

DEFENSIBLE DATA

Presented by:

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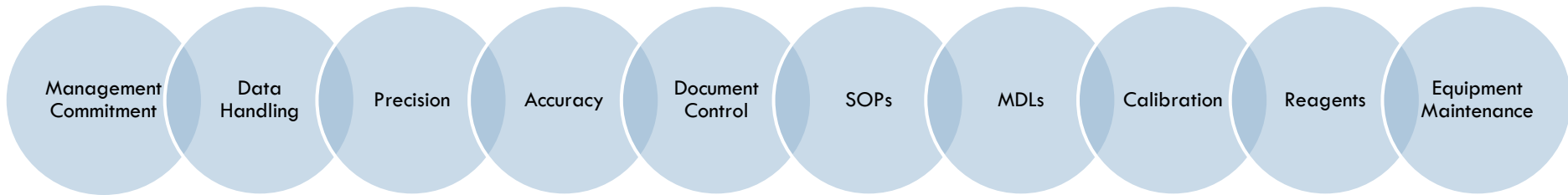


Alloway
Your Resource for Defensible Data

Quality Assurance

- The system by which the laboratory can assure outside investigators that data are of known quality.
- Quality control is only one part of quality assurance.
- Quality is not free.
- Quality is everyone's business!

Data Quality – like a chain – is only as strong as its weakest link.



1. Management Responsibility

- Management Commitment
- Quality Policy
- Organization
- Quality Planning
- Management Review

2. Quality System

- ☑ Is a quality management (QM) system established and maintained?
- ☑ Is a QM system structure described?
- ☑ Is a quality manual issued and maintained?
- ☑ Does the manual contain a table of contents, date of issue, and revision level?
- ☑ Does the manual contain or refer to procedures?
- ☑ Are requirements defined and described, and how are they met for all services, equipment testing, labeling, and quality records?

3. Sample Receiving and Handling

- ☑ Are standard operating procedures (SOPs) in place?
- ☑ Is there a log system for tracking samples?
- ☑ Is there a clear, simple acceptance policy and are protocols in place?
- ☑ Are chain of custody protocols defensible?
- ☑ Is there a sample disposal policy?
- ☑ Are guidelines established for proper storage of samples?
- ☑ Do sample identification procedures prevent samples from being confused?

4. Document Control

- ☑ Are SOPs established and maintained to control all documents and data?
- ☑ Are documents reviewed and approved for accuracy prior to issue?
- ☑ Does a master list of all established documents exist to prevent use of invalid documents?
- ☑ Are forms, logs, SOPs, training records, data sheets, etc. all controlled?
- ☑ Are copies of approved documents available at workstations?
- ☑ Are obsolete documents removed from workstations?
- ☑ Are obsolete documents clearly labeled and maintained for historical purposes?
- ☑ Is the procedure for review and approval of revisions the same procedure used to review and approve the original document?

5. Control of Quality Records

- ☑ Are procedures established and maintained for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records?
- ☑ Are record retention times established?
- ☑ Are quality records available for review (i.e. management review records, contracts, supplier lists, batch records, equipment calibration records, data review records, corrective action records, training records, audits, etc.)?

6. Quality Control

- ☑ Are QC activities and protocols clearly established for each analyte?
- ☑ Are QC activities being performed?
- ☑ Are “decision trees” in place?
- ☑ Is a method blank run with each batch?
- ☑ Is a Laboratory Control Standard (LCS) run with each batch, and is it prepared from a separate lot number than the calibration?

7-8. Accuracy and Precision

- ☑ Are control charts in use?
- ☑ Are limits clearly established?
- ☑ Does a determination of accuracy include QC samples and spikes?
- ☑ Are control charts in use?
- ☑ Are limits established (either using Shewhart constants or RPDs)?
- ☑ Does a determination of precision include duplicates and/or matrix spike duplicates?

9. Methodology

- ☑ Are methods chosen for method compliance?
- ☑ Are approved methods used and cited?
- ☑ Has the method been validated?
- ☑ Are methods being followed?
- ☑ Are SOPs in place?
- ☑ Are holding times being met and is preservation and sample pretreatment proper?

10. Method-Specific and General SOPs

- ☑ Are they in place for all analytes and protocols (sample receiving, training, corrective action, document control, etc.)?
- ☑ Do SOPs come under some type of document control?
- ☑ Can a specific SOP be cited for a prior analysis?
- ☑ Do SOPs refer to an approved method?
- ☑ Is there a standardized format for SOPs?
- ☑ Is there a master list of SOPs?
- ☑ Are revisions tracked?

1 1. Logbooks

- ☑ Are instrument logbooks in use?
- ☑ Do they contain sufficient information (i.e. calibration, maintenance, troubleshooting, etc.)?
- ☑ Are equipment logbooks in use for other key pieces of equipment (i.e. ovens, refrigerators, water baths, autoclaves, etc.)?
- ☑ Are logbooks in use for other processes (i.e. samples, reagents, waste, safety, etc.)?
- ☑ Are pages sequentially numbered and entries made in permanent ink?

12. Reagents

- ☑ Are appropriate grades of reagents in use?
- ☑ Are reagents and solutions traceable to the manufacturer for each analytical run?
- ☑ Are reagents and solutions stored properly?
- ☑ Are reagents and solutions labeled appropriately?

1 2. Reagents (continued)

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13. Method Detection Limits

- ☑ Are studies being performed and are they being performed correctly?
- ☑ Is the frequency of performance appropriate (annually, new equipment, new analyst, etc.)?
- ☑ Are studies evaluated for validity (i.e. 10X rule, all data points above calculated MDL)?
- ☑ Are calculations correct?
- ☑ Are all data points included in the study?

14. Data Handling

- ☑ Are raw data sheets controlled documents?
- ☑ Do they contain essential information, including date of analysis, analyst, etc.?
- ☑ Can QC data be batched with a given analytical run?
- ☑ Are procedures in place to prevent alteration of data?
- ☑ Are calculations performed correctly?
- ☑ Are “decision trees” in place?
- ☑ Are corrections made appropriately?

1.5. Training

- ☑ Is the staff adequately trained (are general analyst training guidelines specified)?
- ☑ Is training documented?
- ☑ Is there initial competency training with documentation?
- ☑ Is there on-going competency training with documentation?
- ☑ Is there specific safety training with documentation?

16. Calibrations

- ☑ Are thermometers tagged with date and correction factor?
- ☑ Are balances calibrated frequently enough and with appropriate weights?
- ☑ Are micro-pipettors calibrated at routine intervals?
- ☑ Are instruments tuned and calibrated properly?

17. Maintenance

- ☑ Are records maintained and is maintenance documented, preferably in a logbook?
- ☑ Is maintenance scheduled?
- ☑ Are maintenance contracts maintained?

18. Corrective Action

- ☑ Are procedures in place to address and document corrective action?
- ☑ Is corrective action documented for out-of-control conditions?
- ☑ Does corrective action extend to broader issues than a single analytical run?

19. Ethics

- ☑ Is there a clear ethics policy with management support?
- ☑ Is there a signed ethics agreement?
- ☑ Is training provide to employees and documented?
- ☑ Do employees know there is a direct regulatory link between testing and public health?

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20. Proficiency Testing Samples

- ☑ Is proficiency testing part of the QA program?
- ☑ Does the laboratory use blind PT samples?

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