

Explanation of Decision Rule

判定规则的说明

1. Definition (small selection) 定义 (摘选)

(1) Measurement (ISO/IEC Guide 99:2007)

process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity

测量 (JJF 1001-2011)

通过实验获得并可合理赋予某量一个或多个量值的过程。

(2) Measurement Uncertainty (ISO/IEC Guide 99:2007)

non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

测量不确定度 (JJF 1001-2011)

根据所用到的信息, 表征赋予被测量量值分散性的非负参数。

(3) Decision Rule (ISO/IEC 17025:2017)

Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

判定规则(CNAS-CL01:2018)

当声明与规定要求的符合性时, 描述如何考虑测量不确定度的规则。

(4) Tolerance Limit (TL) (Specification Limit) (ILAC-G8:09/2019)

specified upper or lower bound of permissible values of a property

容许限 (规范限) (TL) (CNAS-GL015:2022)

可测量属性允许值的规定上限和下限

(5) Acceptance Limit (AL) (ILAC-G8:09/2019)

specified upper or lower bound of permissible measured quantity values

接受限 (AL) (CNAS-GL015:2022)

允许测得值的规定上限或下限

(6) Guard Bands (w) (ILAC-G8:09/2019)

interval between a tolerance limit and a corresponding acceptance limit where length $w = |TL - AL|$.

保护带 (w) (CNAS-GL015:2022)

容许限和对应的接受限之间的区间, 长度 $w = |TL - AL|$

(7) Simple Acceptance (ILAC-G8:09/2019)

a decision rule in which the acceptance limit is the same as the tolerance limit, i.e. $AL = TL$

简单接受 (CNAS-GL015:2022)

接受限等于容许限的判定规则, 也就是 $AL = TL$

2. Measurement Uncertainty and Decision Risk Overview (ILAC-G8:09/2019)

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

- a. A correct decision is made regarding conformance to specification
- b. An incorrect decision is made regarding conformance to specification

Each measured value has an associated measurement uncertainty. Figure 1 shows two identical measurements but with different measurement uncertainties. The expanded measurement uncertainty in the lower result (case A) lies entirely within the tolerance limit. The upper result (case B) has significantly larger measurement uncertainty. The risk of falsely accepting a result in case B is higher due to the larger measurement uncertainty.

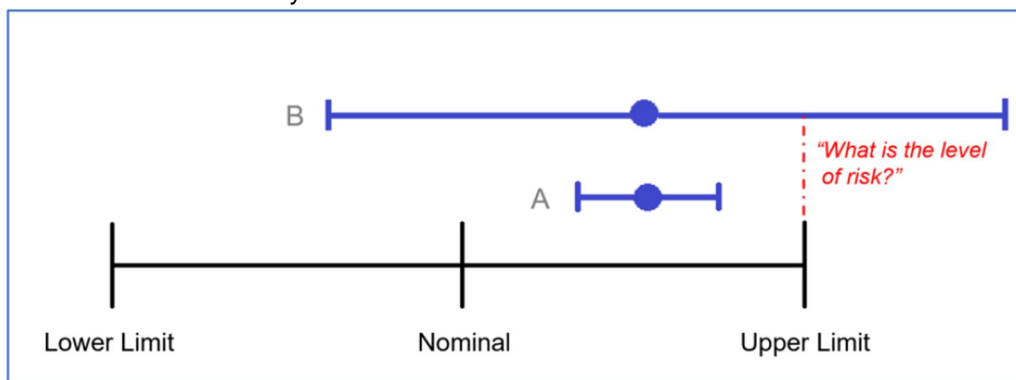


Figure 1. Illustration of Measurement Decision Risk

测量不确定度和判定风险概述 (CNAS-GL015:2022)

基于测得值对测量结果进行与规范或标准（容许限）的符合性判定时，会有正确判定和错误判定两种可能，如下图 1 所示，对于相同的测得值（图中圆点所示），情况 A 的扩展测量不确定度区间全部位于容许区间内，情况 B 则有一部分扩展测量不确定度区间位于容许区间外，此时基于测得值进行判定，情况 B 由于扩展测量不确定度较大，错误接受的风险就较高。

