Kicking It Up A Notch – From Chaos to Basics to Fine-Tuning Your QMS

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Laboratories Made Better!

Where is YOUR Laboratory's QMS?

Progression

Chaos — Your laboratory does not have a documented QMS

Basics — You've learned something about QMS and have tried to start

Fine-tuning — You'd like your existing QMS to bring more benefit

Progression

Chaos

Your laboratory does not have a documented QMS

Chaos – "Are you here? – OR – "You <u>are</u> here"

- **CLIA-based SOPs**

CLIA-Based SOPs

The mindset of the CLIA 14 elements of a procedure manual does not work for administrative documents.

Only Half of a QMS is Testing

The other half is the management activities that support testing. *

- Organization
- Customers
- Facilities and Safety
- Personnel
- Suppliers and Inventory
- Equipment
- Workflow processes *
- Documents and records
- Information
- Nonconforming events
- Assessments
- Improvement

Until you accept this…

CLIA 14-point procedure is about a single *analyte*.

How many of those does your laboratory routinely do?

What about automated testing?

What about all those management activities?

…a successful QMS will be difficult

Chaos – "Are you here? – OR – "You are here"

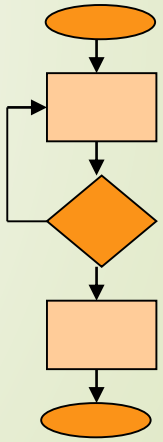
- CLIA-based SOPs
- **Recurring inspection deficiencies**
  - **Competence assessment, PT, method validations and verifications, documents not being followed**
  - **Same laboratory section or different sections each time**

Recurring Inspection Deficiencies

Documents do not reflect the order in which work actually happens.

Lack of "Process" Perspective

- All work is sequential ***processes***
- ISO 15189 and the CLSI Quality System Essentials Model are management and workflow ***process-based*** QMSs
- Lean: Reduce ***process*** waste
  Six Sigma: Reduce ***process*** variation
- Engaging with practitioners through the test ordering and results interpretation ***processes***
- Change leadership: ***process*** and cost thinking



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- **"We do QC and QA" - in line with CLIA**

The Roles of QC, QA, and QMS

Laboratory's Path of Workflow

QC monitors test methods*

Preexamination **Examination*** **Postexamination**

QA measures Path of Workflow process performance**

QMS organizes all the management and workflow processes

Chaos – "Are you here? – OR – "You <u>are</u> here"

- CLIA-based SOPs
- Recurring inspection deficiencies
  - Competence assessment, PT, method validations and verifications, documents not being followed
  - Same laboratory section or different sections each time
- A "We do QC and QA" mentality, in line with CLIA
- **An "administrative manual" organized – or not**

How to Get Started 1.

- Dismantle your laboratory's "administrative manual"
- Collect administrative memos, postings, emails
- Sort each document to its respective management topic and process
- Use Gap Analysis tools to do a gap analysis on your laboratory's
  - Documents
  - Processes
- Prioritize the identified gaps
  - Which documents and/or processes are missing?

