



cap

2010 LABORATORY ACCREDITATION PROGRAM AUDIOCONFERENCES AND WEBINARS Hands-On Help: Setting Up Your Quality Management Plan

November 17, 2010



Elizabeth A. Wagar, MD, FCAP

College of American Pathologists
325 Waukegan Rd.
Northfield, IL 60093
Tel: 800-323-4040
www.cap.org
Version no.1

OBJECTIVES

After participating in this Webinar you will be able to:

- Identify the key elements of a Quality Management Plan.
- Develop and implement a Quality Management Plan for your laboratory.

ACCREDITATION

The College of American Pathologists (CAP) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

CME CATEGORY 1

The College of American Pathologists designates this educational activity for a maximum of 1.5 *AMA PRA Category 1 Credit™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

CE (CONTINUING EDUCATION FOR NON-PHYSICIANS)


The CAP designates this educational activity for a maximum of 1.5 credit/hour of continuing education. Each participant should only claim those credits/hours he/she actually spent in the activity.


ASCP STATEMENT

This activity is acceptable to meet the continuing education requirements for the ASCP Board of Registry Certification Maintenance Program.

CALIFORNIA AND FLORIDA STATEMENT

This activity is approved for continuing education credit in the states of California and Florida.





Laboratory Accreditation Program Webinar
**Hands-On Help: Setting Up Your
Quality Management Plan**
Elizabeth A. Wagar, MD, FCAP

November 17, 2010 www.cap.org

Disclosure

- Dr. Wagar receives an honorarium for advisory work for Becton Dickinson, Franklin Lakes, NJ.
- Dr. Wagar has no other potential conflict of interests to disclose.

© 2010 College of American Pathologists. All rights reserved. 2

The History of Quality

- Joseph Juran: He was arguably the first quality expert to emphasize that no quality management system works unless people are empowered and committed to take responsibility for quality—as an ongoing process—he argued that effectively, quality must become part of people's behavior and attitudes—an “ethos.”
- We will return to this question of culture at the end of the discussion.

© 2010 College of American Pathologists. All rights reserved. 3

What is a Quality Management Plan?

- A plan that spells out the specific steps that a laboratory will take to ensure that quality is being maintained
- Assures that the lab is in compliance with applicable laws and regulations related to quality and patient safety
- Is engaged in credible quality improvement activities

© 2010 College of American Pathologists. All rights reserved.

4

What Does a Quality Management Plan Do?

- Describes the laboratory's approach to the management of quality and patient safety
- Outlines or specifies all quality management activities for a specific program or organization



© 2010 College of American Pathologists. All rights reserved.

5

Course Objectives

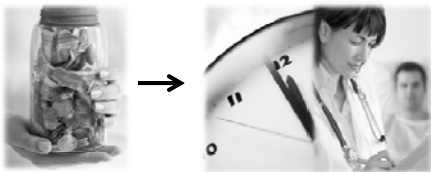
- Identify the key elements of a Quality Management Plan.
- Develop and implement a Quality Management Plan for your laboratory.

© 2010 College of American Pathologists. All rights reserved.

6

Why Quality Management?

- A shift in emphasis from....
- Saving money
- To saving time
- AND providing quality services



© 2010 College of American Pathologists. All rights reserved.

7

Quality Management Plan

- **Authority:** authorized and signed by the Laboratory Director and any additional designees
- Laboratory Director/additional designees must review annually!
- LAP, 2.2% of laboratories inspected by the CAP were cited because the quality management program had not been reviewed for effectiveness the previous year

© 2010 College of American Pathologists. All rights reserved.

8

Laboratory Director Responsibilities

- CLIA '88: The laboratory director is responsible for the overall operation and administration of the laboratory...and for assuring compliance with the applicable regulations (CLIA '88)
- <https://www.cms.gov/CLIA/downloads/brochure7.pdf>
- TLC.10900 Is the laboratory director actively involved in the 1) design, 2) implementation, and 3) oversight of the quality management system?

CAP Team Leader Checklist

© 2010 College of American Pathologists. All rights reserved.

9

When Should the Laboratory Director be Involved?

