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Quality Blind Spot™: Tolerancing Bias

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Abstract:
Have you ever played one of those 'spot the difference' picture puzzles? How many can you find in the pictures[1] below? The differences are right there in front of us. How is it that we think we see so clearly but then discover that there's more to it than meets the eye?

Now imagine trying to spot the difference for a concept rather than a picture. Example: an equipment owner reviews calibration certificates from two suppliers in an attempt to spot the differences. Some of the differences could be evident when comparing the columns of information. But what about determining the difference between the standards used, the measurement uncertainty, or the qualifications of the technician? The task becomes exponentially more difficult, especially if you don't even know to look for a difference. This can lead to potential Quality Blind Spots™[2] in industrial manufacturing that can cause false acceptance/rejection of product or increase a company's costs. There are many QBSs™ which I have introduced in some of my other papers, presentations, and training

sessions. Allow me to present another one: Tolerancing Bias. Tolerancing Bias is the incorrect application of tolerances for instruments that contain a percent of reading component in their specifications. This concept was brought to my attention by one of Transcat's FDA-regulated clients, Stanley Flores. When Stan called me, he prefaced the conversation with, "I need to get your opinion on something I think I'm seeing, but not sure it's right. It's difficult to explain, so bear with me." We spent the next hour discussing this QBS™. At first, I couldn't see it. And it wasn't because Stan wasn't explaining it well. It's just that I had my 'Metrology goggles' on, which I had been wearing for over 34 years at that time. I had to take those off and put on my 'Customer goggles'. The crazy thing about that is, I pride myself in standing in the 'customer's shoes' to gain a different perspective. Having done so, I have discovered potential avenues for QBSs™. Then I would scrutinize each situation with my Metrology lenses to see whether or not it caused a disconnect that opened the door for measurement risk. So the problem wasn't the 'shoes'; it was the 'Metrology goggles' that created a bias and caused me to be blind to this particular QBS™! Patience persevered and Stan finally got me to 'spot the difference'.

In this paper, we will describe the difference between an accuracy specification and a tolerance, explain how to convert a spec to a tolerance, cover the typical method that calibration labs use to apply the tolerance to a calibration result, and then we will introduce a different perspective from the equipment user's point of view. The expected outcome of this paper is for the reader to understand how a bias has been introduced which causes false acceptance/false rejection of calibration results as well as how to avoid this QBS™. And, by the way, there are ten differences between the two pictures.

Foreward

When performing a calibration, it is sometimes advantageous to set the Metrology standard to the nominal value (S_{nom}) and then report the value of the Unit Under Test (UUT). But for other applications it is more efficient to set the UUT to nominal (U_{nom}) and report the value of the standard.

An example of S_{nom} is the use of a pressure calibrator that can be programmed to specific set points in the process of calibrating an analog pressure gauge. The analog gauge cannot be programmed so it makes sense to take advantage of the pressure calibrator's menu and controller features to pressurize the standard to pre-determined values across the range of the UUT, making it simple for the calibration technician to simply wait for stabilization and then enter the value indicated on the pressure gauge. Alternatively, the pressure calibrator could automatically reach a value just below the set point allowing the technician to take it out of the control mode and then bump the pressure up until the gauge reads the nominal value and then enter the standard's actual value into the cal report. But that is not as efficient.

An example of U_{nom} is a weight with a nominal mass value where, depending on the class of the weight, a single substitution or a double substitution method is employed using a standard mass and a comparator to identify the value of the UUT mass. Other examples of U_{nom} include: gage block, pin/plug/ring gage, roughness specimen, angle block, et.al. Basically any artifact that sources a value and is not readily adjustable by the operator.

Foundation

In April 2017 I received an email from one of my customers, Stanley Flores at W. L. Gore & Associates, with whom I have built a good rapport over the years, both from a client-supplier perspective and through professional organizations such as NCSL International and the Measurement Science Conference. Stanley stated that he had recently come across a dispute regarding the application of specifications and calculating Pass/Fail limits. He had found some white papers on the subject and, after reading these, was "falling down the rabbit hole" and wanted to bump the situation up against someone to see if he could get more clarity.

Stanley's instrument (i.e., the UUT) is a flow device. The calibration report he received from the supplier indicated his instrument was found Out Of Tolerance (OOT). One of the OOT points was at the 75 lph (liters per hour) test point.

Standard (lph)	Allowed Tol. (lph)	Lower Limit (lph)	Upper Limit (lph)	UUT As Found (lph)
73.310	1.98	71.33	75.29	75.30

Figure 1: Reported values at 75 lph

In his due diligence to review the cert for omissions and/or errors, Stanley looked up the Original Equipment Manufacturer's (OEM) specification to confirm the tolerances were calculated correctly.

