QMS Quick Learning Activity

Quality Management System Introduction

ISO/IEC 17025:2017

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Abbreviations and Acronyms

- **Assessment**-a systematic process of collecting and analyzing data to determine the condition of an organization
- **Change Management**-a process that supports moving from the current state to a future state by revising policies, processes or procedures
- **Confidentiality**-the principle of using restrictive processes and policies to guard against unauthorized disclosure of client and personnel records and information
- **CI**-Continuous Improvement
- **Customer**-the clients or end users of a product or service; customers may be internal ~~or~~ and external to the company
- **Data Integrity**-guarding against improper information modification or destruction to ensure information is authentic
- **Ethics**-Moral rules that govern a person or group
- **FDA**-Food & Drug Administration
- **ILAC**-International Laboratory Accreditation Cooperation
- **ISO**-International Organization for Standardization
- **IEC**-International Electrochemical Commission

Abbreviations and Acronyms

- **Procedure**-a specified way to carry out an activity or process
- **Process**-a set of interrelated or interacting activities to achieve a particular end
- **Proficiency Testing**-an evaluation of the laboratory's performance by analyzing samples of external origin to determine accuracy and adequacy of the laboratory's pre-analytical, analytical, and post-analytical processes
- **Quality**-the degree in which a set of inherent characteristics fulfills requirements
- **QA**-Quality Assurance: planned and systematic activities implemented in a quality system to ensure quality goals are fulfilled
- **QC**-Quality Control: processes and techniques to detect, reduce, and correct deficiencies in an analytical process
- **QC data**-measures that reflect the accuracy, precision, and reliability of testresults
- **QMS**-Quality Management System: all aspects of the laboratory operation, including the organizational structure, processes and procedures, that need to be addressed to ensure quality

ISO/IEC 17025:2017-Internationally Accepted Standard for Quality Systems

- Launched in 1988 to improve Quality Management Systems (QMS) and updated in 1999, 2005, and 2017
- Compliance with these standards aids the laboratory to:
  - Identify mechanisms to develop and show commitment to continually improving the QMS
  - Communicate with customers by actively soliciting feedback and using the information to improve the QMS
  - Use the information from measurement and quality control (QC) data to evaluate the performance of the QMS and identify opportunities for improvement

Why ISO/IEC 17025:2017 Accreditation?

- Accreditation provides formal recognition that laboratories can achieve a level of reliable testing and measurement
- Customers are then able to identify and select laboratories that produce services to meet their needs
- One element to take appropriate regulatory action based on human and animal food testing
  - Accredited by an International Laboratory Accreditation Cooperation (ILAC) recognized Accrediting Body (AB)

- What is an Accrediting Body?
  - Internationally recognized to carry out quality system assessments of a laboratory (for ISO/IEC 17025:2017 accreditation)
- They also must be accredited
  - Conform to the requirements of the *ISO/IEC 17011:2017, "Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies"*

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What is the Scope of Accreditation?

- Methods and technologies covered by assessment
- Laboratory is accredited for a specific list of methods, analytes, matrices, and/or technologies
- Also called
  - Fields of Accreditation
  - Fields of Testing

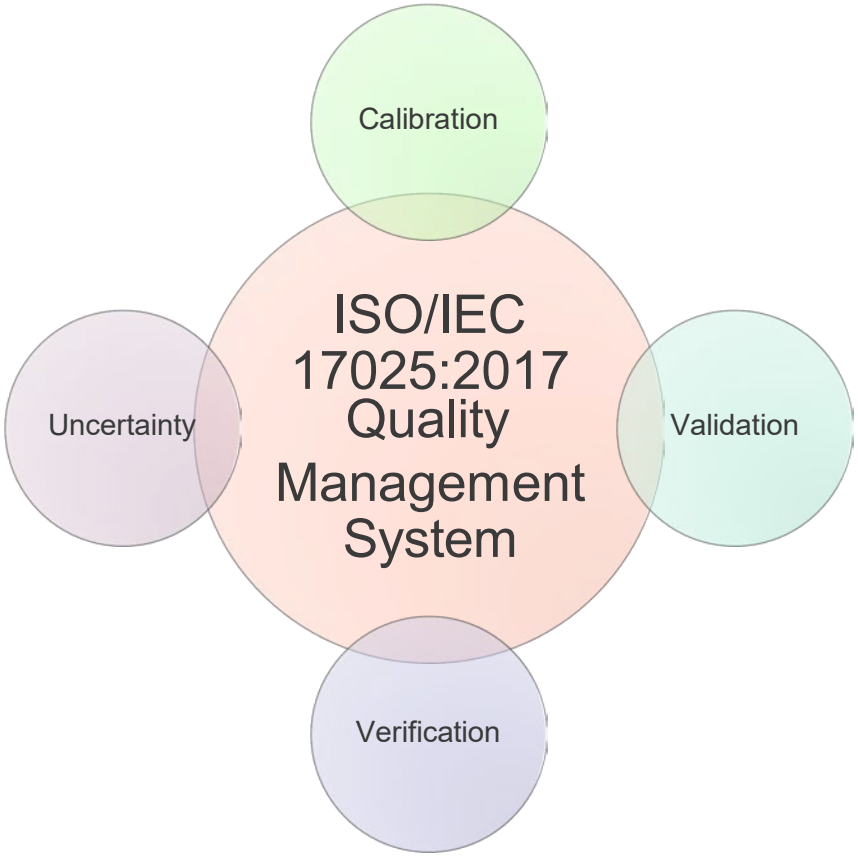
Quality Management System

- The term 'Quality Management System' (QMS) covers the quality, technical, and administrative system that governs the operations of the laboratory
- Quality: How well you do something
- Technical: How you do something (in the laboratory area as well as in the support services area)
- Administrative: How it all comes together

ISO/IEC 17025:2017: "The Laboratory shall establish, document, implement, and maintain a QMS."

