PJLA Policy on Measurement Uncertainty "PL-3"

Presented by:
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PJLA Policy on Measurement Uncertainty "PL-3

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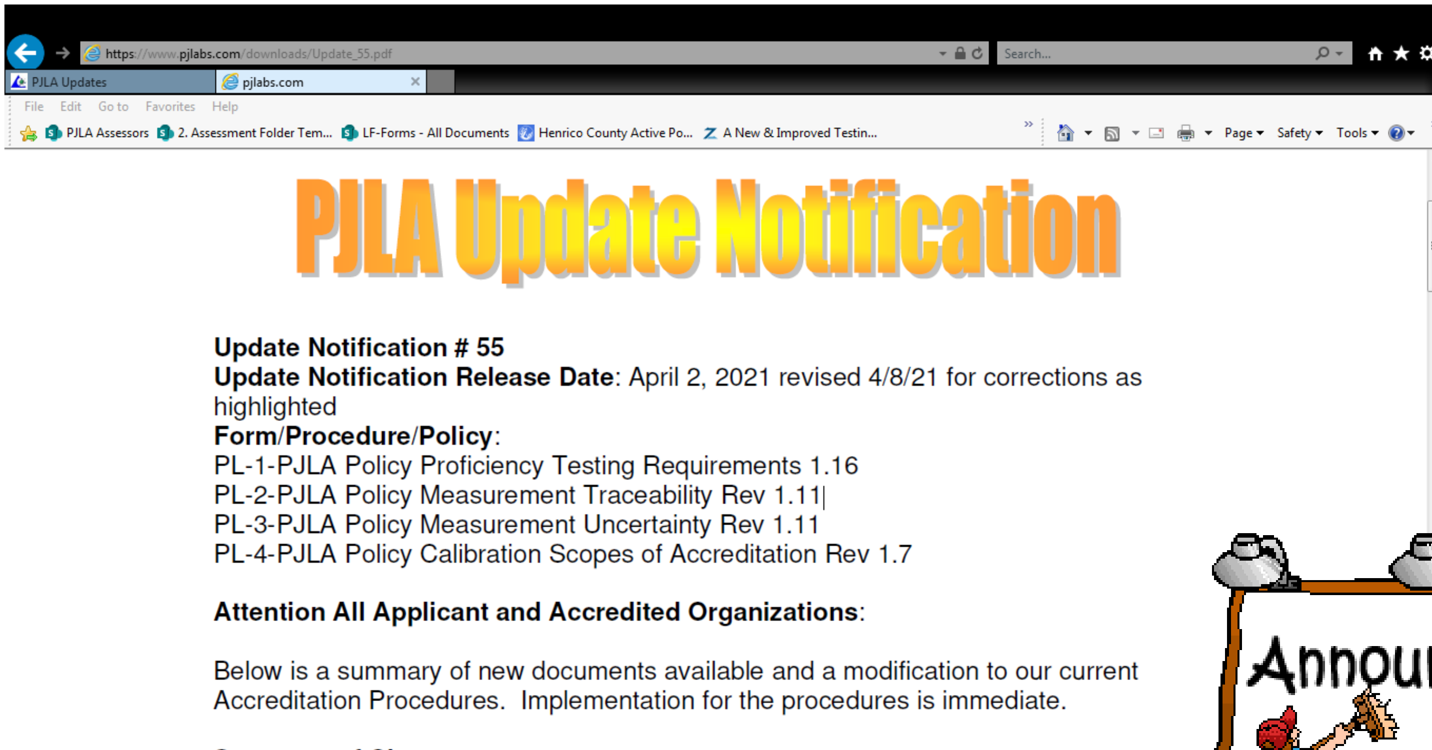
Duration of webinar is set for one hour.