- Development of the document
- Benchmarking
- Ensure implementation
- Assessment/reassessment of activities
- Ensure integration with institution's program
- Strategic and proactive guidance

© 2010 College of American Pathologists. All rights reserved.

10

The Laboratory Director Should...

- Be familiar with the written plan
- Be aware of the key elements
- Assure that the scope of the plan includes
 - All laboratory activities
 - All patients
 - All phases of testing

© 2010 College of American Pathologists. All rights reserved.

11

Twelve Elements of a Quality Management Plan

1. Organization
2. Personnel Resources
3. Equipment
4. Supplier and Customer Issues
5. Procedure Control
6. Documents and Records
7. Occurrence Management
8. Assessments and Audits
9. Process Improvement
10. Facilities and Safety
11. Information Management
12. Customer Service and Satisfaction



© 2010 College of American Pathologists. All rights reserved.

12

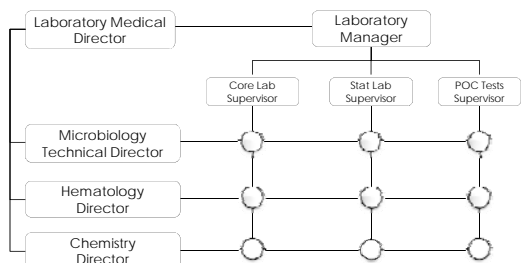
Organization

- Indicate scope (which labs/areas are covered by the Quality Management Plan)
- Briefly describe organization, (may insert an organizational chart), indicate medical and administrative directors and lab manager/supervisors

© 2010 College of American Pathologists. All rights reserved.

13

A Matrix Organizational Chart



Personnel Resources

- List CLIA personnel definitions
- Describe employee orientation
- Describe new employee training and annual competency assessment (age specific as appropriate), safety training
- Provide a summary of educational resources
- Indicate where documentation is kept for employee assessments and competencies

© 2010 College of American Pathologists. All rights reserved.

15

CLIA 2003: Personnel Categories

Moderate Complexity

- Laboratory Director
- Technical Consultant
- Clinical Consultant
- Testing Personnel

High Complexity

- Laboratory Director
- Technical Supervisor
- Clinical Consultant
- General Supervisor
- Testing Personnel

© 2010 College of American Pathologists. All rights reserved.

16

Equipment

- Briefly describe (one paragraph) that policies exist for equipment selection, acquisition, installation, validation, maintenance, investigation of adverse events, and equipment disposal/release

"The laboratory has policies, processes and procedures for the selection, acquisition, installation, validation, periodic maintenance and quality assessment of equipment critical to the provision of services in the Department in the respective laboratory sections. Each piece of equipment is uniquely identified; calibration, maintenance, and monitoring conform to specified requirements. In addition, the laboratory maintains a process to investigate and follow-up equipment malfunctions, failures, and adverse events. Prior to disposal or release to surplus inventory, equipment that may have been in contact with chemical, biohazardous, or radioactive substances is decontaminated and decommissioned."

© 2010 College of American Pathologists. All rights reserved.

17

Equipment

- Know your laboratory "floor"
- Be aware of any vendor issues
- Review recalls
- Understand basic functions



© 2010 College of American Pathologists. All rights reserved.

18

Supplies and Suppliers

- **Supplies:** Indicate who is responsible for supporting laboratory operations with an uninterrupted flow of material and services
- **Supplies,** indicate the objective: right quality, right quantity, right time, right supplier, right price
- Procedure for supply recall



© 2010 College of American Pathologists. All rights reserved.

19

Supplies and Suppliers

- Review storage facilities and their management
- Engage in lean, inventory management activities
- Review back-orders, limited supplies that may affect the laboratory

© 2010 College of American Pathologists. All rights reserved.

20

Customer Issues: Referral Labs

- **Referral Laboratories:** Authority rests with the laboratory medical director in consultation with the facility and physician medical staff
- Referral laboratories should be reviewed and approved annually, review a sampling of results
- Referral laboratory contracts

© 2010 College of American Pathologists. All rights reserved.

