uUUT2)
    End If

    ' Return the uncertainty
    uutUnc = uUUT

End Function
```

Some of this code is courtesy of NSWC. [28]

CPFA Function

Function CPFA(uUUT As Double, uCal As Double, Llow As Double, LUp As Double, ALow As Double, AUp As Double) As Double

' Conditional Probability of False Accept
' (Probability the UUT bias is out of tolerance and
' the UUT is accepted by the Calibrator
' conditional on acceptance.)
'
' Inputs:
'   uUUT: UUT bias std uncertainty
'   uCal: Calibration process std uncertainty
'   LLow: Lower tolerance limit
'   LUp: Upper tolerance limit
'   ALow: Lower acceptance limit
'   AUp: Upper acceptance limit

    Dim uDev As Double

    uDev = Sqr(uUUT ^ 2 + uCal ^ 2)

    CPFA = PFA(uUUT, uCal, Llow, LUp, ALow, AUp) / (CumNorm(AUp / uDev) - CumNorm(ALow / uDev))

End Function

References

1. ILAC-G8:09/2019 "Guidelines on Decision Rules and Statements of Conformity" Section 1.
2. JCGM 106:2012_E "Evaluation of measurement data – The role of measurement uncertainty in conformity assessment," Section 3.
3. ASME B89.7.3.1-2001 "Guidelines for Decision Rules Considering Measurement Uncertainty in Determining Conformance to Specifications," Definitions section 2.
4. ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories."
5. JCGM 106:2012_E "Evaluation of measurement data – The role of measurement uncertainty in conformity assessment," Introduction.
6. JCGM 106:2012_E "Evaluation of measurement data – The role of measurement uncertainty in conformity assessment," Section 8.3.1.1.
7. JCGM 106:2012_E "Evaluation of measurement data – The role of measurement uncertainty in conformity assessment," Introduction.
8. ISO 14253-1:2017, "Decision rules for verifying conformity or nonconformity with specifications," Adopted from Figure .6
9. ASME B89.7.4.1-2005 "Measurement Uncertainty and Conformance Testing: Risk Analysis," Section 7.
10. ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories," Clause 7.1.3.
11. ASME B89.7.4.1-2005 "Measurement Uncertainty and Conformance Testing: Risk Analysis," Section 8.
12. ILAC-G8:09/2019 "Guidelines on Decision Rules and Statements of Conformity," Section 5.2
13. JCGM 106:2012_E "Evaluation of measurement data – The role of measurement uncertainty in conformity assessment," Figure 11.
14. JCGM 106:2012_E "Evaluation of measurement data – The role of measurement uncertainty in conformity assessment," Section 8.3.1.1.
15. JCGM 106:2012_E "Evaluation of measurement data – The role of measurement uncertainty in conformity assessment," Equation 1.
16. JCGM 106:2012_E "Evaluation of measurement data – The role of measurement uncertainty in conformity assessment," Section 9.5.2.2.
17. JCGM 106:2012_E "Evaluation of measurement data – The role of measurement uncertainty in conformity assessment," Section 9.5.2.2.
18. JCGM 106:2012_E "Evaluation of measurement data – The role of measurement uncertainty in conformity assessment," Figure 17.
19. *Measurement Decision Risk – The Importance of Definitions*, by Scott M. Mimbs
20. ANSI/NCSL Z540.3 Handbook "Handbook for the Application of ANSI/NCSLI 540.3-2006 - Requirements for the Calibration of Measuring and Test Equipment."
21. ILAC P-14:2020, "Policy for Uncertainty in Calibration," Clause 5.4.
22. Risk Mitigation Strategies for Compliance Testing – J. Harben & P. Reese
23. Risk Mitigation Strategies for Compliance Testing – J. Harben & P. Reese
24. JCGM 200:2012 "International vocabulary of metrology – Basic and general concepts and associated terms (VIM) 3rd Edition," Section 2.6.
25. JCGM 100:2008 "Evaluation of measurement data — Guide to the expression of uncertainty in measurement," Section 4.3.
26. UKAS LAB 48 Edition 5, July 2024 "Decision Rules and Statements of Conformity," Appendix D.
27. UKAS LAB 48 Edition 5, July 2024 "Decision Rules and Statements of Conformity."
28. UKAS LAB 48 Edition 5, July 2024 "Decision Rules and Statements of Conformity."
29. Corona Naval Surface Warfare Center, specifically the work and information provided by Dr. Dennis Jackson for all his contributions concerning Measurement Decision Risk.

Author Biography

Greg Cenker

Greg Cenker has over 40 years of metrology experience focusing on electrical, primary temperature, mathematics, statistics, and quality. Greg joined **IndySoft** in 2020 as one of the company's Senior Metrologists and the **Calibrations.com** Product Manager. Greg's career began in the **United States Marine Corps** as a **PMEL** trained calibration technician at the **Marine Corps Air Station El Toro, CA**. Post-military Greg has held metrology engineering roles at **Ford Aerospace, Fluke, Southern California Edison, SpaceX, American Technical Services (ATS),** and metrology engineering manager with **Northrop Grumman**. In addition, Greg is currently a Principal of **Euclidean Engineering, LLC**, an independent metrology consulting practice providing **process analysis, uncertainty training, analytics**, and **mathematical tools** using well-tested and proven metrology methods.

