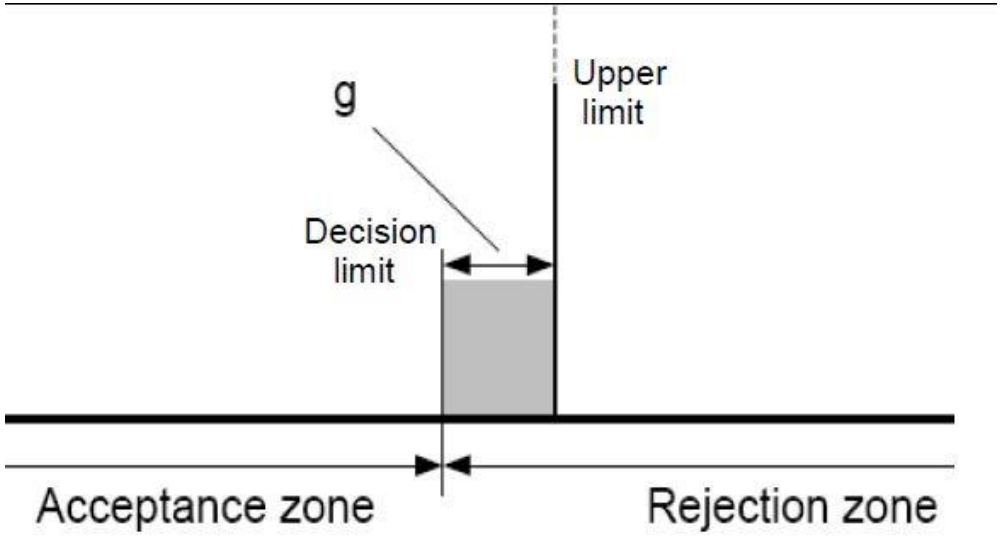
Statements of Conformity

ISO/IEC 17025: 2017 - 7.8.6 - Reporting Statements of Conformity to Include the Decision Rule



Presented by:

Mike Kramer Calibration Program Manager

Perry Johnson Laboratory Accreditation, Inc.

22-May-2018

Statements of Conformity

This webinar is being recorded and will be available in it's entirely on the Perry Johnson Laboratory Accreditation Website.

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Go to the link for recorded webinars.

Duration of webinar is set for one hour. There will be time allocated at the end for questions

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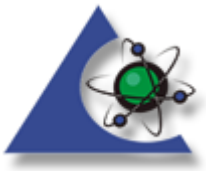
*The standard now (ISO/IEC 17025:2017) has requirements for reports that include statements of conformity. Decision rules need to be documented and need to take **risk** into account. The results with a statement of conformity need to be clearly identified as such, including which specifications are met or not met, and what decision rule has been applied*

Transition From

ISO 17025: 2005
to
ISO 17025: 2017

International Organisation For Standardisation



Statements of Conformity "From ISO/IEC 17025:2005

5.10.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.

When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.

When statements of compliance are made, the uncertainty of measurement shall be taken into account

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Statement of conformity and the decision rule first appears in ISO/IEC 17025:2017 under "Review of Request 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-of-tolerance), 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.

The key here is "when it is requested" which implies it is requested by the customer. •This means that "contract review" must take place and a clear definition agreed on BEFORE the job is started

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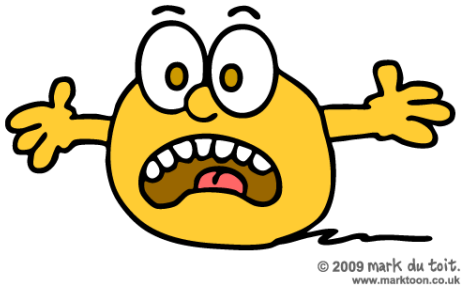
7.1.3 does state the following?

Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.

So what does this mean?



