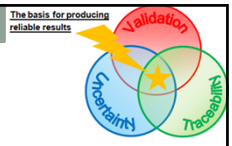


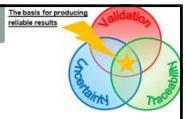
VALIDATION
TRACEABILITY
MEASUREMENT UNCERTAINTY
CHALLENGES FOR THE 21ST CENTURY'S ANALYSTS

Workshop group 1.3:

Validating multi-parameter methods, test kits and automated analytical systems

Convener: Wolfhard Wegscheider

Rapporteur: Claudia Kappler



Workshop group 1.3 – participants:

- Afyon, Osman Muzaffer (TR)
- Bidmon, Clemens (D)
- Kappler, Claudia (D)
- Kreimeier, Maria (D)
- Luong, Thi Mai Hoa (D)
- Möller, Thomas (D)
- Öztürk, Turgay (D)
- Pikkarainen, Anna-Liisa (FIN)
- Simon, Iveson (UK)
- Wawra, Elisabeth (UK)
- Wiesmüller, Thomas (D)
- Yesiloz, Recep (TR)

WG 1.3 questions

a. What should characterize the quality of a good multi-parameter method?
b. How many (and which) parameters should be selected for validation of a multi-parameter method – and can good performance for the measurement of one analyte be extrapolated to the performance of the measurement of analytes with equivalent properties??
c. Must test kits be regarded like empiric methods (i.e. “defining” their results in relation to the specific test) or can they be compared with (and validated in comparison with) traditional methods for the same sample types and parameters?
d. How is instrument performance (qualification) dealt with in relation to Method Validation for these types of methods?
e. How can validation of an automated equipment-based method (“Black Box” method) be planned and performed?
f. What are the conditions for selecting any of these methods (test kits, automated methods) as an alternative to traditional methods in the laboratory?
g. Do you see any needs for special validation parameters for any of these methods in addition to the traditional parameters (see e.g. list under worskhop 1.2)?
h. Which specific topics could be relevant to include in a revised Eurachem Guide on Method validation?

a) What should characterize the quality of a good multi-parameter method?

- Different multi-parameter methods
- Multiple measurands – one signal – one result: comparable to one-parameter measurements with test kits, only reproducability and repeatability, no trueness
- Multiple measurands – multiple signals – one result: validation of individual signals, standardization of the calculation of the result
- The same quality features on as many parameters as feasible

b) How many (and which) parameters should be selected for validation of a multi-parameter method – and can good performance for the measurement of one analyte be extrapolated to the performance of the measurement of analytes with equivalent properties??

- Those parameters that are critical for final decision making (toxic, prohibited, ...)
- No extrapolation (non-standard methods) or extrapolation as prescribed by standard methods

c) Must test kits be regarded like empiric methods (i.e. “defining” their results in relation to the specific test) or can they be compared with (and validated in comparison with) traditional methods for the same sample types and parameters?

- Different test kits:
  - A) for empirical parameters
  - B) ”specific”
- For A) validated like all empirical methods
- For B) validation parameters as in any other method

d) How is instrument performance (qualification) dealt with in relation to Method Validation for these types of methods?

- No general rule
- Depends on principle and purpose of the particular method

e) How can validation of an automated equipment-based method ("Black Box" method) be planned and performed?

- Distinction:
  - A) automation to increase laboratory throughput
  - B) automation to control (production) process
- For A) validition like in non-automated method (validation signal vs. Species)
- For B) validation of signal vs. product quality
- Knowledge of instrument qualification
- Balance between instrument qualification and method validation

f) What are the conditions for selecting any of these methods (test kits, automated methods) as an alternative to traditional methods in the laboratory?

- Speed
- Price
- Acceptabilty for customer

g) Do you see any needs for special validation parameters for any of these methods in addition to the traditional parameters (see e.g. list under workshop 1.2) ?

- No additional parameters

h) Which specific topics could be relevant to include in a revised Eurachem Guide on Method validation?

- Open for discussion by plenum

Additional subjects discussed

- [none]