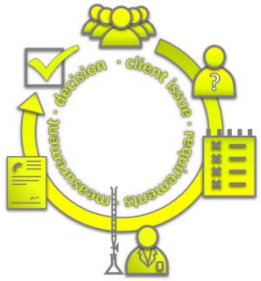
LABORATORIES LAB QUALITY INTERNATIONAL



Method Validation and verification

Presentation for the Eurachem 25th Anniversary Workshop

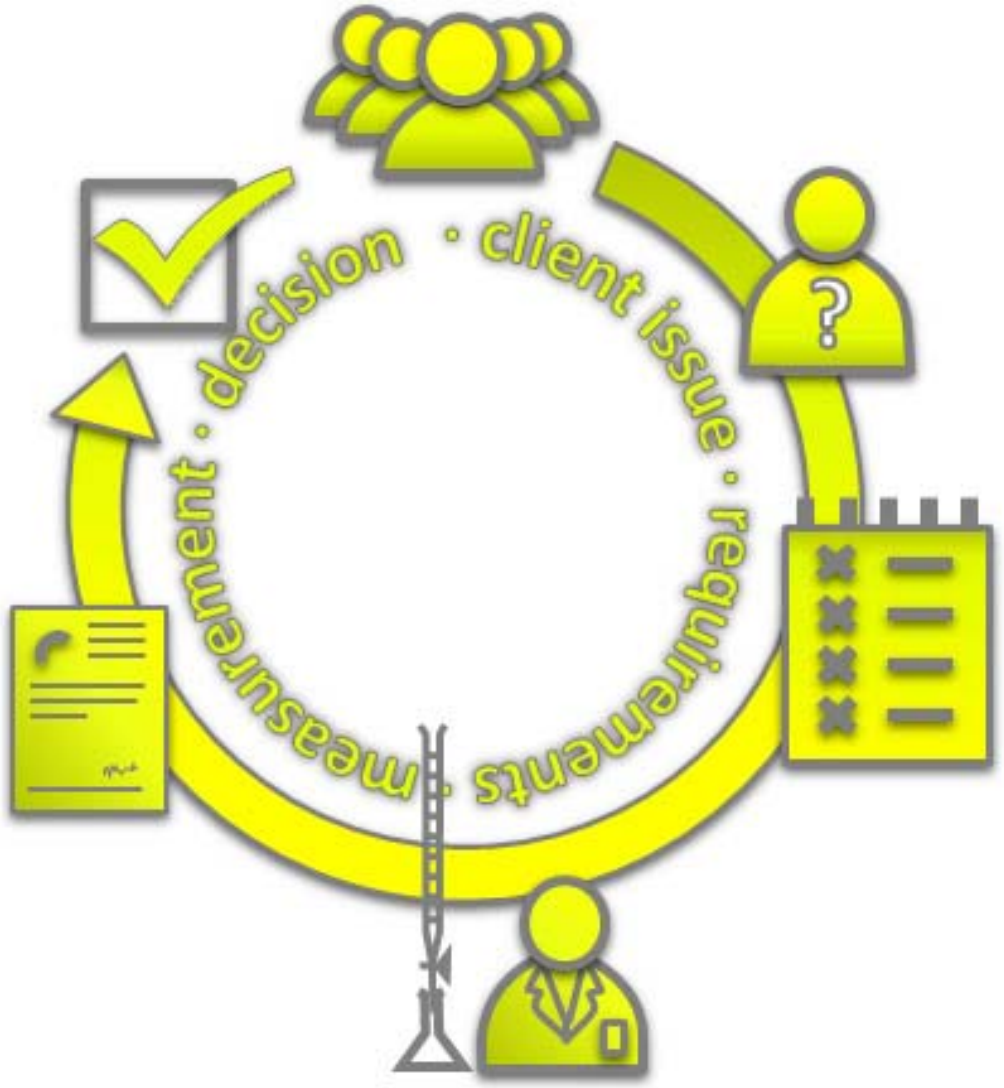
Quality in Analytical Measurements

- from Specification to Decision

by/ Lorens P. Sibbesen, LAB Quality International

DENMARK

Method validation in the big context

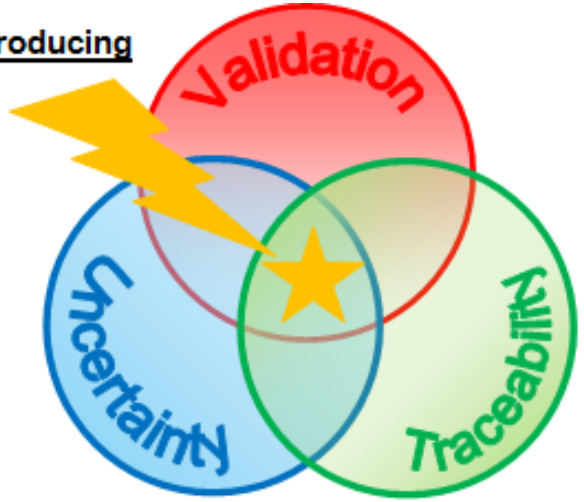


Method validation in the BIGGER context

Reliability !