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There are testing methods that determine how the rules are applied. One good, common illustration is ASTM E18 for Rockwell Hardness where the testing and calibration decision rules take uncertainty into account effectively in the repeat testing and other "limits" as to the spread of the data etc. and the rules are defined in the method.

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Another is ASTM A29 for Standard Specification for General Requirements for Steel Bars, Carbon and Alloy Hot-Wrought where it has an auxiliary table that is based on the method uncertainty to give some "extra" room to make a decision.

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Others are tests where you take two samples, if both pass you "pass". If one passes and the other fails you take two more samples. If both pass it is determined a pass and if either or both fail, it fails. This implicitly takes uncertainty into account and is the defined "decision rule".

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The laboratory needs to be prepared to discuss what the decision rule options are regarding the compliance statement.

Also an understanding of what the customer may require and where the risk of “false accept” or “false reject” lies

As with all statistical analysis, it is open to different interpretations and care must be taken to ensure a correct agreement between parties

ication Max	Unit	Margin	Result
4.000	V/ns	39 %	Pass
2800	ppm	10 %	Pass
10.203	ns	37 %	Pass
150	ps pk	72 %	Pass
1.150	V	15 %	Pass
—	V	56 %	Pass
60	%	49 %	Pass
20	%	0 %	Fail
1250	ppm/us	5 %	Marginal Pass

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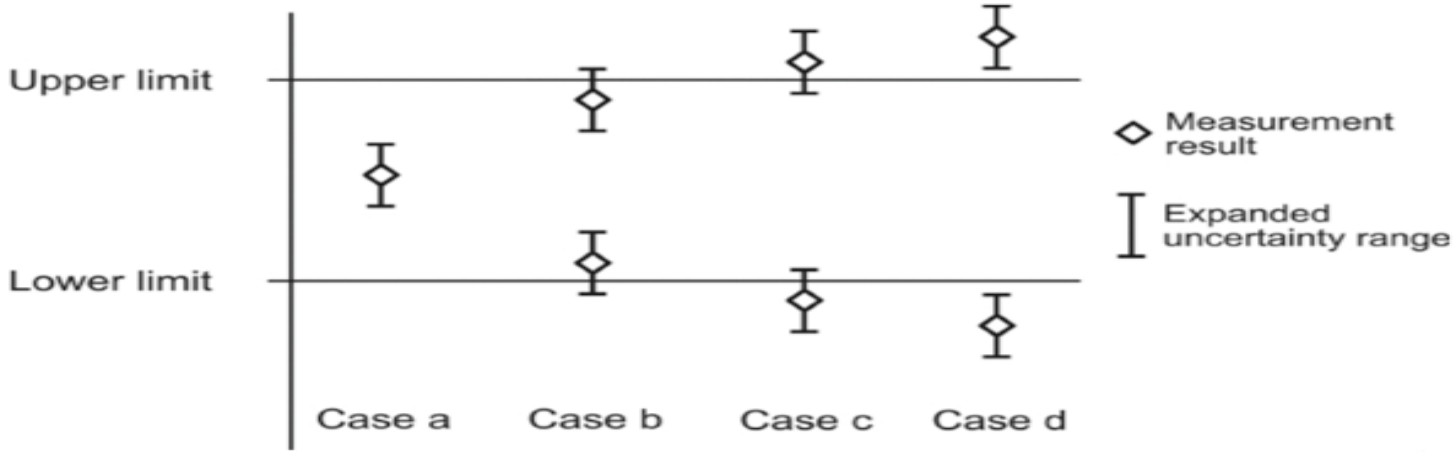

decision rule - rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

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Decision Rule and statement of compliance requirements are also specified in the 2017 Standard in Section 7.8"Reporting the Results".

7.8.6 Reporting statements of conformity

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

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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).

