

Decision Rules Related to ISO/IEC 17025:2017 (มอก. 17025-2561)

พล.อ.ต. ดร. เพ็ชร โตทำโรง

กรรมการที่ปรึกษา สมาคมมาตรวิทยาแห่งประเทศไทย

๒๓ กันยายน ๒๕๖๒

ลำดับการบรรยาย

1. กล่าวนำ แนวคิดของระบบคุณภาพที่เปลี่ยนไปจากเดิม
2. Decision rule, ISO/IEC 17025:2017
3. Compliance with specification, ILAC-G08:1996 (Rev. 2009)
4. Uncertainty info. in compliance assess. EURACHEM/CITAC 2007
4. The role of measurement uncertainty in conformity assessment ,
BIPM-JCGM 106:2012
5. Decision rules applied to conformity assessment, EUROLAB-
Technical Report No. 01/2017
6. Uncertainty in conformity assess. decisions, OIML G 19:2017
7. Decision rules and statements of conformity, ILAC-G08:09/2019

Change of Thinking/Approach

ISO/IEC 17025:2005 ==> rule-based approach/thinking.

ISO/IEC 17025:2017 ==> **risk-based** approach/thinking.

What is risk ?

ISO Guide 73:2009, Risk management - Vocabulary

Clause 1 Terms related to risk

1.1 risk

effect of uncertainty on objectives.

Notes - An effect is a deviation from the expected- positive and/or negative.

- Risk is often expressed in terms of a combination of the consequences of an event and the associated likelihood of occurrence.
- Uncertainty is the state of deficiency of information related to, understanding/knowledge of, an event, its consequence, or likelihood.
- Objectives = **Expected results** (ISO 9001:2015)

Decision Rule: ISO/IEC 17025:2017

Clause 3 Terms and definitions

3.7 decision rule

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

ความสัมพันธ์ของ Risk - Uncertainty - Decision Rule

Decision rule => measurement uncertainty => conformity of result

Risk => measurement uncertainty => expected result

Decision rule => level of risk => conformity of result (compliance with specification)

Decision Rule: ISO/IEC 17025:2017

Clause 5 Structural Requirements

5.3 The lab. shall define and **document** the range of **lab. activities** for which it **conforms** with **this document**. The lab. shall **only claim conformity** with **this document** for this range of **lab. activities**,

Decision Rule: ISO/IEC 17025:2017

Clause 6 Resource requirements

6.2 Personnel

6.2.6 The lab. shall authorize personnel to perform specific lab. activities,

b) Analysis of results, including **statements of conformity** or opinions and interpretations;

Decision Rule: ISO/IEC 17025:2017

Clause 7 Process requirements

7.1 Review of requests, tenders and contracts

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-tolerance), ... the **decision rule** shall be clearly defined. Unless inherent in the requested specification or standard, the **decision rule selected** shall be communicated to, an agreed with, the customer.

Decision Rule: ISO/IEC 17025:2017

7.8 Reporting of results

7.8.3 Specific requirements for test reports

7.8.3.1 Test reports shall, where necessary for the interpretation of the test results, include the following: ...

c) Where applicable, the **measurement uncertainty** present in the same unit as that of the measurand or in a term relative to measurand (e.g. percent) when:

- It is relevant to the validity or application of the test results.
- The **measurement uncertainty** affects **conformity** to a specification limit.

Decision Rule: ISO/IEC 17025:2017

7.8.6 Reporting statements of conformity

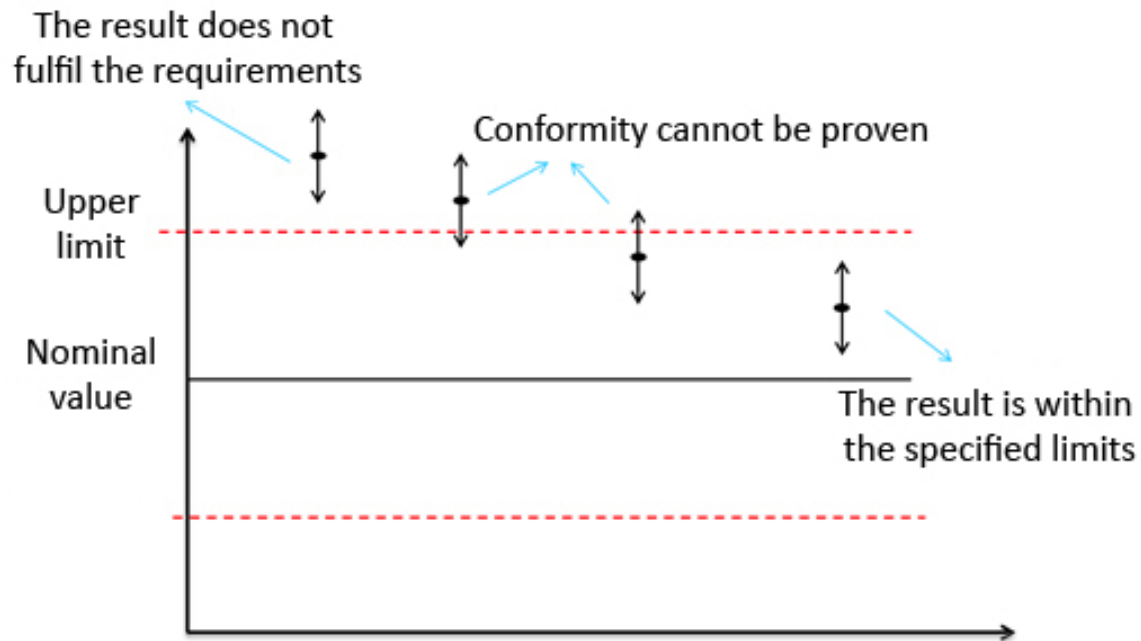
7.8.6.1 When a statement of conformity to a specification or standard is provided, the lab. shall document the **decision rule** employed, taking into account the **level of risk** (false accept and false reject and statistical assumptions) associated with the **decision rule** employed and apply the **decision rule**.

Decision Rule: ISO/IEC 17025:2017

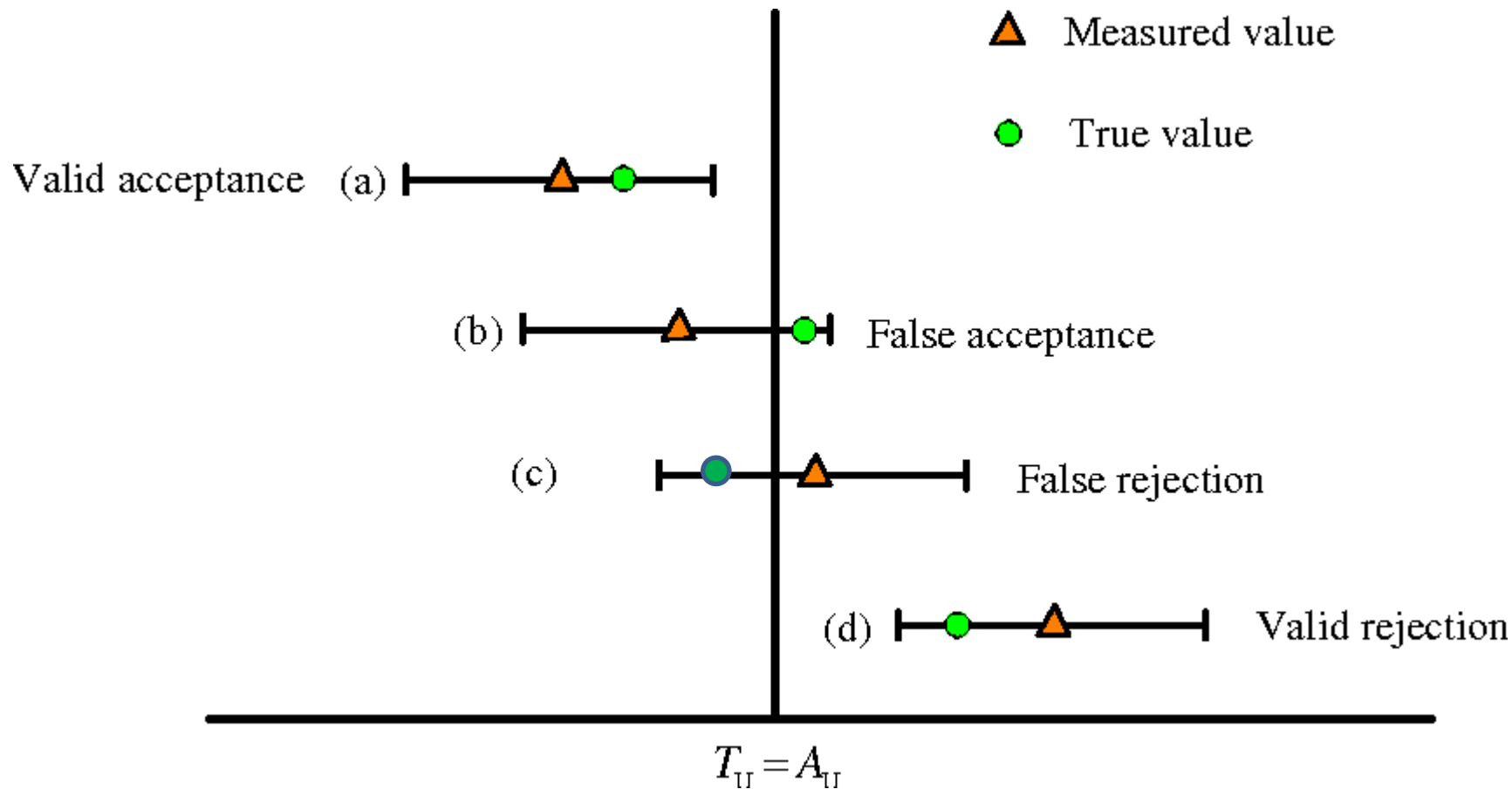
7.8.6.2 The lab. shall report on the **statement of conformity**, such that the statement clearly identifies:

c) The **decision rule** applied (unless it is inherent in the requested specification or standard).

