

Quality.

Yesterday. Today. Tomorrow.

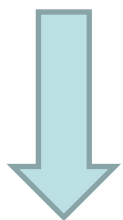
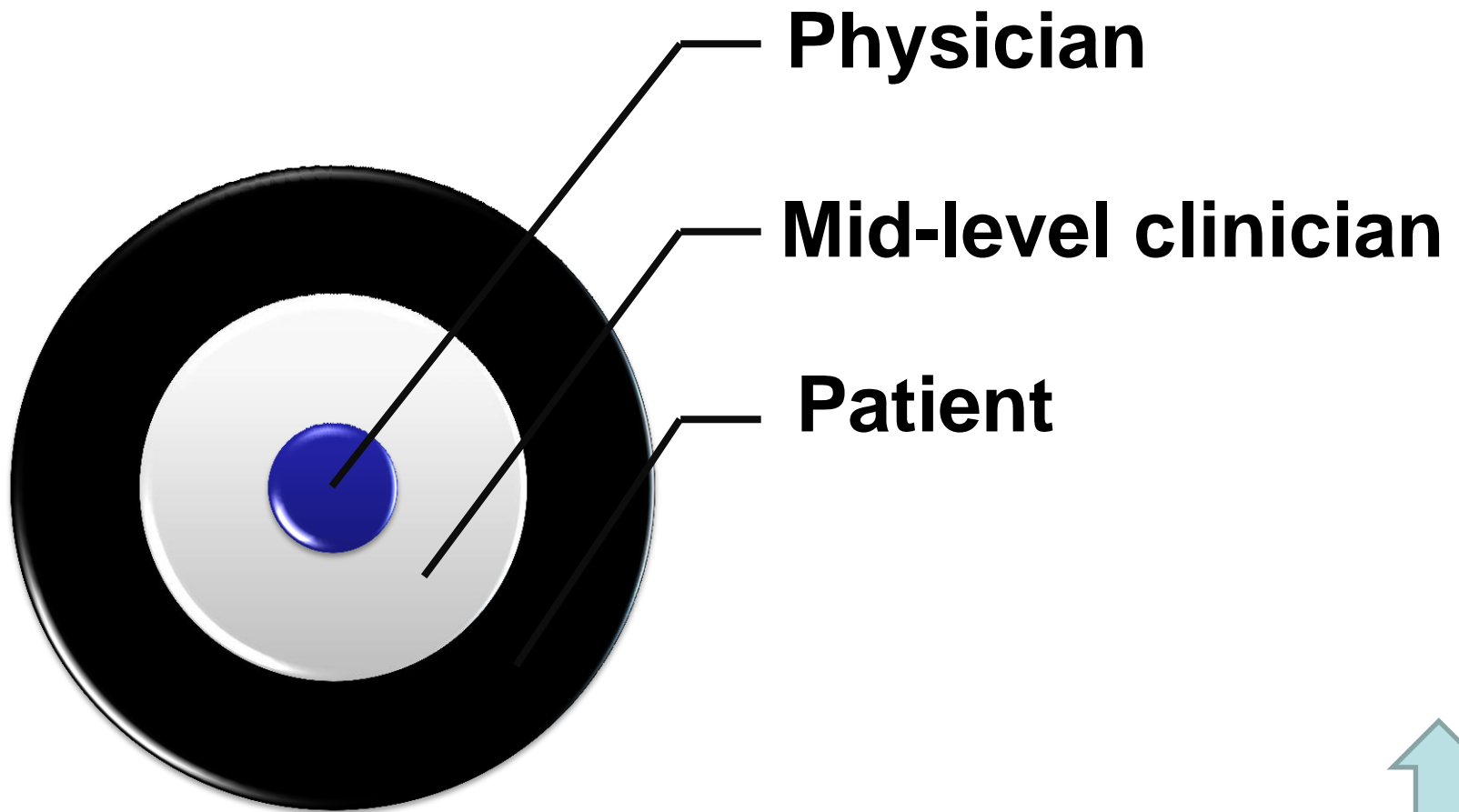
*Where We've Been.
Where We Are.
Where Are We Going?*

Healthcare without the Doctor...

- Key healthcare issues
 - Access to care
 - Quality of care
 - Controlling costs
 - Rapid information access/exchange

Healthcare without the Doctor...

