COLLEGE of AMERICAN PATHOLOGISTS

“Quality Management – Making it Meaningful”

Maximize Your Existing Quality Management System to Deliver Greater Value

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Objectives

Discuss	Discuss quality management requirements in the CAP Laboratory Accreditation Program
Suggest	Suggest best practices in quality management to facilitate compliance with these requirements
Recognize	Recognize how a robust QMS can help a laboratory achieve benefits without compromising test results
Explore	Explore how occurrence management and root cause analysis can improve operations

CAP Laboratory Accreditation Program – Quality Requirements

Where Do I Find Quality Management Requirements in CLIA'88?

- CMS uses "Quality Control" to describe quality management system requirements

- In no instance (either the 1992 or 2003 version of CLIA '88) is "quality control" used specifically for what we consider to be QC

Quality Management Plan (GEN.13806 Documented QM Program)

- The laboratory has a documented quality management (QM) program
  - NOTE: There must be a document that describes the overall QM program. The document need not be detailed, but should spell out the objectives and essential elements of the QM program

Quality Management Plan (GEN.16902 QM Implementation)

- **For laboratories that have been CAP accredited for more than 12 months, the QM plan is implemented as designed and is reviewed annually for effectiveness.**
  - **NOTE: Appraisal of program effectiveness may be evidenced by an annual written report, quality meeting minutes, revisions to laboratory policies and procedures, or revisions to the QM plan, as appropriate**

Quality Management Plan (GEN.20100 QM Extent of Coverage)

- The QM program covers all areas of the laboratory and all beneficiaries of service
  - More than the monitors of performance
  - Can be used to outline the laboratory's approach to the CLIA Quality Systems requirements
  - Can be used for the entire laboratory, but typically individual sections have different aspects of service and may be better served with section-specific programs

Quality Management Plan (GEN.20208 QM Patient Care Services)

- The QM system includes a program to identify and evaluate errors, incidents and other problems that may interfere with patient care services
  - Organized program for documentation
  - Internal and external (outside) sources such as complaints
  - Clinical, rather than business/management issues
  - Root cause analysis of any unexpected event involving death or serious physical or psychological injury, or risk thereof
  - Demonstrates appropriate risk-reduction activities based on such root cause analyses

Quality Management Plan (GEN.20316 QM Indicators of Quality)

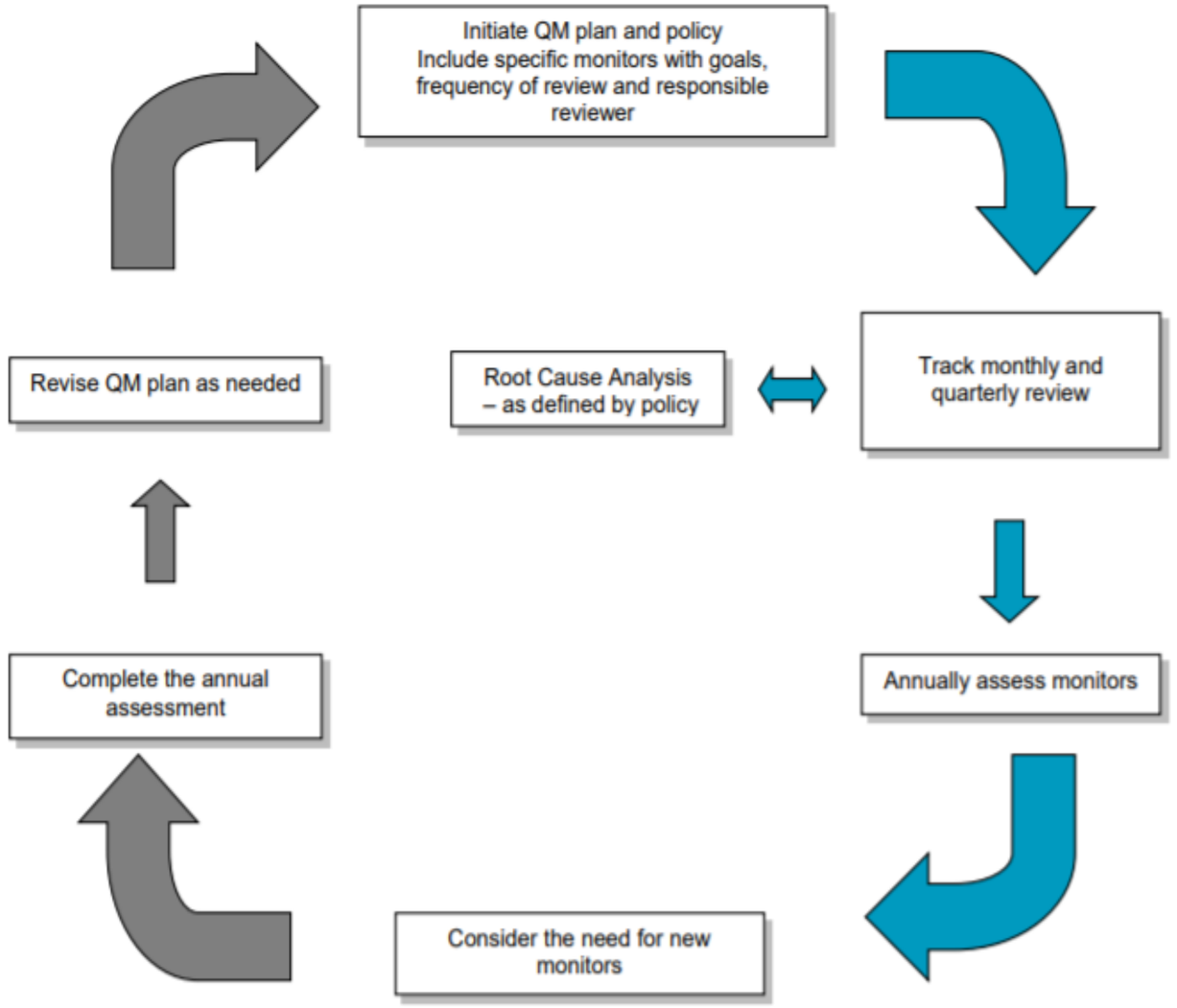
- **The QM program includes monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases**
  - **Critical to patient outcome and/or affect many patients**
  - **Compare performance against available benchmarks**
  - **Number of indicators consistent with the scope of care**

QM Indicators of Quality – Tips and Tricks

- For a small laboratory, a single monitor (such as turnaround time or clinical correlation) may be sufficient and appropriate
- Although external benchmarks are desirable, historic performance may be used to determine targets of acceptable performance
- Consider how you set your thresholds
  - Meaningful
  - Achievable

QM Indicators of Quality – Tips and Tricks (cont.)