ILAC-G08:2009 uses the measurement with 95% coverage interval in conformity assessment.

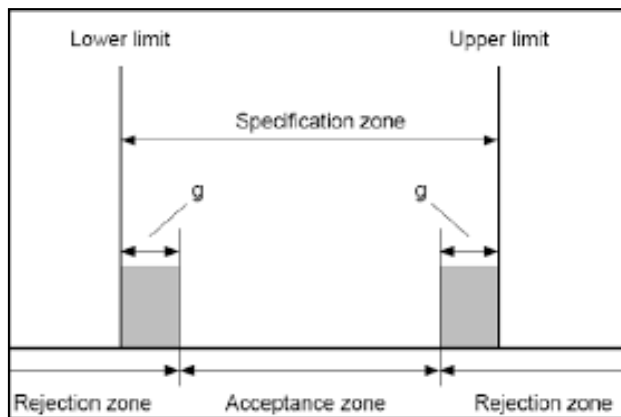
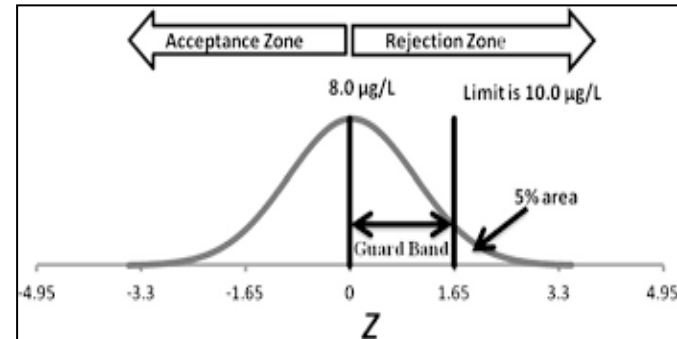
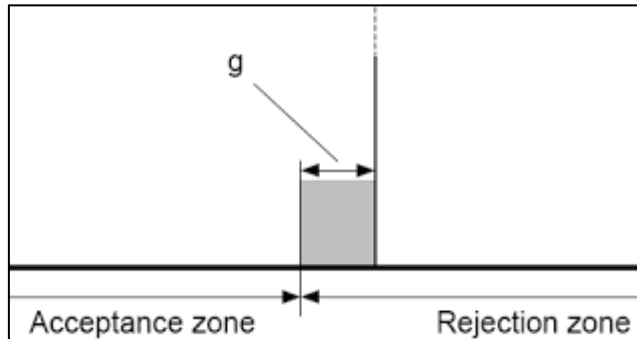


ILAC-G08:2009 uses the measurement with 95% coverage interval in conformity assessment.



EURACHEM/CITAC Guide : 2007, Use of uncertainty information in compliance assessment

(Guard band decision rules, High confidence of correct acceptance)

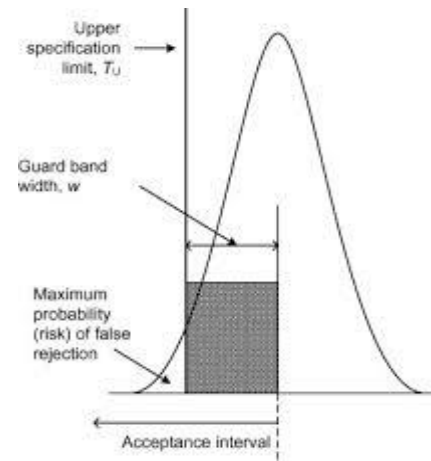
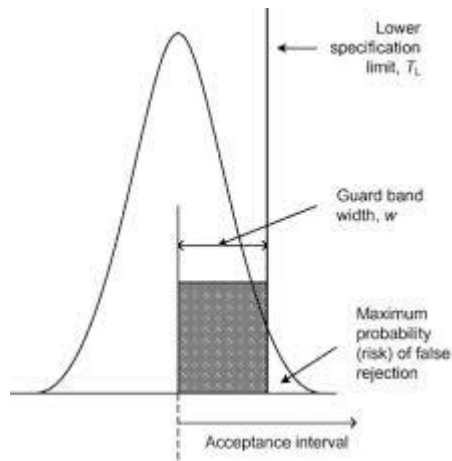
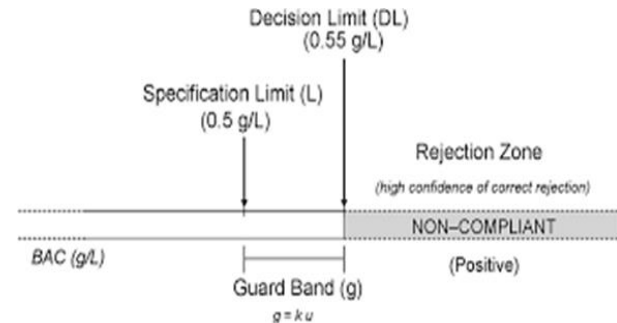


Focusing on correct acceptance,
Low risk of false acceptance,
Guarded acceptance

$g = 1.64 u \rightarrow 5\%$ false acceptance
 $g = 2.33 u \rightarrow 1\%$ false acceptance

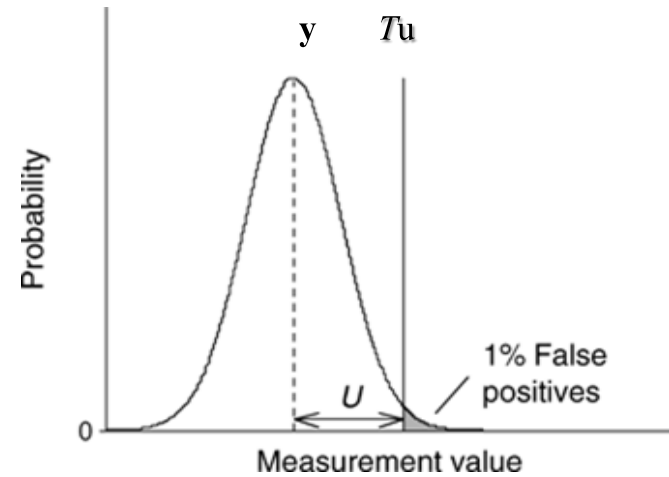
EURACHEM/ CITAC :2007, Decision rules based on guard bands (High confidence of correct rejection)

Focusing on correct rejection,
low risk of false rejection,
guarded rejection



One-Tailed Standard Normal Distribution

z	$\Phi(z)$	% Coverage Interval	% False Acceptance
0.84	0.8	80	20
1.00	0.841	84.1	15.9
1.28	0.9	90	10
1.64	0.95	95	5
1.96	0.975	97.5	2.5
2.33	0.99	99	1
3.08	0.999	99.9	0.1



$\Phi(z)$ = Cumulative Standard Normal Distribution from $-\infty$ to Z

= NORM.S.DIST(z , TRUE) , EXCEL Spread Sheet

$$z = (Tu - y) / u$$

u = Standard Uncertainty, U = Expanded Uncertainty

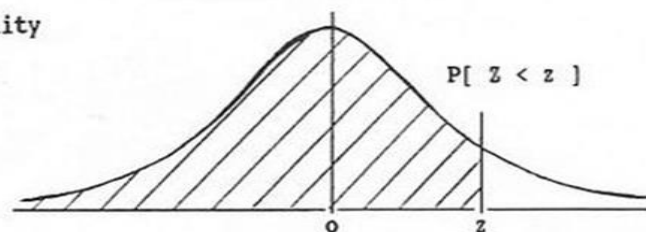
Tu = Upper Specification Limit

STANDARD STATISTICAL TABLES

Areas under the Normal Distribution

The table gives the cumulative probability up to the standardised normal value z i.e.

