ISO 17025 Accreditation/Quality Management Systems Panel Discussion

AAFCO 2014 Annual Meeting

Laboratory Methods & Service Committee

Sacramento, CA

July 26, 2014

AAFCO Association of American Feed Control Officials

Uncertainty of Measurement – Estimation & Reporting

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Relevant sections of the standard

Section 5 – Technical Requirements

5.4.6 Estimation of Uncertainty of Measurement

- 5.4.6.2 Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement.

5.10 Reporting the Results

- 5.10.3.1 c) where applicable, a statement on the estimated uncertainty of measurement;

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Definition and Requirements

- *"a parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand."*
  International Vocabulary of basic and general terms in Metrology. ISO, Geneva, (1993). (ISBN 92-67-10175-1)

- An uncertainty estimate yields information as to the quality of the analytical result and hence the test method used.

- Measurement uncertainty values allow comparison of analytical results within and between laboratories or with specification and regulatory limits.

- It should be noted that ISO 17025 does not recommend one approach over another. Any approach that uses statistically valid methodology and yields a reasonable estimate is as valid as another approach.

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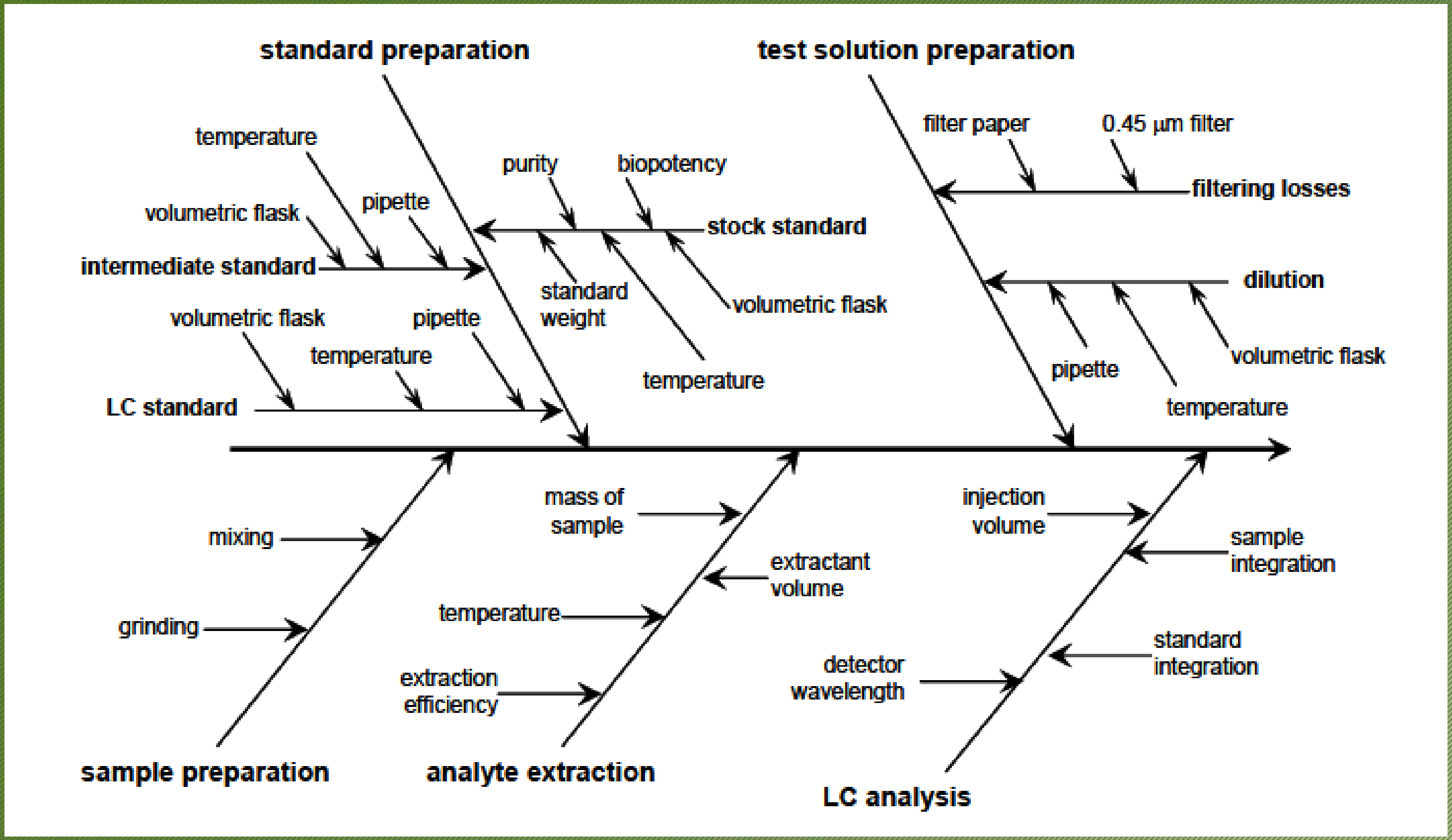
Example Sources of Uncertainty



- Attempt to identify significant uncertainty components
- Typically, components < 1/3 of largest uncertainty component are insignificant
- Cumulative effect of several small components should not be ignored though

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What You're Trying to Accomplish

Two main ways forward:

•**Bottom Up** (Guide to the Expression of Uncertainty in Measurement – GUM)

•**Top Down** (Eurachem – Quantifying Uncertainty in Analytical Measurement, and most others)

For the Top Down method:

•Grouped uncertainty components and remaining uncertainty components are quantified using existing data,

•Typically this includes precision (usually random, various distributions), bias (usually systematic) and any other uncertainty sources (eg. sample processing).