- The annual review should not only assess performance, but look for ways to improve performance
  - Noting “continue to monitor” or “stable and adequate” is not adequate
- Monitors that are stable and acceptable should be evaluated for replacement



Process-Oriented Quality Management:
Best Practices and Benefits

Looking at QM from a PROCESS perspective…

Building quality into our daily work means:

The right test on

The right patient at

The right time for

The right cost delivered to

The right clinician

CLSI Quality System Essentials (QSE) of a Quality Management System (QMS)

1. Organization
2. Customer focus
3. Facilities and safety
4. Personnel
5. Purchasing and inventory
6. Equipment
7. Process management
8. Documents and records
9. Information management
10. Nonconforming event management
11. Assessments
12. Continual improvement

Developing a Quality Management Driven Laboratory

Focus on technical procedures

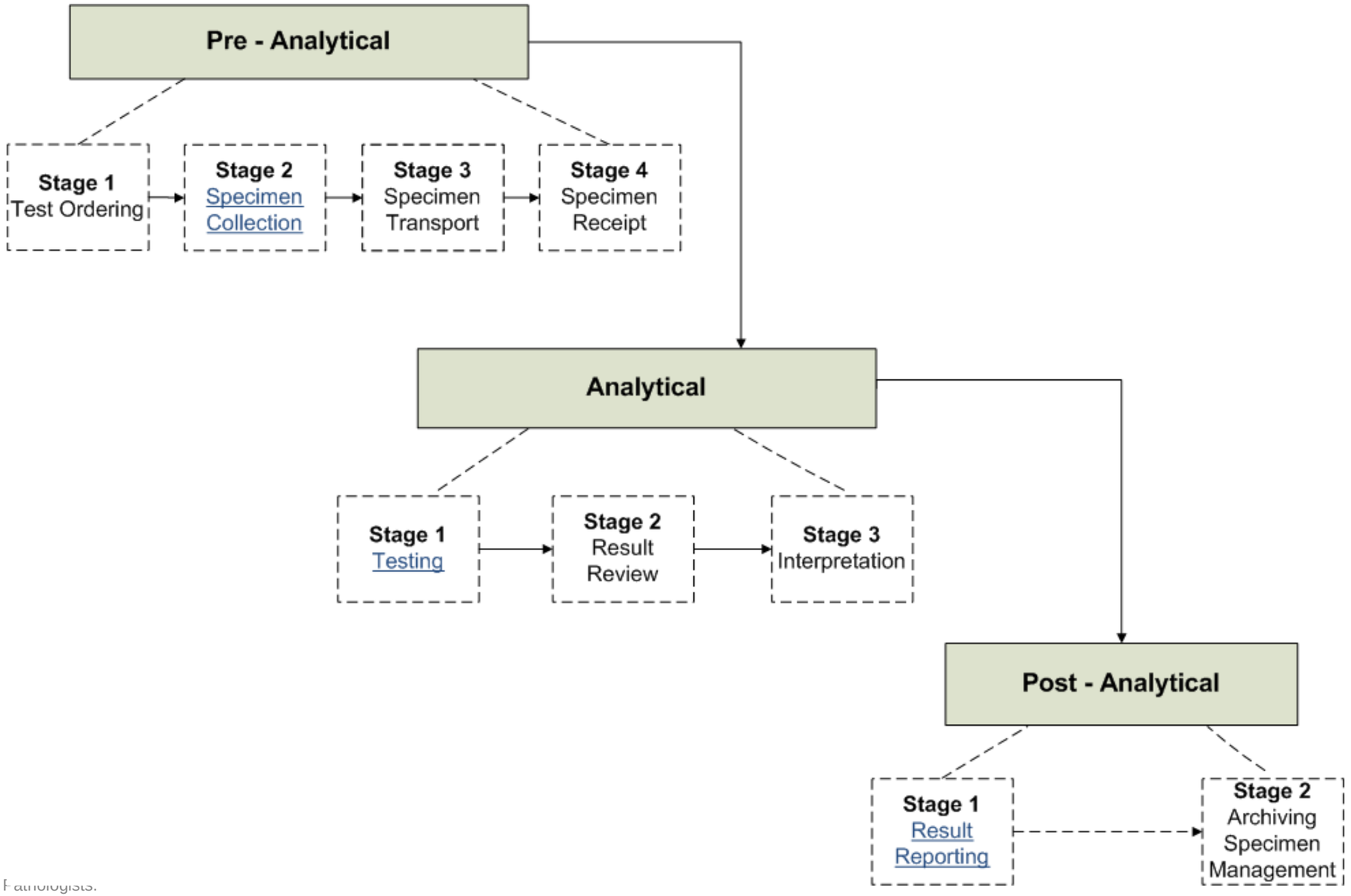
Intense PT monitoring

Rigor in competency assessment of technical staff

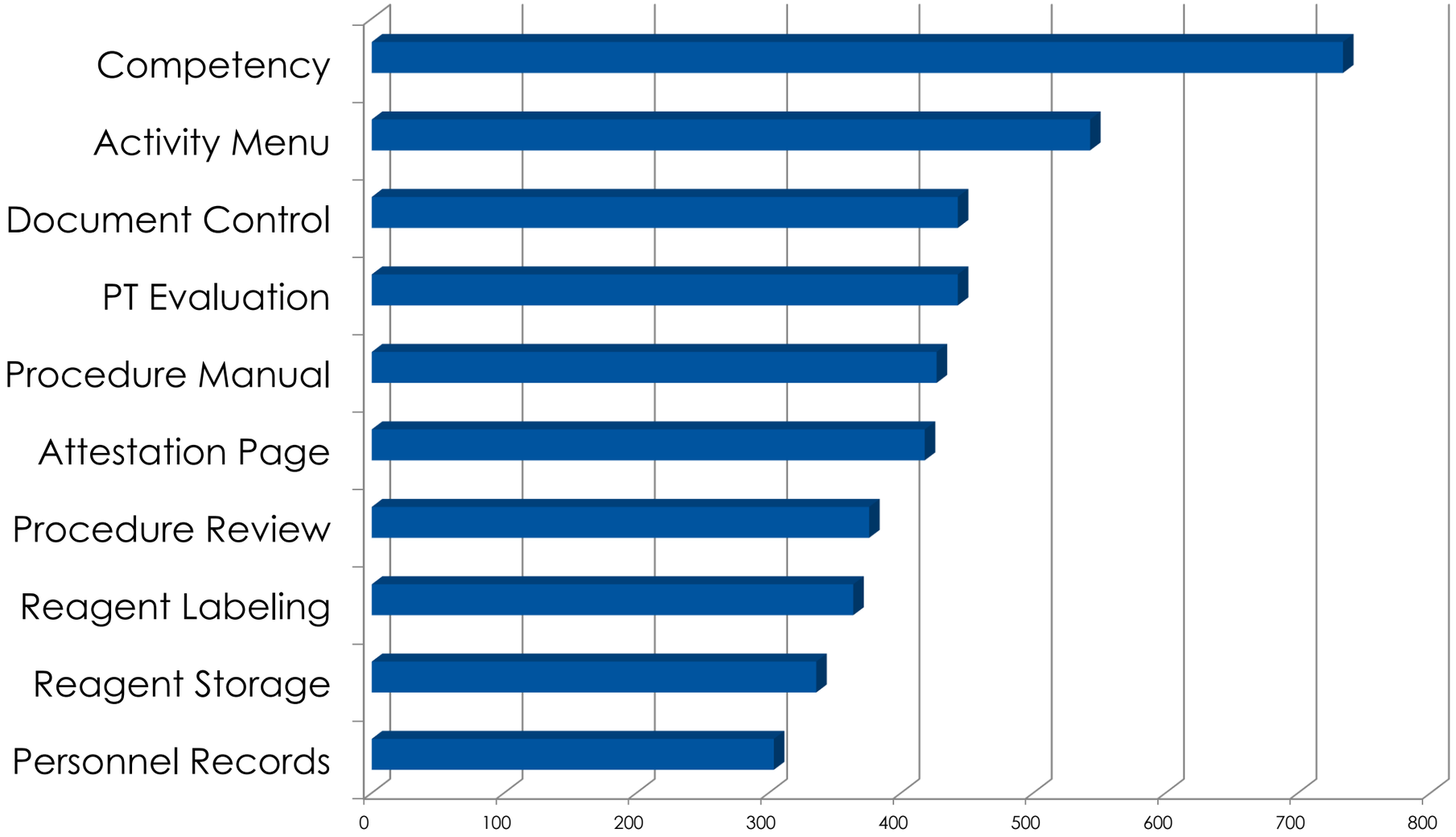
Problem investigation or occurrence management:

- Conduct in-depth root cause analysis
- Focus on process, systems integration, outcomes
- Evolve beyond containment into prevention
- Develop effective corrective actions

Process Focus



How can a process-oriented QMS help address common deficiencies?