$$P[Z < z] = \int_{-\infty}^z \frac{1}{\sqrt{2\pi}} \exp(-\frac{1}{2}z^2) dz$$



z	0.00	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09
0.0	0.5000	0.5040	0.5080	0.5120	0.5159	0.5199	0.5239	0.5279	0.5319	0.5359
0.1	0.5398	0.5438	0.5478	0.5517	0.5557	0.5596	0.5636	0.5675	0.5714	0.5753
0.2	0.5793	0.5832	0.5871	0.5910	0.5948	0.5987	0.6026	0.6064	0.6103	0.6141
0.3	0.6179	0.6217	0.6255	0.6293	0.6331	0.6368	0.6406	0.6443	0.6480	0.6517
0.4	0.6554	0.6591	0.6628	0.6664	0.6700	0.6736	0.6772	0.6808	0.6844	0.6879
0.5	0.6915	0.6950	0.6985	0.7019	0.7054	0.7088	0.7123	0.7157	0.7190	0.7224
0.6	0.7257	0.7291	0.7324	0.7357	0.7389	0.7422	0.7454	0.7486	0.7517	0.7549
0.7	0.7580	0.7611	0.7642	0.7673	0.7704	0.7734	0.7764	0.7794	0.7823	0.7854
0.8	0.7881	0.7910	0.7939	0.7967	0.7995	0.8023	0.8051	0.8078	0.8106	0.8133
0.9	0.8159	0.8186	0.8212	0.8238	0.8264	0.8289	0.8315	0.8340	0.8365	0.8389
1.0	0.8413	0.8438	0.8461	0.8485	0.8508	0.8531	0.8554	0.8577	0.8599	0.8621
1.1	0.8643	0.8665	0.8686	0.8708	0.8729	0.8749	0.8770	0.8790	0.8804	0.8830
1.2	0.8849	0.8869	0.8888	0.8907	0.8925	0.8944	0.8962	0.8980	0.8997	0.9015
1.3	0.9032	0.9049	0.9066	0.9082	0.9099	0.9115	0.9131	0.9147	0.9162	0.9177
1.4	0.9192	0.9207	0.9222	0.9236	0.9251	0.9265	0.9279	0.9292	0.9306	0.9319
1.5	0.9332	0.9345	0.9357	0.9370	0.9382	0.9394	0.9406	0.9418	0.9429	0.9441
1.6	0.9452	0.9463	0.9474	0.9484	0.9495	0.9505	0.9515	0.9525	0.9535	0.9545
1.7	0.9554	0.9564	0.9573	0.9582	0.9591	0.9599	0.9608	0.9616	0.9625	0.9633
1.8	0.9641	0.9649	0.9656	0.9664	0.9671	0.9678	0.9686	0.9693	0.9699	0.9706
1.9	0.9713	0.9719	0.9726	0.9732	0.9738	0.9744	0.9750	0.9756	0.9761	0.9767
2.0	0.9773	0.9778	0.9783	0.9788	0.9793	0.9798	0.9803	0.9808	0.9812	0.9817
2.1	0.9821	0.9826	0.9830	0.9834	0.9838	0.9842	0.9846	0.9850	0.9854	0.9857
2.2	0.9861	0.9865	0.9868	0.9871	0.9874	0.9878	0.9881	0.9884	0.9887	0.9890
2.3	0.9893	0.9896	0.9898	0.9901	0.9904	0.9906	0.9909	0.9911	0.9913	0.9916
2.4	0.9918	0.9920	0.9922	0.9924	0.9927	0.9929	0.9931	0.9932	0.9934	0.9936
2.5	0.9938	0.9940	0.9941	0.9943	0.9945	0.9946	0.9948	0.9949	0.9951	0.9952
2.6	0.9953	0.9955	0.9956	0.9957	0.9959	0.9960	0.9961	0.9962	0.9963	0.9964
2.7	0.9965	0.9966	0.9967	0.9968	0.9969	0.9970	0.9971	0.9972	0.9973	0.9974
2.8	0.9974	0.9975	0.9976	0.9977	0.9977	0.9978	0.9979	0.9980	0.9980	0.9981
2.9	0.9981	0.9982	0.9982	0.9983	0.9984	0.9984	0.9985	0.9985	0.9986	0.9986
z	3.00	3.10	3.20	3.30	3.40	3.50	3.60	3.70	3.80	3.90
P	0.9986	0.9990	0.9993	0.9995	0.9997	0.9998	0.9998	0.9999	0.9999	1.0000

BIPM-JCGM 106:2012, Evaluation of measurement data- The role of measurement uncertainty in conformity assessment

Clause 3 Terms and definitions

3.3 Terms related to conformity assessment

3.3.11 guard band

interval between a tolerance limit and a corresponding acceptance limit.

BIPM-JCGM 106:2012

3.3.12 decision rule

documented rule that describes how **measurement uncertainty** will be accounted for with regard to **accepting or rejecting an item**, given a specified requirement and the result of a measurement.

BIPM-JCGM 106:2012

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documented rule that describes how **measurement uncertainty** will be accounted for with regard to **accepting or rejecting an item**, given a specified requirement and the result of a measurement.