Greg actively supports the **National Conference of Standards Laboratories International (NCSLI)** and the West Coast-based **Measurement Science Conference (MSC)** where he presents sessions, papers, and workshops. Greg is a contributor to the **NCSLI RP-1, RP-18, RP-19,** and **LM-1** committees and chairs the **Airline Metrology** committee.

The **Measurement Science Conference (MSC)** awarded Greg the 2021 **Woodington Award** for his contributions in defining **measurement uncertainty, risk assessment models, and procedural development** for the metrology industry. https://msc-conf.com/woodington-award/

Greg can be reached at greg.cenker@indysoft.com for all **IndySoft** related business information and gcenker@euclideanengineering.com for areas of **metrology consulting, process analysis, uncertainty analysis**, **analytics**, and **uncertainty training**.

Greg's LinkedIn profile: https://www.linkedin.com/in/greg-cenker-a3636a/

Henry Zumbrun

Henry A Zumbrun has over 27 years of industry experience in Metrology, specifically in force and torque measurements. From its founding in 1920 to the present time, **Morehouse Instrument Company** has grown from a local machine shop to one of the most respected names in the calibration and measurement world. Henry likes to think he has helped make an impact with force and torque measurements by helping several organizations be better and make better measurements.

Henry is passionate about helping any lab make better force measurements. He is also passionate about Metrology, Training, Outreach, and running a business based on doing what's right. He is aligning Morehouse so that everyone comes to work with a purpose. That purpose is simple: We create a safer world by helping companies improve their force and torque measurements. We all work as a team and help improve what we can control.

Henry supports continuous learning and, along with several degrees, is a **Six Sigma Blackbelt**, **Lean Champion**, and **Stanford Strategy Business Strategy Class** graduate. He has completed the LMI leadership program, Sandler Management Program, Sales Training, and OSHA 10. Henry is a Dead Head and is ordained by the Church of the Latter-Day Dude He is a current Vistage member and constantly learns from several mentors and his business coach how to make a meaningful impact beyond what a typical business would do.

Henry has taught various classes and sessions at **NCSLI, MSC, ASQ, A2LA**, etc., authored several published papers, written a book titled "**Force Calibration for Technicians and Quality Managers: Top Conditions, Methods, and Systems that Impact Force Calibration Results**," and was the primary Author on the "**G126 - Guidance on Uncertainty Budgets for Force Measuring Devices**" for **A2LA**. Henry is a contributing author to **NCSLI RP-3** and **LM-1**. He is also a co-host of the **Metrology Today Podcast** as well as the host of the **Morehouse Metrology Matters Podcast**.

Henry has written the Chapter on Force in the **Metrology Handbook 3rd Edition** and written and reviewed the Decision Rules and Measurement Uncertainty Chapter with Dilip Shah. He has been part of the **ASTM E28** committee for decades and has made several contributions to the **ASTM E74** and **E2428** standards through the committee.

NCSL International awarded Henry the **2022 Education and Training Award.**

Henry can be reached at hzumbrun@mhforce.com.

Henry's LinkedIn profile: https://www.linkedin.com/in/mhforce/

Dilip Shah

Dilip Shah has over **40 years of industry experience** in metrology, electronics, instrumentation, measurement, and computer applications of statistics in the Quality Assurance areas. He has been employed in various positions with **Philips Electronics (UK), Kodak Ltd. (UK), Instruments Division of Monsanto Corporation, Flexsys America, and Alpha Technologies**. He is currently a Principal of **E = mc³ Solutions**, a consulting practice that provides **training and consulting solutions** in **ISO/IEC 17025, ISO 9001, Measurement Uncertainty, and computer applications.**

Dilip is the co-author of **The Metrology Handbook (1st and 2nd editions) and a reviewer for the 3rd edition** published by the **ASQ Quality Press** and has contributed to the **2010 re-write** of the **CCT Primer** by the **Quality Council of Indiana**. Dilip participated in the initial development of **ASQ's Certified Calibration Technician exam**. Dilip participates actively in measurement-related issues through the **National Conference of Standards Laboratories International (NCSLI)** and the West Coast-based **Measurement Science Conference (MSC),** where he presents sessions, papers, and workshops. Dilip is a member of the **Institute of Electrical and Electronic Engineers (IEEE).**

Dilip is the recipient of **the MSC 2003 Algie Lance Best Paper Award, ASQ MQD's 2005 Max Unis Award, MSC 2010 Andrew Woodington Award, NCSL International 2011 Education and Training Award, and NCSL International 2023 Willam Wildhack Award.**

Dilip has contributed in the past to the **ASQ Quality Progress** Magazine's **Measure for Measure** column and **ASQ Expert Answers Blog**.

Additional Thank You to Many Others who Provided Constructive Feedback

Specific Acknowledgements to Heather Wade, Stephen Puryear, Rick Hogan, and Rob Knake.