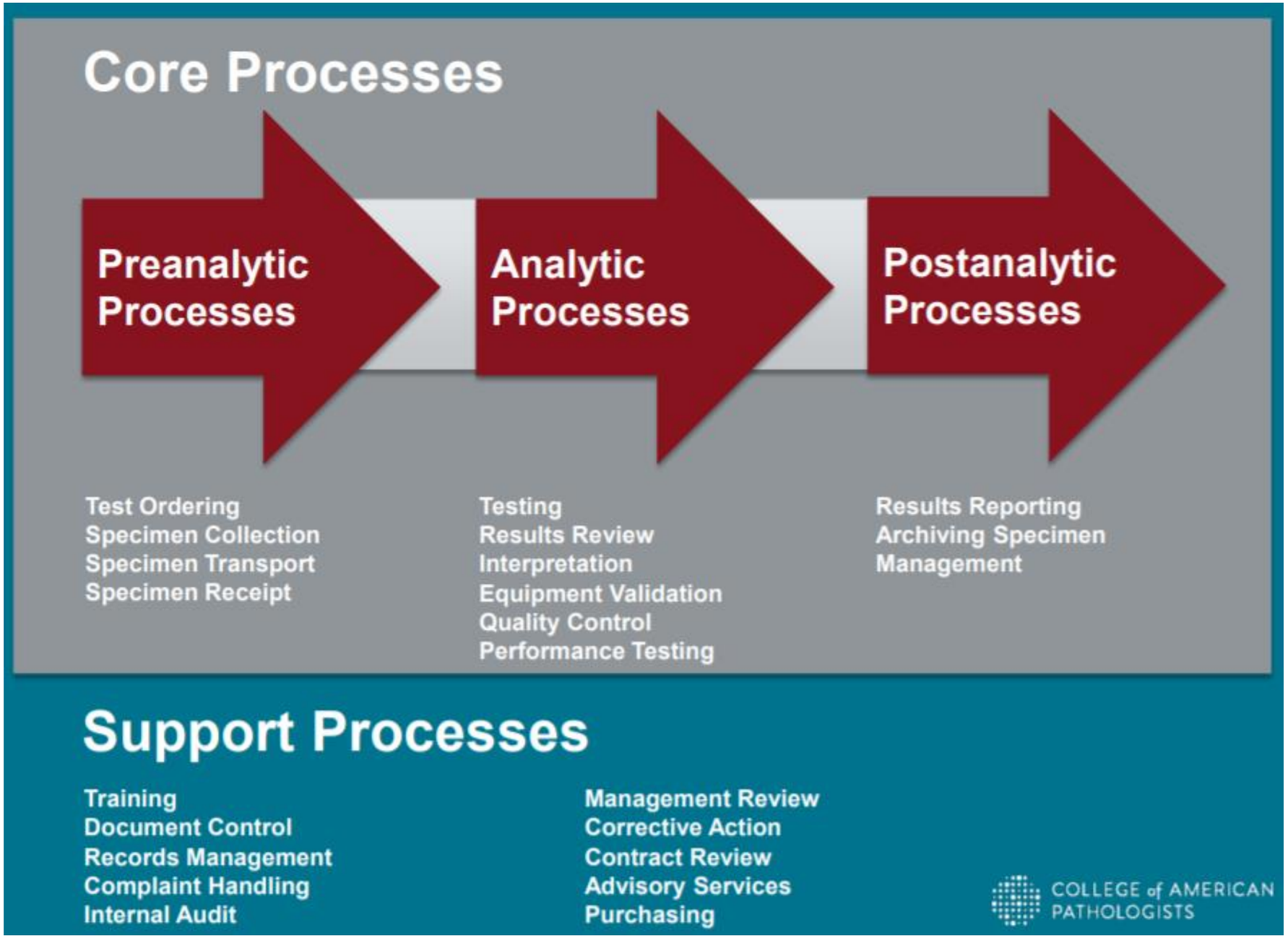


Match Them Up!

• Competency Assessment	• QSE #4 Personnel
• Activity Menu	• QSE #1 Organization
• Document Control	• QSE #8 Documents/Records
• PT Evaluation	• QSE #7 Process Management
• Procedure Manual	• QSE #8 Documents/Records
• Attestation Page	• QSE #7 Process Management
• Procedure Review	• QSE #8 Documents/Records
• Reagent Labeling	• QSE #5 Purchasing/Inventory
• Reagent Storage	• QSE #5 Purchasing/Inventory
• Personnel Records	• QSE #8 Documents/Records

In order to correct process problems, you have to identify them

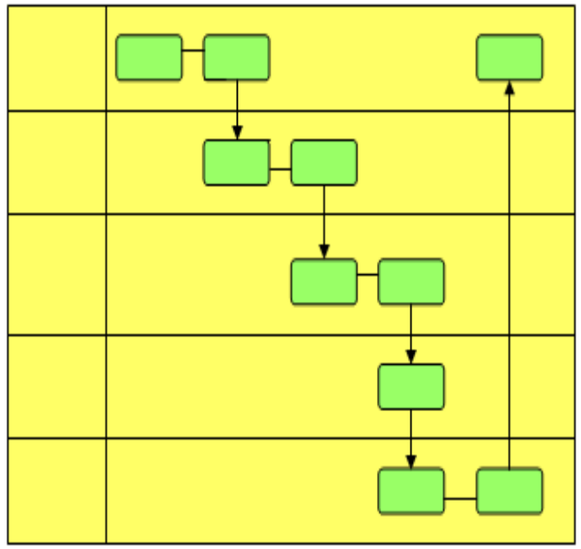
- Use QMS elements to identify problems before they get big
  - Internal audits
  - Management review
- Go beyond “putting out fires”