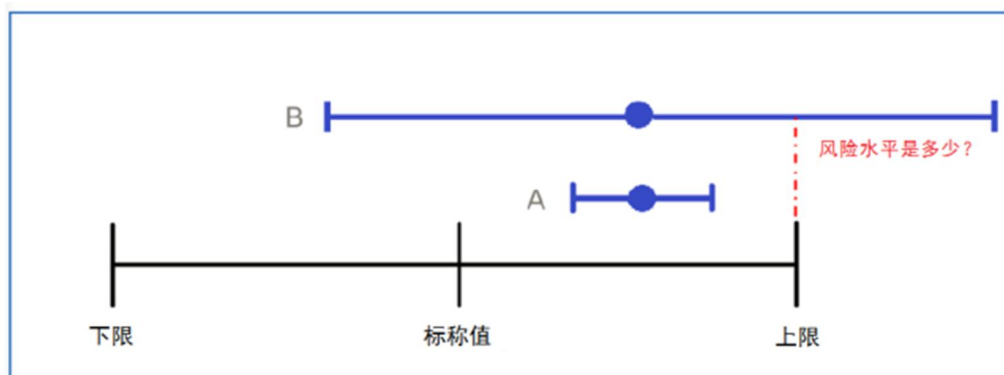


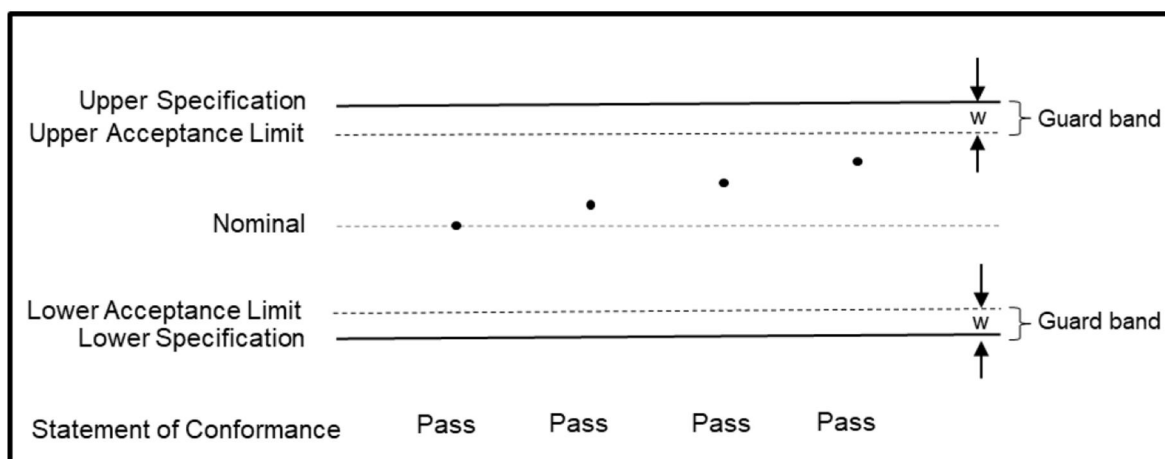
图 1 判定风险图示

3. The function of Guard Band (ILAC-G8:09/2019)

The use of guard bands can reduce the probability of making an incorrect conformance decision. It is basically a safety factor built into the measurement decision process by reducing the acceptance limit below that of the specification/tolerance limit. This is often done to account for measurement uncertainty as is described later in this section.

This guidance document refers to Guard Bands where the length of the Guard Band (w) is the Tolerance/specification Limit (TL) minus the Acceptance Limit (AL) or $w = TL - AL$. This means that if the measurement result is below the Acceptance Limit (AL), then the measurement is accepted as conforming to specification. See Figure 2 below.

With guard band terminology there are often upper and lower limits for a tolerance.



