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# “Quality Management – Making it Meaningful”

## Maximize Your Existing Quality Management System to Deliver Greater Value

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**Inspection Services Team Lead**

# Objectives

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

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# 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.**
  - **Note: QC activities are called "control procedures. " The samples are called "control material" or "controls."**

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# Current CLIA Requirements

## Subpart K--Quality System for Nonwaived Testing

### Sec. 493.1200 Introduction

**The laboratory must have:**

a) **Written policies and procedures that implement and monitor a quality system,**

b) **Quality assessment ensuring continuous improvement through ongoing monitoring that identifies, evaluates and resolves problems with**

c) **Components of the quality system that are appropriate for the testing the laboratory performs, services it offers, and clients it serves**

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# Current CLIA Requirements

**493.1230 Condition: General laboratory systems**

- **Confidentiality**
- **Specimen integrity**
- **Complaint investigations**
- **Communications**
- **Personnel competency**
- **Proficiency testing evaluation**
- **General laboratory systems quality assessment**

**493.1240 Condition: Preanalytic systems**

- **Test request**
- **Specimen handling and referral**
- **Preanalytic systems quality assessment**

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# Current CLIA Requirements

**493.1250 Condition: Analytic Systems**

- **Procedure manual**
- **Equipment, materials and supplies**
- **Performance specifications, maintenance and function checks**
- **Calibration and calibration verification**
- **Control procedures**
- **Comparison of test results**
- **Corrective actions**
- **Analytic systems quality assessment**

**493.1290 Condition: Postanalytic systems**

- **Test report**
- **Postanalytic systems quality assessment**

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# 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**
  - ***The depth and coverage of the QM plan is not specified; a broad-ranging plan can cover all of the CLIA Quality System requirements***
  - ***Although the QM plan is not limited to monitors of key indicators of quality (see GEN. below), this is often the main focus of inspectors***

# 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**
  - ***This is often the weakest part of the QM plan implementation.***
  - ***Although a formal report is not required, demonstration of revisions based on the review and <u>why these revisions were made</u> would be necessary to show compliance***
    - ***This can be integrated into a revised annual QM plan***

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

- **The QM program covers all areas of the laboratory and all beneficiaries of service.**
  - Although the QM program covers more than the monitors of performance as mentioned above, this is often the focus of an inspection
  - The QM plan itself can be used to outline the laboratory (or section's) approach to the CLIA Quality Systems requirements in Subpart K
  - A single QM plan 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

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# 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, should be emphasized**
    - **Laboratories need to perform root cause analysis of any unexpected event involving death or serious physical or psychological injury, or risk thereof (including “near misses” and sentinel events)**
    - **Laboratories need to be able to demonstrate appropriate risk-reduction activities based on such root cause analyses**

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# 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**
    - **Patient/Specimen Identification**
    - **Test Order Accuracy**
    - **Specimen Acceptability**
    - **Stat Test Turnaround Time**
    - **Critical Value Reporting**
    - **Customer Satisfaction**

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

- **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**
- **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**

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# Quality Management - Document Control (GEN.20375)

- **The laboratory has a document control system to manage policies, procedures, and forms.**
  - **All policies, procedures and forms (including quality management documents) for all processes and activities**
  - **Ensure that only current policies, procedures, and forms are in use**
  - **Any instruction found in use (or usable) in the laboratory must, at a minimum, be current and, preferably, under document control**
    - **This includes personal notes**

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# Quality Management - Procedures (COM.10000 Procedure Manual)

- **A complete procedure manual is available at the workbench or in the work area**
- **There is documentation of review of all technical policies and procedures by the current laboratory director or designee at least every two years**
- **The laboratory has a defined process indicating that all personnel are knowledgeable about the contents of the policies and procedures (including changes) relevant to the scope of their testing activities**

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# Online Poll Question

**A question for you…**

# Process-Oriented Quality Management: Best Practices and Benefits

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# CLSI Quality System Essentials

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

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# Developing a Quality Management driven Laboratory

- **Focus on technical procedures**
- **Intense PT monitoring**
- **Rigor in competency of technical staff**
- **Problem investigation or occurrence management:**
  - ✓ **In-depth root cause analysis**
  - ✓ **Move focus to process, systems integration, outcomes**
  - ✓ **Evolve beyond containment into prevention**
  - ✓ **Develop effective corrective actions**

