Conformance Testing: Measurement Decision Rules

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Abstract

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The goal of a Quality Management System (QMS) as specified in ISO 9001 and AS9100 is to provide assurance to the customer that end products meet specifications. Measuring devices, often called measuring and test equipment (MTE), are used to provide the evidence of product conformity to specified requirements. Unfortunately, processes that employ MTE can become a weak link to the overall QMS if proper attention is not given to the measurement process design, capability, and implementation. Documented "decision rules" establish the requirements to ensure measurement processes provide the measurement data that supports the needs of the QMS.

Measurement data are used to make the decisions that impact all areas of technology. Whether measurements support research, design, production, or maintenance, ensuring the data supports the decision is crucial. Measurement data quality can be critical to the resulting consequences of measurement-based decisions.

Historically, most industries required simplistic, one-size-fits-all decision rules for measurements. One-size-fits-all rules in some cases are not rigorous enough to provide adequate measurement results, while in other cases are overly conservative and too costly to implement. Ideally, decision rules should be rigorous enough to match the criticality of the parameter being measured, while being flexible enough to be cost effective. The goal of a decision rule is to ensure that measurement processes provide data with a sufficient level of quality to support the decisions being made – no more, no less.

This paper discusses the basic concepts of providing measurement-based evidence that end products meet specifications. Although relevant to all measurement-based conformance tests, the target audience is the MTE end-user, which is anyone using MTE other than calibration service providers. Topics include measurement fundamentals, the associated decision risks, verifying conformance to specifications, and basic measurement decisions rules.

Introduction

Selection and calibration of MTE has traditionally been the sole emphasis of measurement quality assurance, or in other words, ensuring measurement data adequately supports decisions. With ever increasing technology requirements, current measurement quality assurance needs to include all pertinent variables within the measurement processes that provide the measurement data. There are many general-purpose and discipline-specific documents that provide guidelines for developing decision rules. A few of these are listed at the end of this paper, under the heading "Additional related information." The list is not exhaustive, so further research is recommended prior developing decision rules. Also, selection or development of appropriate decision rules requires a basic understanding of measurement quality assurance. Therefore, this paper will briefly address the background and fundamentals of measurement quality assurance.

Measurements = Decisions

In the simplest terms, measurements are made to gain knowledge or to make decisions. For example, measurements are made in basic research to extend our knowledge, or more commonly, they are used in commerce and industry to verify product conformance prior to acceptance. Many factors can influence a measurement result, and the measurement result can have consequences long after the measurement. Negative consequences from measurement results can range from wasted resources to loss of mission or life. Therefore, before designing a measurement process or establishing a measurement decision rule, the basics of why the measurement is being made, and any associated risks of incorrect decisions has to be understood and considered.

A Place to Begin

In all measurements, including calibration, two questions should be posed prior to making a measurement.

- 1. How good does the measurement need to be?
- 2. How good can the measurement be made?

Many factors can affect the answer to these questions, including available funds and current technology. In most cases, the first question is answered in respect to a business case, balancing between the cost and the required quality, while the second question involves existing technology and processes.

For the first question, the required quality of a measurement depends on the reason for the measurement. Not all measurements require the same level of rigor. By focusing first on the reason the measurement is required, the "how good is good enough" becomes clearer.

The answer to the second question requires an understanding of how to evaluate the "goodness" of a measurement. There are many factors which can negatively influence a measurement result. These factors have to be understood, evaluated, and controlled, to some degree, to achieve measurement results that meet the requirements established by the first question. A "better" instrument does not always guarantee a better measurement, since even a perfect instrument cannot fix a poor measurement process.

Risks Associated with Measurements

There is almost always some type of risk associated with decisions, including decisions based on measurement data. AS9100C [1] defines risk as, "An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence." The focus of measurement quality assurance is to quantify, and/or manage the "likelihood" of incorrect measurement-based decisions. When doing so, there must be a balance between the level of effort and the risks resulting from making an

incorrect decision. In balancing the effort versus the risks, the decision (direct risk) and the *consequences* (indirect risk) of the measurement must be considered.

