# Quality Process Management in Clinical Laboratories

## Calibration and Quality Control Maintenance and Validation

RICKY D. MARTINEZ JR., RMT, BB (ASCP) SBB

# Learning Outcomes:

At the end of the presentation, the participant must be able to:

1. Understand the process of equipment management
2. Identify critical equipment in the laboratory
3. Develop the IQ, OQ, PQ of an equipment in the laboratory
4. Understand the process, principle, and purpose of calibration
5. Appreciate the basic elements of quality control in the laboratory
6. Define validation and the terms used in the validation process
7. Describe the purpose and principle of equipment maintenance

# 12 Quality System Essentials

The quality system essentials are:

organization

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customer focus

facilities and safety

personnel

purchasing and inventory

**equipment**

**process management**

documents and records

information management

nonconforming event management

assessments

continual improvement

# Equipment Management

The process of Equipment Management System (EMS) involves

- monitoring
- supervising
- managing
- maintenance of equipment and other assets of the laboratory.

# Lab Equipment

Critical equipment in the laboratory include :

- instruments
- measuring devices
- computer hardware and software

These equipment must be uniquely identified and operated within specifications as ensured by:

- qualification
- calibration
- maintenance
- monitoring

# Equipment Installation

**I**nstrument reliability is at the heart of accurate laboratory testing – 3 steps

installation qualification/IQ

operational qualification/OQ

performance qualification/PQ

# Operational Qualification – OQ

After a successful IQ , the instrument is ready for operational qualification

OQ is necessary to demonstrate that an instrument will function according to its operational specifications.

This documentation includes secure

- data storage
- backup
- archiving
- functional tests.

Vendor or user - perform OQ

# Performance Qualification (PQ)

Performance qualification (PQ) is done to demonstrate that an instrument performs according to the specifications defined by the user and is appropriate for the intended use.

Users should perform a minimum of 20 tests for positive and negative cases.

OQ and PQ tests should be repeated

When the instrument undergoes

- major repairs
- relocation
- modifications

# Calibration

Calibration - act of evaluating and adjusting the precision and accuracy of measurement equipment.

It is a comparison between a known measurement (the standard) and the measurement using your instrument.

Typically, the accuracy of the standard should be ten times the accuracy of the measuring device being tested.

However, accuracy ratio of 3:1 is acceptable by most standards organizations.

# Difference Between QC and Calibration

Calibrators give a reference point for the instrument to adjust to.

Controls (QC) make sure the instrument is working properly.

If the QC is out of range - a calibrator can be used to adjust the instrument so the QC results can be within the correct ranges.

# Importance of QC in a Laboratory

Quality control (QC) is one of the most important impacts on laboratory testing.

Laboratory quality control is designed to

- detect
- reduce
- correct deficiencies in a laboratory's internal analytical process prior to the release of patient results.

QC ensures both precision and accuracy of patient sample results.

# Out of Range QC

The laboratory should perform comprehensive instrument maintenance followed by recalibration.

The control materials are then retested.

If the results are still out of control, then the laboratory must continue to sequester all patient results and undertake a root cause analysis.

# Process Management

Process managements is a systematic approach in developing new and control changes to policies and procedures including:

- process validation
- test method validation
- computer system validation
- equipment validation and QC

# Maintenance

The technical meaning of maintenance involves:

- Functional checks
- Servicing
- Repairing
- Replacing of necessary devices, equipment, machinery.

# Preventive Maintenance (PM)

Preventive maintenance (PM) is done with the goal of "noticing small problems and fixing them before major ones develop.

Maintenance activities include record of equipment deterioration so they know to replace or repair worn parts before they cause system failure.

# Main Objectives of PM

Main objectives of PM are:

- Enhance capital equipment productive life.
- Reduce critical equipment breakdown.
- Minimize production loss due to equipment failures

# Predictive Maintenance

Predictive maintenance techniques - estimate when maintenance should be performed.

This approach promises cost savings over preventive maintenance, because tasks are performed only when warranted.

The main promise of predictive maintenance is to allow convenient scheduling of corrective maintenance, and to prevent unexpected equipment failures.

# Corrective Maintenance

Corrective maintenance is a type of maintenance - for equipment after equipment break down or malfunction.

