Measurement Uncertainty

AfroCondomNet Webinar

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Measurement of uncertainty:

What is uncertainty ?

Uncertainty is the doubt that exists about the result of any measurement

Difference between error versus uncertainty:

Error is the difference between the measured value and the ‘true value’ of the thing being measured

Uncertainty is a quantification of the doubt about the measurement result

Sources of Uncertainty and Error

Measurement Uncertainty

Sources of uncertainty:

- Measuring instrument -Instruments can suffer from bias, change, wear, drift, poor readability, noise

  Item being measured
- Product may be unstable, flexible, etc
- Measurement process

  Difficult or complex or procedures, etc
- Imported uncertainties

  Calibration, standards, etc

Measurement Uncertainty

Sources of uncertainty:

- Operator skill

  Training, experience, etc
- Sampling issues

  Representative sample
- The environment

  Temperature, air pressure, humidity, etc

Measurement Uncertainty

Types of uncertainty:

Type A

Uncertainty estimated from data using statistics (usually from repeated readings)

Type B

Uncertainty estimates from any other information, e.g. past experience of the measurements, calibration certificates, manufacturer's specifications, calculations, published information, etc

Measurement Uncertainty

Estimation of uncertainty:

Type A

Relevant statistical methods e.g. standard uncertainty of the mean = $s/\sqrt{n}$

(s is the sample standard deviation and n is the sample size)

Type B

E.g. standard uncertainty of a range where upper and lower limits are estimated = $a/\sqrt{3}$

(a is half the range)

Measurement Uncertainty

- Measurement
- Test method
- Test procedure
- Calibrated equipment
- Competent technician
- Result
- Interpretation of results

Measurement Uncertainty

Basic concepts:

Accuracy: Trueness – How close is the measured value with reference to true value

Precision: How consistent are the measured values

Repeatability: Measure of precision between measurements made in the same lab by same operator, same equipment….

Reproducibility: Measure of precision between measurements made in different labs by different operators, using different equipment

Measurement Uncertainty

Factors impacting results:

- **Random distribution of defectives**
- **Statistical sampling plans – capturing the defectives**
- **Equipment sensitivity, resolution, calibration**
- **Operator variations, operational variations**
- **Data processing variations**
- **Reference standards , values used**

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Measurement Uncertainty

- Factors - independent , inter related
- Systematic errors, random errors
- Bias
- Type A errors – follow normal distribution
- Type B errors – infinite degree of freedom

Measurement Uncertainty

Variations:

- Distribution of measured values - Random
- Significance of mean and standard deviation - measure of variation
- confidence level :
- Mean ± 1s.d : 68 %
- Mean ± 2 s.d : 95 %
- Mean ± 3 s.d : 99 %

Measurement Uncertainty

Measurement Uncertainty calculation requirements:

Type I- Qualitative or semi-qualitative tests for which measurement uncertainty will not be required. FFH and Package Seal Integrity.

Type II- Well recognized test methods that specify limits to the values of the major sources of uncertainty of measurement and specify the form of presentation of calculated results. In such cases, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions. Airburst volume , pressure, time.

Measurement Uncertainty

- **Type III- Chemical, biological or environmental test methods based on published regulatory or consensus methods for which the measurement uncertainty is not defined in the method. Eg. Test for Lubricant content (bias)**
- **Type IV- Test methods that need identification of the major components of uncertainty and a reasonable estimate of measurement uncertainty.**
- **Type V- Test methods that need identification of all components of uncertainty and detailed measurement uncertainty budgets calculated in accordance with published methods that are consistent with those described in ISO "Guide to the Expression of Uncertainty in Measurement". In-house developed methods**

Measurement Uncertainty

Calculation of uncertainty:

- **Standard Uncertainty (SU)-** Defined as one standard deviation. Test a reference standard 30 times (for example) and calculate the SU.

- **Combined Standard Uncertainty (CSU)-** The components of uncertainty have to be identified and combined to produce an overall uncertainty.

