

**Regulatory limits and analysis:
Setting limits and
interpreting results with uncertainty**

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Eurachem 2010 :: 1

Introduction

- What is Measurement uncertainty?
- Impact on decisions
- Managing uncertainty in regulation
- Interpreting results

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What is Measurement Uncertainty?



"A parameter, associated with the result of a measurement, that characterises the dispersion of the values that could reasonably be attributed to the measurand"

(ISO Guide)

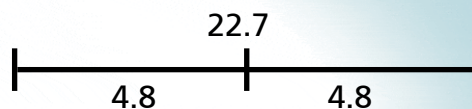
The number after the \pm

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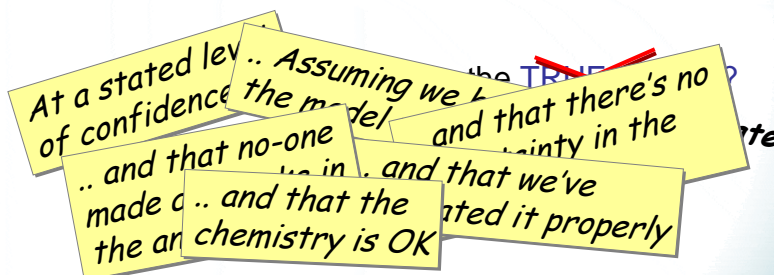
What does Uncertainty mean?



$22.7 \pm 4.8 \text{ g}$



"The amount is between 17.9 and 27.5"

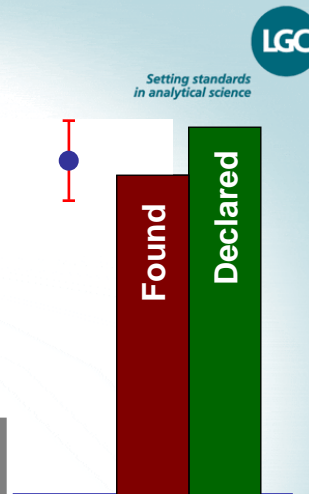


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Interpretation: example

- Declared Meat Content: 67%
- Public Analyst result: 64%
- Referee result: $65 \pm 3\%$
- Trading Standards officer correspondence:

This vague answer has prevented a successful prosecution... **has anyone else experienced these ambiguous results ...?**



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What does Uncertainty mean?

- That the result is uncertain so we can ignore it
- That the analyst doesn't know the answer
- That more crooks will get away with it
- That we need to change the way we interpret results
- That we need to change the law
-



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Measurement uncertainty ...



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- DOES NOT
 - ...just include observed precision
- DOES
 - ... include ALL POSSIBLE effects
 - ... including uncertainties in reference values, environment, method controls....
 - ... *try* to say something about where the true value might lie

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Problems



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- "Correct" evaluation
- Impact on compliance assessments
- Correct interpretation
- Communication
- Management
 - of uncertainty
 - of decisions with uncertainty

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Uncertainty evaluation methods



- Repeatability assessment
 - Always insufficient...
- ISO Guide approach ("the GUM")
 - Accreditation
- Validation-based approaches
- Interlaboratory study
 - Traditional in regulatory analysis

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"Best" Method depends on the problem



"Well characterised"
quantified effects,
differentiable,
continuous, traceable

Poorly characterised;
Unpredictable effects;
Input parameters unclear



WELL ← **Measurement model applies** → **POORLY**

POORLY ← **Whole method study applies** → **WELL**

Use both for mutual confidence

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Estimating measurement uncertainty



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- Use published standards and protocols
 - ISO Guide to the Expression of Uncertainty in Measurement
 - Eurachem: Quantifying Uncertainty in Analytical Measurement
 - ISO TS 21748: Using reproducibility data for measurement uncertainty estimation
- Use data on method performance
- Use published data
- Use data on the particular sample under test
- Use data on reagents and equipment
 - e.g. Calibration material uncertainties

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Why regulate?

