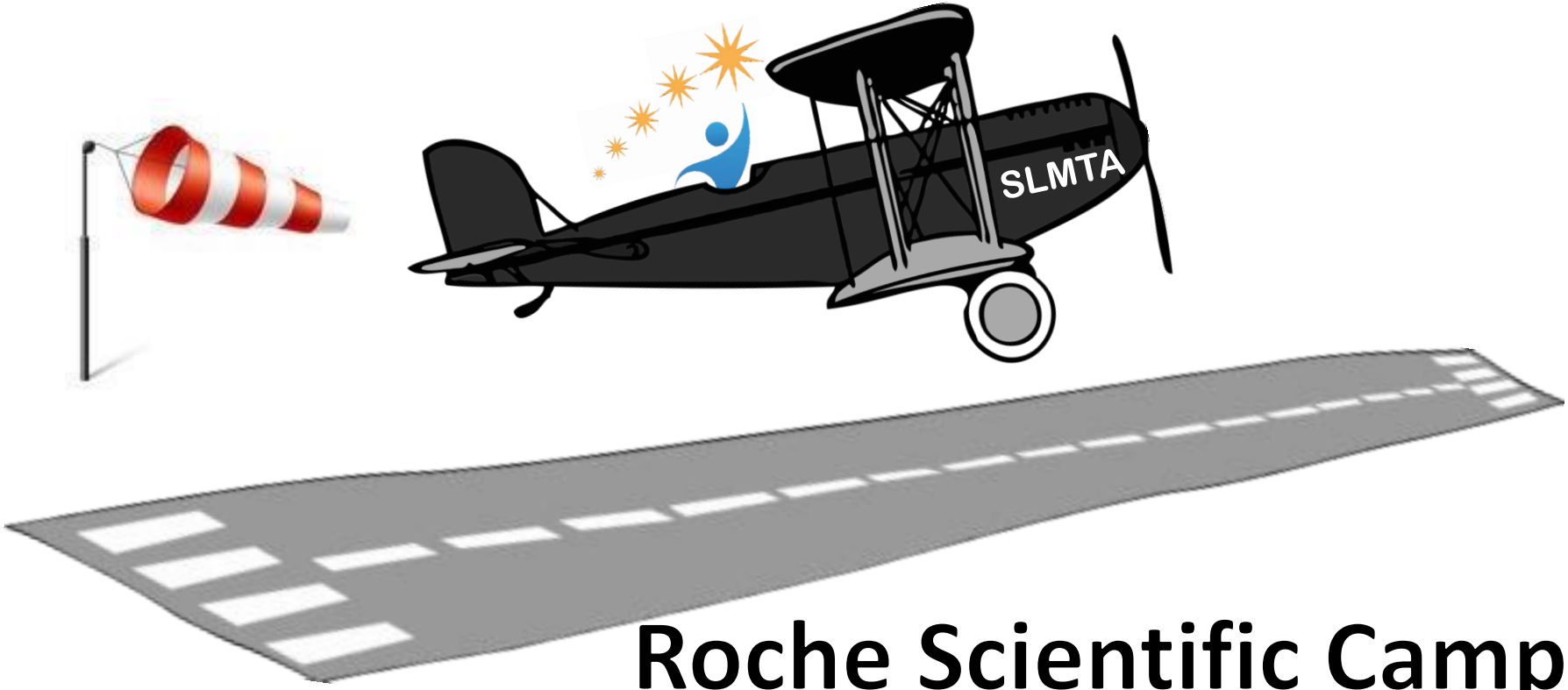
SLMTA 2

Propelling Laboratories towards Accreditation

The SLMTA 2 Pilot has taken off and is climbing.



Roche Scientific Campus
South Africa
September 19-23, 2016

SLMTA 2 Pilot Workshop: 19-23 September 2016,
Johannesburg SOUTH AFRICA

SLMTA 2

- 5 day workshop that provided a practical application to ISO 15189.

1. Unlocking ISO 15189	**8. Introduction to Internal Auditing**
2. Plethora of Processes	**9. Audit Process – Planning to Succeed**
3. Mapping NCE	**10. Audit Process – Review, Study, and Understand**
4. Selecting the Winning Problem	**11. Audit Process - Conducting the Audit**
5. Just Culture	**12. Audit Process – Reporting the Audit**
6. RCA + PDCA = CA	**13. Internal Audit Program**
7. Preventive Action	**14. Management Review**

What did participants say?

This workshop helped me realize why NCEs reoccur in our system and provided tools on how to conduct effective root cause analysis and corrective action.

This training is another barrier breaker for pushing labs to five stars. It's a must have for labs seeking improvement beyond 3 stars.

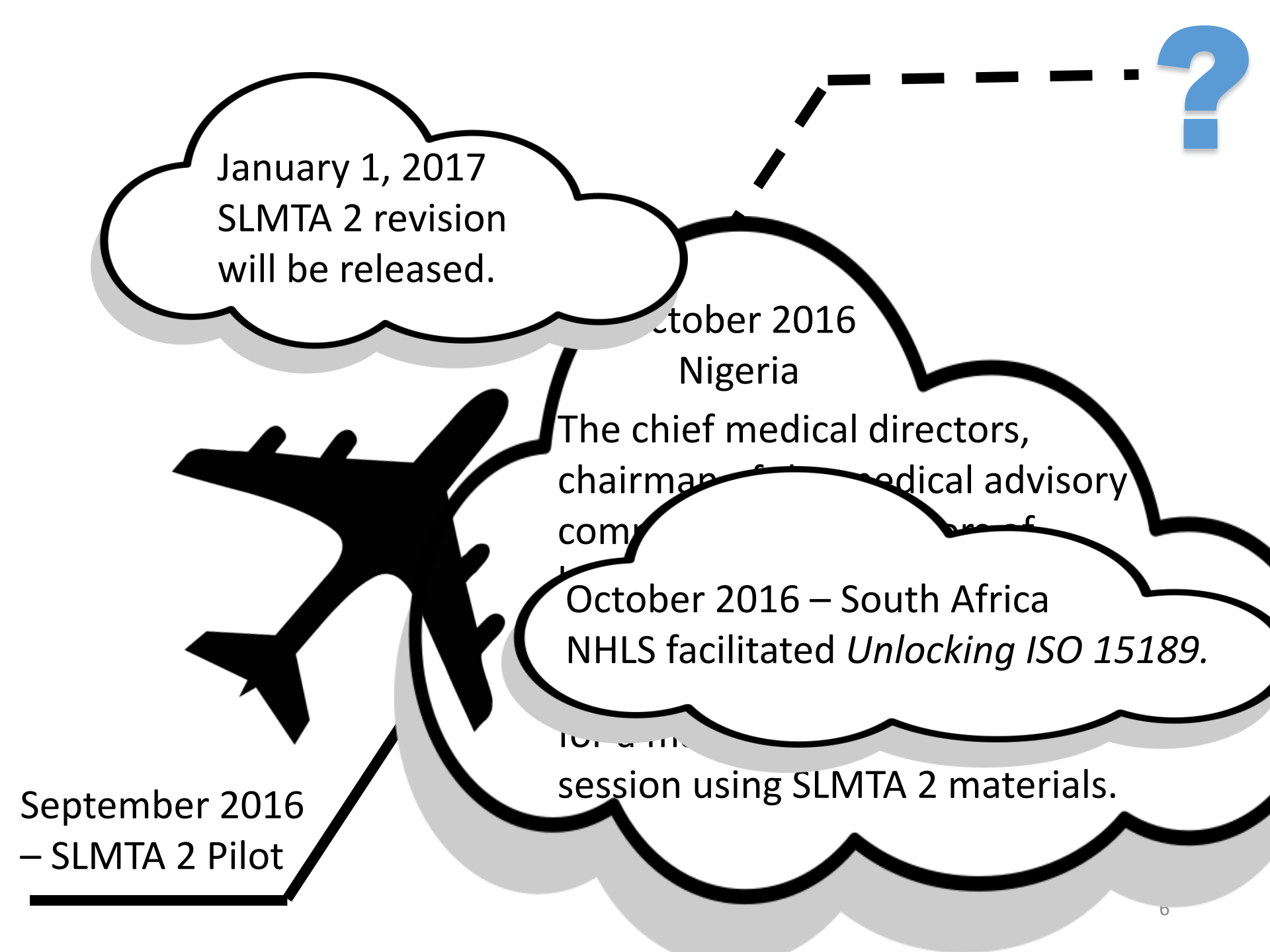
SLMTA 2 offers the best approach to help labs realize their full potential to accreditation.

