# Laboratory Quality Tools in Practice

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# Remember the 12 QSEs


1. Ordinary _____(Organization)
2. People _____(Personnel)
3. End-up_____(Equipment)
4. Purchasing _____(Purchasing and Inventory)
5. Products_____ (Process Management)
6. In _____(information Management)
7. Default _____(Documents and Records)
8. Of_____ (Occurrence Management)
9. Africa's _____(Assessment)
10. Careless _____(Continual Improvement)
11. Conformity _____(Customer Service)
12. Formula _____(Facility and Safety)

# Organization and Personnel

# Organizations and Personnel

Concepts:

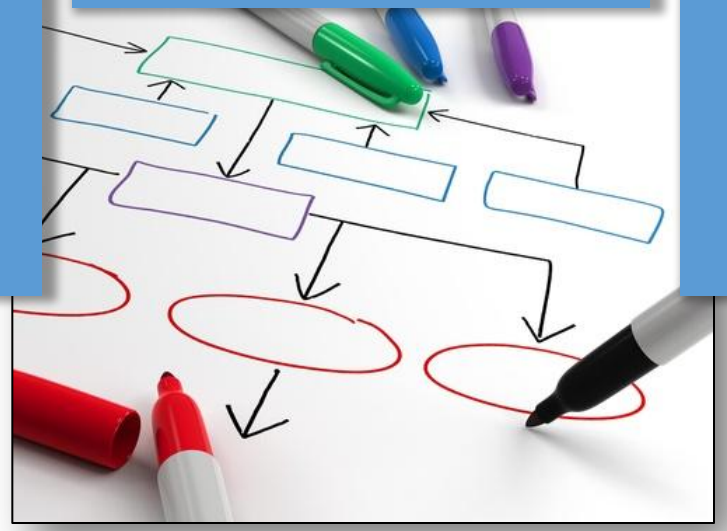
- A laboratory is defined by the people who work in it.
- A laboratory's success depends on the management and staff who maintain continuity and ensure that all procedures are conducted adequately.
- Personnel and organizational policies must be documented.


Laboratory floor plan – requirement ISO15189 standard

# Organizational Charts

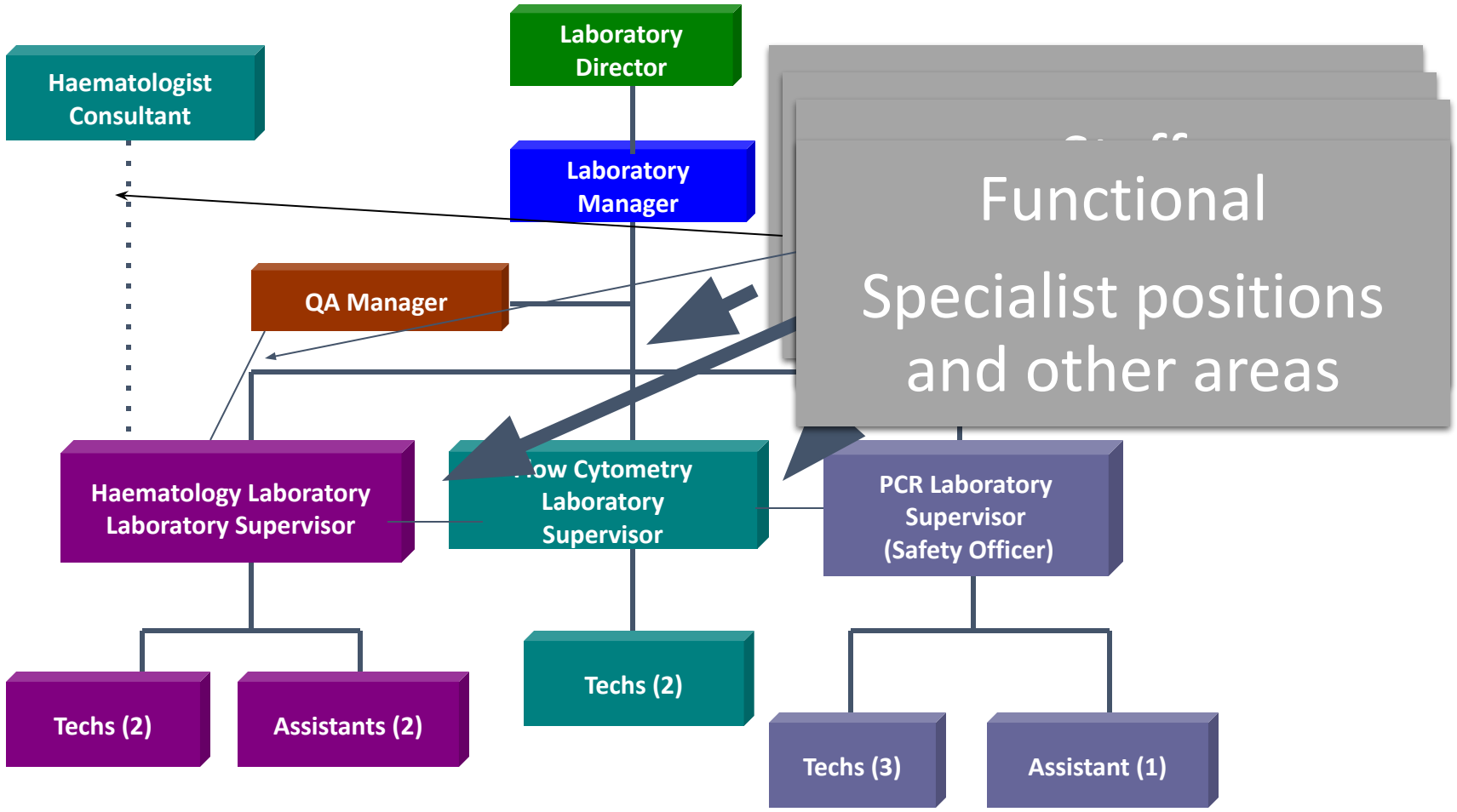
Should list all positions and how they relate to each other

Effective way to communicate organizational, employee, and enterprise information



Allows for organizing the laboratory team with clear responsibilities, titles, and lines of authority