2010

The basis for producing reliable results

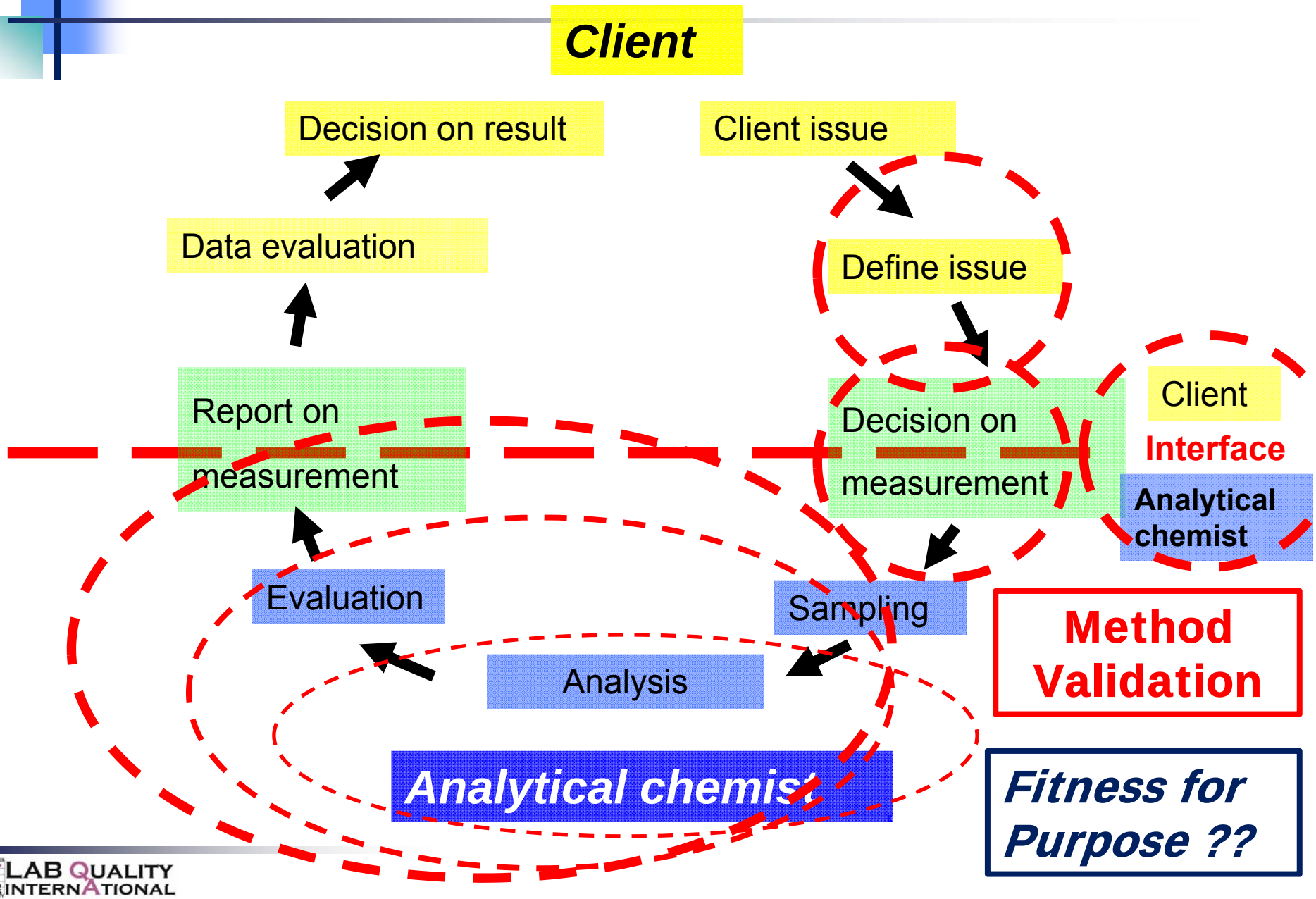