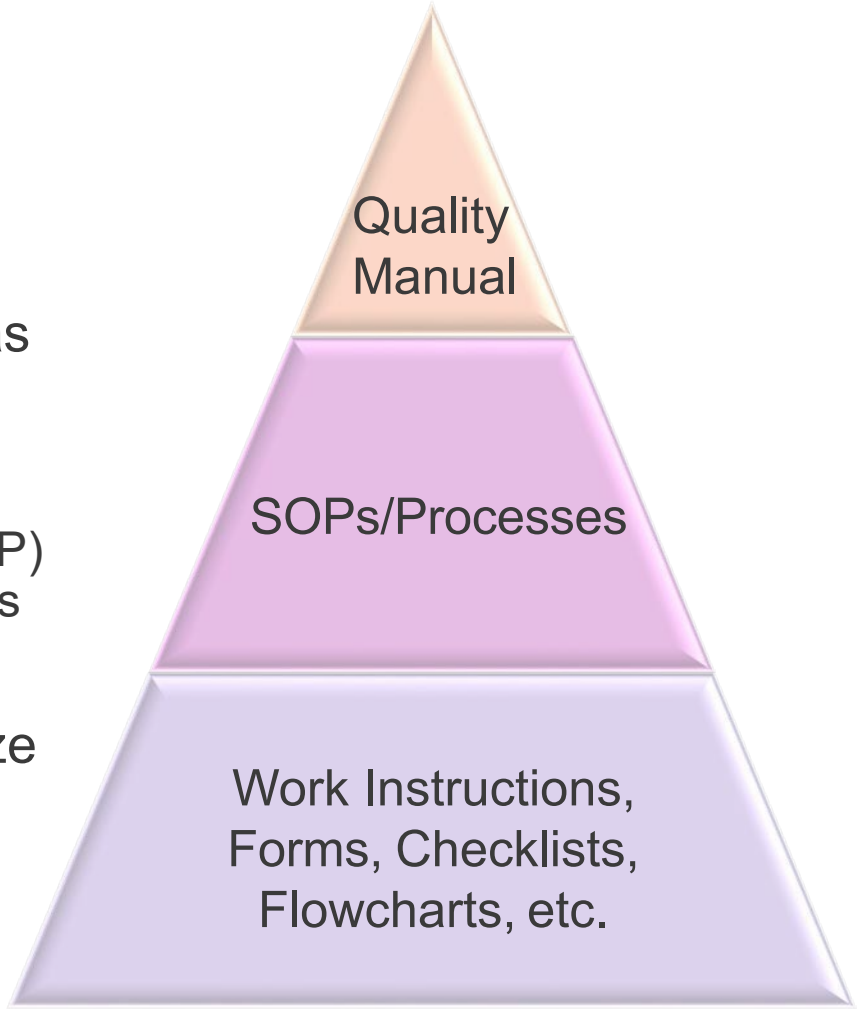
Quality Management System

- The laboratory shall document its policies, systems, procedures and instructions to the extent necessary to assure quality test results
- The QMS shall be communicated to, understood by, and implemented by ~~the~~ appropriate staff
  - Training on ISO/IEC 17025:2017
  - Review policies & objectives



Quality Management System

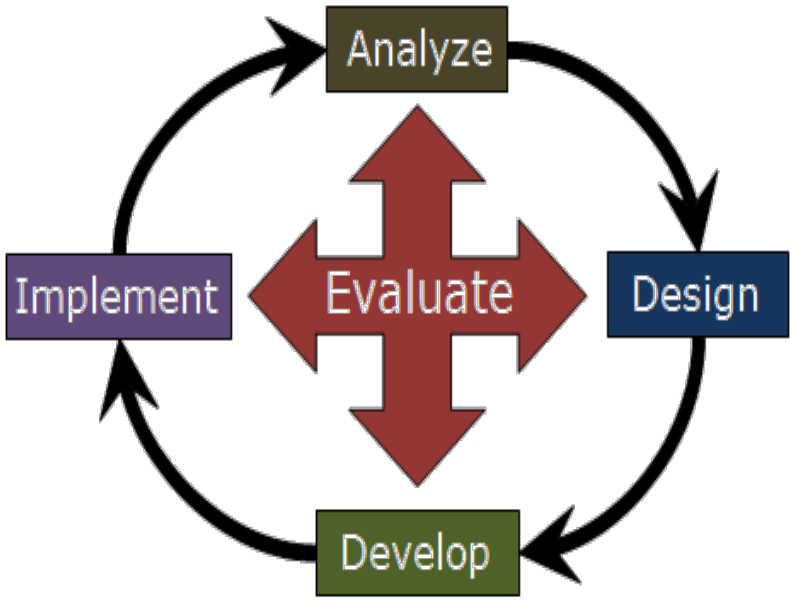
- QMS policies and procedures must be applied comprehensively, appropriately, and consistently.
- A QMS assures that all testing is performed with the utmost quality as described in
  - Quality Manual (or equivalent)
  - Standard operating procedure (SOP) manuals, or documented processes
- Staff use these procedures and management processes to minimize errors before they occur (error prevention)



Objectives of the QMS

- Establish procedures, which ensure that data generated ~~in~~ by the laboratory are within acceptable limits of accuracy and precision
- Ensure that Quality Control (QC) measures are performed
- Ensure accountability of data through sample/specimen and data management procedures
- Perform complete and accurate documentation
- Maintain confidentiality and practice the highest ethical standards.
- Evaluate the quality of data
- Sustain data integrity through technical data reviews, internal audits, and SOPs that cover all aspects of the testing, such as chromatographic manipulations or calculations, documentation of training and competency, and adherence to the error correction protocol

Quality Management System Activities



- Examples include
  - Client satisfaction surveys
  - Internal Audits
  - Management Reviews
  - Corrective Actions & Risk Assessment
  - Identifying and addressing Risks & Opportunities
  - Determining & implementing quality policies and objectives
  - Proficiency Testing

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Quality Management System (QMS)

The QMS documents the Laboratory's policies regarding these topics:

- Chain of Custody
- Method Validation/Verification
- Document Retention
- Manual Integration/Processing Chromatography Data
- Management of Risks and Opportunities
- Impartiality
- Consistent Laboratory Operations
- Fulfilling Purposes of this Document