# Organizational Charts (cont'd)

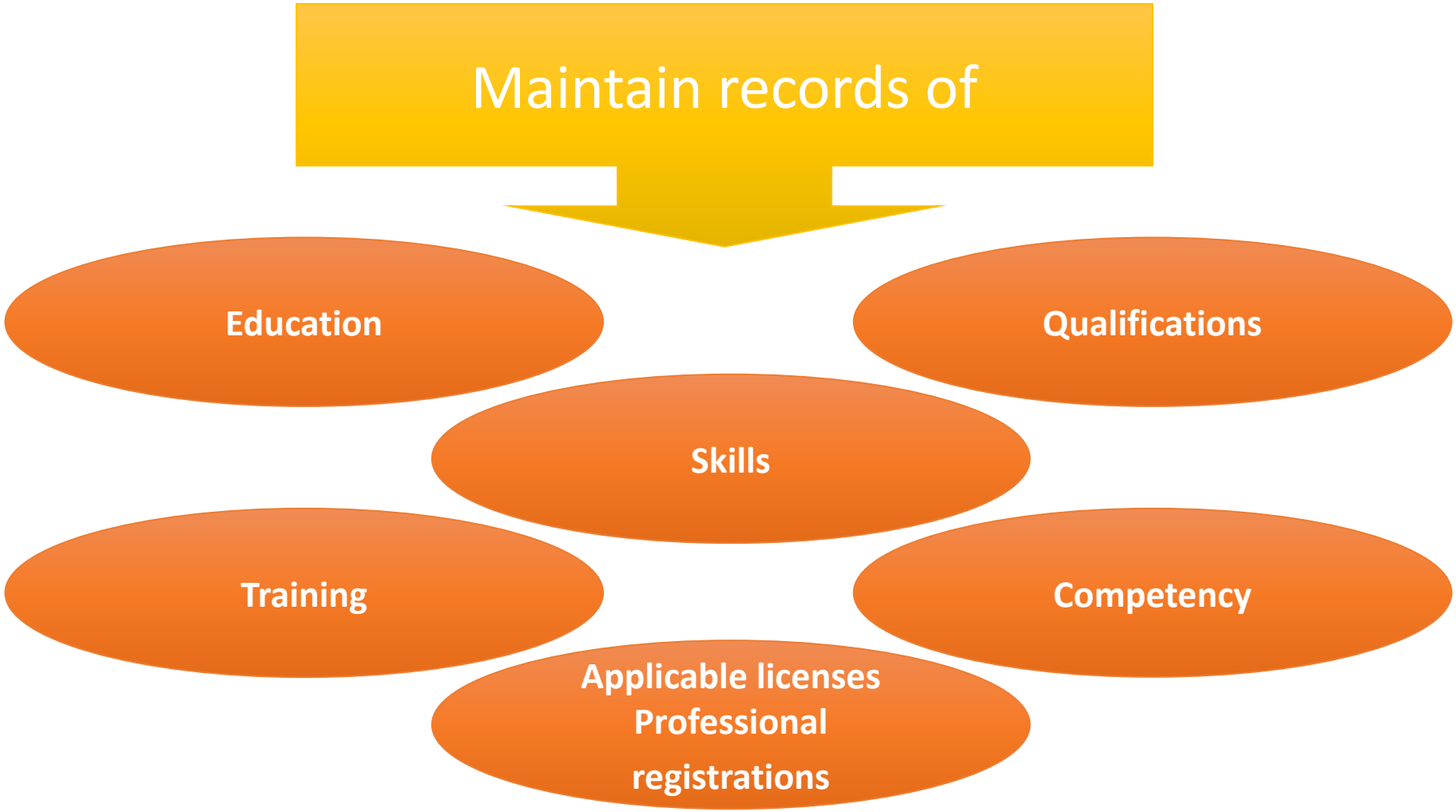


# Personnel

**The laboratory is required to demonstrate that its personnel is adequately…**


**…to perform their assigned activities.**

# Personnel Records

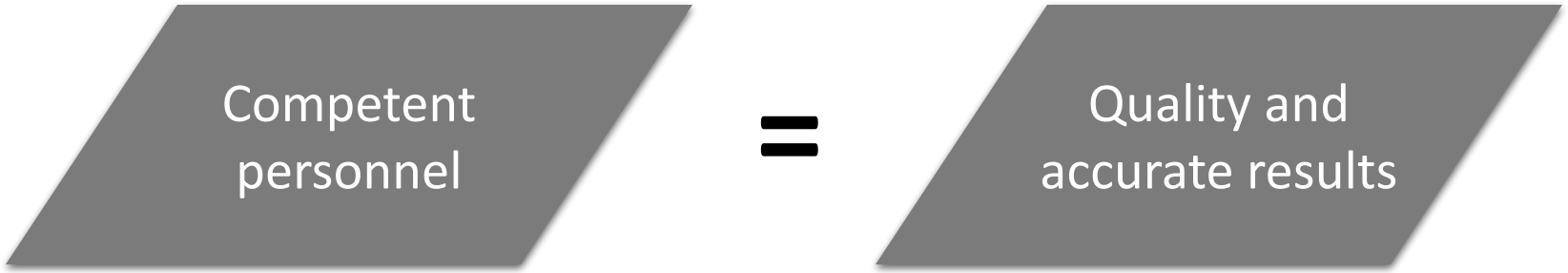



Clause 6.2.5 Personnel Records

# Competency

Application of knowledge, skills, and behaviors in performance

Compares employee performance against a standard



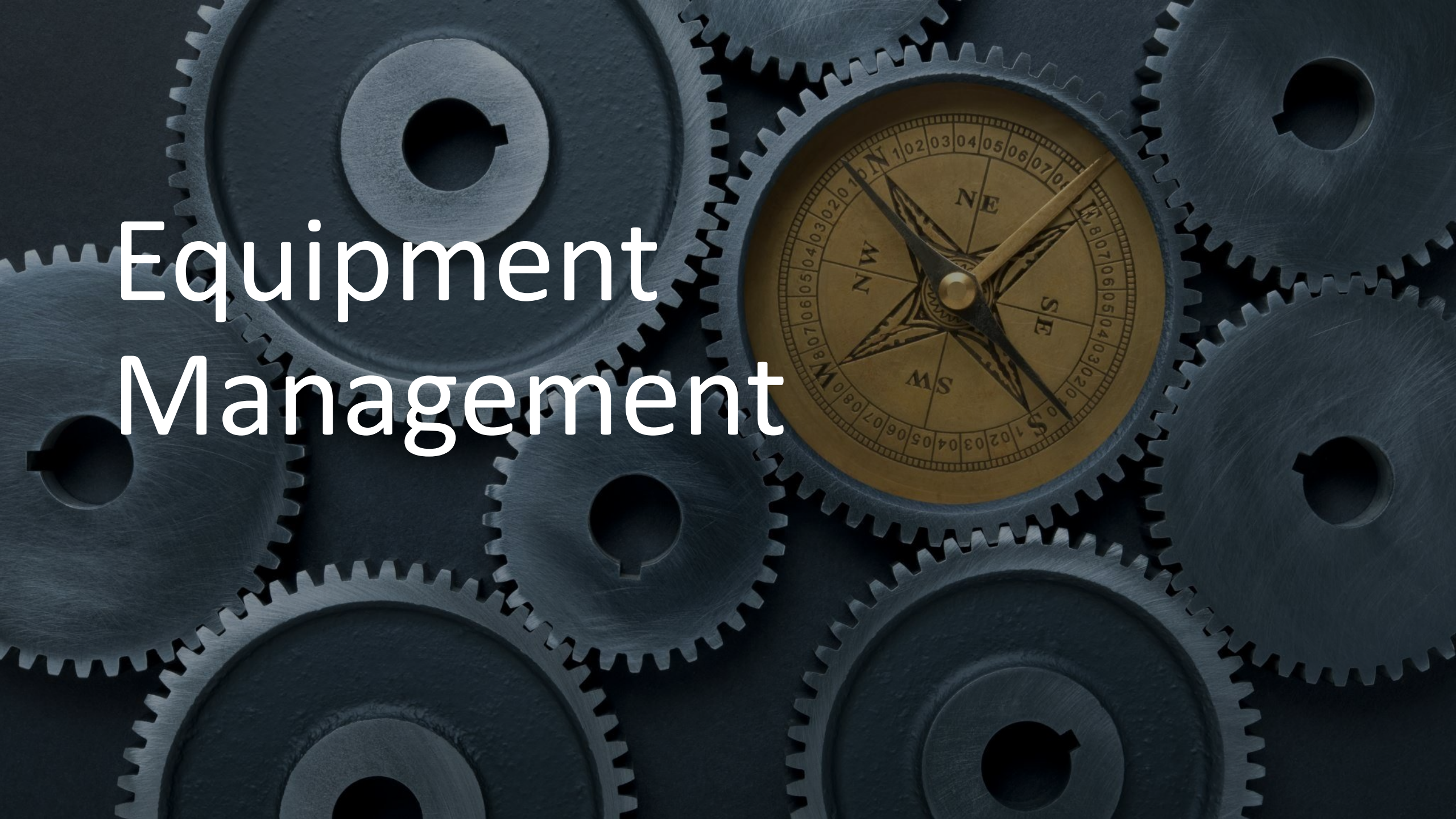
# Competency (cont’d)

**Assessments should:**

- Verify employees are competent to perform testing and report accurate and timely results
- Be able to effectively evaluate competency as well as identify areas for improvement
- Be meaningful and instructive

https://www.formydesk.com/Products/ACCO-Pressboard-6-Part-Classification-Folders--Letter--Blue--Box-of-10---3-Folder-Capacity---Letter---8-12-x-11-Sheet-Size---6-Fastener%28s%29---1-Fa__ACC15026.aspx

# Equipment Management



# Before Equipment Installation

- ✔ confirm vendor's responsibilities *in writing*
- ✔ establish checklist
- ✔ Creat a book of life for each assay equipment

# Implementing a Maintenance Program

- assign responsibility
- develop written policies and procedures
- maintain records
- train staff

# Develop a Maintenance Plan

For **each piece** of equipment establish **routine maintenance plan to include:**

- **frequency** of all maintenance tasks
- **function checks**
- routine replacement of **parts**

# Preventive Maintenance/Calibration Plan

**ABC Laboratory**

**Equipment Preventative Maintenance and Calibration Schedule– 2008**

| Equipment | Calibration/Validation/PM Frequency | Schedule | | | |
|---|---|---|---|---|---|
| | | Due Date | Performed? Sign/Date | Due Date | Performed? Sign/Date |
| Cobas Integra 400+ | Semi annual | February | | July | |
| Coulter AcT-5 Diff | Semi Annual | April | | September | |
| Safety Cabinets | Annual | July | | | |
| Centrifuges | Semi Annual | May | | October | |
| Pipettes | Semi Annual | January | | June | |
| Balances | Annual | May | | | |

Calibrate pipette - adjustabled and fixed volumes

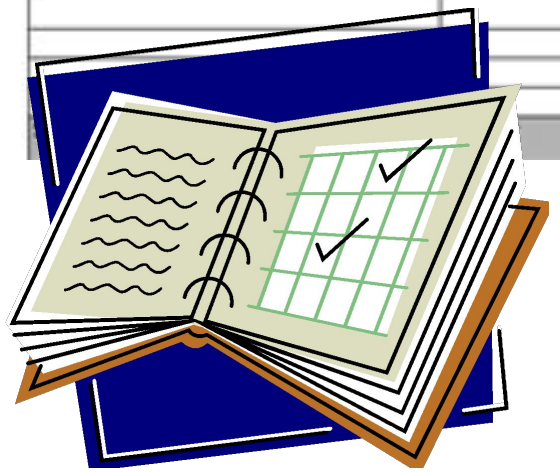
- Before placing into service
- Minimally, every six months

# Create an Equipment Inventory Log

## Record:

- instrument type, model number, serial number
- location in laboratory
- date purchased
- manufacturer and vendor contact information
- warranty, note expiration date
- spare parts

| Equipment identification | |
|---|---|
| Equipment type | |
| Trade mark | |
| Type | |
| Serial# | |
| Register record# | |
| Date first use | |
| Reseller | |
| Buying type (new, reconditioned, used) | |
| **Equipment performance** | |

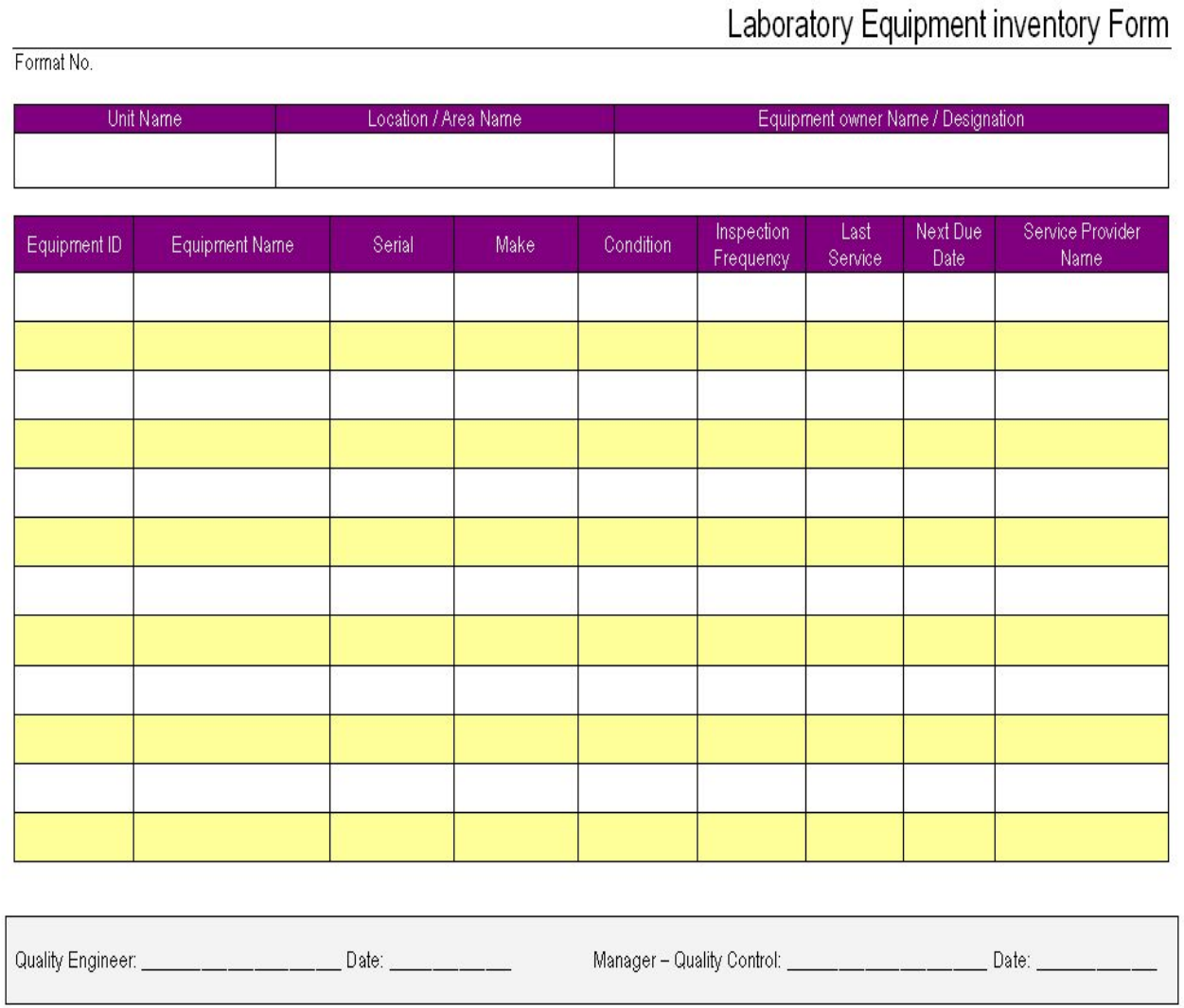


# Spare Parts Inventory

Include:

- record of spare parts
- log to track stock
- cost and ordering

information



Laboratory Equipment inventory Form

Format No.

| Unit Name | Location / Area Name | Equipment owner Name / Designation |
|---|---|---|
| | | |

| Equipment ID | Equipment Name | Serial | Make | Condition | Inspection Frequency | Last Service | Next Due Date | Service Provider Name |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
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| | | | | | | | | |

Quality Engineer: _____ Date: _____ Manager – Quality Control: _____ Date: _____

# Refrigerators and Freezers

- Establish tolerance limits
- Monitor temperature
- Check for ice build-up regularly
- Document corrective action for equipment failures
- Establish backup plan for malfunctions

**Temperature Monitoring Chart – Refrigerators**

Refrigerator #: _____ Month:_____ Year:_____

**Acceptable Range: 2 - 8°C**

| | Day | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Reading °C | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
| 13 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 12 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 11 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 9 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 7 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| -1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| -2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| -3 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Initials | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

**Reviewed by:_____** **Date:_____**

Comments:_____

_____

_____

SOP 132: V4

# Autoclaves

Verification of processing with each batch

Verification of sterilization weekly

Performance and documentation of maintenance

Verification of timing

# Analytical Balances

- Check accuracy with standard weights
  - Frequency determined by manufacturer
- Service/maintenance performance and documentation
- Placement of balance

ABC Laboratory

Weight Verification Log – Mettler Balance

Date:_____ Performed by:_____

| | Reference Weights | | | | | |
|---|---|---|---|---|---|---|
| | 0.100 g | 0.200g | 0.500g | 1.0g | 5.0g | 10.0g |
| 1 | | | | | | |
| 2 | | | | | | |
| 3 | | | | | | |
| 4 | | | | | | |
| 5 | | | | | | |
| 6 | | | | | | |
| 7 | | | | | | |
| 8 | | | | | | |
| 9 | | | | | | |
| 10 | | | | | | |
| Mean | | | | | | |
| SD | | | | | | |
| %CV | | | | | | |
| Pass/Fail | | | | | | |

Reviewed by:_____ Date:_____

Comments:_____

_____

_____

# Biosafety Cabinets

Verification/ visual checks

Certification before use and annually

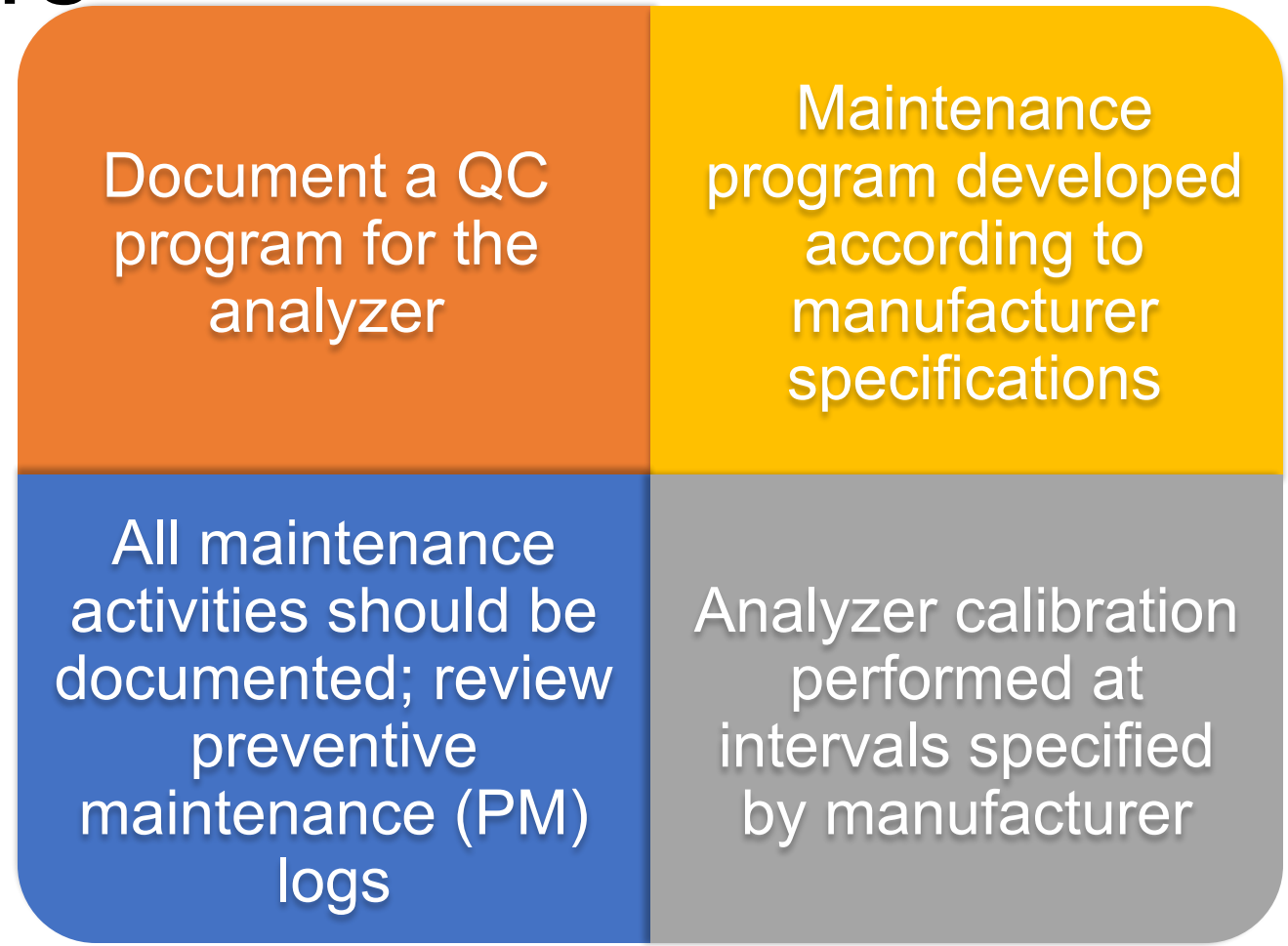
Daily air flow checks

Cleaning

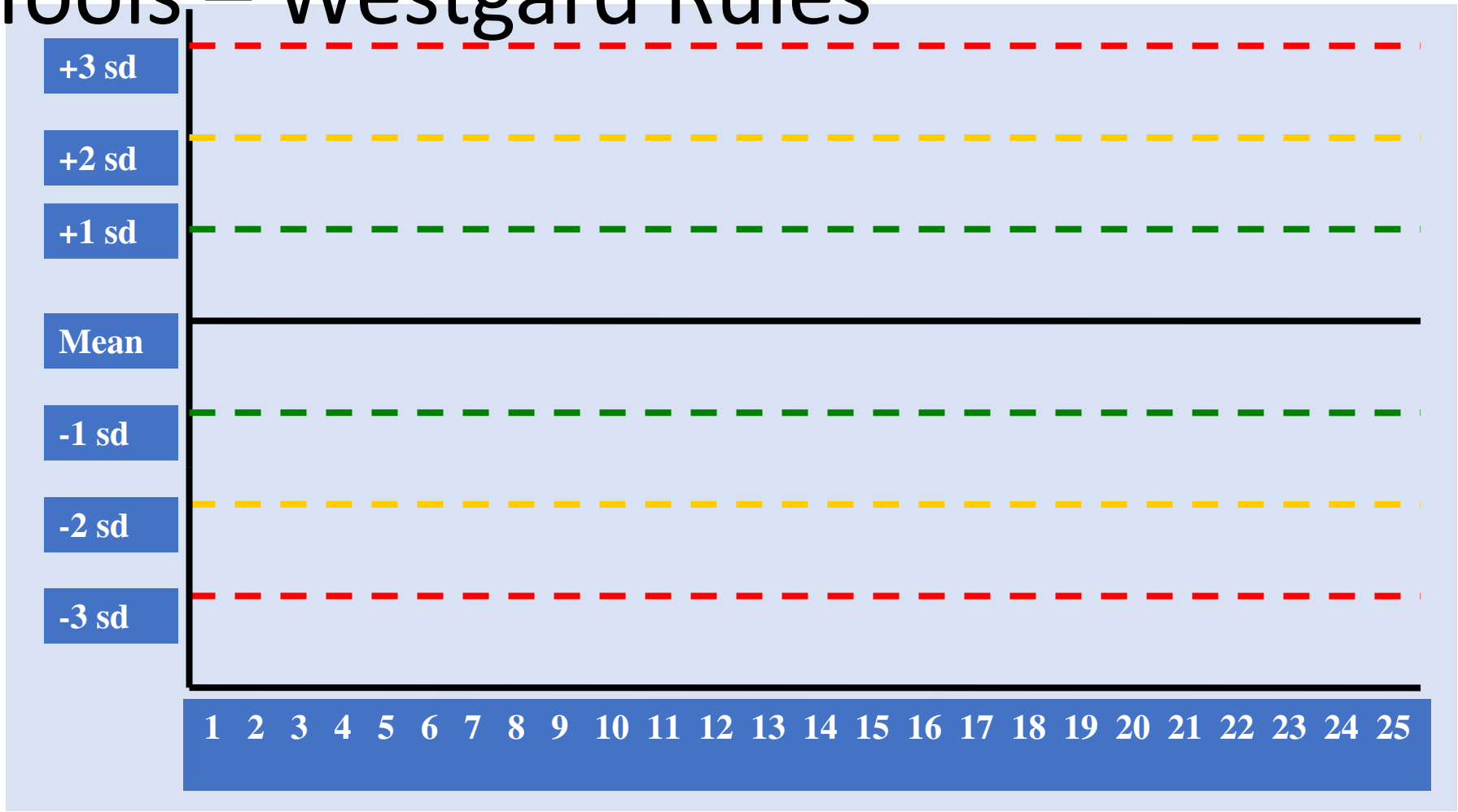
UV Lamp

Documentation

# Analyzers


Document a QC program for the analyzer
Maintenance program developed according to manufacturer specifications
All maintenance activities should be documented; review preventive maintenance (PM) logs
Analyzer calibration performed at intervals specified by manufacturer

# QC Tools – Westgard Rules



“Maintaining your equipment is paramount in maintaining the quality of your product.”

