ISO/IEC 17025:2017 Section 7.6 Evaluation of Measurement Uncertainty "Requirements and Fundamentals"



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What is Measurement Uncertainty Uncertainty can be looked at as the doubt that exists about the result of any measurement. You might think that well-made measuring tapes, stopwatches and thermometers should be trustworthy, and give the right answers. But for every measurement there is a margin of doubt.

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You can think of this as give or take in today's everyday language. For example a rod may be two meters "give or take a centimeter.



What is Measurement Uncertainty

- Since there is always a margin of uncertainty about any measurement, we need to ask 'How big is it. Two numbers are really needed in order to quantify the measurement.
- One is the width of the uncertainty and the other is the confidence level. Which states how sure we are that the 'true value' is within that margin.
- We might say that the length of a rod measures one meter plus or minus 1 centimeter at the 95 percent confidence level. This result could be written:
- 1 meter ± 1 cm, at a level of confidence of 95%.



What is Measurement Uncertainty Error vs Uncertainty

Error is the difference between the measured value and the 'true value'

Uncertainty is the quantification of the doubt about the measurement result.

Looking at a 50 gram analytical test weight used to check laboratory balances.

Measured value 50.000112 grams with 0.000112 being the error. Reported uncertainty of 0.000013 Grams.

Can be reported as 50.000112 ± 0.000013 Grams at k=2 or 95% confidence interval.



Traceability

Definition: Metrological traceability (VIM clause 2.41): Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement **uncertainty**.

ISO/IEC 17025:2017 "6.5 Metrological traceability"

6.5.1 The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement **uncertainty**, linking them to an appropriate reference.



Traceability

- A chain of traceability exist when all of the measurements are known or can be known for each link or comparison along with the associated uncertainty of measurement
- Each link has an associated uncertainty. Each uncertainty with each associated link will increase the further you get away from the origin (NIST)



Lab

Through NIST to the SI



Traceability

A broken link may be an instance for example that the measurement uncertainty was not estimated for that calibration and thus traceability stops at that point



Be aware that in a successive chain of calibrations, the uncertainty increases at every step of the chain.



7.6 Evaluation of Measurement Uncertainty 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.

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tenuation of th	e attenuator to be calil	orated				
certainty Budg	get:					
Quantity	Value	Standard Uncertainty	Degrees of Freedom	Sensitivity Coefficient	Uncertainty Contribution	Index
LS	30.04025 dB	9.13·10·3 dB	3	1.0	9.1·10·3 dB	16.6 %
δLS	3.00·10·3 dB	2.50·10·3 dB	50	1.0	2.5·10·3 dB	1.2 %
6LD	0.0 dB	1.15·10·3 dB	00	1.0	1.2·10·3 dB	0.3 %
õLм	0.0 dB	0.0200 dB	00	1.0	0.020 dB	79.7 %
öL _K	0.0 dB	1.73·10·3 dB	00	1.0	1.7·10-3 dB	0.6 %
δL _{ib}	0.0 dB	289-10-6 dB	00	1.0	290-10-6 dB	0.0 %
6Lia	0.0 dB	289-10-6 dB	00	-1.0	-290-10-6 dB	0.0 %
6Lob	0.0.dB	2.00·10·3 dB	50	1.0	2.0·10·3 dB	0.8%
L×	30.0432 dB	0.0224 dB	110			
lesult:	Expa	anded Lincertainty	Coverage E	actor: Cove	rage:	
30.043 dB	+ 0.0	45 dB	▼ 2.00	95%	(t-table 95.45%)	-

Sounds like an uncertainty budget as specified in PL-3 "PJLA Policy on Measurement Uncertainty"

ISO/IEC 17025:2017 does not require a formal procedure as , however a procedure can still be used to incorporate the required elements of 7.6.1



Necessary steps in developing an estimate of measurement uncertainty

Step 1
Step 2
Step 3
Step 4

Identify: Make a list of all equipment or conditions that diminish the "correctness" of the measurement result. Quantify: Determine reasonable values for the standard uncertainty of each identified contributor. Combine: Combine all standard uncertainties using the RSS (Root Sum of Squares) method.

Expand the uncertainty: Multiply by the appropriate coverage factor to obtain the expanded uncertainty of the measurement result.



