Evaluation of Measurement Uncertainty for Testing Laboratories

ISO/IEC 17025:2017 7.6

Perry Johnson Laboratory Accreditation, Inc.

Discussion Points

- Measurement Uncertainty
- Standard Requirements
- Identifying Contributions
- Evaluating Measurement Uncertainty
  - Pros/Cons of Approaches

Measurement uncertainty

Non negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information ….

(VIM: 2012, 2.26)

JCGM 200:2012

International vocabulary of metrology – Basic and general concepts and associated terms (VIM)

3rd edition

2008 version with minor corrections

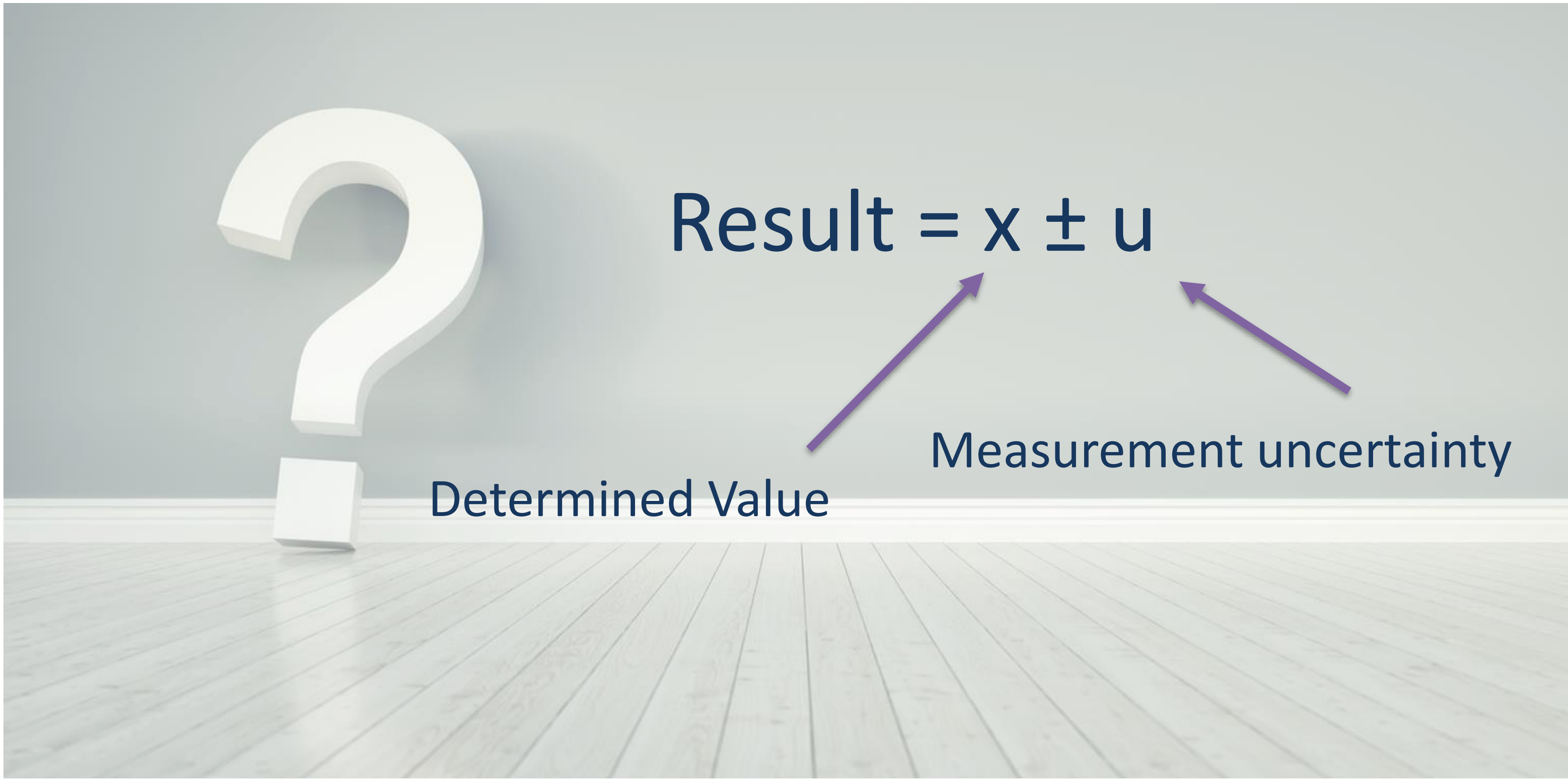
Vocabulaire international de métrologie – Concepts fondamentaux et généraux et termes associés (VIM)