Familiarizing Staff with the QMS

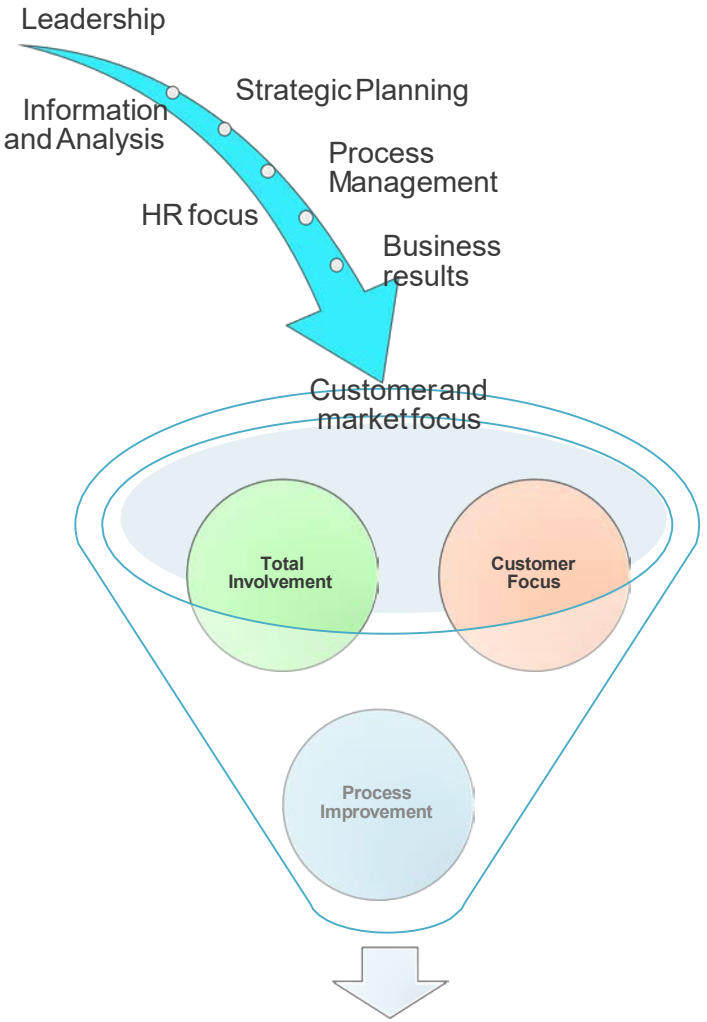
It is a requirement that all staff familiarize themselves with quality documentation and implement the policies & procedures in their work.

Example of a Quality Policy:

- The Laboratory holds firmly that the validity of testing decisions made by data users are determined by the reliability of laboratory data.
- The validity and reliability of the information generated is maximized by adherence to documented QC procedures and QMS protocols that are based upon principles of
  - Data quality indicators.
  - Good professional practice and good laboratory practice (GLP).
- The purpose of management is to provide the highest quality product to its customers.
- Management is committed to these practices, and the quality of testing provided to all customers, and to continual improvement.

Contributions to a Quality Culture

- A quality culture can only be accomplished when all staff are involved in the following:
  - Focusing on the customer
  - Leading by example
  - Continually improving
  - Using information and analysis when making decisions (Project Planning)
  - Strategically planning for the future
  - Knowing that cost effective quality measures can improve laboratory performance and decrease costs



The Organization

- Must be a legal entity in order to be held responsible for actions of the laboratory
- Must meet requirements of the ISO/IEC standard, satisfy the needs of the customer, and regulatory agencies
- Every location and all testing areas within the organization must adhere to a QMS for in-scope methods.
  - Many laboratories have one overarching QMS that governs all sections and locations.
  - Some have separate yet aligned QMS.
  - Others have whole sections that do not fall under a QMS.

Staff Must be Committed to Achieving and Maintaining Quality

- All staff are accountable to the QMS.
- All staff should have knowledge of quality concepts.
  - All work occurs in a system of interconnected processes
  - Variation exists in all processes, but can be controlled with the correct checks and balances
- All staff should practice ethical behavior.
  - All staff must be committed to integrity of data and confidentiality
- Skilled Staff Performance
  - Staff should have the proper skills, education, competencies, training, experience and certification/license (if required) for position
  - Staff should use Critical Thinking Skills
- Continue with Training
  - Staff continue to seek professional development and training opportunities

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Staff Responsibilities

- All staff must be committed and competent to safe work practices.
  - Perform risk assessments
  - Know emergency protocols
  - Participate in required training
  - Competent to perform testing
- Know that
  - What you do is relevant and important!
  - You contribute to the overall effectiveness of the QMS

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Staff Responsibilities

- Conflict of interest: Staff should be free from undue commercial, financial, or other undue pressures.
- Staff should authorized to perform testing and there should be record of that authorization.
- Identify management with responsibility for the laboratory.

Staff Responsibilities

- Staff should be impartial and objective.
  - Carry out duties.
  - Conduct laboratory activities without bias
  - Cannot be influenced by internal or external pressures
  - Relationships (e.g. business, family, financial) cannot influence laboratory activities.

- The laboratory is required to identify potential risks to impartiality and demonstrate that the risk has been eliminated or minimized.

Staff Responsibilities

- Management & technical personnel must have the appropriate decision making authority and resources to:
  - Carry out duties.
  - Identify when there are departures from the QMS and test procedures.
  - Initiate actions to prevent or correct these departures.
- There must be adequate supervision by those familiar with:
  - Methods & procedures.
  - Purpose of each test.
  - Assessment of test results.

Examples of Staff Responsibilities

- Use Proper Measurement Tools
  - All staff are committed to using appropriate quality control measures and fit for purpose testing methods.
- Protect customers' confidential information. For example:
  - Use a "Declaration of Confidentiality & Ethics" statement and/or form which staff must sign.
  - HIPAA training (Health Information Portability & Accountability Act), if applicable
  - Follow correct procedures for electronic storage & transmission of results.

Staff Responsibilities

- Follow policies and procedures for competence, impartiality, judgement, or operational integrity.
  - Take Ethics Training.
  - Take Data Integrity Training.
  - Perform Documentation of Competencies.
  - Annual Document Demonstration of Capabilities
- There should be an organization chart or other description of the interrelationship of staff and supervisory personnel.

