QUALITY MANAGEMENT
PLAN, IMPLEMENT, TRACK, IMPROVE

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LEARNING OBJECTIVES

This lecture will enable the participant to:

1. List the elements of a quality management plan
2. Describe key stake holders of the planning, implementation, maintenance, and improvement stages of total quality management plans
3. Explain ways to monitor elements of the plan, key performance indicators, and improvement initiatives

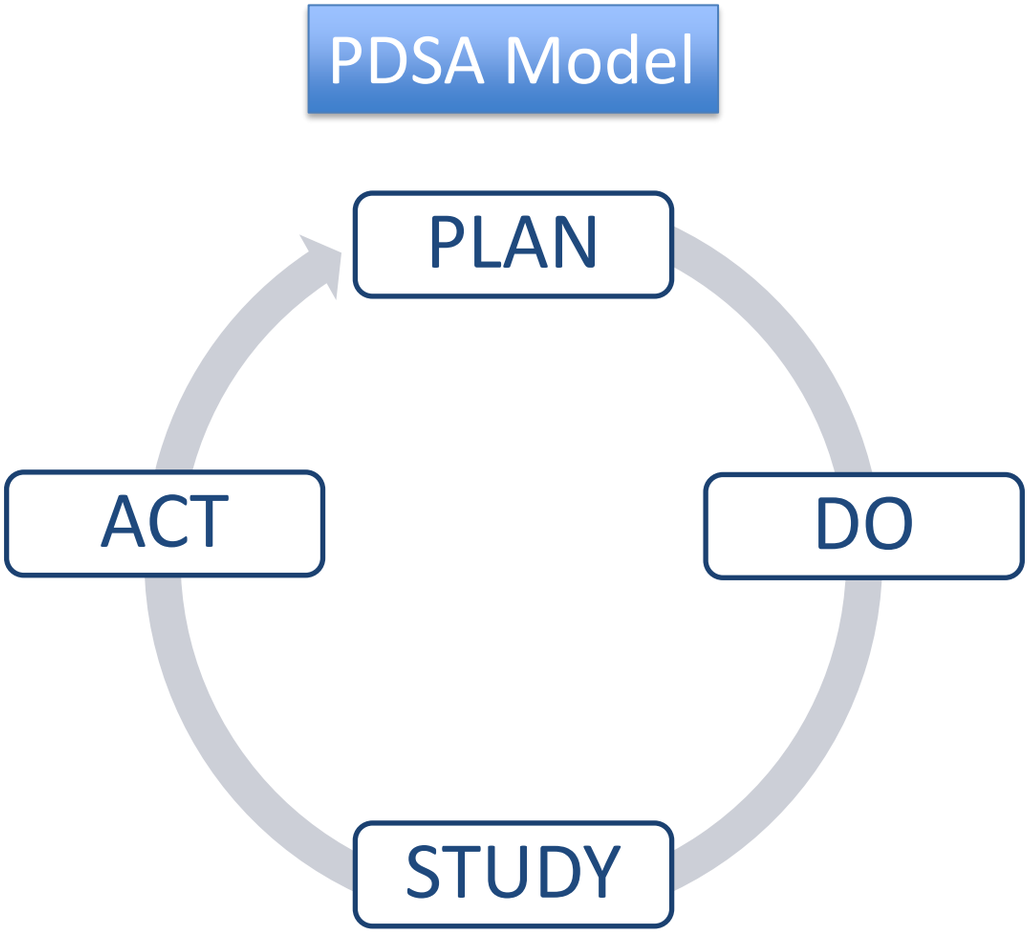
WHY THIS TOPIC IS IMPORTANT TO ME?

- Two experiences soon out of fellowship:
  1. Lead an effort to start a new department in a large lab network
     - How do I fit this new effort into an existing quality framework?
  2. Get a quickly growing lab CAP accredited
     - How do I build the quality framework and make it continuously work?

OUTLINE

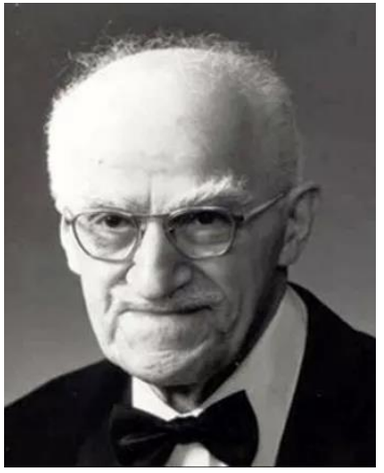
I. History of Quality Management – PDSA model
II. Quality Management Fundamentals
III. Responsibilities of Lab Directors and Pathologists
IV. Elements of a Quality Management Plan
V. Making the Quality Management Plan Operational
VI. Tools, Metrics, and Outcomes
VII. Risk Assessment Across the Process
VIII. Resources

HISTORY OF QUALITY MANAGEMENT



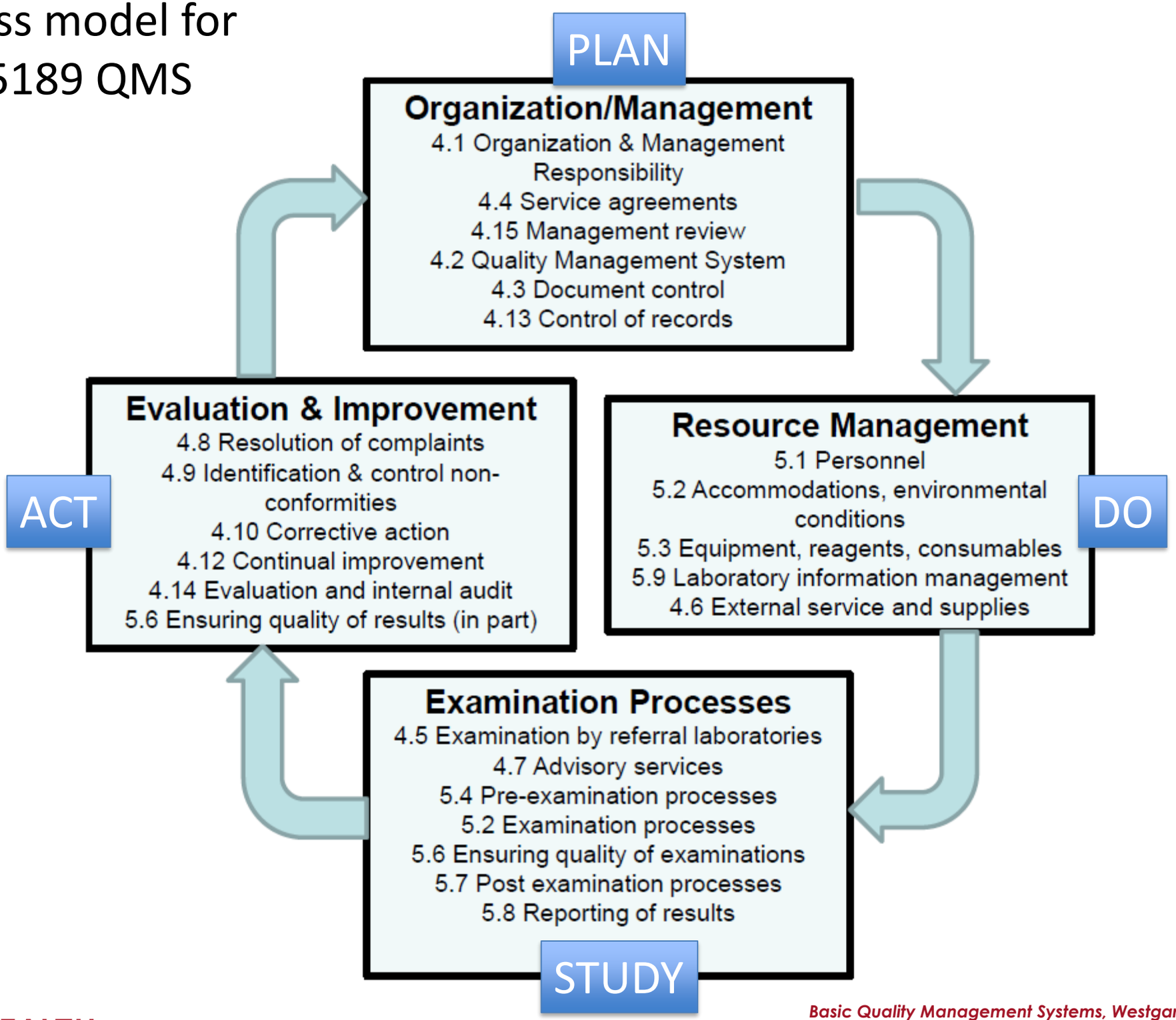
W. Edwards Deming
(1900-1993)