3e édition

Version 2008 avec corrections mineures

© JCGM 2012

WHAT IS UNCERTAINTY



Standard Requirements

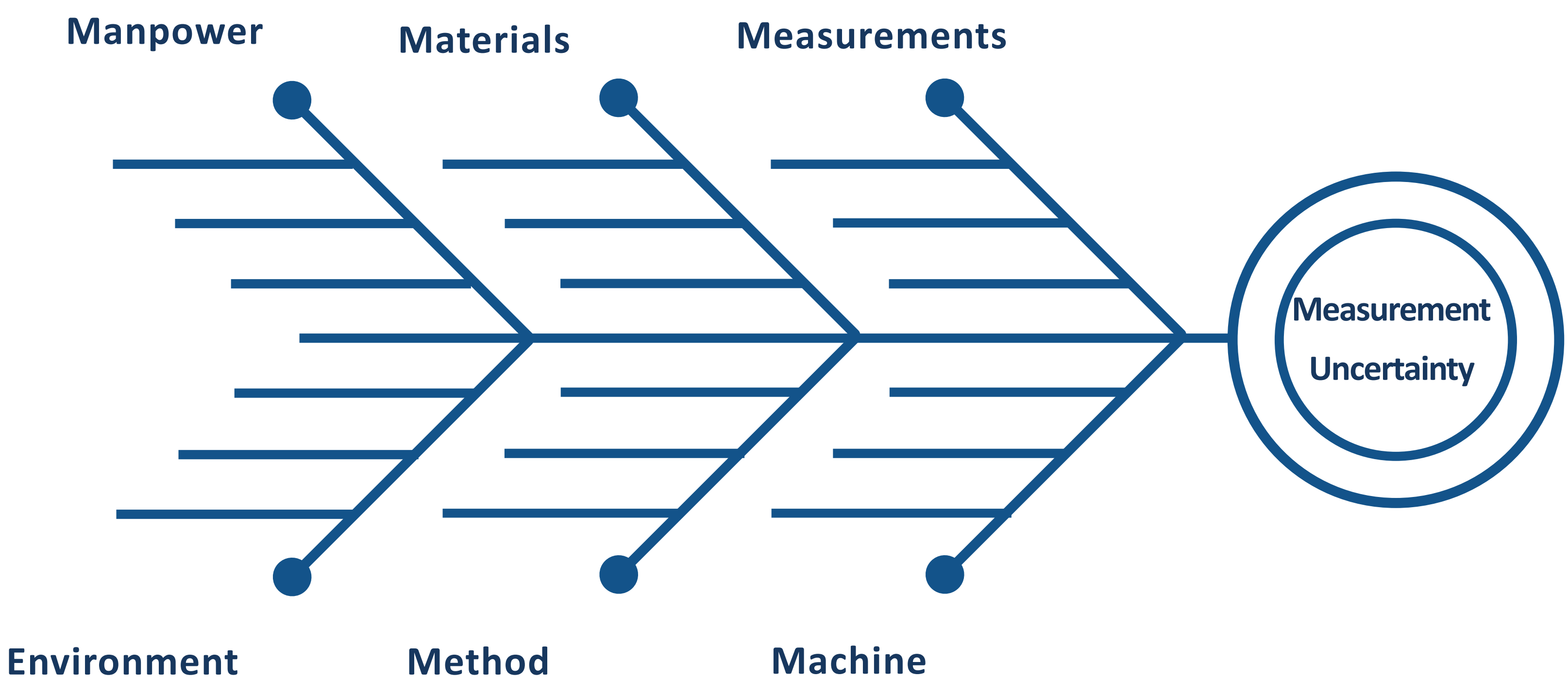
IDENTIFY CONTRIBUTIONS

EVALUATE MEASUREMENT UNCERTAINTY

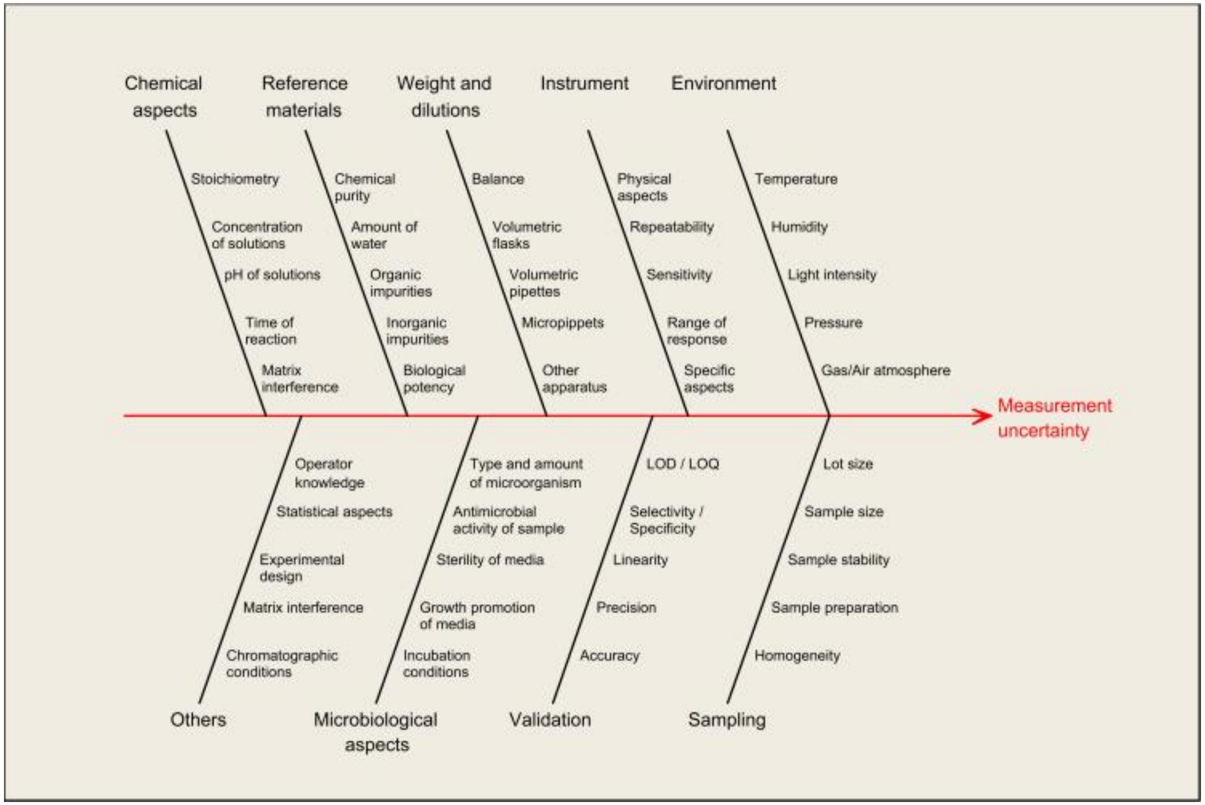
Standard Requirement

IDENTIFY
CONTRIBUTIONS

IDENTIFY CONTRIBUTIONS



Example for Pharmaceutical Analysis



Traple, Saviano, Francisco, Lourenço, Measurement uncertainty in pharmaceutical analysis and its application, Journal of Pharmaceutical Analysis, Volume 4, Issue 1, 2014,

Standard Requirement

EVALUATE MEASUREMENT
UNCERTAINTY

GUM Approach

- Define measurand
- Identify sources of uncertainty
- Quantify each source
- Identify significant factors
- Determine probability distributions
- Divide component by appropriate divisor for standard uncertainties
- Calculate combined standard uncertainty (u)
- Calculate expanded uncertainty (U)

Pros/Cons to Approach

Pros

- Critically assesses the test method for uncertainty contributors
- Consistent with other fields of metrology