Necessary steps in developing an estimate of measurement uncertainty <u>Combine:</u> Combine all standard uncertainties using the RSS (Root Sum of Squares) method.

$$u_c = \sqrt{u_1^2 + u_2^2 + u_3^2 + u_4^2 + u_5^2 + u_6^2}$$

Expand the uncertainty: Multiply by the appropriate coverage factor to obtain the expanded uncertainty of the measurement result

$$u_{c*}k$$



Necessary steps in developing an estimate of measurement uncertainty

- For all uncertainty budgets the following always would be included as contributors.
- Uncertainty associated with the standard used in the calibration Would be captured on the traceable calibration report. Normal expanded divide by 2
- Uncertainty associated with the limited resolution of the device calibrated Would be the smallest division which could be read of the unit under test. Rectangular divide by 1.73
- Uncertainty associated with repeatability Standard deviation of repeatability studies performed by the lab. Normal – standard deviation divided by 1



Uncertainty of the Standard

Comes of the traceable calibration report provided by the supplier. This is considered a normal distribution and would be divided by the k factor identified on the certificate.

		41			Amendeo	Certificat	e: 4381-1	0654703		
echnicia est Conc	n: 104 h: 104	.67%RH 23.7	Procedure 73°C 1012	: CAL-17 2mBar	Cal	Date: 24 A	ug 2019	Cal D	ue Date: 24 Aug	2022
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alibrati	on Data:		In Tol	Nominal	Asleft	In Tol	Min	Max	±U	TUR
alibrati Unit(s)	on Data: Nominal	As Found	In Tol	Nominal	As Left	In Tol	Min	Max 57	±U 0.74	TUR >4:1
alibrati Unit(s) %RH	Nominal	As Found 51	In Tol Y	Nominal 51.98	As Left 51	In Tol Y	Min 47	Max 57	±U 0.74	TUR >4:1

This certificate indicates Traceability to standards provided by (NIST) National Institute of Standards and Technology and/or a National Standards Laboratory.

A Test Uncertainty Ratio of at least 4:1 is maintained unless otherwise stated and is calculated using the expanded measurement uncertainty. Uncertainty evaluation includes the instrument under test and is calculated in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement : (GUM). The uncertainty represents an expanded uncertainty using a coverage factor k=2 to approximate a 95% confidence level. In tolerance conditions are based on test results falling within specified limits with no reduction by the uncertainty of the measurement. The results contained herein relate only to the item calibrated. This certificate shall not be reproduced except in full, without written approval of Control Company.

Nominal=Standard's Reading; As Left=Instrument's Reading; In Tol=In Tolerance; Min/Max=Acceptance Range; ± U=Expanded Measurement Uncertainty; TUR=Test Uncertainty Ratio; Accuracy=±(Max-Min)/2; Min=As Left Nominal(Rounded) – Tolerance; Max= As Left Nominal(Rounded) + Tolerance;

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Uncertainty associated with the Resolution of Device Under Test This would be the smallest division which can be seen on the unit under test.

From below if calibrating temperature of this device this would be 0.1°C. This is a rectangular distribution and would be divided by 1.73





Uncertainty due to Repeatability

This would be a normal distribution of repeatability study of at least 10 measurements and would be the standard deviation divided by one.