Walter A. Shewhart
(1891-1967)



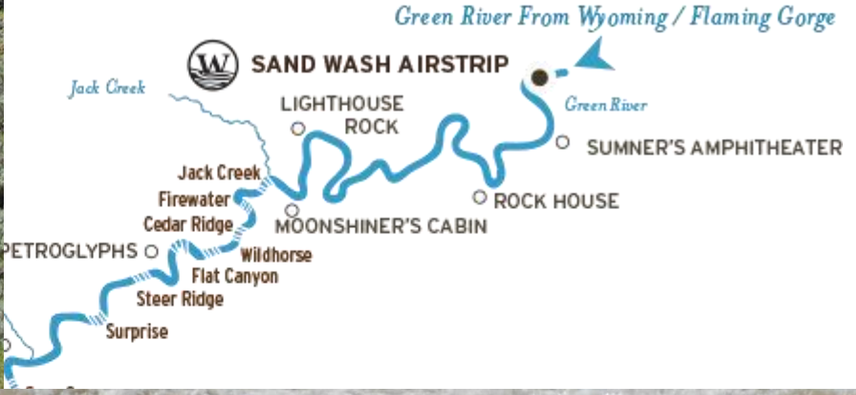
Joseph M. Juran
(1904-2008)

Process model for ISO 15189 QMS



Basic Quality Management Systems, Westgard, JO et al. 2014

QUALITY MANAGEMENT FUNDAMENTALS



pixabay.com/users/272447-272447

https://www.moabadventurecenter.com/desolation-canyon-rafting/map

KEY QUALITY MANAGEMENT ELEMENTS

- Statement affirming commitment to quality and patient safety
- Risk assessment
- Monitoring and control activities
  - Identify indicators and metrics
- Response to identified problems
- Information and communication
- Continuous improvement

KEY QUALITY MANAGEMENT COMPONENTS

- Written Quality Plan (CAP & CLIA)
  - High emphasis by CAP (critical deficiency)
- Annual review & approval by director
  - 2.2% of CAP labs had not performed!
- Specify information/reporting method
- Accuracy of results (analytic)
- Integrity of pre & post-analytic processes in all sections

QUALITY MANAGEMENT PLAN FORMATS

- Format may be Laboratory designed
- CLSI (NCCLS) guidelines (GP-22 or GP-26)
- ISO 9000 series
- ISO 15189 accreditation and standards
- JC model for improvement of organizational performance
- AABB quality program
- Safety plan integrated or separate

WHAT WILL INSPECTORS BE LOOKING FOR?

- Written QM plan
- Lab director involvement
- Monitoring of process and improvement
- Communication within organization
- Incorporation of PT data & corrective action
- Attention to employee and "client" concerns
- Use of incident reports to improve process and practice
- All shifts and all sections

RESPONSIBILITIES OF LAB DIRECTORS AND PATHOLOGISTS

"Stereoscopic View"

Kelly Doyle

Clinical

Analytical

RESPONSIBILITIES OF LAB DIRECTORS AND PATHOLOGISTS

CLIA:

It is the responsibility of the lab director to *"…ensure that the laboratory **develops and uses a quality system** approach to laboratory testing that provides accurate and reliable patient test results."*

CLIA Brochure - Laboratory Director Responsibilities
CMS.gov

RESPONSIBILITIES OF LAB DIRECTORS AND PATHOLOGISTS

CAP Accreditation:

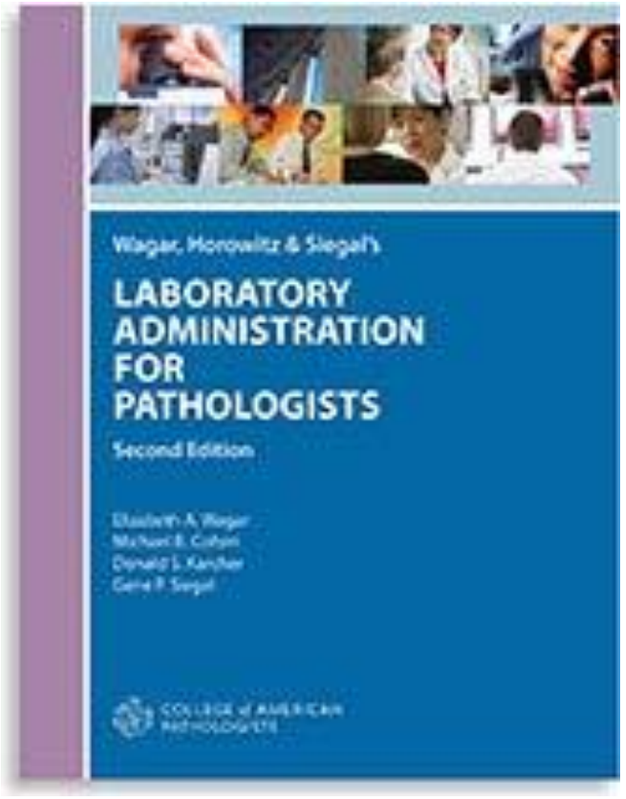
*"Director must assume responsibility for **implementation** of the quality management plan. The director and professional laboratory personnel must **participate** as members of the various quality management committees of the institution."*

RESPONSIBILITIES OF LAB DIRECTORS AND PATHOLOGISTS

CAP Accreditation:

"Ensure that the laboratory participates in the **monitoring** and evaluation of the quality and appropriateness of services rendered within the context of the quality assurance program appropriate for the institution, regardless of testing site(s).

ELEMENTS OF A QUALITY MANAGEMENT PLAN (QMP) -RESOURCES



QUALITY MANAGEMENT PLAN

Why is the QM Plan important?

- CAP and CLIA accreditation requirement
- Will improve patient care and safety
- Will help you to improve lab services (money, time)
- Ensures continuing surveillance and management
- Always ready for inspection

What are the key compliance issues?

- Plan format
- Components (entire analytic cycle, all sections)
- Metrics, benchmarks, and indicators
- Corrective action and follow-up to problems
- A focus on how the plan contributes to patient safety

TEMPLATE FOR QM PLAN - 12 QUALITY SYSTEM ESSENTIALS

1. Organization
2. Personnel Resources
3. Equipment
4. Supplier, Customer Issues, and Referral Laboratories
5. Process and Performance Control (QC, PT)
6. Documents and Records
7. Occurrence Management
8. Assessments and Audits
9. Process & Performance Improvement
10. Facilities and Safety
11. Information Management
12. Customer Service and Satisfaction

12 QUALITY SYSTEM ESSENTIALS

1. **Organization**

- Geographical scope and locations
  - one or multiple labs, mobile, POC, etc
- Organization
  - Organization charts
    - medical and administrative leaders
    - managers, supervisors
    - updated as needed and reviewed annually

12 QUALITY SYSTEM ESSENTIALS

2. Personnel Resources

- List the CLIA personnel and definitions
  - Cross-reference chart of local versus CLIA personnel titles
- Employee orientation, training, annual competency assessment, CE, safety training
- Summary of educational resources
- Location and process of documenting employee assessments and competencies

12 QUALITY SYSTEM ESSENTIALS

3. Equipment

- Briefly describe that equipment policies exist for:
  - Selection
  - Acquisition
  - Installation
  - Validation
  - Maintenance
  - Malfunction response
  - Disposal

12 QUALITY SYSTEM ESSENTIALS

4. Supplier, Customer Issues, and Referral Laboratories

Supplies

- Who is responsible for supporting lab operations?
  - Uninterrupted flow of supplies and services?
  - Quantity, quality, right time, price
  - Procedure for supply recall

12 QUALITY SYSTEM ESSENTIALS

4. Supplier, Customer Issues, and Referral Laboratories

Customer Issues (Surveys)

- Clinicians and nurses
  - TAT, critical values, phlebotomy response, test menus, consultation, courtesy
- Employee satisfaction
  - Communication, work environment and facilities, pay & promotion, "morale"
- Patients
  - phlebotomy, wait times, courtesy, complaints

12 QUALITY SYSTEM ESSENTIALS

4. Supplier, Customer Issues, and Referral Laboratories

Referral Laboratories

- Selection is the responsibility of director
  - consult with facility and medical staff
- Annual review/audit
  - Results
  - Service and support
  - Contracts
    - Compliance with federal requirements

12 QUALITY SYSTEM ESSENTIALS

5. Process and Performance Control (QC, PT)

Quality Control (QC)