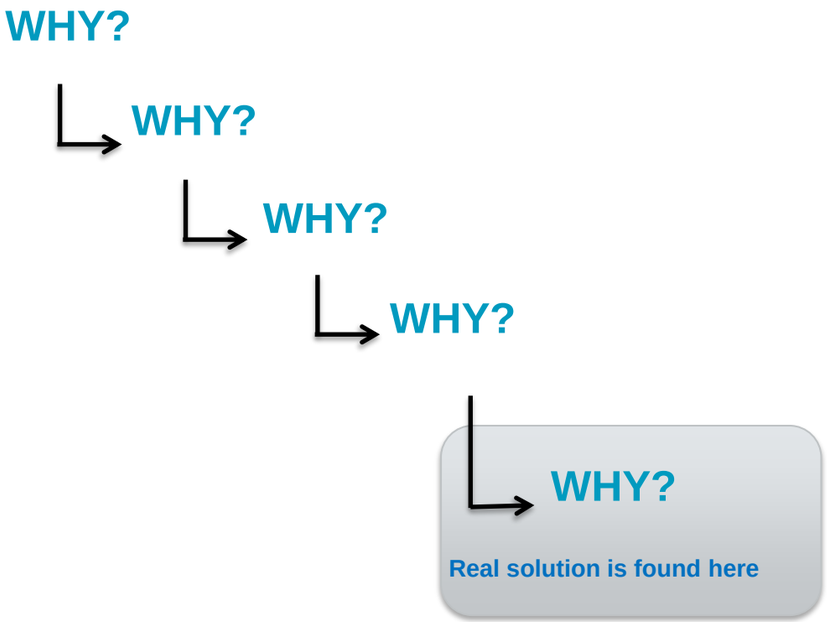
Occurrence Management – Best Practices

- **Use the right root cause analysis tool for the situation**

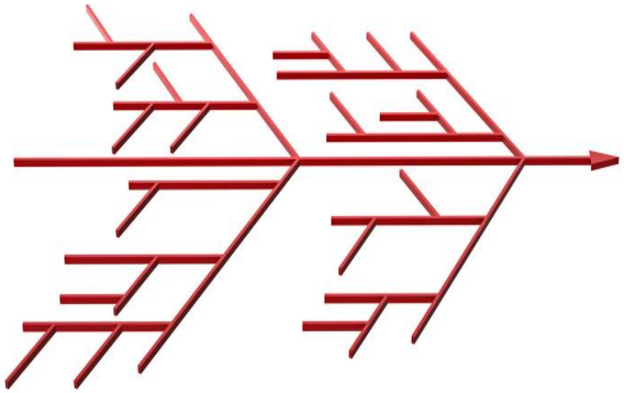
Process Mapping



Five Why's



Fishbone Diagram



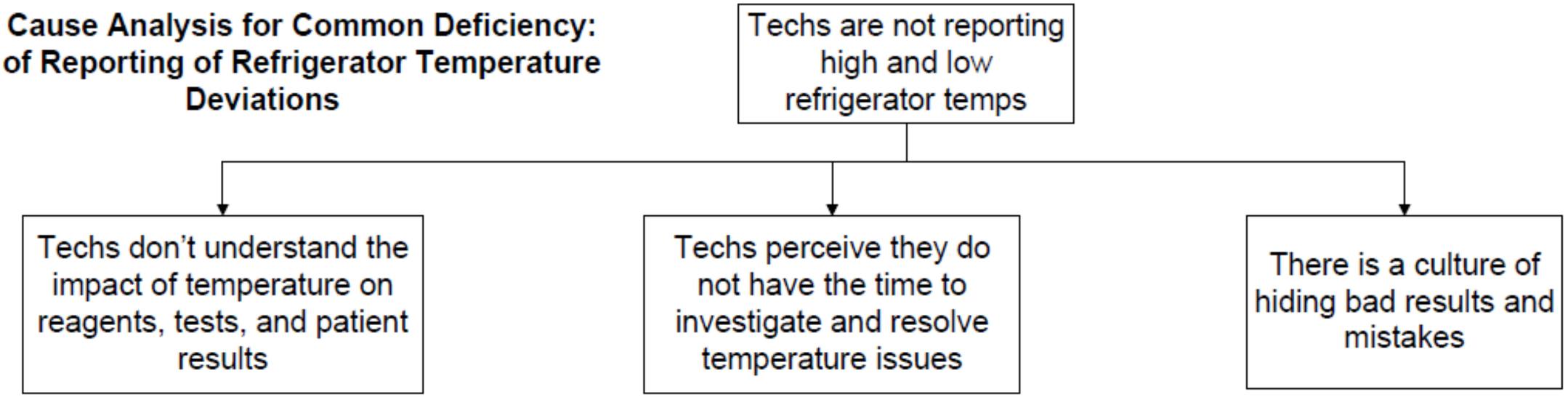
Occurrence Management – Best Practices (cont.)

Don’t look for errors….

look for FAILURES!

Issue	Number of Errors
Pre-Analytical	
Specimen labeling errors / Recollection	232
Quantity Not Sufficient / Recollection	149
Requisition incorrect	33
Patient injured during phlebotomy	158
Patient unhappy with phlebotomy customer service	31