Frank Rabey

# Documentation

"If it is not documented, it never happened!"

Maintenance of prompt, accurate, and complete records

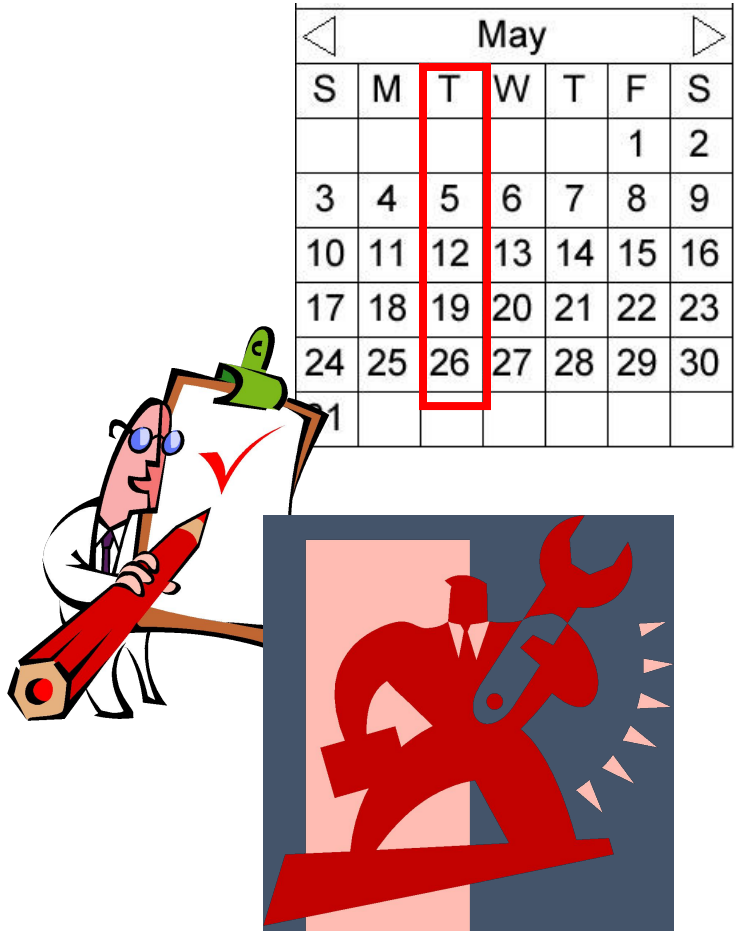
Why, how, when, and by whom was the test performed

"Write down what you do, do what is written down!"

# Documents

Develop written procedures for:

- **routine maintenance**
- **function checks**
- **calibration**
- **troubleshooting**
- **manufacturer's service**



# Recording Problems

- date problem occurred, equipment removed from service
- reason for breakdown or failure
- corrective actions taken
- date returned to use
- change in maintenance or in function checks

# Example of logbook 1

**EQUIPMENT LOGBOOK / EQUIPMENT FOLLOW UP**

*Laboratory* .....
*Logbook for*
*Establish by* .....
*Date* .... / ..... / .....

| **LOGBOOK FOR** | |
|---|---|
| **Equipment identification** | |
| Equipment type | |
| Trade mark | |
| Type | |
| Serial# | |
| Register record# | |
| Date first use | |
| Reseller | |
| Buying type (new, reconditioned, used) | |
| **Equipment performance** | |
| | |
| | |
| | |
| | |
| **Specific items when using the equipment** | |

# Example of logbook 2

| | |
|---|---|
| **Equipment performance** | |
| | |
| | |
| | |
| | |
| **Specific items when using the equipment** | |
| Documentation available: | |
| Spare parts available: | |
| | |
| **Preventive maintenance activities** | |
| * **To be done by end-user** | |
| | |
| 1/day | |
| 2/week | |
| 1/week | |
| 1/month | |
| 1/3 months | |
| 1/6 months | |
| * **To be done by external assistance** | |
| (Factory / nature / periodicity) | … … … … . / … … … … … … … / … … … … … … … … / … … . |
| | |

# Facilities and Safety

# Safety Signage

Should be placed in relevant laboratory areas and be visible


Escape Route


Eyewash


First Aid


Corrosive


Explosive


Flammable



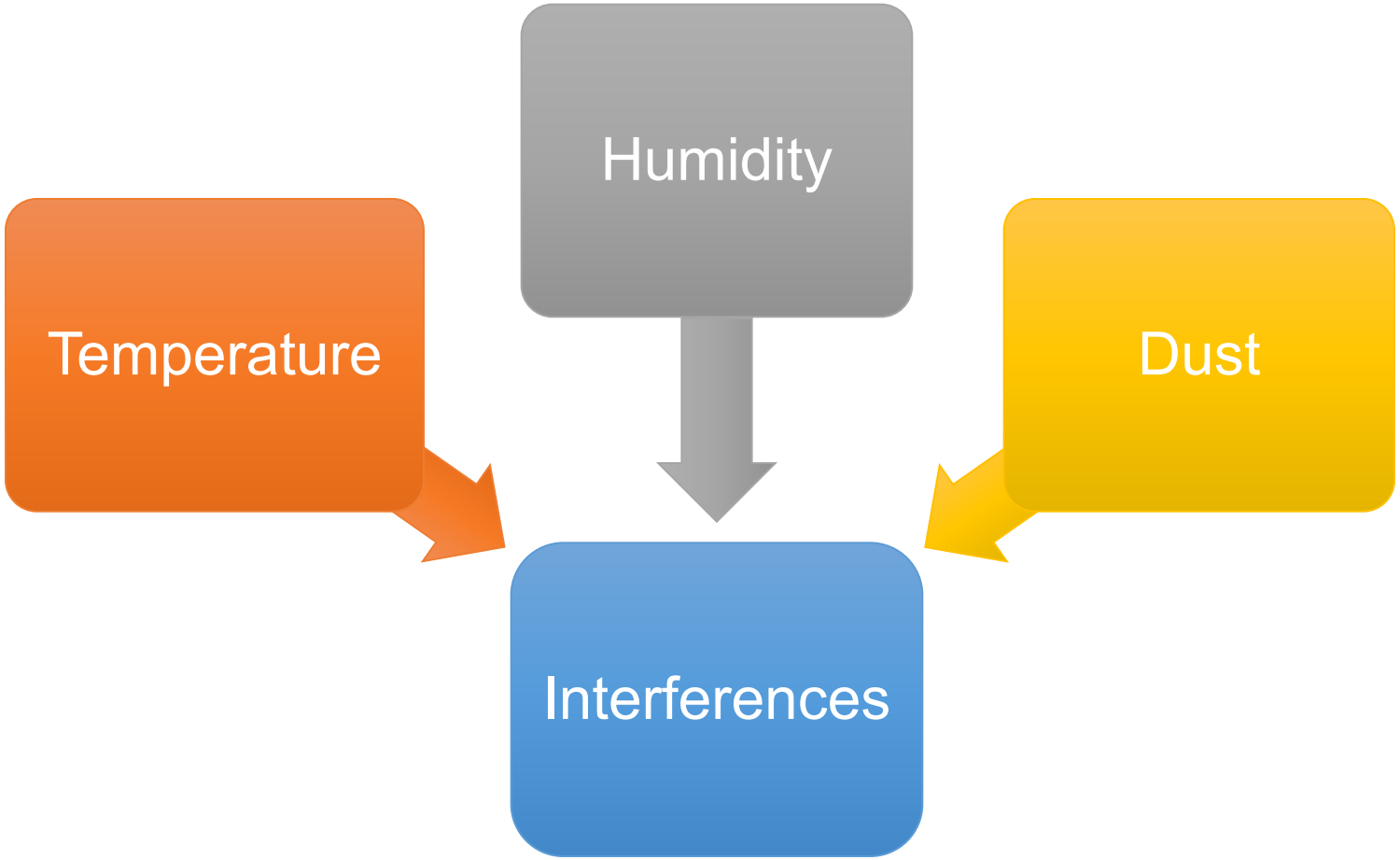

Hazardous


Toxic


Biohazard


Fire Extinguisher

# Environmental Control



# Temperature Control

## Temperature Recording

- Temperature monitoring activities should be documented

## Tolerance Limits

- Established by determining the minimum range of values common to the defined tolerance limits for reagents in storage or the recommended incubation temperature for the assays being performed

## Temperature Review

- Monthly review of temperature charts

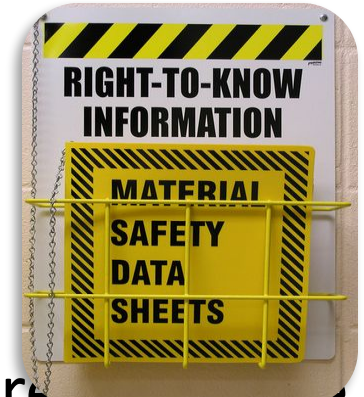
# Temperature Logs

Temperature records should include the following information:

- Specific equipment being monitored for temperature
- Temperature values
- Date when the temperature was read
- Initials of laboratory personnel monitoring and recording the temperature
- A section to record corrective action for out-of-range limits
- Space to record supervisor review signature and date

# Material Safety Data Sheets (MSDS)

- Product-specific information for chemicals
  - Name of Chemical
  - Physical Characteristics and Hazards
  - Health Related Info
  - First Aid
  - Spill and Disposal
  - Date of most recent change
  - Name and address of party responsible for MSDS