Single Upper Tolerance Limit

$P_C = \Phi((T_u - y)/u)$ = conformity
probability

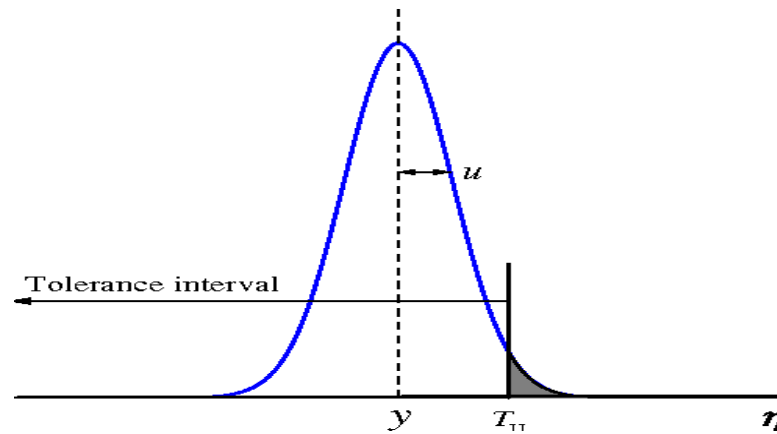


Figure shows upper tolerance limit and rejection zone

Single Lower Tolerance Limit

$$P_c = 1 - \Phi((T_L - y)/u) = \text{conformity probability}$$

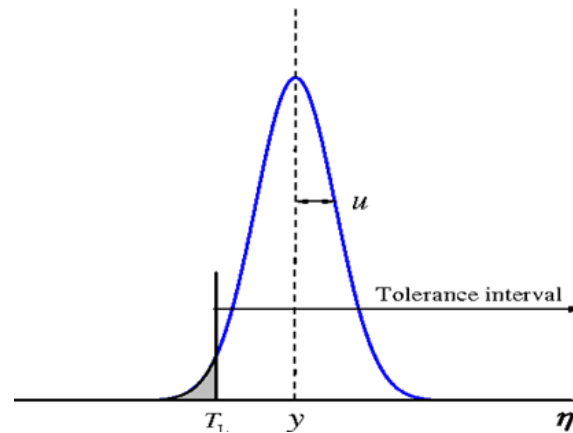


Figure shows single lower tolerance limit, T_L

$$P_c = \Phi((T_u - y)/u) - \Phi((T_L - y)/u)$$

= conformity probability

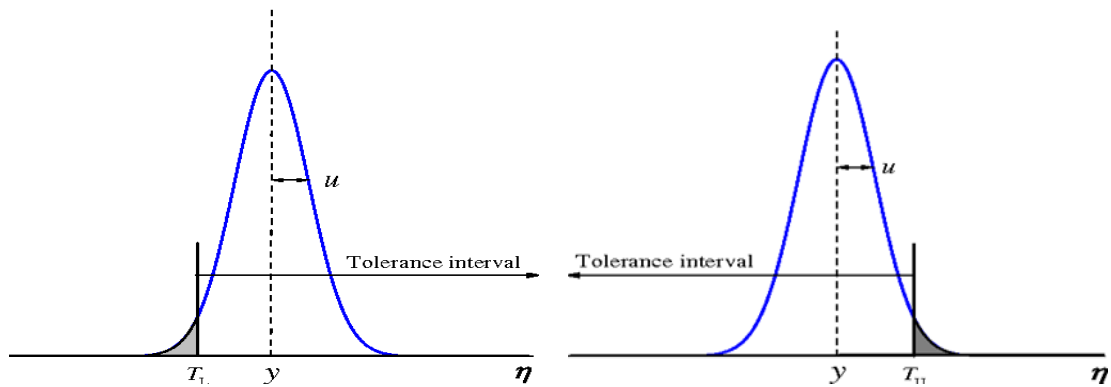


Figure shows lower tolerance limit, upper tolerance limit and rejection zone

BIPM-JCGM 102:2012

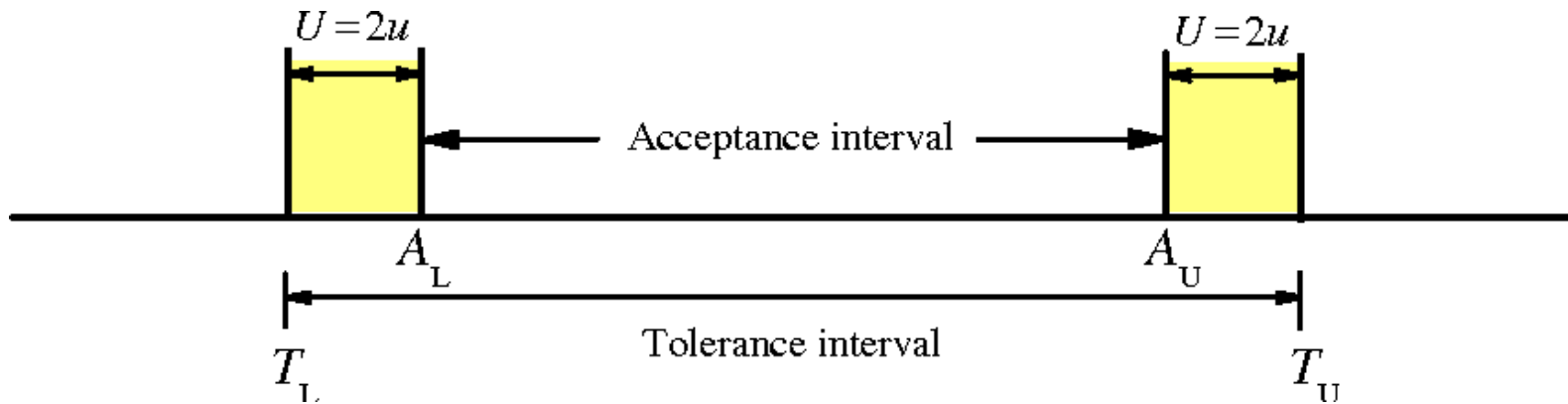


Figure shows Guard band (yellow area). Guarded acceptance decision rule reduces false acceptance of non-conforming item (consumer's risk).

BIPM-JCGM 106:2012

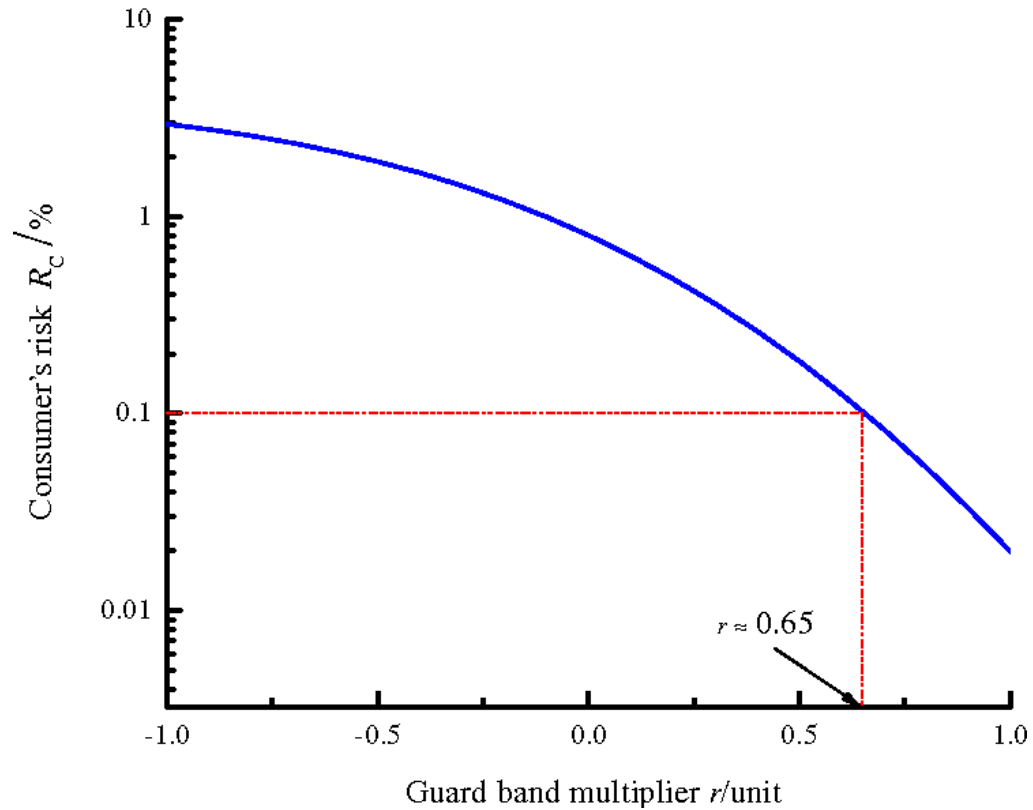


Figure shows consumer's risk vs guard band multiplier

BIPM-JCGM 106:2012

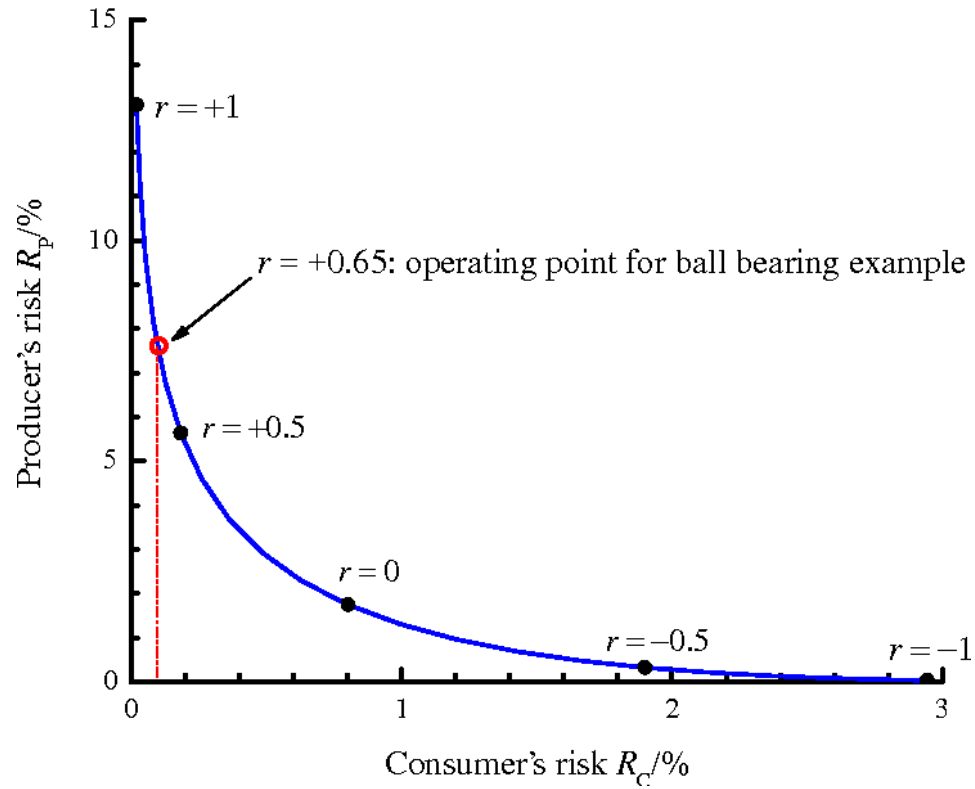
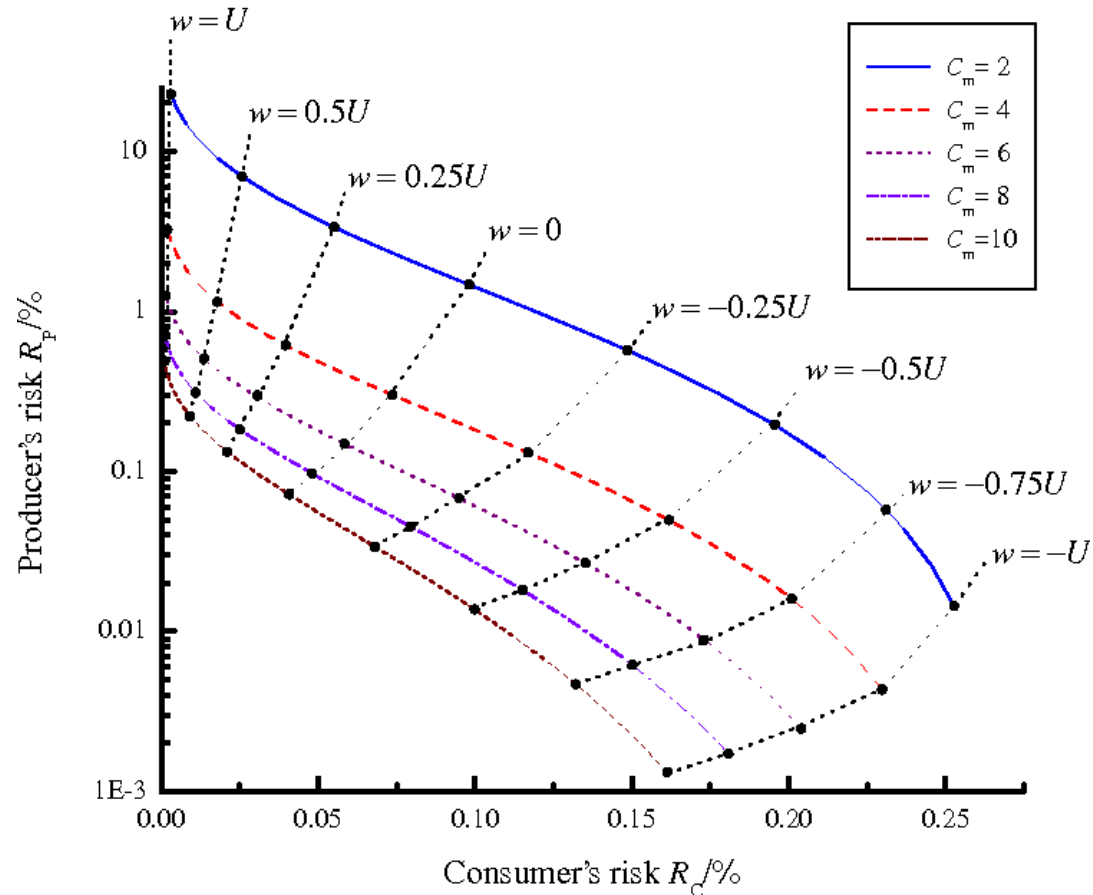