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19	1	99.51020	49.98560	19.99850	10.16723	4.98237	1.00118	0.49968	0.20101	0.10018	0.01988	0.00992	0.00200	0.00101	0.00021						_
20	2	99.44580	49.88750	20.00450	9.95764	4.95872	1.00203	0.49928	0.20042	0.10001	0.02001	0.00991	0.00203	0.00103	0.00020						_
21	3	99.93310	49.64750	19.87640	9.99203	4.96628	0.99876	0.49931	0.20077	0.10048	0.02008	0.00999	0.00206	0.00100	0.00022						_
22	4	99.53470	49.86580	19.63520	10.05863	4.97224	0.99725	0.49998	0.20018	0.10008	0.02003	0.00994	0.00201	0.00101	0.00020						_
23	5	99.87750	49.92140	19.58760	10.01250	4.95887	0.99903	0.49876	0.20056	0.09998	0.02006	0.00990	0.00202	0.00102	0.00019						
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26	8	99.66870	49.67540	19.69870	10.05820	4.98279	0.99887	0.49988	0.19961	0.10044	0.01984	0.00999	0.00198	0.00101	0.00018						_
27	9	99.51420	49.53140	19.76480	10.02540	4.98740	0.99555	0.49728	0.20009	0.10023	0.01990	0.00996	0.00201	0.00102	0.00020						_
28	10	99.92020	49.84350	20.01050	9.98672	4.98875	0.99487	0.49952	0.20031	0.09999	0.01997	0.00991	0.00199	0.00100	0.00020						
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35	4	99 845003	50.021258	19.5555505	10.020180	4.987741	1.001374	0.501539	0.201350	0.100793	0.020143	0.000021	0.002000	0.001003	0.000221						-
36	5	100 188871	50.077032	19 648665	10.043714	4.974329	1.002145	0.500315	0.201185	0.100392	0.020032	0.009931	0.002026	0.001023	0.000191						-
37	6	100.035394	49 889148	20.059843	10.016801	4 960717	0.999847	0.500237	0.200965	0.100362	0.020022	0.009961	0.002006	0.000993	0.000191						-
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39	8	99.979420	49.830265	19.760111	10.089557	4.998324	1.001984	0.501438	0.200232	0.100753	0.019902	0.010021	0.001986	0.001013	0.000181						-
40	9	99.824439	49.685816	19.826417	10.056654	5.002948	0.998654	0.498830	0.200714	0.100542	0.019962	0.009991	0.002016	0.001023	0.000201						-
41	10	100.231704	49.998889	20.072883	10.017854	5.004303	0.997972	0.501077	0.200934	0.100302	0.020032	0.009941	0.001996	0.001003	0.000201						-
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- Uncertainty contributors are categorized as "Type A" or "Type B" based on the manner in which they are evaluated.
- A Type A evaluation involves evaluation by statistical methods of a series of results.
- Type B evaluation is evaluation by any means other than statistical (Reference books, published values, experience, judgment etc



Common Sources of Uncertainty

- Uncertainty associated with the standard used
- Uncertainty associated with limited resolution
- Uncertainty due to repeatability
- Uncertainty associated with the environment
- Uncertainty associated with equipment accuracy, ie drift
- Uncertainty in regards to properties and condition of the unit under test-e.g., reflectance, hardness, unit exhibits wear
- Manufacturer Specifications
- Homogeneity or Uniformity





- Several types of distribution are commonly encountered in estimating uncertainty
- 1. Normal Distribution (1 standard deviation is 1 standard uncertainty
- 2. Rectangular Distribution (1 standard deviation is obtained by dividing the limits of the distribution by $\sqrt{3}$)
- 3. Triangular Distribution (1 standard deviation is obtained by dividing the limits of the distribution by $\sqrt{6}$)
- 4. U Distribution (1 standard deviation is obtained by dividing the limits of the distribution by $\sqrt{2}$)



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1			expanded u	ncertainty for in	frared tempe	rature			
uncertai	nty description	uncertainty [in K]	source	distribution	divisor	standard uncertainty [in K]	comments		
u1 3	homogeneity of black body	0.4	testing	Gaussian	2	0.20	Temperature profile from top to bottom of the black body		
u2	repeatability	0.07	testing	Gaussian	1	0.07	Comparison of results of calibrations using two reference instruments		
u3	uncertainty reference system	0.0034	Calibration Certificate	Gaussian	2	0.00	Measurement uncertainty of the reference calibration		
u4	drift of reference	0.03	calibration certificate derivation	rectangular	-√3	0.02	Reference standard drift - derived from past 2 years' calibration data		
u5	digit error reference 2	0.0005	manufacturer information/ estimation	rectangular	-√3	0.00	Least significant digit on digital display		
u6	influence of emissivity	0.5	manufacturer information/ estimation	rectangular	-√3	0.29	Temperature difference due to deviation of stated emissivity from actual		
simple und	ertainty with k=1 (68.3%)(R	SS Method)				0.36	Emissivity is a measure of the efficiency in which a surface emits thermal energy. It is defined as the fraction of energy being emitted relative to that emitted by a thermally black surface (a black body)		
expanded	uncertainty with k=2 (95%))				0.72			
11									
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Calibration and Measurement Capability "CMC"

- CMC is a calibration and measurement capability available to customers under normal conditions:
- a) as described in the laboratory's scope of accreditation granted by a signatory to the ILAC Arrangement; or
- b) as published in the BIPM key comparison database (KCDB) of the CIPM MRA.