Expanded Uncertainty (EU)- The uncertainty required by ISO 17025. Normal distribution is assumed and a value of k=2 defines having a level of confidence of approximately 95%. Multiply SU or CSU by 2 to arrive at the Expanded Uncertainty.
K= 3 defines approximately 99% confidence

Standard Measurement Uncertainty – Example of Mass testing.

Test #	Weight Result (mg)
1	6.990
2	7.020
3	7.010
4	7.007
5	7.017
6	7.005
7	7.010
8	7.007
9	7.017
10	7.005
Average	7.009
Standard Deviation or Standard Measurement Uncertainty	0.009
Expanded Measurement Uncertainty @ k=2	**0.017**

Example- continued

Burst Volume

Ua- Repeatability- Standard deviation of 4 readings divided by the square root of the number of readings (normal distribution).

Ub1- Uncertainty of gas flow meter (± 0.310 L/min) divided by 2 (normal distribution). .

Ub2- Resolution of gas flow meter (0.005 L/min) divided by √3 (rectangular distribution*).

Uc- Square root of the sum of each component squared.

Uncertainty- Expanded Uncertainty at k=2 which is equal to ± 0.310 L/min

Set your flow rate at 28 L/min (or other flow rates between 24-30 L/Min) on each head of the airburst machine, then take the flow rate reading with the calibrated mass flow meter.

A. Flowrate Calibration

Actual Flowrate (L/min)	UUC of reading(L/min) 1	2	3	4	Average (L/min)	SD (L/min)	Correction (N)- (L/min)	Ua SD/√n (±L/min)	Ub1 (Uncertainty of standard) UB1/2 (±L/min)	Ub2 (Uncertainty of resolution) UB2/√3 (±L/min)	Uc (Combined uncertainty) $\sqrt{((Ua)^2+(Ub1)^2+(Ub2)^2)}$	Uncertainty (±L/min)
28.000	28.000	28.000	28.000	28.000	28.000	0.000	0.000	0.000	0.155	0.003	0.155	0.310

*In rectangular distributions all values are equally likely, where in a normal distribution modal numbers are more likely than extreme values.

Example- continued

Burst pressure

- Ua- Repeatability- Standard deviation of 4 readings divided by the square root of the number of readings at several pressure points within the working range (normal distribution).
- Ub1- Uncertainty of manometer (± 0.013 kPa) divided by 2 (normal distribution). .
- Ub2- Resolution of manometer (0.005 kPa) divided by $\sqrt{3}$ (rectangular distribution).
- Uc- Square root of the sum of each component squared.
- Uncertainty- Expanded Uncertainty at k=2 which is equal to ± 0.014 -0.015 kPa.

Example- continued

Burst pressure

Actual Pressure (kPa)	UUC of reading(kPa) 1	2	3	4	Average (kPa)	SD (kPa)	Correction (N)- (kPa)	Ua SD/√n (±kPa)	Ub1 (Uncertainty of standard) UB1/2 (±kPa)	Ub2 (Uncertainty of resolution) UB2/√3 (±kPa)	Uc (Combined uncertainty) $\sqrt{((Ua)^2+(Ub1)^2+(Ub2)^2)}$	Uncertainty (±kPa)
0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.0000	0.0065	0.0029	0.0071	0.014
0.196	0.195	0.193	0.195	0.194	0.194	0.001	0.002	0.0005	0.0065	0.0029	0.0071	0.014
0.392	0.389	0.389	0.399	0.390	0.392	0.005	0.000	0.0024	0.0065	0.0029	0.0075	0.015
0.588	0.589	0.584	0.584	0.588	0.586	0.003	0.002	0.0013	0.0065	0.0029	0.0072	0.014
0.785	0.789	0.786	0.783	0.784	0.786	0.003	-0.001	0.0013	0.0065	0.0029	0.0072	0.014
0.981	0.981	0.984	0.985	0.983	0.983	0.002	-0.002	0.0009	0.0065	0.0029	0.0072	0.014
1.177	1.179	1.173	1.170	1.174	1.174	0.004	0.003	0.0019	0.0065	0.0029	0.0074	0.015
1.373	1.375	1.375	1.375	1.376	1.375	0.000	-0.002	0.0002	0.0065	0.0029	0.0071	0.014
1.569	1.565	1.567	1.569	1.563	1.566	0.003	0.003	0.0013	0.0065	0.0029	0.0072	0.014
1.765	1.766	1.762	1.769	1.762	1.765	0.003	0.000	0.0017	0.0065	0.0029	0.0073	0.015
1.961	1.963	1.962	1.951	1.961	1.959	0.006	0.002	0.0028	0.0065	0.0029	0.0076	0.015
2.157	2.158	2.155	2.158	2.160	2.158	0.002	-0.001	0.0010	0.0065	0.0029	0.0072	0.014
2.354	2.359	2.359	2.357	2.357	2.358	0.001	-0.004	0.0006	0.0065	0.0029	0.0071	0.014
2.550	2.554	2.554	2.556	2.557	2.555	0.002	-0.005	0.0008	0.0065	0.0029	0.0072	0.014