# Material Safety Data Sheets (MSDS) (cont'd)

- Maintain MSDS for:
  - Reagents/chemicals
  - Test kits
  - General-use supplies (e.g., bleach)
- Document staff training
- Organize alphabetically or numerically
- Update at least every two years
- Maintain index of all MSDS; can serve as chemical inventory
- Accessible to everyone at all times
- Create a hazardous chemicals chart for first aid

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# Process Management

# SOP Guidelines

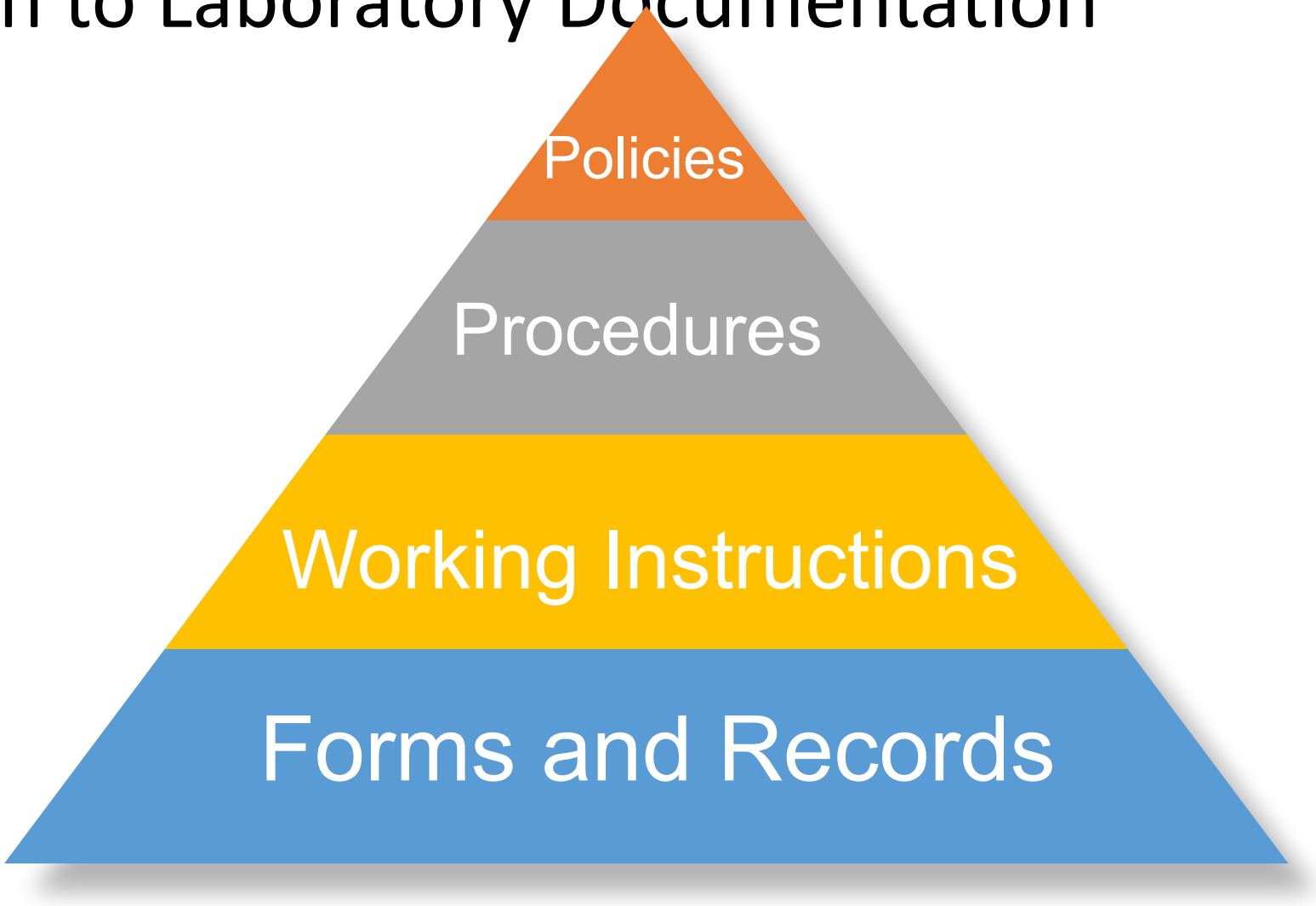
Each laboratory should have SOPs for ALL procedures being performed

SOPs are written for the benefit of the laboratory employees, not auditors

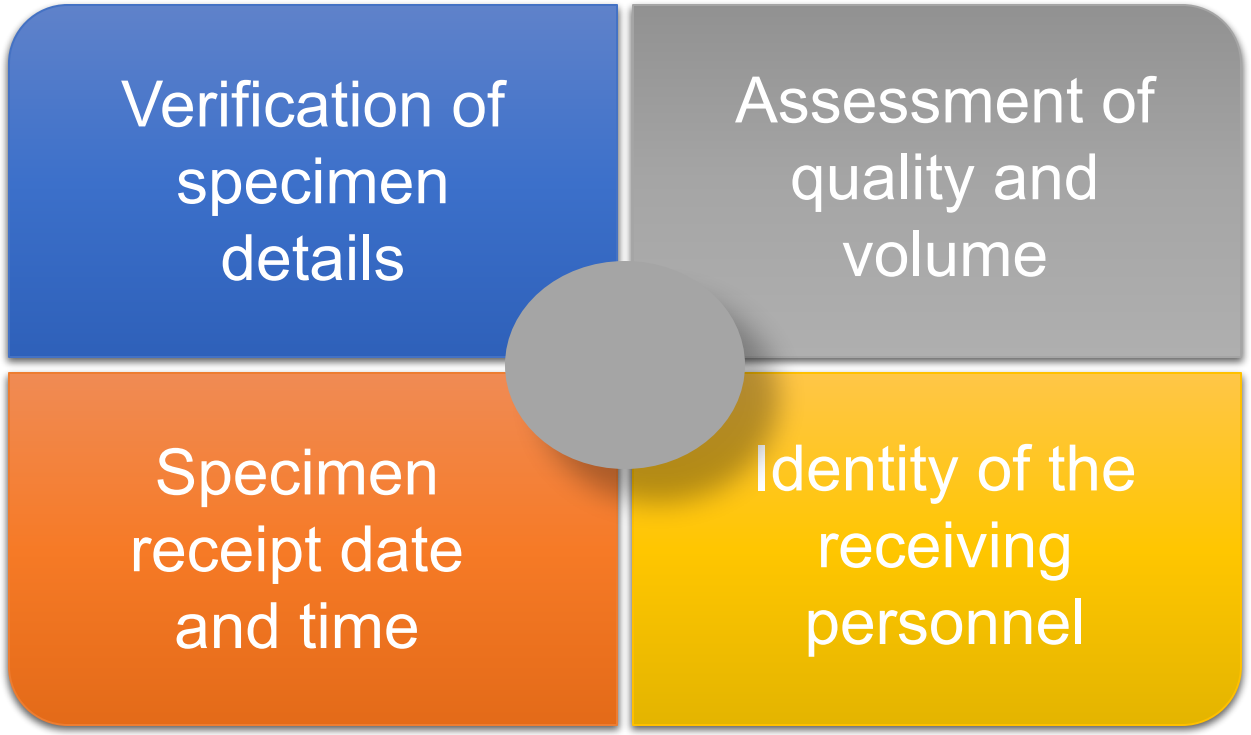
SOPs should be written in a manner and language that is appropriate to the laboratory personnel conducting the procedures

Current SOPs must be available in the work areas and accessible to staff

# Approach to Laboratory Documentation



# Specimen Receipt

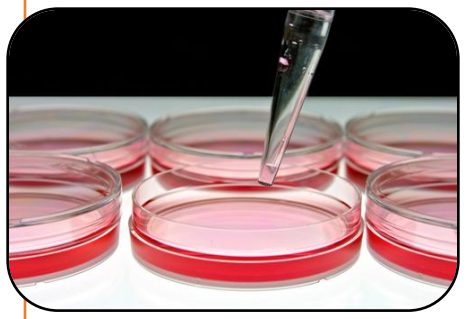


# Specimen Rejection Criteria

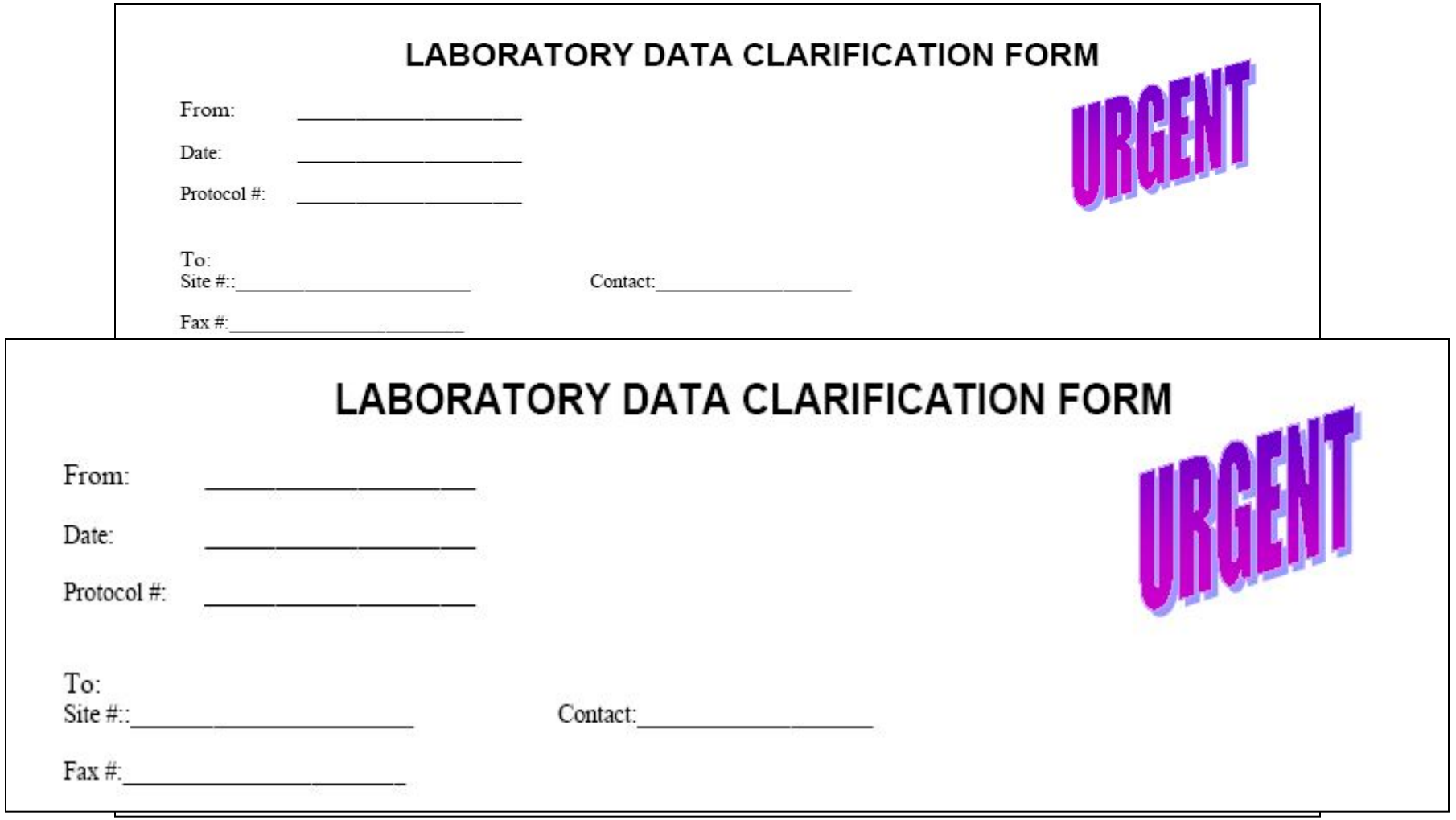
- Unlabeled specimen
- Mislabeled/incompletely labeled specimen
- Inadequate information on request form
- Specimen collected in a wrong tube
- Insufficient or clotted specimen
- Specimens received past assay stability