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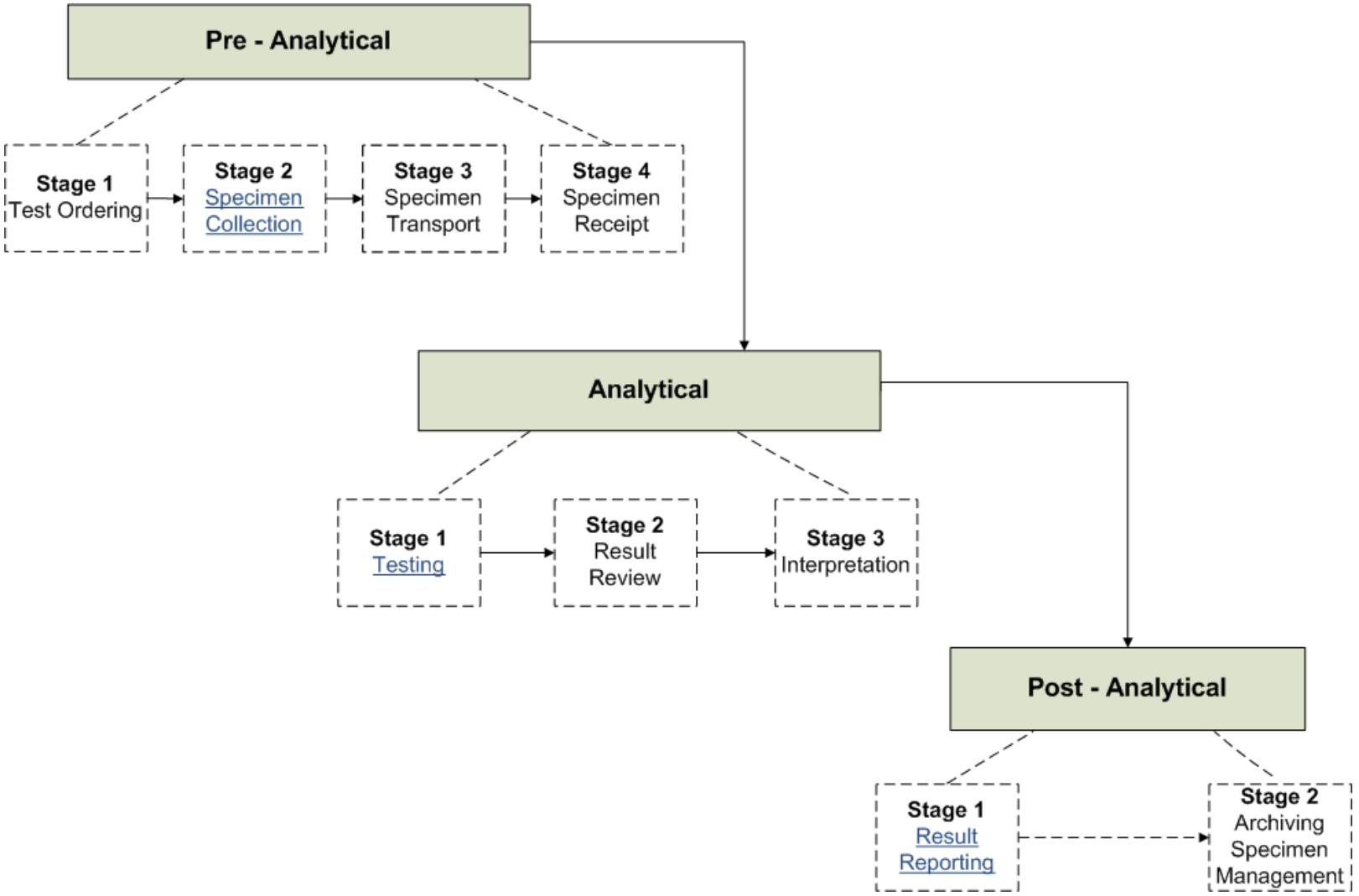
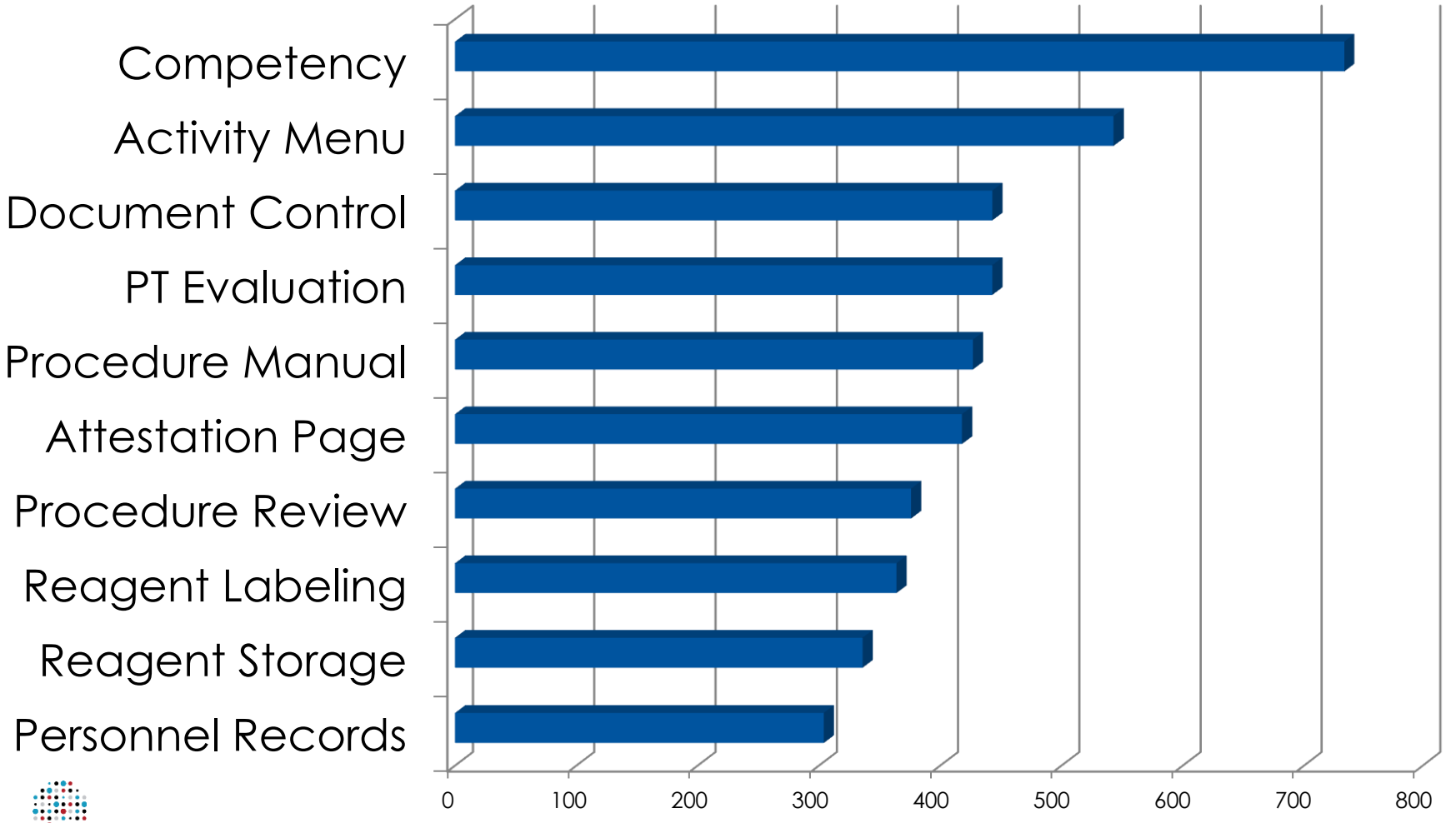
# Process Focus