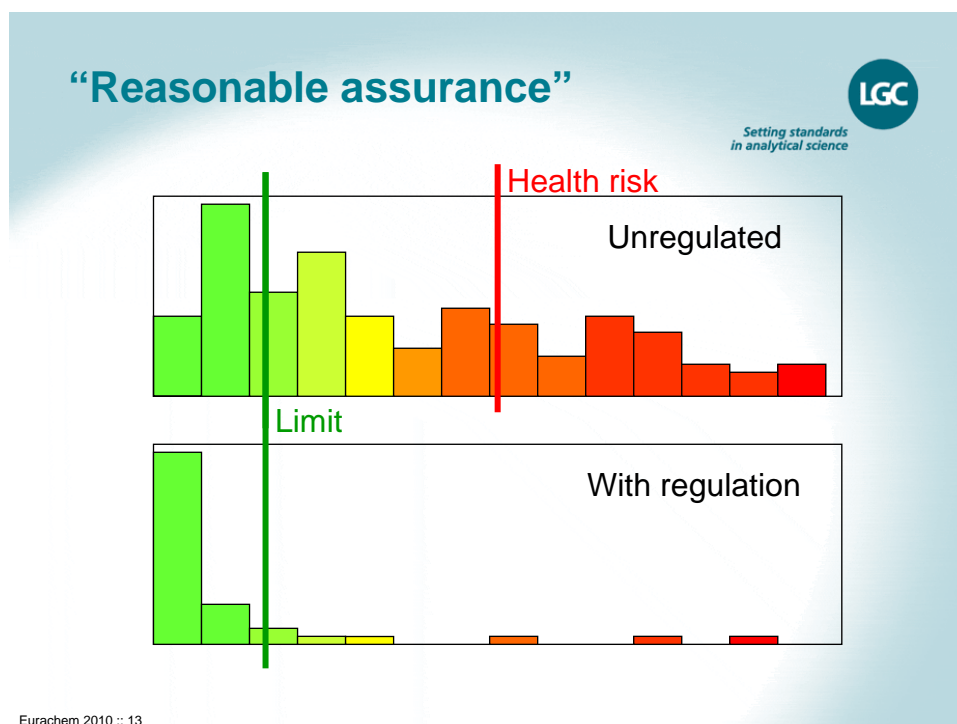


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- To reduce risks to health and environment
- To control trade and prevent fraud

Both require only
"Reasonable assurance"

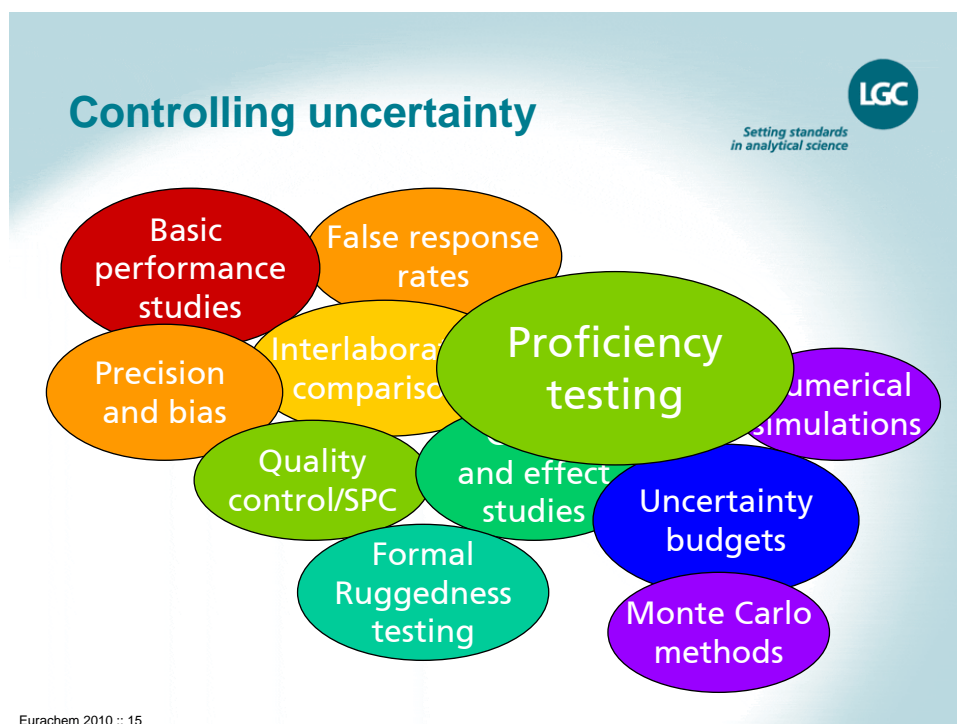
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Managing uncertainty in regulation

- Know and control the uncertainty
- Establish rules for interpretation
 - Whether to use uncertainty
 - How to evaluate
 - Positive compliance versus positive non-compliance