Scott; 2009



Cost



Convenience



Quality Buzzwords

- QC
- QA
- QMS
- Path of Workflow
- Continuum of care
- LEAN
- Six Sigma
- ISO
- TAT



Progression of Quality in the Clinical Laboratory

1940's-1960's	Quality Control (QC)
1970's	CAP Proficiency Testing program introduced
1980's	Quality Assurance (QA) in healthcare advanced by JCAHO
1990's	Quality systems introduced by FDA, AABB, NCCLS (CLSI) and ISO 9000
1999	National Quality Forum created

Progression of Quality in the Clinical Laboratory

2003	CLIA '88 revised to include Quality Management System (QMS) guidelines
2004	Maryland General Hospital Scandal
2006	Un-announced inspections
2006	CAP launches ISO 15189 accreditation program
2010	FDA tightens standards for POCT

To Err is Human

- 1999: Institute of Medicine (IOM) published report
- Medical errors = 8th leading cause of death in the US.
- Estimated 44,000 – 98,000 deaths each year due to preventable medical errors
- Raised the quality standards and expectations of healthcare providers, payors, and patients
- Subsequent follow-up reports by the IOM (2001 and 2003), have continued to make patient safety and the reduction of medical errors a key issue in healthcare.

To Err is Human

- Approximately 7 billion laboratory tests performed each year in the US
- Numerous opportunities for error
 - Specimen labeling
 - Specimen handling
 - Analytical
 - Reporting
- Patient safety initiatives and innovations just beginning to be implemented in laboratory industry
- AACC Patient Safety Group
 - Educational programs
 - Categorizing laboratory errors
 - Rule-based decision making built into LIS'

Other Patient Safety Reports

- IOM. *Crossing the Quality Chasm: A New Health Care System for the 21st Century*. 2001.
- Aspden, Corrigan, Walcott, and Erikson. *Patient Safety. Achieving a new standard for care*. 2004.
- Brennan, Gawande, Thomas, and Studdert. *Accidental deaths, saved lives, and improved quality*. 2005.
- Bell, McNaney, and Jones. *Improving health care through redesign*. 2006.

US Healthcare...

50/50 chance of proper healthcare

Elizabeth A. McGlynn, PhD, et. al.

“The Quality of Health Care Delivered to Adults in the United States”. NEJM, June 2003.

Laboratory Errors

Primary care

1.1 per 1000 visits

27% effect patient care

Nutting et. al. JAMA 275:8, 1996

The Issues

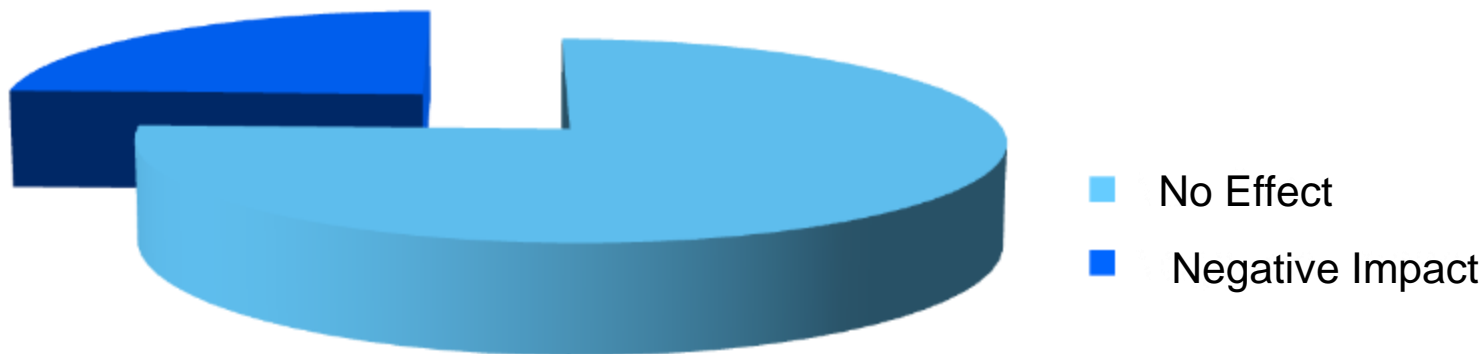
Mis-identification of laboratory specimens:
> 160,000 adverse medical events each year