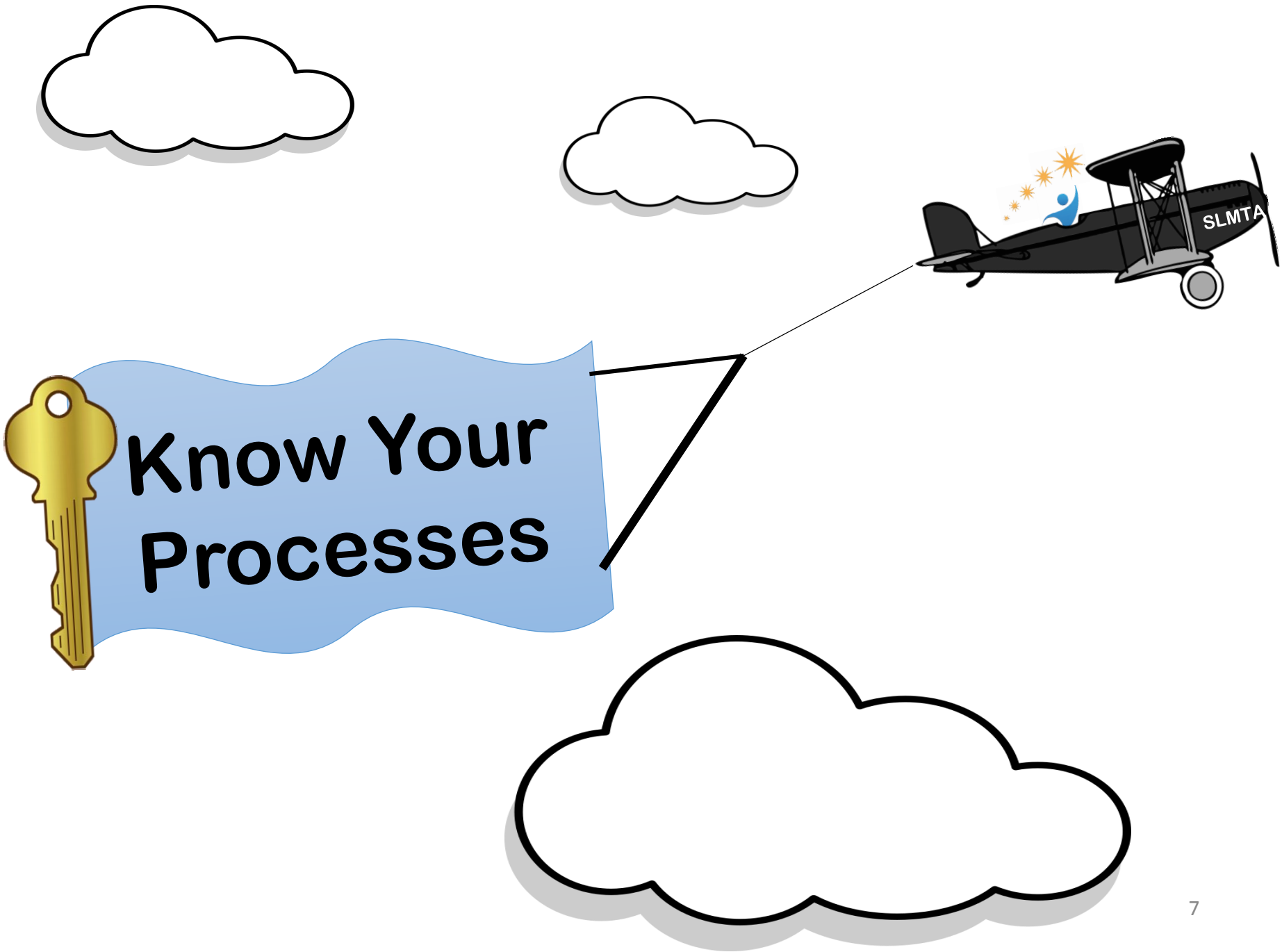
Amazing workshop, a must attend to bridge the gaps between SLIPTA 2-3 and accreditation.

I believe this program was long overdue and even with my 20 years experience in QMS, I learned a whole lot of new concepts which I would recommend to all laboratorians.

[This workshop is] useful in overcoming the 4 game changers (MR, IA, CA, and continual improvement).

SLMTA 2 workshop is unimaginably a WOW eye-opener. The quality of training is above many I have been through.


January 1, 2017
SLMTA 2 revision
will be released.
ctober 2016
Nigeria
The chief medical directors,
chairman
edical advisory
com
October 2016 – South Africa
NHLS facilitated *Unlocking ISO 15189.*
session using SLMTA 2 materials.
September 2016
– SLMTA 2 Pilot


SLMTA
Know Your Processes

If you cannot describe what you are doing as a process, then you do not know what you are doing.

W. Edwards Deming

In order to audit a process, you must first understand what it is.

J.P. Russell

ISO 15189:2012
4.2 Quality management system
4.2.1 General requirements

The quality management system shall provide for the integration of all processes required to fulfil its quality policy and objectives and meet the needs and requirements of the users.

The laboratory shall:

a) determine the processes needed for the quality management system and ensure their application throughout the laboratory;

b) determine the sequence and interaction of these processes;

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective;

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes;

e) monitor and evaluate these processes;

f) implement actions necessary to achieve planned results and continual improvement of these processes.