Progression

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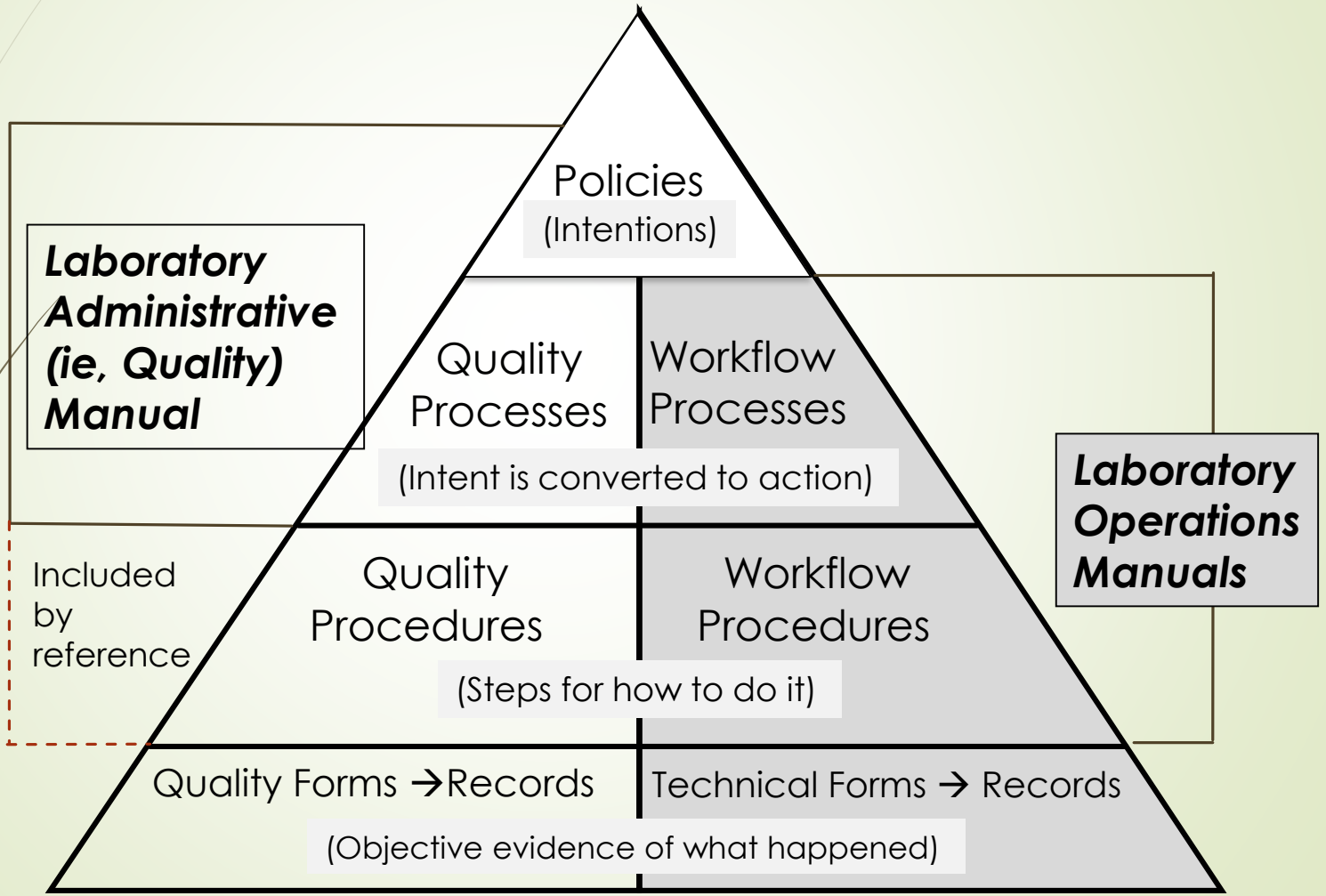
Creating the Basic QMS

1) Understand the relationships between types of documents and their related records
2) Close documentation gaps
3) Analyze nonconforming events to identify the problematic processes they represent
4) Conduct and record improvement projects

Creating the Basic QMS

1) **Understand the relationships between types of documents and their related records**

QMS vs Technical Documents: How to organize in a way that makes sense



Creating the Basic QMS

1) Understand the relationships between types of documents and their related records
2) **Close documentation gaps**

How to Get Started 2.

- Close the gaps with documented processes and procedures
- Use the new administrative manual (aka "quality manual") as ***management's procedures manual***
- Train all new management personnel on management policies, processes, and procedures
- Train all personnel on management procedures they will routinely perform
  - Correcting errors on paper and electronic records
  - Reporting a nonconformance

Creating the Basic QMS

1) Understand the relationships between types of documents and their related records
2) Close documentation gaps
3) **Analyze to identify problematic processes**
   - **Nonconforming events**
   - **PT problems**
   - **Findings from internal audits**
   - **Findings from external assessments**

Creating the Basic QMS

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   - Findings from external assessments
4) **Conduct and record improvement projects**

Progression

Chaos	Your laboratory does not have a documented QMS
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Fine-tuning	You'd like your existing QMS to bring more benefit

