QMS Quick Learning Activity

Sample Handling and Assuring the Quality of Test Results

ISO/IEC 17025, clauses 5.8 and 5.9

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Abbreviations and Acronyms

- **QC**-Quality control

What will be covered in this training?

- Sample Handling
  - What does this encompass?
  - What does the laboratory need to consider?
- Quality Control (QC)
  - Requirements of ISO/IEC 17025
  - What happens when QC fails?
  - Proficiency testing

Connections

- How are sample handling and QC related to each other?
  - Results are only as good as the sample which is tested
  - Ensuring proper sample handling supports the validity of testing
  - Sample handling and QC also play a part in regulatory work by ensuring sample integrity and data defensibility

Sample Handling

ISO/IEC 17025 clause 5.8

- 5.8.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention, and/or disposal of test items, including all provisions necessary to protect the integrity of the test item, and to protect the interests of the laboratory and the customer.
  - ➢ *This also means the laboratory must be aware of any customer requirements for sample handling*

Sample Handling

- 5.8.2 The laboratory shall have a system for identifying test items:
  - Retain the identification on the sample throughout its time in the laboratory (including conditions such as freezing, autoclaving, etc.)
  - Procedures to avoid mixing up samples physically or in records
  - Address subdividing samples and retaining identity
  - Address how to transfer items within and from the laboratory

Sample Handling

- 5.8.3 Upon receipt of a sample the laboratory must:
  - Record abnormalities or departures from normal or specified sample conditions
  - Consult the customer if samples may not be suitable for testing, do not conform to the description provided, or the requested test is not specified in sufficient detail
  - Discussions with the customer and instructions received from the customer must be recorded

Sample Handling

- 5.8.4 The laboratory must have procedures and facilities for avoiding deterioration, loss, or damage to the test item during storage, handling, and preparation.
  - **Any handling instructions that come with the sample must be followed**
  - **If samples must be stored or conditioned under specific environmental conditions, these conditions must be maintained, monitored, and recorded**
  - **The laboratory must be able to store and secure samples if required to maintain their integrity**

Ensuring the quality of test results

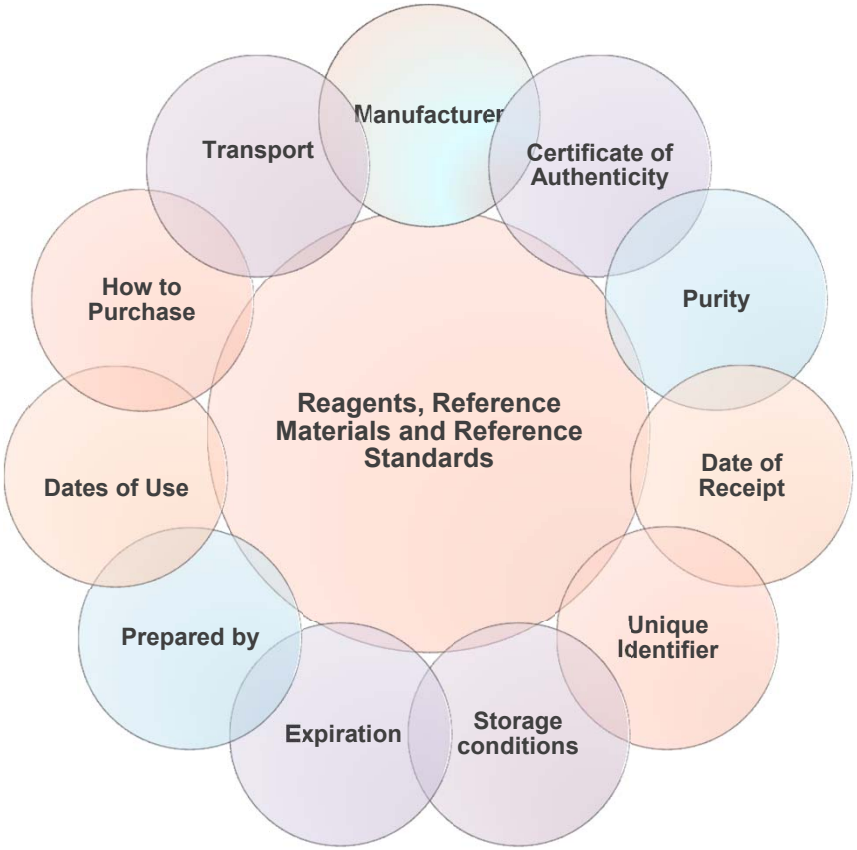
- 5.9 The laboratory must have QC procedures
  - To monitor validity of testing (plan the monitoring, review the results) to ensure:
    - Accuracy
    - Precision
  - Record QC results so that trends can be detected
  - Apply statistical techniques to review of QC data, where practical

What does ISO/IEC 17025 require as a QC sample?

