



Quality

Quality **M**anagement



Quality Management System

Quality Management System

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

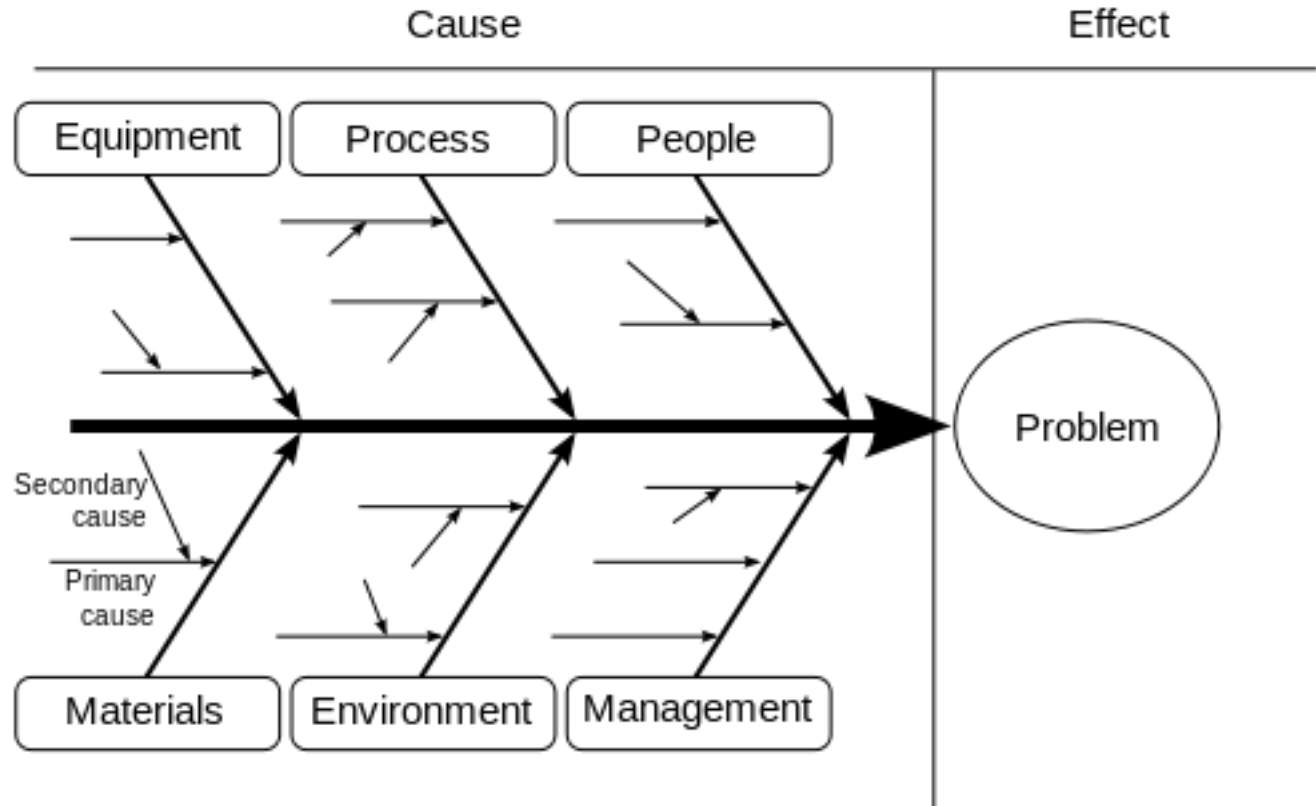
Quality Management System Definition

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
- Methods
- Men
- Materials
- Management
- 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