How to Bring More Benefit to Your QMS

A. Think "PDCA"

B. Apply, track and manage the Cost of Quality

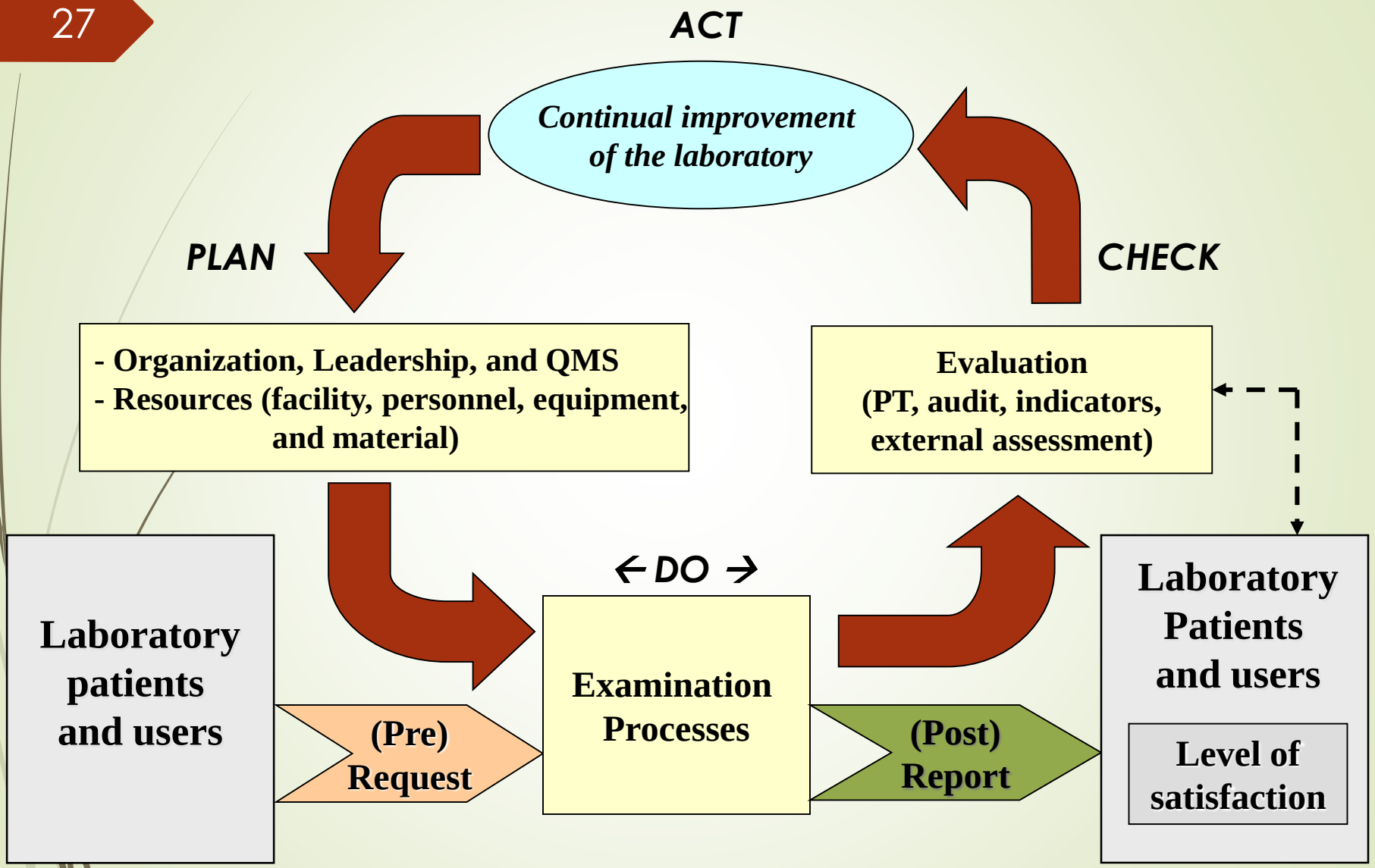
C. Conduct meaningful management review

D. Get accredited

How to Bring More Benefit to Your QMS

A. Think "PDCA"

A PDCA Perspective on a QMS



"Live" in Your QMS

- The QMS is how to manage your laboratory.
- The QMS is not meant as something to trot out for external accreditation assessors!
- Identify where, in the QMS, requirements…
  - need to happen
  - have happened
  - should have happened.
- Adjust the processes and procedures as needed.