2012

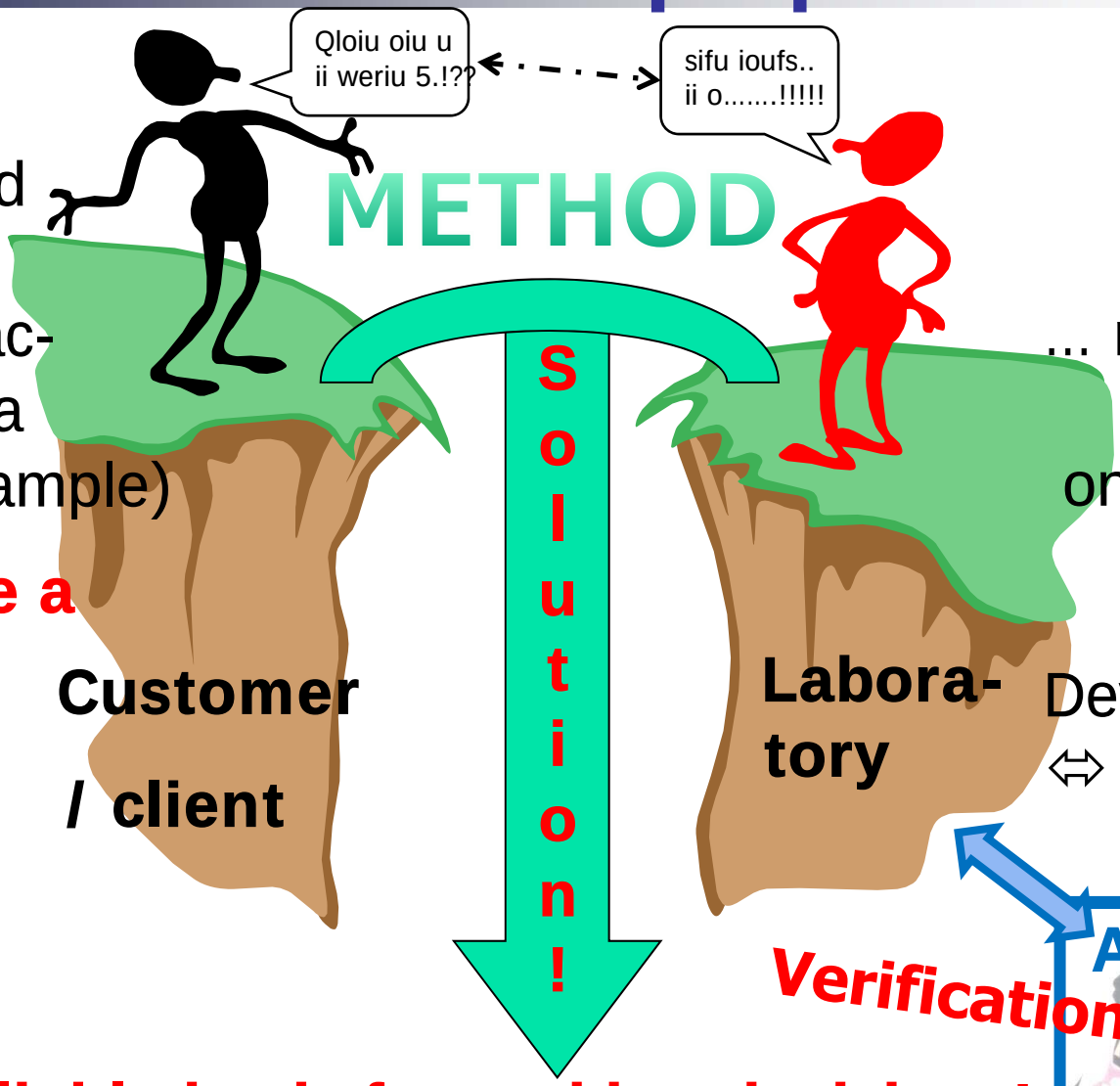
1998 :