NOTE For further information, see ISO/IEC Guide 98-4

ISO/IEC Guide 98-4= "Uncertainty of measurement - Part 4: Role of measurement uncertainty in conformity assessment"

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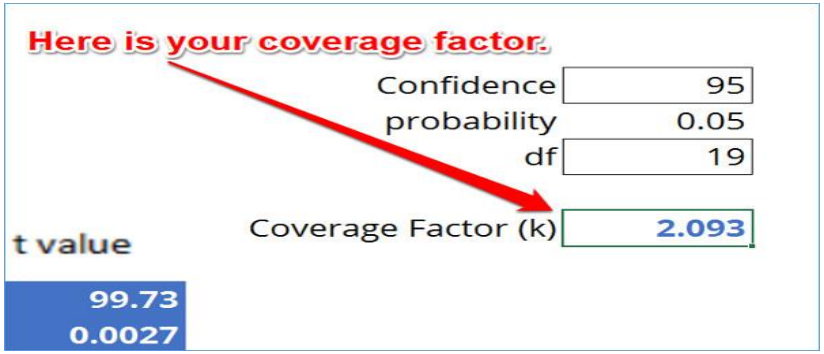
Decision rules for proving conformance or non-conformance with specifications makes a differentiation whether conformance or non-conformance shall be determined with a high probability. The expanded measurement uncertainty *U* and a confidence level of approx. 95% (expansion factor k = 2) will generally be considered to be adequate. There may be cases that would require a higher confidence level of e.g. 99% (expansion factor k = 3) be chosen



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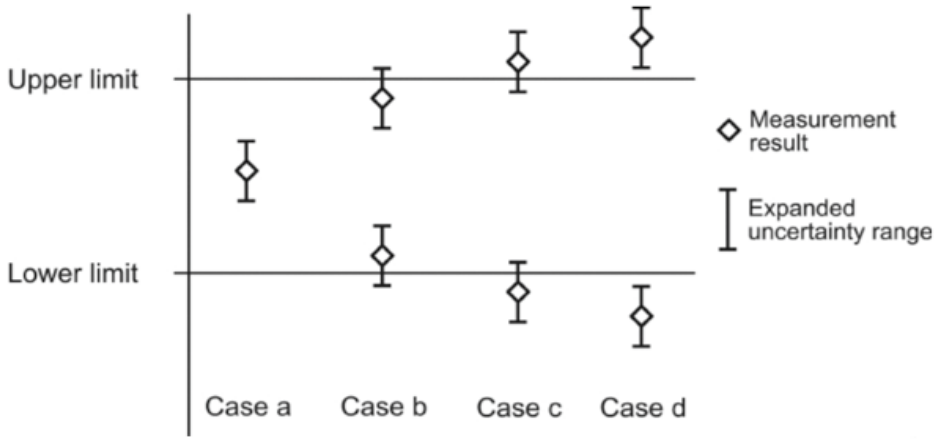
Where the measurement uncertainty interval is overlapping the limit value, implies a careful analysis that should establish objective criteria (decision rule) to accept the measurement having part of the uncertainty interval outside the tolerance ;



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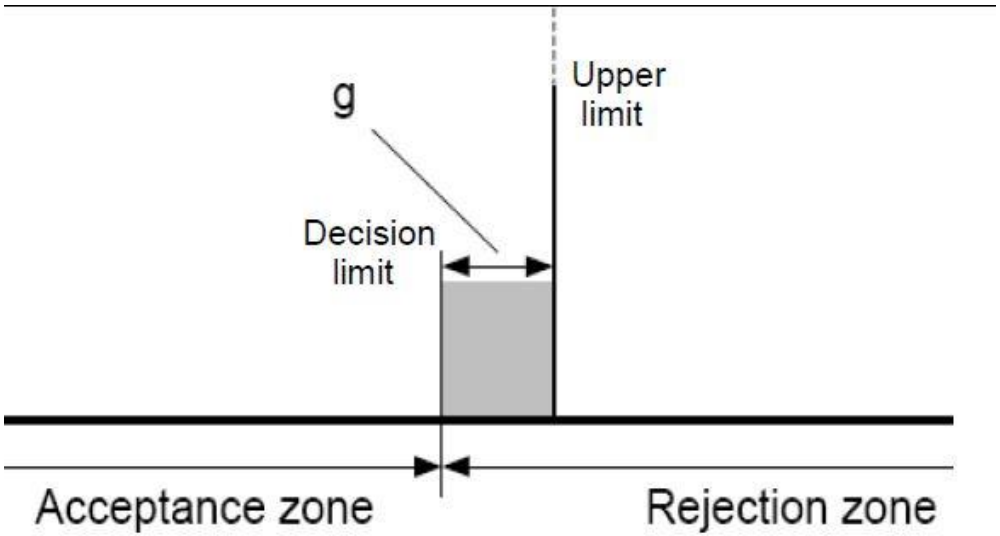
Guard band: the magnitude of the offset from the specification limit to the acceptance or rejection zone boundary.