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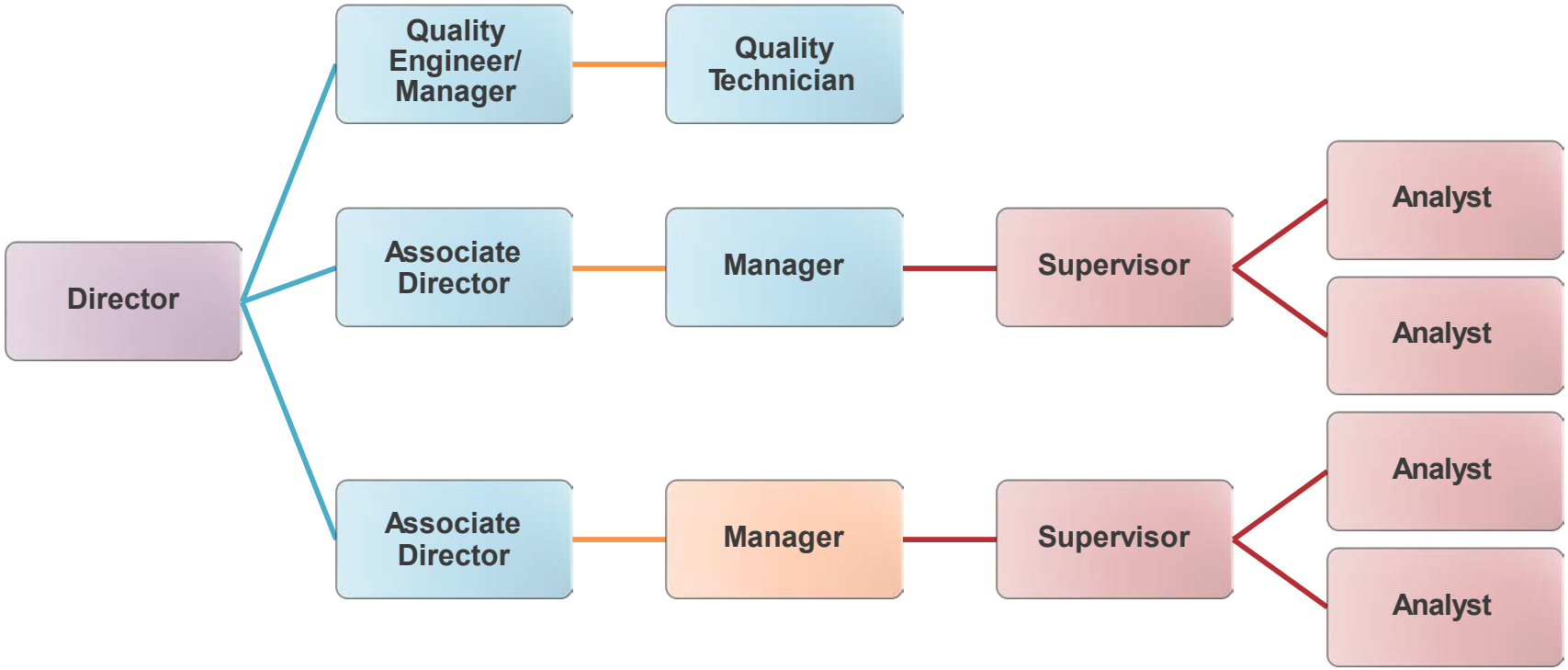
Organization Chart - where are you?



Management Responsibilities

- Provide overall management of personnel, facilities and equipment, ensuring they are adequate to meet client, agency, regulatory and certification / accreditation requirements and needs are met
- Monitoring standards of performance in QMS/QC and compliance to ISO/IEC 17025:2017
- Periodically review QMS reports and provide feedback to sections as appropriate
- Monitor the validity of the analyses performed and data generated in the laboratory to assure reliable data
- Technical Managers must be named and have deputies or designated representatives.

Management Responsibilities

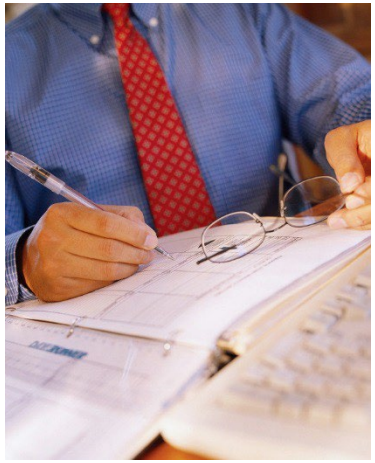
- Top management must ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.
  - Are changes in the QMS carefully planned?
- Perform an annual documented management review of the QMS.
  - SOPs and other documents must align with the policies set forth in the QMS
- Review training requirements to ensure that staff understand the importance of the QMS and adhere to ethical practices and data integrity.
  - Ensure employees meet the qualifications defined in the job description. Authorize employees to perform quality management functions.
- Ensure audits are carried out (internal, external, and proficiency).

Management Responsibilities

- Monitoring risks and opportunities, showing documentation of risk elimination or minimization.
- Providing access to necessary resources to perform job duties
- Validate laboratory information management system (LIMS)

Quality Manager Responsibilities

- Quality Managers have defined responsibility and authority to ensure that the QMS is followed at all times.
- Have direct access to the highest level of management at which decisions are made on laboratory policy and use of resources
- Responsible for monitoring and verifying QMS activities for compliance with ISO/IEC 17025:2017 (e.g., review QMS annually)
- Report QMS activities to top management
- Review assessments
- Coordinate accreditations
- Coordinate training with Human Resources (HR) & Safety Directors
- Maintain QMS documents