保护带的作用 (CNAS-GL015:2022)

采用保护带将接受限调整到容许区间内，可以降低做出错误接受的概率。保护带长度 w 是容许限 (TL) 和接受限 (AL) 的差值 ($w = |TL - AL|$)，通常选取扩展测量不确定度 (即 $w = U$)。如果测得值在接受区间内，则做出符合规范/标准的判定，如图 2 所示。

容许限通常包含容许上限和容许下限，对应的接受限包含接受上限和接受下限。

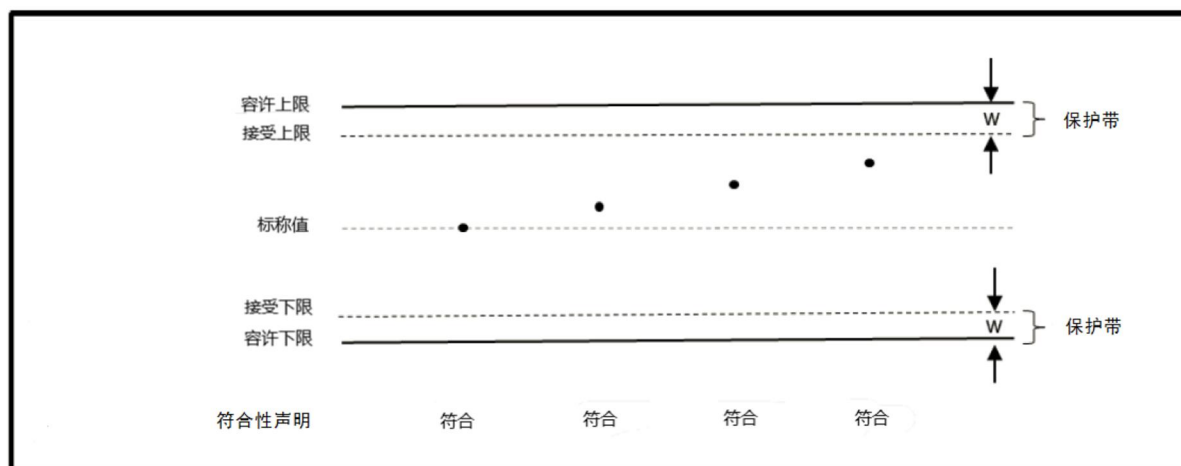


图2 保护带图示

4. Common Types of Decision Rules

判定规则的常见种类

Note1:

This section doesn't include any specific decision rules in laws, standards, scheme, customer etc.

备注 1:

这部分内容不包括法律，标准，认证方案，客户等规定的特别的判定规则。

Note2:

If the acceptance limit is set as " \leq " (such as "not exceeding" or "MAX") or " \geq " (such as "not less than" or "MIN"), then "Pass" includes the situation that measured value is equal to the limit, and "Fail" doesn't include the situation that measured value is equal to the limit;

If the acceptance limit is set as " $<$ " (such as "less than") or " $>$ " (such as "more than"), then "Pass" doesn't include the situation that measured value is equal to the limit, and "Fail" include the situation that measured value is equal to the limit.

备注 2:

当接受限设定为" \leq "（如“不大于”或“最大值”）或" \geq "（如“不小于”或“最小值”），则“通过”包含测量结果等于限值的情况，“不通过”不包含测量结果等于限值的情况；

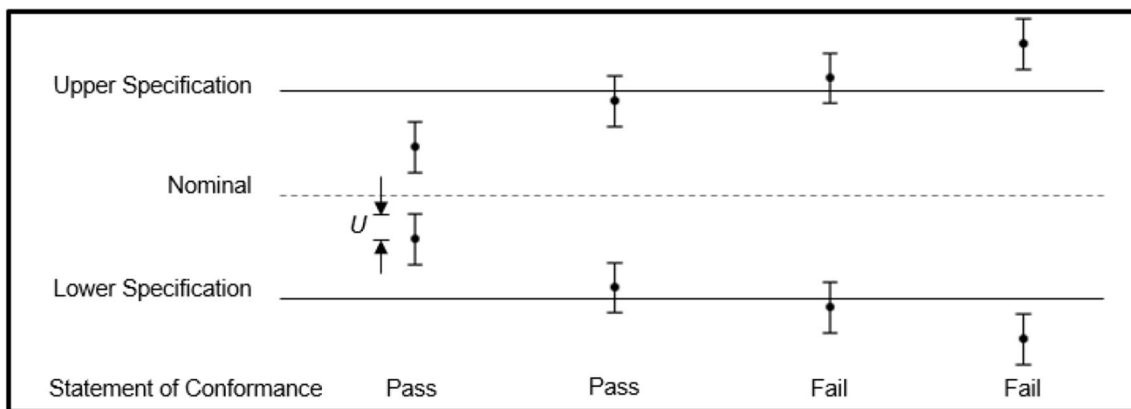
当接受限设定为" $<$ "（如“小于”）或" $>$ "（如“大于”），则“通过”不包含测量结果等于限值的情况，“不通过”包含测量结果等于限值的情况；

