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A Focus for Analytical Chemistry in Europe

8th PT/EQA Workshop - Berlin 2014

Report from WG1

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Review of ISO/IEC 17043

- Convenors:
  - Brian Brookman, LGC, UK
  - Christian Lehmann, DAkkS, Germany
- Objective – Consider the issues that have been experienced when implementing the requirements of ISO/IEC 17043

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WG Members

- 68 members
  - 55 PT providers
  - 11 ABs or technical assessors
  - 1 laboratory
  - 1 university lecturer for metrology

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Question 1

- Which requirements in the standard have caused most debate/discussions with regards to the interpretations/implementation?

- Discuss from point of view of both accreditation body and PT/EQA provider?

Question 1

- Homogeneity
  - Assessment criteria, sometimes too tight
  - Not always possible to do duplicate samples – recent paper published around single samples
  - Use of historical data to show processes are under control – greater emphasis in revised ISO 13528
  - IUPAC Harmonized Protocol gives alternative approaches
  - Post distribution data analysis
  - Homogeneity can be very costly for same samples, need to do less

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- Subcontracting
  - Grey area around design is subcontracted
  - Suppliers/subcontractors difference – difference in level of evaluation needed
  - How to evaluate, what is accepted by ABs, no experience of an AB ever assessing a subcontractor

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- Software/computer maintenance
  - How much validation and documentation
  - What maintenance documentation is required
- Metrological traceability
  - Not really possible for consensus means
  - Key is to show that fit for purpose

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- Demonstrating experience of advisors
  - What is required e.g. short CV or full training programme
- Feedback to participants
  - Agreed not necessary to every individual participant
  - Just general comments in the report

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- Certificates
  - Clarity on what is misleading
  - Should certificates of successful participation be allowed (general view No)

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Question 2

- Which issues in Question 1 have not yet been fully resolved?
- Discuss from point of view of both accreditation body and PT/EQA provider?

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Question 2

- Aspects of different approaches to homogeneity/stability assessment
  - Particularly in biological field
- Certificates
- Should ISO/IEC 17043 be revised?
  - Some felt it should be simplified
  - No overlap of clauses between Management/Technical requirements

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Question 3

- Are there any sectors where the present standard has proved difficult to apply?
- Discuss from point of view of both accreditation body and PT/EQA provider?

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Question 3

- In some biological areas e.g. genetics, clinical, maybe microbiology
- Sampling PT

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Question 4

- Given the discussion in Questions 3, do you think detailed specific guidance is required (specify the sectors)?

Question 4

- EEE-PT WG currently producing guidance on PTs for sampling