Range	Resolution	Accuracy
Low: 0 – 30 lph	0.001 lph	±(2.5% Reading + 0.1% Range)
High: 0 – 150 lph	0.01 lph	±(2.5% Reading + 0.1% Range)

Figure 2: OEM Performance Specifications for flow device

Specifications can be written as an accuracy statement, as shown in figure 2. However, some instrument specifications are written directly as a tolerance, such as a 0.5 inch Class X pin gage, which per the ANSI/ASME B89.1.5 standard is ±0.000040 inch, or ±40 µin. If a specification is stated as a percentage or in parts per thousand or parts per million, some math must be performed in order to convert it to a tolerance in the engineering unit of the UUT. In this case, Stanley's math resulted in the following tolerance:

$$\begin{aligned} Tolerance &= \pm(2.5\%\,Reading + 0.1\%\,Range) \\ &= \pm(2.5\% \times 75.30\,lph + 0.1\% \times 150\,lph) \\ &= \pm(1.8825\,lph + 0.15\,lph) \\ &= \pm 2.0325\,lph \end{aligned}$$

Rounding to the resolution of the High Range, Stanley calculated the tolerance to be ±2.03 lph. Applying this to the reported value, the limits are:

$$LL = 75.30\,lph - 2.03\,lph = 73.27\,lph$$
$$UL = 75.30\,lph + 2.03\,lph = 77.33\,lph$$

But wait, this didn't agree with the supplier's cal cert at all!

	Standard (lph)	Allowed Tol. (lph)	Lower Limit (lph)	Upper Limit (lph)	UUT As Found (lph)
Supplier	73.310	1.98	71.33	75.29	75.30
Stanley	73.310	2.03	73.27	77.33	75.30

Could it be the supplier made a mistake in their math or in the application of the tolerance? Could this be a S_{nom} vs. U_{nom} phenomenon? Did Stanley spot a quality difference?

Being an experienced Metrology Engineer (now a Sr Quality Engineer at Alcon Surgical Division) Stan quickly determined that the supplier calculated the tolerance based upon the Standard's value and then applied it around the Standard's value. This is a *Standard-centric* tolerance window as opposed to the *UUT-centric* tolerance window that Stanley had calculated. A quick check of the math confirmed the supplier's tolerance:

$$\begin{aligned} Tolerance &= \pm(2.5\%\, Reading + 0.1\%\, Range) \\ &= \pm(2.5\% \times 73.31\, lph + 0.1\% \times 150\, lph) \\ &= \pm(1.83275\, lph + 0.15\, lph) \\ &= \pm 1.98275\, lph \end{aligned}$$

Rounding to the resolution of the High Range, the supplier's tolerance is ±1.98 lph.

Tolerancing Bias

So which tolerance is correct? This is critical for Gore or for any FDA-regulated manufacturer who must demonstrate that their Measurement Decision Risk Control Plan is meeting the design requirements for the manufacturing or inspection measurement process. An incorrect OOT event costs them hundreds or thousands of dollars, depending on the product and the resources involved to conduct the non-conformance investigation to determine impact on product. Quite honestly, it matters to <u>any</u> consumer of calibration services to ensure a False Rejection or a False Acceptance is not created by the calibration provider, whether from an internal cal lab or a supplier.

In this case, the supplier's data indicates an OOT condition while Stanley's calculation indicates an In-Tolerance condition. This was the basis of Stanley's dilemma and it took a bit longer for him to get me up to speed on the phone than it did for you to read it here. But that wasn't the most difficult part of the problem. The difficulty was for Stanley to get me to grasp his reasoning for calculating a UUT-centric tolerance window.

As a veteran Metrologist with 3+ decades of experience, I had been aware that a specification that uses percentage of the indication (% reading, ppm, etc.) could have different results when applied to the UUT value vs. the standard's value, depending on how far apart they are as well as taking into account resolution of the UUT. However, many if not the majority of Metrologists view the calibration process as the UUT being the 'unknown' or 'undetermined' value and the standard as revealing the 'true' value – that is, within the measurement uncertainty, which should be small relative to the tolerance of the UUT. Because the standard represents the 'true' value in the calibration process, most cal labs apply the specification of the UUT to the 'known' value of the standard and then the UUT's value must lie within that tolerance window for a passing condition.

Stan's point of view was that the equipment user relies upon the instrument to tell him/her the quantified value in their measurement process. The operator can then expect that value to be within a range according to the OEM's performance specification. So when this flow device was indicating 75.30 lph for the flow rate in the production process, the operator understood that this flow rate could be (2.5% Reading + 0.1% Range) lower than this value (i.e., as low as 73.27 lph) or it could be (2.5% Reading + 0.1% Range) higher than this value (i.e., as high as 77.33 lph). The operator does not know the 'true value' of that measurement – they only know the value the flow device is indicating at that point in time and that, per the OEM, it has a relatively high expectation of being with the window of (73.27, 77.33) lph. Immediately following the operator's measurement of the production process, if we were to calibrate the flow device we would discover that the true value of the flow measurement would be 73.31, which would lie toward the low end of that window but would be In Tolerance (not considering measurement uncertainty, for simplification).