Incorrect tube used	66
Specimen ruined	102
Specimen lost in transport / recollection	241
Tissue sample incorrectly cut/ modification of specimen in lab	141
Specimen delayed in transport	151
Data entry error or other LIS problem	50
Analytical	
Multiple QC re-runs	48
Post-Analytical	
Results not reported	32
Delay in reporting results	101
Reporting to wrong person	199
Incorrect results because of post-analytic data entry errors	100

Root Cause Analysis for Common Deficiency: Lack of Reporting of Refrigerator Temperature Deviations



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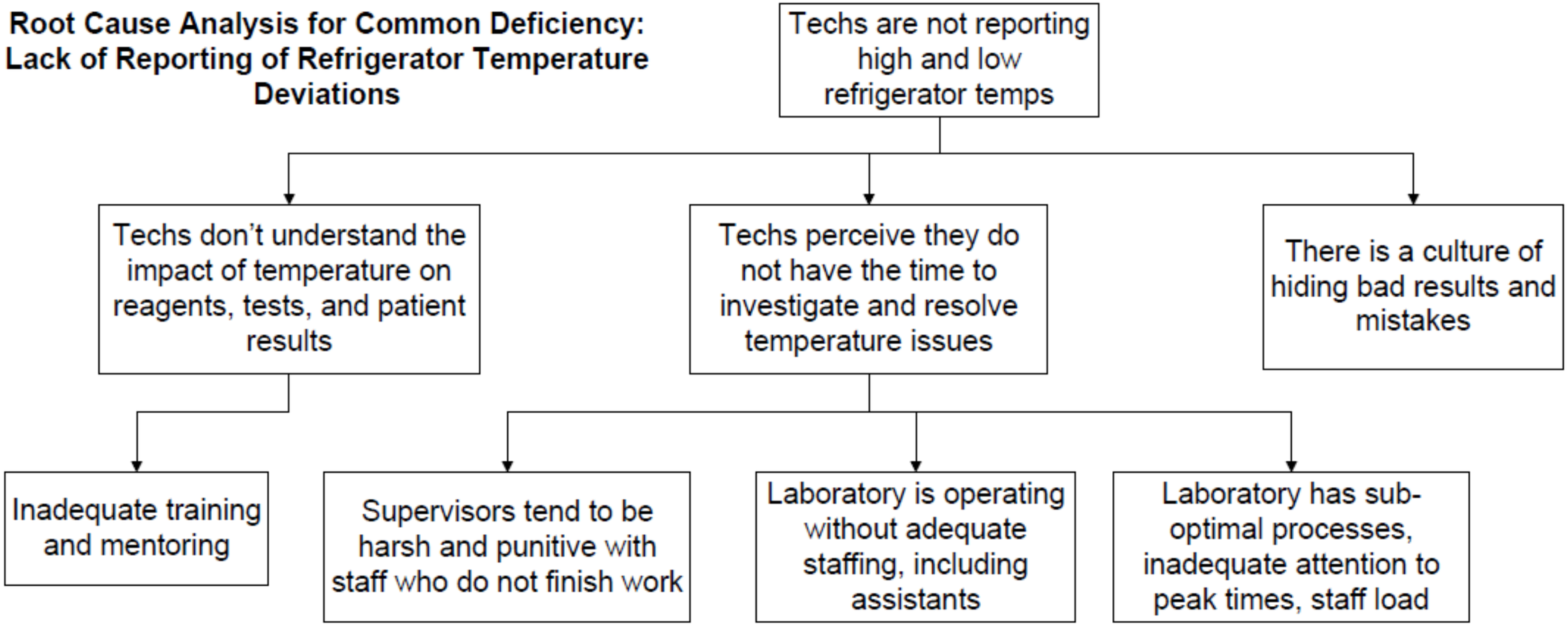