You can type any questions directly into your webinar box; We will review them at the conclusion of today's session;

Update Notification 55 "April 2, 2021"



PJLA Update Notification

Update Notification # 55
Update Notification Release Date: April 2, 2021 revised 4/8/21 for corrections as highlighted
Form/Procedure/Policy:
PL-1-PJLA Policy Proficiency Testing Requirements 1.16
PL-2-PJLA Policy Measurement Traceability Rev 1.11
PL-3-PJLA Policy Measurement Uncertainty Rev 1.11
PL-4-PJLA Policy Calibration Scopes of Accreditation Rev 1.7

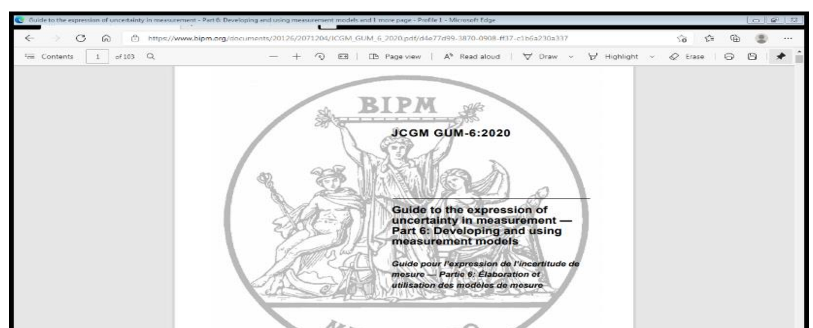
Attention All Applicant and Accredited Organizations:

Below is a summary of new documents available and a modification to our current Accreditation Procedures. Implementation for the procedures is immediate.

PJLA Policy on Measurement Uncertainty "PL-3"

The requirement to estimate CMC (Calibration and Measurement Capability)applies to calibration organizations only. This policy is based on the requirements outlined in ISO/IEC 17025:2017, ISO 15189:2012, ISO 17034:2016, ISO/IEC 17011:2017 and ILAC P-14:09/2020 and applies only to calibrations or tests for which an accredited result is to be reported.

In accordance with ILAC P14, laboratories will be required to determine measurement uncertainty in accordance with the GUM "Guide to the Expression of Uncertainty in Measurement"



Calibration and Measurement Capabilities

Calibration and Measurement Capabilities: Is an effort to express "The smallest uncertainty which an organization can attain when performing a more or less routine calibration of a nearly ideal device under nearly ideal conditions".

Accredited calibration laboratories shall not report a smaller measurement uncertainty than the uncertainty described by the CMC for which the laboratory is accredited

Pressure Gage Certification ID 190523.pdf - Adobe Acrobat Reader DC (32-bit)

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Home Tools Update_55.pdf PL-3 Uncertainty.pdf Pressure Gage Cert...

Sign In

Loc/Dept.: NA/NA **Procedure:** T.O. 33K6-4-427-1 **Rev:** 04/2019
Technician: Steven Housley-Follis **Units:** psi **Range:** 200
Comments: NA **Resolution:** 5

Service Date: 07/15/2020 **Due Date:** 07/15/2021
Temp: 21.4° C **Humidity:** 46.2% **Barometric Pressure:** N/A
Received Condition: In Tolerance **Returned Condition:** In Tolerance

Test Point Parameters	UOM	Nominal	Tolerance		Readings Before*	Readings After*	UNC
Increasing Pressure	psi	0.00	+6.00	-6.00	0.00	0.00	5.8
	psi	40.00	+6.00	-6.00	42.28	42.28	5.8
	psi	80.00	+6.00	-6.00	80.57	80.57	5.8
	psi	120.00	+6.00	-6.00	120.15	120.15	5.8
	psi	160.00	+6.00	-6.00	160.27	160.27	5.8
	psi	200.00	+6.00	-6.00	202.89	202.89	5.8
Decreasing Pressure	psi	80.00	+6.00	-6.00	81.08	81.08	5.8

*Bold reading entries indicate they are out of tolerance.

Calibration Standards Used

Asset Number	Manufacturer	Model	Calibration Date	Due Date	NIST #

PJLA Policy on Measurement Uncertainty "PL-3"

Accredited organizations 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. The organization must estimate the CMC for every measured quantity, instrument or gauge listed in its desired scope of accreditation in accordance with its documented procedure.

The organization shall then prepare an uncertainty budget containing all relevant information related to the identified significant sources of uncertainty.