# Specimen Rejection Requires

- Prompt notification of rejected specimens to the clinic
- Documentation of notification
- Cumulative review of notification records to be discussed at study team meetings



# Clarification/Notification Form



LABORATORY DATA CLARIFICATION FORM

URGENT

From: _____

Date: _____

Protocol #: _____

To:
Site #:: _____ Contact: _____

Fax #: _____

LABORATORY DATA CLARIFICATION FORM

URGENT

From: _____

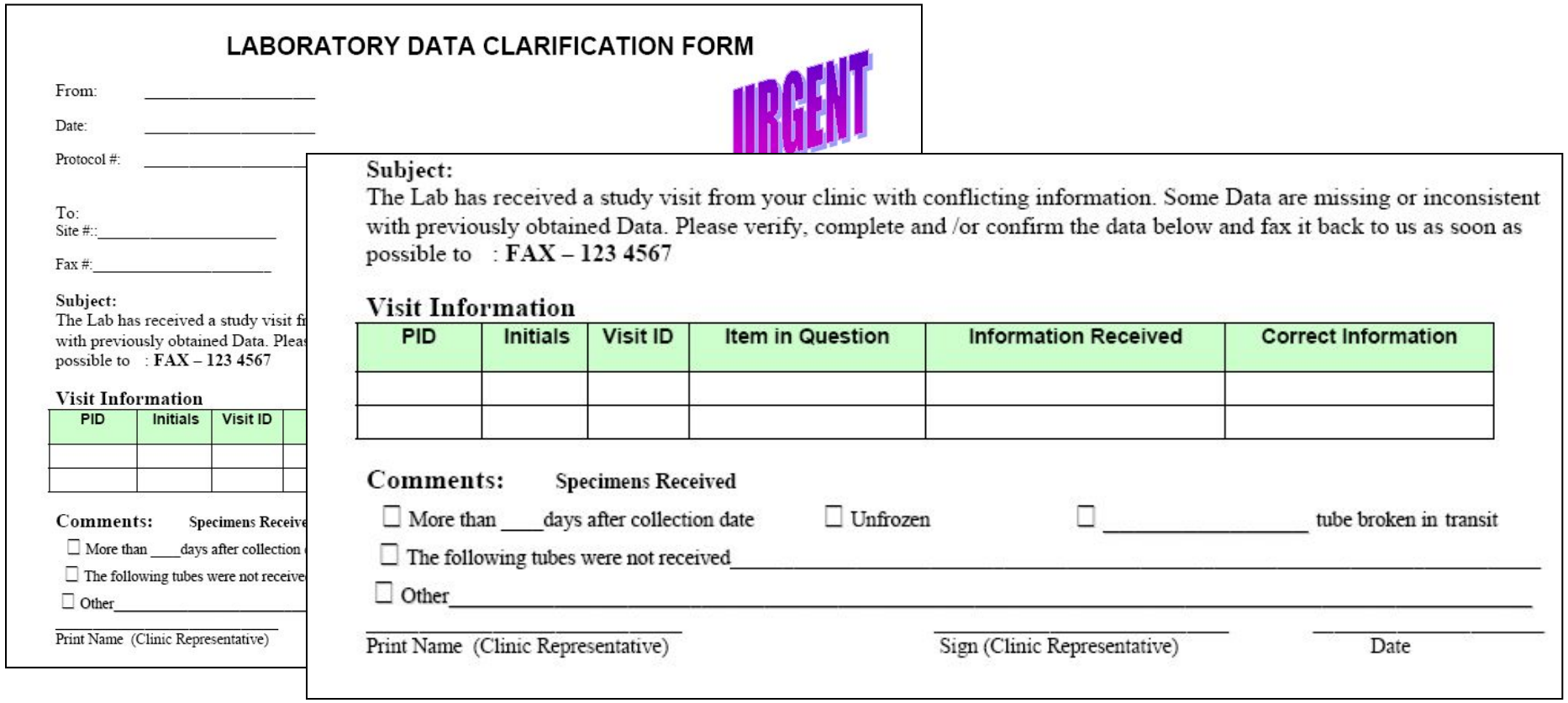
Date: _____

Protocol #: _____

To:
Site #:: _____ Contact: _____

Fax #: _____

# Data Clarification/Notification Form



LABORATORY DATA CLARIFICATION FORM

URGENT

From: _____

Date: _____

Protocol #: _____

To:
Site #:: _____

Fax #: _____

**Subject:**
The Lab has received a study visit fr
with previously obtained Data. Pleas
possible to : **FAX – 123 4567**

**Visit Information**

| PID | Initials | Visit ID | |
|---|---|---|---|
| | | | |
| | | | |

**Comments:** Specimens Receive

☐ More than ____days after collection

☐ The following tubes were not receive

☐ Other_____

_____
Print Name (Clinic Representative)

**Subject:**
The Lab has received a study visit from your clinic with conflicting information. Some Data are missing or inconsistent with previously obtained Data. Please verify, complete and /or confirm the data below and fax it back to us as soon as possible to : **FAX – 123 4567**

**Visit Information**

| PID | Initials | Visit ID | Item in Question | Information Received | Correct Information |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

**Comments:** **Specimens Received**

☐ More than ____days after collection date ☐ Unfrozen ☐ _____ tube broken in transit

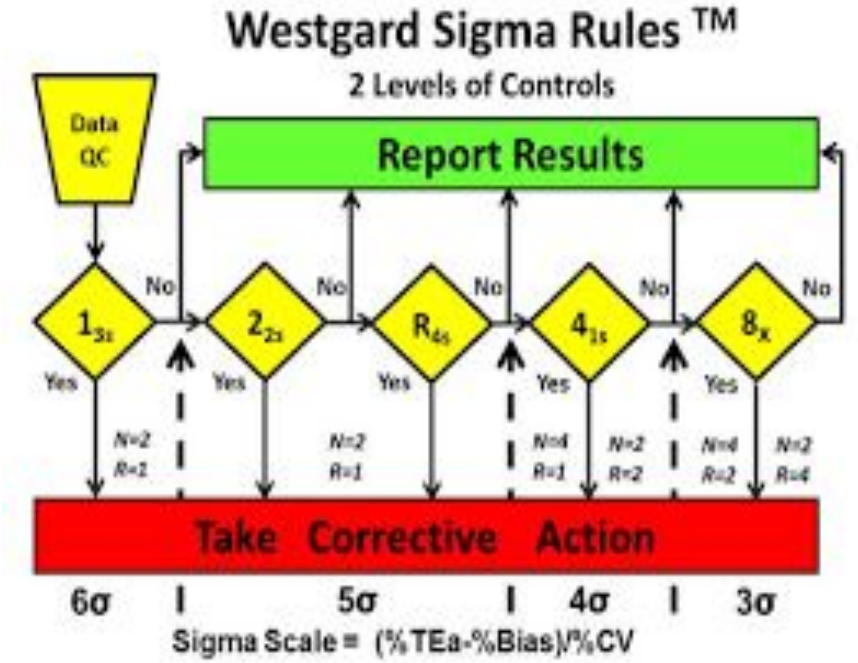
☐ The following tubes were not received_____

☐ Other_____

_____ _____ _____
Print Name (Clinic Representative) Sign (Clinic Representative) Date

# Selecting a Method

- Evaluate diagnostic tests
  - Characteristics of testing methods
  - References: Technical literature and manufacturer's information
- Select method of analysis
- Validate method performance
- Implement method
- Perform tests with appropriate Quality Control (QC) and External Quality Assurance (EQA)



# Method Validation

What is method validation?

Why must we validate?

When should we validate?

What should we validate?