Understand QMS as a whole and its interrelated processes

Unlocking ISO 15189
Plethora of Processes

Target the *Measurement, Analysis, and Improvement* component of a QMS

Occurrence Management System

Part I

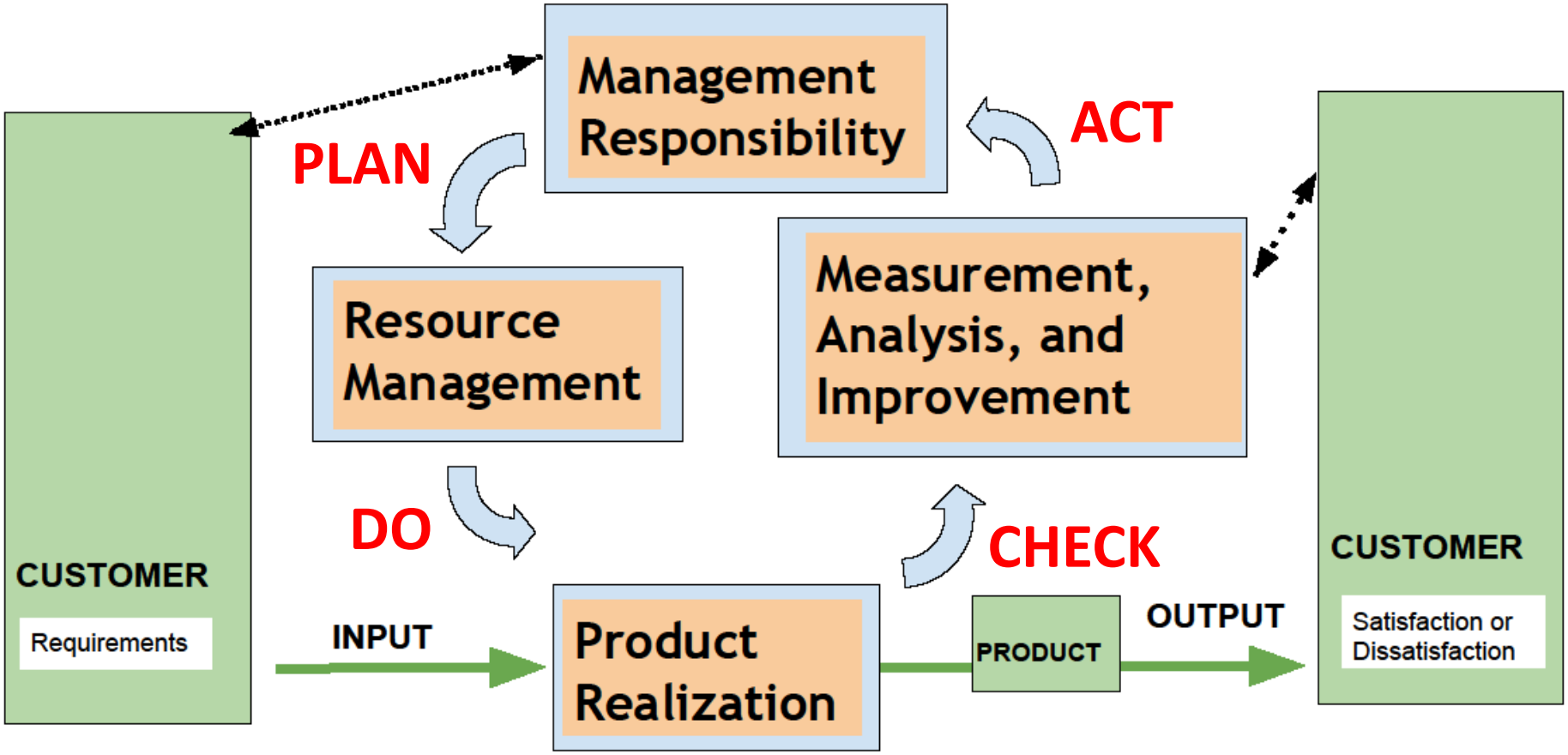
Internal Audit Program

Part II

Management Review System

Part III

Process-based Approach to a Continuously Improving a QMS



ACT

Measurement, Analysis, and Improvement

4.8 Resolution of Complaints

4.9 Identification and Control of Nonconformities

4.10 Corrective Action

4.11 Preventative Action

4.12 Continual Improvement

4.13 Evaluation and Audits

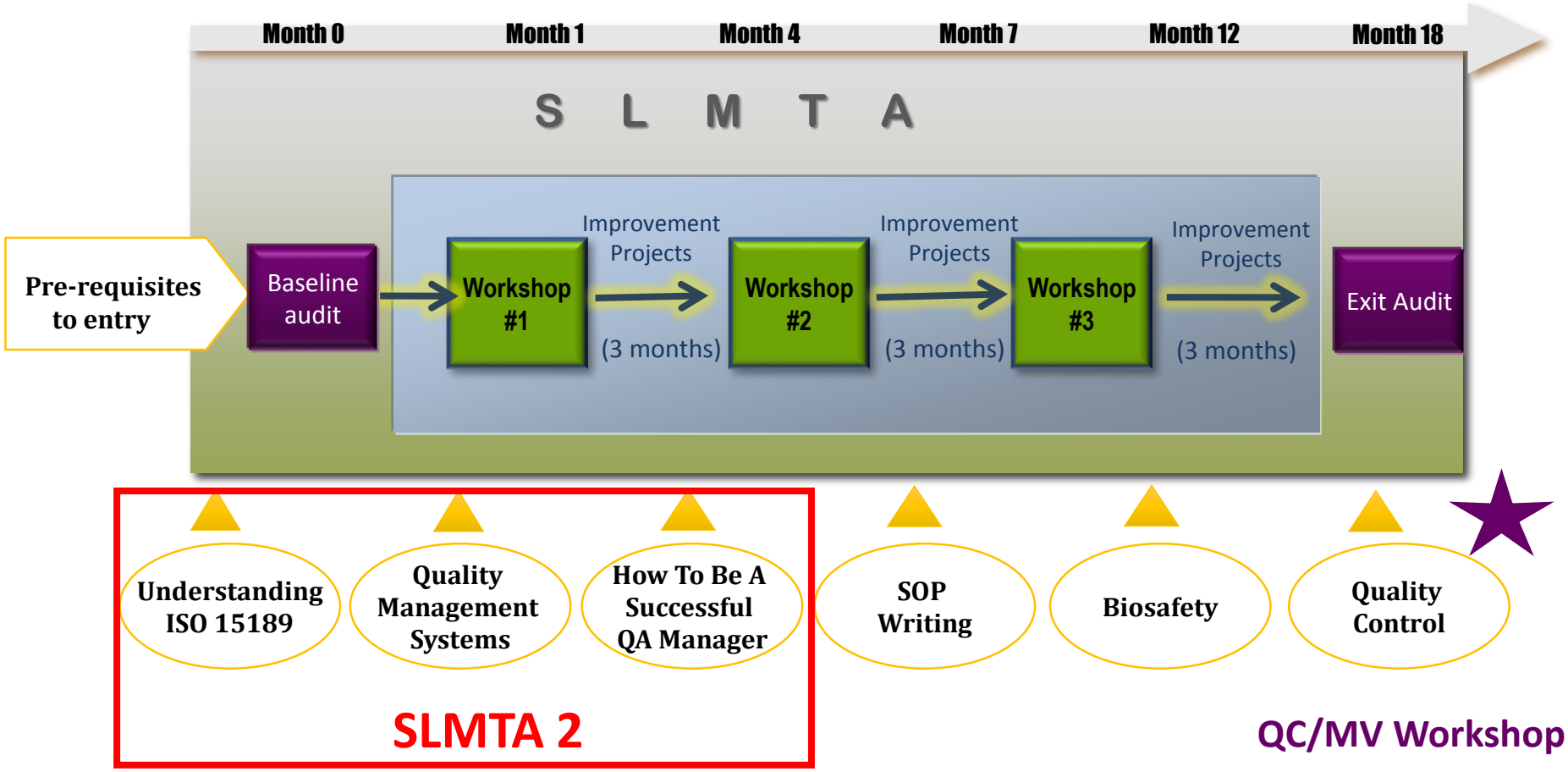
4.15 Management Review

5.6 Ensuring the Quality of Examination Results

addressed in QC/MV Workshop

CHECK

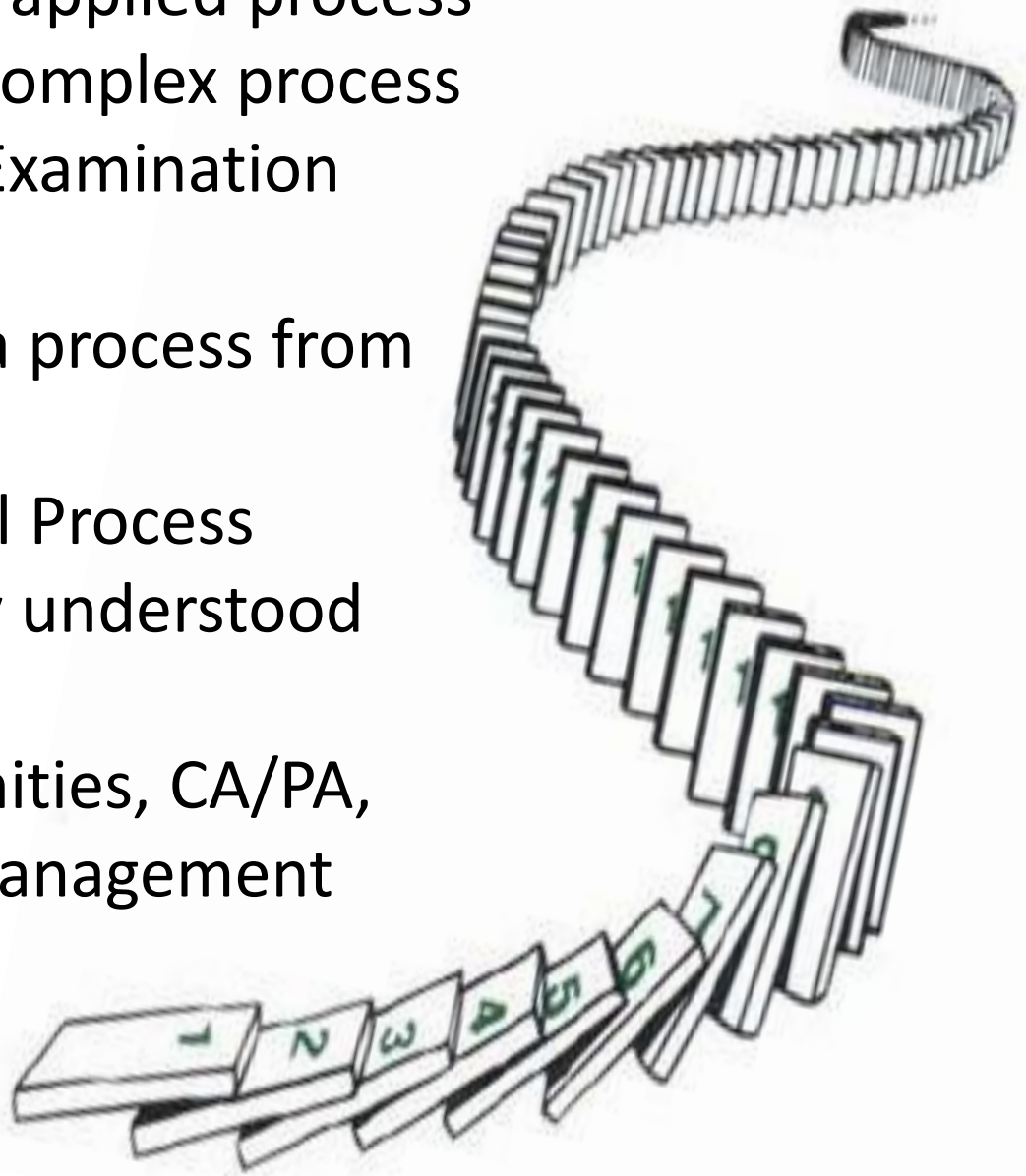
SLMTA Roadmap



Complementary Training or Mentoring

The SLMTA Approach To Process Mapping

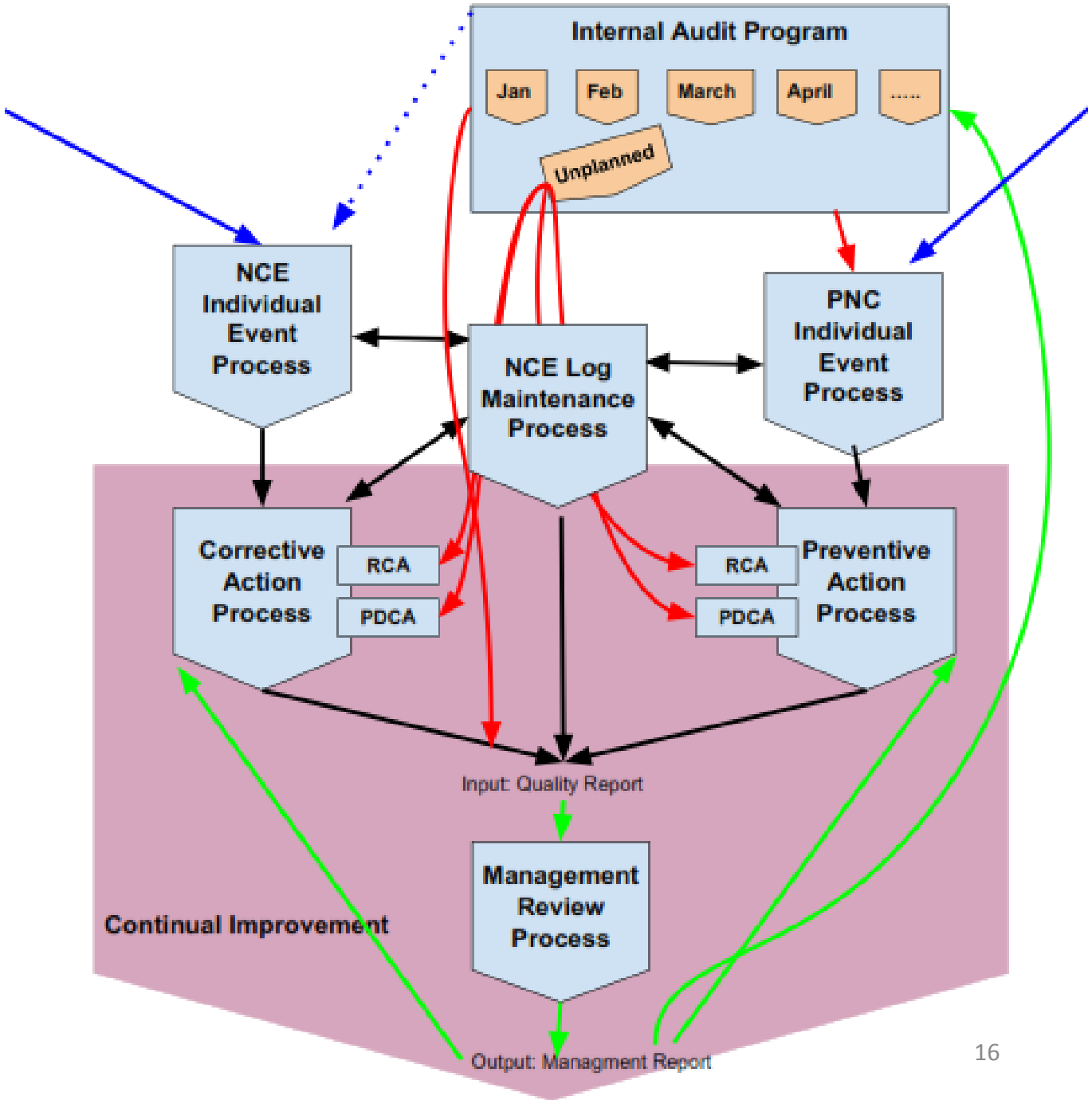
I. Start with a commonly applied process
   A. Learning to read a complex process
      - Generic Analyzer Examination Process