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Regulators' behaviour*

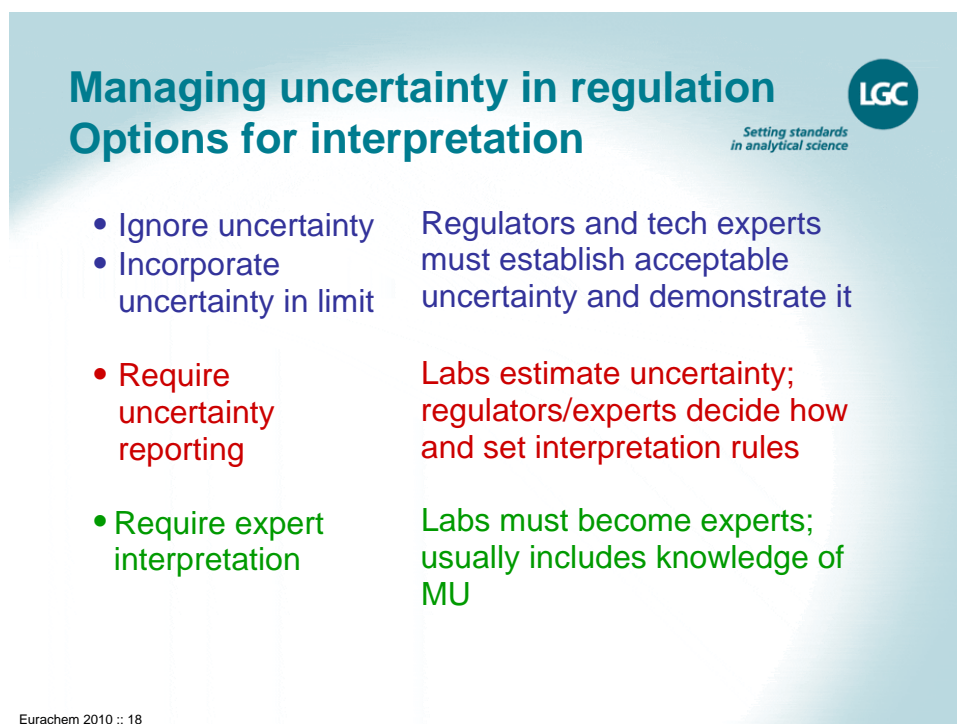
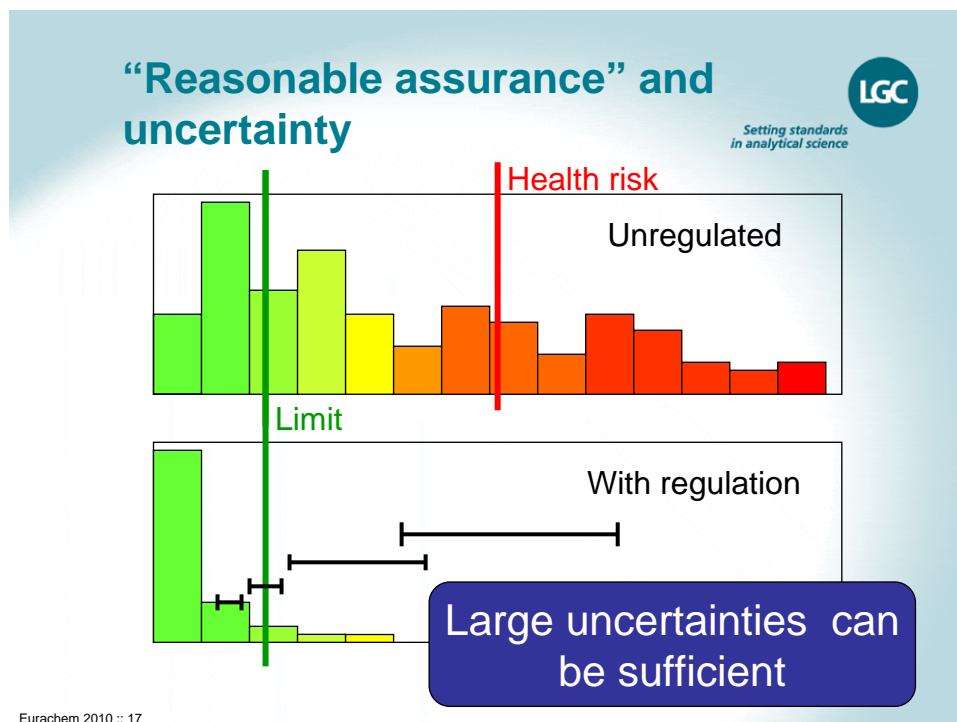
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LGC

