Why regulate?

[redacted]

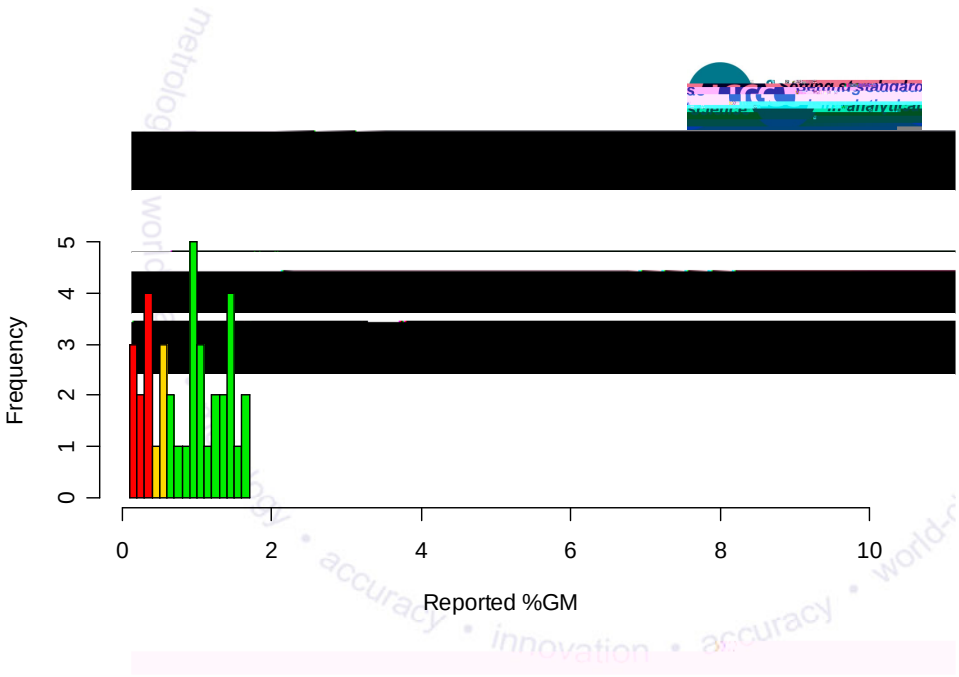
[redacted]

[redacted]

Why measure?

- Ensuring compliance with regulation is the most frequently reported reason for undertaking analysis
  - (may be in combination with others)
- An
limits

Why worry?


Frequency
0
1
2
3
4
5
0
2
4
6
8
10
Reported %GM

Improving quality - VAM* Principles

[redacted]

- [redacted]

"Metrology"

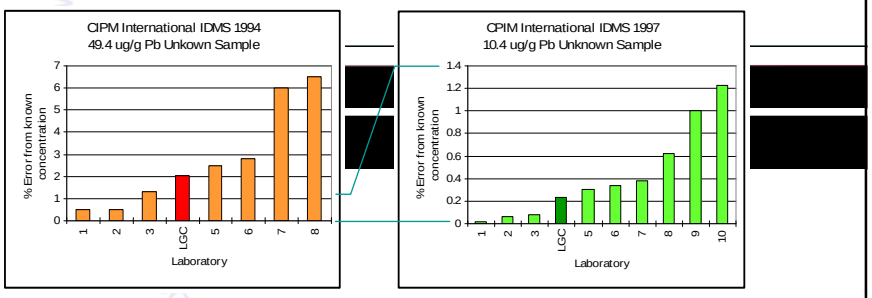
Standardisation: Pros & Cons

[redacted]

Pro:

- Specific to application
- [redacted]

Key Comparison development



Round 1: 1994

Round 2: 1998

Practical implementation - Reference materials

- CRM definition
- We
- Sta
-

Quality systems

- ISO 9000: Consistency and contract
- GLP/GMP: Documentation and (via cGMP) technical requirements
- IS
- Monitored by Accreditation Bodies or GxP approval bodies
- Mandatory for most important measurements

Training and Competence

- All quality systems require appropriate training
- Te
  -
  -
- Continued dialogue works better than one-way specification
- Proficiency testing promotes technical dialogue

Intercomparison by Proficiency testing (EQA)

- Pros:
  - [redacted]
  - [redacted]
- Co[redacted]
  - Requires sufficiently stable material
  - Infrequent - monthly

Measurement uncertainty estimation

- One of the most important tools for practising metrologists
- “Pr[redacted]
- Pro[redacted]
- … [redacted] now required by all accreditation bodies
- … even in analytical chemistry and biological measurement

What is Measurement Uncertainty?

"A parameter, associated with the result of a measurement, that characterises the dispersion

The number after the ±

Measurement uncertainty ...