Source of Uncertainty	Value a_i	Units	Probability Distribution	Divisor	Sensitivity Coefficient c_i	Standard Uncertainty $U_i(y)$ (mm)
Calibration Uncertainty	0.01	mm	Normal (k=2)	2	1	0.005
Resolution	0.005	mm	Triangular	√6	1	0.002
Cosine error	3	deg	Rectangular	√3	0.046	0.080
Temperature	2	C	Rectangular	√3	0.0023	0.003
Repeatability	0.02	mm	Normal (k=1)	1	1	0.020
					Combined Standard Uncertainty $u_c(y)$	**0.082**
					Expanded Uncertainty (k=2, 95% confidence) U	**0.165**

PJLA Policy on Measurement Uncertainty "PL-3"

Necessary steps in developing an estimate of measurement uncertainty

Step 1 ***Identify:*** *Make a list of all equipment or conditions that diminish the "correctness" of the measurement result*

Step 2 ***Quantify:*** *Determine reasonable values for the standard uncertainty of each identified contributor.*

Step 3 ***Combine:*** *Combine all standard uncertainties using the RSS (Root Sum of Squares) method.*

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

Step 4 ***Expand the uncertainty:*** *Multiply by the appropriate coverage factor to obtain the expanded uncertainty of the measurement result*

$$u_{c} * k$$

Uncertainty Contributors

The minimum you should consider

Reference Standard

Repeatability

Resolution, if you are calibrating an instrument

From there it depends on the type of calibration as to what contributors should be considered. May include Specification or drift of equipment, Environmental effects “temperature, humidity, barometric pressure, Coefficient of Thermal Expansion, Physical Constant & Conversion Factors, Metrologist Effects

Uncertainty Contributors

Pipette – Temperature/Humidity Effects

Mass – Air buoyancy associated with temperature, humidity and barometric pressure

Electronic – Drift associated with the Standard,

Caliper, Micrometer, Gauge Blocks, Uncertainty associated with Thermal Expansion of material,

Thermometer via liquid bath – uniformity of bath

IR Temperature - influence of emissivity

Uncertainty

1) Type A,

Type A contributors to uncertainty are those that you have statistical data for. Use this data if you have it.

E.g., For **Standard Uncertainty** in the mean of repeated measurements (preferably 10 or more) use the experimental standard deviation of the mean.

2) Type B

Type B contributors to uncertainty are those that you have no statistical data for; e.g.,

Manufacturer's specification

Professional judgement

Uncertainty in cal certificate for your reference standard

PJLA Policy on Measurement Uncertainty “PL-3”

When using the uncertainty budget to estimate CMC for inclusion on its desired scope of accreditation, the calibration organization shall consider the performance of the “best existing device” available for each calibration sub-discipline. This means that for sources which can be expected to vary from calibration to calibration, identify the smallest contribution, which will occur when the conditions, which cause it, are at optimum and use these values in the estimate of CMC.

Remember you can never report an actual uncertainty which is less than the stated CMC on the scope of accreditation.

Sample Uncertainty Budget Pipette

Pipette.pdf - Adobe Acrobat Reader DC (32-bit)

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Home Tools PL-3 Uncertainty.pdf Pipette.pdf

1 / 2 135%

This uncertainty budget applies to the following type of measurement: Pipette Dispenses on Analytical Balances

Applicable range of measurement: 200 ul

Following calibration procedure no. and rev.:

All uncertainties are expressed in units of: uL

Number of significant figures for reporting of expanded uncertainty: 2 Date prepared: 2014-07-24

Uncertainty budget prepared by: John Doe

i	Component of Uncertainty	Uncertainty, U(xi)	Distribution	Divisor	Std Unc, u(xi)	
1	Uncertainty of Balance from Cal Report	0.053	Normal, 2s	2.00	0.0265	uL
2	Linearity of Balance	0.15	Rectangular	1.73	0.0866	uL
3	Repeatability of Pipette	0.0918	Normal, 1s	1.00	0.0918	uL
4	Resolution of Balance	0.01	Rect x 2	3.46	0.00289	uL
5	Temperature of Water	0.00001	Rectangular	1.73	0.00000577	uL
6	Pipette Resolution	0.2	Rect x 2	3.46	0.057735027	uL
7	Cubic Expansion Coefficient	0.00009	Rectangular	1.73	5.19615E-05	uL
8	Evaporation	0.001	Rectangular	1.73	0.00057735	uL
9						
10						

combined standard uncertainty, u_c	0.141	uL
coverage factor, k	2	
expanded uncertainty, U_c	0.282	uL
Expanded uncertainty rounded UP to 2 significant figures	**0.29**	**uL**

i	Notes that document the basis for the above uncertainty estimates

Power Torque Tools Calibration Uncertainty Budget

Copy of Power Tool Torque.pdf - Adobe Acrobat Reader DC (32-bit)