Figure shows relationship of consumer's and producer's risk

BIPM-JCGM 106:2012

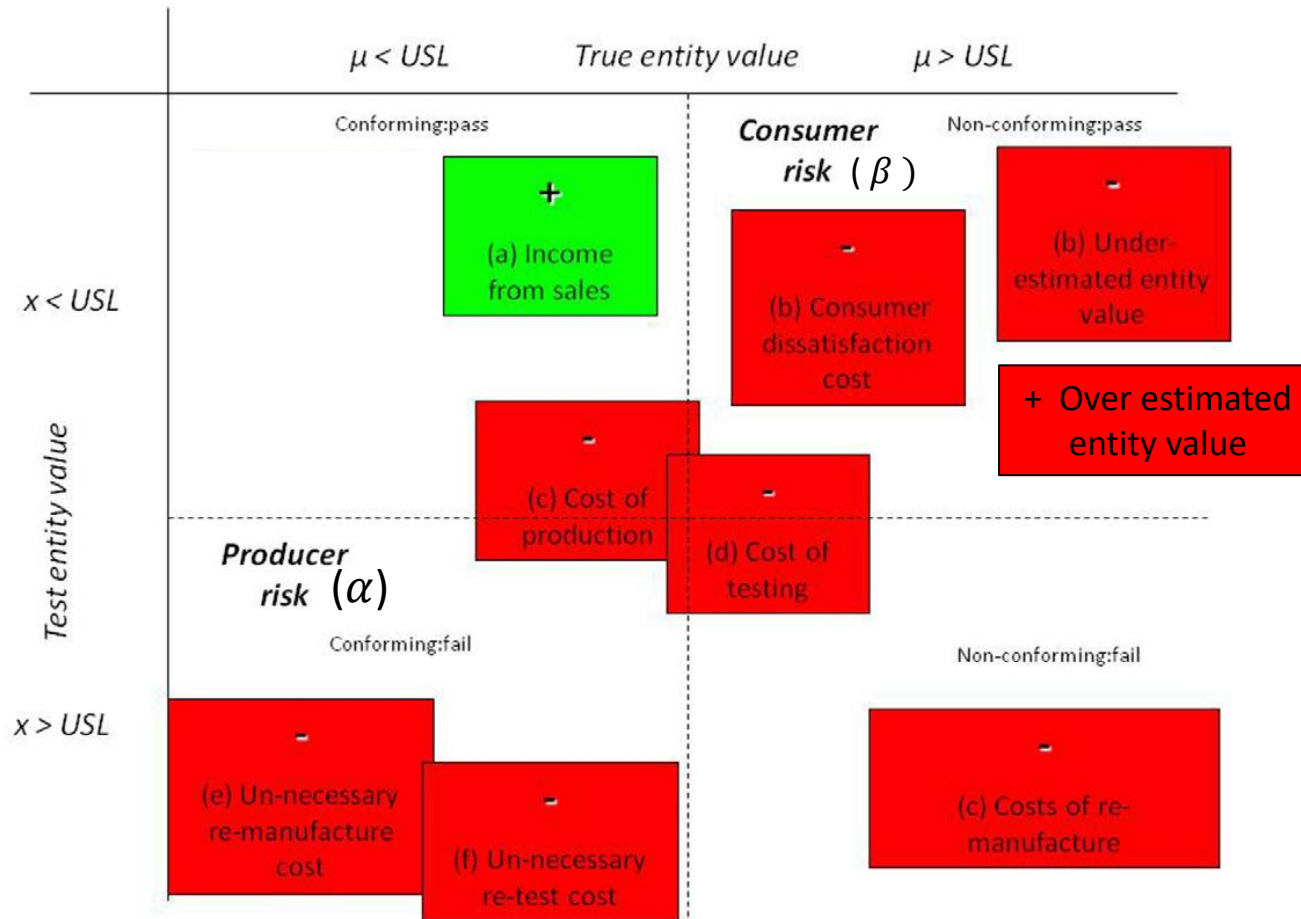


$$C_m = T / 4 u$$

Measurement Capability Index

u = standard measurement uncertainty

EUROLAB Tech. Report No. 01/2017, Decision rules applied to conformity assessment



Supplier income and cost due to conformity (adapted from L.R. Pendrill, 2007)

(True Value)	Decision (Test value)	
	Accept H_0	Reject H_0
H_0 (True)	Correct decision	Type I error (α error) (False positive, False rejection) Producer risk
H_0 (False)	Type II error (β error) (False negative, False acceptance) Consumer risk	Correct decision

Conformity probabilities related to correct/ incorrect decision

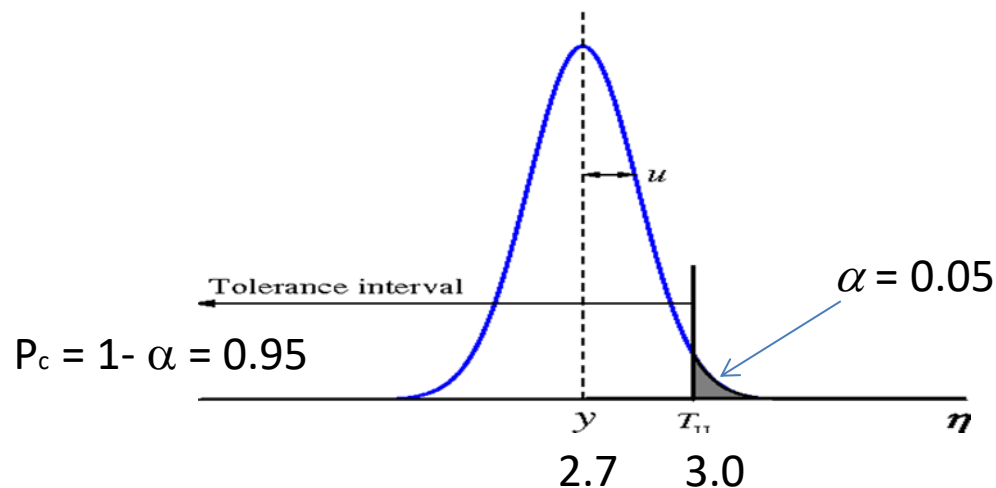
Example 1 : A measurement value $y = 2.7$ mm with a standard uncertainty, $u = 0.2$ mm, given a single tolerance upper limit, $T_U = 3.0$ mm, conformity spec. = 95 %, this entity is found to conform with the spec. or not?

Decision rule will be:

Acceptance if hypothesis $H_0 : \Pr(y \leq 3.0\text{mm})$ is true.