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

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# 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 |

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# 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”**

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# Internal Audit – Best Practices

- **Differentiate internal audit from self-inspection**
  - **Self-inspection**
    - **Do we satisfy the checklist requirement?**
    - **The answer is always “yes or no”**
    - **Evaluate based on number of deficiencies**
  - **Internal audit**
    - **Are we adhering to our own quality system?**
    - **Is this process effective?**
    - **Is the system as a whole effective?**
    - **Look for opportunities to improve**

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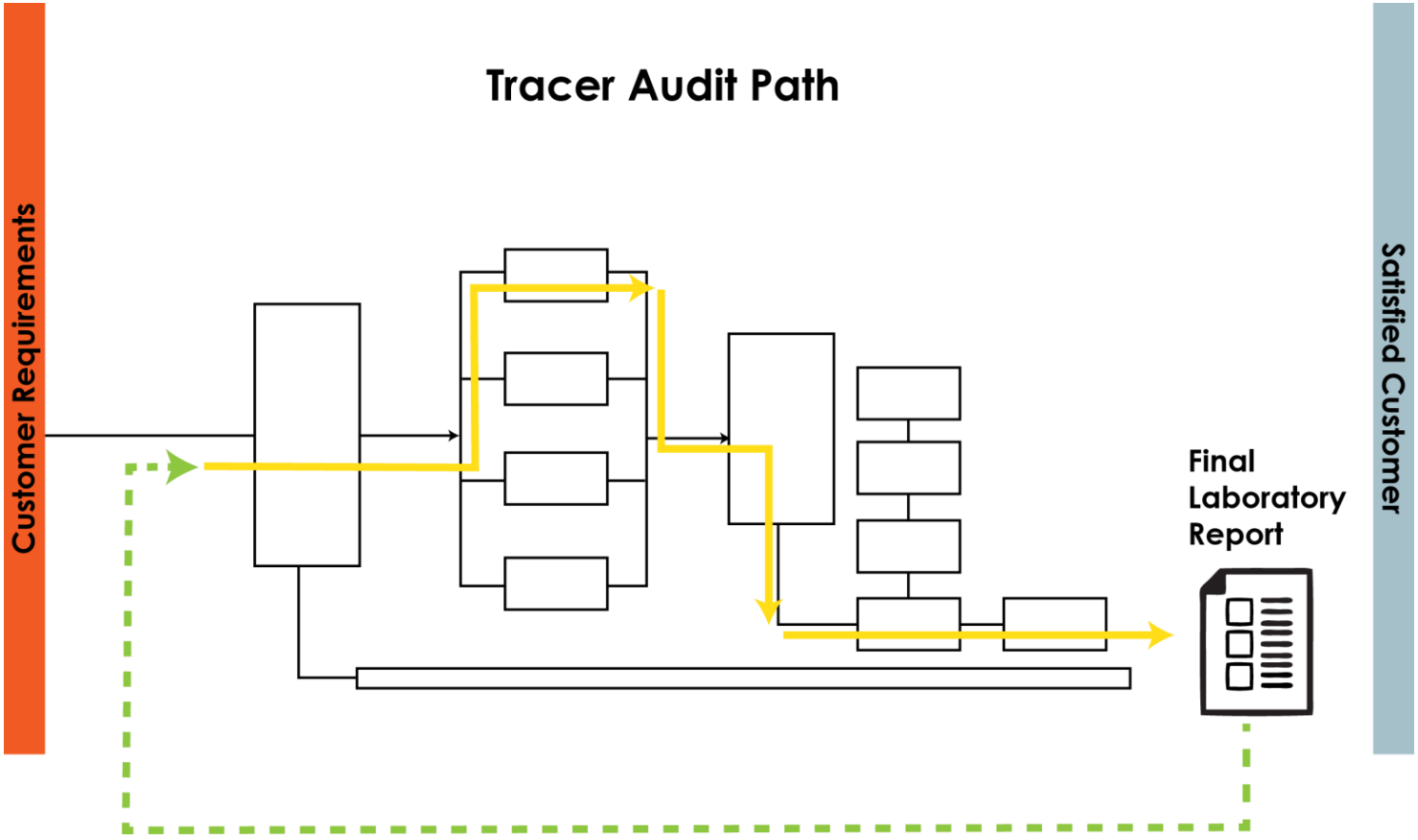
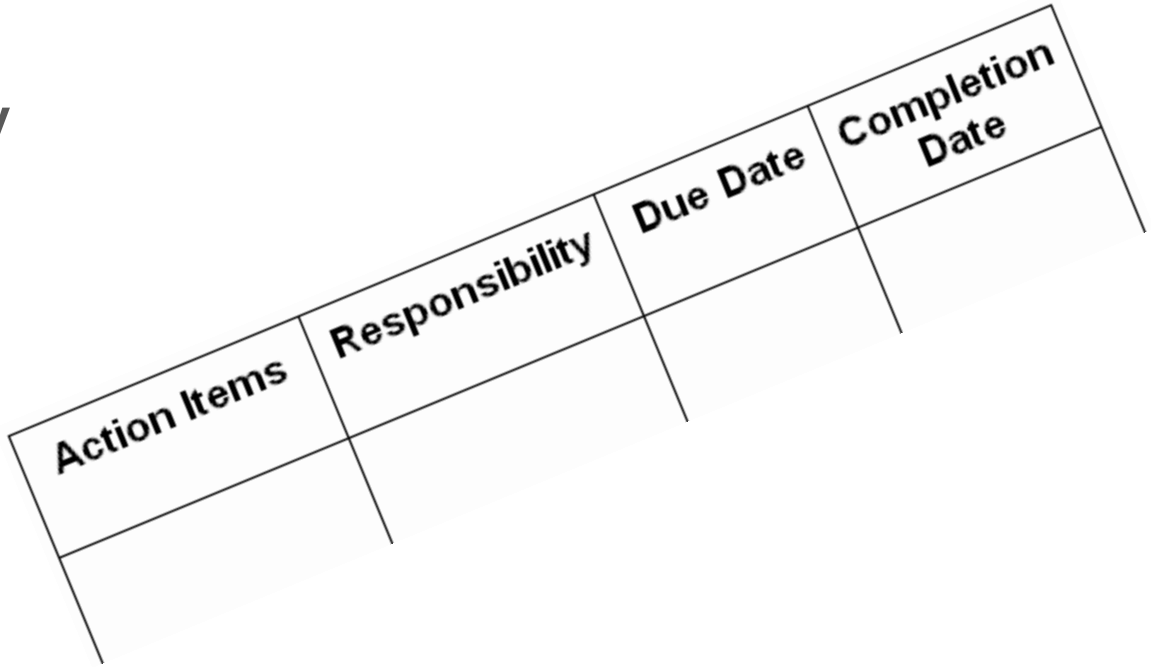
# Internal Audit – Best Practices