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Home | Tools | PL-3 Uncertainty.pdf | NISTIR 6919- scale.... | Thermometer in liq... | Copy of Power Tool... | Sign In

	Description of Uncertainty Contributor	Type A/B	Parameter Uncertainty Limits	Parameter Units	Distribution	Level of Confidence	Coverage Factor (k)	Std Dev in Parameter Units	Effective Degrees of Freedom	Sensitivity Coefficient	Computed Uncertainty in Analysis Units	Effective Uncertainty in Analysis Units	Relative % of Total
A	MFG Spec.	B	1.4	ozf-in	Rectangular	100.00%	1.732	0.808290377	50	1	0.808290377	0.808290377	11.43
B	Calibration Error	B	0.4	ozf-in	Normal	95.45%	2.000	0.199999756	50	1	0.199999756	0.199999756	2.83
C	Calibration Resolution	B	0.01	lbf-in	Resolution	100.00%	3.464	0.002886751	50	1	0.002886751	0.002886751	0.04
D	UUT Resolution	B	0.5	ozf-in	Resolution	100.00%	3.464	0.144337567	50	1	0.144337567	0.144337567	2.04
E	Operator Variable COS Error	B	0.4	ozf-in	U-Shaped	100.00%	1.414	0.282842712	50	1	0.282842712	0.282842712	4.00
F	Joint Rate Simulator addition	B	2	ozf-in	Rectangular	100.00%	1.732	1.154700538	50	1	1.154700538	1.154700538	16.3
G	R&R and Stability	A	4.479528599	ozf-in	Std Dev	1 Std Dev	1	4.479528599	17	1	4.479528599	4.479528599	**63.34**
H													
I													
J													
K													
L													
M													
N													
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$$u_x = \sqrt{u_1{}^2 + u_2{}^2 \ldots u_n{}^2 + 2\rho_{1,2}u_1u_2}$$

Variable 1	Variable 2	Correlation Coefficient from 1.0 to -1.0	"Percent of Total" takes correlations into account via use of the "Effective Uncertainty" values.	Corr Values	**Uncertainty Toolbox**	GUM Method Calculator
		ρ of 1,2 =		**0.0000E+00**		
		ρ of 1,2 =		**0.0000E+00**		

Bolded Percent of Total Values are > or = to: 25% of Total Uncertainty | Total Eff. Degrees of Freedom (u)= **20.76** | Std Unc = **4.7110E+00** | **4.7110E+00** Std Unc

$$u_{1eff} = \sqrt{u_1{}^2 + \left(\left(\frac{u_1{}^2}{u_1{}^2 + u_2{}^2}\right) 2\rho_{1,2}u_1u_2\right)}$$

Where u_1 & u_2 are correlated

Level of Confidence	Distribution		k-factor			Expanded Unc	Units
95.45%	Student's t-Distribution	To achieve the stated "Level of Confidence" using t-statistics and Effective Degrees of Freedom, the calculated k-factor =	2.133	○	Expanded Unc =	1.0049E+01	ozf-in
	Normal Distribution	To achieve the stated "Level of Confidence" for an assumed "Normal" distribution, the calculated k-factor =	2.000	◉	Expanded Unc =	9.4220E+00	ozf-in

$$\nu = \frac{u_T^4}{\sum_{i=1}^{n} \frac{u_i^4}{v_i}}$$

Electrical Simulation Temperature Calibration Uncertainty Budget

SampleK Type TC Source UNC simulation Jerry.pdf - Adobe Acrobat Reader DC (32-bit)