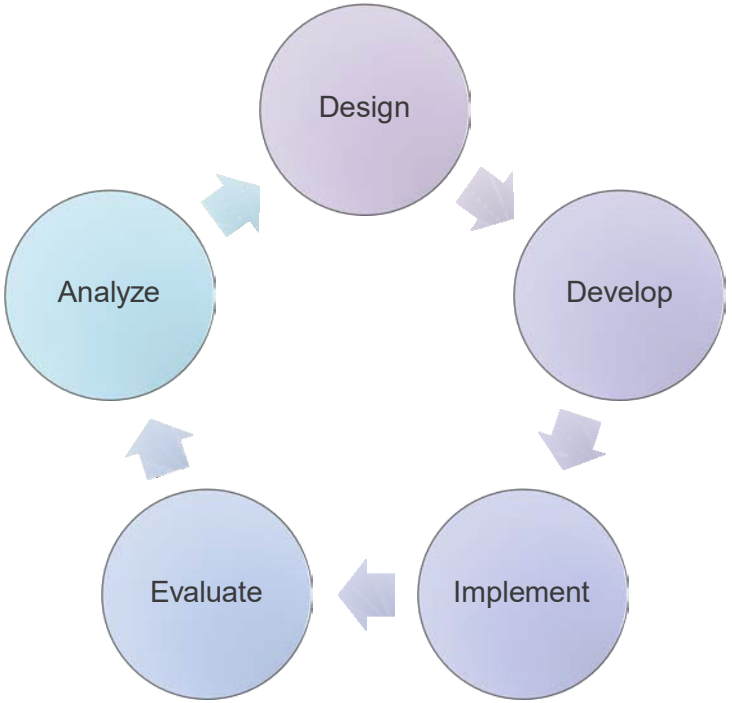


Communication

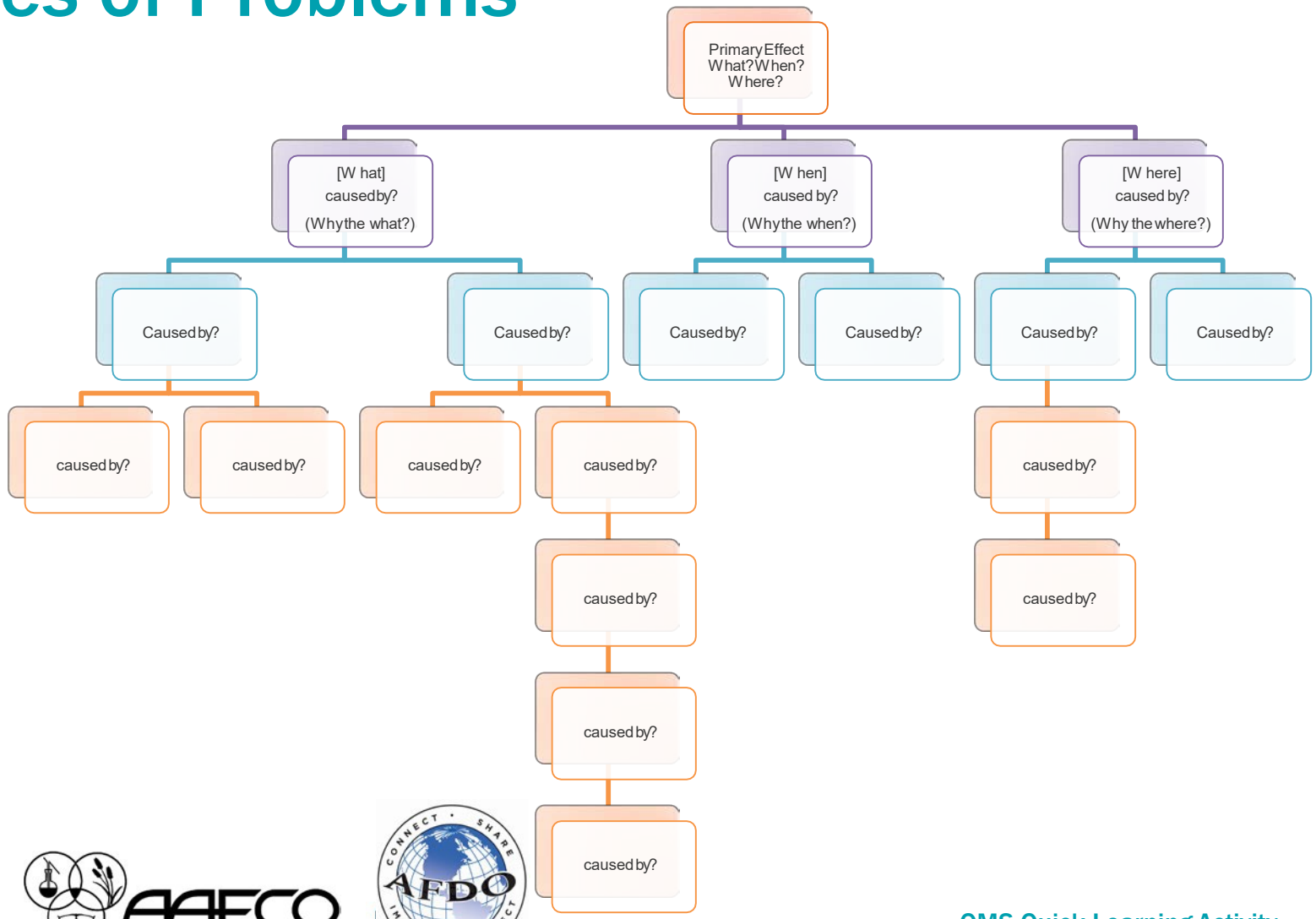
- There must be appropriate communication about the effectiveness of QMS.
  - Staff Training
  - Meetings
    - Administrative
    - Sections/Areas
    - All staff
    - Strategic Planning
  - Project meetings with outside partners and customers
  - Reviews/Audits
    - Internal Audits
    - Management Reviews

Staff Must Know How to Use Quality Tools

- Know how to establish an audit trail to track:
  - where errors have occurred
  - make modifications which address the cause(s) of the problem
- Look at the process—identify the primary event
- Ask questions
  - What is the problem?
    - We don't want this to happen again
  - When did it happen?
  - Where did it happen?