   B. Learning to design a process from simple to complex
      - Document Control Process
II. Transfer skills to poorly understood processes
   (Mapping Nonconformities, CA/PA, Internal Audits, and Management Review)



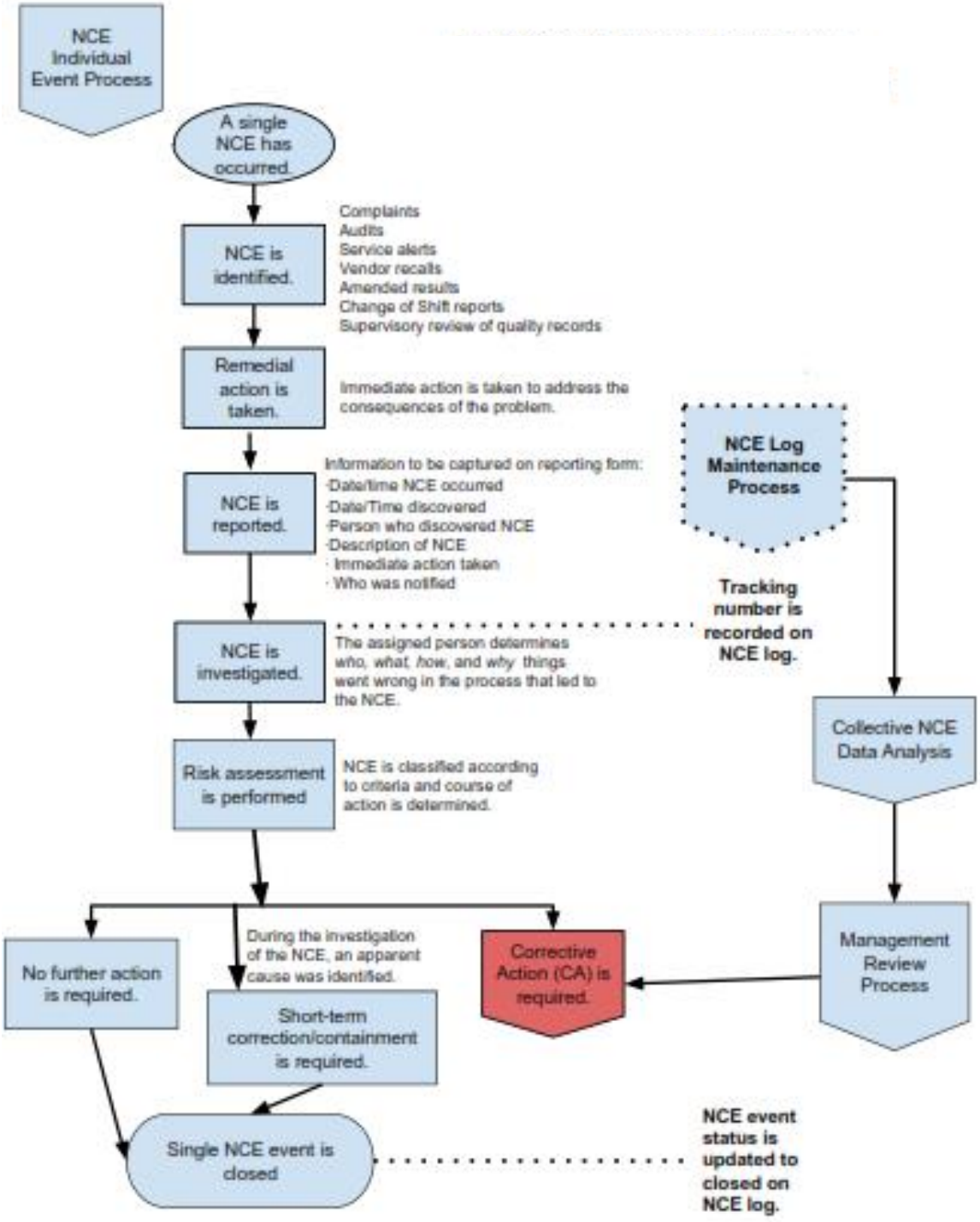
Flowchart Considerations

Don’t worry too much about drawing the flowchart (process map) the *right way*. The right way is the way that helps those involved understand the process.

Measurement, Analysis, and Improvement Element of a QMS



4.9 Identification and Control of Nonconformities



WHO participates in this process?

- All staff (identification of NCE)
- Heads of Section
- Quality Manager
- Management Review Team

What **INFORMATION** is needed to perform the process? (procedures, methods, forms, information, etc.)

- NCE Individual Event Process
- NCE Log Maintenance Process
- NCE Identification and Control of Nonconformities Procedure
- NCE Report Form
- Analysis of trends

With **WHAT?** (tools, reagents, equipment, hardware, software, infrastructure, safety, etc.)