21

Reference Lab Management Table

Reference Lab	Contact Info and Address	CLIA Number and Expiration	CAP Number and Expiration	Comments

© 2010 College of American Pathologists. All rights reserved.

22

Customer Issues: Service and Satisfaction Surveys

- Referring physicians and nursing: survey for satisfaction, TAT, critical values, phlebotomy, test menus, courtesy of lab staff no less than every 2 years
- Employee satisfaction: 1) communication, 2) work/life balances, 3) support systems, 4) rewards/recognition, 5) culture of excellence
- Patient satisfaction: phlebotomy, patient relations department

© 2010 College of American Pathologists. All rights reserved.

23

Procedure Control: QC

- Quality Control = QC, sometimes called Process Control. Provide a definition: "The analysis of materials of known composition or reactivity in conjunction with patient sample testing to verify the performance of a test."
- QC a measure of precision, confirms maintenance of calibration. Discuss internal vs. external QC materials.
- QC frequency, refer to individual test procedure.
- Violation of QC rules, refer to individual test or lab procedure.
- QC record retention, specify duration of retention.



© 2010 College of American Pathologists. All rights reserved.

24

Procedure Control: Proficiency Testing

- Define PT: periodic testing of samples whose composition or reactivity is unknown to the testing lab, typically externally provided
- Note that CMS requires enrolling in CMS-approved PT programs where available and required
- Also note that CMS forbids labs to “engage in any inter-lab communications pertaining to the results of proficiency test samples” or to “send PT samples or portions of samples to another lab for analysis”
- PT to be integrated with routine lab workload/standard and performed by routine testing personnel
- If no graded PT available, check semi-annually using an alternate performance assessment system (responsibility of the laboratory director)

© 2010 College of American Pathologists. All rights reserved.

25

Proficiency Testing

- “Clinical Laboratory Improvement Amendments (CLIA), Proficiency Testing, Dos and Don’ts”
- <https://www.cms.gov/CLIA/downloads/CLIAbrochure8.pdf>
- Know your PT provider’s processes
- Be aware of the federally regulated analytes

© 2010 College of American Pathologists. All rights reserved.

26

Case 1: Proficiency Testing

- During a CAP inspection, the inspector decides to review the Proficiency Testing related to an elevated bilirubin in a tracer case. When he asks the laboratory technologist how he performs bilirubin Proficiency Testing, the technologist replies that he performs the test 3 times and averages the 3 results to report the PT result.
- What part of the Quality Management Plan will you consult to determine proper Proficiency Testing management and your oversight role?

© 2010 College of American Pathologists. All rights reserved.

27

Case 1: Proficiency Testing

- You review the Quality Management Plan and determine that Proficiency Testing requires testing in the same manner as patient testing
- Also you note that as Laboratory Director, you have primary responsibility for the proper management of Proficiency Testing
- You are able to anticipate the inspector's next question and follow-through, which is.....

© 2010 College of American Pathologists. All rights reserved.

28

Case 1: Proficiency Testing

- The CLIA inspector asks, "Is that the way you perform all patient testing for bilirubin?"
- The technologist replies, "No, patient testing is only performed once."
- Responsibilities now track into Personnel Competencies in the Quality Management Plan.
- Most preliminary actions can be anticipated by knowing the elements of the Quality Management Plan!

© 2010 College of American Pathologists. All rights reserved.

29

Occurrence Management

- "The laboratory is actively involved in capturing and analyzing information from nonconforming events to identify systematic laboratory problems."
- 3 methods: 1) random review (predetermined, internal), 2) lab detection (technologist detected), 3) external detection (physician, nurse, other customer)
- Capture and evaluate using these 3 methods, present data including trends at Quality Committee meetings

© 2010 College of American Pathologists. All rights reserved.