- 1. **Direct Risk:** This risk is directly associated with the measurement data and impacts the decisions involving a measurement (e.g., accept, reject, rework, scrap).
- 2. **Indirect Risk:** This risk affects the quality or performance of end products which stem from measurements. In other words this is the "*consequence*" of an incorrect decision. This type of risk may not be evident until after the product is in service.

Figure 1 illustrates direct and indirect measurement risk through a lifecycle. The negative impact of measurement decisions can carry through the entire lifecycle; therefore, managing measurement-based risks during each phase of the lifecycle is an essential part of a quality system.



Figure 1: A partial lifecycle phase illustrating Direct and Indirect Risk associated with measurements. As illustrated, consequences can promulgate through the lifecycle.

Metrology's Two Fundamental Tenets

Balancing the cost of measurement processes and the consequences of incorrect decisions can be challenging. Key to developing cost-effective measurement processes that adequately manage the decision risks is the application of metrology's two fundamental tenets.

- Measurement Traceability
- Measurement Uncertainty

Proper application of these two tenets provides a flexible, thus cost-effective, measurement quality assurance program.

Measurement Traceability

Traceability establishes the link for a given measurement unit (e.g., kg, °C, etc.) to the national or international standard for that unit of measure. The Bureau International des Poids Mesures (BIPM) is the organization charged with maintaining the International System of Units (SI) reference standards, which are the global references for measurement units. Each industrialized country also has its own National Measurement Institute with legal authority to maintain and disseminate measurement units, but ultimately all are traceable to the BIPM.

Figure 2 illustrates this "chain of traceability" along with each "link's" level of risk to the end product, based on errors or incorrect decisions.



Figure 2: Traceability and level-of-risk, flowing high to low for measurements.

Measurement Traceability is accomplished through an *unbroken* sequence of *competent* and documented calibrations. *Unbroken* and *competent* mean that accepted measurement best practices were applied and all known error sources were taken into account in the calibration process. Traceability relates a measurement result to the corresponding SI unit, thereby providing the ability to compare measurements (and the related decisions) within and between organizations or even international borders.

Measurement Uncertainty

Uncertainty in measurements is the second fundamental tenet of metrology. Measurement uncertainty is the doubt that exists about a measurement's result. Every measurement - even the most careful - *always* has a margin of doubt. Evaluating the uncertainty in the measurement process determines the "goodness" of a measurement. Measurement uncertainty is an estimation of the potential error in a measurement result that is caused by variability in the equipment, the processes, the environment, and other sources. Every element within a measurement process contributes errors to the measurement result, including characteristics of the item being tested. Evaluation of the measurement uncertainty characterizes what is reasonable to believe about a measurement result based on knowledge of the measurement process.

Evaluation of measurement uncertainty can be qualitative or quantitative. Not all tasks require the same level of quality, thus the rigor of the uncertainty evaluation should be determined by the importance of the measurement result to the function of the end-item. Regardless of the level of rigor, uncertainty analysis is necessary to identify and possibly reduce errors within a measurement process. Typical error sources are:

- Instrument Accuracy
- Repeatability Error
- Resolution Error
- Digital Sampling Error
- Computation Error
- Operator Bias
- Environmental Factors Error

A lack of standardization for quantified estimation of measurement uncertainty often causes disagreements and confusion in trade, scientific findings, and legal issues. The International Organization for Standardization (ISO) *Guide to the Expression of Uncertainty in Measurement* (GUM) [2] is the international standardized approach to estimating uncertainty. ANSI/NCSL Z540.2-1997 (R2007), U.S. *Guide to the Expression of Uncertainty in Measurement* (U.S. Guide) [3], is the U.S. adoption of the ISO GUM. Additional guidance on estimating measurement uncertainty is available in various engineering discipline-specific voluntary consensus standards and complimentary documents. However, for consistent results, it is imperative that the quantification of measurement uncertainty be based on the ISO GUM.