NCE tracking software

PROCESS:
Identification and Control of Nonconformities

PROCESS OWNER:
Quality Manager

OUTPUTS:

- Identification, reporting and correction of problems throughout the laboratory.
- Detect trends of system level problems

RECORDS:

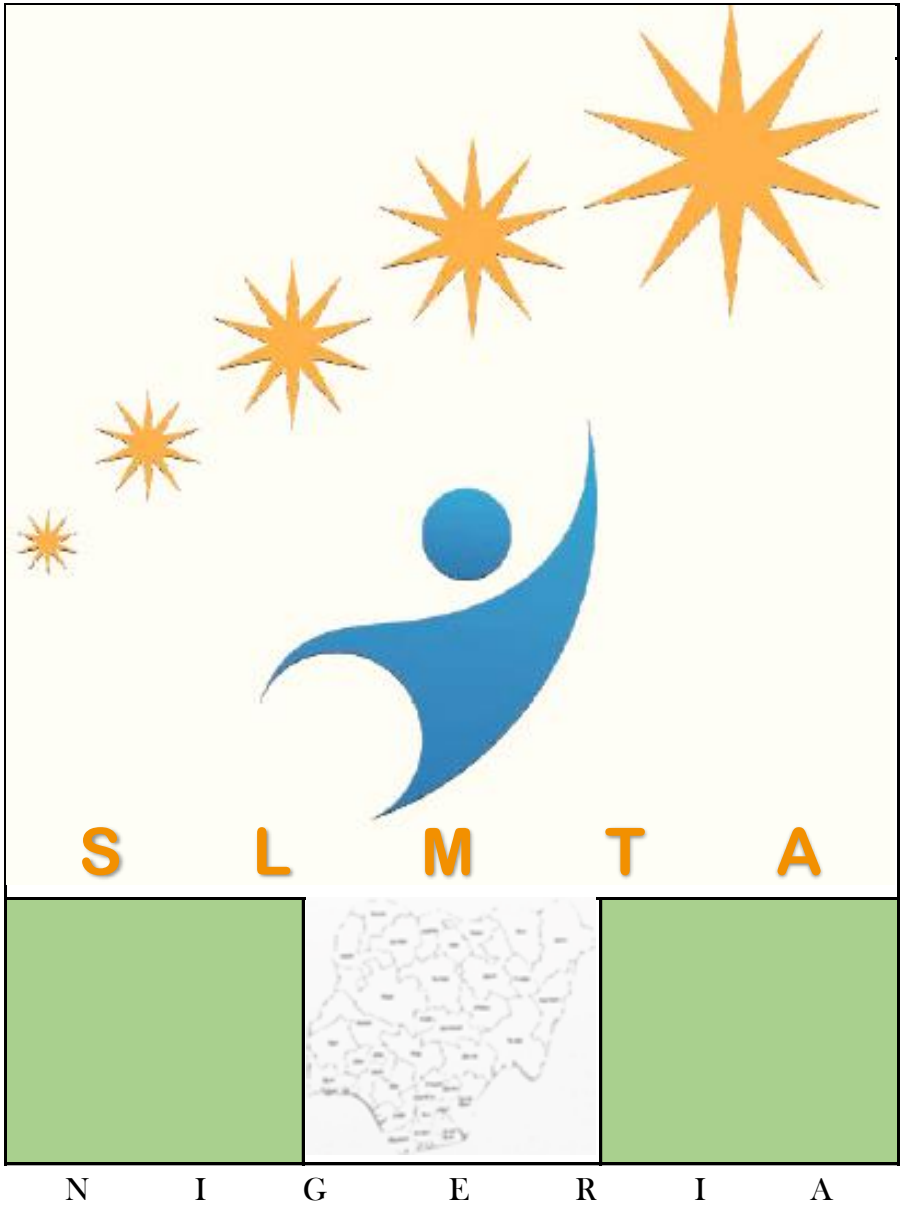
- NCE Reports
- NCE Log

What **METRICS** are maintained to determine process effectiveness?

- Number of Customer complaints
  - physicians
  - other health care staff
  - patients
- Numbers and types of nonconformances
- Number of investigations or proposed corrective actions returned for insufficiency

SLMTA 2

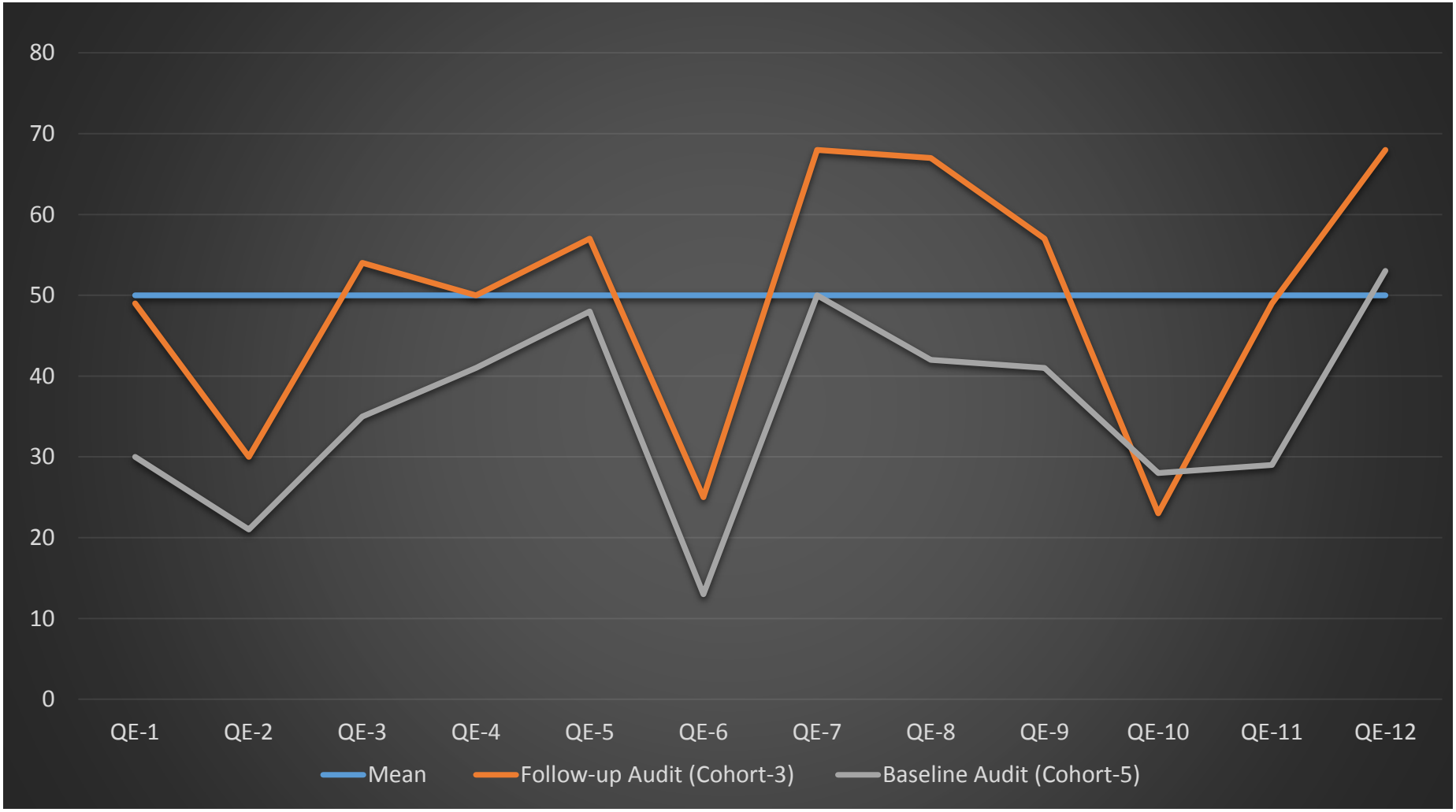
Propelling Laboratories Towards Accreditation



Use of SLMTA 2 Tools in Nigeria

Odafen Oke
SLMTA-Program POC
CDC/Nigeria
ASLM 2016
Cape Town
December 3 – 9, 2016

Performance of Labs on 12 Quality Essentials (Baseline and Follow-up Audits)



Our Interventions Using SLMTA-2

- Shared focus and outcome of SLMTA-2 workshop with the National Laboratory Technical Working Group – Oct 2016
  - ✓ Highlighting major areas of weaknesses as found in analysis of audit data

- Held Conference of SLMTAns in Nigeria – Nov 2016
  - ✓ Shared SLMTA-2 focus
  - ✓ Shared analysis of lab audit data
  - ✓ Re-trained SLMTANS on audit

- Held SLMTA step-down workshop; #1 for cohort 5, and #3 for Cohort 3 (Oct – Nov, 2016)
- What was new:
  - ✓ workshops conducted with key management staff participating
  - ✓ Shared areas of poor performance by each cohort presented the role of management and the value of their involvement in performance improvement
- Outcomes

NIGERIANS AMERICANS
IN PARTNERSHIP TO FIGHT HIV AIDS

SLMTA-2: Next Steps for Nigeria

- Hold Special Sessions for Management staff in all future stepdown workshops
  - To intimate them of roles and responsibilities, and seek Commitment
  - Monitor Progress from Management Perspective

- Conduct SLMTA 2 workshop for in-country SLMTAns

- Conduct workshop for mentors/IP staff providing oversight to participating labs