- **Conduct your own tracer audits**



# Internal Audit – Best Practices

- **Create a structure to insure follow-up on audit findings.**
  - **Action Items**
  - **Responsibility**
  - **Due Date**
  - **Completion**

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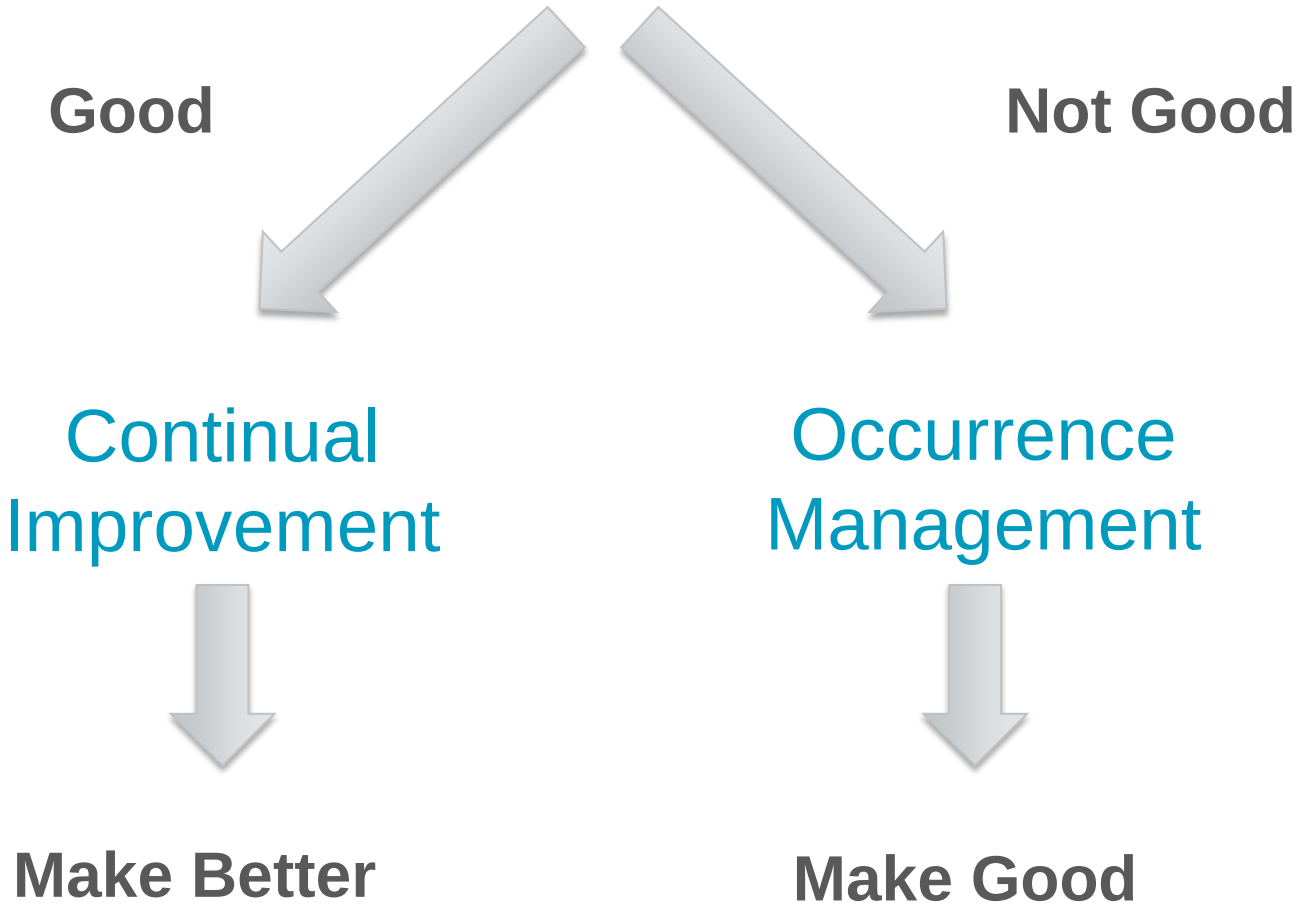
# Results of Internal Audit



