QMS Quick Learning Activity

Sample Handling and Assuring the Quality of Test Results

ISO/IEC 17025:2017
clauses 7.3, 7.4 and 7.7

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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)
  - 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

7.4 *Handling of test or calibration items**

- 7.4.1 *The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.*

**italics is actual ISO text*

  - This also means the laboratory must be aware of any customer requirements for sample handling

Sample Handling

- 7.4.1 The laboratory must have procedures and facilities for avoiding *deterioration, contamination, loss or damage to the* test *item during handling, storage/waiting, and preparation for testing*.
  - **Any handling instructions that come with the sample must be followed**
- 7.4.4 If samples must be *stored or conditioned under specific environmental conditions, these conditions must be maintained, monitored, and recorded.*

Sample Handling

- 7.4.2 *The laboratory shall have a system for the unambiguous identification of test or calibration items.*

  - Retain the identification on the sample throughout its time in the laboratory (including conditions such as storing and destruction)
  - Have procedures to avoid mixing up samples physically or in records
  - Address subdividing and analysis of samples and retaining identity
  - Address how to transfer items within and from the laboratory

Sample Handling

- 7.4.3 Upon receipt of a sample the laboratory must:
  - Record *deviations from* normal or *specified conditions*
  - Consult the customer if a sample may not be suitable for testing, *does 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

Ensuring the quality of test results

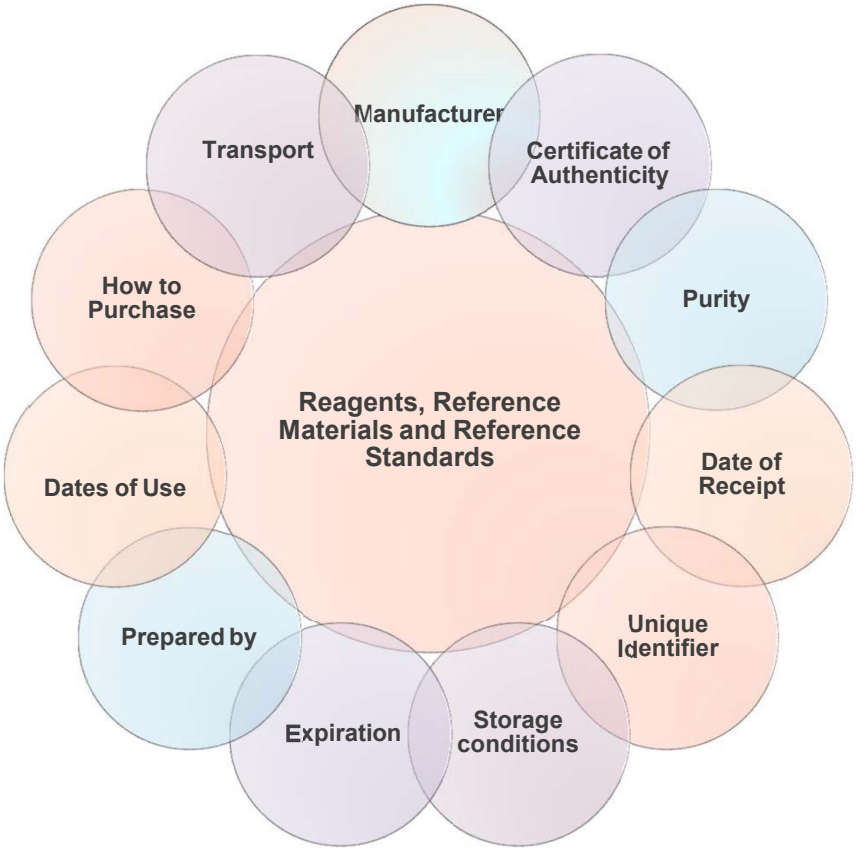
7.7 *Ensuring the validity of results*

- The laboratory must have QC procedures
  - *For monitoring the validity of results* (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 specific QC sample. These are dictated by test methods and accreditation bodies.
- The standard recommends are use of the following :
  - Certified Reference Materials
  - Internal QC using secondary Reference Materials
  - Participation in proficiency testing or *interlaboratory comparison* programs
  - *Replicate tests using the same or different methods*
  - *Retesting retained samples*
  - *Correlation of results for different characteristics of a item*

Most Accrediting Bodies Require Procedures and Documentation for:



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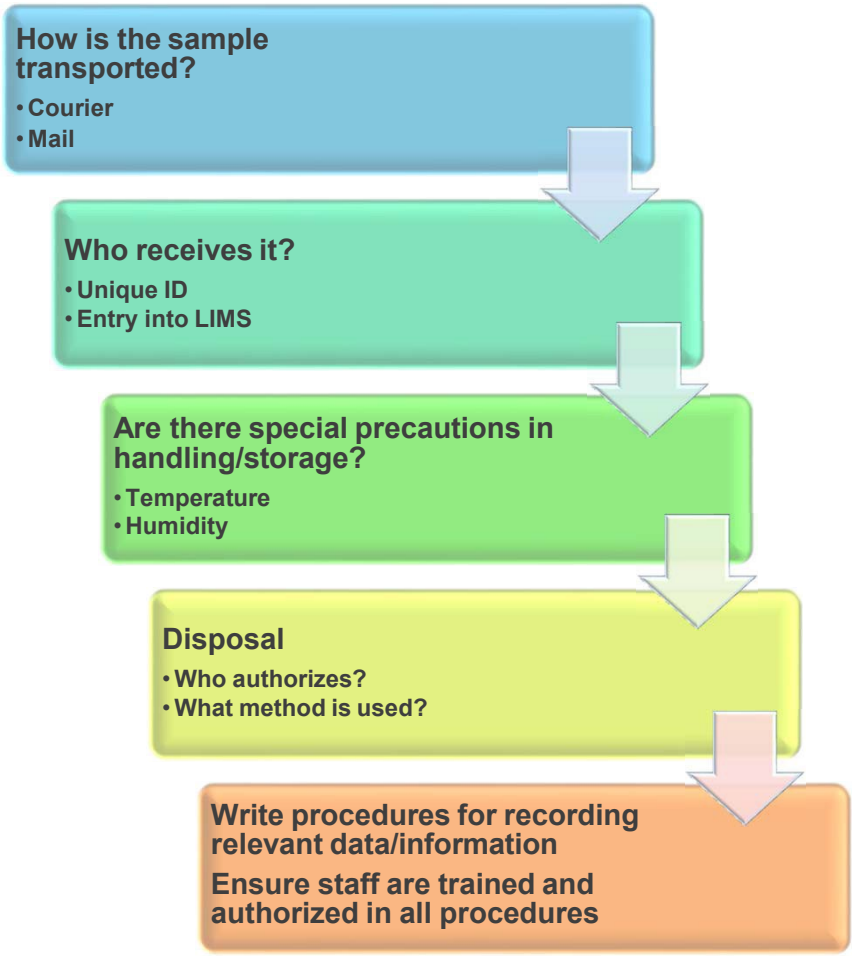
What happens when QC fails?

- 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
- Additional information in **Proficiency Testing** QMS module

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

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Reference

- ISO/IEC 17025:2017
  - –https://www.iso.org/standard/66912.html