(1) Binary Statement for Simple Acceptance Rule ($w = 0$) (ILAC-G8:09/2019)

A guard band which has a length equal to zero, $w = 0$, infers that acceptance is when a measurement result is below a tolerance limit. This is called simple acceptance. Simple acceptance is also called "shared risk" because the probability to be outside the tolerance limit may be as high as 50% in the case when a measurement result is exactly on the tolerance limit (assuming a symmetric normal distribution of the measurements).

Statements of conformity are reported as:

- Pass - the measured value is below the acceptance limit, $AL = TL$.
- Fail - the measured value is above the acceptance limit, $AL = TL$.

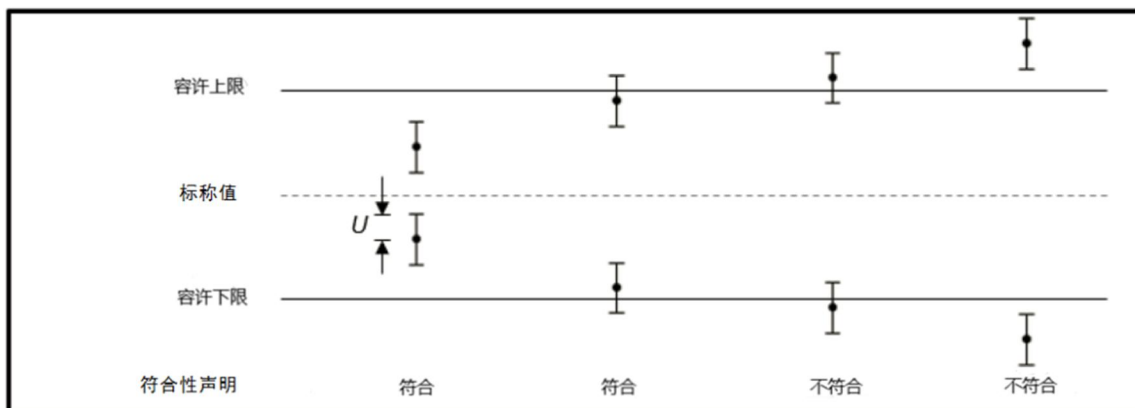


简单接受 ($w = 0$) 的二元判定规则 (CNAS-GL015:2022)

保护带长度为 0（即 $w = 0$ ）时，意味着测得值落在容许区间内就判为符合，这种判定方式叫简单接受，也叫“风险共担”。被测量值服从对称正态分布时，当测得值正好落在容许限上时，做出错误判定的概率高达 50%。

如图 3 所示，此时接受限等于容许限 $AL = TL$ 。测得值有两种情况，对应的符合性声明为：

- 符合（接受）——测得值位于容许区间以内。
- 不符合（拒绝）——测得值位于容许区间以外。



$U = 95\%$ 扩展测量不确定度

图 3 二元判定规则图示——简单接受

(2) Accuracy Method (IEC guide 115:2021)