"Fitness for Purpose of Analytical Methods"

The measurement cycle & Method Validation



What is fit for the purpose?!



Need to find out about some charac-teristics of a material (sample)

..and **make a decision**

Competent in analytical chemistry

... must **make a decision** on best method for the task

Develop (modify) ⇔ **Validation!**

Verification!

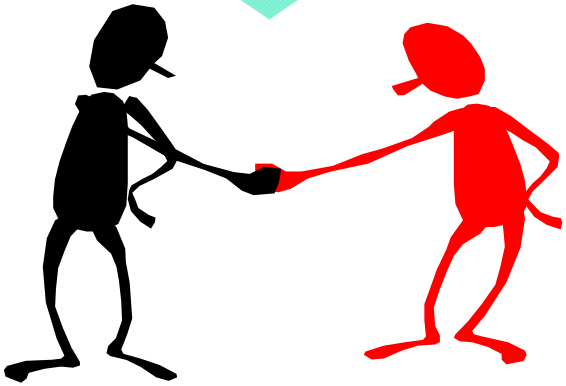
Analytical R&D Stand. Methods

Reliable basis for making decisions!

..if the method is valid!!!

Method Validation

- ..... the process of proving that an analytical method is acceptable for its intended purpose

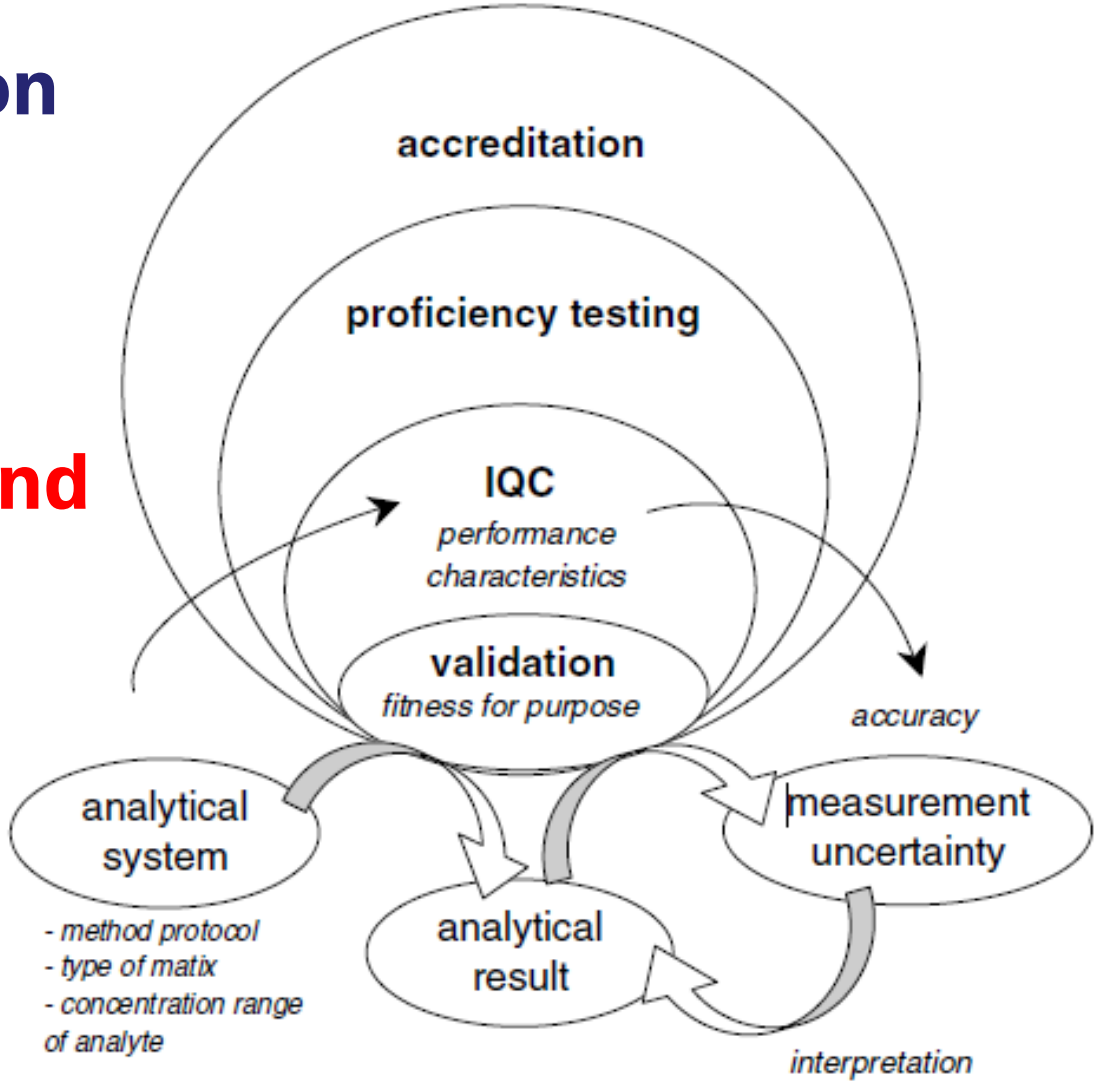


Validation / Verification
(Acc. to VIM3)

- **3.8.5**
  validation
  - confirmation, through the provision of **objective evidence** (3.8.1), that the **requirements** (3.1.2) for a specific intended use or application have been fulfilled
- **3.8.4**
  verification
  - confirmation, through the provision of **objective evidence**, that specified **requirements** have been fulfilled
- **3.8.1**
  objective evidence
  - data supporting the existence or verity of something
  - NOTE: Objective evidence may be obtained through observation, measurement, **test**, or other means

Met. Val. crucial in the ”QA picture!

- ✓ **Method Validation** has become an intrinsic part of QA
- ✓ **But it cannot stand alone!!!**