Five Whys — Brainstorm about Root Causes of Problems



Challenges

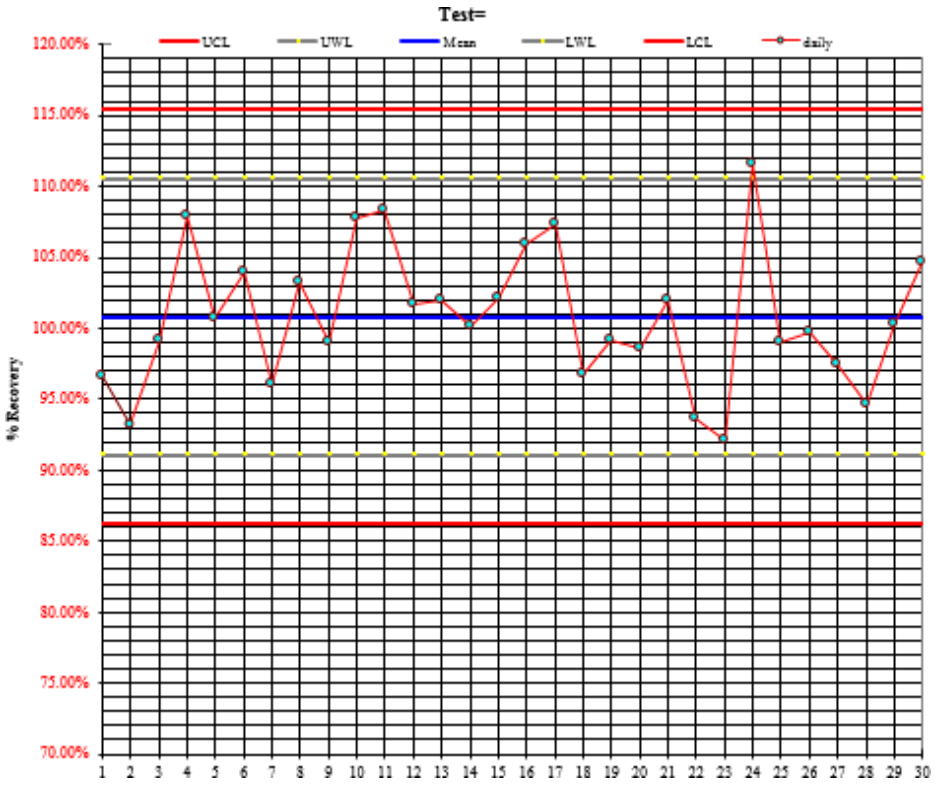
- Invalid cause(s) (e.g., excuses); dig deeper to find out the 'why' of the following:
  - Human Error
  - Mistake
  - Distraction
- Unacceptable Corrective Actions
  - Reminded employees
  - Retraining (may use if process has changed or SOPs are updated or training was inadequate)
  - Instructed to pay more attention

Instead:

- Improve processes and/or procedures
- Utilize engineering controls to minimize human error, mistakes, distractions, etc.
- Use checklists as reminders of tasks
- Communicate new processes with training and ensure it is conducted and documented prior to employee performing work
- Evaluate new processes to ensure success

What is Quality Control (QC)?

- A set of procedures laboratories follow that compares performance against specific requirements and defined standards (e.g., positive, negative, duplicates, spikes, blanks).
- QC must be continuously monitored to ensure reliability and to study how a process changes over time.
- QC is designed to show that nothing has gone wrong in the testing process (error detection).
- QC is designed to monitor and document, track and trend method performance.



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Checklists/Check Sheets are Used to:

Collect and analyze data using a structured form

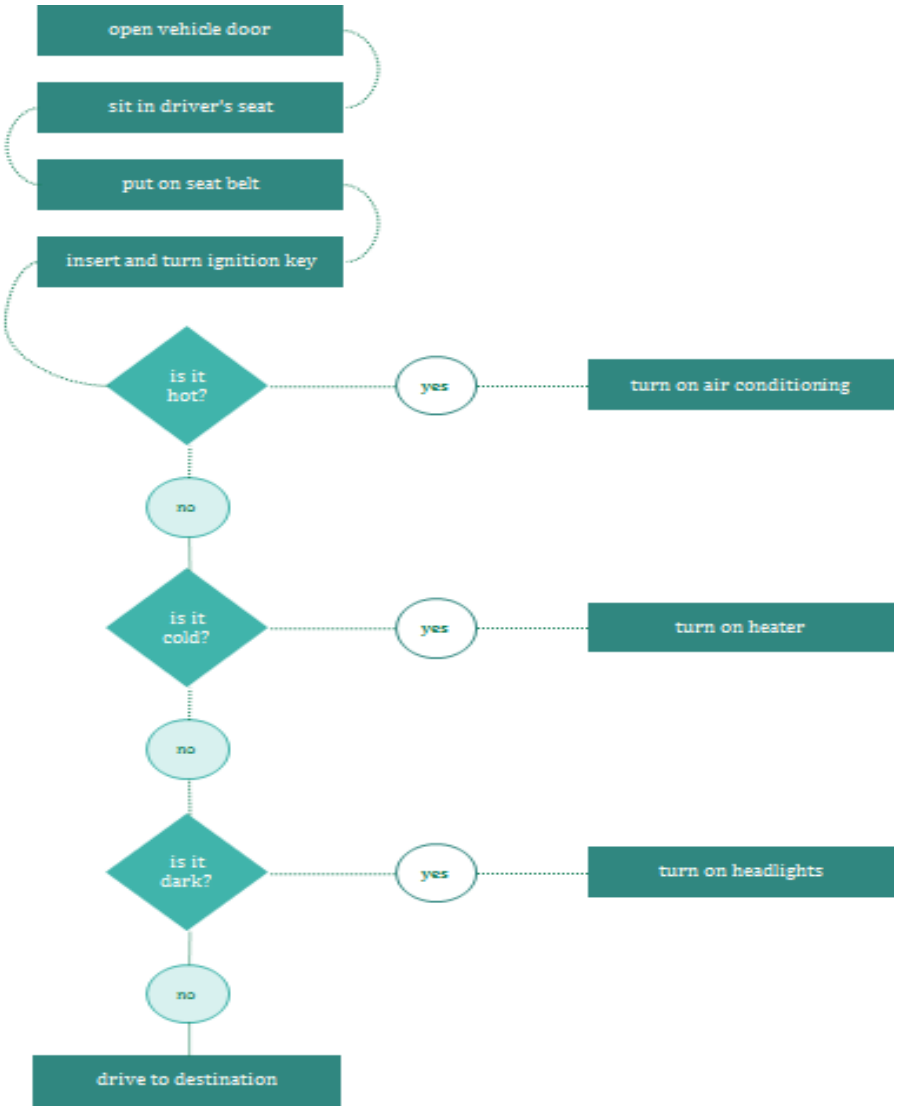
Example Maintenance Checklist:

Serial No 2350287 Maintenance Month/Year _____

Daily Maintenance	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
Check History File After Every Run. Print as needed.																															
Unload plates from previous run. Check/put away reagents. Refill the Reagent Rack.																															
Empty/Clean the Waste Tray																															
Check Enhancement solution; replace as necessary.																															
Turn unit off. Order not important.																															
Check, fill if needed, rinse and wash solutions. Empty the waste bottle.																															
Turn unit on (instrument 1st). Confirm Multi-Calc/Workstation open without error.																															
Washer Test																															
Check Printer Paper.																															
Initials																															

Flow charts

Visualize a process; Can contain decision points along the way



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BEFORE WE CONTINUE, YOU MUST ALSO KNOW THIS…

For any result, do you have documentation to demonstrate the following?

Training Documentation and Authorization

- Was the work performed by a qualified person who was trained in the relevant technical operations and had access to all necessary information?
- Were they authorized to perform that task?
  - Per method and/or SOP with Documentation of Capability/Competence

- Have they had the proper:
  - Safety training?
  - Ethics & Data Integrity training?

Methods & Equipment

- The method must be approved, validated or verified, authorized, and appropriate to the sample and the requirements of the customer.
- The equipment must be properly maintained and calibrated when data is generated.
- All QC checks must be carried out and the results within specifications of the method or SOP.
- All staff must be adequately trained to use, calibrate, and maintain equipment.