35% of high-severity transfusion medicine events
and 25 deaths/year due to specimen labeling
errors

Test order errors: 5% - 18% of all test orders

Impact of Errors on Patient Outcomes

24.4% of errors negatively impacted patient care



Inappropriate laboratory test repeats: 17%

Inappropriate laboratory investigations: 6%

JCAHO Patient Safety Goals

- 50 percent of Joint Commission standards are *directly* related to safety
 - medication use
 - infection control
 - surgery and anesthesia
 - Transfusions
 - restraint and seclusion
 - staffing and staff competence
 - fire safety
 - medical equipment
 - emergency management
 - security
- 2001: Additional patient safety standards
- 2003: Behavioral health care and long term care organizations
- 2004: Ambulatory care and home care organizations

Quality Systems Management



CLSI (NCCLS) Guidelines

- A quality management system for healthcare; Approved guideline HS1-Second edition. Wayne, PA: Clinical Laboratory Standards Institute, 2004. First edition: 1999.
- Application of a quality management system for laboratory services; Approved guideline GP-26-Third edition. Wayne, PA: Clinical Laboratory Standards Institute, 2004. First edition: 1999.

JCAHO: Tracer Methodology

- Initiated end of 2004
- Traces a patient stay through-out the hospital
 - Point of entry through post-discharge
- “Focus less on paper, more on patients and patient experience”
- Follows a patient through the “continuum of care”

Maryland General Hospital

- First reported in 2004
- Inaccurate HIV and HCV results
- Initiated a GAO audit of lab inspection process
- Congressional hearings on lab safety
- CAP and its inspection processes came under heavy scrutiny
 - Initiated drastic changes to the inspection process
- JCAHO also criticized
- Reference Pathology Services of Maryland shut down to quality violations representing “immediate jeopardy”

*Preferred Practices for Measuring and Reporting
Patient Safety and Communication in Laboratory
Medicine – 2009*

- Project began in 2006
- Collaboration with the CDC to define laboratory measurement and reporting.
- Defined 6 preferred practices as national voluntary consensus standards to drive quality improvement efforts within the pre and post analytic phases of laboratory testing.

National Quality Forum

Laboratory Leadership

- Leaders of organizations that order tests and leaders of clinical laboratories should work together to ensure that specific expectations regarding communication to and from the laboratory are met.

Patient/Specimen Identification

- Standardized policies, processes, and systems should be implemented to ensure the accurate and legible labeling of laboratory specimens.

Sample Acceptability

- Collection and processing facilities should ensure that acceptable specimens are collected using appropriate techniques.

Test Order Accuracy

- Organizations should implement systems to ensure that all test orders are accurately communicated to laboratory staff in a timely manner.

Verbal Communication

- For verbal or telephonic reporting of critical test results, verify the tests results by having the person who is receiving the information record and read back the complete test result.

Critical Value/Result Reporting

- Communicate critical laboratory values/results to the individuals who require them and appropriately document them in a secure, confidential, accurate, and timely manner.

Leadership

- Encourage electronic communication
- Coordination of efforts to ensure communication of critical values
 - Investigation when the process fails
- Monitor verbal and electronic communication of results

Patient/Specimen Identification

- Verbal, self-identification of patients
- Use of at least 2 patient identifiers
 - Investigation when the process fails
- Specimen collection containers labeled at the time of collection and in the presence of the patient
- Safe labeling practices
- Sample rejection criteria for incomplete or inappropriately labeled specimens

Sample Acceptance

- SOP for specimen collection & processing
- Define maximum number of collection attempts
- SOP to address collection in specific patient populations
 - e.g. fingersticks, heel sticks
- Policies which reduce blood culture contamination
- Quality & appropriateness of the specimen determined before the patient leaves

Sample Acceptance

- Unacceptable specimens NOT TESTED
- Communication when specimens cannot be tested
- Specimen processing and transport consistent with producing quality results
- Track and monitor specimen collection failures

Test Order Accuracy

- Specific SOP's for electronic, verbal, and telephone communication of test orders
- All non-written orders followed up with a written request
- Standard nomenclature
- SOP for add on's which determines if the existing specimen is available and acceptable for testing

- International Standards Organization 15189:2007 is an internationally recognized laboratory accreditation standard.
 - Originally proposed in 1994
 - 1999 competency requirements for calibration labs
 - 15189 published in 2003 and revised in 2007
- ISO 15189 specifies quality management systems and competencies unique to medical laboratories.