- Analysis of materials of known composition or reactivity in conjunction with patient samples
- Measure of precision and confirms instrument calibration
  - QC frequency (min. vendor or CAP)
  - Process for QC drift, shifts, outliers
  - QC record retention policy (hard copy and digital)

12 QUALITY SYSTEM ESSENTIALS

5. Process and Performance Control (QC, PT)

Proficiency Testing (PT)

- Periodic testing of blinded samples
  - sent to the lab by an approved agency
  - If not available, alternate performance assessment (APA) must be defined and followed semi-annually
- No inter-lab sharing/communication
- Integration into routine workflow
- Process to address failures and near misses

12 QUALITY SYSTEM ESSENTIALS

5. Process and Performance Control (QC, PT)

Test validation

- Formal validation of
  - Laboratory-developed test (LDT)
  - Laboratory-modified test (LMT)
- Minimum requirements:
  - Test performance (accuracy, precision, linearity, carryover, sensitivity, etc.)
  - Intended use and applicable specimens
  - Clinical validity
  - External verification (PT)

12 QUALITY SYSTEM ESSENTIALS

6. Documents and Records

- Management policy for documents
  - Policies, procedures, QC records, PT records, etc
  - Appropriateness (up to date)
- May use master lists and SOPs for document management
- Who is responsible for management, review, signatures
- Document retention and discard
- Helpful to list as a table

HANG IN THERE

www.savagechickens.com

12 QUALITY SYSTEM ESSENTIALS

7. Occurrence Management

- Systemic analysis of events that affect lab services, quality, and patient safety
  - Serious, common, recurring, or systemic problems
- Capture and analyze nonconforming events
  - Random review
  - Detection by laboratory or technologist
  - External detection (clinicians, nurses, patients, clients)
- Corrective actions
- Root cause analysis for serious or frequent events
- Discussion at quality meetings/committees

KEEP IN MIND

- CAP Patient Safety Goals
  - Improve patient & sample identification
  - Improve verification and communication of life-threatening information (critical values, tests)
  - Improve identification, communication and correction of errors
  - Improve integration & coordination of the laboratory patient safety role within the healthcare organization
  - Utilize data within system to improve care

12 QUALITY SYSTEM ESSENTIALS

8. Assessments and Audits

- List expected external assessments
  - CAP, CMS, FDA, AABB, CDC, state agencies, Joint Commission
- Describe internal
  - CAP interim, personnel competency assessments, quality indicators, periodic audit of QM plan, safety audits
- Can refer to individual SOPs to keep this section simple

12 QUALITY SYSTEM ESSENTIALS

9. Process and Performance Improvement

- Define the authority, responsibility, and delegation
  - Lab director and quality management team
- Define basis for review (including establishment of a quality committee), and organizing an improvement project (e.g., FOCUS-PDCA)
- Involve all lab sections, pre-analytic, analytic, and post-analytic processes

12 QUALITY SYSTEM ESSENTIALS

9. Process and Performance Improvement (cont.)

- List hospital/clinic or other committees
  - Infection control
  - Transfusion
  - Safety
  - Quality Committee(s)

Interdisciplinary involvement critical to improvement and to demonstrate lab integration with institutional QM programs

12 QUALITY SYSTEM ESSENTIALS

9. (continued) How to do it

- FOCUS
  - **F**ind a process to improve
  - **O**rganize a team
  - **C**larify current knowledge
  - **U**nderstand variation
  - **S**elect process to improve
- PDCA/PDSA
  - **P**lan the improvement action
  - **D**o/test the action
  - **C**heck to determine the effects of the action
  - **A**ct to implement or change approach

12 QUALITY SYSTEM ESSENTIALS

9. (continued) Sample QM Indicators

- Diabetes monitoring (system)
- Hyperlipidemia screening (system)
- Test order accuracy (preanalytic)
- Patient identification (preanalytic)
- Blood culture contamination (preanalytic)
- Adequacy of specimen information (system/preanalytic)

Laboratory Administration for Pathologists, CAP, 2011
CAP Presentation by Paul Bachner, MD, FCAP
The Institute for Quality in Laboratory Management; CAP TODAY, June 2005

12 QUALITY SYSTEM ESSENTIALS

9. (continued) Sample QM Indicators

- Accuracy of point-of-care testing (analytic)
- Cervical cytology/biopsy correlation (analytic)
- Critical value reporting (postanalytic)
- Turnaround time (postanalytic)
- Clinician satisfaction (system & postanalytic)
- Clinician follow-up (system & postanalytic)

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12 QUALITY SYSTEM ESSENTIALS – SAMPLE QM INDICATORS

Laboratory Medicine Quality Indicators by Stage of the Total Testing Process

Stage	IOM Domains*
Test ordering	
Test order appropriateness†	Effectiveness, efficiency, timeliness
Patient identification/specimen collection	
Inpatient wristband identification error	Safety
Patient satisfaction with phlebotomy	Patient-centeredness
Specimen identification, preparation, and transport	
Specimen inadequacy/rejection	Effectiveness, efficiency, safety, timeliness
Blood culture contamination	Efficiency, safety
Specimen container information error	Efficiency, safety
Analysis	
Proficiency testing performance	Safety
Gynecologic cytology-biopsy discrepancy	Effectiveness, efficiency, safety
Result reporting	
Inpatient laboratory result availability	Patient-centeredness, timeliness
Corrected laboratory reports	Efficiency, safety
Critical values reporting	Safety, timeliness
Turnaround time	Timeliness
Clinician satisfaction with laboratory services	Effectiveness, timeliness
Result interpretation and ensuing action	
Follow-up of abnormal cervical cytology results	Effectiveness, timeliness

* Descriptions of the Institute of Medicine (IOM) health care domains are as follows: effectiveness, providing care processes and achieving outcomes supported by scientific evidence; efficiency, avoiding waste, including waste of equipment, supplies, ideas, and energy; equity, providing care that does not vary in quality because of personal characteristics such as sex, ethnicity, geographic location, and socioeconomic status; patient-centeredness, meeting patient needs and preferences and providing education and support; safety, preventing or reducing actual or potential bodily harm; and timeliness, obtaining needed care while reducing delays.

† See Table 2 for selected laboratory tests by disease/condition as noted in the Agency for Healthcare Research and Quality National Quality Measures Clearinghouse.

Shahangian, S. Snyder SR. *AJCP, 2009,* 131(3), 418–431

12 QUALITY SYSTEM ESSENTIALS

10. Facilities and Safety

- Describe participation in facilities and safety
- Refer to the safety manual (usually large)
- Annual safety audit of lab sections
- Lab safety committee manages safety and facilities initiatives

12 QUALITY SYSTEM ESSENTIALS

11. Information Management

- Authority to approve users and access
- States that policies and procedures exist for data security and transfer integrity
- List security measures (passwords, security levels, access)
- Document audit of data transfer
- HIPPAA compliance is described
- Frequency of system checks
- Annual report of system integrity

12 QUALITY SYSTEM ESSENTIALS

12. Customer Service and Satisfaction

- State frequency of surveys
- Physicians and nurses
  - TAT, critical values, phlebotomy, test menus, consultation, courtesy
- Employee satisfaction
  - Communication, work environment, pay & promotion, "morale"
- Patients
  - phlebotomy, wait times, courtesy, complaints