How to Bring More Benefit to Your QMS

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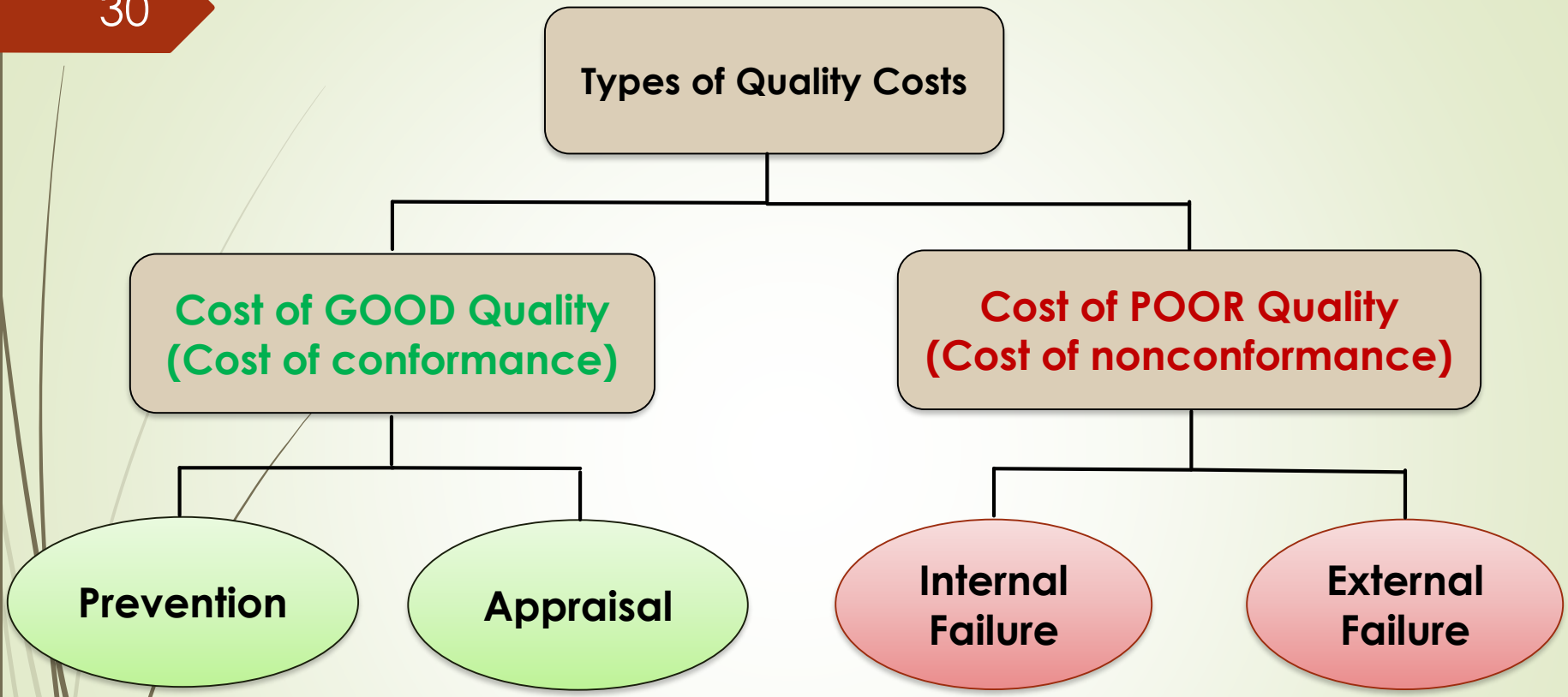
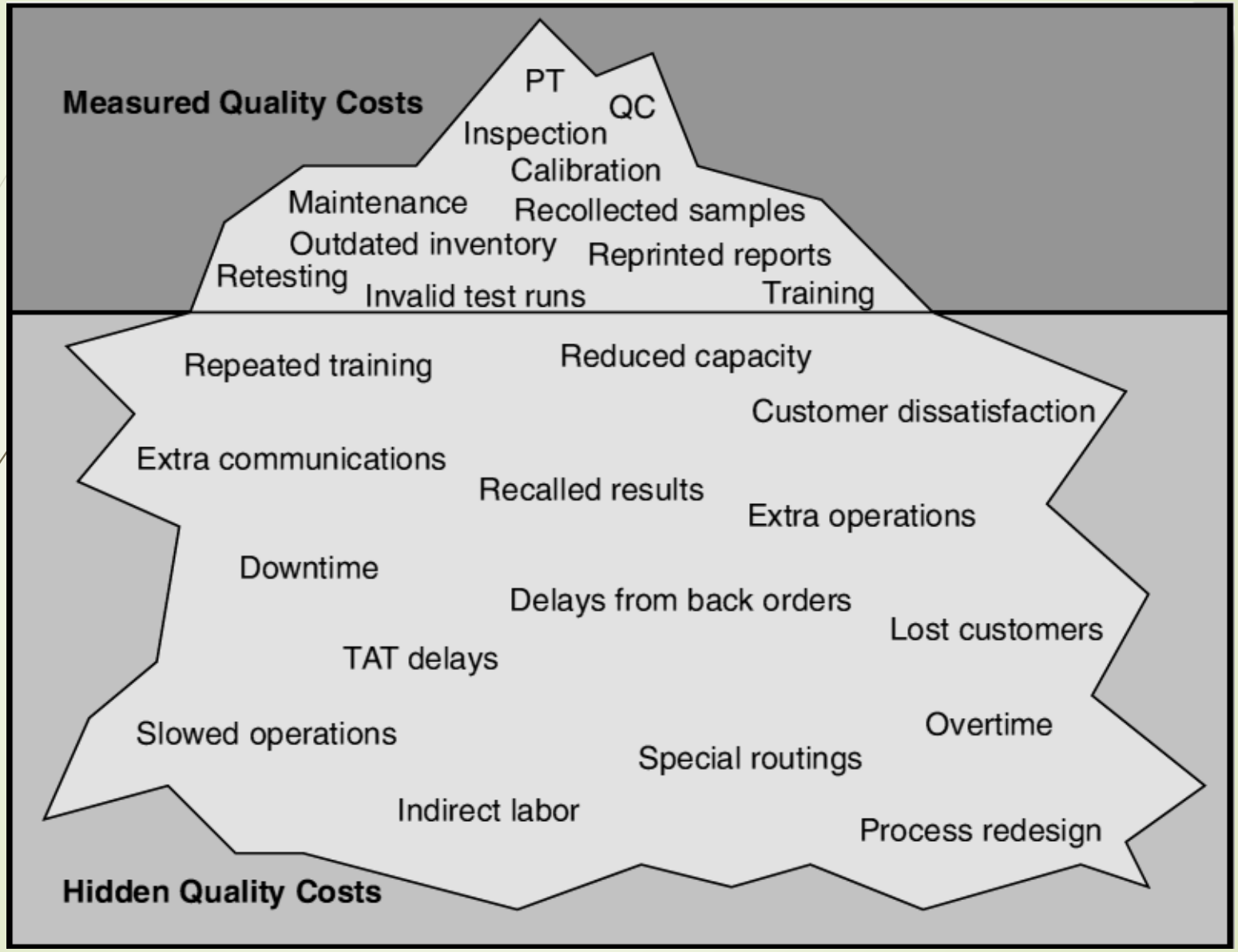
B. Apply, track and manage the Cost of Quality