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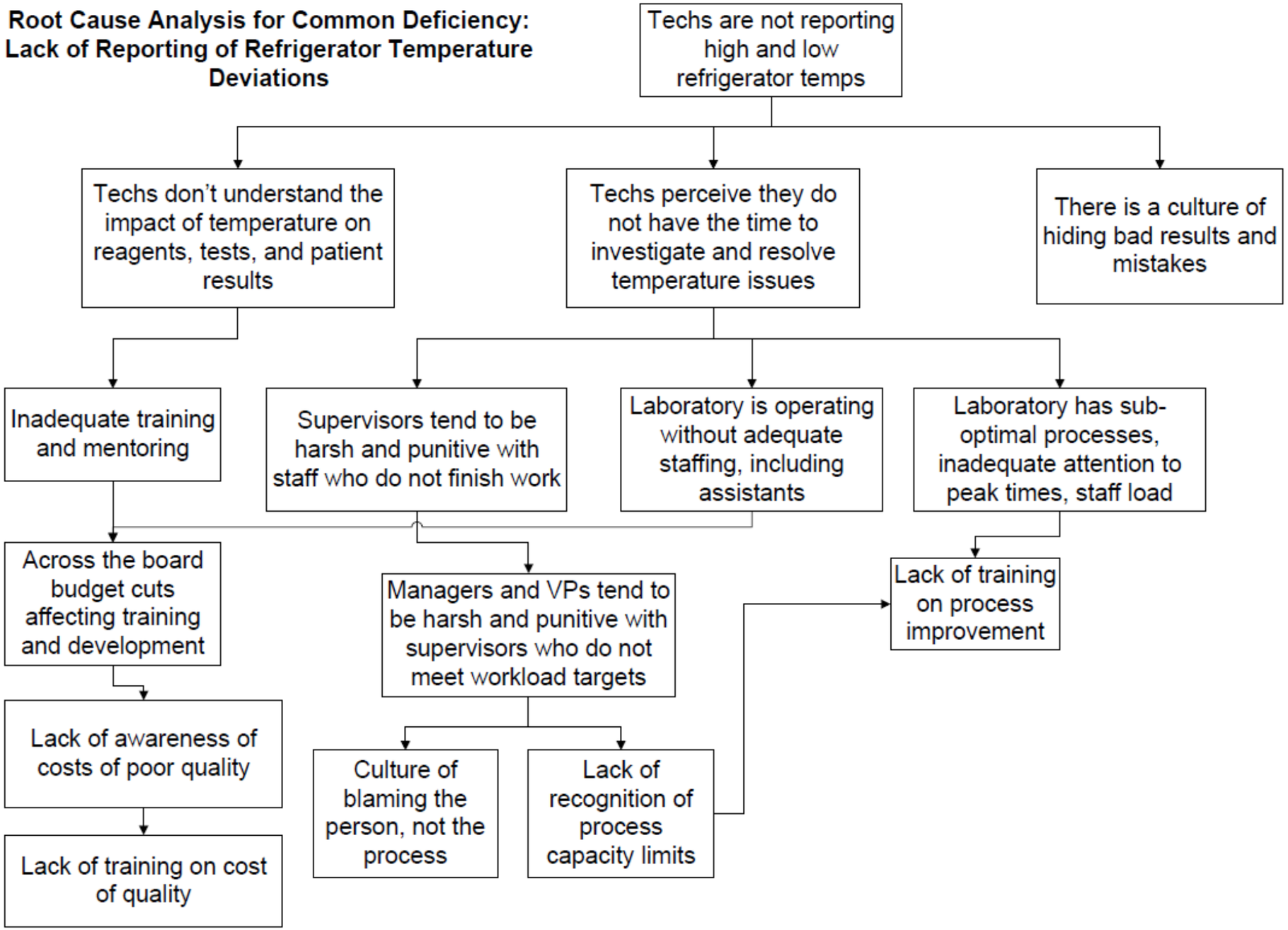

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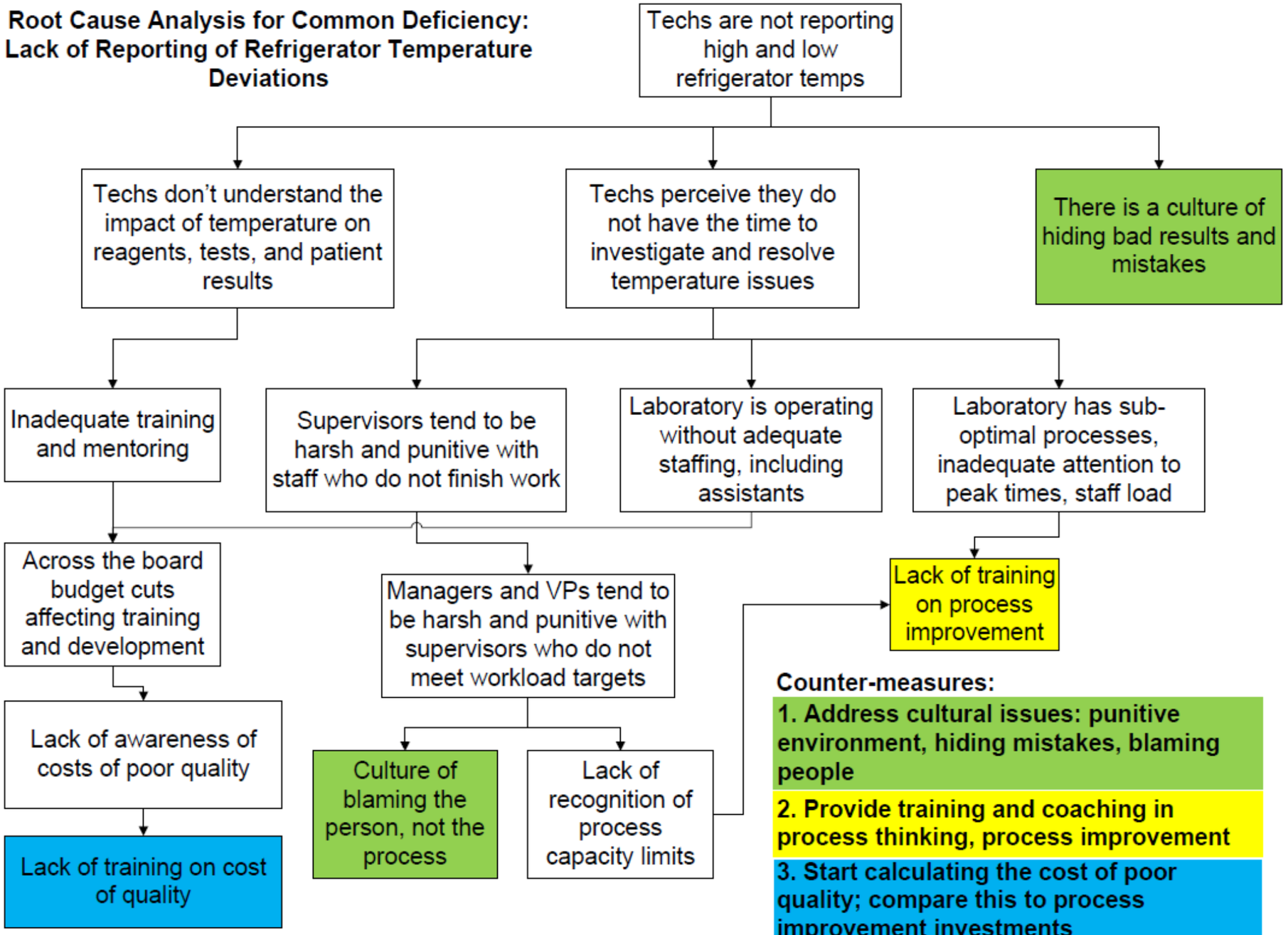