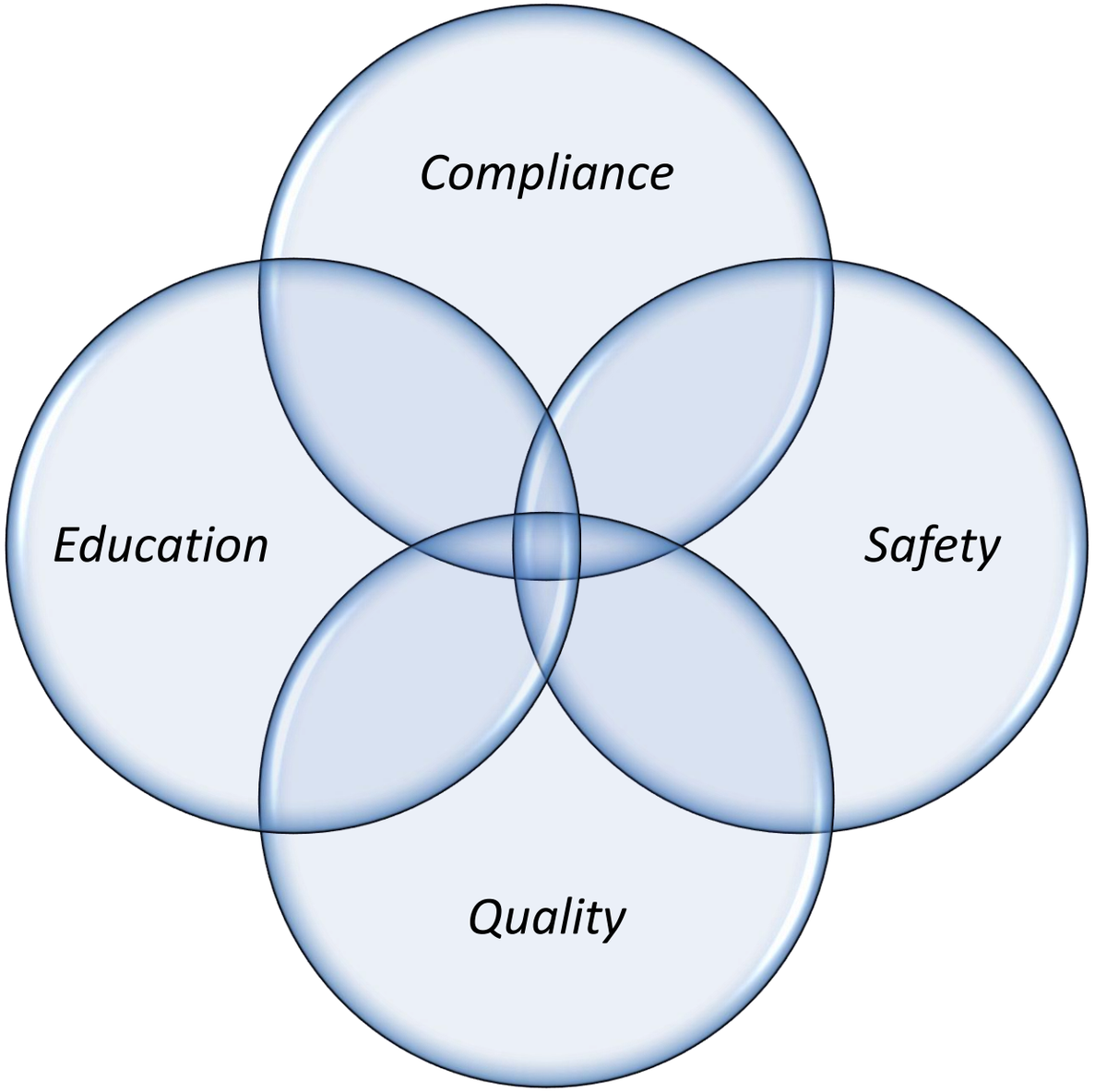
Photo by Tom Fisk from Pexels

MAKING THE QUALITY MANAGEMENT PLAN OPERATIONAL

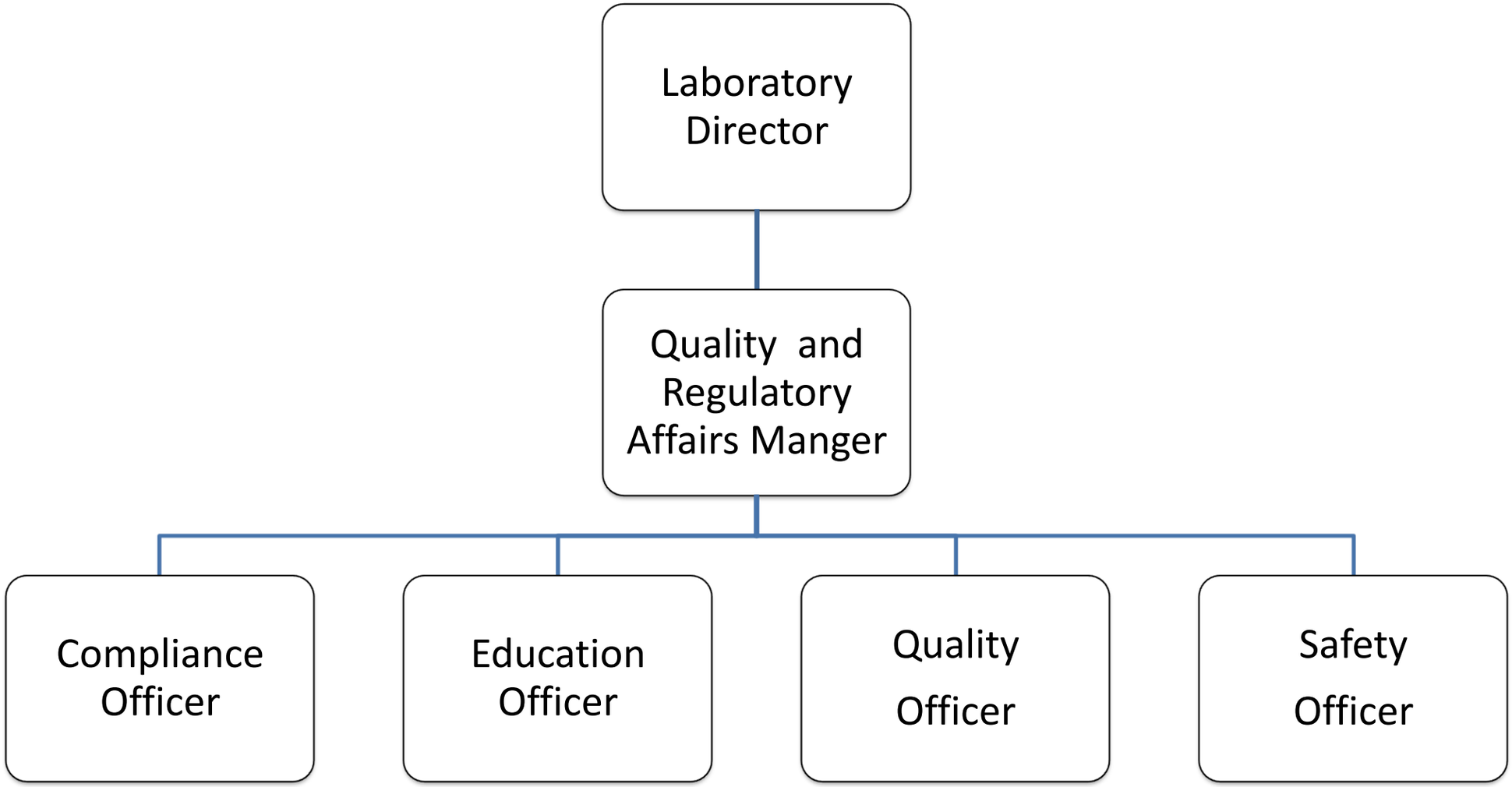
FUNDAMENTALS OF QUALITY MANAGEMENT IMPLEMENTATION

- Implement as designed in the QM plan
- Explicit delegation of responsibility
- Specify frequency of activities
- Create quality committee(s)
- Evidence and documentation
  - Committee minutes
  - QI reports
  - Documents responding to complaints, problems, adverse events

