INTRODUCTION

This document is meant to consolidate and clarify the definitions, requirements and guidance related to decision rules as they relate to the A2LA calibration accreditation program. ISO/IEC 17025 was revised in 2017 with a 3-year implementation period requirement for accreditation bodies to transition all their laboratory accreditations to the new standard. The revised standard added some specific requirements for laboratories to document, communicate, gain customer acceptance, and report their decision rules for how they take measurement uncertainty into account when making statements of conformity (pass/fail, in/out of tolerance, etc.)

During the transition process, it became apparent that there is some confusion regarding these new requirements and that areas for improvement and education exist in how laboratories document and communicate their decision rules to their customers. A2LA determined that actions were required to help assist our accredited laboratories in educating their customers about decision rules by providing guidance in this document.

This document is not a requirements document, but it does contain references to requirements from ISO/IEC 17025:2017. These are included in this document for the sake of consolidation of the many relevant references to requirements and guidance found in a variety of different sources published by different organizations. Any instances of non-compliance to the requirements should be cited against the relevant requirement document and not this guidance document.

DEFINITIONS

Decision Rule[1]: rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

Measurement Capability Index (Cm)[3]: tolerance divided by a multiple of the standard measurement uncertainty associated with the measured value of a property of an item.

Shared Risk[3]: same definition as Simple Acceptance below

Simple Acceptance[2]: a decision rule in which the acceptance limit (AL) is the same as the tolerance limit (TL), i.e. $AL=TL$ (ASME B89.7.3.1[3])

Test Uncertainty Ratio (TUR)[2]: the ratio of the tolerance, TL, of a measurement quantity, divided by the 95% expanded measurement uncertainty of the measurement process, U, where $TUR=TL/U$.

Test Uncertainty Ratio (TUR)[4]: The ratio of the span of the tolerance of a measurement quantity subject to calibration, to twice the 95 % expanded uncertainty of the measurement process used for calibration.

NOTE: This applies to two-sided tolerances.

RELEVANT REQUIREMENTS

ISO/IEC 17025:2017 Clause 7.1.1: The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:

a) the requirements are adequately defined, documented and understood;

b) the laboratory has the capability and resources to meet the requirements;

c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;

NOTE 1 It is recognized that externally provided laboratory activities can occur when:

— the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full;

— the laboratory does not have the resources or competence to perform the activities.

d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.

— NOTE 2 For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way.

ISO/IEC 17025:2017 Clause 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.

ISO/IEC 17025:2017 Clause 7.6.1: Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

ISO/IEC 17025:2017 Clause 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.

ISO/IEC 17025:2017 Clause 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).

ILAC P14:09/2020 Clause 5.1: The Accreditation Body shall ensure that an accredited calibration laboratory reports the measurement uncertainty in compliance with the GUM.

ILAC P14:09/2020 Clause 5.4: 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. Contributions that cannot be known by the laboratory, such as transport uncertainties, should normally be excluded in the uncertainty statement. If, however, a laboratory anticipates that such contributions will have significant impact on the uncertainties attributed by the laboratory, the customer should be notified according to the general clauses regarding tenders and reviews of contracts in ISO/IEC 17025.

GUIDANCE

The definition of Decision Rule (DR) requires that Measurement Uncertainty (MU) be accounted for when making a statement of conformity. As such, it is impossible to separate MU from the description of the DR when contracting with the customer and reporting the results. That is why this document includes relevant references to the requirements for decision rules and measurement uncertainty. You cannot meet the requirements of these standards or of accreditation without taking MU into account in your DR.

A common approach to accounting for MU in a DR is to use a Test Uncertainty Ratio or TUR. This document provides three definitions for TUR (JCGM 106 uses the term Measurement Capability Index) which all are fundamentally correct and the equivalent with differing levels of specificity. These definitions are provided to demonstrate that no matter the reference to the term TUR, a TUR is ratio of the tolerance to the reported MU with the MU being the denominator in the ratio and the tolerance is the numerator. As MU is a denominator in the ratio of TUR, it is critical that MU is evaluated correctly and consistently so that the user of that information is clear on the level of risk associated with the stated decision rule using a TUR consideration. Correct MU statements are critical in every decision rule as the inclusion or exclusion of significant contributions to the MU calculation will have a significant impact on the TUR, or other guardband method, and thus the results (pass/fail) of the decision rule applied to the evaluation of conformity.