- Set regulations to achieve aims
 - allow experts, courts and industry to establish methods of policing and compliance detection
- Do not assume measurement is the only enforcement method
- Set limits such that 'borderline cases' are not very important
- Act further if disagreement undermines regulation

**Inferred from observation*

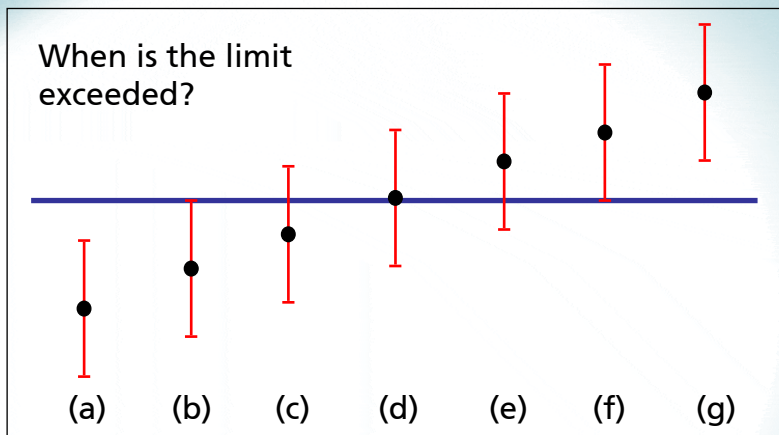
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Interpretation



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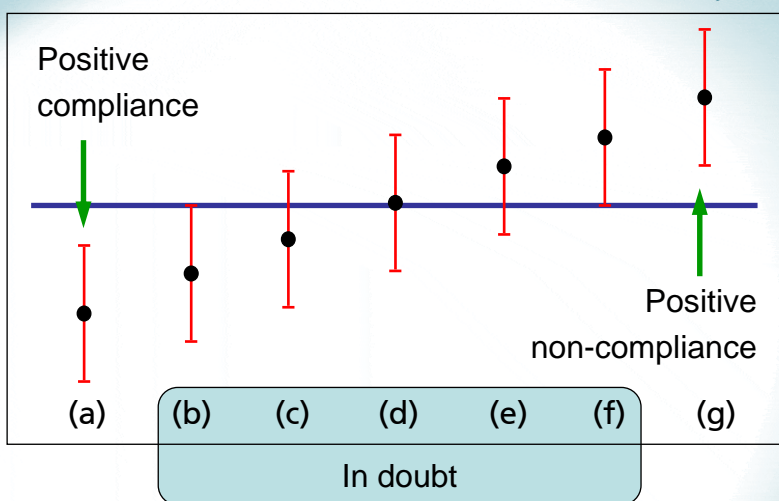


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Typical Current guidance



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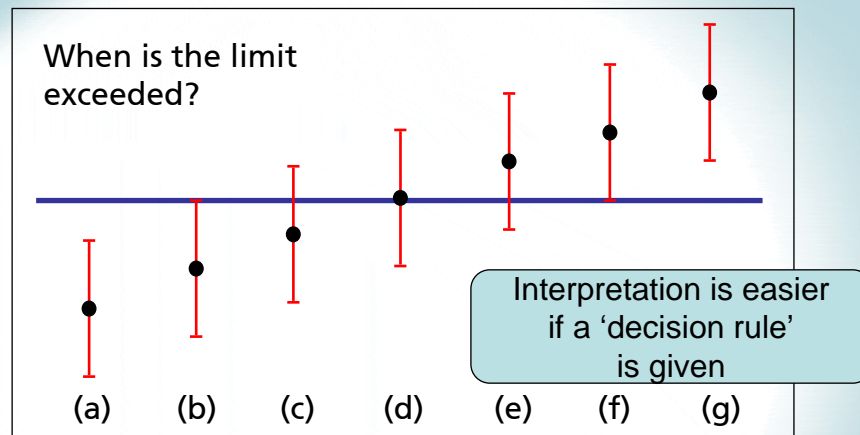
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How does Measurement Uncertainty affect interpretation?



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Recent guidance on interpretation



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- Eurachem: "Use of uncertainty information in compliance assessment"
- Published 2007
 - available from <http://www.eurachem.org>
- Adds detail to existing EA and UKAS guidance
- Based on 'decision rules' and consequent 'guardbands'

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Required Information



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- A specification giving upper and/or lower permitted limits
- A decision rule that describes how the uncertainty will be taken into account.
- The limit(s) of the acceptance or rejection zone (i.e. the range of results), derived from the measurement result and a stated uncertainty decision rule

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Simple example of a Decision Rule



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- A result equal to or above the upper limit implies non-compliance
- A result below the limit implies compliance.
- Provided that
 - uncertainty is below a specified value (e.g. small compared with the limit)
- The risk of making a wrong decision is then acceptable.