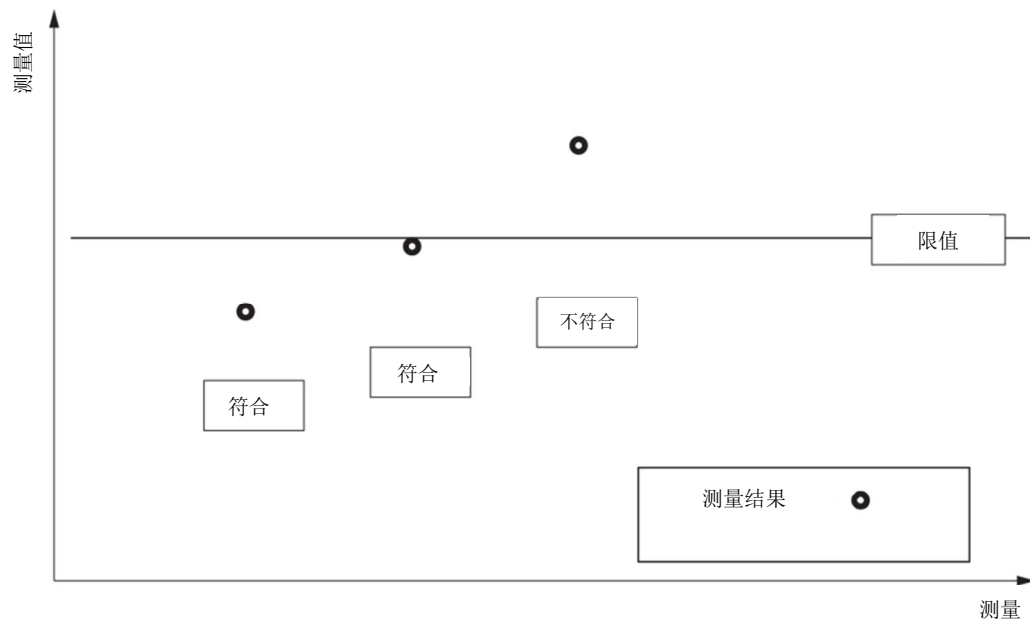
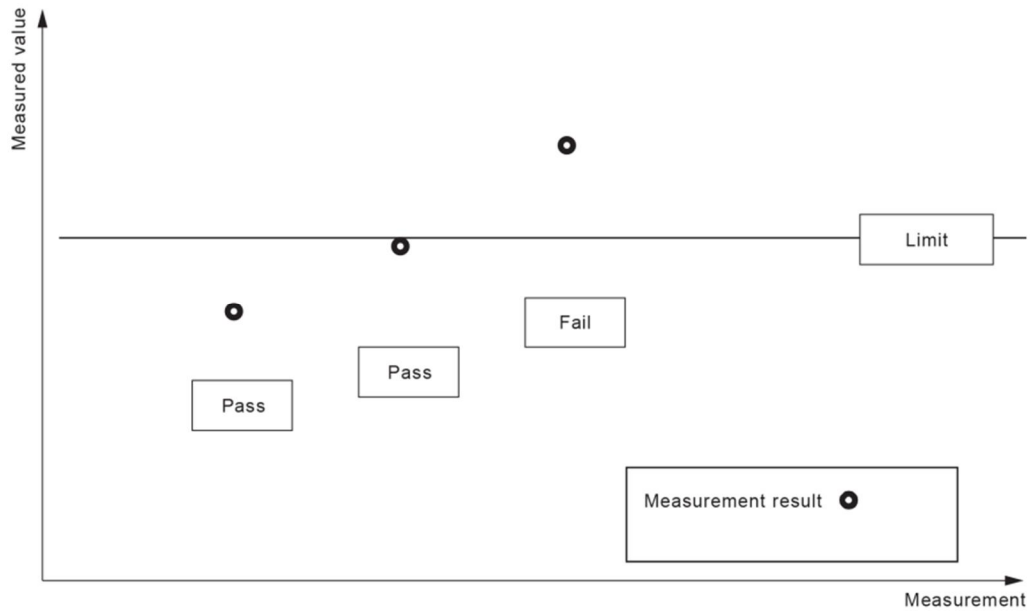
The test performed is routine. Sources of uncertainty are minimized so that the uncertainty of the measurement need not be calculated to determine conformance with the limit. Variability in test parameters is within acceptable limits. Test parameters such as power source voltage, ambient temperature and ambient humidity are maintained within the defined acceptable limits for the test. Personnel training and laboratory procedures minimize uncertainty of measurement due to human factors. Instrumentation used has an uncertainty within prescribed limits.

Accuracy method also belongs to “Simple acceptance rule ($w = 0$)”.