Evaluating Measurement Results

Understanding how measurement error impacts the functionality of the end-item answers the question, "How good does the measurement need to be?" Having a reasonable estimate of the size of the error answers the question, "How good can the measurement be made?" Measurement uncertainty is the best way to evaluate this error. It is an estimate of the possible range of true values about a measurement result, caused by measurement errors. This knowledge of the measurement uncertainty is important for determining the usefulness of the measurement process as it applies to a given product or service. In other words, it provides a way to determine if a measurement result is adequate.

Figure 3 illustrates three different measurement processes and the corresponding measurement uncertainty for each, as indicated by the error bars. Each of the three processes provides a different result. When three different measurement processes are used to measure the same item, it is reasonable to expect three different answers due to the uncertainties of the processes. An example would be the differing measurement

results obtained using a steel machinist rule, dial caliper, and micrometer to make the same measurement.



Figure 3: Three different measurement indications with the nominal value contained by each measurement process uncertainty range.

Note that in Figure 3, the nominal value is contained within each measurement's process uncertainty range. One may ask which is correct. The answer is all three are correct within the capability of each measurement process. However, the measurement with the lowest uncertainty is a better estimate of the quantity of interest. A better question is which measurement process will support the test objectives with acceptable risk and cost.

The key to evaluating any measurement process is an understanding of the relationship between the measurement result and the functionality of the end-item. In other words knowing how "good is good enough." It is not necessary to use a micrometer if a steel rule provides adequate results for the end-item.

Verifying Conformance to Tolerances

Demonstration of conformity is not always straightforward, yet is crucial to managing the risks associated with measurements. AS9100 [1] requires that organizations "demonstrate conformity of the product," which is another way of saying "prove a product is in-tolerance." Requirements for quality products are not new, but now the requirement to "demonstrate conformity" meets head-on with the technical challenge of proving it. This section provides the information needed to understand and develop decision rules required to manage the risks associated with tolerance testing.

Risks in tolerance testing

As discussed earlier, *direct* risk is associated with decisions at the time of measurement and *indirect* risk is the consequence of the measurement decision. For verification of tolerances, *direct* risk can be broken down into two categories:

1. False Accept Risk is the probability of an *out-of-tolerance* item or parameter being unknowingly accepted by test or calibration.

Depending on the criticality of the measurement, this type of error can lead to loss of mission or loss of life, reduced end-item function or capacity, damaged corporate reputation, warranty expenses, shipping and associated costs for returned items, loss of future sales, punitive damages, legal fees, etc [4].

2. False Reject Risk is the probability of an *in-tolerance* item or parameter being unknowingly rejected by testing or calibration.

False rejects in test and calibration processes lead to unnecessary rework and handling. For test processes, higher rejection rates imply poorer production controls, thus false rejects also create an excessively pessimistic view of the quality of the end-item production process. This view may lead to more frequent disassembly and repair of end items than is necessary [4].

It can be surmised from the definitions and descriptions that both types of risk can have a cost impact. Although false rejects have an immediate cost impact with unnecessary rework or scrap, it is false accepts that have the potential for larger cost impacts. This is because false accepts are hidden and their impact may not be felt until much later, after the end-item is in service.

Both false accept risk and false reject risk are functions of the uncertainty in the measurement process. Jointly, they comprise measurement decision risk, which is a key element and metric of measurement quality assurance.

Tolerance testing

It cannot be overstated - uncertainty exists in all measurements. The amount of uncertainty in the measurement process and where the measurement result lies with respect to the tolerance limit determines the probability of an incorrect decision. Figure 4 illustrates this key problem in proving conformity to a specification. Using the same three measurement processes from Figures 3, Figure 4 adds a tolerance limit of \pm L which indicates the acceptable range of measurement results.



Figure 4: Three different measurement processes are used to verify a nominal value with a tolerance of \pm L. Although all three have the same indication, measurement A has some probability of non-conformance.

In Figure 4, all three measurements indicate the same value which is off-nominal. A portion of measurement A's uncertainty range extends beyond the + L limit, which means there is some probability that the true value estimated by measurement A is, in reality, outside of the specified limits.