Types of Quality Costs
Cost of GOOD Quality
(Cost of conformance)
Cost of POOR Quality
(Cost of nonconformance)
Prevention
Appraisal
Internal
Failure
External
Failure

Managing Quality Costs



From Harmening's *Laboratory Management: Principles and Processes*, 3rd edition. Used with permission.

How to Bring More Benefit to Your QMS

A. Think "PDCA"

B. Apply, track and manage the Cost of Quality

C. **Conduct meaningful management review**

How Often Do You Do Management Review?

Once a year - because that's all that's required

Quarterly – to be sure we stay on top of improvements

Management Review Inputs*

- Preexamination
- User feedback
- Staff suggestions
- Internal audits
- Risk management
- Use of quality indicators
- External organizations
- PT program results
- Complaint monitoring
- Supplier performance
- Nonconformities
- Improvement activities
- Follow-up from previous management review
- Workload changes
- Recommendations for improvement

*ISO 15189:2012, Clause 4.15

Management Review Process

- Compilation of timely information
- Identification of trends and patterns indicative of process problems
- Identification of opportunities for improvement
- Assessment of whether changes to the quality objectives and QMS are needed
- Evaluation of laboratory contribution to patient care

Management Review Outputs

- Records of decisions made and actions taken
- Communication to laboratory personnel
- Actions completed within defined timeframe

How to Bring More Benefit to Your QMS

A. Think "PDCA"

B. Apply, track and manage the Cost of Quality

C. Conduct meaningful management review

D. **Get accredited**

Get Accredited

ISO

A2LA

CAP 15189 Accreditation Program

ANSI National Accreditation Board
ANAB

Get Moving

Road construction sign, Singapore

"Prepare and prevent

– OR –

repair and repent."

Resources

- CLSI. **QMS01**, 5th edition. *A Quality Management System Model for Laboratory Services*
- CLSI Guidelines **QMS02 through QMS24** *Guidance for implementing a laboratory QMS*
- CLSI. **QMS25**. *Handbook for Developing a Laboratory Quality Manual*
- CLSI **Key to Quality**. *Fundamentals for implementing a QMS in the clinical laboratory*
- Burnett David. ***A Practical Guide to ISO 15189 in Laboratory Medicine*** http://www.acbstore.org.uk/site/product.aspx?productuid=257253&clickproductonpage=/site/category.aspx?categoryid=39

- A2LA instructor-led and e-learning training
- CAP *QMEd* modules, tools, and templates