

Quality



Quality Management



Quality Management System



Quality Management System

N. Jayaram Anand Diagnostic Laboratory – Bangalore jayaram@anandlab.com



Quality Management System Definition

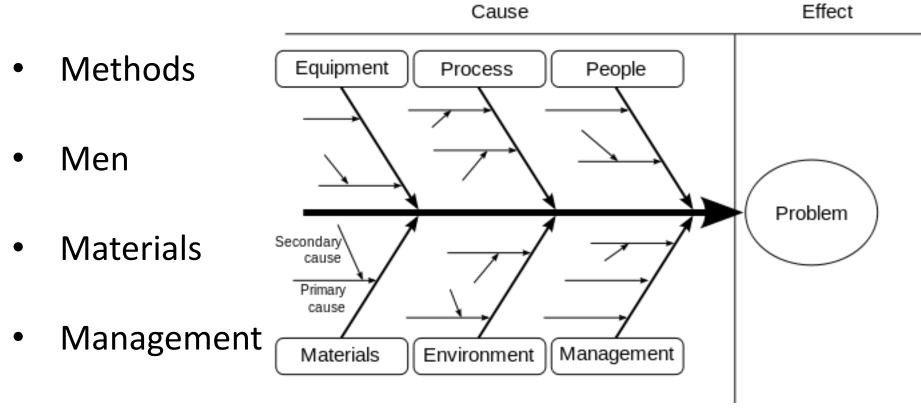
Coordinated activities to direct and control an organization with regard to quality (ISO,CLSI).

All aspects of the laboratory operation need to be addressed to assure quality; this constitutes a quality management system.



Quality Management System

• Machines



Environment

Ishikawa Fish-bone Diagram



Quality Management System

WHY?



Quality Management System WHY?

- Major clinical decisions are based on or confirmed by the laboratory test result
- Laboratory errors can have telling effect
- Accurate and timely report is the bottom line





How do we achieve excellent performance in the laboratory?



CLSI Quality System Essentials (QSEs), HS1-A2



Twelve Quality System Essentials

set of coordinated activities that function as building blocks for quality management





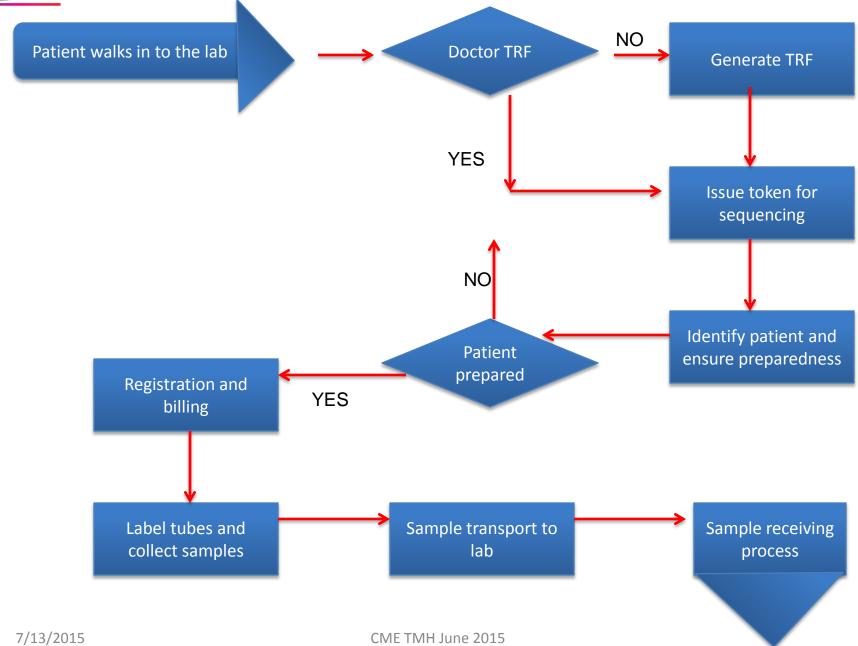
Process:



Process:

- Set of inter-related activities that convert inputs to outputs (ISO 9000:2005)
- Processes encompass all activities of the lab
- "The QMS shall provide for integration of all processes required to fulfill its quality policy and objectives and meet the needs and requirements of the users" (ISO 15189:2012)

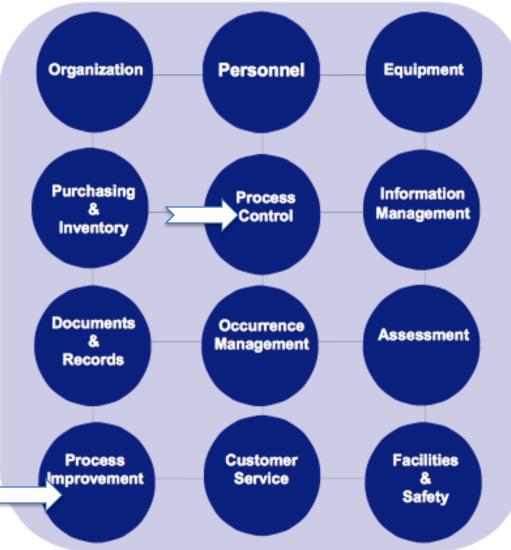
Pre-examination process flow chart





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Organization & Management responsibility

- Legal responsibility
- Commitment to ethical practice
- <u>Quality policy</u> and objectives
- Job responsibilities and authorities
- Organization hierarchy
- Appointing key personnel and deputies
- Effective communication processes

Memo from CEO to Manager:

Today at 11 o'clock there will be a total eclipse of the sun. This is when the sun disappears behind the moon for 2 minutes. As this is something that cannot be seen every day, time will be allowed for employees to view the eclipse in the parking lot. Staff should meet in the lot at 10 minutes to 11, when I will deliver a short speech introducing the eclipse, and giving some background information. Safety goggles will be available at a small cost

Memo from Manager to Department Head:

Today at 10 to 11, all staff should meet in the car park. This will be followed by a total eclipse of the sun, which will appear for two minutes. For a moderate cost, this will be made safe with goggles. The CEO will deliver a short speech beforehand to give us all some information. This is not something that can be seen every day



Memo from Department Head to Floor Manager: The CEO will today deliver a short speech to make the sun disappear for two minutes in the form of an eclipse. This is something that cannot be seen every day, so staff will meet in the park at 10 or 11. This will be safe, if you pay a moderate cost.



Memo from Floor Manager to Supervisor:

Ten or eleven staff are to go to the car park where the CEO will eclipse the sun for two minutes. This doesn't happen every day. It will be safe, and as usual it will cost you



Memo from Supervisor to Staff:

Some staff will go to the car park today to see the CEO disappear. It is a pity this doesn't happen every day



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Personnel

- Define minimum qualifications
- Define specific job responsibilities
- Training plan covering various aspects
- Continuing education & professional development
- Competence evaluation and records



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Why documents?



Why documents?

• What are records?



Why documents?

• What are records?

Why records?



QMS Quality Planning Operation Document Control Record Retention Resource Management Education and Training Regulations Management Responsibility Personnel Workmanship Certification Quality Policy Quality acility Equipment Management Business Planning Management Review Resource Management Management Responsibility Customer Customer QMS Satisfaction Requirement Measurement, Product Analysis & Realization Improvement Measurement, Analysis & Improvement Customer Satisfaction Management Product Realization Internal Audit Process/ Product Monitor

- Quality Improvement Team

- Customer Requirement Management
- · Advanced Product Quality Planning
- Validation of processes for production and service provision
- Control Plan
- Travel Card
- Process Control
 - * SPC/OCAP
- Operation Procedure & Work Instruction
- Engineering Change Notification
- Identification & Traceability