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A Focus for Analytical Chemistry in Europe

Workshop
Method Validation in Analytical Sciences
Current practices and future challenges

Gent, 9-10 May 2016

Report from WG 1 / Day 1

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Setting requirements for method to be validated
(the single performance characteristics or Measurement Uncertainty ("Target MU"))

- Moderator:
  - Marina Patriarca
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Participants

- Austrian Agency for Health and Food Safety, Elisabeth REITER
- ILVO Bavo DE WITTE
- ILVO DIER (STAAT) Daphné DELOOF
- Coca-Cola An VIDTS
- Chemical Lab WOOD.BE Jason BLOMME
- Vinçotte Philippe DEWOLFS
- Vivaqua Arlette DELVILLE
- APB-DGO Colette FIERENS
- BELAC Bart VAN HAUTE, Els KESTENS, André MATHIEU, Ann RUYSSEVELDT
- CARAH Sabine VICO

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Participants

- LtD "Wine Laboratory" Tinatin JAJANIDZE
- Georgian Laboratory Association Irma TCHANTURIA
- Wine Laboratory Nino MAISURADZE
- ISWA University of Stuttgart Michael KOCH
- Pasargad Quality Pioneers Behnam Khanmohammadi MARIAN
- The State Laboratory Colmán Ó RIORDAIN
- CQE-FCUL-Universidade de Lisboa Ricardo BETTENCOURT DA SILVA
- SP Bertil MAGNUSSON
- Ringhals Nuclear Power Plant Ulrika PICHLER

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Participants from

- Accreditation bodies
- Laboratory Associations
- Laboratories, public
- Laboratories, private
- Universities
- Other

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VIM 2.34
Target measurement uncertainty

- measurement uncertainty specified as an upper limit and decided on the basis of the intended use of measurement results

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Points for discussion

- Where do you get the requirements for method validation?
- What are the approaches applied in different fields?
- What are the advantages of the two approaches (The individual performance characteristics vs the Target MU)?
- What are the challenges experienced in different areas?
- Requirements for verification vs. validation – any differences?

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How to work?

- Time: 14:00 – 15:30
- Work in pairs
- Introduction to each question (1‘)
- Discuss each question (3‘)
- Each pair report their views to the group (1’ x 11)
- Move to next question

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Where do you get the requirements for method validation?

- Legally binding limits (EU / national)
  - May be in the form of performance characteristics or target measurement uncertainty
  - Sometime just general guidance available
- Values applied to evaluate laboratory proficiency or data distribution, e.g. in PT
- In multisite companies, requirements set at a central level
  - Sometime too general, may not be pratical
  - May be very strict, if economically critical (Identical value, MU=0.1%

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Where do you get the requirements for method validation?

- Working range must be considered as well as MU
- No requirements, just work as good as possible. Once done the testing, judge the results
- Not the lab job, but those of regulators / customers,

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What are the approaches applied in different fields?

- Drinking water: performance characteristics, will change to MU
- Food (regulated substances): both
- In several sectors, standard methods are used and requirements are stated in the method
- Fitness for purpose of intended use required for validation
- Do we need a requirement on MU if all other parameters are fit?
- Checking a new method not validation, but method equivalent
- Customers just wish MU as low as possible and

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What are the advantages of the two approaches (individual performance characteristics vs target MU)?

- There are no differences as long as requirements (for individual performance characteristics or target MU) are set at various levels of the working range
- It may be easier to set requirements just for target MU
  - One parameter instead of many
  - it can be derived from rules for compliance / intended use
  - Less paperwork

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What are the advantages of the two approaches (individual performance characteristics vs target MU)?

- Some performance characteristics are not included in MU and need separate requirements anyway
  - LOD / LOQ
  - Specificity / confirmation of identity (as for vet drug residues)
- What is the line between method development / method validation?
- Easier to ask the customer to set requirements on MU than on many analytical parameters
  - MU easier to explain than bias or precision

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What are the challenges experienced in different areas?

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Requirements for verification vs. validation – any differences?

- For verification, requirements are set in the standard methods
  - repeatability, reproducibility / uncertainty)
- Stated performances may not cover
  - The whole working range
  - The whole scope (e.g. matrices)
- Requirements for some parameters may not be available
  - e.g. LOD / LOQ