# Occurrence Management – Best Practices

- **Do root cause analysis at the appropriate level for all occurrences, not just sentinel events**

| 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 |

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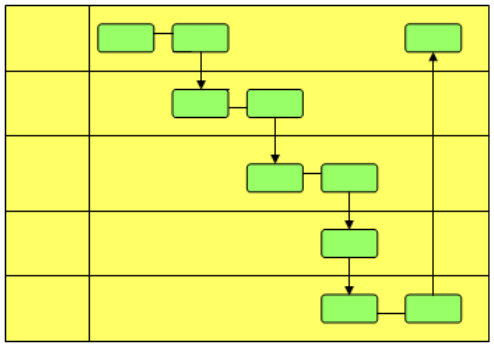
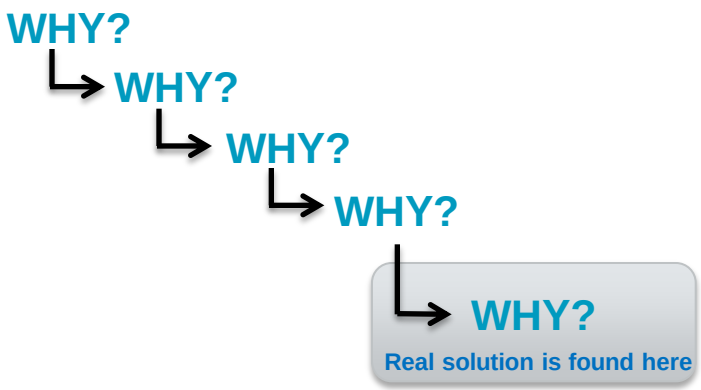
# Occurrence Management – Best Practices

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

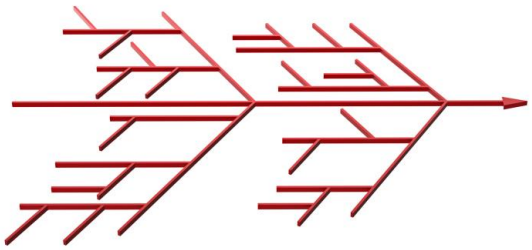
Process Mapping



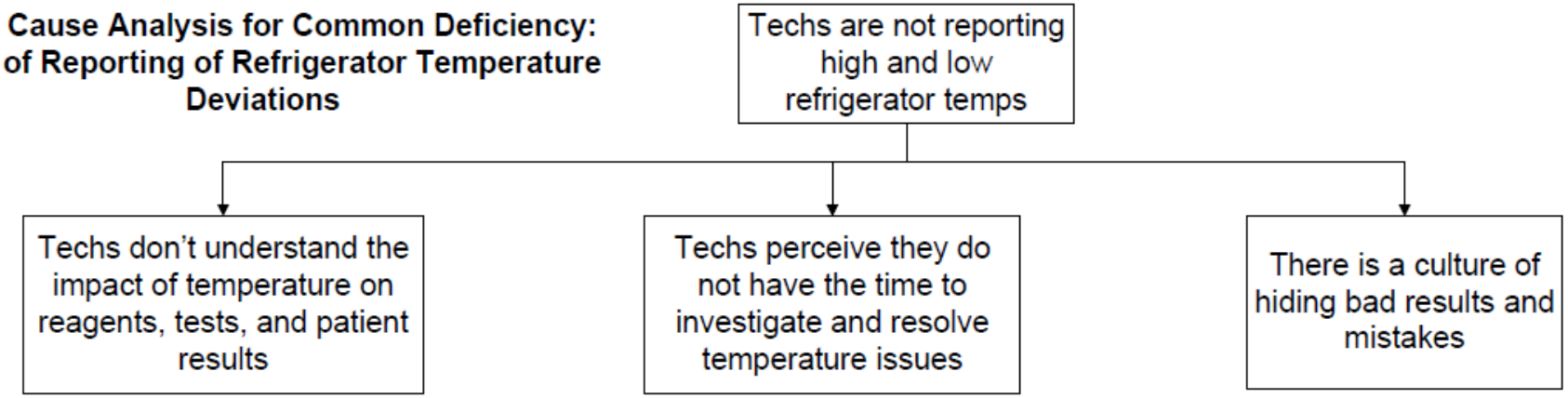
Five Why's




Fishbone Diagram



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



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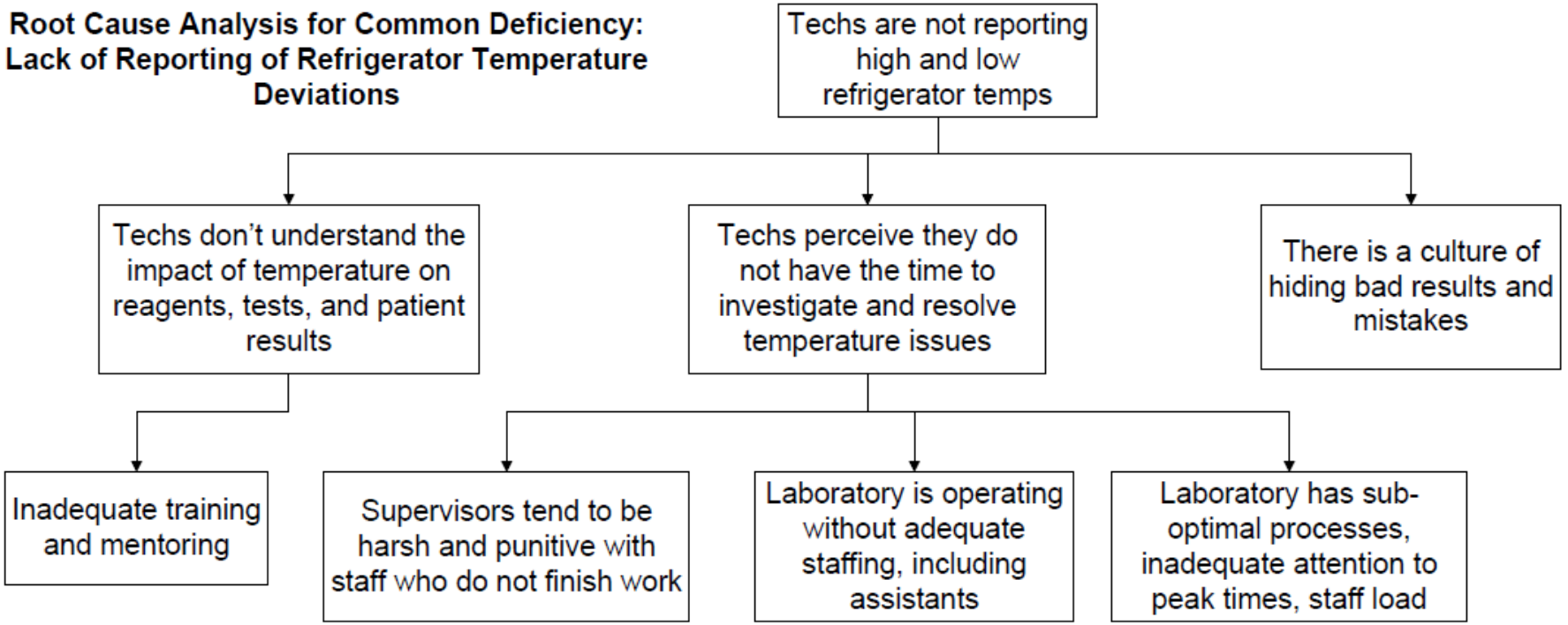