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	Conductivity FO	100 μS/cm	2.9 μS/cm	Conductivity Solutions	20
		1 413 μS/cm	10.5 μS/cm	QAI-A02	
		5 000 μS/cm	35.9 μS/cm		
		10 000 μS/cm	56.4 μS/cm		
		100 000 μS/cm	726 μS/cm		
	Dimensional				
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	QUANTITY OR GAUGE	DEVICE SIZE AS APPROPRIATE	MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (±)	AND REFERENCE STANDARDS USED	1
	Outside Micrometers FO	0.05 in to 4 in	$(60 + 0.052L) \mu in$	Gage Blocks	
		4 in to 40 in	(730 + 0.018L) μin	QAI-MXX procedures	~ ~
	Height Gages FO	0.05 in to 4 in	(86 + 0.052L) μin		
		4 in to 40 in	(360 + 0.18L) μin		
	Depth Gages FO	0.05 in to 4 in	$(180 + 0.052L) \mu in$	1	
	Calipers FO	0.05 in to 4 in	$(310 + 0.052L) \mu in$	1	
		4 in to 40 in	(730 + 0.018L) μin		<u> </u>
	Dial Indicators FO	0.000 5 in to 4 in	(36 ± 0.0521) uin	7	



Distribution Types: Four common types of error distributions Normal distribution:

- Defined by the mean (µ) and the standard deviation (u). +/-2 standard deviations
- Frequently encountered in uncertainty analysis.
- Usually has a divisor of 1 or 1 standard deviation. Usually associated with Type A (statistical)



Distribution Types: Four common types of error distributions

Uniform (Rectangular) distribution:

- ► Not fully defined by the mean (µ) and the standard uncertainty (u). $u = \frac{a}{\sqrt{3}} = 1.73$
- Population has finite boundaries and all elements have an equal probability of occurrence.



Distribution Types: Four common types of error distributions **Triangular** distribution:

- Not fully defined by the mean (μ) and the standard uncertainty (u). $u = \frac{a}{\sqrt{6}} = 2.45$
- Population has finite boundaries and elements near the center have a higher probability of occurrence.



Distribution Types: Four common types of error distributions

U distribution: (Do not confuse with "U" the expanded uncertainty)

- Not fully defined by the mean (μ) and the standard uncertainty (u). $u = \frac{a}{\sqrt{2}} = 1.41$
- Population has finite boundaries and elements near the boundaries have a higher probability of occurrence.



Measurement Uncertainty - Terminology

Random or Systematic Variation

- **Random Variation** where repeating the measurement gives a randomly different result. If so, the more measurements you make, and then average, the better estimate you generally can expect to get.
- Examples: Posture changes affect height measurements, Reaction speed affects timing measurements, Slight variations in viewing angle affect volume measurements.





Measurement Uncertainty - Terminology

Random or Systematic Variation

Systematic Variation - where the same influence affects the result for each of the repeated measurements (but you may not be able to tell). In this case, you learn nothing extra just by repeating measurements. Other methods are needed to estimate uncertainties due to systematic effects, e.g. different measurements, or calculations.

Examples of Systematic Variation: A scale gives a mass measurement that is always "off" by a set amount, Metal rulers consistently give different measurements when they are cold compared to when they are hot due to thermal expansion, Drift occurs when successive measurements become consistently higher or lower as time progresses. Electronic equipment is susceptible to drift.



Measurement Uncertainty - Terminology

Systematic errors are a bigger problem than random errors. This is because random errors affect precision, but it's possible to average multiple measurements to get an accurate value. In contrast, systematic errors affect Accuracy. Unless the error is recognized, measurements with systematic errors may be far from true values and increase the chances of false accept/reject.





7.6 Evaluation of measurement uncertainty The terms estimation and evaluation is utilized in ISO/IEC 17025:2017 concerning uncertainty requirements

Evaluation Est

Estimation



Where the test method precludes rigorous evaluation of measurement uncertainty, an **estimation** shall be made

A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty

7.6.2 A laboratory performing calibrations, including of its own equipment, shall **evaluate** the measurement uncertainty for all calibrations.