	Description of Uncertainty Contributor	Type A/B	Parameter Uncertainty Limits	Parameter Units	Distribution	Level of Confidence	Coverage Factor (k)	Std Dev in Parameter Units	Effective Degrees of Freedom	Sensitivity Coefficient	Computed Uncertainty in Analysis Units	Effective Uncertainty in Analysis Units	Relative % of Total
A	744 Acc spec Measure	B	0.3	°C	Rectangular	100.00%	1.732	0.173205081	50	1	0.173205081	0.173205081	39.87
B	744 Cal UNC	B	0.08	°C	Normal	95.45%	2.000	0.039999951	50	1	0.039999951	0.039999951	9.21
C	744 resolution	B	0.1	°C	Resolution	100.00%	3.464	0.028867513	50	1	0.028867513	0.028867513	6.64
D	744 CJ error	B	0.2	°C	Rectangular	100.00%	1.732	0.115470054	50	1	0.115470054	0.115470054	26.58
E	EMF Voltage error	A	0.02	°C	U-Shaped	100.00%	1.414	0.014142136	50	1	0.014142136	0.014142136	3.26
F	DUT resolution	B	0.1	°C	Resolution	100.00%	3.464	0.028867513	50	1	0.028867513	0.028867513	**6.64**
G	Repetabality Data study	A	0.03391165	°C	Std Dev	1 Std Dev	1	0.03391165	29	1	0.03391165	0.03391165	7.81
H													
I													
J													
K													
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T													
U													
V													
W													
X													
Y													

$$u_x = \sqrt{u_1^2 + u_2^2 \ldots u_n^2 + 2\rho_{1,2}u_1u_2}$$

Variable 1	Variable 2	Correlation Coefficient from 1.0 to -1.0	"Percent of Total" takes correlations into account via use of the "Effective Uncertainty" values.	Corr Values	Uncertainty Toolbox	GUM Method Calculator
		ρ of 1,2 =		0.0000E+00		
		ρ of 1,2 =		0.0000E+00		

Bolded Percent of Total Values are > or = to: **25%** of Total Uncertainty | Total Eff. Degrees of Freedom (u)= **106.05** | Std Unc = **2.1897E-01** | **2.1897E-01** Std Unc

$$u_{1eff} = \sqrt{u_1^2 + \left(\left(\frac{u_1^2}{u_1^2 + u_2^2}\right)2\rho_{1,2}u_1u_2\right)}$$

Where u_1 & u_2 are correlated

95.45% Level of Confidence

Distribution		k-factor		Expanded Unc =	Units
Student's t-Distribution	To achieve the stated "Level of Confidence" using t-statistics and Effective Degrees of Freedom, the calculated k-factor =	**2.024**	○	4.4318E-01	**°C**
Normal Distribution	To achieve the stated "Level of Confidence" for an assumed "Normal" distribution, the calculated k-factor =	**2.000**	◉	**4.3795E-01**	**°C**

Significant Digits

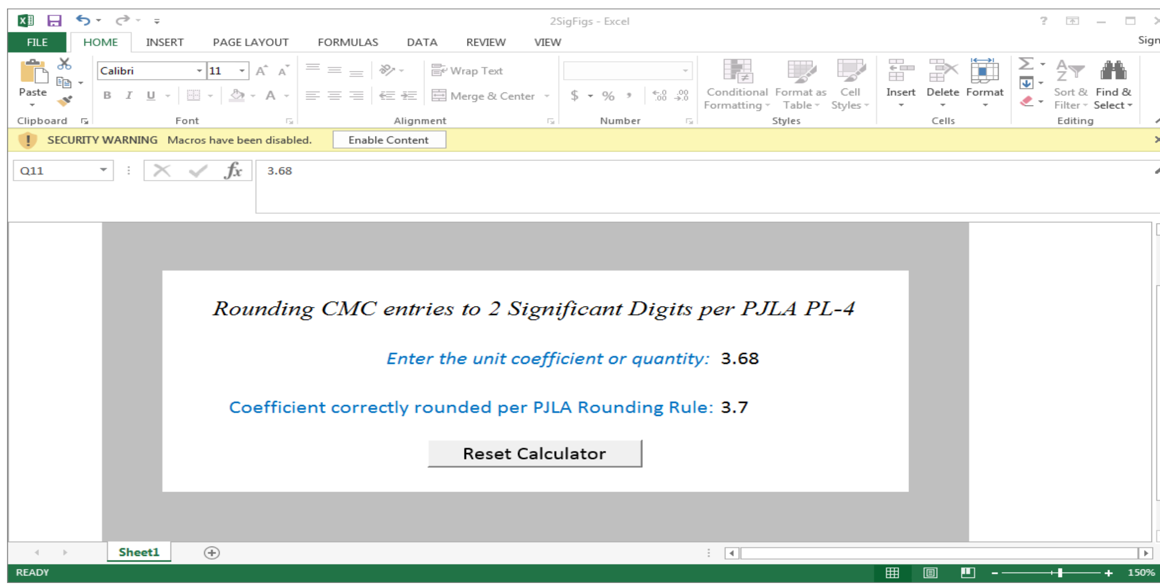
As entered on the scope and uncertainty as reported on the calibration certificate, test report, or reference material certificate shall be expressed using no more than 2 significant digits and no insignificant digits. For guidance on methods to identify significant and insignificant digits as well as rules for rounding of numbers used to express the CMC or uncertainty refer to PJLA PL-4.