准确度方法 (IEC guide 115:2021 中文翻译)

进行的测试是例行的。不确定度的来源被最小化，因此不需要计算测量的不确定度来确定是否符合限值。测试参数的可变性在可接受的范围内。电源电压、环境温度和环境湿度等测试参数保持在规定的测试可接受范围内。人员培训和实验室程序将人为因素造成的测量不确定性降至最低。使用的仪器在规定限度内具有不确定性。

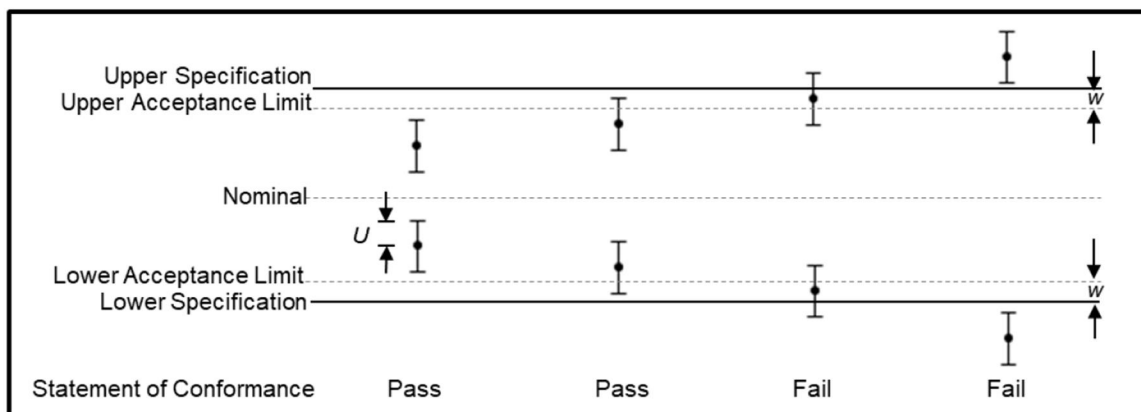
准确度方法也属于“简单接受判定规则($w = 0$)”。



(3) Binary Statement with Guard Band (ILAC-G8:09/2019)

Statements of conformity are reported as:

- Pass - acceptance based on guard band; the measurement result being below the acceptance limit, $AL = TL - w$.
- Fail - rejection based on guard band; if the measurement result is above the acceptance limit, $AL = TL - w$.



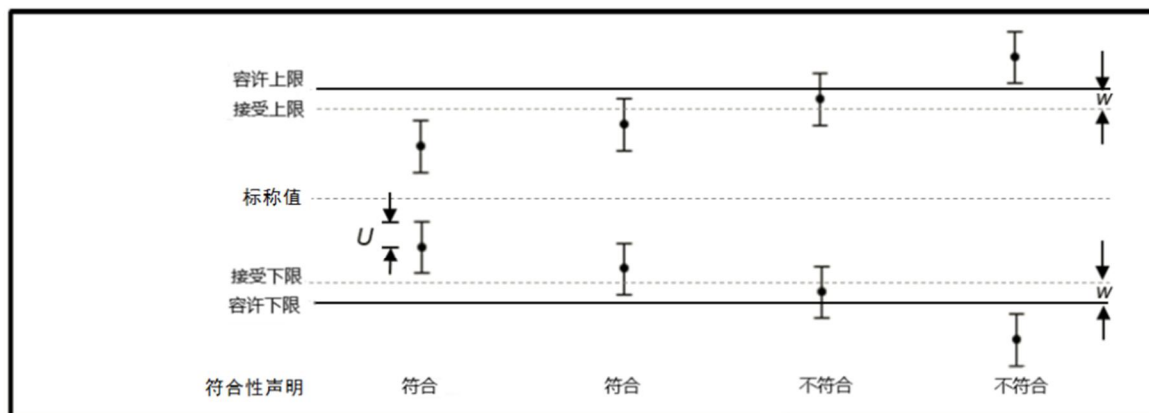
$U = 95\%$ expanded measurement uncertainty

有保护带的二元判定规则 (CNAS-GL015:2022)