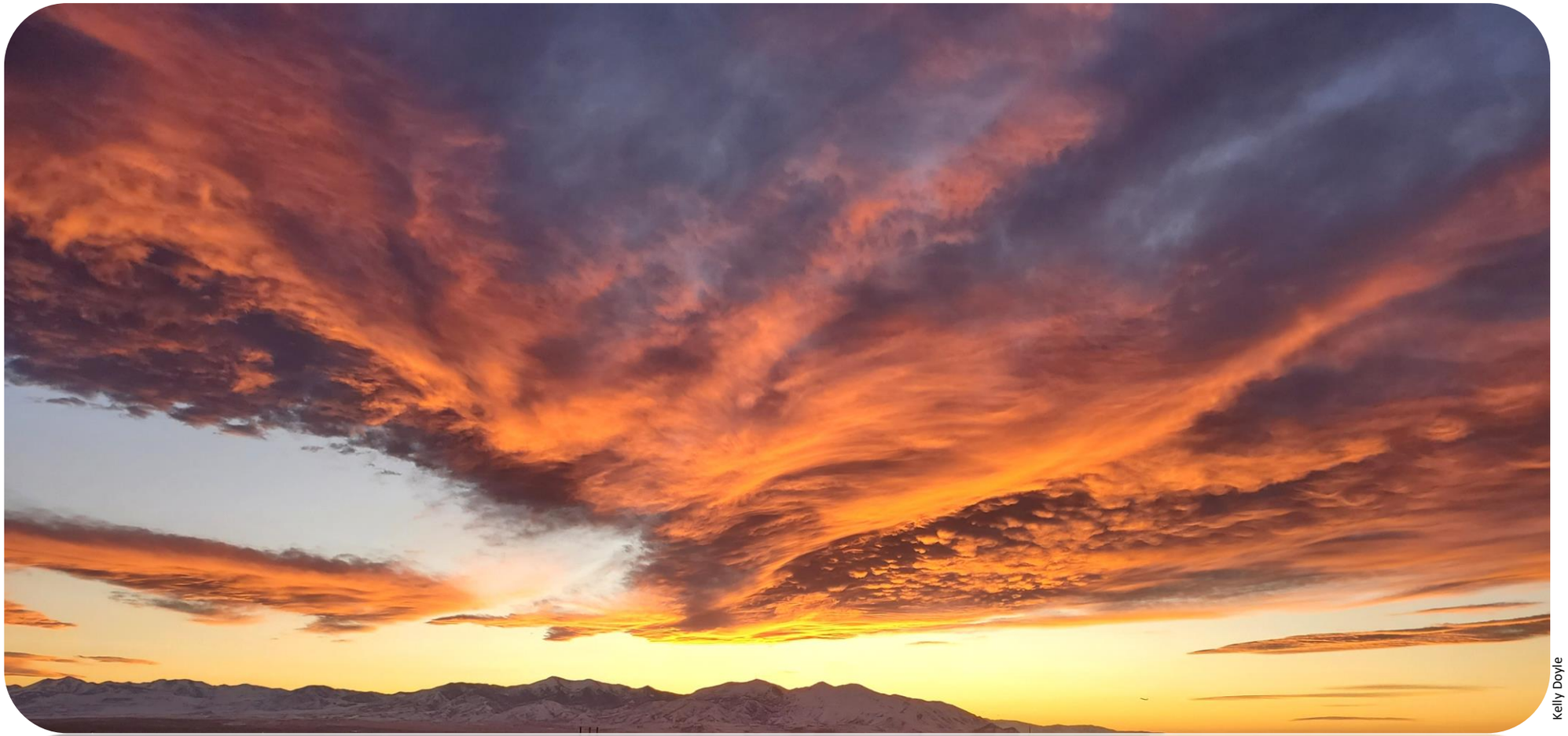
MAKING THE QUALITY MANAGEMENT PLAN OPERATIONAL



MAKING THE QUALITY MANAGEMENT PLAN OPERATIONAL



TOOLS, METRICS, OUTCOMES



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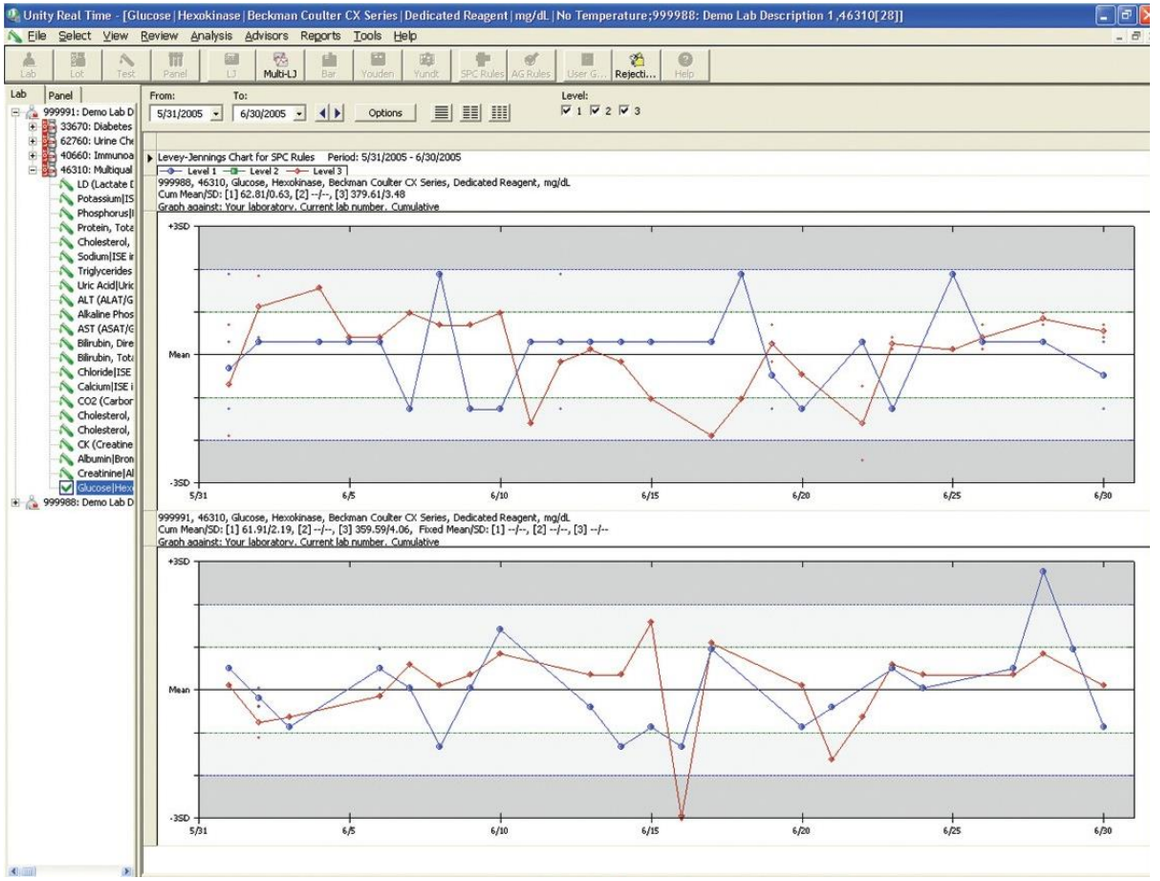
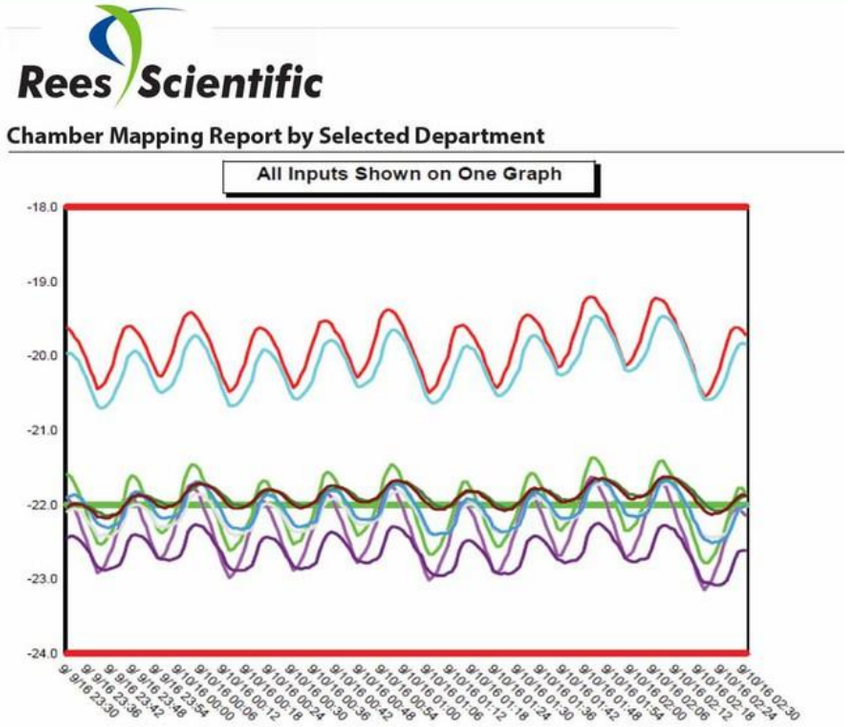
TOOLS, METRICS, OUTCOMES

- Statistical control charts
- Process and workflow design charts
- Root cause analysis
  - Process mapping, 5 whys, fishbone diagram
- Lean six sigma
- External quality activities
- Quality dashboards
- Spreadsheets
- Risk analysis
- Non-conformance reports