30

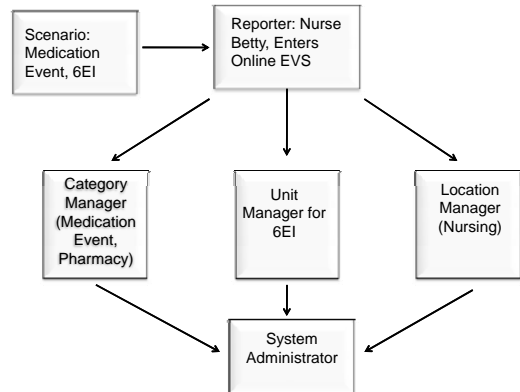
Occurrence Management: Some Options

- Paper-based event reporting
- Electronic event reporting systems
- Trend analysis for more frequent events
- Isolated serious events investigated, referred for root cause analysis



© 2010 College of American Pathologists. All rights reserved.

31



It Helps to Have a Ranking System

1. No Harm: Did not reach patient
2. No Harm: Reached Patient
3. Minimal Harm or Impact
4. Moderate Harm or Impact
5. Serious Harm or Impact
6. Patient Death
7. Unable to Determine

© 2010 College of American Pathologists. All rights reserved.

33

Assessments and Audits

- Describe individual lab external assessments in which the lab participates: CAP, FDA, AABB, CDC (select agents), state agencies, Joint Commission (JC)
- Define responsible parties (Lab Director)
- Describe internal assessment audits: CAP interim, annual environment of care audit (safety), personnel competencies

KEEP DESCRIPTIONS BRIEF AND REFER TO OTHER SOPs FOR DETAIL!

© 2010 College of American Pathologists. All rights reserved.

34

Documents and Records

- Define document control for your institution
- May refer to a master list for document management, other SOPs for document control
- Define responsibility for document management, review, signatures
- Define time periods for which documents must be retained, and after discontinuation

© 2010 College of American Pathologists. All rights reserved.

35

Documents and Records

- CLSI: "Laboratory Documents: Development and Control; Approved Guideline," 5th ed. GP2-A5, vol. 26, no. 12, Wayne, PA.

© 2010 College of American Pathologists. All rights reserved.

36

Process/Performance Improvement

- Define authority: laboratory director, quality management team
- Establish a quality committee to review PI projects (quarterly?)
- Define mechanism for organizing a PI project
- Assure all laboratory sections participate in a PI project and the lab as a whole adequately covers pre-analytical, analytical, and post-analytical processes

© 2010 College of American Pathologists. All rights reserved.

37

**Process/Performance Improvement:
Mechanisms for Improving Quality**

- FOCUS PDCA
- FMEA
- Six Sigma
- Lean

© 2010 College of American Pathologists. All rights reserved.

38

Performance Improvement (PI): FOCUS PDCA

- Find a process to improve
- Organize a team that knows the process
- Clarify current knowledge of the process
- Understand sources of process variation
- Select the process improvement

© 2010 College of American Pathologists. All rights reserved.

39

Performance Improvement (PI): FOCUS: PDCA

- Plan the improvement action
- Do test the action
- Check to determine the effects of the action
- Act to implement or solidify
- Shewhart (PDSA=Plan-Do-Study-Act)

© 2010 College of American Pathologists. All rights reserved.

40

Process Improvement: Interdisciplinary Activities

- List hospital or any other outside committees
- Examples: Infection Control, Transfusion Medicine, Emergency Medicine, Safety, Quality Committees
- Note interdisciplinary activities in the Quality Management Plan as a means of demonstrating integration of lab and hospital/administrative quality management programs

© 2010 College of American Pathologists. All rights reserved.

41

Facilities and Safety

- The importance of a laboratory safety audit!
- Examples, can be coordinated with institutional "environment of care" for Joint Commission
- Annual audit of lab sections
- Scoring of audits (to 100%) allows intra-laboratory comparison
- Winning lab section each year gets a pizza party!

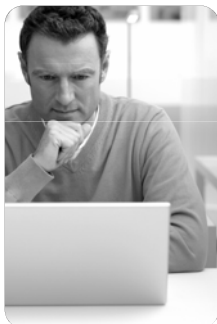


© 2010 College of American Pathologists. All rights reserved.

42

Information Management

- Indicates who has authority to approve authorization of users
- States that policies and procedures exist for data access security and transfer integrity
- Lists representative security measure categories (password, user profile, access level groups)
- Describes security from viruses
- System checks quarterly or other schedule
- Annual summary report of integrity, accuracy of data transmission
- Describes compliance with HIPAA



© 2010 College of American Pathologists. All rights reserved.