如图 4 所示，此时接受区间是容许区间的一部分，接受上限等于容许上限减去保护带，接受下限等于容许下限加上保护带。测得值有两种情况，对应的符合性声明为：

符合（接受）——基于保护带接受；测得值位于接受区间以内。

不符合（拒绝）——基于保护带拒绝；测得值位于接受区间以外。



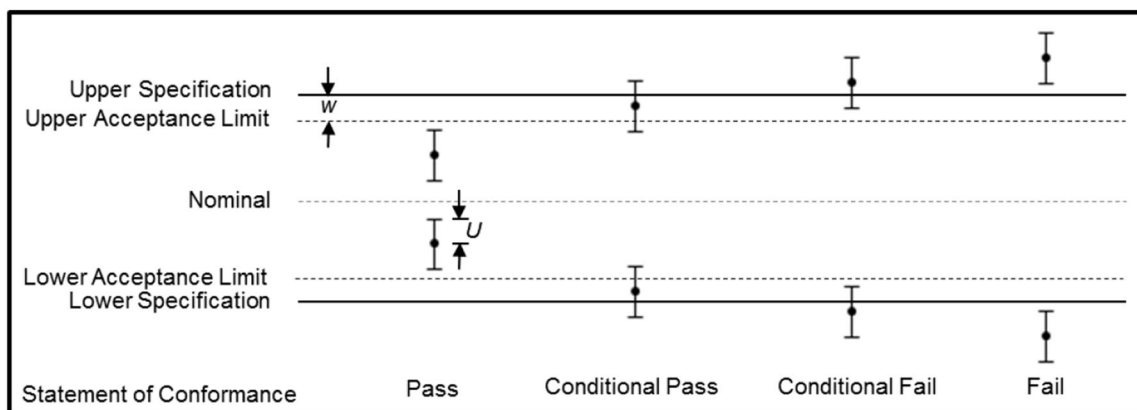
$U = 95\%$ 扩展测量不确定度

图 4 有保护带的二元判定规则图示 ($w = U$)

(4) Non-binary Statement with Guard Band (ILAC-G8:09/2019)

Statements of conformity are reported as:

- Pass - the measured result is below the acceptance limit, $AL = TL - w$.
- Conditional Pass - the measured result is inside the guard band and below the tolerance limit, in the interval $[TL - w, TL]$.
- Conditional Fail - the measured result is above the tolerance limit but below the tolerance limit added to the guard band, in the interval $[TL, TL + w]$.
- Fail - the measured result is above the tolerance limit added to the guard band, $TL + w$.



$U = 95\%$ expanded measurement uncertainty

有保护带的非二元判定规则 (CNAS-GL015:2022)

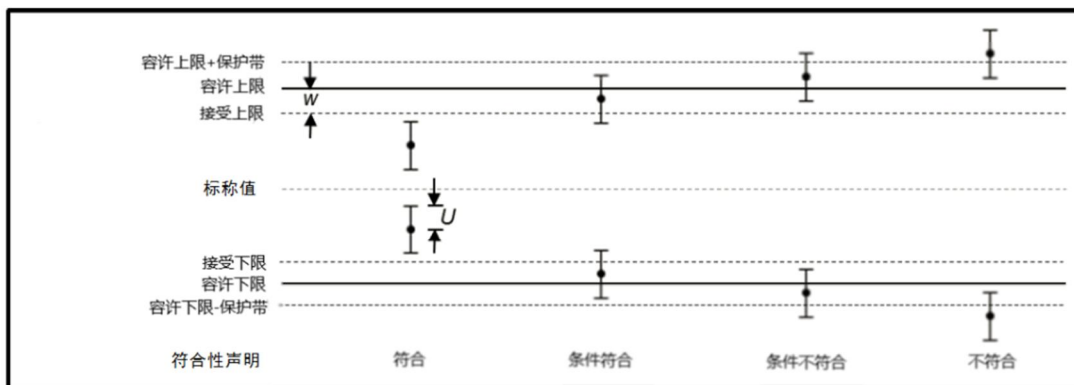
如图 5 所示，此时接受区间是容许区间的一部分，接受上限等于容许上限减去保护带，接受下限等于容许下限加上保护带，测得值有四种情况，对应的符合性声明为：

符合（接受）——测得值在接受区间内。

条件符合（条件接受）——测得值在接受区间以外，但在容许区间以内。

条件不符合（条件拒绝）——测得值在容许区间以外，但在容许区间叠加保护带以内。

不符合（拒绝）——测得值位于容许区间叠加保护带以外。



$U = 95\%$ 扩展测量不确定度

图5 有保护带的非二元判定规则图示 (图中 $w = U$)

5. Measurement Uncertainty Taken Directly into Account (ILAC-G8:09/2019)

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.

