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A Focus for Analytical Chemistry in Europe

Scientific Workshop in Connection with Eurachem General Assembly 2022

"Quality Assurance Challenges of Measurements from Field to Laboratory with a Focus on ISO/IEC 17025:2017 Requirements"

WG 1.1.

Selection and use of certified reference materials

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Participants

- About 40
- From different background, including: laboratory staff/head, teachers / trainers, academia & research, PhD students, QMS consultants
- From different geographical areas:
  Asia, Africa and Europe

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Background

- Certified reference materials (CRMs) are a key-element in assuring metrological traceability of measurement results, in particular in analytical sciences.
- Over the years, guidance for the production and use of CRMs evolved considerably.
- Eurachem is currently revising its guidance on the selection and use of reference materials, to meet laboratories (and other parties) needs.

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Objectives

- To consider the state-of-the art for the selection and use of CRMs in terms of laboratories' practice.
- To consider what is needed to support improvements in the selection and use of CRMs by laboratories.

The following issues were explored:

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1. What are certified reference materials (CRMs)?

- There is a difference between RM and CRM
- CRMs shall be produced by competent organizations (RMP)
- CRMs must have traceable assigned values and associated MU

2. How to identify CRMs?

Accompanying documents (certificate) shall provide:

- Evidence of accreditation or compliance of the RMP to ISO 17034
- Evidence of metrological traceability
- Certified values and their associated MU
- Additional information for appropriate use of the CRM
- Contact information of the RMP

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3. Do you use CRMs and for what?

- Calibration
- MU estimate
- Trueness estimate
- Method verification
- Checks of instrument performance, when more detailed investigations are necessary
- PT providers may use CRMs in PT scheme
- In some areas (e.g. pharma), regulations may require daily use of CRMs – as IQC

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4. Most important criteria used for the selection of CRMs

- Closeness between CRM and test sample matrix
  - Important also for calibration in some cases (e.g. XRF)
  - How close should it be? (e.g. drinking water vs. river water….)
  - Which criteria can be used?
- Purity / Concentration of the analyte
- MU of the certified values
- Stability / Storage and transport conditions (e.g. temperature)
- Minimum weight
- Shelf-life
- For microbiological CRMs: be easy to cultivate; low virulence and biochemical variability
- For medical labs: traceability of CRMs according to IVD directive / new regulation to be published soon

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5. Most important problems experienced with the use of CRMs

- The CRM MU can be too high for the need of the lab
- How to establish the requirement for the MU for a matrix CRM?
  - It depends on the analytical method to be applied
  - Software based on decision rules aimed to minimize the contribution of the CRM's MU to the overall MU of results
- Stability of certified values after opening
  - How to establish it?
- Price / availability / difficulties in purchasing / delivery time
- Small set(s) of certified values

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6. Most important areas where further guidance is needed

- Specify the difference between different types of CRMs (pure substances, matrix, …) and what they can be used for.
- Can the same CRM be used for both calibration and validation (this include solutions used for spiking)
- How to assess matrix similarity
- Expired CRMs: can they be used / re-validated and what for?
- Certain areas (e.g. forensic) need specific CRMs and guidance on how to use them