- Focus is on the quality management system and all of the elements that interact in all phases of testing.
- Outlines controls required to manage risks that impact lab quality.
- Provides tools to improve lab operations and customer service.

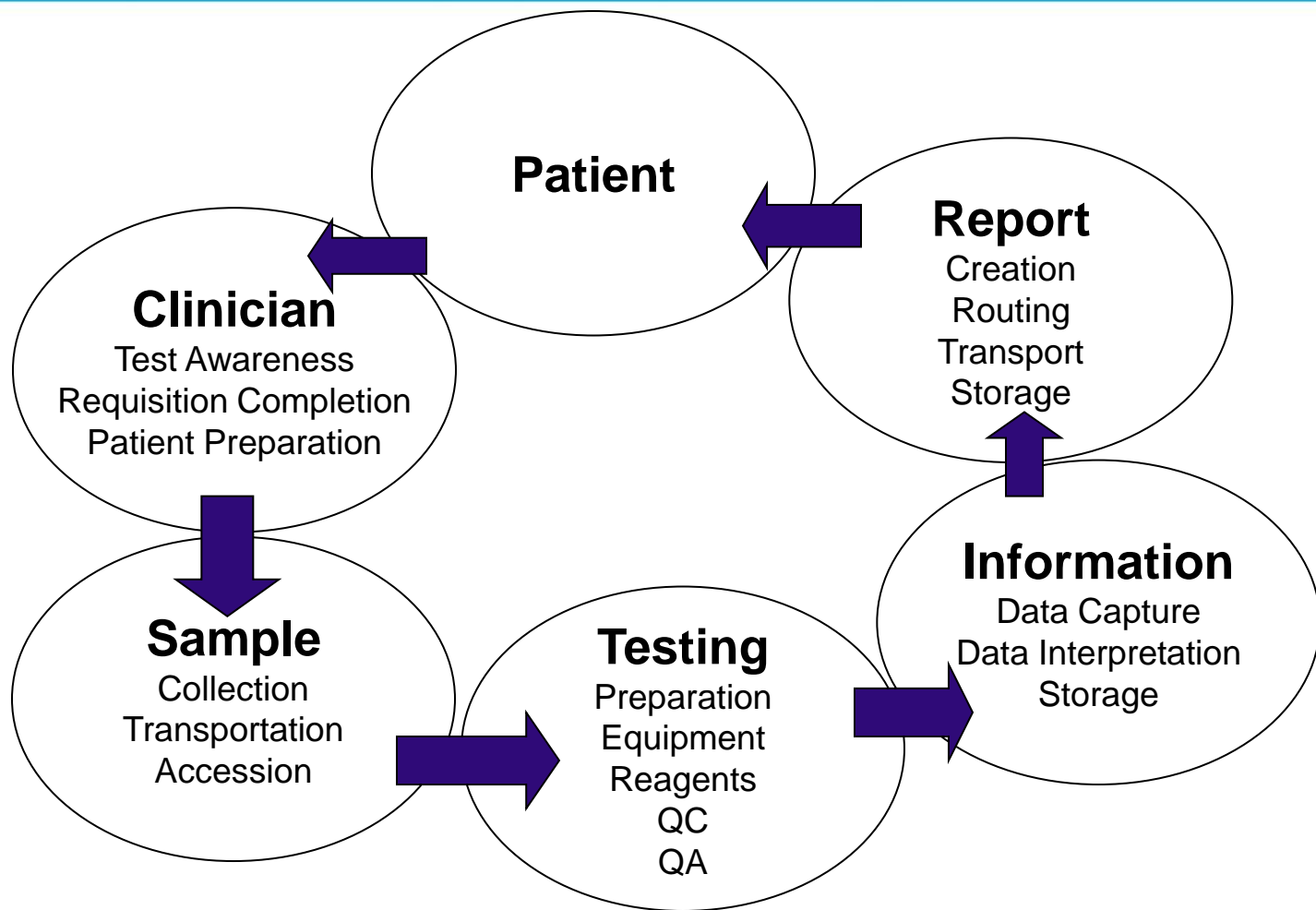
ISO 15189 Philosophy

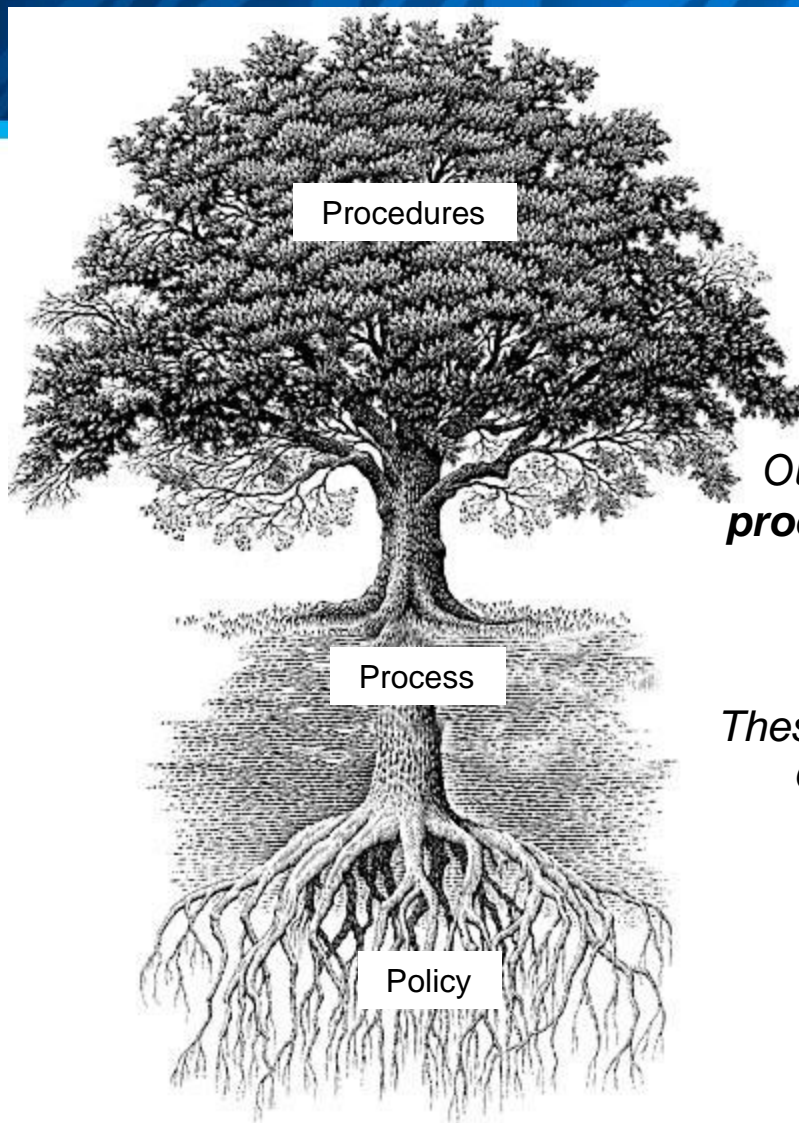
- Continuous quality improvement.
- Issues represent opportunity for improvement.
- Staff at all levels are empowered to identify issues and participate in corrective action.
- Customer satisfaction is key.
- Job satisfaction is important.
- A safe clean lab is needed for quality.

Quality Systems Management



ISO 15189: Patient-Centric





Our goal is to connect **policy** to **procedure** using **processes** which sustain the **Path of Workflow**.

These **actions** are supported by the **Quality System Essentials**

LEAN Principles

- **Value** is defined by the customer.
- Eliminate **Waste**
- Involve and **empower** employees
- **Continuous improvement**

www.oregon.gov/DHS/transformation/images/lean.jpg

The elements of production that do not add value.