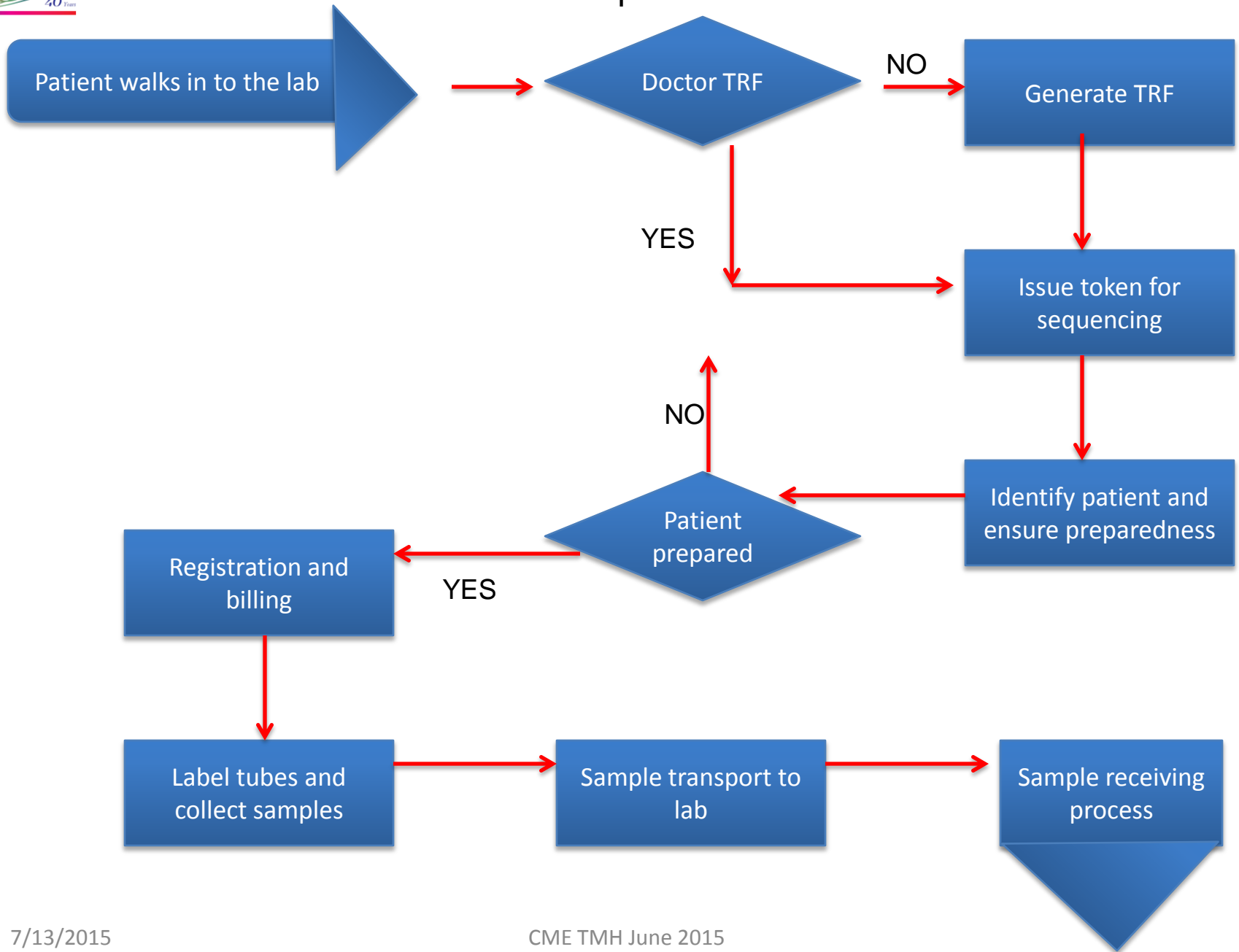


Process:

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



Twelve Quality System Essentials

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Organization & Management responsibility

- Legal responsibility
- Commitment to ethical practice
- Quality policy 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

Twelve Quality System Essentials

set of
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management



- What are documents?

- What are documents?

Why documents?

- What are documents?

Why documents?

- What are records?

- What are documents?

Why documents?

- What are records?

Why records?