Figure 5 is a rotated view of Figure 4, illustrating the assumed Gaussian nature of the error distributions. Again, it is apparent that measurement A has some probability of being out-of-tolerance.



Figure 4 and Figure 5 illustrate different measurement processes with different sized error distributions. The "error bands" of each measurement in Figure 4 represent the 95.5% confidence level of the Gaussian distribution shown in Figure 5. This means there is a 95.5% probability the "true" value of the measurement result lies within the error bands, which represents two standard deviations ($\pm 2\sigma$) about the measurement result. For most measurement systems, a 95% confidence level is adequate, although the criticality of the end product may dictate a higher level of confidence. Lean Six Sigma uses $\pm 3\sigma$, which is a 99.7% confidence level. Figure 6 illustrates the Gaussian distribution curve with the standard deviation and corresponding probabilities.



Figure 6: The Gaussian distribution (i.e., normal), illustrating the containment probabilities for one, two, and three standard deviations.

As a measurement result approaches a specified tolerance limit, the measurement process uncertainty creates an area of transition sometimes called an *indeterminate zone*. The size of the *indeterminate zone* is dependent on the size of the measurement process uncertainty distribution - the larger the measurement uncertainty, the larger the *indeterminate zone*. ASME B89.7.3.1-2001, *Guidelines for Decision Rules* [5], discusses these transition zones with respect to establishing decision rules for conformance testing. Acceptance and rejection zones can be established inside or outside of the specified tolerance depending on the criticality of the measurement. Using the same three measurement process as before, Figure 7 illustrates the concept of the *indeterminate* zones with *stringent* and *relaxed* acceptance zones for measurement processes B and C. The *indeterminate* zone for measurement A's process covers the entire specified tolerance.



Figure 7: Indeterminate zones are based on the size of the measurement process uncertainty. According to ASME B89.7.3.1-2001, acceptance zones can be established inside or outside of the specification limits depending on the criticality of the measurement.

Basic Measurement Decision Rules

Performing a rigorous uncertainty analysis for each measurement result provides the surest way to obtain the best measurement data possible. However, it is not always necessary. For most measurement-based decisions, less rigorous measurement processes are more than adequate to obtain the requisite measurement data quality. Decision rules can be developed to provide quality measurement data in a cost-effective manner.

This section covers a few basic decision rules that can provide flexibility to meet most measurement quality assurance requirements.

Ratio-Based Decision Rules

One of the oldest and most common decision rules in tolerance testing involves a comparison of the test tolerance to the accuracy of the measuring instrument or to the measurement process uncertainty. Originally called accuracy ratios, these methods were "rules of thumb" that were not always directly linked to an engineering or scientific basis. In the early part of the Twentieth Century, the most common accuracy ratio required the measuring instrument accuracy to be ten times better than the tolerance of the quantity being measured. This was referred to as the 10:1 rule. In the late 1940's and early 1950's, Alan Eagle, Frank Grubbs, and Helen Coon pioneered work on consumer and producer risk analysis [6, 7], which was a rigorous, statistical method of controlling measurement decision risk in manufacturing. Building upon Eagle's published work, Jerry Hayes established a basis for linking measurement decision risk to accuracy ratios for application in the Navy's calibration program [8]. The objective was to provide an

improved decision rule without requiring statistical calculations, which were very tedious with the limited computing power of the early 1950's [9]. Hayes' work was the genesis of what is now known as the 4:1 test accuracy ratio (TAR), a rule of thumb used extensively within the U.S. calibration system.

Although easily applied, there are two major pitfalls with rudimentary rules of thumb such as the 4:1 TAR. First, a "one size fits all" approach may not be appropriate for all circumstances. In the case of life or mission critical measurements, detailed analysis of the measurement process should be the rule. However, there may be valid rationale for using accuracy ratio methods in the majority of less critical test process situations. The second pitfall is a lack of standardization of rules of thumb that can lead to varied results and a false confidence in measurement processes. This is compounded when products are manufactured, assembled, and tested in different locations.