- Monitor Outcome on Labs and Share Experience in ASLM 2018

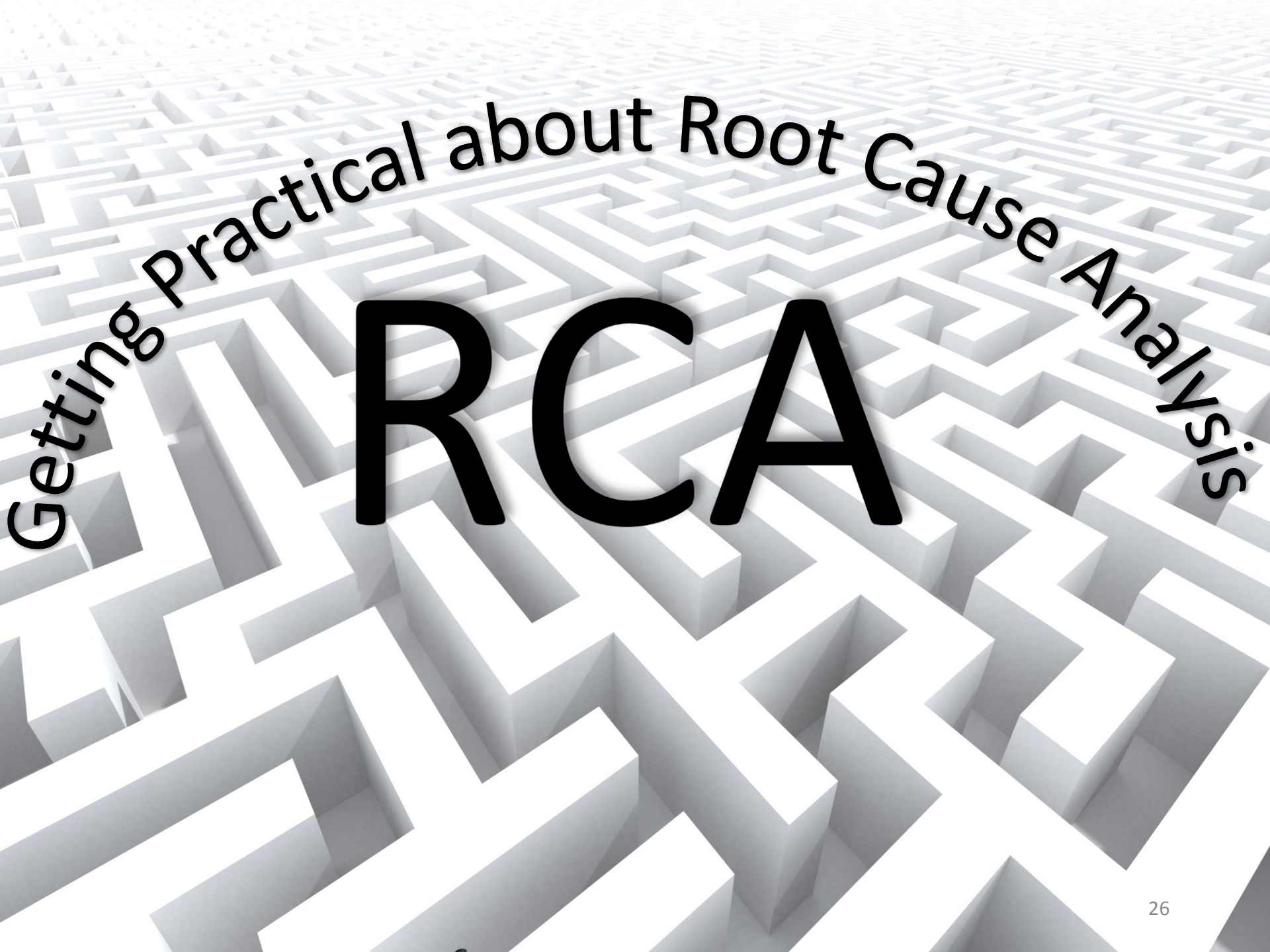
NIGERIANS AMERICANS
IN PARTNERSHIP TO FIGHT HIV AIDS

Acknowledgement

- CDC – ILB
- PEPFAR - Nigeria
- Anna Murphy
- Katy Yao
- ASLM 2016

NIGERIANS AMERICANS
IN PARTNERSHIP TO FIGHT HIV AIDS

Questions ????
Comments !!!!!


Getting Practical about Root Cause Analysis
RCA

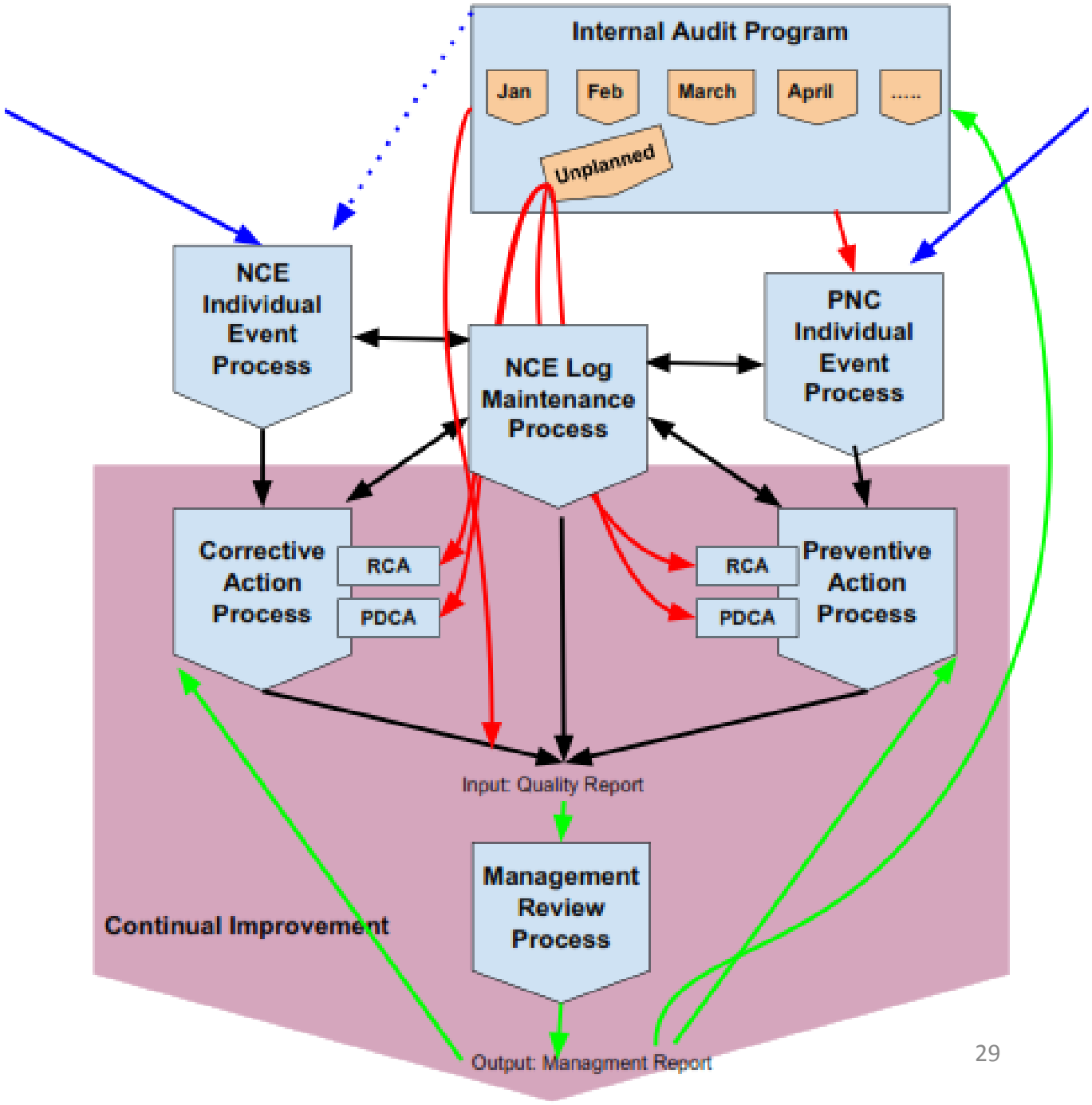
There will be problems.

The laboratory shall have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes. ISO 15189 4.9