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Technical problems



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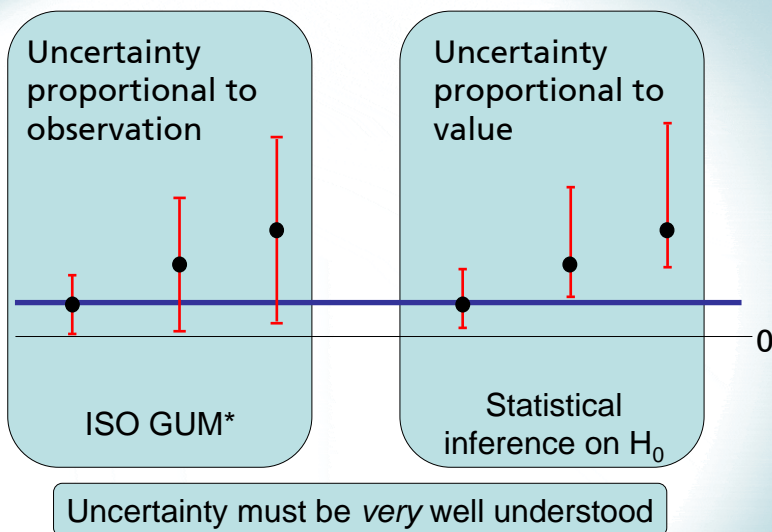
- Proportionality
- Results near zero

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Proportionality

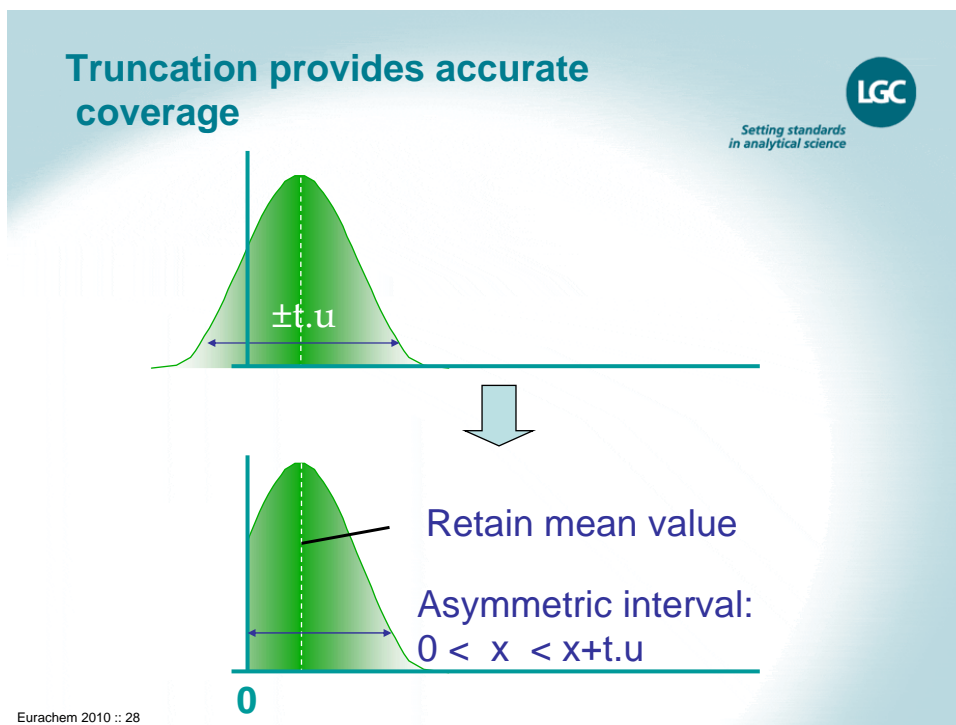
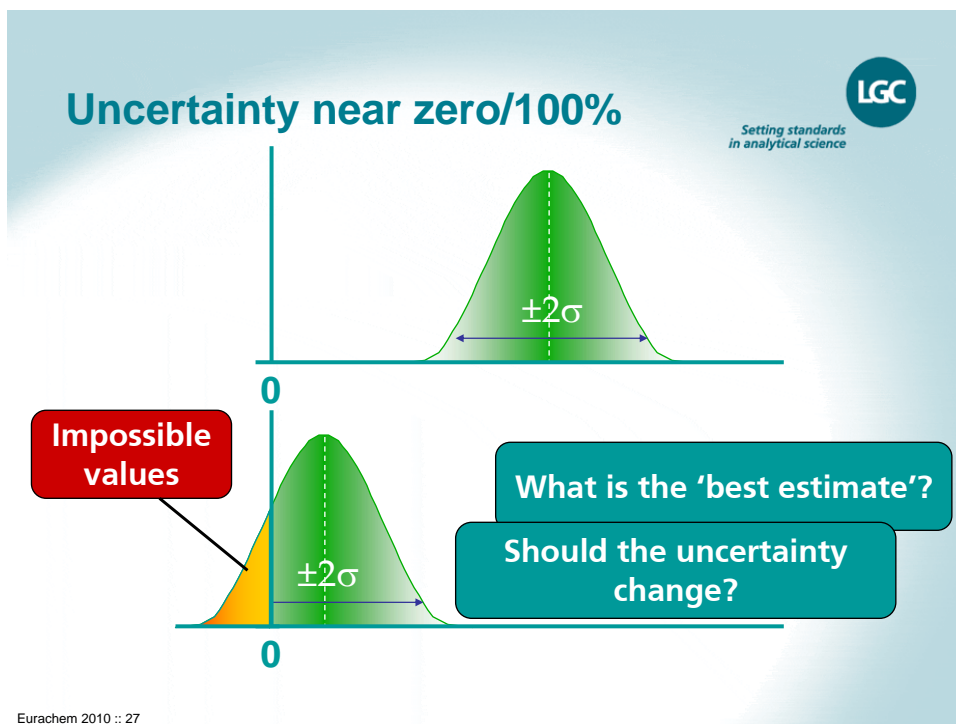