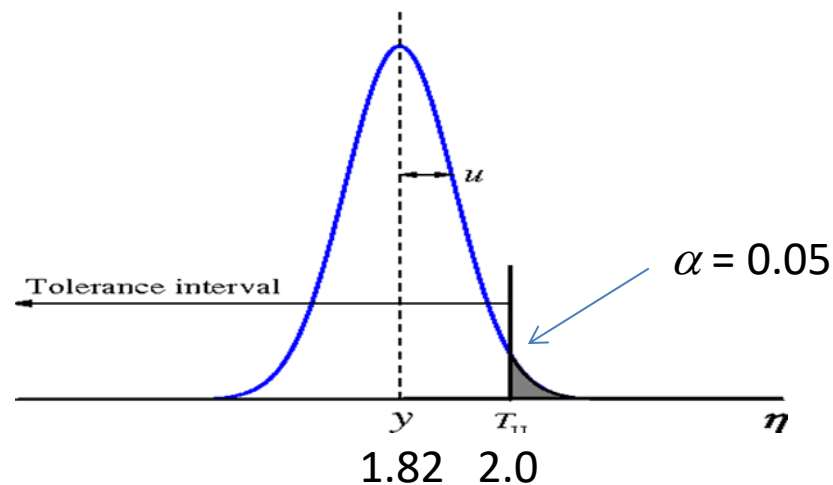
Conformity probability, $P_c = \Pr(y \leq T_U) = \Phi((T_U - y) / u) = \Phi((3.0 - 2.7) / 0.2) = \Phi(1.5) \approx 0.933$ (93.3%) < 0.95 (95%) . Then the hypothesis H_0 is false and the entity does not conform with the spec. (the decision is of non-conformity).

(Adapted from EUROLAB Tech. Report No.1/2017)



Example 2 : ในการทดสอบหาปริมาณ cadmium ในดินตกตะกอนได้ค่า $y = 1.82 \text{ mg/kg}$ โดยมีค่าความไม่แน่นอนของการวัด (standard uncertainty, u) = 0.1 mg/kg , กำหนดให้ค่า tolerance upper limit, $T_u = 2.0 \text{ mg/kg}$, กำหนดเกณฑ์การตัดสิน (conformity spec.) ที่ระดับความเชื่อมั่น 95 % ($\alpha=0.05$) ปริมาณ cadmium น้อยกว่าค่า upper limit , ถามว่าในการทดสอบหาปริมาณ cadmium ครั้งนี้ สามารถยอมรับได้หรือไม่ว่ามีค่าน้อยกว่าปริมาณที่กำหนด

หาค่า Conformity probability, $P_c = \Pr(y \leq T_u) = \Phi((T_u - y) / u) = \Phi((2.0 - 1.82) / 0.1) = \Phi(1.8) \approx 0.964 \text{ (96.4\%)} > 0.95 \text{ (95\%)}$ ดังนั้น ในการทดสอบครั้งนี้พบว่า มีค่า cadmium น้อยกว่าค่า upper limit ที่กำหนดด้วยค่าระดับความเชื่อมั่น 96.4 %
(from EURACHEM/CITAC leaflet , ver. 19: 2015)



การหาค่า decision limit โดยใช้ guard band

กรณี single upper tolerance limit

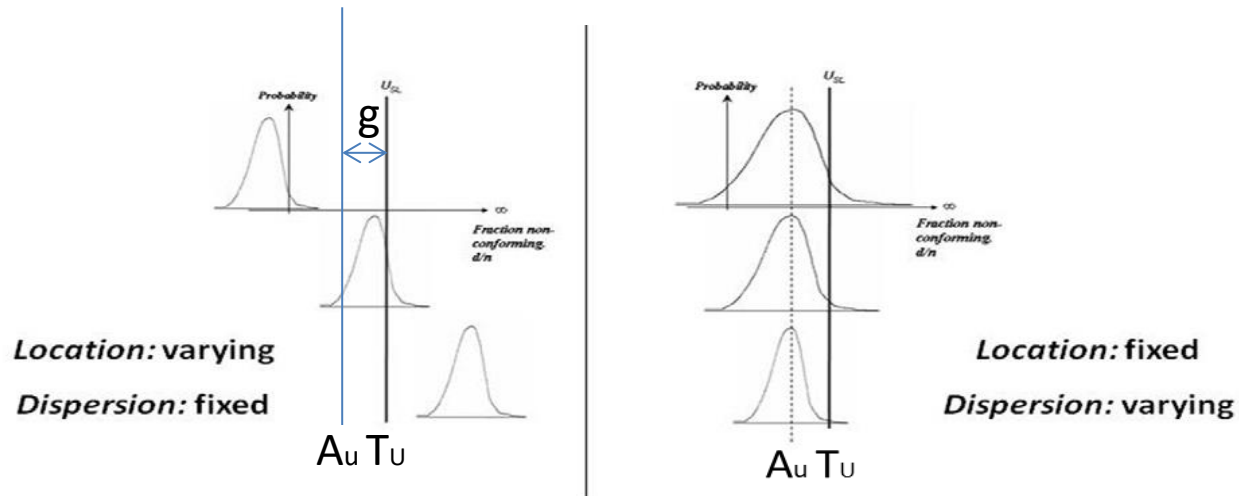
$$\Phi\left(\frac{T_U - y}{u}\right) = 1 - \alpha = \text{conformity probability}$$

$$\left(\frac{T_U - y}{u}\right) = \Phi^{-1}(1 - \alpha)$$

$$A_u = y = T_U - u \times [\Phi^{-1}(1 - \alpha)] \quad \text{where } g = \text{guard band} = u \times [\Phi^{-1}(1 - \alpha)]$$

A_u = decision limit

u = standard uncertainty



Example 3 : จากตัวอย่างที่ 2 จงหาค่า decision limit สำหรับการทดสอบที่ต้องการความเชื่อมั่นที่ระดับ 95% ว่ามีปริมาณ cadmium น้อยกว่า 2.0 mg/kg โดยใช้วิธีหาค่าขนาดของ guard band ที่ระดับความเชื่อมั่นที่กำหนด

$$\begin{aligned} \text{decision limit} &= T_U - u [\Phi^{-1} (1 - \alpha)] = 2.0 - 0.1 \text{ Inverse}[\Phi (1 - 0.05)] \\ &= 2.0 - 0.1 \times 1.64 = 1.836 \text{ mg/kg} \end{aligned}$$

ค่าปริมาณ cadmium ที่วัดได้เท่ากับ 1.82 mg/kg ดังนั้น **สรุป**ได้ว่าการทดสอบหาปริมาณ cadmium ในดินครั้งนี้พบว่า มีปริมาณน้อยกว่า upper limit ที่กำหนด (ตัวอย่างนี้เป็นกรณีของ guarded acceptance คือเพิ่มความเชื่อมั่นในการยอมรับการทดสอบ, **Guarded acceptance is the decision rule focusing on correct acceptance, low risk of false acceptance.**)

(Adapted from EURACHEM/ CITAC leaflet ver. 19: 2015)

Example 4: การหาปริมาณ alcohol ในเลือด กำหนดให้ expanded uncertainty = 0.013 mg/g, $k = 2$ (95 % level of confidence) จงหาค่า decision limit ที่ระดับความเชื่อมั่น 99.9 % ว่าเกินที่กฎหมายกำหนด (upper permitted limit) 0.2 mg/g
ใช้วิธีการคำนวณหาความกว้างของ guard band ดังนี้

standard uncertainty, $u = 0.013 / 2 = 0.0065$ mg/g

หาค่า conformity probability ที่ 99.9 % = $1 - \alpha = 1 - 0.001 = 0.999$ โดยใช้ตาราง cumulative one-tailed standard normal distribution หรือใช้ EXCEL spread sheet
 $NORM.S.INV(0.999) = 3.1$

ความกว้างของ guard band = $3.1 \times u = 0.02$ mg/g

ดังนั้น ขนาดปริมาณ alcohol ในเลือดที่จะใช้เป็น decision limit ที่ระดับความเชื่อมั่น 99.9% ว่าเกินที่กฎหมายกำหนด = $0.2 + 0.02 = 0.22$ mg/g

(ตัวอย่างนี้เป็นการใช้ guard band เพิ่มความเชื่อมั่นในการระบุว่าผลการทดสอบเกินปริมาณที่กฎหมายกำหนด, **Guarded rejection is focusing on correct rejection,**)

(Adapted from EURACHEM/ CITAC leaflet ver. 19: 2015)

Example 5: Speed limit enforcement ใช้ doppler radar ในการตรวจจับความเร็ว ยานยนต์ว่าเกิน speed limit 100 km/h หรือไม่ กำหนดให้ radar มีค่า relative standard uncertainty, $u(v)/v = 2\%$ ซึ่งจะได้ standard uncertainty, $u(v) = 2$ km/h ที่ความเร็ว 100 km/h เพื่อความมั่นใจว่าผู้ขับรถขับเร็วเกินกฎหมายกำหนดด้วยความน่าจะเป็น (probability) 99.9% จะคำนวณหา decision limit โดยใช้ guard band ดังนั้นขนาดความกว้างของ guard band, $g = u(v) \times \text{conformity probability}$

$$g = u(v) \times [\Phi^{-1}(0.999)] \approx 2 \times 3.1 \approx 7 \text{ km/h}$$

ดังนั้น decision limit ที่ใช้ guard band เพิ่มเชื่อมั่นในการตรวจจับความเร็วของรถยนต์ที่ขับเกินกฎหมายกำหนด $\approx 100 + 7 \approx 107$ km/h