Once I removed my Metrology bias that caused me to view calibrations as a Standard-centric process and put on my Customer goggles to understand the equipment operator's point of view, I began to see Stan's point. Still not convinced?

Right now, you may be saying to yourself, "The cal process identifies the true value and therefore the true tolerance for Pass/Fail must be determined by applying the UUT specification to that true value!" I get it. I was thinking the same way for a good half hour when Stan first explained this situation to me. So keep that thought in your head while I turn the tables a bit. And for this situation, let's say you were the supplier that calibrated the flow device for Gore.

Going back to the owner of the flow device, in the measurement process for their product the operator knew their process had a flow rate and that it was 'unknown' before measuring it. They selected this flow device to quantify the flow rate. For them this measurement, as indicated on the flow device, represented the 'true' value of that flow rate at that point in time within the limits of error stated by the OEM of the flow device.

When the flow device came due for cal, the operator submitted it to your lab for calibration. In the cal process, you knew your standard indicated the 'true' value of the flow device and that this 'true' value was 73.310 lph, which you reported on their cal cert. That 'true' value indicated by your standard must lie within the tolerance window <u>you</u> expect as the user of that standard. That tolerance window is determined by the limits of error stated by the OEM of your flow standard as applied to your reading of 73.310 lph. Let's say the OEM spec for your standard is ±(1% Reading + 0.01% Range) and it has a range of 100 lph. These tolerance limits must be calculated based on your observation and use of the standard. That means your standard's value could lie somewhere between (72.567, 74.053) lph (again, not considering other uncertainty components, for simplification). Notice that this is not a tolerance window based upon the 'true' value of the primary standard that was used to calibrate your flow standard during the last calibration of your standard. It is a tolerance window based on the indication of your flow standard while you used it to determine the 'true' value of your customer's flow device to indicate the limits within which you can expect your flow standard to perform while you are using it.

While I was thinking about this UUT-centric tolerance window, I correlated this situation with The Price is Right game show and one of their games called the Range Game [3] (see fig. 3). In this game a prize is presented to the contestant, such as a car or a trip to some destination, and the contestant then watches a board that has a scale, much like a ruler, with prices on it rather than length measurements (shown in white in fig. 3). This *Prize Scale* has a price range of $600 across it from top to bottom and somewhere on that scale is the actual price of the prize. A smaller window in red represents a price range of $150 across it, called the *$150 Range* scale. The *$150 Range* scale begins sliding from the bottom of the *Prize Scale* upward. The contestant must push the stop button when they believe the price for the prize is within the *$150 Range* window. Then the actual retail price (i.e., the 'true' value) lights up and, if it is within the $150 Range window, the contestant wins. If not, the contestant loses. As a side note, I find it interesting that the ratio of the larger *Prize Scale* to the smaller *$150 Range* scale is exactly 4:1! That strictly must be a coincidence though.