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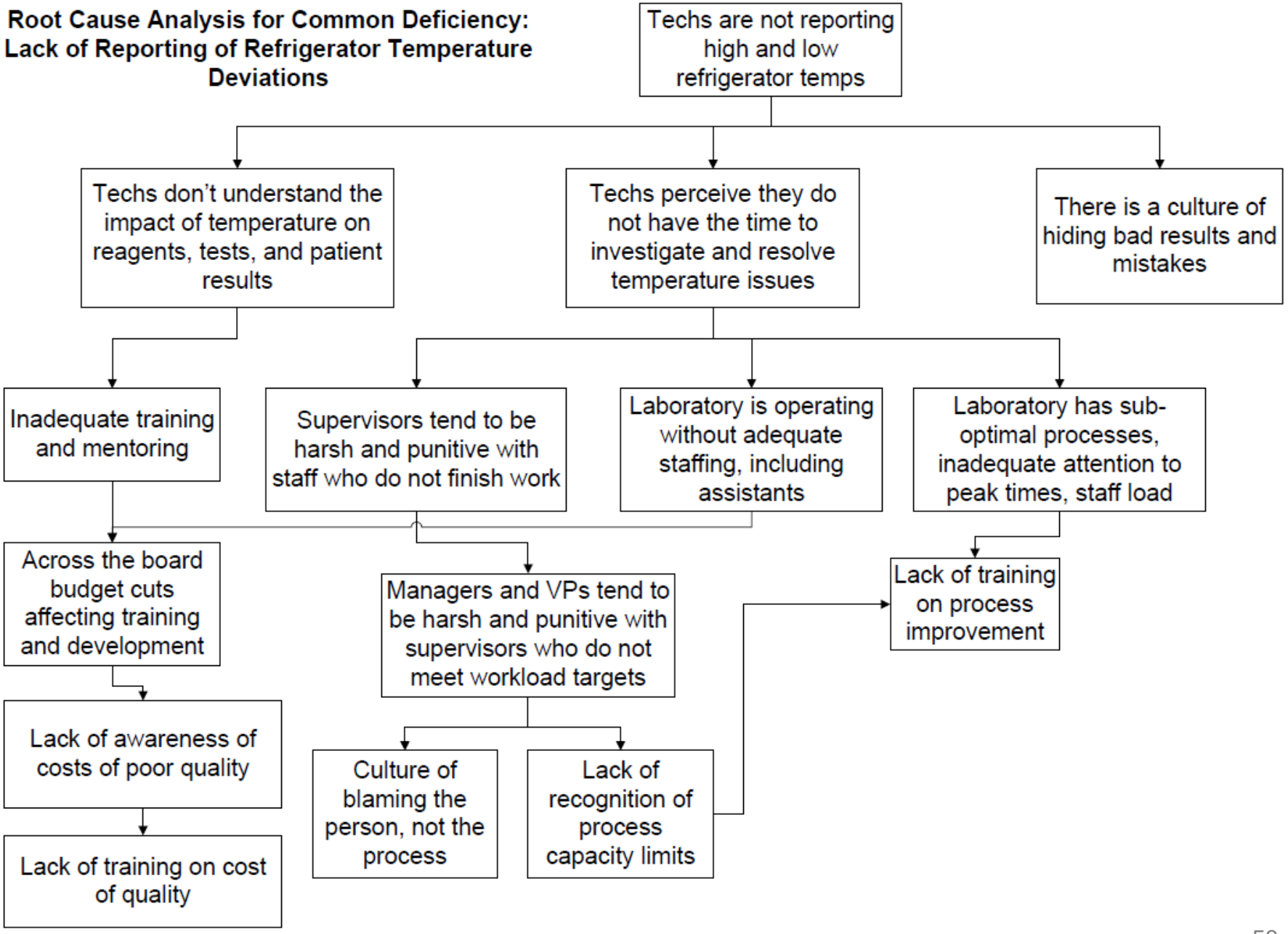