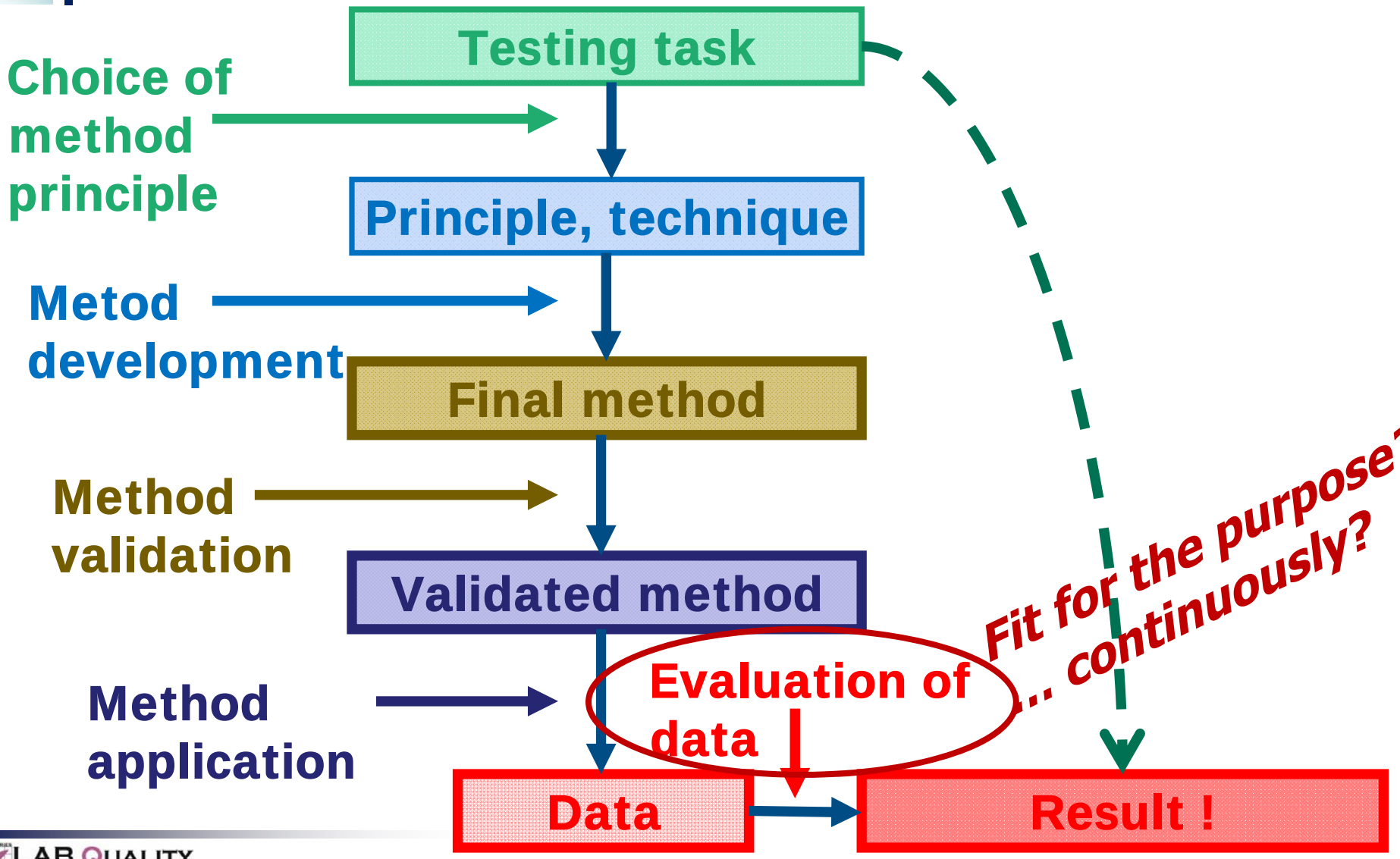


Method validation ⇔ Fitness for Purpose

- ✓ The Method Validation must secure that the method is fit..
  - **For solving the analytical task for the client**

  ... but also...
  - **For being applied in the laboratory (routinely!?)**
- ✓ Nice to have / Need to have - be realistic!!
- ✓ Requirements / Expectations
  - What is taken for granted?!
- ✓ Information needed as basis for making important decisions – BOTH for the client AND the laboratory!!
  - Must be trustworthy!
  - Blind faith – or documented evidence ?