43

Customer Service and Satisfaction

- Physicians, nursing staff, other clients
- State survey frequency (no less than every 2 years)
- Phlebotomy, can be a patient survey administered by hospital
- Employee satisfaction
- Role of a Patient Relations office
- Note any institutional satisfaction initiatives (C-ICARE)
- Notification processes for errors, commercial service issues

© 2010 College of American Pathologists. All rights reserved.

44

Risk Assessment: A 13th Category?

- Institutional priorities (cancer care, cardiovascular disease)
- Known lab operations problems
- Customer feedback
- Recurring incidents and sentinel events
- * **Work with your Risk Management Department!**
Identify control activities that mitigate risks. CLIA and CAP have identified 90% of likely generic risks.

© 2010 College of American Pathologists. All rights reserved.

45

Case 2: Creatinine Levels

- As Laboratory Director, you are informed by your Chemistry Section Leader that the creatinine levels are running "high."
- The Section Leader has called the vendor and begun an investigation into equipment performance and reagents.
- Your institution specializes in performing kidney transplantations.
- What element of the Quality Management Plan would guide you in this scenario?

© 2010 College of American Pathologists. All rights reserved.

46

Case 2: Creatinine Levels

- Three elements of your Quality Management Plan are important references for this incident: 1) Equipment, 2) Supplies and 3) Risk Management
- The Equipment and Supplies sections refer you appropriately to the sources for the ongoing investigation
- The important element from a Laboratory Director's perspective is Risk Management

© 2010 College of American Pathologists. All rights reserved.

47

Case 2: Creatinine Levels

- The Risk Management section emphasizes correlating risks for your patient population, in this case subjecting patients to unnecessary kidney biopsies on the kidney transplantation service
- You note the Risk Management contacts in the Elements and call an appropriate contact to start a clinical investigation to assure no unnecessary procedures have occurred based on creatinine results

© 2010 College of American Pathologists. All rights reserved.

48

Ways a Quality Management Plan Contributes to Operational Efficiencies

- Provides for real-time review of personnel orientation, training, competency records
- Defines document control as a real-time activity, constant review and approval schedules
- Continuous management of safety and environment of care
- Constant inspection readiness
- Real-time event reporting and occurrence management
- It is the BLUEPRINT for all quality activities!

© 2010 College of American Pathologists. All rights reserved.

49

The Culture of Quality

- Leadership determines the attitude toward any activity
- As leaders, it is our responsibility to embrace Quality if not for personal reasons, for the purposes of patient care
- Extends the Culture of Quality to all laboratory personnel

© 2010 College of American Pathologists. All rights reserved.

50

Pearls: Make It *Real Time!*

- Personnel and document records
- Performance improvement
- Safety management
- Equipment and supplies
- Occurrence management
- Satisfaction survey review
- Information technology management
- Accreditation and other assessments

© 2010 College of American Pathologists. All rights reserved.

51

Examples Provided For Your Reference

- Quality Management Plan
- Environment of Care Checklist (for safety or facility audits)



© 2010 College of American Pathologists. All rights reserved.

52

Tools to Put QM Into Practice



© 2010 College of American Pathologists. All rights reserved.

53

Toolkit

Toolkit Contents

© 2010 College of American Pathologists. All rights reserved.

54

Documents being reviewed

- Slide 56 – QM Cycle Document
- Slide 57 QM-F001 QA Monitoring and Performance Improvement
- Slide 58 QM-F002 Quality Oversight Committee Report
- Slide 59 QM-F003 Annual Assessment Flowchart
- Slide 60 QM-F004 Individual QM Monitor/Indicator Assessment Form
- Slide 61 QM-F006a-d Annual Appraisal of the QM Plan for Effectiveness
- Slide 62 QM-F007 Root Cause Analysis Check Sheet
- Slide 63 QM-F009 Quality Management Monitor Spreadsheet

© 2010 College of American Pathologists. All rights reserved.

55

Cover Document – QM Cycle

1. Includes where toolkit documents would be used in the QM Cycle.
2. Describes the QM continuous cycle from plan initiation to revising the plan.