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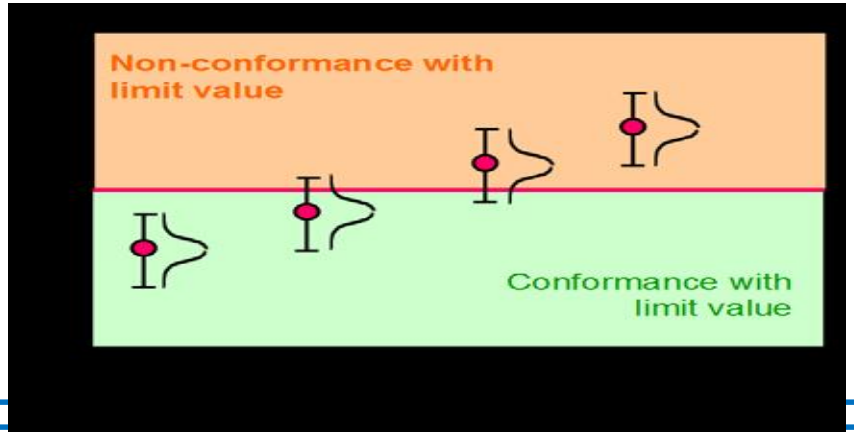
Compliance: If the specification limit is not breached by the measurement result plus the expanded uncertainty with a 95% coverage probability, then compliance with the specification can be stated . This can be reported as "*Compliance*" *The measurement result is within (or below) the specification limit when the measurement uncertainty is taken into account*". In calibration this is often reported as "*Pass*

*** *cat A*** ***cat B*** ***cat C*** ***cat D***



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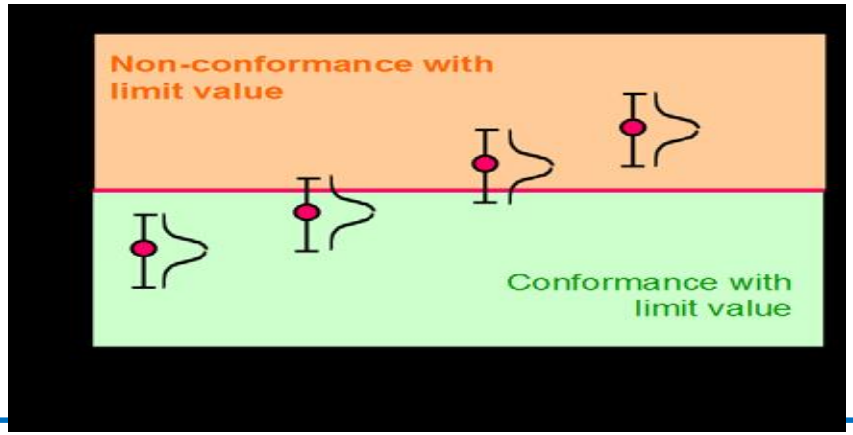
Non-compliance: If the specification limit is exceeded by the measurement result minus the expanded uncertainty with a 95% coverage probability, then noncompliance with the specification can be stated. This can be reported as "*Non-compliance*" – *The measurement result is outside (or above) the specification limit when the measurement uncertainty is taken into account*". In calibration this is often reported as "*Fail*";