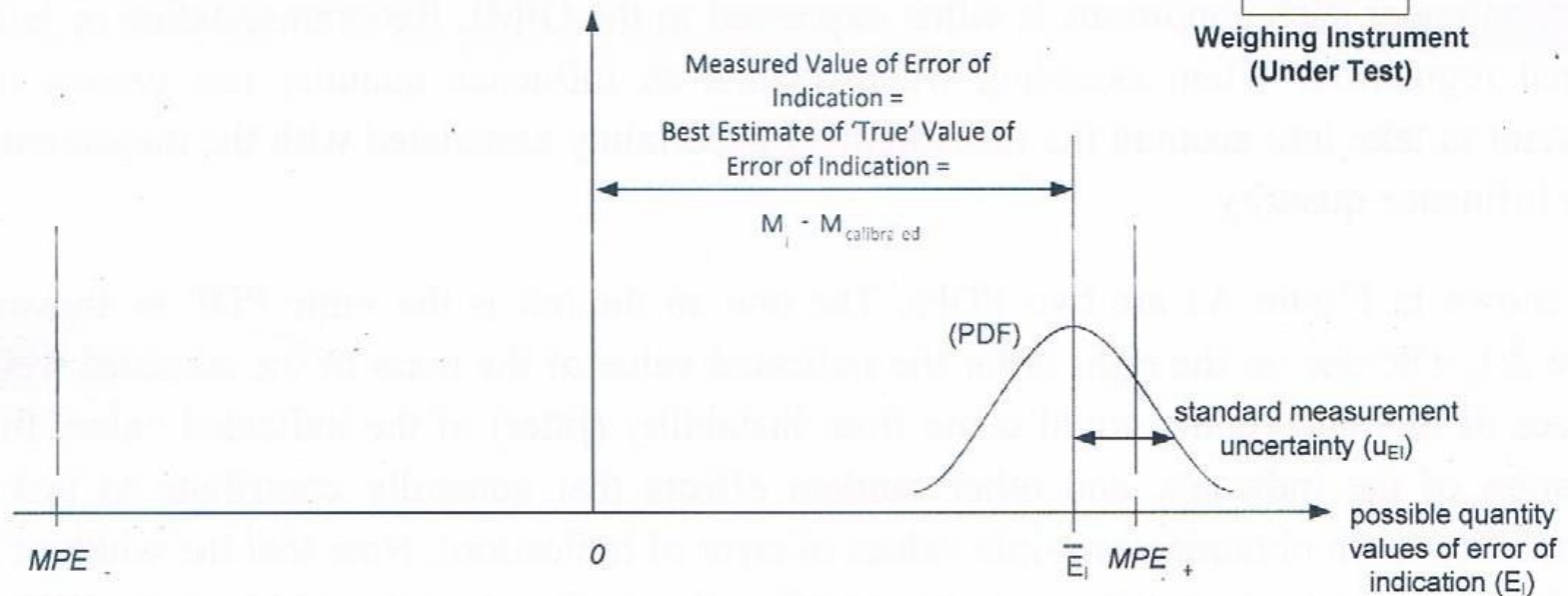
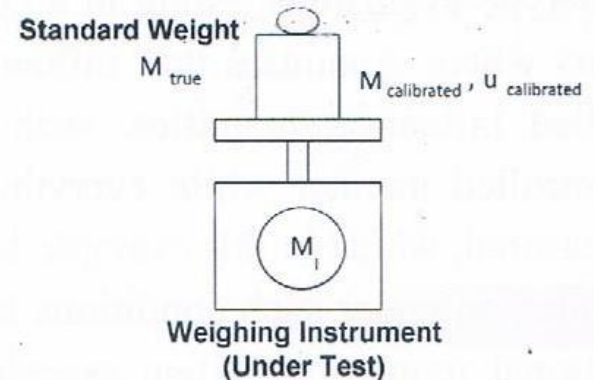
(เป็นการใช้ guard band แบบ **upper limit guarded rejection** เพิ่มความเชื่อมั่นให้กับ **rejection zone, high confidence of correct rejection, low risk of false rejection**)

(Adapted from BIPM, JCGM 106:2012)

OIML G 19:2017, The role of measurement uncertainty in conformity assessment decision in legal metrology

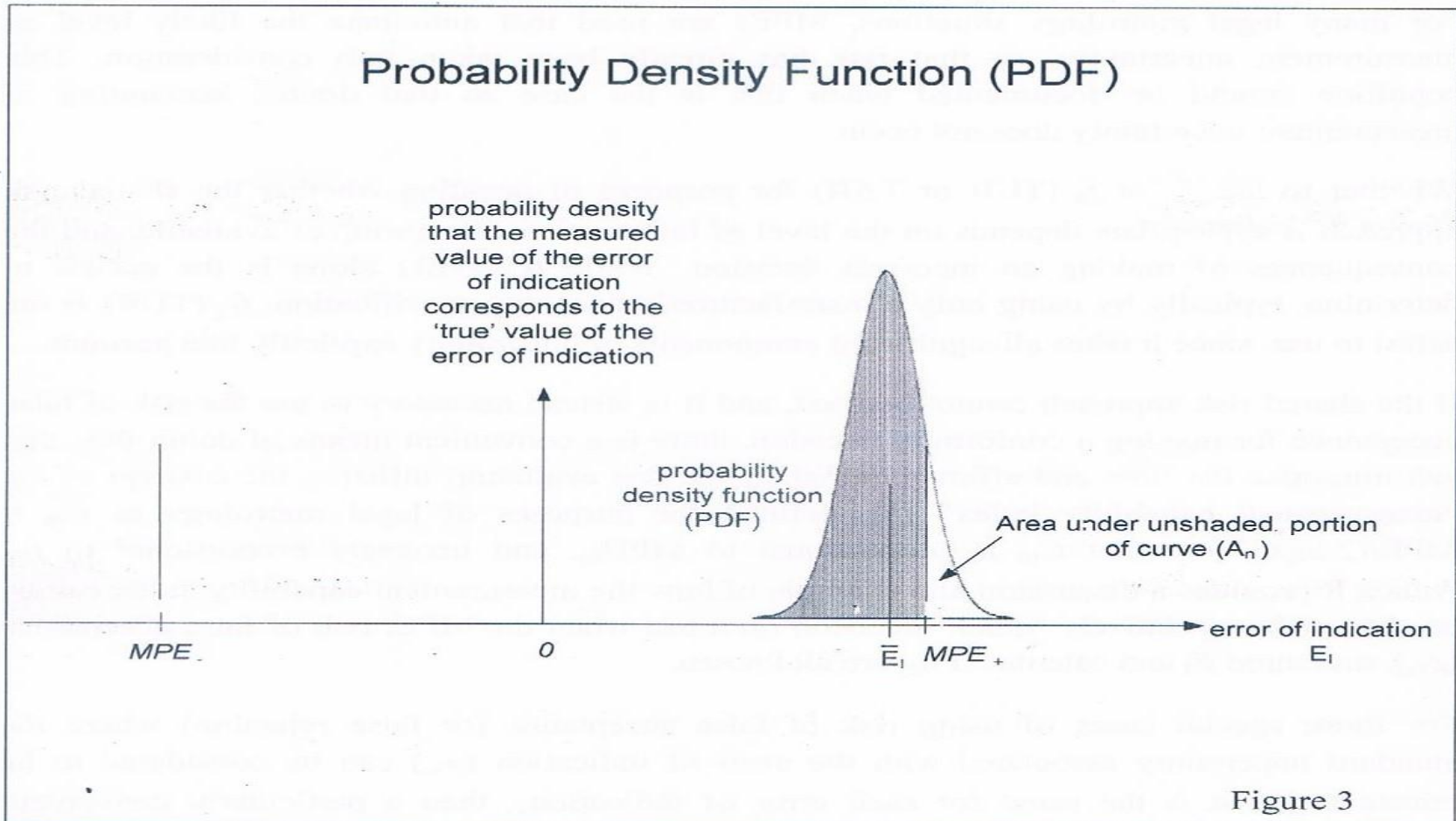
Error of Indication: Example for Weighing Instrument (Under Test)

probability density that a measured value of the error of indication corresponds to the 'true' value of the error of indication



OIML G 19:2017, The role of measurement uncertainty in conformity assessment decision in legal metrology

OIML G 19:2017 (E)



OIML G 19:2017, The role of measurement uncertainty in conformity assessment decision in legal metrology

Conformity Criterion: What is the prob. Of the error of indication (E) lie inside of the conformance zone?