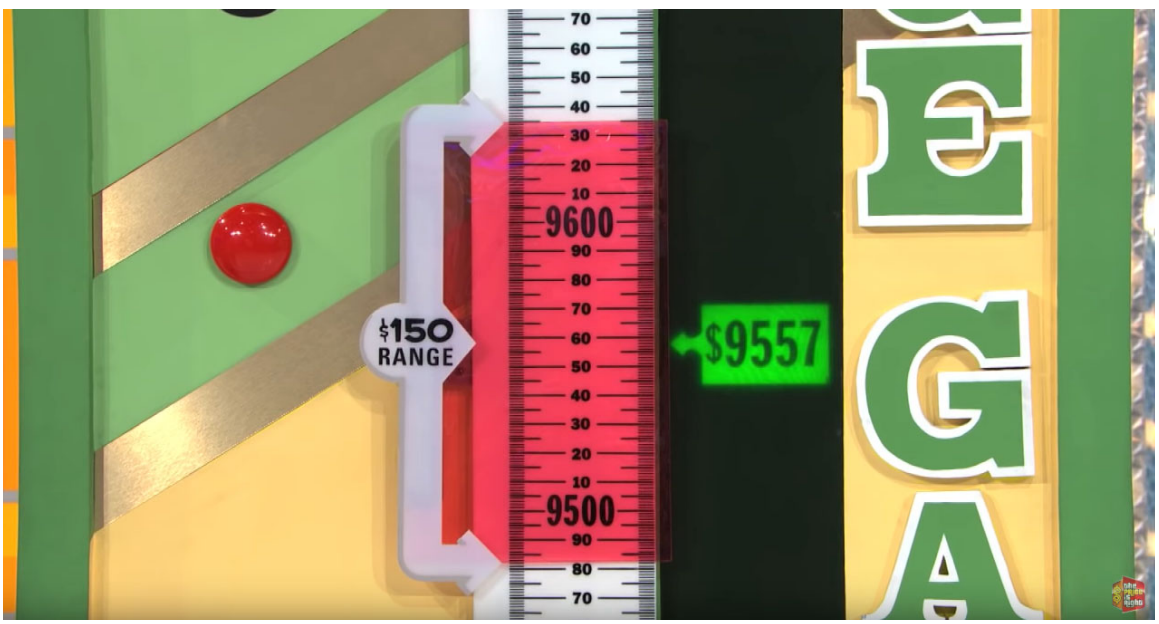

Figure 3: The Price is Right "Range Game"[3]

Similarly, the flow device indicates a value for the operator when it is being used to quantify the unknown flow of a process. And the equipment operator realizes that the flow value indicated on the flow device quantifies that value for the process but that it has a "Range" window within which the 'true' value is expected to lie, as determined by the OEM's performance specification. When the flow device is submitted for calibration, the Range window does not change; the 'true' value is simply revealed by the standard (i.e., symbolically, the green value in fig. 3). If the standard's value lies within the Range window, the UUT is In Tolerance (i.e., the customer wins ☺). If not, the UUT is OOT (i.e., the customer loses ☹). The Range window is still the tolerance window defined by the OEM, as applied to the indication on the flow device, not the indication of the standard.

With this in mind, it seems to me that the Metrology world is, in many instances, 'doing it wrong' when it comes to the application of UUT specifications for percentage-of-indication-type specs. Another thought that crossed my mind is this: for UUTs that have solely a % Range spec, has there ever been a question as to whether this should be calculated as a percentage of the UUT's range as opposed to it being a percentage of the standard's range? Probably not. I'm thinking most, if not all, cal labs apply a UUT's % Range spec as a UUT-centric tolerance and not a Standard-centric tolerance. So then why would % Reading be applied any differently?! It should not. For Gore's flow device the tolerance window developed by the OEM of the flow device is literally:

±(2.5% Reading *of the flow device* + 0.01% Range *of the flow device*)

but is not:

±(2.5% Reading *of your flow standard* + 0.01% Range *of the flow device*).

Similarly, for the calibration of your flow standard the tolerance window is literally:

±(1% Reading *of your flow standard* + 0.01% Range *of your flow standard*)

but is not:

±(1% Reading *of your cal supplier's primary flow standard* + 0.01% Range *of your flow standard*).

The OEM develops a performance spec for the instruments they produce so that their clients know what to expect from the instrument. That spec isn't written for the standard(s) that are used to calibrate the instrument. Therefore, within the calibration process the UUT spec should always be applied to the UUT's reading/range to determine the tolerance window and then the standard's value along with its corresponding measurement uncertainty should simply be evaluated to fall within that tolerance window or outside of it for Pass/Fail evaluation. Cal labs must remove their Standard-centric tolerancing bias, if it exists, because a Standard-centric tolerance has the possibility of creating a False Reject, as occurred in this flow device example.

Summary

Tolerancing Bias is one of many Quality Blind Spots™ that can cause False Accept/False Reject results. Most QBSs are unintentional but, in the end, still result in a burden to the calibration customer for measurement risk and associated costs. Identifying and eliminating or minimizing these measurement risks is the responsibility of Measurement Science professionals working closely with their customers to understand their calibration needs.

For labs that have been applying a *Standard-centric* tolerance window, there is certainly a cost implication for this type of corrective action. Calibration tolerances must be changed for hundreds if not thousands of calibration data sheets across many internal labs as well as many commercial labs. As with the identification of any massive error, the most acceptable way to do this is to work through these changes as each data sheet is used until the problem has been fully resolved.

Another consideration is that other uncertainty components must be taken into account (i.e., the expanded measurement uncertainty surrounding the Standard's reported value), which would potentially change the outcome of the Pass/Fail decision and which also requires the equipment owner to identify their decision rules for False Accept/False Reject decisions. Alas, that is (was) a topic for another paper[4].

And finally, a big Thank You to Stanley Flores for helping me (and all who read this paper) to 'spot the difference'!

References

[1] *Spot-the-Difference* pictures provided by Coolmath Games (https://www.coolmathgames.com/0-spot-the-difference)

[2] *Quality Blind Spot*™ is a trademark of Client Focus Group, LLC and reprinted with permission.

[3] *Range Game* picture and video is a copyright of The Price Is Right game show, owned by Fremantle.

[4] Source: *Who's Making the Decisions About Your Decision Rule* by H. Zion, NCSLI 2010, Providence, RI

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