



Eurachem

A Focus for Analytical Chemistry in Europe

Data Quality Breakout session feedback

Conveners

Kyriacos Tsimillis & David Milde



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Data Quality

- Introduction
 - 39 participants, 20 countries
 - 8 universities + institutions
 - 16 authorities
 - 7 labs
 - 1 industry
 - 7 others

- Participants divided into 4 groups, each dealing with two questions.



Q1: What is data quality?

- Fitness for purpose
- Consistent
- Complete – gives a full picture
- Representative/planned
- Accurate
- Origin known
- 'FAIR'
 - (Findable, Accessible, Interoperable, Reusable)
- Correct/usable format
- Integrity maintained
- Relevant – data addresses the right question



How do you ensure data quality?

- 1) Explicit definition of the intended use.
- 2) Tailoring the quality measures to meet those needs.



Have there been any significant changes in regulatory/accreditation requirements in relation to ensuring/demonstrating data quality?

- In relation to updated ISO 17025:2017
 - Stronger emphasis on LIMS and Information Management Systems
 - Commercial LIMS products are deemed to be prevalidated_
 - Change to risk based approach and identifying opportunities
 - New clause 7.8.1 requires results to be reviewed and authorised before reporting
 - More accreditation bodies specifying requirement for participation in PT schemes
 - In case of management system option B, labs must be compliant with ISO 9001
- EU regulation 679/2016 – general data protection



What are the challenges?

- Appropriate quality management system in place (commitment of top management to data quality).
- Proper definition of fit for purpose of the data
- Requirements: from customers, standards
- Lack of standard methods for specific applications
- Lack of RMs for QC, MV and representative matrices
- Amount and increase of cost and time „repeated analysis“
- Personnel competence/skills
- Maintenance and control of environment in labs



What guidance/standards do you use – is further guidance needed?

- Guidance-Standards
 - ISO 17025
 - MU Guidance Documents, e.g. Eurachem, Sante, Nordtest
 - EU regulations e.g. pesticides, specifying limits, and associated data and quality parameters
- Further Guidance Required:
 - How accreditation bodies interpret changes in ISO 17025
 - More guidance on calculation of MU for multivariate analytical methods
 - Clarity on access to data by 3rd party in cases of legal disputes



Q6: Data analysis for quality

- Wrong question?
Quality cannot be 'tested in'
 - Better to assure data quality at origin than test for failure
 - Good QA and IQC practice
- Tests for departure from 'good' data
 - Anomaly/Outlier inspection
 - Distribution checks – unusually poor OR unusually good
 - Correlation



How do you distinguish between “data quality” and “data integrity”?

- It is difficult to distinguish quality from integrity (...we can't define it but we know when you see it)?
- (the integrity of the sampling and the people are critical)