SHORT TERM/REAL-TIME MONITORING

- Assay-specific statistical control charts

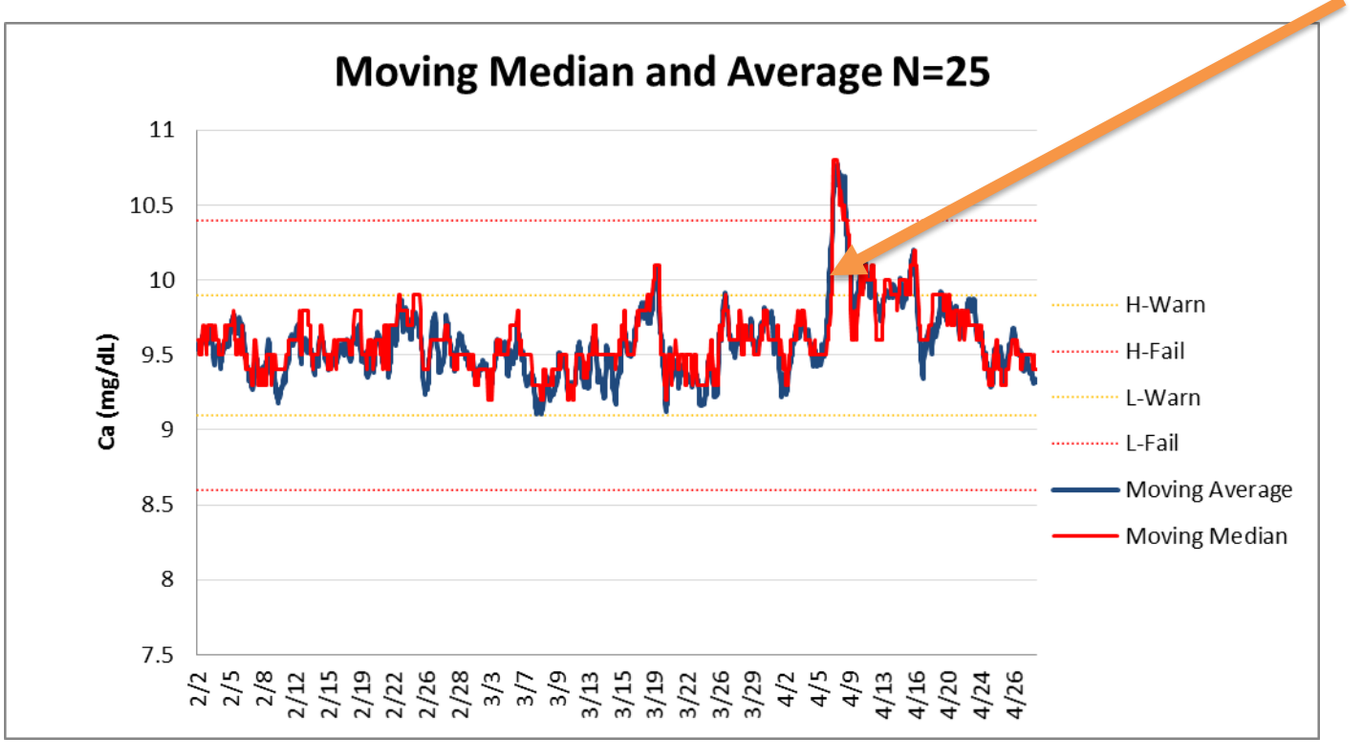




Device-specific temperature charts

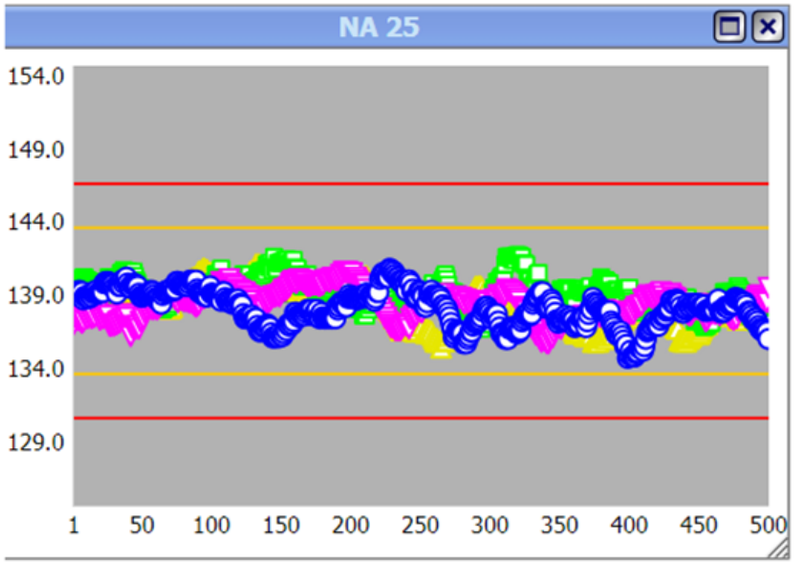
BioRad Unity. www.QCNET.com
Rees Scientific. www.reesscientific.com

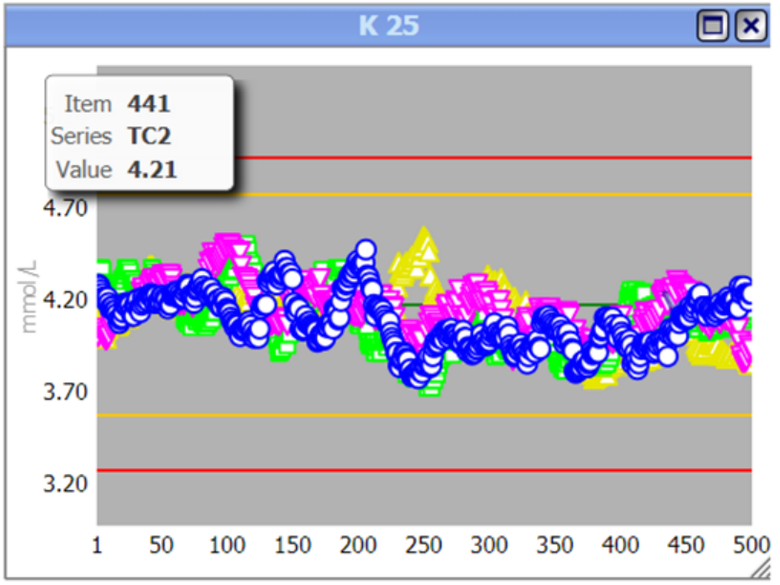
SHORT TERM/REAL-TIME MONITORING – MOVING AVERAGES/MEDIANS

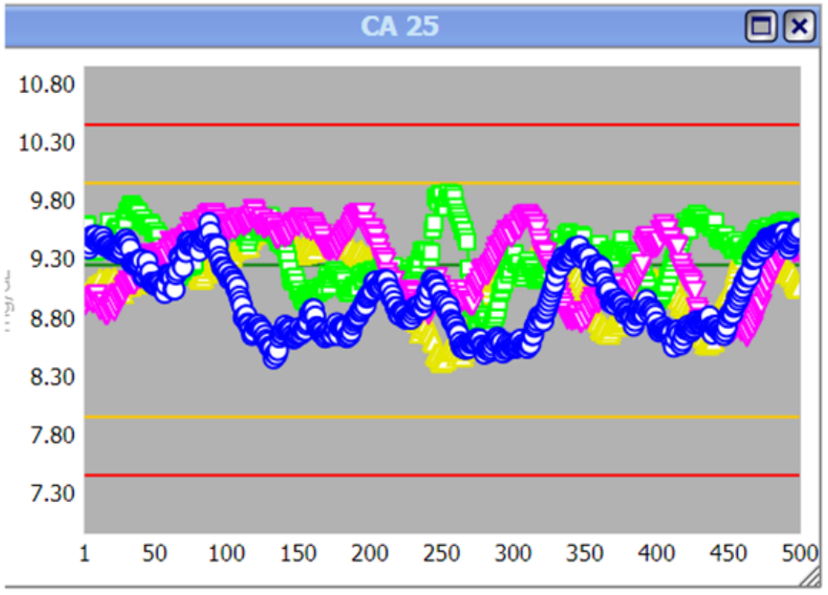


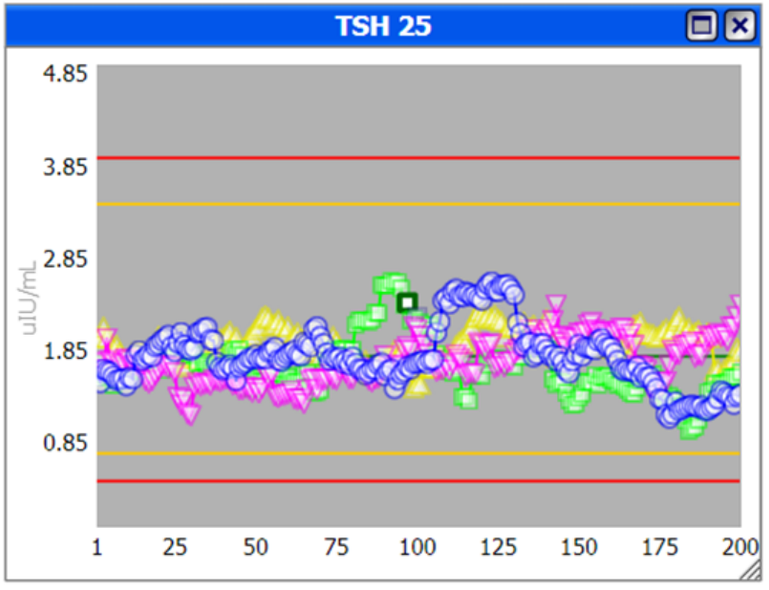
ED started calling the lab - “all my patients have high calcium”