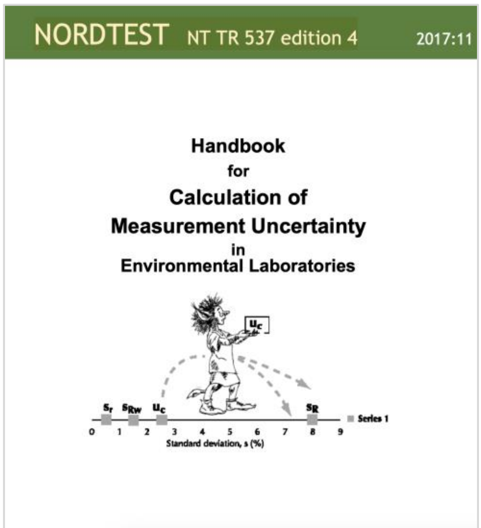
Cons

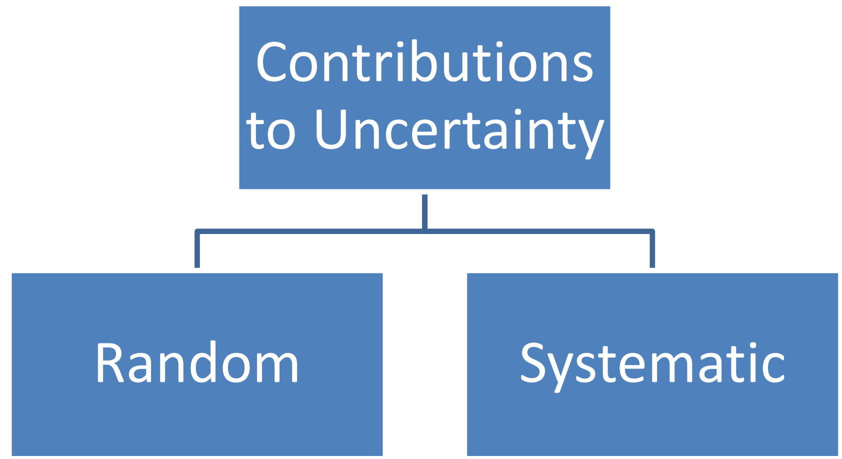
- Not practical in testing environment
- Need to understand mathematical model/ equation

Data Driven Approaches

- NORDTEST NT TR 537 – "Handbook for calculation of measurement uncertainty in environmental laboratories"
- ISO 21748 - "Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation"
- ISO 11352 - "Water quality - Estimation of measurement uncertainty based on validation and quality control data"

NORDTEST NT TR 537 edition 4





Single Lab

http://www.nordtest.info/wp/2017/11/29/handbook-for-calculation-of-measurement-uncertainty-in-environmental-laboratories-nt-tr-537-edition-4/

Nordtest

Combined Std Uncertainty

$$u_{c} = \sqrt{u(Rw)^2 + u(bias)^2}$$

Within lab Reproducibility

Bias

Nordtest Approach

- Define measurand
- Quantify within lab reproducibility
- Quantify bias
- Convert to standard uncertainties
- Combine standard uncertainties
- Calculate expanded uncertainty

Reproducibility

- Includes sample prep
- Homogenous sample
- Sufficient timeframe
- Concentration match
- Matrix match
- Enough replicate measurements

Bias

- Reliable reference value
- Include sample preparation
- Matrix match
- Sufficiently long timeframe
- Concentration range match
- Homogeneous sample
- Large number of replicate measurements

Bias from CRMs use

$$u_{\text{bias}} = \sqrt{(RMS_{bias})^2 + u(C_{ref})^2}$$

Average Bias

Average uncertainty of reference values From Certificate

RMS $_{\text{bias}} = \sqrt{\sum (RMS_{bias})^2 / n}$

Nordtest

Combined Std Uncertainty

$$u_{c} = \sqrt{u(Rw)^2 + u(bias)^2}$$

Within lab Reproducibility

Bias

Pros/Cons to Approach

Pros	Cons
• Assesses method performance of lab • Covers the analytical process • Uses QC data	• Not IDing of sources (required by standard) • Single Estimate may not be feasible

In Summary

IDENTIFY CONTRIBUTIONS

EVALUATE MEASUREMENT UNCERTAINTY

Thank You!

Matthew Sica

PJLA Testing Program Manager

msica@pjlabs.com

www.pjlabs.com