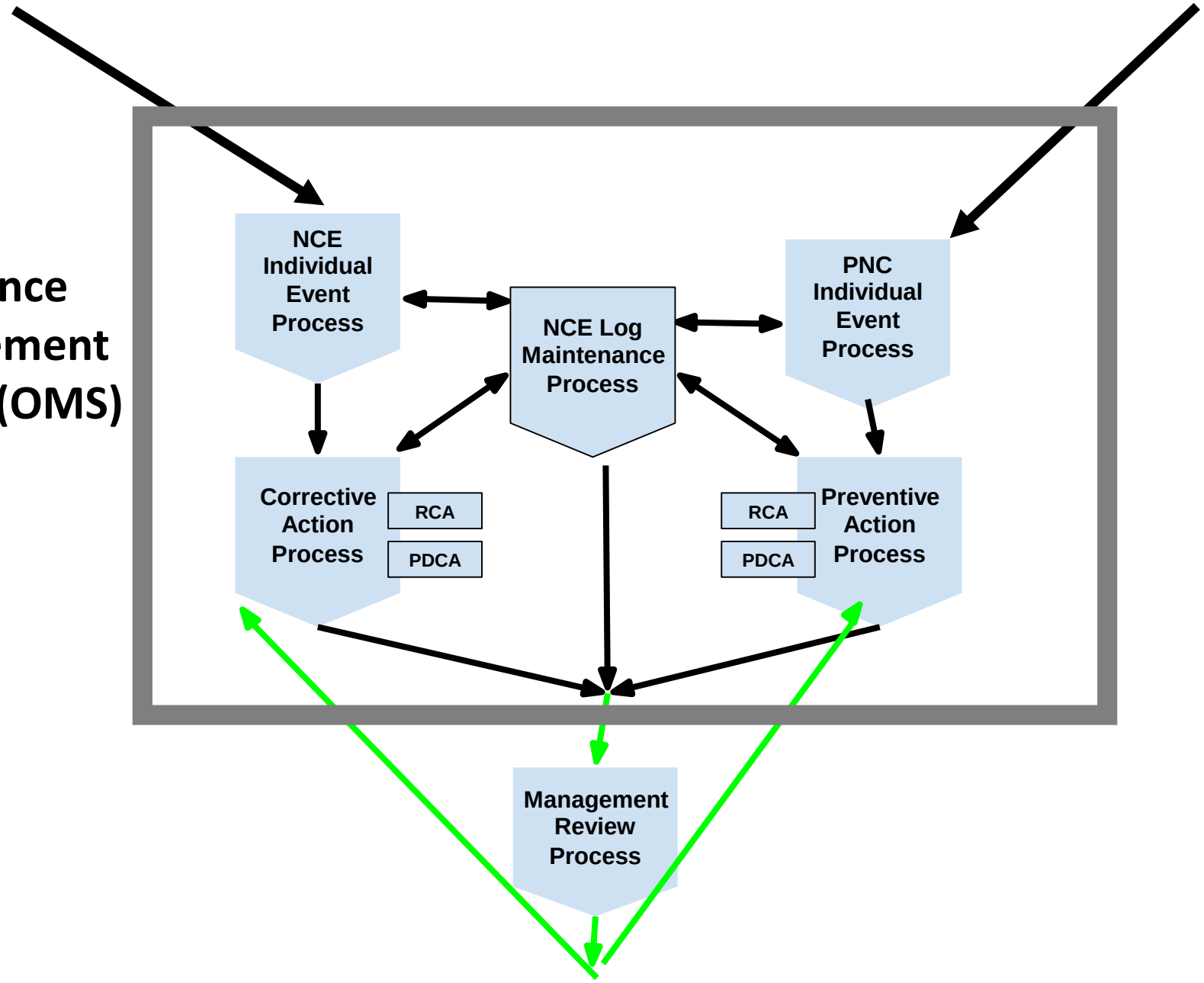
It’s not complicated, but it is a process

OMS SESSION 6: RCA + PDCA = CA

Measurement, Analysis, and Improvement Element of a QMS



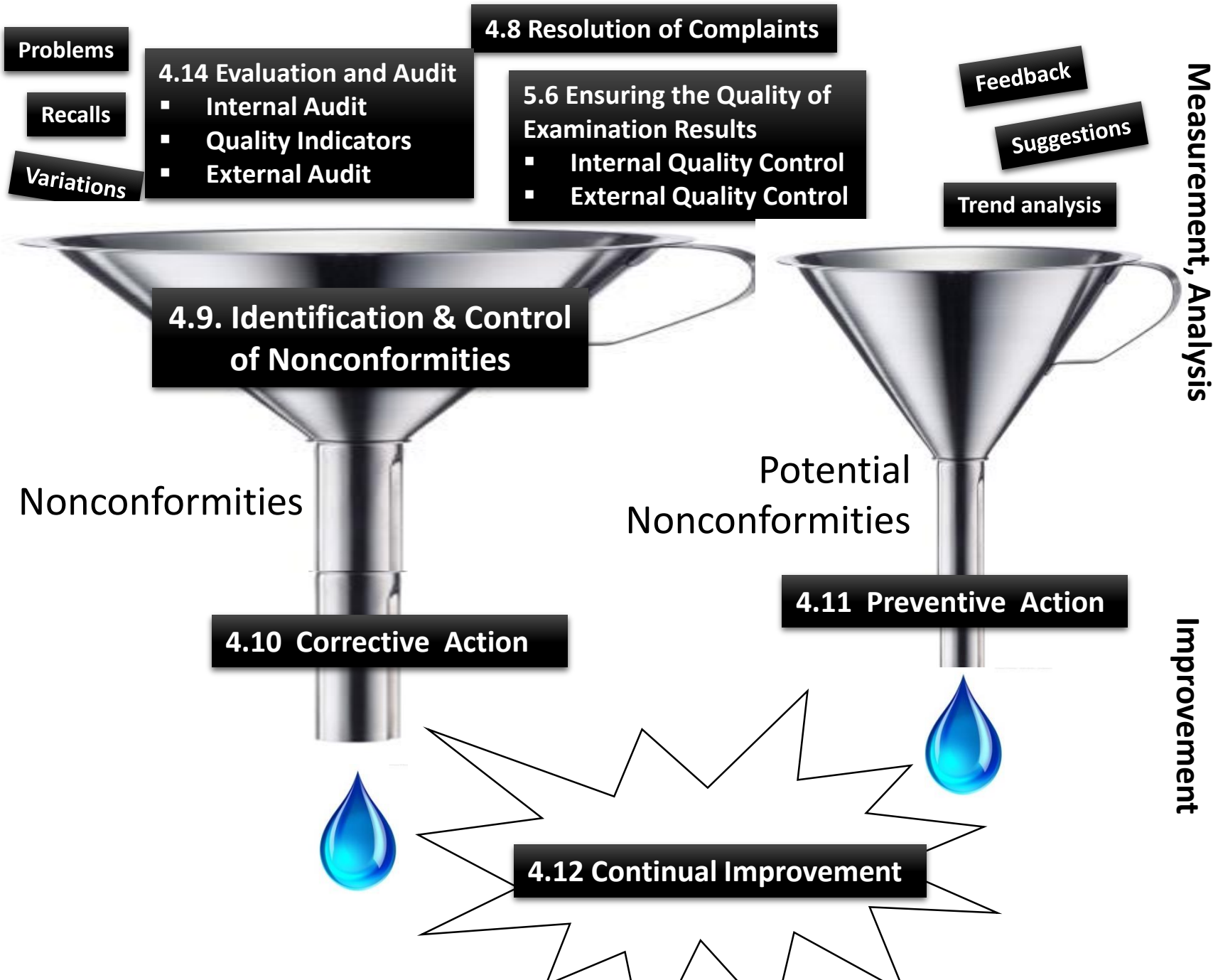
Occurrence Management System (OMS)



Occurrence Management System (OMS)

Purpose: To identify and characterize problem-prone laboratory processes so improvement projects (IP) can be prioritized, designed, and implemented.

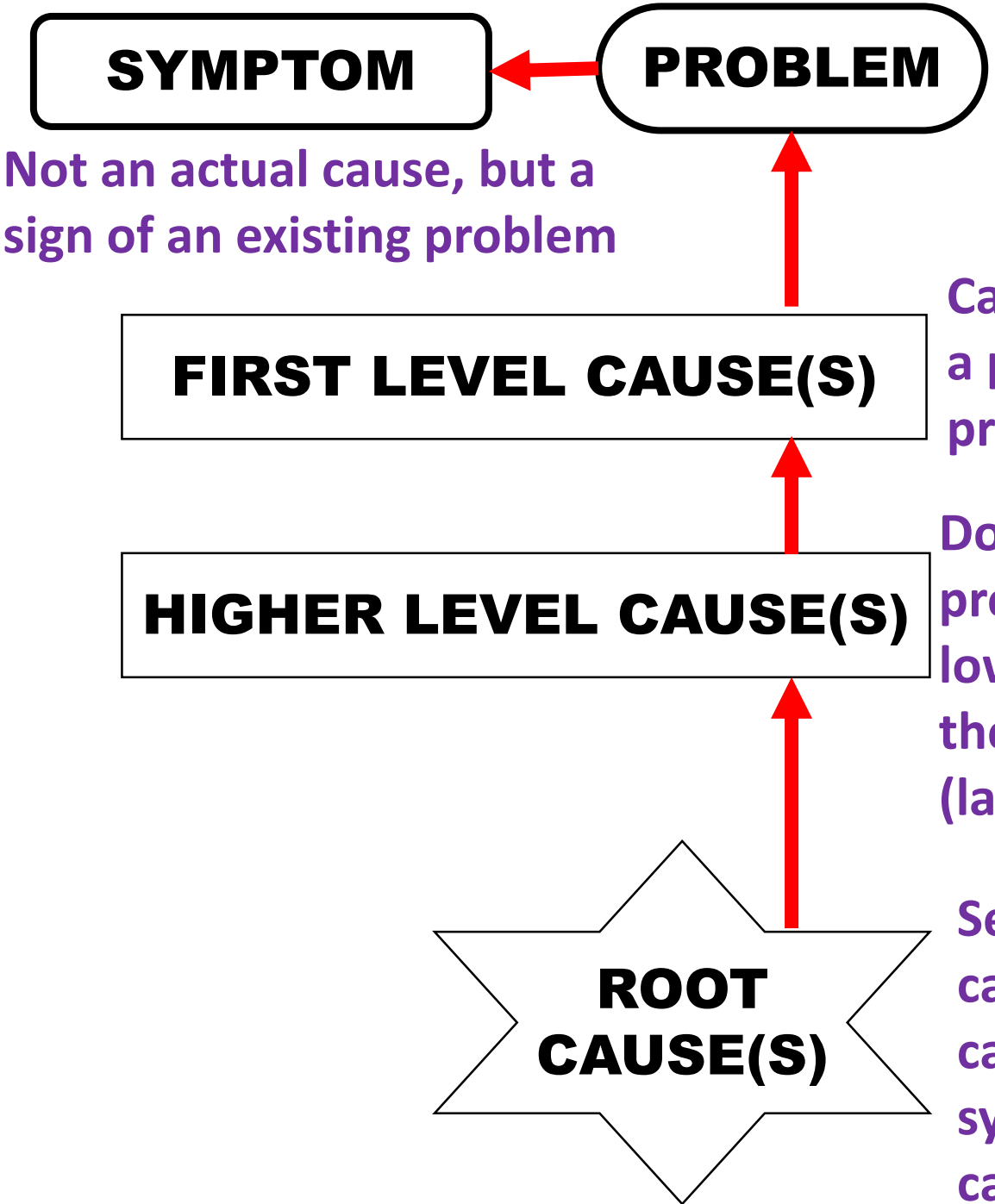
adapted from (CLSI QMS 11,2015, p. 2)