0.149 mg = 0.15 mg

2.85mg = 2.9 mg

1.16 lb = 1.2 lb

3.68 lb = 3.7 lb



PJLA Policy on Measurement Uncertainty "PL-3"

The uncertainty covered by the CMC shall be expressed as the expanded uncertainty having a coverage probability of approximately 95 %. The unit of the uncertainty shall always be the same as the measured or in a term relative to the measured, e.g., percent, μV/V **Because of the ambiguity of definitions, the use of terms."PPM" and "PPB" are not acceptable.**

PL-3 addresses in-house calibrations. Requirements concerning uncertainty budgets are the same as accredited calibration laboratories.

Testing Labs

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.

When rigorous, mathematically, and statistically valid estimate of the measurement uncertainty may not be possible, so the requirements in ISO/IEC 17025:2017 7.6.3 would apply. In such cases the organization must identify all the components of uncertainty and make a “reasonable estimation”. The “reasonable estimation” is to be based on knowledge of the performance of the method and on the measurement.

Testing Labs

In those cases where a well recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the organization is considered to have satisfied ISO/IEC 17025:2017 clause 7.6.3 or ISO 15189:2012, Section 5.5.1.3. by following the test method and reporting instructions.

Examples include ASTM, AOAC, BAM, USP, FDA,EPA, etc. methods as well as regulatory, legal methods – US CFR, EU/EC methods and associated reporting.

Testing Labs

Other example include 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, (for example, a semi-quantitative kit assay that reports qualitative results such as “presence” or “absence” based on a numeric value*)*.

As a general rule qualitative or semi--quantitative tests or test that require personal judgement will not incorporate uncertainties.

PJLA Policy on Measurement Uncertainty "PL-3"

Upon achieving accreditation, the uncertainty budgets and the decisions regarding sources of uncertainty shall be periodically reviewed and updated by the organization to reflect changes in the organization, its equipment, procedures or personnel that might influence the ability of the organization to perform specific calibrations or tests for which they are accredited. These changes shall be documented.

In other words, preparing your uncertainty budget would need to be re-evaluated. An organization should always verify the uncertainty associated with standards used to detect any changes. Changes in facility and environment can impact uncertainty by affecting repeatability associated with the measurements.

PJLA Policy on Measurement Uncertainty "PL-3"

ISO/IEC 17025:2017 (clause 7.8.4.1 a) requires calibration certificates to report 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 (i.e., percent). 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