# Tests to Validate


- Unmodified FDA-approved
- Modified and/or Non-FDA-approved

# Method Validation

- Before you begin:
  - Be sure you are familiar with the test method before starting
  - Know what to expect from the method (package insert, discussions with technical assistance, and field service representatives)
  - Do not include results outside of stated reportable ranges
  - Predict your findings; establish limits/evaluation criteria

# Error in Test Methods

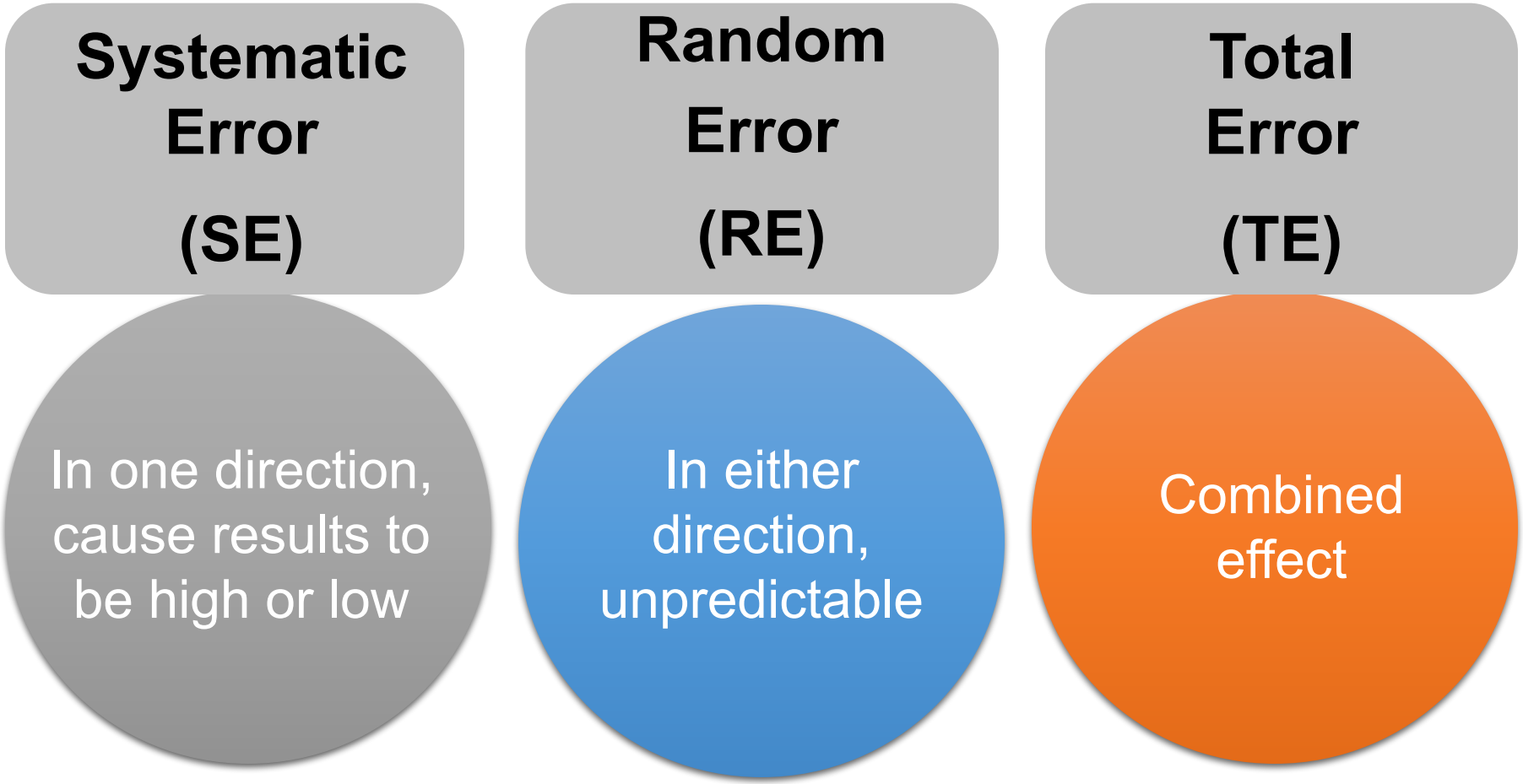
- Some errors are expected
  - Examples
- Error must be managed
  - Understanding
  - Defining specifications of allowable error
  - Measurement

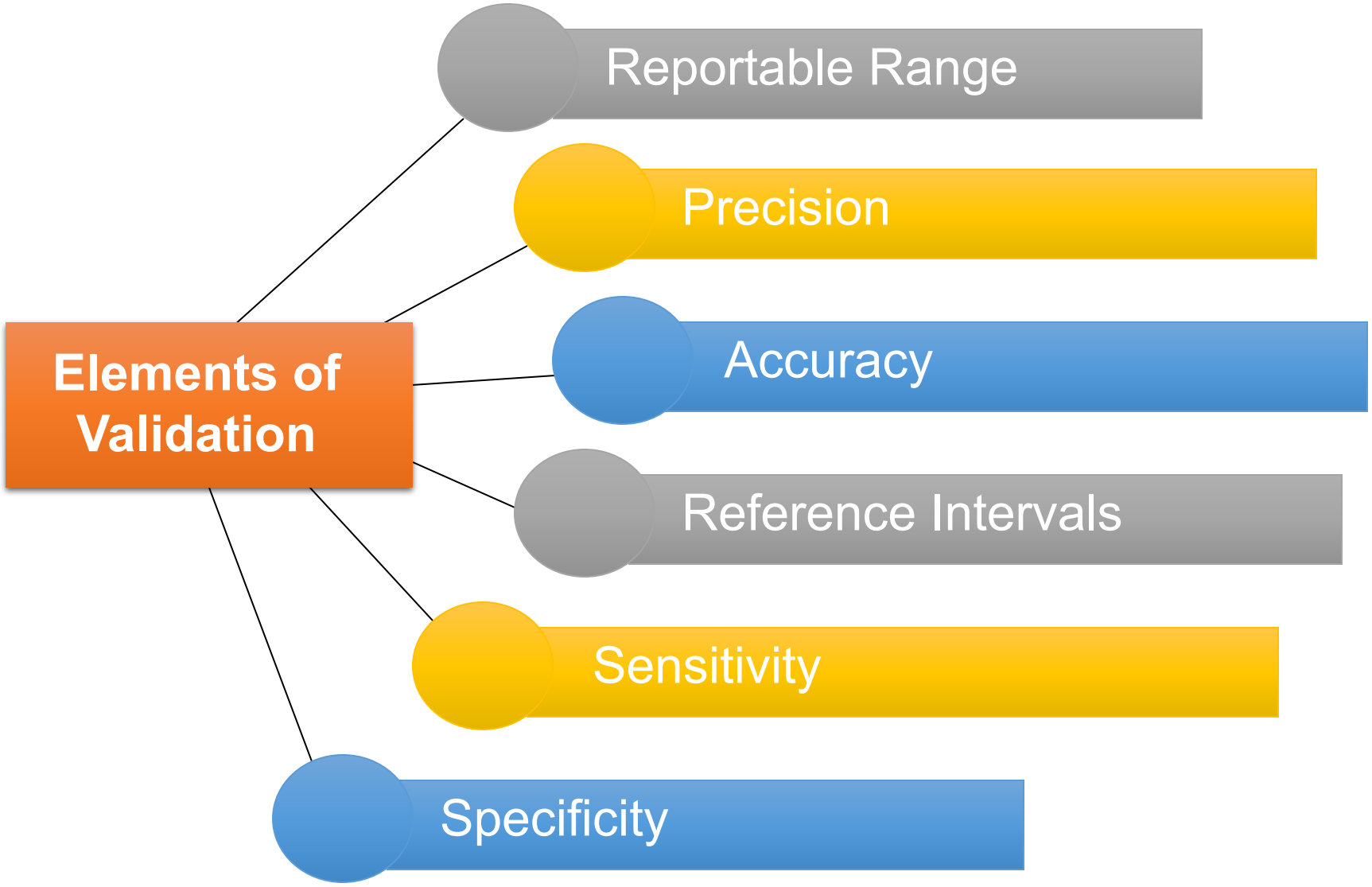
# Total Error of Testing System

## Total Allowable Error

- CLIA Guidelines per analyte
- Other Guidelines

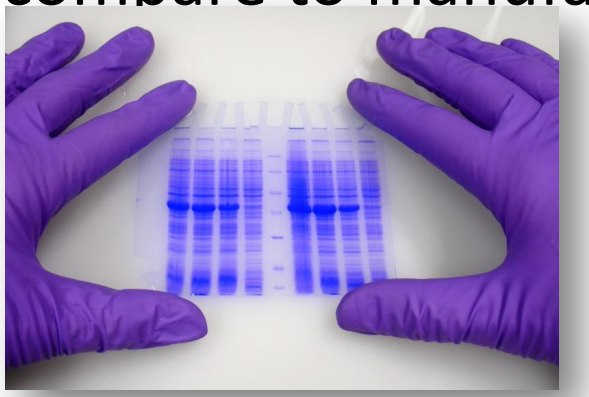
# Error Assessment




Elements of Validation
Reportable Range
Precision
Accuracy
Reference Intervals
Sensitivity
Specificity

# Qualitative Assays

- Compare diagnosis
- Assume comparative (reference) method is accurate
- Determine the following:
  - True Positives, True negatives
  - False Positives, False negatives
- Calculate sensitivity and specificity and compare to manufacturer