What is the Intent of Quality Management?

The Intent	Not the Intent
• Create a system as failure resistant as possible • Help identify opportunities for improvement • Involve and empower staff • Instill confidence in staff that the system will catch mistakes before they become a problem • Reduce errors by doing things right the first time	• Be a tool to meet accreditation requirements • Be a “band-aid” fix for individual mistakes

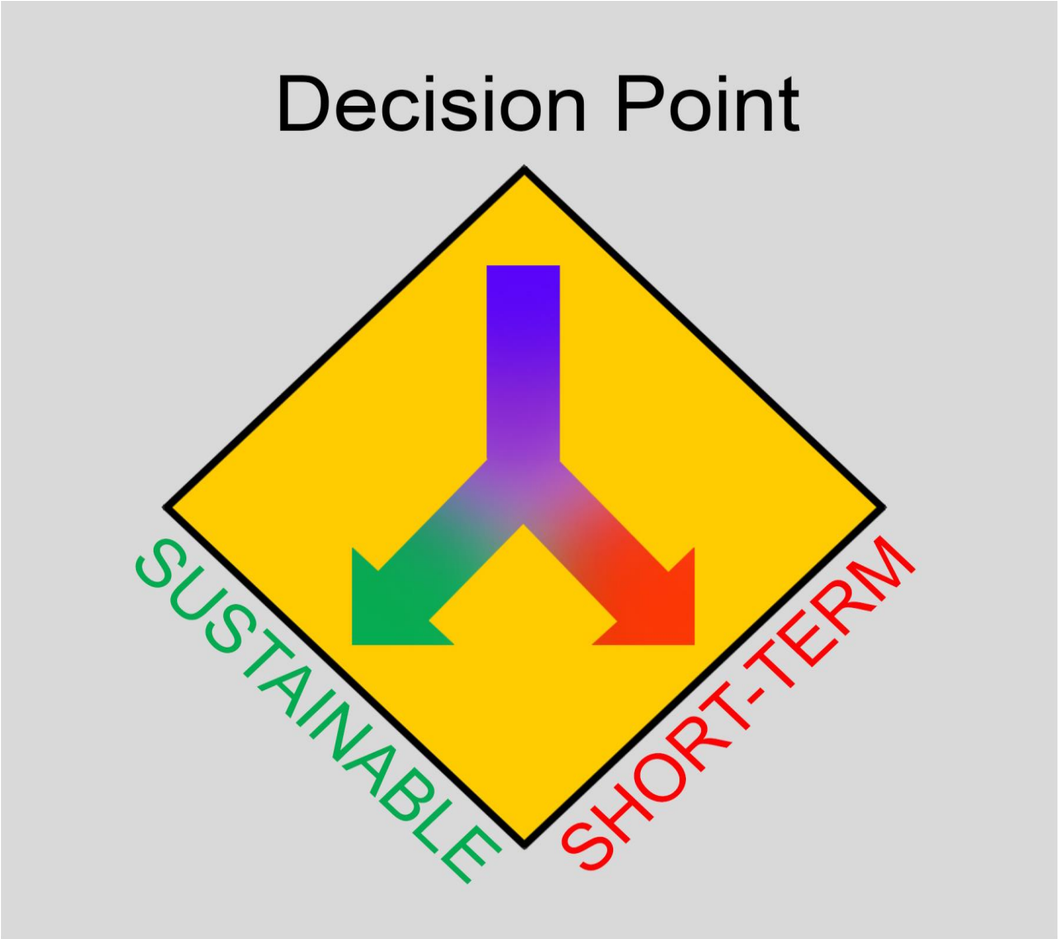
The Value in Process-Oriented Quality Management: A Client's Perspective

Value of Meaningful Quality Management

- Inspection Readiness
  - *“the lab is the one department I don’t worry about”*
- Reduce number of CAP inspection deficiencies
- Increase market share in competitive markets
- Maximize gains from LEAN processes
- Extend laboratory quality initiatives outside normal laboratory boundaries
- Engage staff in the quality process
- Raise the bar on service quality for all patients and customers

Ways to reduce costs…which would you rather apply?

