

Everything You Need to Know About
How a Quality Management System
Helps Your Laboratory Achieve a New
Paradigm in Quality at a Lower Cost
....OR

Lucia Berte
www.LaboratoriesMadeBetter.com

Looking at Old Things in a New Way

Old things...

New way...

The Quality Hierarchy

Modified from:
Clairmont CA, Tsiakalos JJ, West JE. The ASQ ISO 9000:2000 Handbook. Milwaukee, WI: American Society for Quality; 2002.

WHY Quality Management?

- It prevents medical errors that harm patients !!
- It saves money
- It's the laboratory's best advantage in competitive challenges

EYNTKAH* = Make sense of these!!

* Everything You Need To Know About How

How to Make Sense??

- Sort the common elements of regulatory and accreditation requirements
- Group the like elements
- Arrange elements in the order in which they occur in the laboratory
- Develop policies, processes, and procedures to accomplish the elements

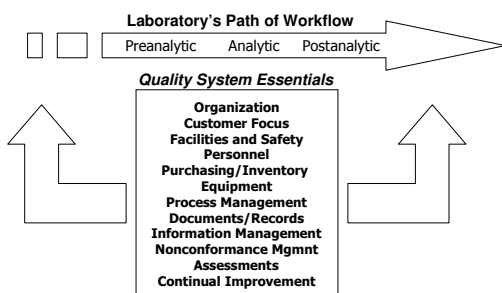
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EYNTKAH:

A systematic approach
to quality!

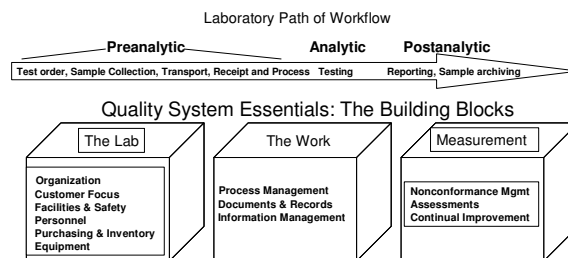
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EYNTKAH: Quality System Model



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A Quality Management System for the Laboratory



Adapted from CLSI guideline HS1-A2, A Quality Management System Model for Health Care, Second Edition, Wayne, PA: CLSI, 2006.

EYNTKAH: QMS Framework

- Management infrastructure built upon quality requirements
- Infrastructure support of work performed
 - Requirements *built into* work processes (*not* as workarounds or add-ons!)

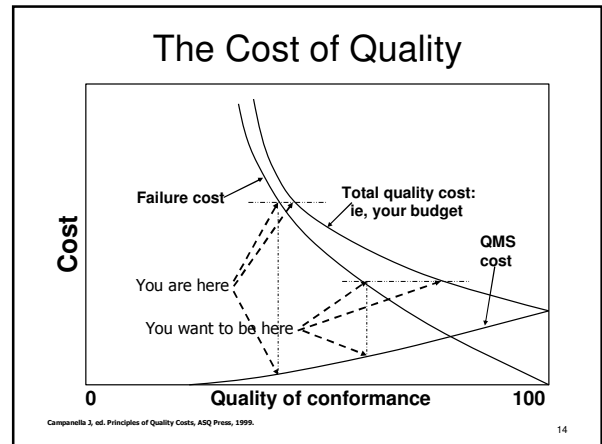
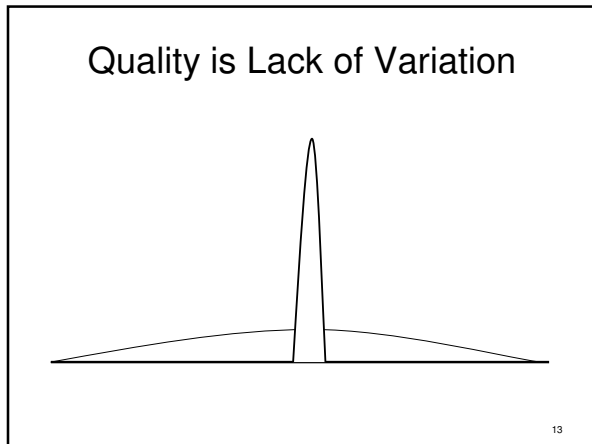
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"For organizations that do not have a formal effort to reduce chronic and sporadic problems, operations managers often spend 30% of their time on troubleshooting;

... for the supervisors reporting to these managers, the time consumed frequently exceeds 60%."

Joseph Juran

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It's cheaper to do the job right the first time than to recover from an error.

Philip Crosby

(Ask the labs that made the news...)

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- ### EYNTKAH:
- #### Four Types of Quality Costs
- Prevention – quality management activities
 - Appraisal – accreditation, QC, PT
 - Failure
 - Internal – rework of anything
 - External – patient harm, lawsuits
-
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EYNTKAH:

Can you identify prevention and appraisal costs on your operating budget?

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EYNTKAH:

Can you identify internal and external failure costs on your operating budget?

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**“Costs do not exist to be calculated.
Costs exist to be reduced.”**

Taiichi Ohno

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EYNTKAH:
QMS Ways to Eliminate Failure Cost

- Streamline processes
 - Process analysis
 - Six Sigma
 - Lean
- Apply prevention
 - Design FMEA
 - Process validation
- Reduce turnover
 - Training programs
 - Effective training
 - Competence assessment
- Effective documents
 - Process flowcharts
 - Procedures
 - Job aids

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EYNTKAH:
Quality = Process Control

- Work processes are designed to meet requirements
 - Regulatory and accreditation
 - Customer
- Work processes are
 - Controlled
 - Measured and monitored
 - Improved



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EYNTKAH:
Actions by your laboratory

- Build processes and procedures such that requirements are met when doing the job
- Train to the processes and procedures to ensure competence
- Measure and monitor process performance
- Take action on opportunities for improvement

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What is the Value of QMS?

- Increases ability to achieve your laboratory's / organization's mission
- Provides a systematized customizable approach to laboratory processes
- **Higher quality with less failure cost**
- **Built-in patient safety**

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**“Quality management is needed
because nothing is simple anymore...
if indeed it ever was.”**

Philip Crosby

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