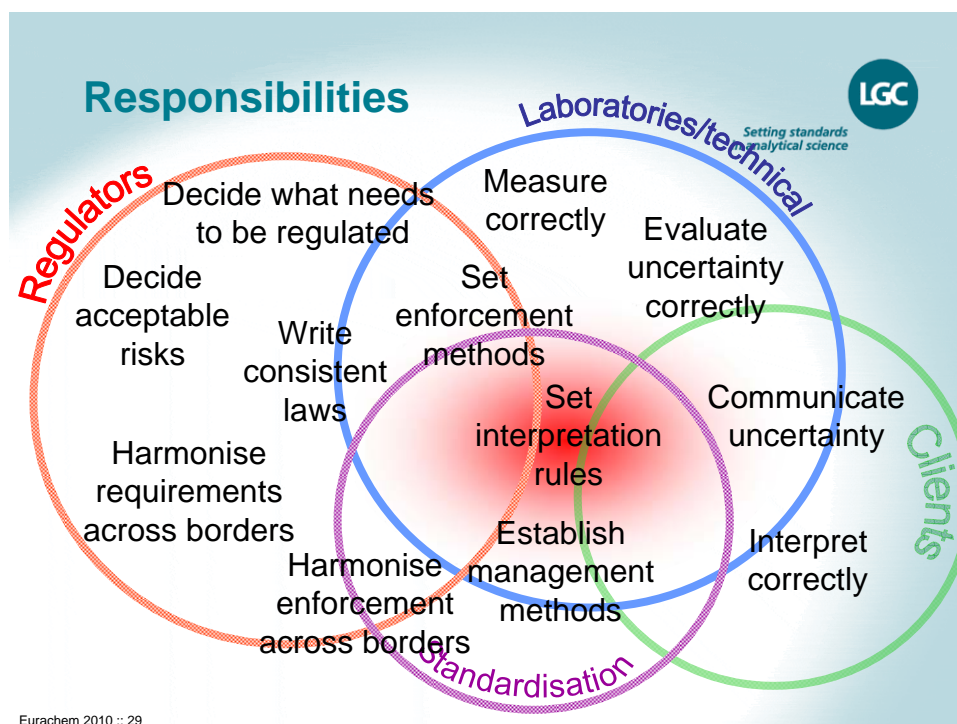
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Conclusions

- Measurement uncertainty guides interpretation
- Most regulators accept interlaboratory study basis for chemical measurement uncertainty
- Regulators set limits to control behaviour
 - not to make analysts' lives easier!
- Setting interpretation rules simplifies matters for enforcers
 - .. and should be a co-operative activity

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