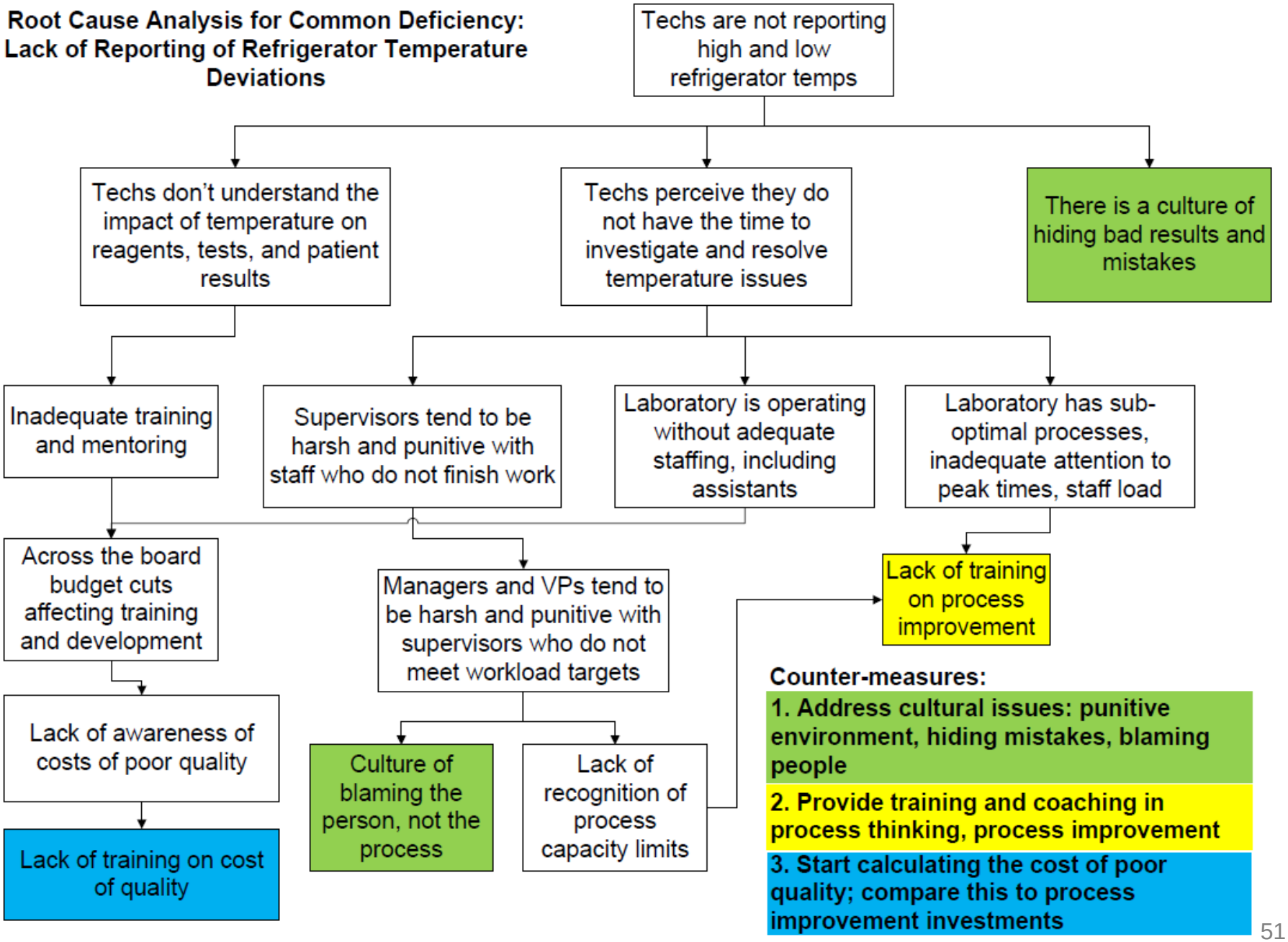
Root Cause Analysis for Common Deficiency: Lack of Reporting of Refrigerator Temperature Deviations
Techs are not reporting high and low refrigerator temps
Techs don't understand the impact of temperature on reagents, tests, and patient results
Techs perceive they do not have the time to investigate and resolve temperature issues
There is a culture of hiding bad results and mistakes
Inadequate training and mentoring
Supervisors tend to be harsh and punitive with staff who do not finish work
Laboratory is operating without adequate staffing, including assistants
Laboratory has sub-optimal processes, inadequate attention to peak times, staff load
Across the board budget cuts affecting training and development
Managers and VPs tend to be harsh and punitive with supervisors who do not meet workload targets
Lack of training on process improvement
Lack of awareness of costs of poor quality
Culture of blaming the person, not the process
Lack of recognition of process capacity limits
Lack of training on cost of quality
Counter-measures:
1. Address cultural issues: punitive environment, hiding mistakes, blaming people
2. Provide training and coaching in process thinking, process improvement
3. Start calculating the cost of poor quality; compare this to process improvement investments

# Occurrence Management – Best Practices

- **Check effectiveness of corrective actions**


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# What is the Intent of Quality Management?

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

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

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# 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**