- DOES NOT
  ...j
- DO
  ...
  ... Pointing out limitations in reference values, environmental controls...
  ... to say something about where the true value might lie

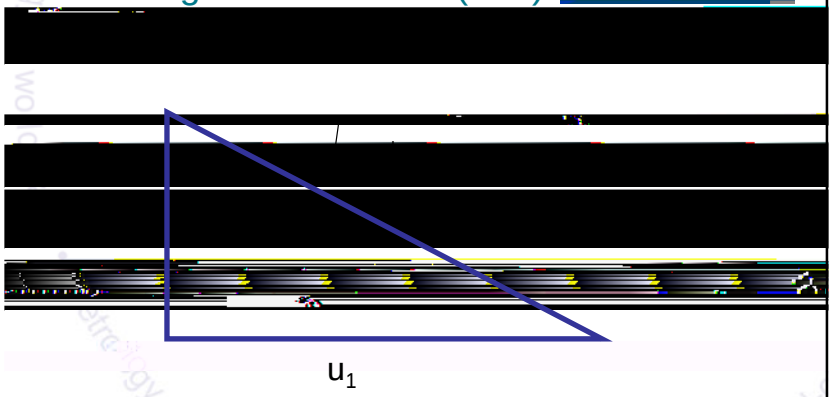
Problems

- “Correct” evaluation
- Imp
- Co
- Management
  - of uncertainty

ISO Guide approach

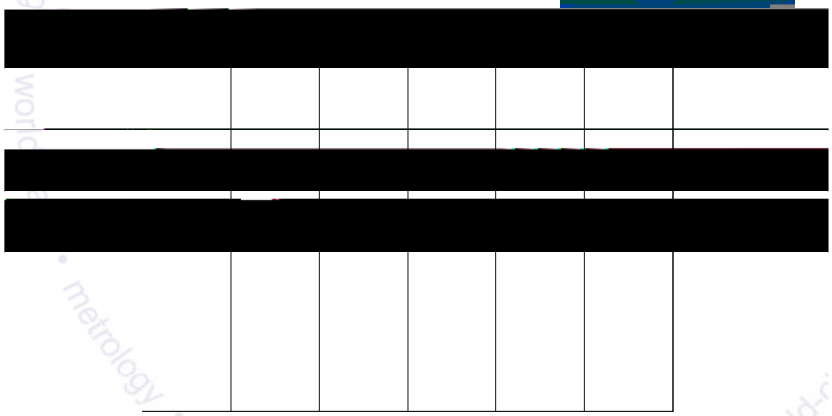
- Specify the measurand
  - including complete equation
- Quantity symbol and uncertainties for all parameters
  - A: by statistical means
  - B: by any other means (theory, certificates, judgement...)
- Express as standard deviation
- Combine according to stated principles
- Multiply by “coverage factor”

Combining uncertainties (ISO)



u_1

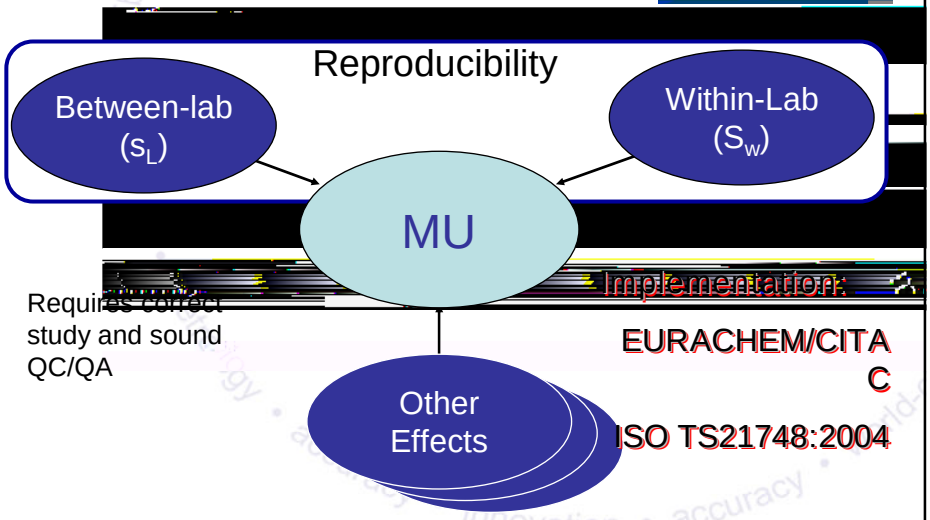
Example: Forensic alcohol reference standard titration



MU based on validation

- The best available estimate of precision
  - An effect varied representatively during a precision experiment requires no further study
- Th[illegible] and its uncertainty
- Other significant effects evaluated
  - By experiment, or from standing data