© 2010 College of American Pathologists. All rights reserved.

56

QA Monitoring and Performance Improvement Form – QM-F001

1. Designed for monthly monitoring.
2. Includes the laboratory section, indicator, monitor frequency, threshold, year monitor initiated, and actions taken.

© 2010 College of American Pathologists. All rights reserved.

57

**Quality Oversight Committee QM Report –
QM-F002**

1. Used in conjunction with the QA Monitoring and Performance Improvement Form – QM-F001.
2. Designed to review the 12 elements of the QM plan and the Monitors/Indicators.

©2010 College of American Pathologists. All rights reserved.

58

Annual Assessment Flowchart – QM-F003

1. Describes the process for assessing the QM Monitors/Indicators annually.
2. Aids in helping the laboratory staff determine whether to continue, discontinue, or setup a root cause analysis for the monitors/indicators.

©2010 College of American Pathologists. All rights reserved.

59

**Individual Quality Management Monitor/Indicator
Assessment Form – QM-F004**

1. This form is designed to complete electronically or it can be printed and completed manually.
2. Use to evaluate each monitor individually to determine if the monitor requires further assessment.

©2010 College of American Pathologists. All rights reserved.

60

**Annual Appraisal of the QM Plan for Effectiveness
- QM-F006a - QM-F006d**

1. There are four forms in the toolkit for the annual assessment. Each form can be completed electronically or printed and completed manually.
2. The forms include versions for the assessment of the 12 QM Plan elements and without the enumerated 12 elements.

©2010 College of American Pathologists. All rights reserved.

61

Root Cause Analysis Check Sheet - QM-F007

1. Designed to conduct an effective, complete Root Cause Analysis (RCA).
2. Helpful tool when laboratory staff fail to achieve the desired threshold for their monitors.

©2010 College of American Pathologists. All rights reserved.

62

**Quality Management Monitor Spreadsheet -
QM-F009**

1. Aids in tracking monitors.
2. Uses colors to accentuate areas that require improvement.
3. Aids in ensuring that the laboratory QM Plan addresses all the CAP Patient Safety Goals.
4. There are versions for Office 2003 and 2007.

©2010 College of American Pathologists. All rights reserved.

63

Safety /EOC Checklist Audit Template – QM-F011

- Example of a Safety Audit / Environment of Care Rounds Checklist.
- This document can be used to assess laboratory areas for safety compliance.

©2010 College of American Pathologists. All rights reserved.

64

Other Toolkit Documents

1. QM-F005 – New QM Monitor Flow Chart
2. QM-F008 – QM Monitors Currently in the June 17, 2010 Checklist Version
3. QM-F010 – Example QM Plan

©2010 College of American Pathologists. All rights reserved.

65

References

- Application of a Quality Management System Model for Laboratory Services: Approved Guideline, 3rd Ed. GP26-A3 CLSI, 2004
- A Quality Management System Model for Healthcare: Approved Guideline, 2nd Ed. HS1-A2, CLSI, 2004
- Quality Manual Preparation Workbook for Blood Banking, 2nd Ed. L. M. Berte, 2005, AABB.
- Quality Management in Clinical laboratories, P. Valenstein, CAP, 2005.
- Laboratory Accreditation Manual (most current copy), College of American Pathologists, 325 Waukegan Rd. Northfield, IL, 60093
- The Key to Quality-Fundamentals for Implementing a Quality Management System in the Clinical Laboratory, CLSI, 940 W. Valley Rd., Suite 1400, Wayne, PA, 19087, 2006.

© 2010 College of American Pathologists. All rights reserved.

66

Thank You!

Elizabeth A. Wagar, MD
Professor and Chair
Department of Laboratory Medicine
Univ. of Texas M. D. Anderson Cancer Center
eawagar@mdanderson.org
713-792-6313

© 2010 College of American Pathologists. All rights reserved.

67

Panel Members

- Jean Ball
- Trudy Darden
- Susan Donatell
- Carolyn Gandy
- Adrienne Malta
- Bessie Motley
- Joan Rose

© 2010 College of American Pathologists. All rights reserved.

68