From ISO/IEC 17025:2017

7.8.4.1 In addition to the requirements listed in 7.8.2, calibration certificates **shall** include the following:

a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent

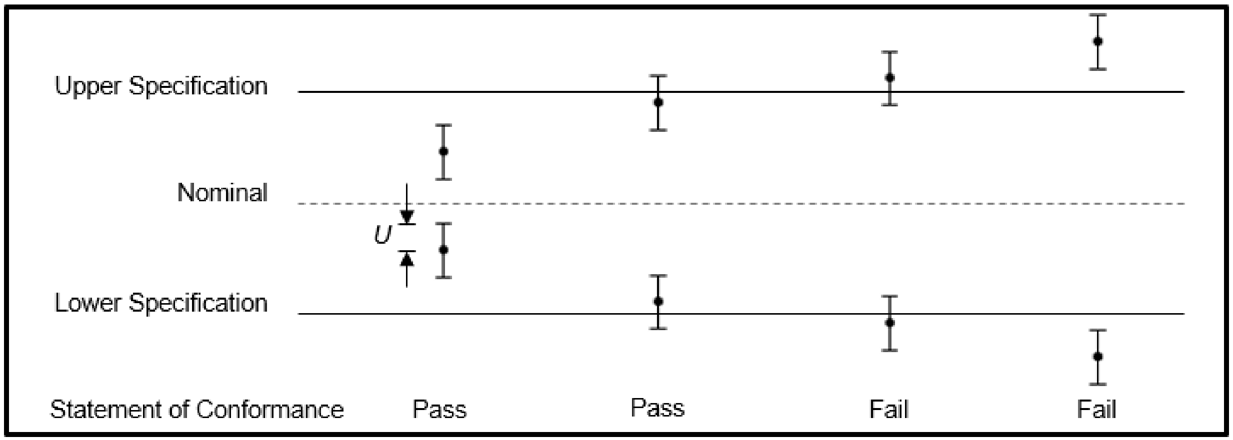
Decision Rule

Also, during contract review, the laboratory is required as per ISO/IEC 17025:2017 (clause 7.1.3) to define and capture the customer agreement as to the decision rule which will be employed when making statements of compliance. The decision rule is defined as a rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement. If a statement of compliance is being

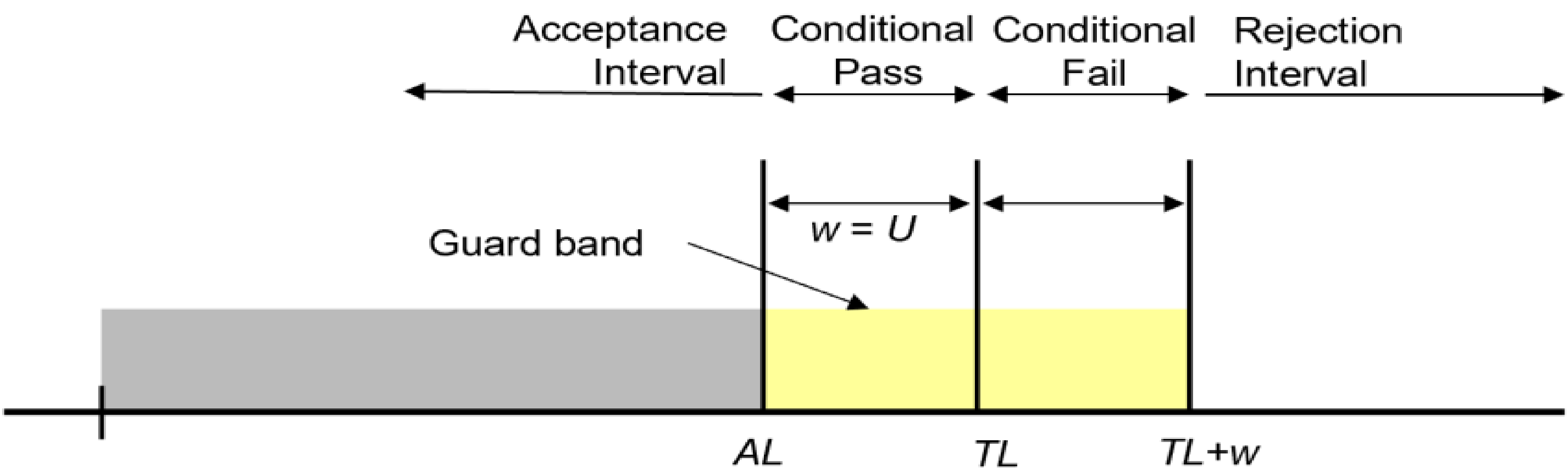
made on calibration reports, the agreed to decision rule is required as per ISO/IEC 17025:2017 (clause 7.8.6.1) to document the calibration report

For guidance in determining and selecting appropriate decision rules to meet these requirements specified in ISO/IEC 17025:2017, PJLA encourages the usage of ILAC G 8 “Guidance on Decision Rules and Statements of Conformity.