In-house calibrations are specified in PJLA PL-2 for traceability.

Example: Testing lab calibrates their own balances which are used in testing activities.

Source of Uncertainty	Value a _i	Units	Probability Distribution	Divisor	Sensitivity Coefficient c _i	Standard Uncertainty U <u>(y)</u> (mm)
Calibration Uncertainty	0.01	mm	Normal (k=2)	2	1	0.005
Resolution	0.005	mm	Triangular	v 6	1	0.002
Cosine error	3	deg	Rectangular	v 3	0.046	0.080
Temperature	2	C	Rectangular	v 3	0.0023	0.003
Repeatability	0.02	mm	Normal (k=1)	1	1	0.020
			Combined Star	idard Uno	ertainty u _c (y)	0.082
		Expand	led Uncertainty (k	=2, 95% o	onfidence) U	0.165



7.6.3 A laboratory performing testing shall **evaluate** measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an **estimation** shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

What does this Mean?





NOTE 1 In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied <u>7.6.3</u> by following the test method and reporting instructions.

Rapid method kits that specify limits to the values of the major sources (contributors) of uncertainty, as well as well-recognized rapid methods where kits are used to determine qualitative results,



- NOTE 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.
- NOTE 3 For further information, see ISO/IEC Guide 98-3, ISO 21748 and the ISO 5725 series.
- ISO/IEC Guide 98-3 Uncertainty of measurement —Part 3: Guide to the expression of uncertainty in measurement (GUM:1995
- ISO 21748 -Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation
- ISO 5725 Accuracy (trueness and precision) of measurement methods and results -Part 3: Intermediate measures of the precision of a standard measurement method





Designation: D 6184 - 98 (Reapproved 2005)

ASTM D 6184 – 98 Standard Test Method for Oil Separation from Lubricating Grease (Conical Sieve Method)

Compliance of Test Results with Performance Specification:



Repeatability: The difference between two test results, obtained by the same operator with the same apparatus under constant specified operating conditions on identical test material would, in the long run, in the normal and correct operation of the test method, exceed the following values only in 1 case in 20:

Repeatability: % oil separation = $1.151 x (M)^{0.5}$

Reproducibility: The difference between two single and independent results by two different operators working in different laboratories on identical test material would. in the long run, in the normal and correct operation of the test method, exceed the following values only in 1 case in 20: $1.517 \ x(M)^{0.5}$

Reproducibility: % oil separation =

Note: In both cases M is the mean of two tests or determinations

• What does this mean?



Here's what it means: ASTM D 6184

- A trained laboratory technician performing the tests
- ✓ in accordance with the prescribed method (consistently following the procedure)
- ✓ under the prescribed conditions (environmental conditions such as temperature, barometric pressure, local value of g etc. are within the acceptable limits)
- ✓ using specified equipment (not substituting equipment which may perform differently than the equipment specified)
- ✓ in a continued state of known performance capability (in a state of current calibration or verification)
- can evaluate its results against the stated acceptance criteria and can then report acceptance or rejection against the stated acceptance criteria with a 95% confidence level.

Uncertainty Included In Test Method Acceptance criteria are developed by in depth statistical analysis of sample results from multiple laboratories performing the same test multiple times.

Sample data obtained from multiple laboratories performing the same test multiple times, permits the determination of the mean (μ) of the distribution of sample averages. (i.e. the experimental standard deviation of the mean) and the standard deviation. This is used to establish acceptance criteria with a probability of 19 times out of 20 or 95%.

Uncertainty is present due to variation of equipment, operator skill and reproducibility but the manner by which the acceptance criteria is determined includes the uncertainty in the method of the analysis and therefore does not require further analysis.

Summary of Test Method 4.1

The weighed sample is placed in a cone-shaped, wire cloth sieve, suspended in a beaker, then heated under static conditions tor the specified time and temperature.

Unless otherwise required by the grease specification, the sample is tested at standard conditions of $100 \,^{\circ}\text{C} + 0.5 \,^{\circ}\text{C}$ for $30 \, \text{+/-} 0.25$ hr. The separated oil is weighed and reported as a percentage of the mass of the starting test sample.