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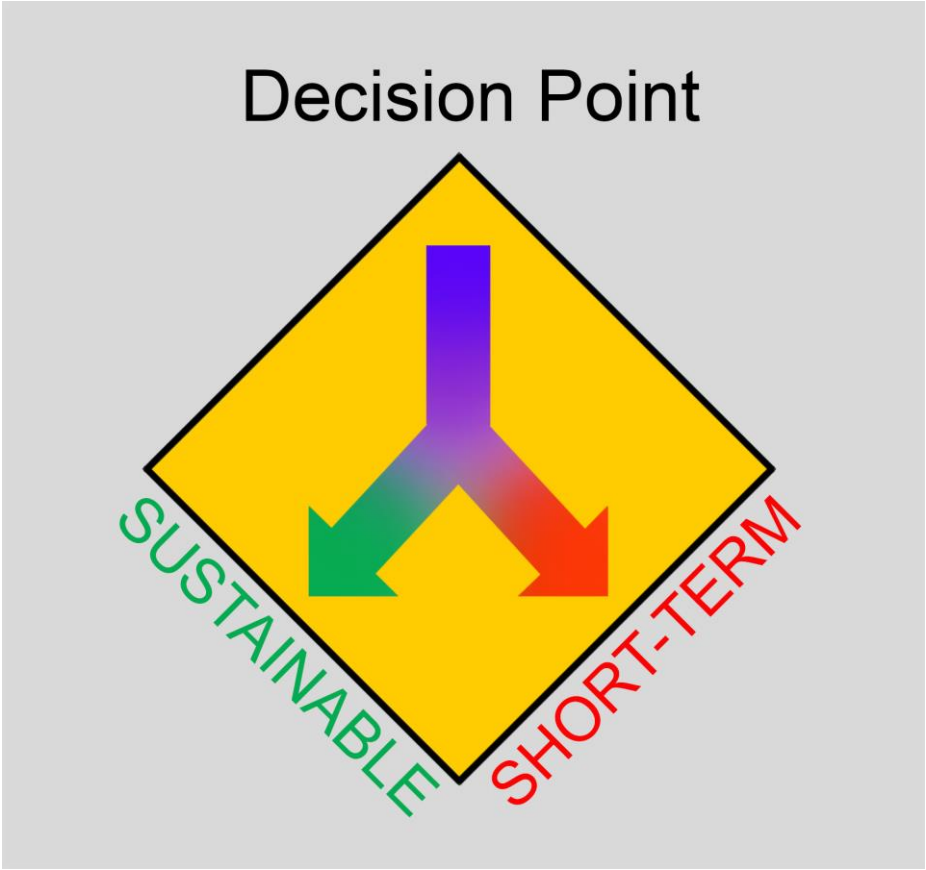
# Ways to reduce costs

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




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

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# 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**


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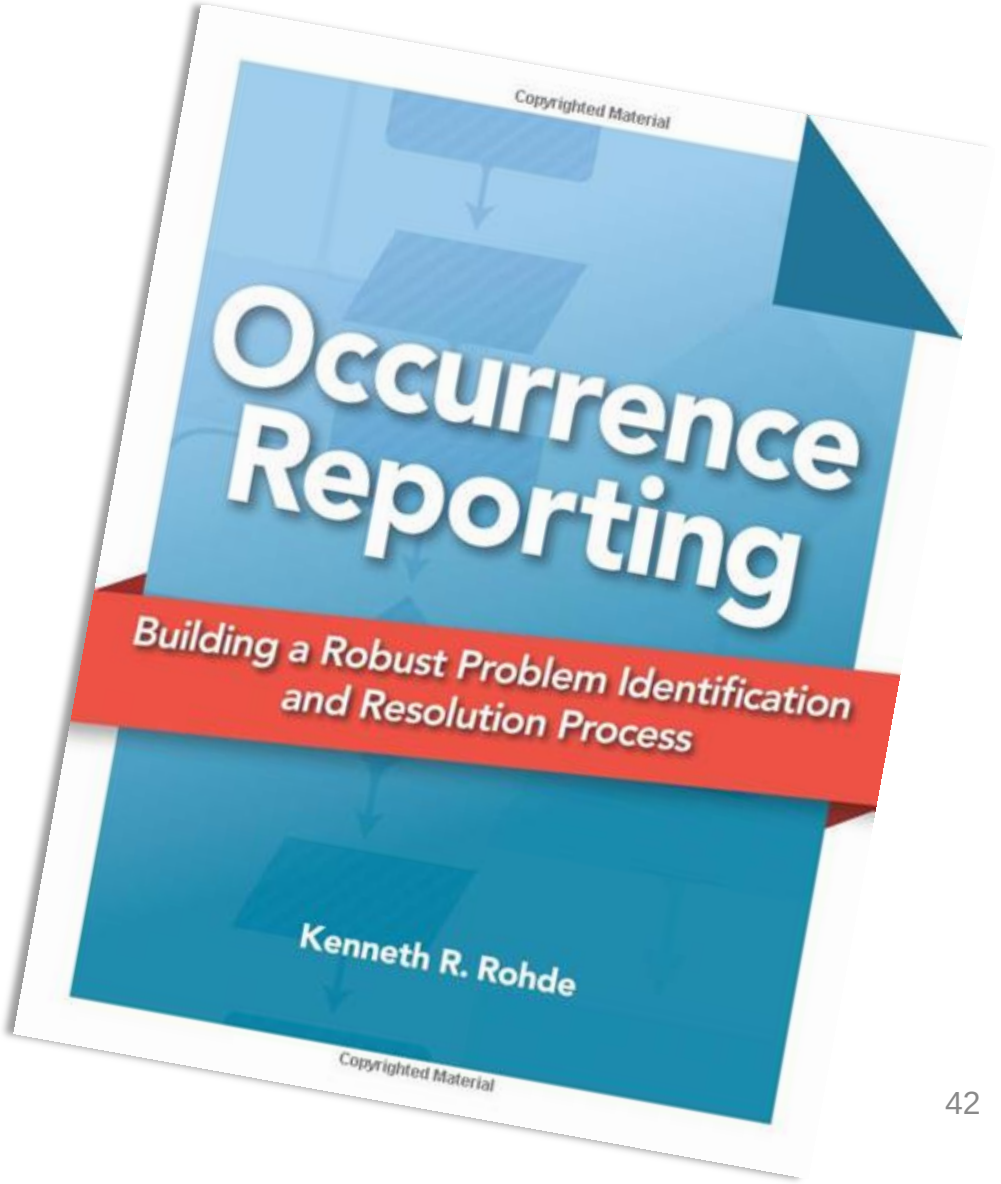
# Quality Management Education Options

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

# Quality Management Education Options

- **HCPro, Inc., Kenneth Rohde**
  - **Occurrence Reporting: Building a Robust Problem Identification and Resolution Process**
  - **Effective Process Management: Improving Your Healthcare Delivery**

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# 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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