SHORT TERM/REAL-TIME MONITORING – MOVING AVERAGES/MEDIANS









Example of monitoring medians at Intermountain Healthcare using Data Innovations software

EXAMPLE MONTHLY QC REVIEW – PEER BASED

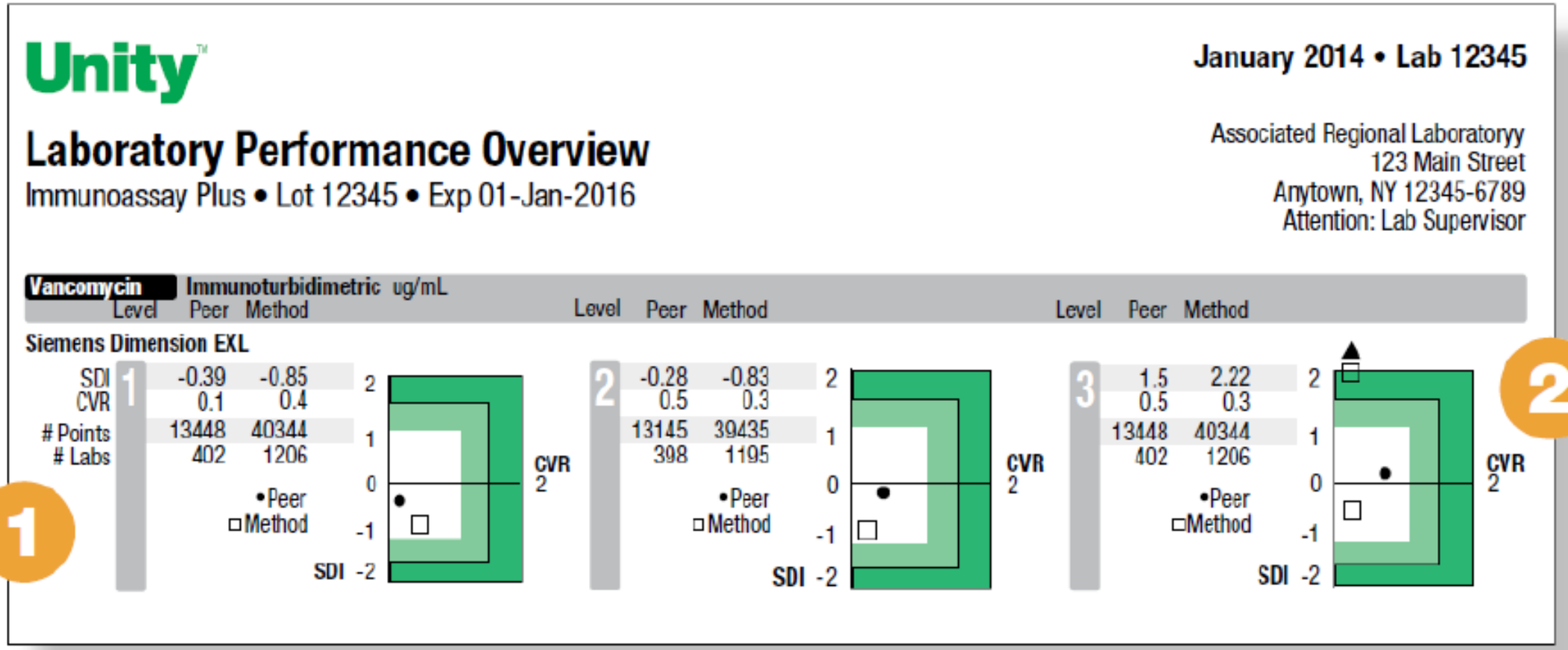
Instrument(s) evaluated: C1 AND I1

Month in Review: Mar-19

TEST	METHOD	LOT#	Lab Count	Peer Count	Set Mean	Lab Mean	Peer Mean	Lab z-score	Lab CV	Peer CV	Lab CVR	Set S.D	Lab SD	Peer SD	Lab SDI	Peer Set SD	Lab SD MoM	Comments
ACETDA	I1	40951	64	626	9.5	**9.6**	9.6	-0.19	**6%**	5%	1.2	1	0.6	0.49	-0.02	1.0	1.0	
ACETDA	I1	40952	64	603	37	**37.1**	37.3	-0.21	**2%**	2%	1.1	1	0.7	0.62	-0.22	1.0	1.0	
ACETDA	I1	40953	64	640	107	**106.8**	107.5	0.14	**1%**	2%	0.8	3	1.3	1.65	-0.44	3.0	1.0	
ALB	C1	47951	67	1309	2.6	**2.6**	2.6	-0.58	**2%**	2%	1.3	0.1	0.1	0.04	0.41	0.1	1.0	
ALB	I1	47951	33	1309	2.6	**2.6**	2.6	-0.42	**1%**	2%	0.9	0.1	0.0	0.04	0.06	0.1	1.0	
ALB	C1	47953	65	1303	4.6	**4.6**	4.6	0.42	**1%**	1%	1.2	0.1	0.1	0.05	0.36	0.1	1.0	
ALB	I1	47953	33	1303	4.6	**4.6**	4.6	0.23	**1%**	1%	1.1	0.1	0.1	0.05	0.61	0.1	1.0	
ALB	C1	56611	10	37	2.6	**2.6**	2.7	0.82	**2%**	20%	0.1	0.1	0.0	0.54	-0.27	0.1	1.0	
ALB	I1	56611	11	37	2.6	**2.5**	2.7	1.63	**2%**	20%	0.1	0.1	0.0	0.54	-0.33	0.1	1.0	
ALB	C1	56613	10	29	4.6	**4.6**	4.6	0.47	**1%**	1%	1.2	0.1	0.1	0.05	-0.01	0.1	1.0	
ALB	I1	56613	11	29	4.6	**4.6**	4.6	0.44	**1%**	1%	1.2	0.1	0.1	0.05	0.04	0.1	1.0	
ALC	C1	54261	33	263	40	**41.0**	60.1	-0.74	**3%**	96%	0.0	2	1.3	57.9	-0.33	2.0	1.0	
ALC	I1	54263	32	162	247	**246.1**	251.8	0.14	**3%**	2%	1.0	8	6.2	6.18	-0.92	7.0	1.1	
ALKP	C1	47951	65	1320	31.5	**32.5**	29.7	-0.63	**5%**	6%	0.8	2.5	1.6	1.77	1.61	2.5	1.0	
ALKP	IC	47951	37	1320	32	**31.5**	29.7	0.36	**5%**	6%	0.8	2.5	1.4	1.77	1.02	2.5	1.0	
ALKP	C1	47953	64	1316	325	**324.3**	318.5	0.12	**2%**	2%	1.0	9	5.8	5.92	0.99	8.0	1.1	
ALKP	I1	47953	37	1316	328	**325.7**	318.5	0.43	**2%**	2%	0.9	9	5.3	5.92	1.23	8.0	1.1	
ALKP	C1	56611	10	37	32	**31.4**	55.5	0.17	**12%**	136%	0.1	2.5	3.6	75.4	-0.32	2.5	1.0	
ALKP	I1	56611	11	37	32	**31.3**	55.5	0.20	**12%**	136%	0.1	2.5	3.7	75.4	-0.32	2.5	1.0	
ALKP	C1	56613	10	29	304	**304.0**	307.0	0.00	**2%**	2%	1.3	9	6.8	5.32	-0.57	9.0	1.0	
ALKP	I1	56613	11	29	304	**309.2**	307.0	-1.08	**2%**	2%	0.9	9	4.8	5.32	0.40	9.0	1.0	