The sample is weighed on a balance

It is heated to a specified temperature

It is maintained at the specified temperature for a specified time

The sample is visually examined to detect non-homogeneity such as oil separation, phase changes or gross contamination.

Detailed dimensions with tolerances are provided for the cone and the wire mesh material of which it is constructed.

A target dimension is provided to insure that the amount of sample material in the sieve is approximately the same for each test.

The sample is visually examined to detect non-homogeneity such as oil separation, phase changes or gross contamination.

The balance must have a 250 g capacity with 0.01 g resolution.

The sample is heated to a 100 °C +/- 0.5 °C.

The sample is maintained at the specified temperature for 30 hours +/- 15 minutes.

These potential variations were present during the statistical analysis which developed the acceptance criteria. As a result, further evaluation of measurement uncertainty is not required.



Requirements: ISO/IEC 17025:2017 Section 7.8 "Reporting of Results"

7.8.3.1 In addition to the requirements listed in <u>7.8.2</u>, **test reports shall**, where necessary for the interpretation of the test results, include the following:

c) where applicable, the measurement uncertainty presented in the same unit as that of the measured or in a term relative to the measured (e.g. percent) when:

— it is relevant to the validity or application of the test results;— a customer's instruction so requires, or— the measurement uncertainty affects conformity to a specification limit;



Reporting Uncertainty Test Labs

In the following examples, it will normally be necessary to report measurement uncertainty in order to comply with 7.8.3.1 c), if the laboratory is not required to report a statement of conformity:

Environmental tests conducted regularly and where conformity to a specification limit is assessed by the customers. Such cases may be mandated by legislation or be voluntary. In order for customers to assess if a test parameter is subject to change and poses a risk for not complying with the regulation, the measurement uncertainty needs to be known. The measurement uncertainty is necessary for the customers to make a qualified decision, e.g., on changes to their water or waste water treatment facilities.



Reporting Uncertainty Test Labs

Product tests where a product is tested for conformity to a specification. In such cases the test result may be quantitative as well as pass/fail. In both cases the reporting of measurement uncertainty should be important for a customer to assess the risk of product failure for an item near the specification limit. This is particularly relevant if the customer is the product manufacturer.

If unclear the determining factor should be determined during contract review.

As per 7.8.3.1

customer's instruction so requires



Requirements: ISO/IEC 17025:2017 Section 7.8 "Reporting of Results"

- **7.8.4.1** In addition to the requirements listed in <u>7.8.2</u>, **calibration** certificates **shall** include the following:
- a) the measurement uncertainty of the measurement result presented in the same unit as that of the measured or in a term relative to the measured (e.g. percent);
- As per PJLA PL-3 on Measurement Uncertainty

Any deviation from this requirement would need to come under the realm of simplified reporting as specified in ISO/IEC 17025:2017(clause 7.8.1.3). This is only permissible, if agreed to by the customer during the contract review process. This agreement **shall** be documented.



Requirements: ISO/IEC 17025:2017 Section 7.8 "Reporting of Results"

7.8.5 Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports shall include the following, where necessary for the interpretation of results:

f) information required to evaluate measurement uncertainty for subsequent testing or calibration.

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

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.



Decision Rule

Conditions associated with taking measurement uncertainty into account when making a statement of compliance.



Pass Pass? Fail? Fail



Statements of Conformity

7.8.6.2c state the following

The laboratory shall report on the statement of conformity, such that the statement clearly identifies the decision rule applied (unless it is inherent in the requested specification or standard)."

Unless it is inherent in the requested specification or standard; So what does this mean?





Statements of Conformity

There are testing methods that determine how the rules are applied. One good, common illustration is ASTM E18 for Rockwell Hardness where the testing 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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Statements of Conformity

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.





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

This guidance document has been prepared to assist laboratories in the use of decision rules when declaring statements of conformity to a specification or standard as required by ISO/IEC 17025:2017

ISO/IEC 17025:2017 recognizes that no single decision rule can address all statements of conformity across the diverse scope of testing and calibration



Keep in mind as per Review 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 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.



- This time is allocated for questions. You should have a space provided for submitting questions.
- If a question is not answered, please submit directly to webinar@pjlabs.com



Save the Date

ISO/IEC 17025:2017 -7.9 Complaints: Overview of Requirements

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Monday, Jul 25th 2022

