VALIDATION
TRACEABILITY
MEASUREMENT UNCERTAINTY
CHALLENGES FOR THE 21ST CENTURY’S ANALYSTS

Workshop group 2.3:
How do laboratories document traceability?

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Rapporteur: …

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WG 2.3 questions

a. What are the common ways of establishing traceability in the analytical laboratory?

b. Will the laboratory distinguish between “Metrological traceability” and “Analytical traceability”?

c. Are there problems in identifying calibrations needed to establish traceability?

d. Are these calibration procedures and the standards required set out in a SOP?

e. What are the difficulties in getting the appropriate standards

f. Is further guidance needed in addition to that in the EURACHEM/CITAC Guide: “Traceability in Chemical Measurement and Meeting the traceability requirements of ISO 17025: An analyst's guide”? If so on what topics?

g. How should traceability of empirical measurements be defined and shown?

h. Does your laboratory ever document traceability based on participation in PT schemes?

a) What are the common ways of establishing traceability in the analytical laboratory?

- Certified Reference materials
  - including ‘complete’ items (test pieces etc)
- Self-made reference materials
  - often based on CRMs (eg dilutions)
- Calibrated devices (thermometers, balances, ...)
- Uncalibrated devices (watches etc)
- Non-certified pure materials
- Manufacturer’s standards
  - Sometimes accredited
- Ambient conditions
  - Often need close control of temperature, pressure, humidity etc
  - Do we need calibrated monitoring equipment?
    - Often overlooked in laboratories
b) Will the laboratory distinguish between “SI traceability” and “Analytical traceability”?

- Example; dosimetry, measuring ‘darkness’ on a grey scale
- Example: pH. Certificates come with pH standards ‘traceable to NIST’.
  - which means ... ?
  - ... checking the NIST policy could be useful ...
- Pure substances
  - lack of SI traceability
  - Do pure materials provide SI traceability?
    - and does accreditation improve it?
    - needed for long term trends?
- Pure materials are a bit contentious

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c) Are there problems in identifying calibrations needed to establish traceability?

- Sometimes environmental conditions are ignored

- Noted that calibration is not _always_ necessary to show sufficient control
d) Are these calibration procedures and the standards required set out in a SOP?

- Yes
- …. of course!!

e) What are the difficulties in getting the appropriate standards

- Availability varies
- Reliability can also vary (depending on how matrix CRMs are certified)
f) Is further guidance needed in addition to that in the EURACHEM/CITAC Guide: “Traceability in Chemical Measurement and Meeting the traceability requirements of ISO 17025: An analyst's guide“ ?? If so on what topics?

- Pure materials
- Environmental conditions
- Complex equipment
- Calibration frequency

g) How should traceability of empirical measurements be defined and shown?

- [See presentation by Alex Williams]
h) Does your laboratory ever document traceability based on participation in PT schemes?

- Q: How can one get traceability from a PT?

- Need to distinguish comparison (no need for traceability) with measurement of a certified material used in a PT (same as a CRM)
- Use of a PT material for calibration makes the calibration traceable to the PT value.

- Discussed whether 'check' materials confer traceability
  - Balance of opinion was 'no'...
  - Implication; they aren't part of the uncertainty either
  - ... or are they?

Additional subjects discussed

- What do we do with sophisticated equipment dependent on the manufacturer?

- How often should we calibrate?

- Types of calibration
  - Official (eg States in Germany – state institutes not always accredited)
  - Any others
  - Sometimes involves paying twice...
Documenting traceability

- Documentation is very important
  - Certificates, log books etc
  - Numbering system to identify individual items
    - (allows tracing back to original item)

- Procedures for calibration, including calibration frequency

- Certificates don’t always show accreditation status
  - don’t know whether the certification is valid

- ’Internal calibration’ also needs qualified staff ...
  - May need separate accreditation for calibration

Metrological traceability

- Question: is training part of metrological traceability?
  - Some discussion...
    - training is part of establishing traceability
    - .. but this is separate from the ‘technical part’ of metrological traceability

- There are different views of the ‘scope’ of traceability
  - everything necessary to ensure reliable results vs just the activity concerned with calibration

- Also still some need to be careful using metrological as opposed to any other traceability

- Traceability chain can be defined on a technical basis; other issues can be dealt with by management system and uncertainty
  - Comment: ‘breaks’ – such as matrix effects – can be ‘fixed’ by incorporation in uncertainty
  - not unanimous ...

- ... and “What is a calibration”? ...