It is often most expensive:

- equipment damage other parts and cause multiple damage
- consequential repair and replacement costs of worn parts
- loss of revenues due to down time during overhaul

# Validation

As a process, validation involves collecting and analyzing data to assess the accuracy of:

- 1. instrument and equipment
- 2. process
- 3. test method
- 4. computer system

# Purpose of Validation

Validation is done to ensure a product, service, or system meets the operational needs of the user.

Validation is done to assure that the processes will produce consistent and repeatable results within the predetermined specifications.

# Four Main Types of Validation

Prospective Validation.

Concurrent Validation.

Retrospective Validation.

Revalidation (Periodic and After Change)

# Validation of Clinical Laboratory Instrument

The ultimate goal of method validation is to provide objective evidence that the evaluated method will show acceptable reproducibility and accuracy so as to be clinically applicable.

# Method Validation

Method validation is the process used to confirm that the analytical procedure employed for a specific test is suitable for its intended use.

# Instrument Validation

It is a series of processes through which you test your system to verify the performance specifications given by the manufacturer of the instrument.

# Prospective Validation

Prospective validation is conducted prior to:

Distribution of a new product

Product made under revised process

Computer upgrade

After revision of existing validation plan

# Retrospective Validation

Retrospective validation is utilized for products and services already in place and not yet validated.

Based on historical date, QC

Should be planned and controlled

Should be documented

# Revalidation

Maybe necessary when:

There is a change in the actual process that may affect quality of the end result

There is a negative trend in quality indicators

There is a change in product design which affects the process itself

Move or relocation

# Accuracy / Precision

Accuracy

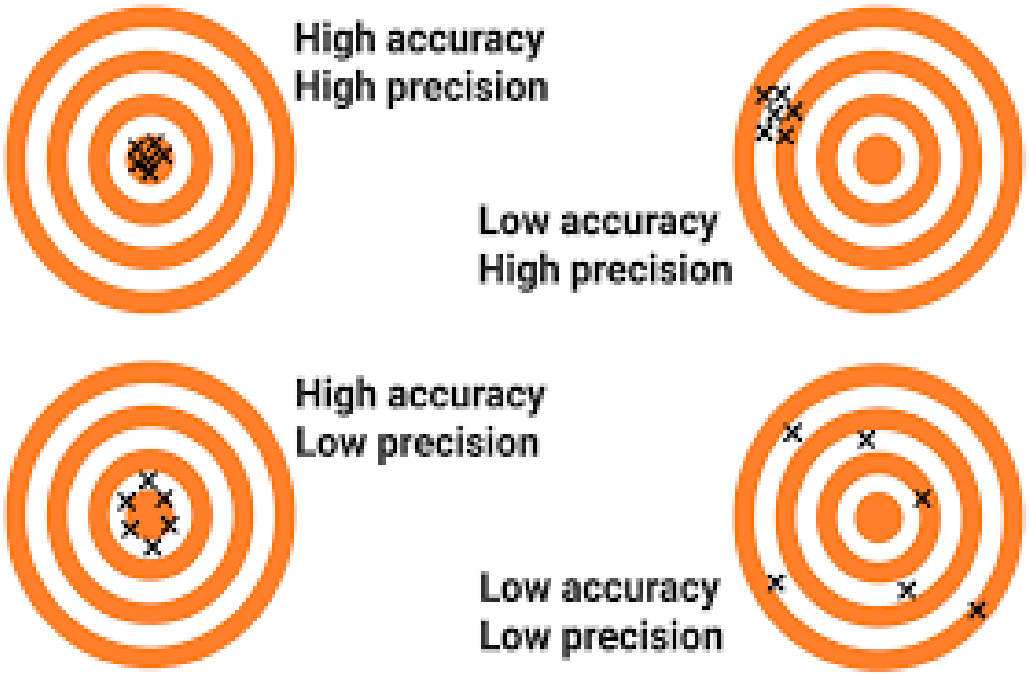
Accuracy is how close a measured value is to the actual (true) value.

Precision

Precision is how close the measured values are to each other.

The more measurements you make and the better the precision, the smaller the error will be.

# Precision / Accuracy



# Bias

Bias is a systematic (built-in) error which makes all measurements wrong by a certain amount.

Examples of Bias

The scales read "1 kg" when there is nothing on them

You always measure your height wearing shoes with thick soles

A stopwatch that takes half a second to stop when clicked

In each case all measurements are wrong by the same amount.

That is bias.