Lean focuses on the elimination of waste in a process



Persoon, Zaleski, and Freichs; 2006

Workplace Organization: 5 S

- Sort
- Set in Order
- Shine
- Standardize
- Sustain

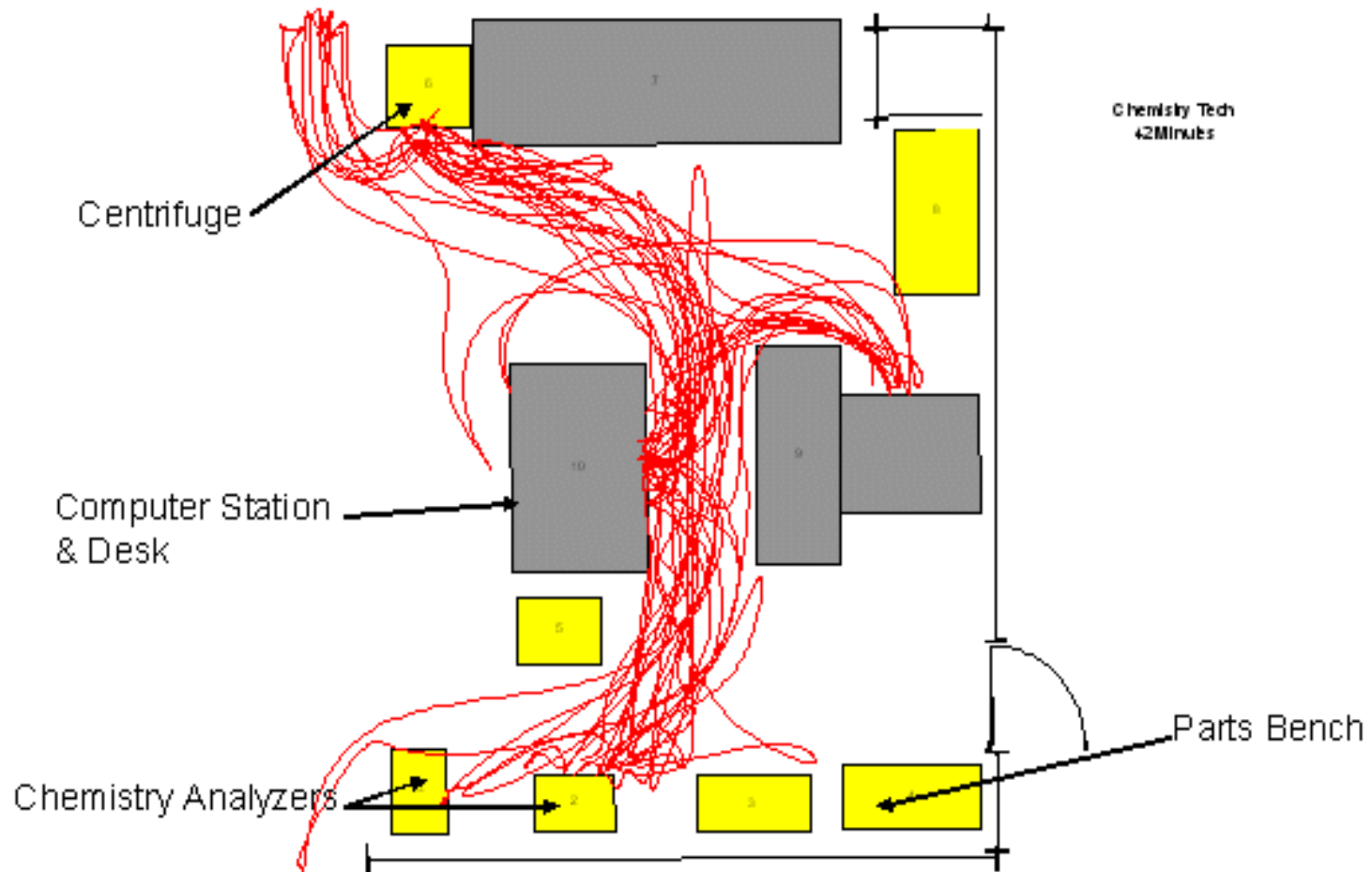


Coons, TechSolve; 2009

Standard Work

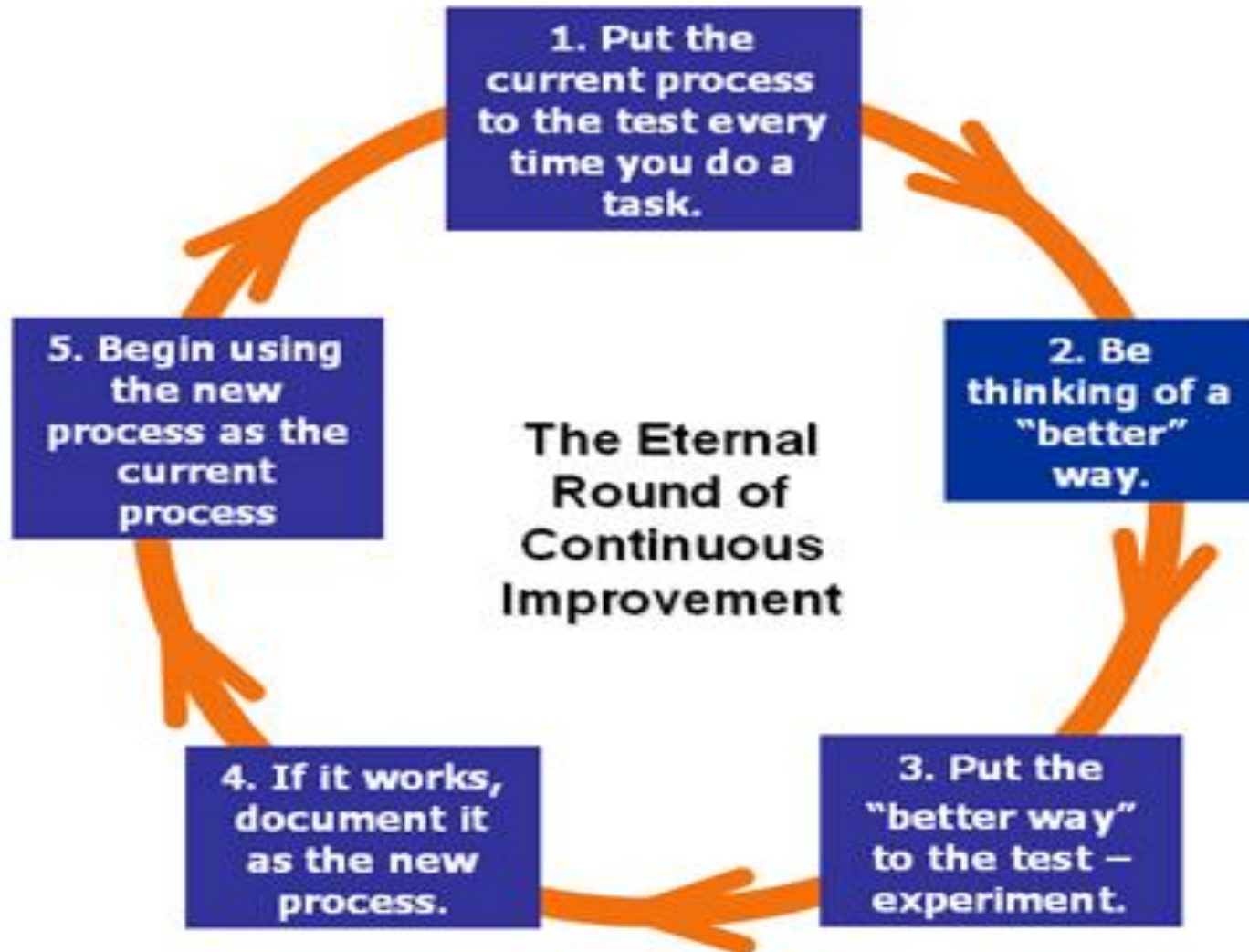
- Procedures and work practices are defined and written to document the best practices as *defined by the staff performing the work.*
 - Not written to please a regulatory body.

Value Stream Mapping



LEAN: Continuous Improvement

http://www.ferguson.com/Integ/images/Lean_Graphic.jpg



Today's Quality Philosophy

***Action
Oriented
Culture***

.... And so they said.....

“Healthcare must expand its view of quality beyond the departmentalized quality control and quality assurance activities of the last decades to keep pace with the growing role of total quality management in today’s competitive environment.”

Competitive Edge....

- Anticipation
- Action
- Communication
- Know your customer
- *Know thyself*

Quality..... An objective approach

Use data to support quality and quality initiatives.

Use quality as a means to positively effect change in your laboratory.

What Does Quality Mean?

- Improving patient's lives.....
 - Accurate results
 - Appropriate patient care
 - Excellent customer service
 - Employee satisfaction
 - Others??

Quality..... Why Do We Care?