- **Process control**
- **Solve problems at root**
- **Prevention**
- **Quality focus**



- **Staff reductions**
- **Percentage cuts in budget across all departments**

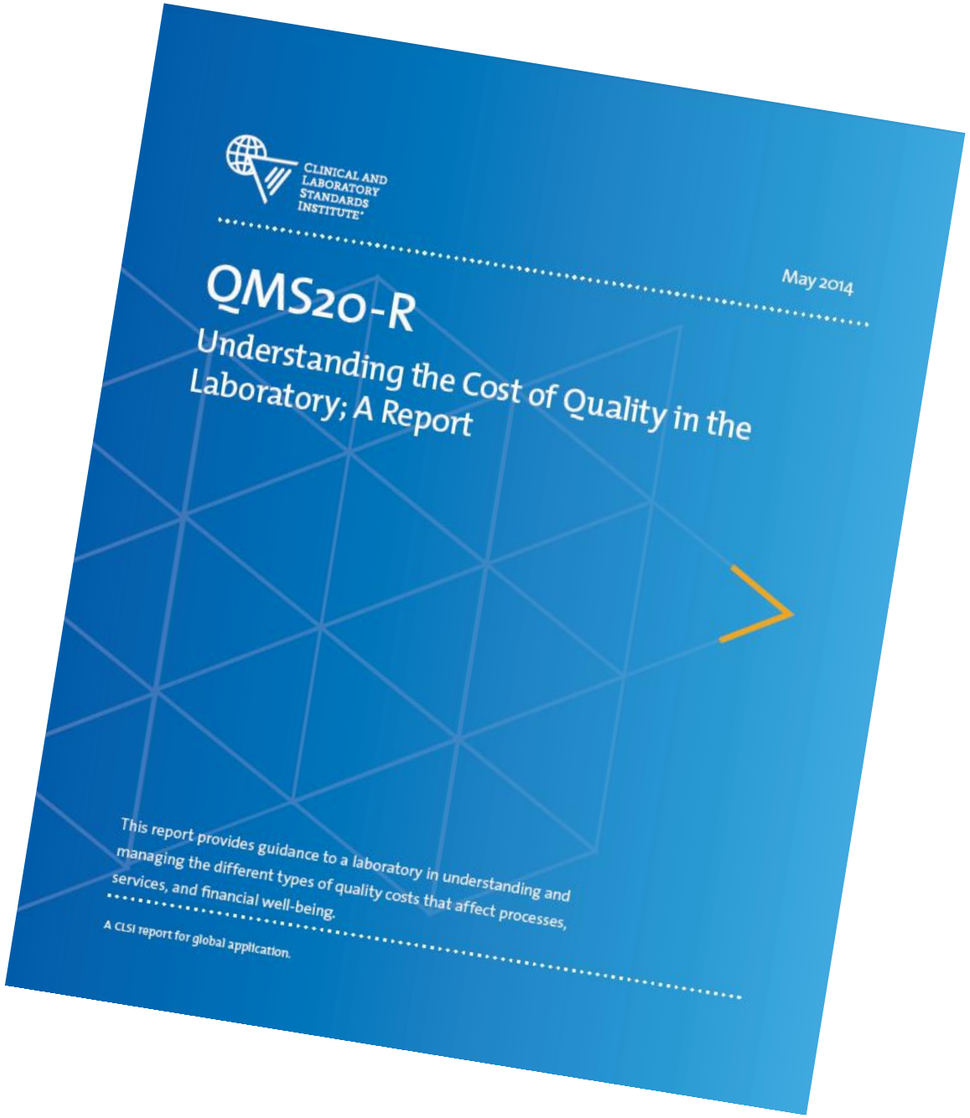
Options for Quality Education and Accreditation Preparation

Quality Management Education Options

- **CAP Education**
  - **Laboratory Medical Director Advanced Practical Pathology Program (LMD AP[3])**
  - **Quality Management Education Resources (QM*Ed*), eg:**
    - **Root Cause Analysis**
    - **Internal Auditing**
    - **Quality Manual Development**
    - **Management Review**

Quality Management Education Options

- **CLSI Guidelines**
  - **GP2-A5**
    - **Laboratory Documents: Development and Control**
  - **QMS20-R**
    - **Understanding the Cost of Quality in the Laboratory**
  - **QMS01-A4**
    - **Quality Management System: A Model for Laboratory Services**



Quality Management Resources

The CAP website!

Log in to eLab Solution Suite!

Accreditation Resources!

- **FAQs**
- **Videos**
- **Webinars**
- **Examples/templates**

Quality Management Resources (cont.)

Focus on Compliance

This library of past webinars focuses on timely compliance topics.

2021

CAP Accreditation During the COVID-19 Crisis: A Novel Approach

Focus on Compliance (FOC) webinar that addresses the COVID-19 pandemic and its impact on CAP accredited laboratories.

- Presentation Slides (PDF)
- Question & Answers (PDF)
- Toolkit (ZIP)

Preanalytical Errors: Taking the Garbage Out

Focus on Compliance (FOC) webinar that addresses preanalytical errors.

- Presentation Slides (PDF)
- Question & Answers (PDF)

Responding to Deficiencies: Clear, Concise, and Complete Compliance

Focus on Compliance (FOC) webinar that addresses responding to deficiencies.

- Presentation Slides (PDF)
- Question & Answers (PDF)
- Toolkit (ZIP)

Focus on Compliance Webinar Laboratory Safety: Think Outside the Cabinet

Focus on Compliance (FOC) webinar that addresses safety in the laboratory. Learn how to improve compliance with safety requirements.

- Presentation Slides (PDF)
- Question & Answers (PDF)
- Toolkit (ZIP)

Quality Management Resources (cont.)

Fast Focus on Compliance Mini-training Vignettes

To supplement the inspector training courses, Fast Focus on Compliance mini-training vignettes give inspectors practical approaches to handle new and perplexing topics using real-world examples.

Summation Solutions		Take the Survey
Exploring and Eliminating Expungements		Take the Survey
Inspecting Laboratory Director Responsibility: Delegation Junction What's Your Function?		Take the Survey
Cite or Recommend? Know Before you Go!		Take the Survey

Quality Management

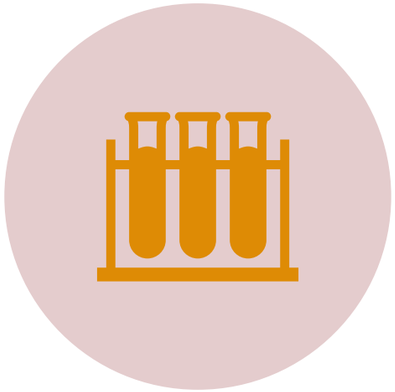
Quality is never an accident.

It is always the result of intelligent effort.

That’s Quality Management!

Two things…

DO YOUR PEOPLE KNOW
WHAT THEY ARE DOING?



DOES YOUR PROCESS
PRODUCE QUALITY RESULTS?

Both answers lie within your

Quality Management System!!!

Thank You!!!

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