Collaborative Study basis



Requires correct study and sound QC/QA

Implementation:

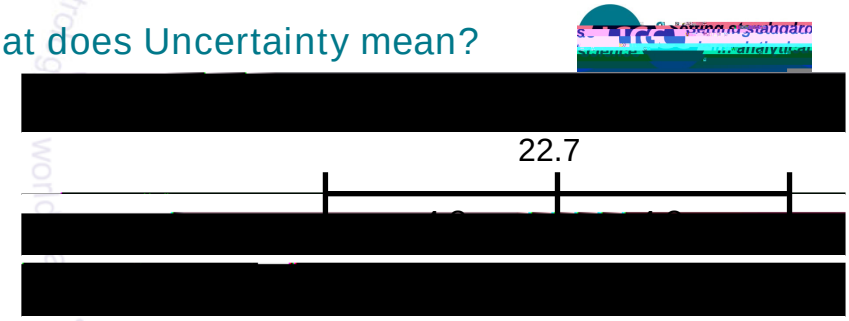
EURACHEM/CITAC

ISO TS21748:2004

“Best” Method depends on the problem

[redacted]

What does Uncertainty mean?

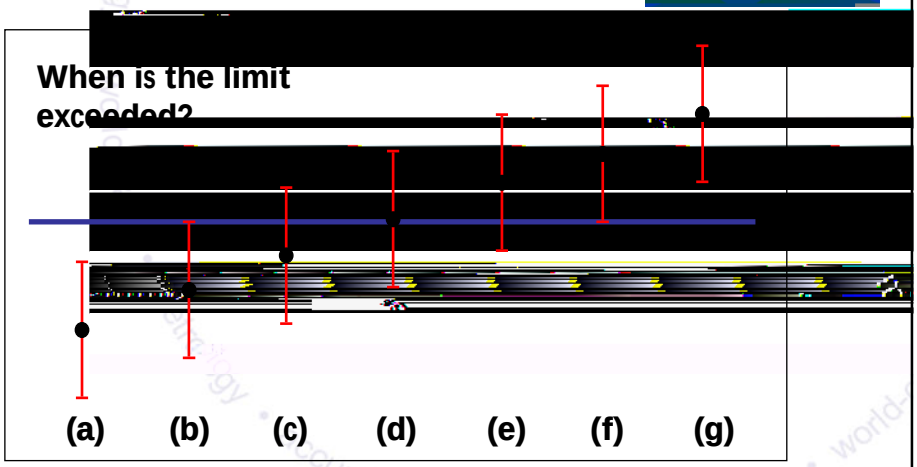


A RANGE containing the TRUE VALUE?

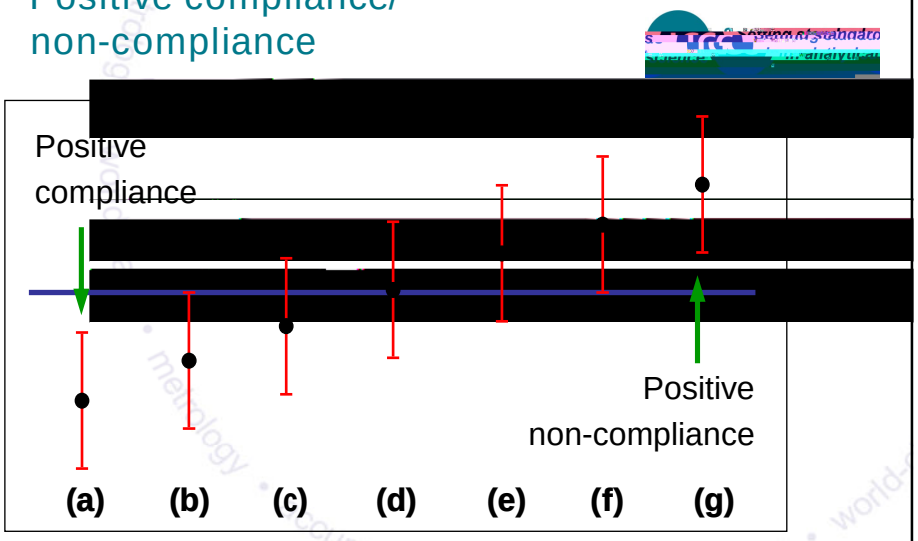
Impact on regulation and compliance

- Changes in interpretation
- Am
- Cre

Interpretation



Positive compliance/ non-compliance



Interpretation: example

- Declared Meat Content: 67%
  - **Public Analyst result: 64%**
  - **L**
  - **Trading Standards officer**
    c

This vague answer has prevented a successful prosecution… has anyone else experienced these ambiguous results from LGC?