- The standard does not require any particular QC sample. These are dictated by test methods and accreditation bodies.

- The standard recommends use of the following :
  - Certified Reference Materials
  - Internal QC using secondary Reference Materials
  - Participation in proficiency testing or interlaboratory comparison programs
  - Replicate tests
  - Retesting retained samples
  - Correlation of results for different characteristics of a item

Most Accrediting Bodies Require Procedures and Documentation for:



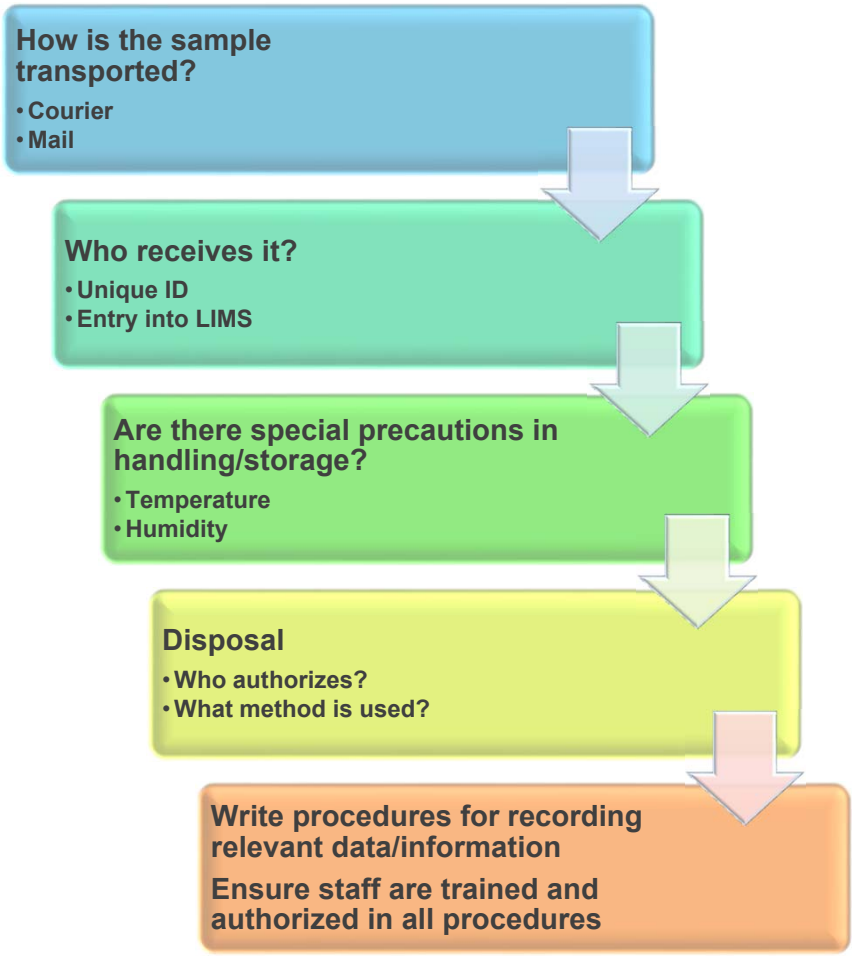
What happens when QC fails?

- When QC is outside predefined criteria, planned action must be taken to:
  - Correct the problem
  - Prevent incorrect results from being reported
- Key terms:
  - **Predefined criteria**: The laboratory must define acceptance criteria for its routine QC
  - **Planned action**: The laboratory must specify what to do if QC fails to meet acceptance criteria. This may be corrective action

Proficiency Testing

- ISO/IEC 17025 does not require any particular amount or frequency of proficiency testing
- Accrediting bodies have their own requirements for amount and frequency of proficiency testing that laboratories must follow

Summing it up: Sample Handling



- Sample handling includes ensuring the laboratory meets customer requirements, protects sample integrity, and provides appropriate security of samples

Summing it up: QC

QC— A system that compares performance against specific requirements and defined standards

- QC data must be monitored, reviewed, and analyzed
- Failing QC requires action
- Proficiency testing is part of the laboratory's overall QC plan

APHL

AAFCO
Association of American Feed Control Officials

AFDO

Reference

- ISO/IEC 17025:2005
  - https://www.iso.org/standard/39883.html