EXAMPLE MONTHLY QC REVIEW – PEER BASED

- Other sources of peer-based QC monitoring



BioRad Unity. www.QCNET.com

EXAMPLE – WEEKLY NONCONFORMANCE REPORT

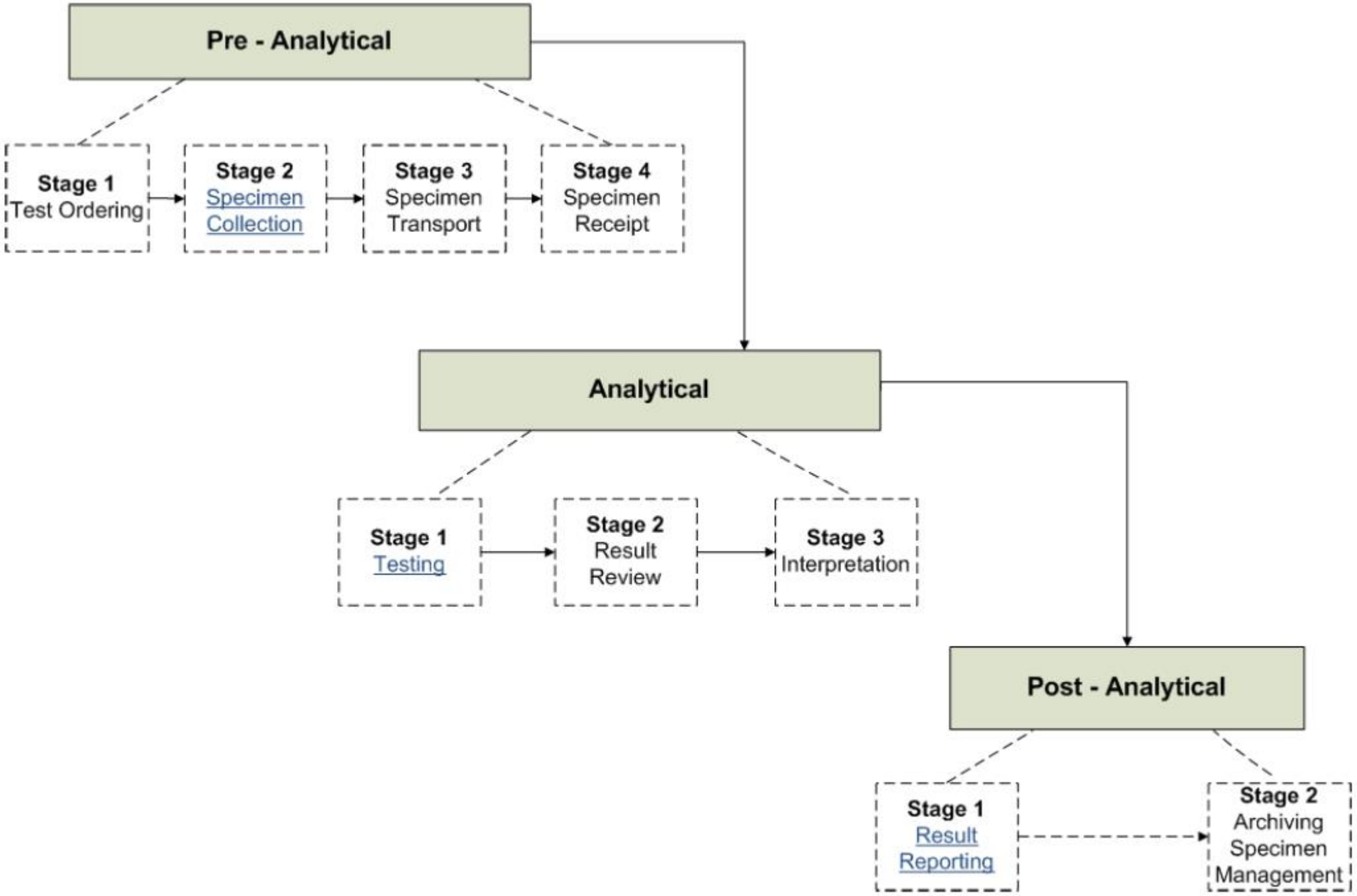
Mass Spectrometry 2

Results from 4/10/2020 to 4/16/2020

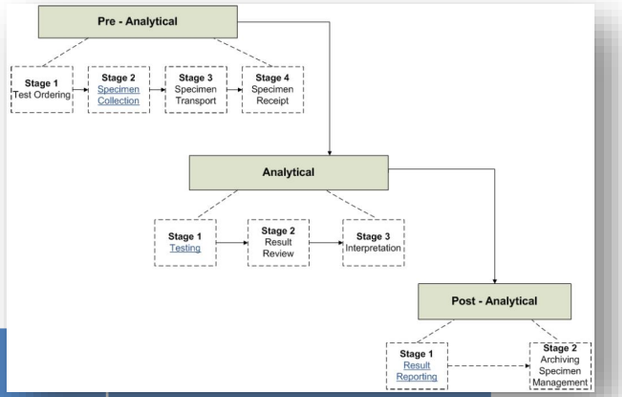
Total Occurrences: Total Patients: Total PSID:

	QAR Completed: 4/15/2020				
QAR ID					
Patient Count					
Problem Statement					
Immediate Action					
Case					
Accession		**Mnemonic**			
Accession		**Mnemonic**			
Client ID					
Category	**Subcategory**	**Rating**	**Outcome**	**Reportable**	**PSID**
Post-Analytical	Reporting Results	Minor Nonconformance	Corrected Report	Yes	No
Investigation					
Investigation					
Root Cause					
Notes					
	QAR Completed: 4/16/2020				

PROCESS-BASED RISK ASSESSMENT



PROCESS-BASED RISK ASSESSMENT



Preanalytic				
Stage	Item Description	Risk	Mitigation Plan	Tracking/Log
A				
B				
C				
Analytic				
A				
B				
C				
Postanalytical				
A				
B				
C				

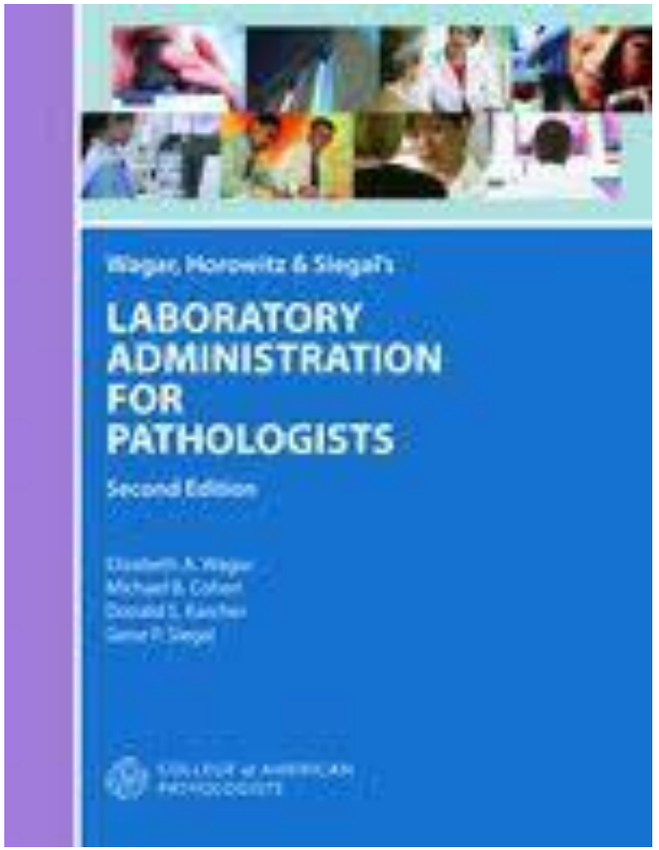
RESOURCES

- Description of CLIA

  https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index?redirect=/clia/
- CLIA Laboratory Requirements

  https://www.govinfo.gov/content/pkg/CFR-2003-title42-vol3/xml/CFR-2003-title42-vol3-part493.xml
- Quality Management in Clinical Laboratories: Promoting Patient Safety Through Risk Reduction And Continuous Improvement, P. Valenstein, CAP, 2005
- CAP Laboratory Accreditation Manual: http://www.cap.org/apps/docs/laboratory_accreditation/standards/lapmanual_0707.pdf
- CLSI Guidelines: GP2-A5, QMS20-R, QMS01-A4

RESOURCES



Wagar, Horowitz & Siegal's Laboratory Administration for Pathologists

Elizabeth A. Wagar, MD, Michael B. Cohen, MD, Donald S. Karcher, MD, and Gene P. Siegal, MD, PhD

SUMMARY

Do your people know what they are doing?

Does your process produce quality results?

Thank you!