Example 6 : The indicated value of length (L_I) of Caliper under test is 10.006 mm when the value of reference guage block (L_R) is 10.003 mm. The measured value of the error of indication is then:

$$E = L_I - L_R = 0.003 \text{ mm}$$

The standard uncertainty of the error of indication, u , is 0.0018 mm

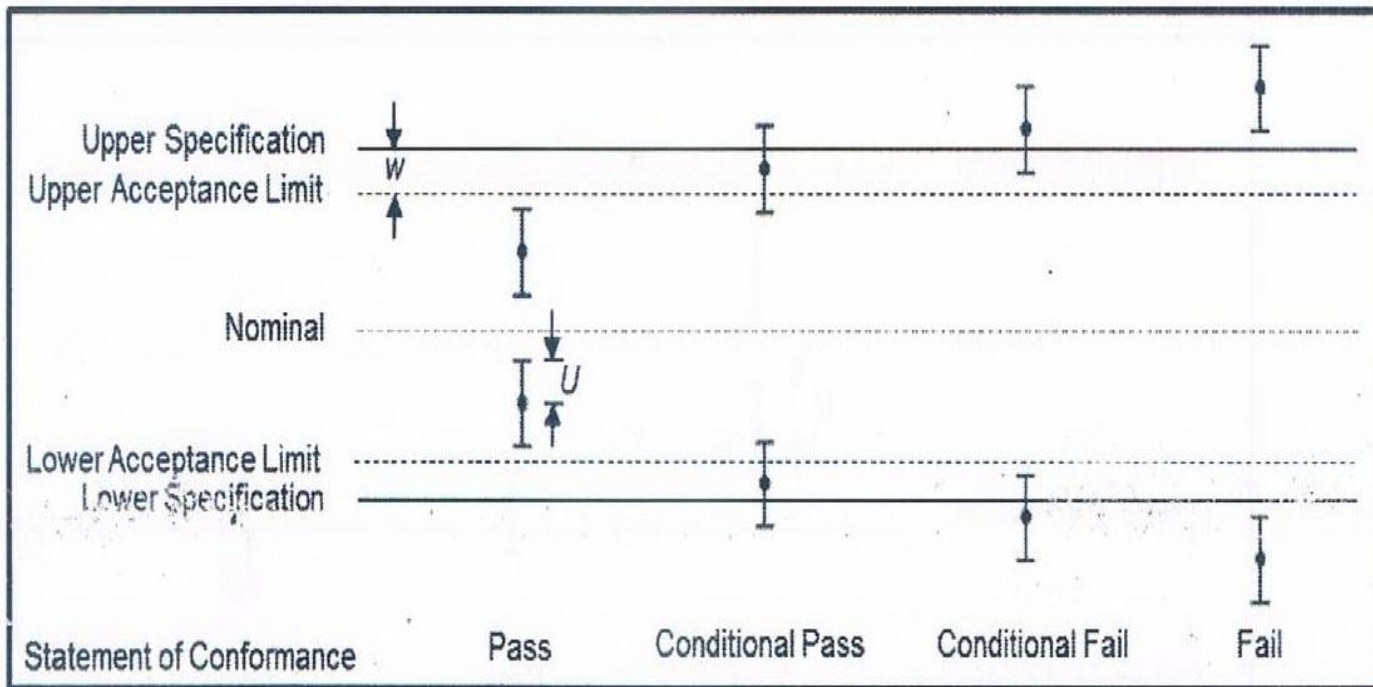
If the maximum permissible error, MPE, for this test is 0.005 mm, then z is calculated as $z = [(MPE - E) / u] = [(0.005 - 0.003) / 0.0018] = 1.11$

From the cumulative standard normal distribution table the cumulative probability is 0.8665 (86.7 %). Thus, the risk of false acceptance is $1 - 0.867 = 0.133$ (13.3%).

If the decision limit (non-conformity) is 2%, then the **maximum permissible uncertainty test** would fail . Another way to state conformity is to use Tolerance Uncertainty Ratio (TUR): $TUR = MPE / u = 0.005 / 0.0018 = 2.78$

The typical value of TUR is 3, therefore the above maximum permissible uncertainty test would fail.

ILAC-G8:09/2019, Guidelines on Decision Rules and Statement of Conformity



U = 95% expanded measurement uncertainty

ILAC-G8:09/2019, Guidelines on Decision Rules and Statement
of Conformity

Decision Rules	Guard Band	Specific Risk
6 sigma	$3 U$	$< 1 \text{ ppm PFA}$
3 sigma	$1.5 U$	$< 0.16\% \text{ PFA}$
ILAC G8:2009 rule	$1 U$	$< 2.5\% \text{ PFA}$
ISO 14253-1:2017	$0.83 U$	$5\% \text{ PFA}$
Simple acceptance	0	$< 50\% \text{ PFA}$
Uncritical	$-U$	Item rejected for measured value $> AL = TL + U$ $< 2.5\% \text{ PFR}$
Customer defined	$r U$	Customers define arbitrary multiplier, r .

$\text{PFA} = \text{Prob. of False Accept}, \quad \text{PFR} = \text{Prob. of False Reject}$
 $U = \text{Expanded Uncertainty}, \quad AL = \text{Acceptance Limit}$
 $TL = \text{Tolerance Limit}$

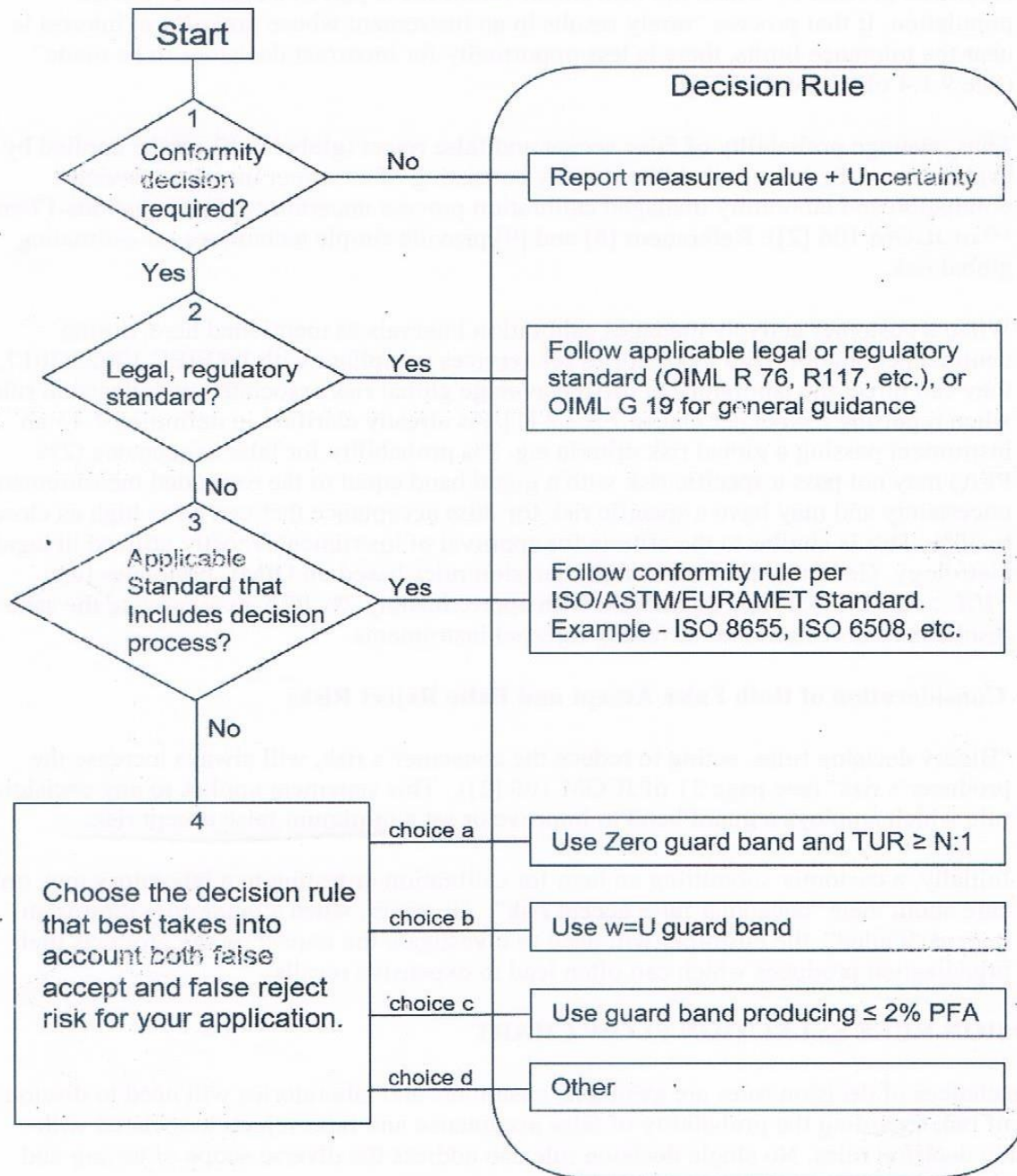


Figure 7. Pass/Fail Conformity Decision Rule selection flow chart.

Decision rules reduce the level of risk
and finalize the conformity.

Thank you for you attention

WWW.MST.OR.TH

ptotarong@gmail.com