ILAC G8:09/2019 Guidelines on Decision Rules and Statements of Conformity provides useful guidance on the selection and application of DR. A flowchart from that document is provided as a quick reference to assist in the evaluation of applicability and selection of an appropriate DR. It is important to remember that the customer should be the party who is most knowledgeable about the application and appropriateness of the DR chosen. However, in many instances the customer relies on the calibration/testing provider to be the source of the knowledge for the selection of an appropriate DR for their calibration or testing results. The references to ISO/IEC 17025:2017 Clauses 7.1.1 & 7.1.3 were included in this document because they relate specifically to the interaction between the customer and the laboratory when selecting a DR.

Not all DRs are created equal, and not all laboratories can provide the necessary level of MU to ensure an appropriate application of the chosen DR. In most cases, a laboratory should not accept work from a customer when their MU is greater than the tolerance limit requirements from the customer (TUR <1:1) as the level of risk associated with making an incorrect statement of conformance could exceed 50%. There are technically valid reasons that a laboratory would accept this level of risk, such as with Class XXX Ring Gages where the specifications were set at levels that are not reasonably achievable with correct MU calculations and a TUR of greater than 1:1. There are also industries where cutting-edge technology has led to a situation where the capability of the reference standards used are at almost equal levels of the specification tolerances of the item under test which can results in TURs around 1:1. However, these are exceptions and the generally accepted industry standard is to achieve a TUR of 4:1 or greater.

During the contract review process and selection of DR the laboratory needs to ensure that they have appropriate levels of MU to provide the customer with appropriate and technical valid results or they should not accept the work. It is not enough to document a DR, it must meet the needs of the customer and be technically valid. Decision rules implemented when the MU is larger than the tolerance should be thoroughly scrutinized and only be acceptable in rare instances depending on the state of technology or some other industry specific issue.

A significant issue identified during the transition to ISO/IEC 17025:2017 and the implementation of the requirements for definition of the DR is the use of the term “Simple Acceptance”. Many laboratories have chosen to use the Simple Acceptance DR as their default DR. This practice is valid, but many laboratories have also included language such as “MU not taken into account” when defining their Simple Acceptance DR. As noted earlier, the definition of DR requires the account of MU so a DR without accounting for MU is not a DR and does not meet the requirements of the ISO/IEC 17025:2017 standard or the requirements for accreditation.

The use of this “MU not taken into account” terminology is meant to express the tolerance limit is set as the acceptance limit and that there is no guardbanding for the value of MU. This is also sometimes called “zero guardbanding”. When a laboratory uses the phrase “MU not taken into account”, they are trying to convey that

they have not guardbanded their acceptance limits. However, they likely have indeed taken MU into account by considering some level of TUR, typically that 4:1 industry standard. As such, the correct statement should be that they have a Simple Acceptance DR with a TUR constraint of 4:1, or whatever appropriate ratio is agreed upon with the customer. In this manner they have indeed accounted for MU and meet the requirements of the standard. A statement of "MU not taken into account" (or similar) is technically incorrect and DOES NOT meet the requirements of the standard. Instead, a statement of Simple Acceptance will need to further describe how MU is taken into account by inclusion of a TUR constraint or some other description of MU constraint.

The intent of defining a DR is to ensure that the user of that statement of conformity understands the level of risk associated with that measurement decision. This cannot be achieved without a clear definition of the DR including a clear description of how MU was taken into account and correct and appropriate calculation of MU. This document attempts to consolidate and clarify the most common questions and issues that we have seen in our accreditation programs. There are numerous resources available that discuss various decision rules that could be appropriate depending on the industry and application. This document focuses on the requirements associated with DRs and the most common issues discovered during our assessment process. This is not meant to be a comprehensive document for creation of decision rules as there are potentially infinite variations of acceptable DRs that could be applied.

EXAMPLES OF ACCEPTABLE AND UNACCEPTABLE USES OF SIMPLE ACCEPTANCE DR

Example 1: Acceptable: The decision rule used is Simple Acceptance as defined in ILAC G8 with a TUR of 4:1 or greater.

Example 2: Acceptable: The decision rule used is Simple Acceptance as defined in ILAC G8 with measurement uncertainty value that will not exceed 10% of the tolerance.