Decision Rule



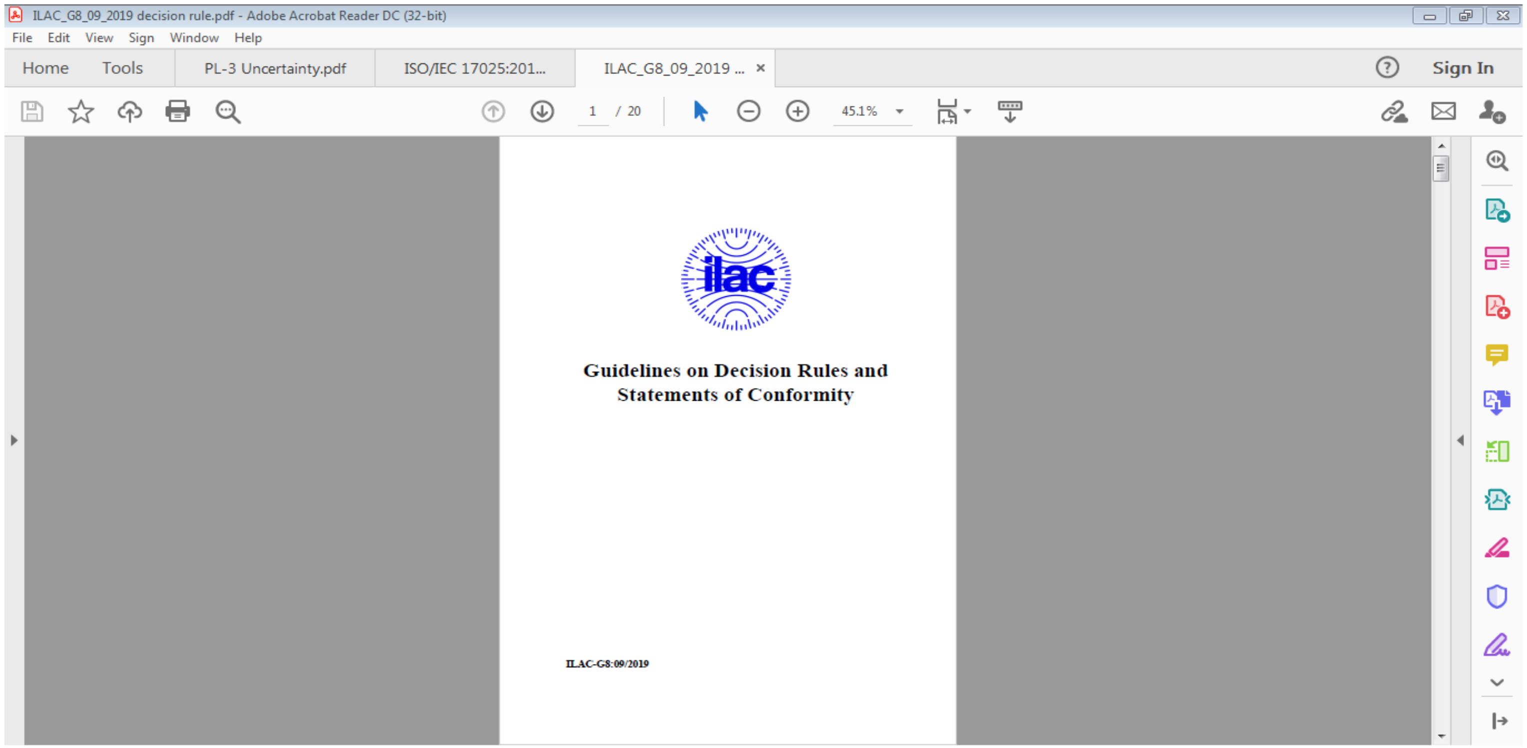
U = 95% expanded measurement uncertainty



ILAC G8

https://ilac.org/publications-and-resources/ilac-guidance-series

Or google ILAC G documents



PL-3 other revisions

Modified to include appropriate requirements and references for RMPs

Additional measurement uncertainty source for medical labs ISO/TS 20914:2019 added

See:

Section 7.0 REFERENCE MATERIAL PRODUCERS (RMPS) AND CERTIFIED REFERENCE MATERIAL PRODUCERS (CRMS)

Section 8.0 MEDICAL/CLINICAL LABORATORIES (15189)

This time is allocated for answering questions. You should have a space provided for submitting questions.

Please keep questions related to the topic covered in this webinar;

Save the Date

Next PJLA Webinar

August 2021

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	**30**	31				

Monday, Aug 30th 2021

ISO/IEC 17025:2017 Requirements for Corrective Action