- Professional obligation
- Promotes quality healthcare
- Competitive market demands

Quality CAREs

C Customer Service

A Action

R Results

with

E Enthusiasm

Progression of Quality

QA

Testing

QMS

Process

ISO

The Customer Experience

Progression of Our Profession

HOME

Community

The World

QA

Testing

QMS

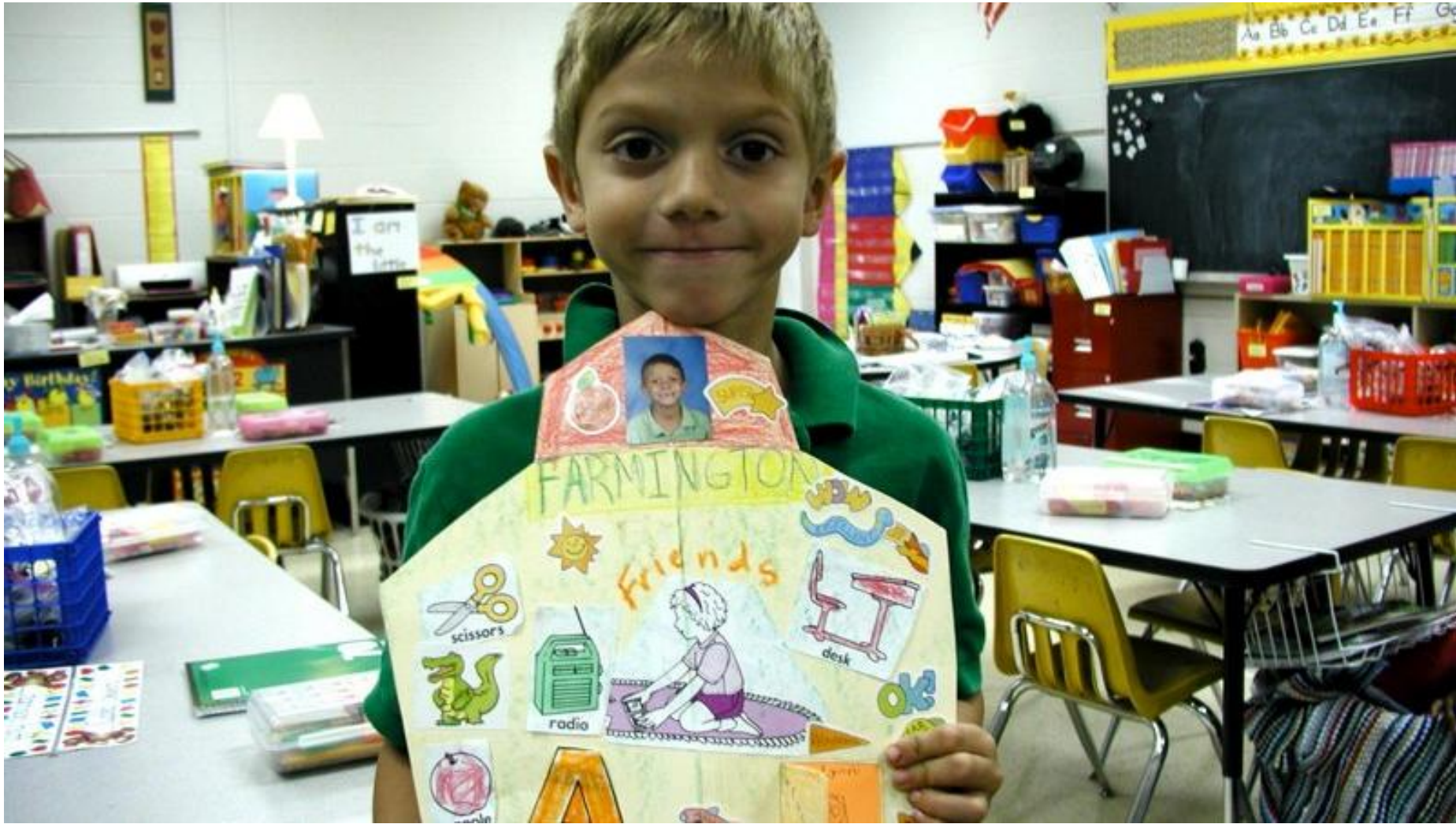
Process

ISO

The Customer Experience

Make It Real.

What face is behind that specimen?



What would Grandma say?



Quality Starts with **YOU**....



Get it started.
Pass it on.