A good estimate will:

•Be as representative as possible,

•Ensure concentration ranges and different sample types covered,

•Make sure method performed over a range of conditions under which it might reasonably be expected to be used.

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Steps to Estimate Uncertainty

- Step 1: Specify the Measurand
- Step 2: Identify the Uncertainty Sources
- Step 3: Quantify the Uncertainty Components
  - QC, PT, validation data can be used
  - Equations depend on type of data used
  - components in standard deviation (standard uncertainty)
- Step 4: Calculate the Combined Standard Uncertainty

  $u_c(y) = \sqrt{u(p)^2 + u(q)^2 + \ldots}$ OR $u_c(y) = y\sqrt{\left(\frac{u(p)}{p}\right)^2 + \left(\frac{u(q)}{q}\right)^2 + \cdots}$
- Step 5: Calculate the Expanded Uncertainty
  - coverage factor (k), usually 2 (95% confidence)

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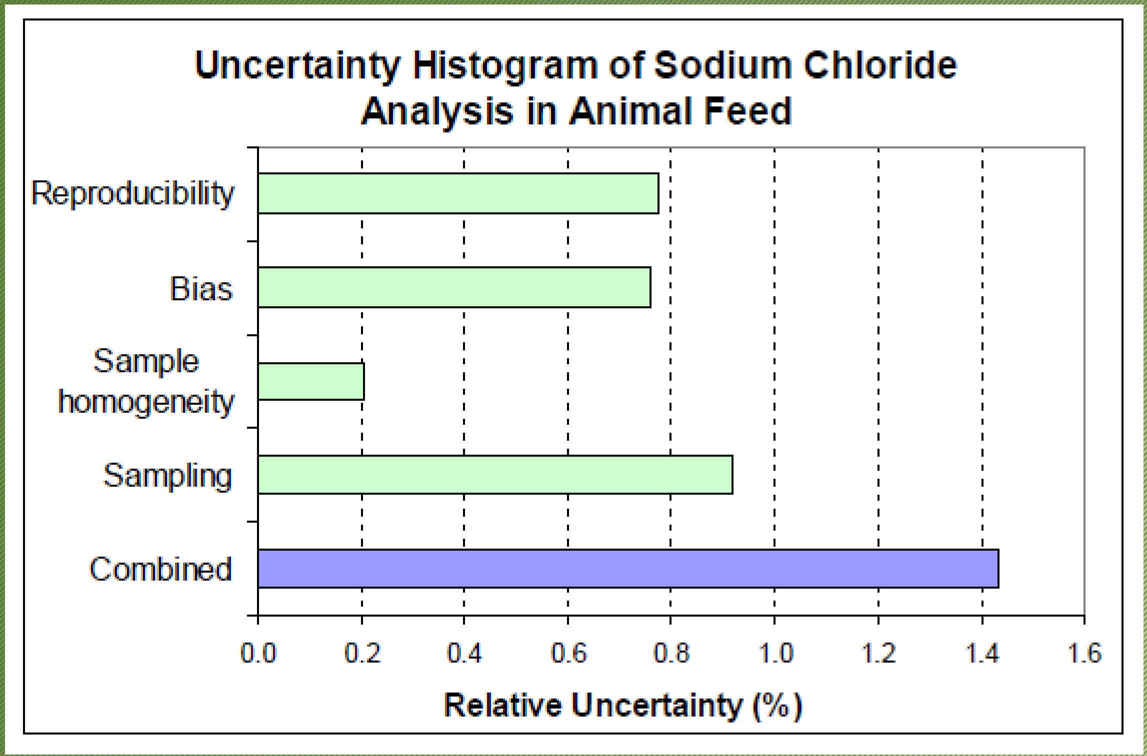
Reporting Uncertainty

Result: y +/- U(y) (% or units)

This means that the true value is within U(y) (% or units) of the measured result, 95%* of the time

*Provided a coverage factor at 95% confidence was used



Tips and Helpful Hints

- Use the top down approach, probably already have enough data,
- A robust single laboratory validation should contain enough data for a strong uncertainty estimate,
- Extra studies may be required to examine uncertainties due to sample processing, homogeneity, standard preparation, etc,
- Can also use QC samples run with each batch, also PT samples can be used,
- Be careful not to take into account analyst errors or changes in the samples over time,
- Be aware of certain basic statistical principles, eg. square root of the sum of the squares,
- Uncertainty estimates don't need to be updated if nothing has changed,
- Be careful of the uncertainty down at the method's limit of detection/quantitation (it is likely larger!),
- Don't forget to add the coverage factor, and don't be surprised by very large uncertainties.

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Useful References

- Guide to the Expression of Uncertainty in Measurement (GUM), ISO, Geneva, 1993.
- Eurachem/CITAC guide: Quantifying Uncertainty in Analytical Measurement, Third edition, (2012).
- AAFCO QA/QC Guidelines for Feed Laboratories, 3rd edition, 2014.
- VAM Project 3.2.1 Development and Harmonisation of Measurement Uncertainty Principles, Part (d): Protocol for uncertainty evaluation from validation data.
- Eurachem/CITAC guide: Measurement Uncertainty Arising from Sampling: A guide to methods and approaches. EURACHEM, (2007).
- ISO 5725: 1994 (Parts 1-4 and 6): Accuracy (trueness and precision) of measurement methods and results. ISO, Geneva (1994).
- ISO 21748:2010: Guide to the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation. ISO, Geneva (2010).
- NORDTEST Technical Report 537: Handbook for calculation of measurement uncertainty in environmental laboratories. NORDTEST 2003.
- P19 – CALA Measurement Uncertainty Policy, Revision 1.10 – May 2010.
- A2LA, Guide for the Estimation of Measurement Uncertainty in Testing, Rev. 1.8.

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