cat A *cat B* *cat C* **cat D*



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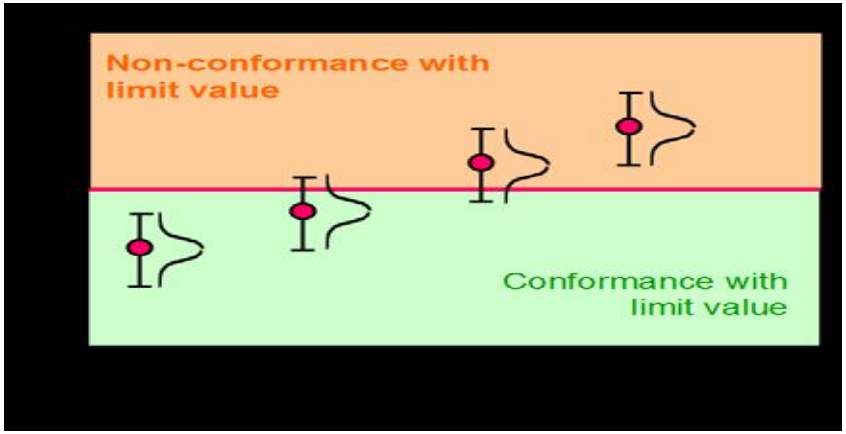
If the measurement result plus/minus the expanded uncertainty with a 95 % coverage probability overlaps the limit, it is not possible to state compliance or non-compliance. The measurement result and the expanded uncertainty with a 95 % coverage probability should then be reported together with a statement indicating that neither compliance nor non-compliance was demonstrated

*cat A *cat **B** ***cat C** *cat D*



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PL-3 "PJLA Policy on Measurement Uncertainty

Clause 5.4.6 of the standard contains the requirement that calibration and testing laboratories have and apply a procedure defining the manner by which they estimate the uncertainty of measurement for calibrations and test performed. Additionally for calibration laboratories, PJLA requires that this procedure also define the manner by which uncertainty is accounted for when making a statement of compliance with a specification

If the laboratories uncertainty procedure **does not** address the manner in which uncertainty is accounted for PJLA will require that it be accounted for using the method suggested in ILAC G8 03 2009

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PJLA PL-3 continued

If taking uncertainty into account would result in a possible failure where the measured value actually passes, the following example compliance statement can be used. "*It is not possible to state compliance using a 95 % coverage probability for the expanded uncertainty although the measurement result falls within specified limits.* Optionally, if the organization wishes, it can simply state "*It is not possible to state compliance".*

PJLA defines this condition as ***Pass-Indeterminate***

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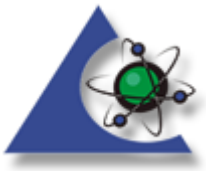
PL-3 Continued

If taking uncertainty into account would produce a possible pass where the measured value actually failed, the following example compliance statement can be used. "*It is not possible to state noncompliance although the measurement result falls outside specified limits using a 95 % coverage probability for expanded uncertainty may produce values within specified limits.*" Optionally, if the organization wishes, it can simply

state "*It is not possible to state noncompliance*

PJLA defines this condition as ***Fail-Indeterminate***



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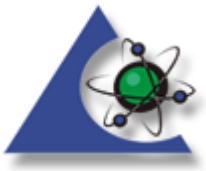
Based on the previous models, and if accepted by the customer as per the requirements specified in 7.1.3, the following decision rules can be documented:

Accounting for the uncertainty will be taken to mean that at a 95% confidence level the measurement result plus and minus the expanded uncertainty (k=2) shall be totally within the specification limits

Or

The result cannot be reported as being in specification if the risk of false acceptance to the customer is greater than 5%.