Example- Continued

Time

Ua- Repeatability- Standard deviation of 4 readings divided by the square root of the number of readings at several times within the working range (normal distribution).

Ub1- Uncertainty of stopwatch (± 0.096 sec.) divided by 2 (normal distribution).

Ub2- Resolution of stopwatch(0.005 sec.) divided by √3 (rectangular distribution).

Uc- Square root of the sum of each component squared.

Uncertainty- Expanded Uncertainty at k=2 which is equal to ± 0.096 sec.

Actual Time (Sec)	UUC of reading(Sec) 1	2	3	4	Average (Sec)	SD (L/min)	Correction (N)- (Sec)	Ua SD/√n (±Sec)	Ub1 (Uncertainty of standard) UB1/2 (±Sec)	Ub2 (Uncertainty of resolution) UB2/√3 (±Sec)	Uc (Combined uncertainty) $\sqrt{((Ua)^2+(Ub1)^2+(Ub2)^2)}$	Uncertainty (±Sec)
20	20.016	20.008	20.008	20.016	20.012	0.005	-0.012	0.00231	0.0480	0.0029	0.048	0.096
40	40.000	40.012	40.012	40.012	40.009	0.006	-0.009	0.00300	0.0480	0.0029	0.048	0.096
60	60.000	60.008	60.016	60.008	60.008	0.007	-0.008	0.00327	0.0480	0.0029	0.048	0.096
80	80.004	80.012	80.004	80.004	80.006	0.004	-0.006	0.00200	0.0480	0.0029	0.048	0.096
100	100.004	100.008	100.008	100.000	100.005	0.004	-0.005	0.00191	0.0480	0.0029	0.048	0.096
120	120.004	120.012	120.008	120.012	120.009	0.004	-0.009	0.00191	0.0480	0.0029	0.048	0.096
140	140.004	140.008	140.012	140.012	140.009	0.004	-0.009	0.00191	0.0480	0.0029	0.048	0.096

Summary

The expanded combined uncertainty contribution at k=2 for this example to airburst testing for volume, pressure and time is 0.310 L/Min, 0.015 kPa, and 0.096 seconds, respectively

Measurement Uncertainty - Application

Decision rule:

Analysis and interpretation of data to arrive at "Pass" / "Fail" decision

Decision – Test level

– Product batch level

– Consignment level

– Product level

Measurement Uncertainty

Decision rule:

- **Normal random products - clear**
- **Marginal quality level**
- **Unexpected/ abnormal results – current level of technology and quality levels**
- **Too good results**
- **Excessively bad results**
- **Actions: "Approve"/ "Reject"/ "Quarantine"**

Measurement Uncertainty

Decision rule:

Out of Specification (OOS) investigation:

- **Sampling and condition of samples**
- **Equipment – condition, calibration, adjustments**
- **Operator – competence, training**
- **Method – deviations**
- **Environmental conditions - deviations**
- **Data - accuracy, calculations, recording, transposition, alterations**
- **Application of calculated uncertainty**

Measurement Uncertainty

Thank you

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