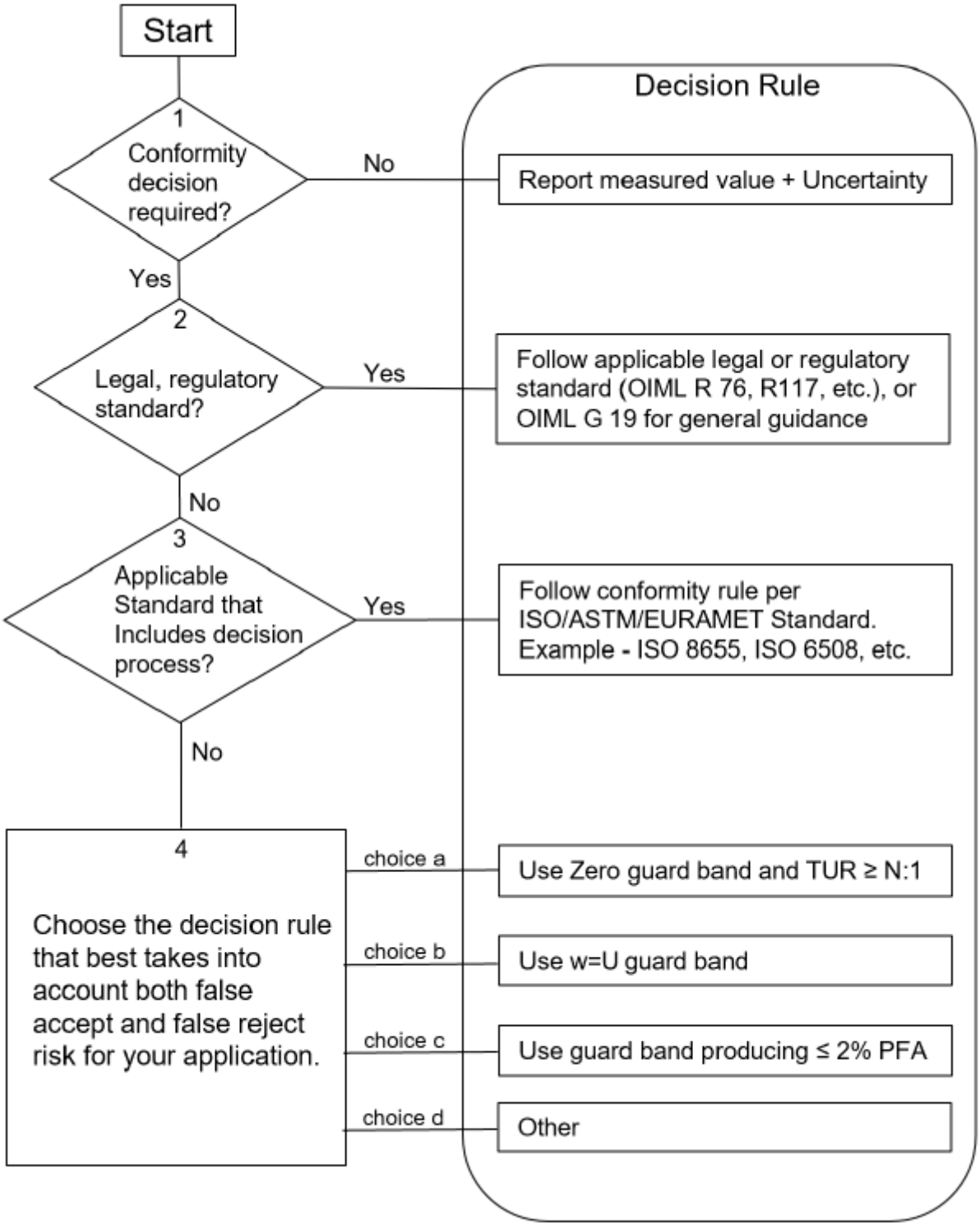
Example 3: Unacceptable: The decision rule used is Simple Acceptance and measurement uncertainty is not taken into account.

Example 4: Unacceptable: The decision rule used is Simple Acceptance as defined in ILAC G8.

Note 1: The TUR and MU values chosen for the examples were chosen as a demonstration of the required content and your TUR and MU values will differ depending on how you have accounted for MU in your chosen DR. These are only examples to demonstrate the required elements of a defined decision rule that describes how MU is taken into account.

Note 2: The examples of acceptable simple acceptance DRs listed above are not the only ways/methods for determining an acceptable decision rule.

DECISION RULE FLOWCHART



Reference ILAC G8:09/2019 Figure 7

REFERENCES

The following documents are referenced by their superscript number throughout this document:

1. ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories

2. ILAC G8:09/2019 Guidelines on Decision Rules and Statements of Conformity

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

4. NCSL Recommended Practice 21: Assessment of ANSI/NCSL Z540.3 Sub-clause 5.3

5. ILAC P14:09/2020 ILAC Policy for Measurement Uncertainty in Calibration

DOCUMENT REVISION HISTORY

Date	Description
10/10/22	Initial Publication