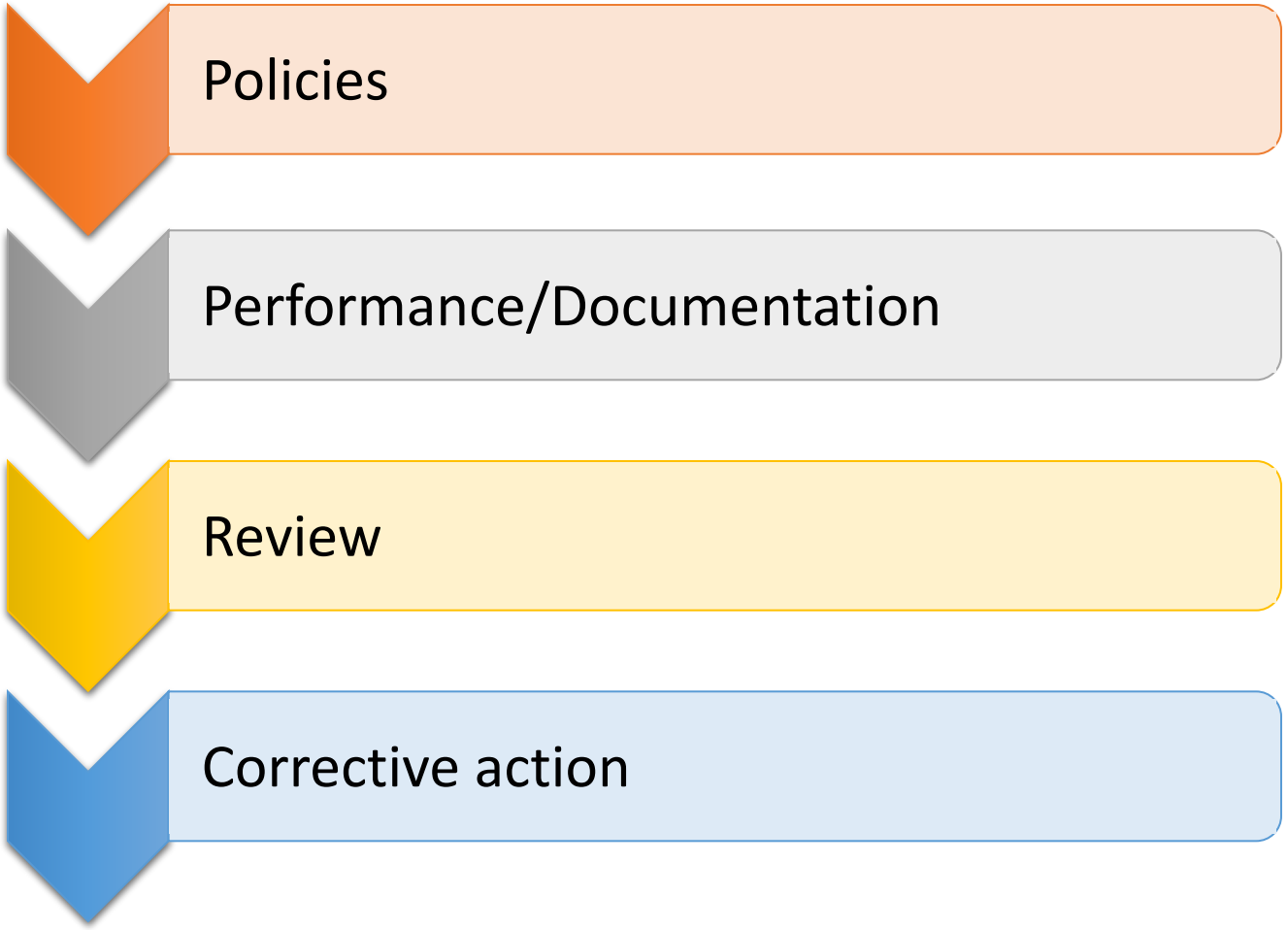
# Qualitative Assays: Control of Validation

- Negative and Positive Quality Controls
  - Use QC materials recommended by manufacturer for verification purposes
  - Determine validity of other results, e.g., method comparisons
  - Evaluate failed runs if they occur during verification process

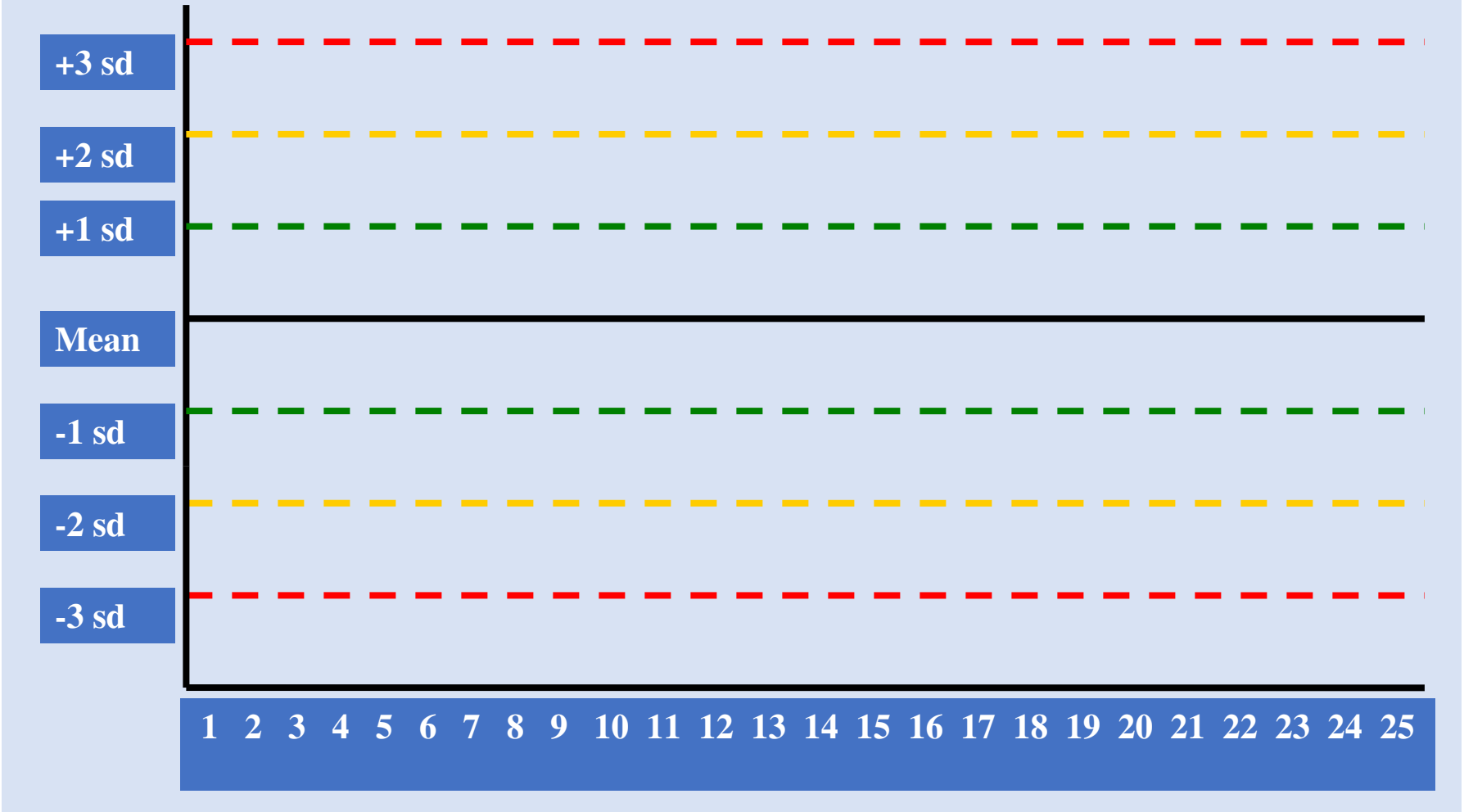
# Quality Control (QC)


"…procedures for monitoring the work processes, detecting problems, and making corrections prior to delivery of products or services. Statistical process control, or statistical quality control, is the major procedure for monitoring the analytical performance of laboratory methods. "

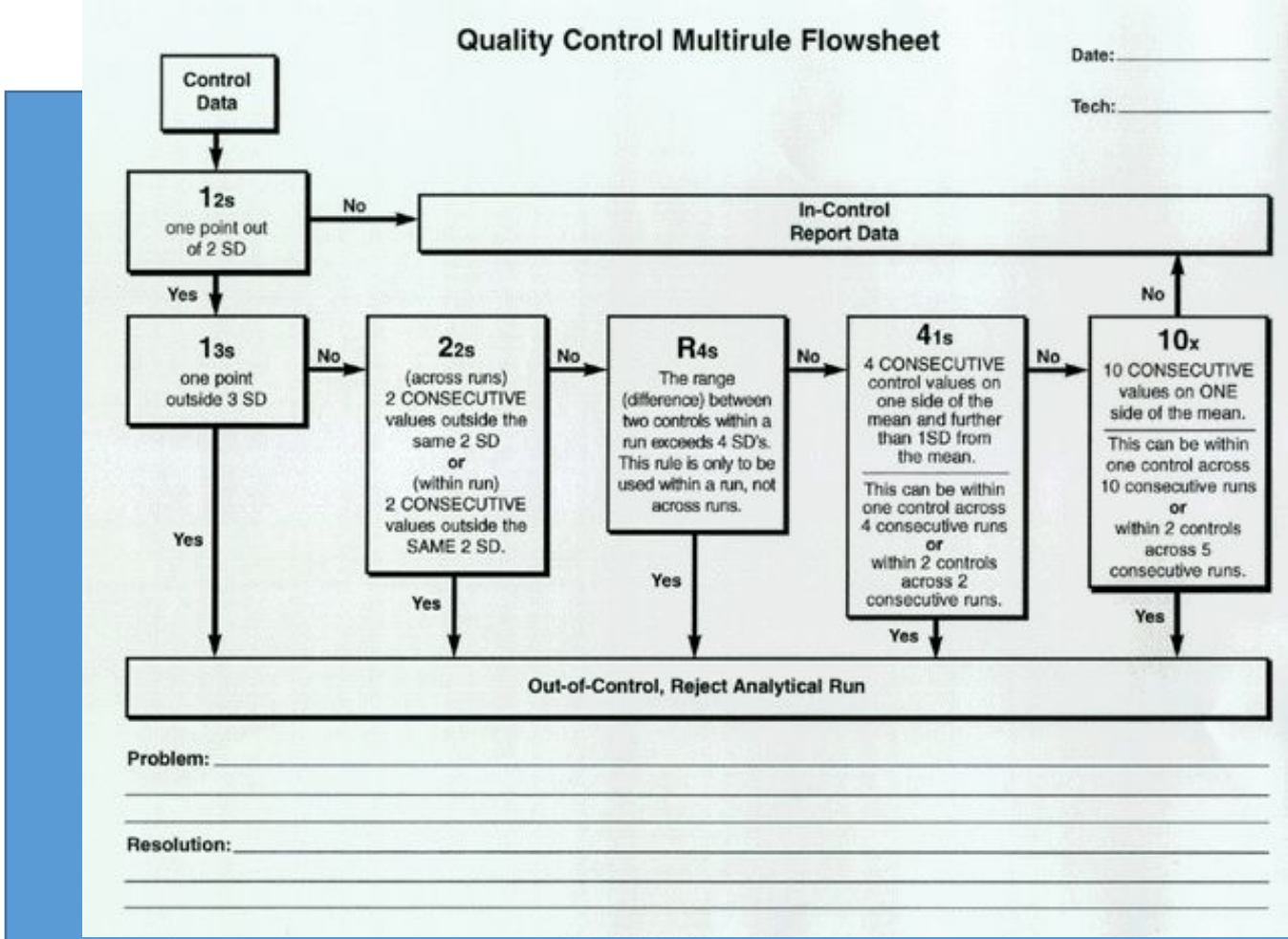
# Elements of Quality Control



# QC Tools – Westgard Rules



# Quality Control Multi-Rule Flowsheet



# Teamwork

Teamwork is the ability to work together toward a common vision—the ability to direct individual accomplishments toward organizational objectives. It is the fuel that allows common people to attain uncommon results.

Andrew Carnegie

# THANK YOU SO MUCH FOR LISTENING