For NASA, it is imperative that acceptance/rejection rules be standardized across programs or projects to ensure uniform application, thus results. There are two prevalent accuracy ratio rules that have been used within NASA and Industry. Both can be applied to two-sided, symmetrical, or asymmetrical tolerance limits.

 Test Uncertainty Ratio (TUR). The combination of the uncertainties of all the elements of the measurement process must be no greater than a given percent (such as 25%) of the overall tolerance of the item being measured. The combined uncertainties of the measurement process would require a level of confidence, such as 95%, which would then be called the 95% expanded uncertainty of the measurement process.

"Expanded uncertainty" is defined in the ISO GUM (or Z540-2), where k is the coverage factor and u is the combined uncertainty of the measurement process. The following is a mathematical expression of the TUR based on the definition found in ANSI/NCSL Z540.3, *Requirements for the Calibration of Measuring and Test Equipment* [10]. Although taken from a calibration standard, this definition is relevant for all measurement applications where a TUR is used.

$$TUR = \frac{L_{upper} - L_{lower}}{2 \cdot U_{95}} \quad U_{95} = k \cdot u \qquad k \approx 2$$

By accounting for all relevant uncertainties, and with an adequate ratio value, the TUR can provide for effective measurement quality assurance for most measurement scenarios. Measurements B and C in Figure 4 illustrate this point.

2. Test Accuracy Ratio (TAR). The accuracy of the measuring instrument will be no greater than a given percent (such as 10%) of the measurement tolerance.

The TAR uses the specified accuracy of the measuring instrument and does not consider uncertainties due to other measurement process errors. Thus, caution must be exercised when using the TAR because other sources of measurement process error can often be larger than the accuracy of the measuring instrument. Although the TAR has this limitation, it can still be used effectively in low-criticality applications.

For effective use in conformance testing, the TUR and TAR must have an appropriate ratio value. This is especially true for the TAR because it does not account for other

measurement process error sources, providing only an optimistic view of the measurement quality. The larger the TUR/TAR, the higher the confidence of correct accept/reject decisions as the measurement result moves closer to the specification limits. Figure 8 illustrates this point for a TUR.

Figure 8 uses the same three measurement processes as in previous figures. This time the indicated measurements are positioned so that the extreme edge of the 95% uncertainty range is approximately even with the tolerance limit. To put the figure in perspective, using the Z540.3 TUR definition, the approximate ratios are: measurement process A = 1:1, measurement process B = 4:1 and measurement process C = 10:1. Figure 8 illustrates how close to the tolerance (± L) a measured value can be made and still have adequate confidence the measurement is in-tolerance.



Figure 8: Three different measurement processes are used to verify a nominal value with a tolerance of \pm L. Each measurement is shown at its capability limit prior to exceeding the tolerance limit.

It is important to note that measurement process A, with the 1:1 TUR, provides the same confidence at nominal as measurement processes B and C, although they are much closer to the tolerance limits. In a conformance test, it would be difficult to defend using measurement process A if better measurement processes were available, such as B or C.

Decision rules for Single-Sided Tolerances

For single-sided tolerances, the uncertainty, or accuracy, is used to manage the decision risk. As the measurement result approaches the tolerance limit, the uncertainty of the process creates an indeterminate zone, as discussed above. The decision rule adds or subtracts the uncertainty/accuracy to the limit in such a way as to create an *acceptance* limit, also known as a guardband. Figure 9 illustrates this concept, using the acceptance zone terms from ASME B89.7.3.1.





Risk-based decision rules

As demonstrated in Figure 8, a smaller TUR (e.g., 1:1) offers significantly lower confidence for off-nominal measurements than a larger TUR (e.g., 10:1). This confidence can be quantified across a tolerance range for specific TURs. Figure 10 does this by linking the measurement result to the false accept risk over the tolerance range of \pm L. Using the TUR of the three measurements, Figure 10 illustrates that smaller ratios are less capable of demonstrating conformity over the full range of a specification. As shown in Figure 10, a TUR of 1:1 measured at the nominal value has about a 5% out-of-tolerance probability, while a TUR of 10:1 will have a negligible out-of-tolerance probability for a large percentage of the tolerance range.



