



Eurachem

A Focus for Analytical Chemistry in Europe

Data Integrity Breakout session feedback

Conveners

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Break out session on Data Integrity - participants

- Lorens Sibbesen, Denmark (convener)
- Alessandra Rachetti, Austria (convener)
- 18 participants
- 4 from forensic labs
- 1 consultant
- 4 food and water testing
- 2 quality control company
- 3 from clinical laboratories
- 1 from microbiological laboratory
- 1 from university



Data integrity - guiding questions for discussion

- 1) What do you understand the term 'data integrity' to mean?
- 2) How do you ensure data integrity? (↓ 4)
- 3) Have there been any significant changes in regulatory/accreditation requirements in relation to ensuring/demonstrating data integrity?
- 4) What are the challenges?
Meta-data!?
- 5) What guidance/standards do you use – is further guidance needed?
- 6) How do you distinguish between “data integrity” and “data quality”?
- 7) Can “data integrity” be compromised by too much “data analysis”?



Data integrity *What do you understand the term 'data integrity' to mean?*

- Completeness of data
- Trustworthiness
- Settings around creation of data
- Evidence of data collection in labs
- Controlling access of who can do what
- Include data supplied by customers
- Be open about errors



Data integrity

What do you understand the term 'data integrity' to mean? (Cont'd)

- How do you confirm that data have not been tampered with
- Cross check against loss of data in transfer
- Data storage and retrieval



Data integrity

How do you ensure data integrity?

- Audits help to check samples from start to finish
- Assess risks, ensure that procedure is fit for purpose, adjust QA/QC system accordingly
- Emphasize current documentation, eventually install bar codes, trackability of samples
- Pay attention to measurement uncertainty, may relate to Data Quality
- Create an environment of openness and trust
- Education about consequences of tampering with data
- Disclose doubts about questionable steps prior to the analysis
- Forensic: chain of custody, documentation



Data integrity

How do you ensure data integrity? (Cont'd)

- Inspecting outliers (see DQ)
- Trying to identify information in outliers (see DQ)
- Removing outliers only with a set protocol (see DQ)
- Digital 1:1 imaging of a computer hard drive when investigated



Data integrity

What are the challenges?

- and which meta-data are important to secure data integrity?

- Which data have to be recorded pertaining to the sample ?
- Data which might have influence on the final results which do not necessarily have to be in the final report (not a part of calculations)
- Peer review of final report may include inspection of meta data
- Instrumentation qualification data are a part of meta data and should be recorded



Data integrity

What are the challenges?

- and which meta-data are important to secure data integrity? (Cont'd)

- Record date and time and identity of persons eventually modifying data
- Trade off between cost and benefit, difficult in forensic field
- Establish a detailed protocol depending on laboratory and type of test (similar to in-flight procedures)
- Record all possible observations (like in a lab book)



Data integrity

How do you distinguish between "data integrity" and "data quality"?

- Data integrity is a subset of data quality management
- Lack in data quality might be an indication of lack of integrity
- Data integrity includes storage and retrieval of data of a certain quality



Data integrity

Can "data integrity" be compromised by too much "data analysis"?

- Yes, if data are massaged to get results that were not intended