The process from task to solution



What are the new challenges?

- The process from **Task** to **Result** is undergoing constant changes at an increasing pace!!
  - **New tasks / applications**
    - new needs for analysis
    - new parameters
    - complicated matrices
    - lower levels
    - bulk analysis (routine) / specific analysis (non-routine)
    - prices / competition
  - **More advanced (and sensitive) technologies**
    - new principles of preparation (separation) and detection
    - micro-systems (”Lab on a chip”)
    - automation
    - computer power (FT-IR, chemometrics ...)

… the new challenges (cont'd)

- **New methods**
  - multiparameter methods
  - quick methods (test kits)
  - automated methods (micro-, in-process etc.)

✓ Can we follow up by **Validating Methods** properly?

- What does "Fitness for purpose" mean now?
- **Reliable results**

.. but also

- **Manageable methods**
- **Affordable methods**

Making a guide on Method Validation!!

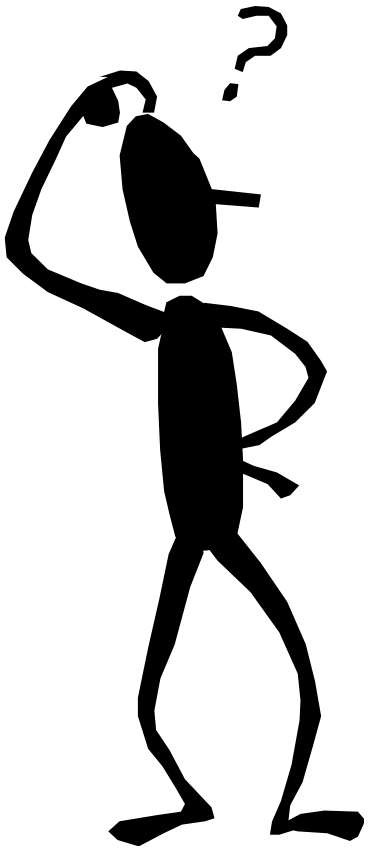
- ✓ Not an easy task!
- ✓ Working on revision for the Eurachem ”Fitness for Purpose” guide for more than 2 years.
  - Working group of 18-20 people
  - Several meetings / Several drafts – causing hundreds of comments
  - Now finally out for comments among all members Foreseen release autumn 2014
- ✓ The difficult issues
  - Method scope / Method range / Measurement range
  - Measurement limits (LOD, LOQ ...)

- but also making a guide which is understandable and applicable in all (most!) laboratories!!

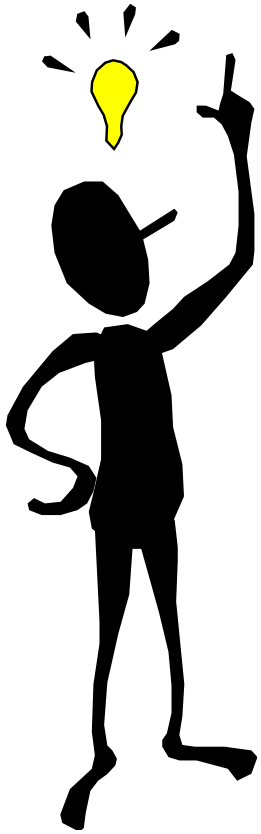
Still a lot of challenges in the field

- ✓ Advanced/New techniques
  - Multi-parameter methods
  - Multi-matrix methods
  - Verification of test kits/automated analysis (black box)
- ✓ Setting performance requirements
- ✓ How to do a proper validation study – securing ”Fitness for Purpose” both outside AND inside the lab.?
  - Planning including efficient design
  - Elaboration of the validation protocol
  - How to plan verification based on info in the standard
- ✓ Method validation/instrument qualification
- ✓ Calibration / Traceability.

Thank you very much for your attention!



Questions?



Comments?

…. !! (hopeless!!)