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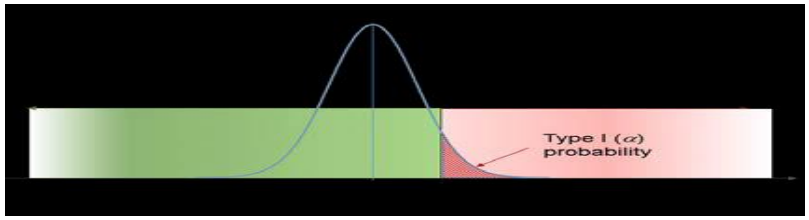
For the cases using guard bands, particularly suitable for measurement results with fixed uncertainty, a simple strategy to establish a decision rule is to compare the measurement results with the acceptance zone limits, being considered in compliance (accepted) if the measured value is inside this zone and non-compliant (rejected) otherwise.

If measurement results could have variable values of uncertainty, a different approach without considering guard bands is recommended



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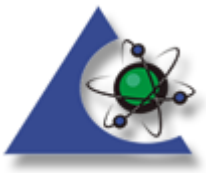
In these cases, the criteria can be established performing a test of hypothesis in which fulfilment of Ho condition implies the decision of acceptance and otherwise implies the decision of rejection. Therefore, assuming a probability of type I error (α), the decision rule can be expressed as:

Decision Rule:

Acceptance if the hypothesis Ho: $P(Y \leq T_u) \geq (1-\alpha)$ is true

Rejection if the hypothesis Ho : $P(Y \leq T_u) \geq (1-\alpha)$ is false

Expression to Test Pc $= P((n \leq T_u) = \phi\left(\frac{Tu-y}{u(y)}\right)$



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Example provided by

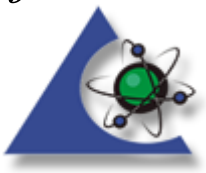
EUROLAB "Cook Book" – Doc No. 8 "Determination of Conformance With Specifications Using Measurement Uncertainties " Possible Strategies"

Consider a measurement estimate y = 2.7 mm with a standard uncertainty of $u(y)$ = 0.2 mm, a single tolerance upper limit of TU = 3.0 mm, and a specification of conformity (1 – α) of 0.95 (95 %) thus assuming a type I error α = 0.05 (5%).

With the experimental result and tolerance limit, assuming a normal PDF (Probability Distribution function), the decision rule will be

Acceptance if the hypothesis Ho $P(Y \leq 3.0\ mm) \geq 0.95$ *is true*

Rejection if the hypothesis Ho $P(Y \leq 3.0\ mm) \geq 0.95$ *is false*



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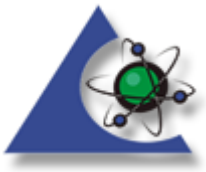
To estimate probabilities related with the example given, the conformance probability (Pc) need to e calculated using the general expression for normal PDF's.

PDF = Probability Distribution Function

$P((n \leq T_u) = \phi\left(\frac{Tu-y}{u(y)}\right)$

$Pc = \left(\frac{3.0-2.7}{0.2}\right) = \phi(1.5) \approx\approx 0.933\ (93.3\%)$ Then, the hypothesis Ho is false and the decision to take is of rejection (non-compliant). Φ ???



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The value of ϕ (z) can be obtained using tables of standard Gaussian PDF or software having functions to perform this type of calculations eg:

MS Excel functions NORMDIST(x,mean, standard deviation, cumulative), for the example given.

MS Excel Function NORMDIST (x, mean, standard deviation, cumulative for the example given would provide a calculated result of (0.933)

PDF = Probability Distribution Function

Save the Date

Thursday, June 28 – 1:00pm EST

ISO/IEC 17025:2017 A Look at Section 8.5 – Actions to Address Risks and Opportunities – Including Tools that can be Utilized by Organizations to Comply with this Section