Figure 10: The risk probabilities for the three different measurement processes over the tolerance range of ± L. The probabilities are shown for each measurement result over the tolerance range as a percentage of the tolerance. TURs are calculated per the Z540.3 definition.

The false accept risk illustrated in Figure 10 uses a "confidence level method" [11] for the calculation. This method is applicable to measurements where no prior measurement history is available. This method has the advantage of either being applied directly to a measurement result at the time of test, or used for developing risk-based decision rules at the program level. Although, the false accept risk (*FAR*) and in-tolerance (P_{in}) algorithms are complimentary, in that their sum is unity, they are given here independently:

$$FAR = 2 - \Phi\left(\frac{L-x}{u_{mp}}\right) - \Phi\left(\frac{L+x}{u_{mp}}\right) \qquad P_{in} = \Phi\left(\frac{L-x}{u_{mp}}\right) + \Phi\left(\frac{L+x}{u_{mp}}\right) - 1$$

Where $\Phi()$ is the standard normal distribution function found in most spreadsheet programs. For Microsoft Excel, the function is NORMSDIST().

-12-

2010 NCSL International Workshop and Symposium

Table 1 puts Figure 10's graph into tabular form for three in-tolerance confidence levels. A risk-based decision rule establishes a specific confidence level, and establishes acceptance limits for conformance testing. This approach allows for different confidence levels depending on both the criticality of the item being measured and the capability of the measurement process.

TUR	In-tolerance confidence level	Percent of Tolerance
10:1	99.7% (± 3o)	86.3%
4:1	99.7% (± 3σ)	65.7%
1:1	99.7% (± 3 0)	Not possible
10:1	95.45% (± 2σ)	91.5%
4:1	95.45% (± 2σ)	78.9%
1:1	95.45% (± 2σ)	Nominal only
10:1	68.3% (± 1σ)	97.6%
4:1	68.3% (± 1σ)	94.0%
1:1	68.3% (± 1σ)	76.2%

Table 1: Percentage of usable tolerance for a desired confidence level.

Considerations and Cautions

Although no measurement system can provide 100% assurance of conformity, the probability of an undetected non-conformance can be greatly reduced by using appropriately designed measurement decision rules. The underlying foundation for the best decision rules is the fundamental tenets of metrology. Without traceability and measurement uncertainty, assurance of conformity to specified requirements is greatly reduced and acceptance or rejection becomes a gamble.

There are many points to consider when developing or implementing measurement decision rules. While the following list reiterates some points already discussed, it is far from exhaustive.

- 1. **Measurements support decisions** accept, reject, rework, scrap, or even launch a space vehicle. In conformance testing, if a measurement does not support a decision, it is unnecessary.
- 2. Know how good the measurement needs to be. Decisions based on measurement data can be routine or life critical. The criticality of the measurement is the same as the criticality of the decision.
- 3. Know how good the measurement can be made. All measurements have errors. Measurement uncertainty analysis is the process that identifies and quantifies measurement errors. The TUR differs from the TAR by the inclusion of all pertinent

measurement process errors. Frequently, measurement process errors are larger than the error of the measuring instrument being used; therefore, the TAR only provides an "optimistic" view of the measurement quality.

4. All specified tolerances are not created equal. The quality of specification limits can complicate measurement quality assurance applications. Some design centers provide excessive margin in tolerances, without proper documentation. This can unnecessarily inflate costs to the program by "margin-stacking" if those responsible for verifying the tolerance are not aware of the additional margin and apply strict measurement decision rules such as a 10:1 TUR. The converse can also be true when those responsible for conformance testing believe the measurement reliability margins are contained within the tolerance, when in reality they are not. In the latter case, without the application of appropriate measurement decision rules, there is not only an increased false accept risk, but more importantly, there may also be increased safety risks if critical limits are unintentionally exceeded.

The more critical the decision, the more critical the data. The more critical the data, the more critical the measurement.

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9 - 30

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