While it is common to use a guard band $w = U$, there may be cases where a multiplier other than 1 is more appropriate. Table 1 provides examples of different guard bands to achieve certain levels of specific risk, based on the customer application.

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

Table 1. PFA – Probability of False Accept and PFR – Probability of False Reject (Assumes a single sided specification and normal distribution of measurement results)

直接考虑测量不确定度 (CNAS-GL015:2022)

直接考虑测量不确定度时，通常会采用有保护带的判定规则，且保护带长度 w 是扩展测量不确定度 U 的倍数 ($w = rU$)。对于二元判定规则，接受限 ($AL = TL - w$) 以内的测得值是可以判为合格的。

对于不同的判定情况，实验室可以采用不同长度的保护带。表 2 是几种不同长度的保护带对应的特定风险水平。

表 2 不同保护带对应的特定风险（单侧容许限且假设被测量值服从正态分布）

判定规则	保护带长度 w	特定风险
6σ	$3U$	错误接受率: <0.0001%
3σ	$1.5U$	错误接受率: <0.16%
ILAC G8 规则	U	错误接受率: <2.5%
ISO 14253-1:2017	$0.83U$	错误接受率: <5%
简单接受	0	错误接受率: <50%
宽松的判定规则	$-U$	测得值大于 $AL = TL + w$ 时判为不符合, 错误拒绝率: <2.5%
客户指定	rU	由客户指定的任意倍数 r , 风险与 r 的大小有关

6. Sequence of Selection of Decision Rule

- (1) Required by legal regulations
- (2) Required by standards
- (3) Required by schemes or relevant recognized bodies
- (4) Required by the customer
 - a. Use Zero guard band, $w = 0$: Simple Acceptance Rule, or Accuracy Method; See above section 4(1) and 4(2)
 - b. Use non-Zero guard band $w = rU, r=1$; See above section 4(3), 4(4)
 - c. Use non-Zero guard band $w = rU, r\neq 1$; See above section 4(3), 4(4)
 - d. Other

判定规则的选择次序

- (1) 法律法规要求
- (2) 标准要求
- (3) 认证方案或相关承认机构的要求
- (4) 客户的要求
 - a. 使用零保护带的判定规则, $w = 0$: 简单接受判定规则, 或准确度方法; 见上述 4(1)和 4(2)
 - b. 使用非零保护带的判定规则, $w = rU, r=1$; 见上述 4(3), 4(4)
 - c. 使用非零保护带的判定规则, $w = rU, r\neq 1$; 见上述 4(3), 4(4)
 - d. 其他

Bibliography 参考文献

- [1] ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories 检测和校准实验室能力的通用要求
- [2] CNAS-CL01 检测和校准实验室能力认可准则 (ISO/IEC 17025:2017) Accreditation criteria for the competence of testing and calibration laboratories
- [3] ISO/IEC GUIDE 99:2007 International vocabulary of metrology — Basic and general concepts and associated terms (VIM) 国际计量学词汇 – 基础通用的概念和相关术语 (VIM)
- [4] JJF 1001-2011 通用计量术语及定义 General Terms in Metrology and Their Definitions
- [5] ISO/IEC guide 98-3:2008 Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995) 测量不确定度 – 第 3 部分: 测量不确定度的表示指南 (GUM:1995)
- [6] ILAC-G8:09/2019 Guidelines on Decision Rules and Statements of Conformity 判定规则和符合性声明的指南
- [7] IEC guide 115:2021 Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector 测量不确定度在电气技术领域的符合性评估活动中的应用
- [8] CNAS-GL015:2022 判定规则和符合性声明指南 Guidelines on Decision Rules and Statements of Conformity