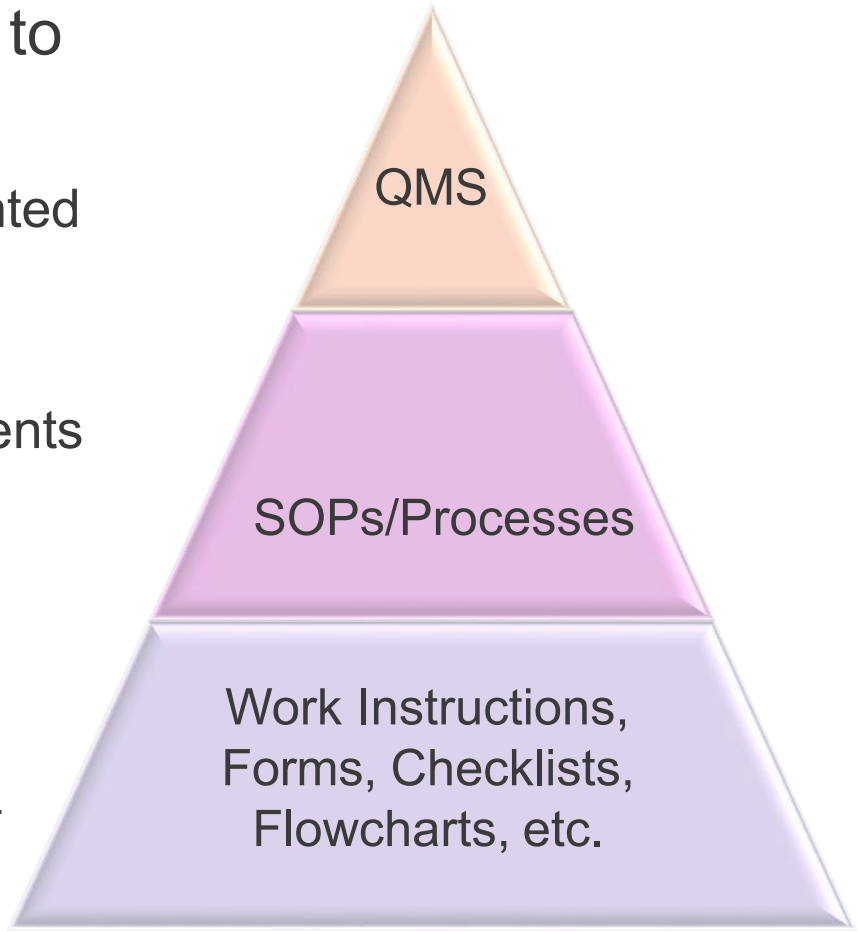
SUMMARY

Responsibilities

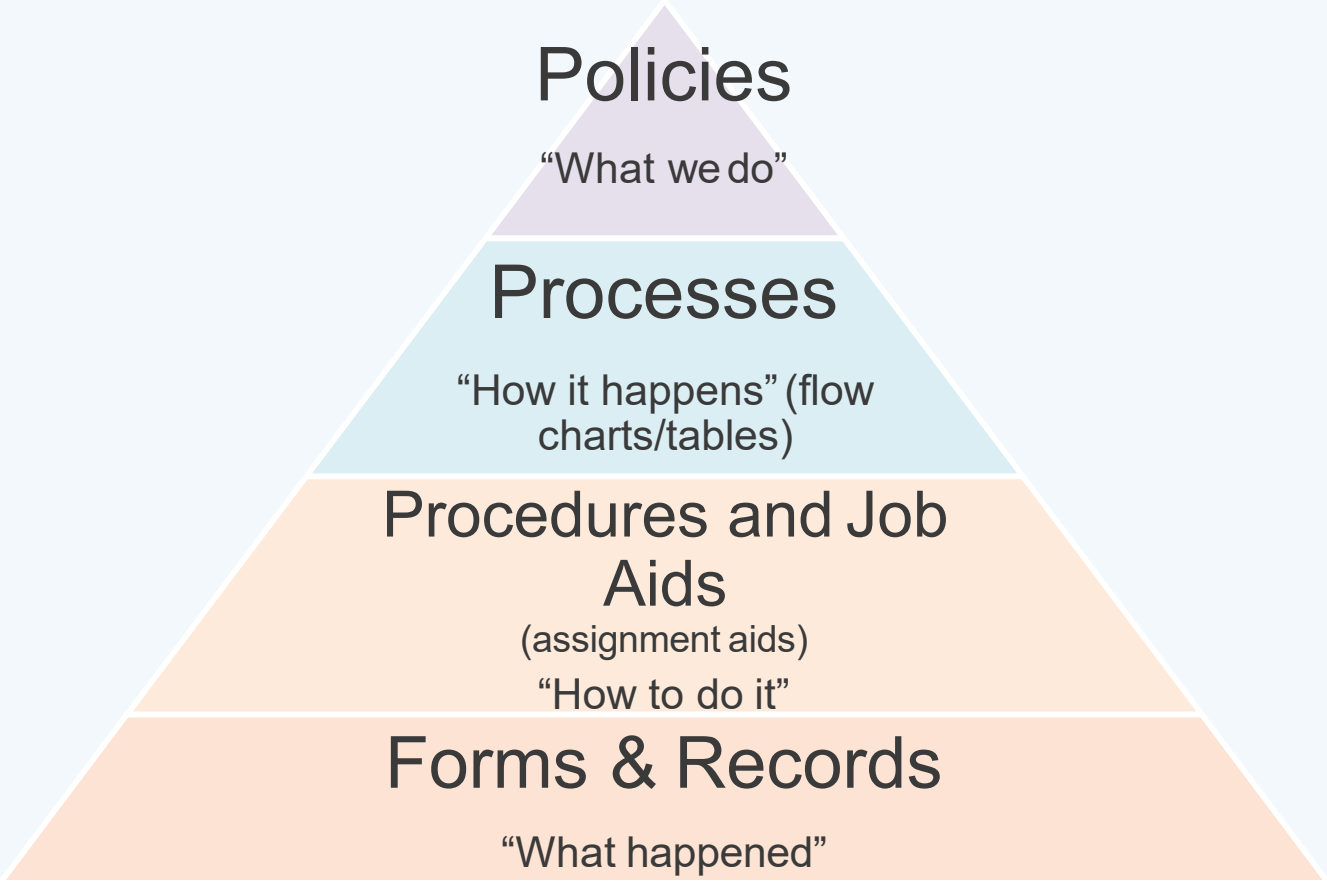
- Quality responsibilities must be clearly assigned.
- Staff training must be documented.
- Staff should know and use quality tools.
  - Quality Control in testing
  - How to perform Corrective Actions
  - Use Critical Thinking Skills

Implement Document Control

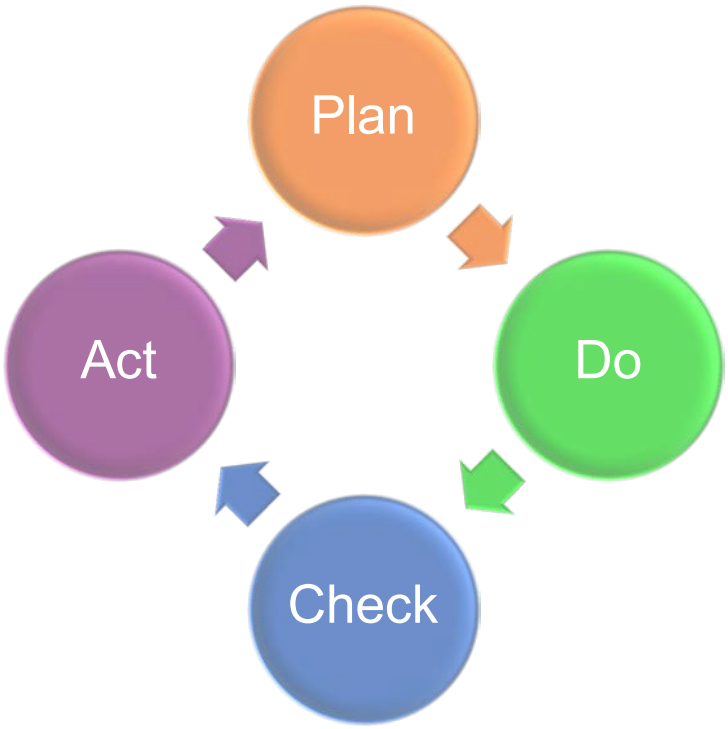
- Procedures must be in place to ensure quality is maintained.
  - Are these procedures documented and controlled?
  - Do you have (and follow) a procedure to ensure all documents are kept up to date?
  - Staff must know and follow all document control policies and procedures.
    - This must be documented, as well.



Know the Difference between a Policy, Process, Procedure and Records



Management must ensure that



- The QMS is reviewed and monitored and is implemented and followed by all staff.
- Staff are trained to identify departures from the management system, and take action to manage them.
- Staff are trained on and follow a corrective action procedure.
- There is a mechanism to identify possible problems (risks) and ways to take action to prevent them (risk assessment).
- Opportunities to improve the effectiveness of the quality system are identified and implemented.

Ensure Data Integrity

- What precautions do professionals take to secure the integrity of data generated in the laboratory?
  - Ethics trainings are provided, and steps are taken to ensure no conflicts of interest.
  - Instruments must be calibrated.
  - Calibrations must be checked.
  - QC samples must be used.
  - Use Proficiency Testing as an external check.
  - Perform InternalAudits as scheduled.

How Does the Laboratory Ensure Confidentiality of Customer Information?

- Unless otherwise agreed with the customer, or required by law, customer information is safeguarded against disclosure.
- The laboratory informs customers in advance, when confidential information must be publicly disclosed (for example, when legally required).

Ensure the Integrity of the QMS

- Top management must ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.
  - Are changes in the QMS carefully planned?
- Perform an annual management review of the QMS.
- Review training requirements to ensure that staff understand the importance of the QMS and adhere to ethical practices and data integrity.
  - Do all understand that ‘management system integrity' means that there is a lack of contradiction between documents?

References

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