Problems
Recalls
Variations
4.14 Evaluation and Audit
Internal Audit
Quality Indicators
External Audit
4.8 Resolution of Complaints
5.6 Ensuring the Quality of Examination Results
Internal Quality Control
External Quality Control
Feedback
Suggestions
Trend analysis
Measurement, Analysis
4.9. Identification & Control of Nonconformities
Nonconformities
Potential Nonconformities
4.10 Corrective Action
4.11 Preventive Action
Improvement
4.12 Continual Improvement

4.10 Corrective Action

NOTE: Action taken at the time of the nonconformity to mitigate its immediate effects is considered *immediate* action. Only action taken to remove the root cause of the problem that is causing the nonconformities is considered *corrective* action.
ISO 15189:2012

Different Level of Causes



Fact or Fiction

Determine if the following statement is fact or fiction.

Every time something goes wrong, corrective action must be taken, regardless of cost.

Fiction: **Corrective a**

to be taken every tim

should be fixed whe

business sense.

Quality SnapShot:

Corrective Action

A Practical AND Effective Approach For ISO 9001:2008

Presented by Mark Ames
Hosted by Pablo Baez

ASQ
The Global Voice of Quality™

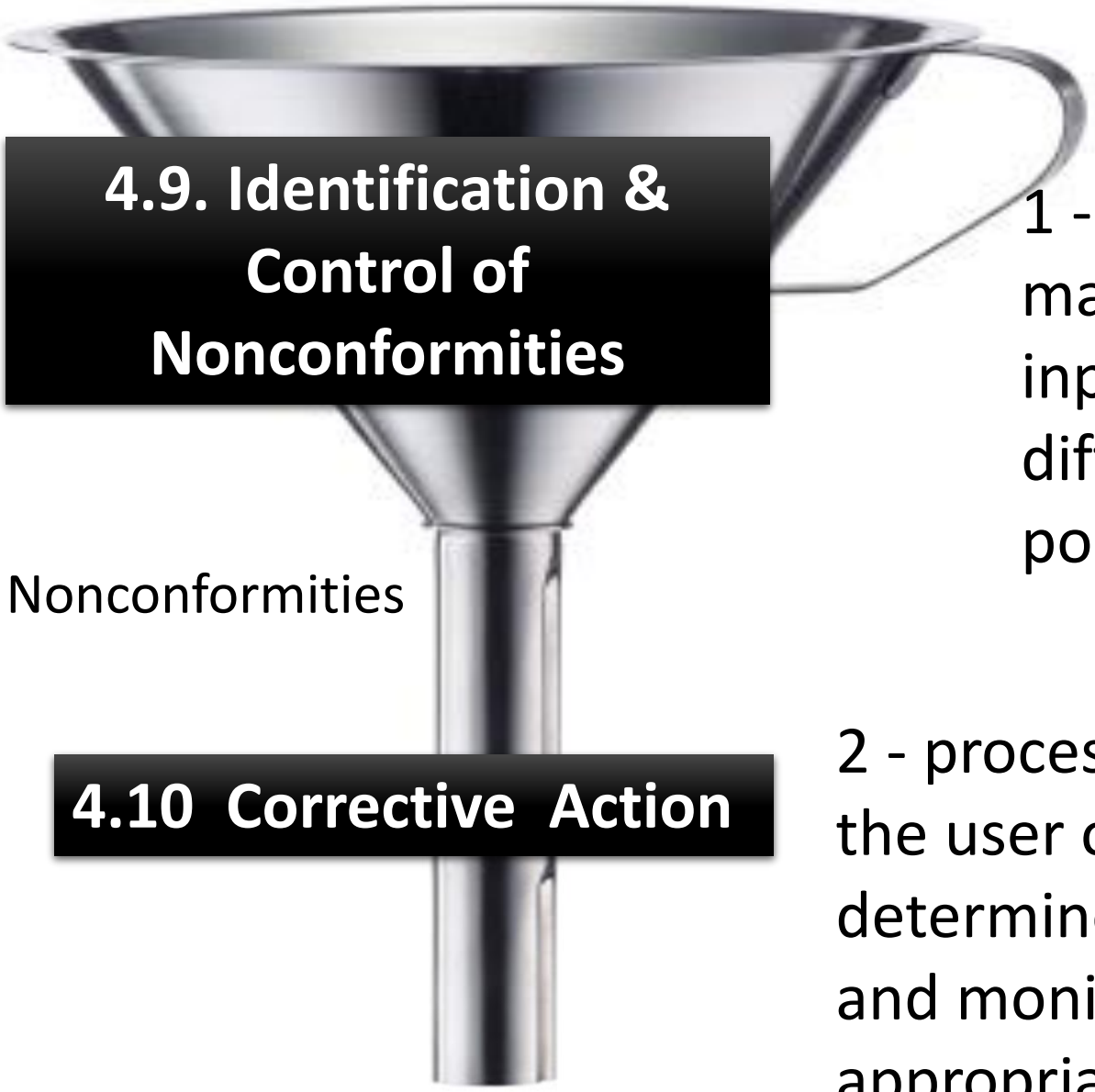
Google

ASQ Corrective Action Webcast

Many people have been misled to believe that any occurrence of a nonconformance warrants the initiation of a corrective action request. They often reach this conclusion through error or intimidation. They would rather err on the side of caution than take a chance of getting caught during a surveillance audit for failing to perform the requisite corrective actions. Consequently, everything automatically triggers the issuance of a CAR [corrective action request].

Denise Robitaille

author of The Corrective Action Handbook and Root Cause Analysis: Basic Tools and Techniques



4.9. Identification & Control of Nonconformities

1 - process which manages all the inputs from different control points

Nonconformities

4.10 Corrective Action

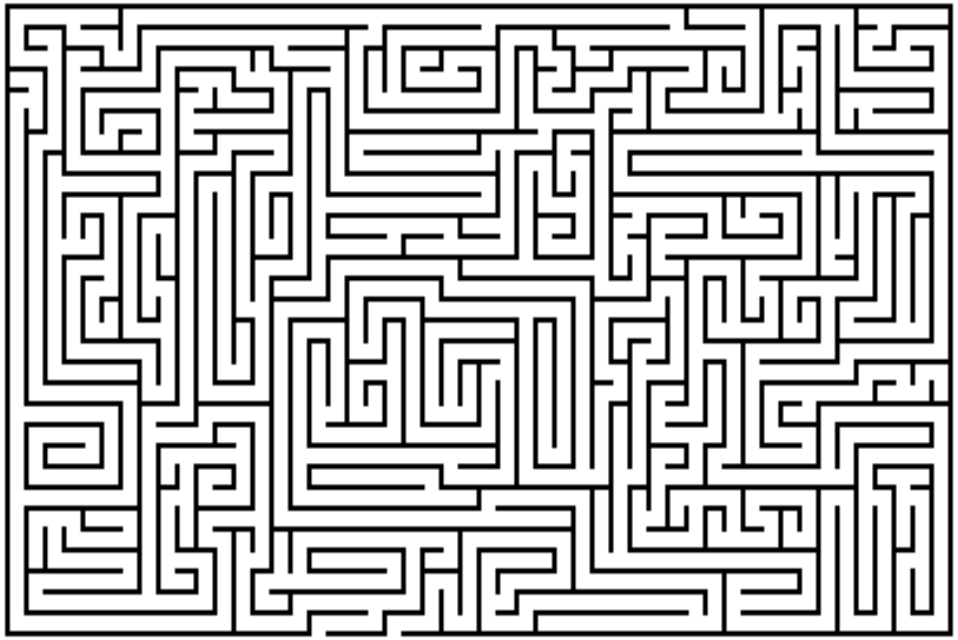
2 - process which guides the user or team to determine, implement, and monitor the appropriate action specific to the site.

Measurement, Analysis

Improvement

Problems come in different sizes. In other words, they pose a different level of risk to the laboratory.

Problem



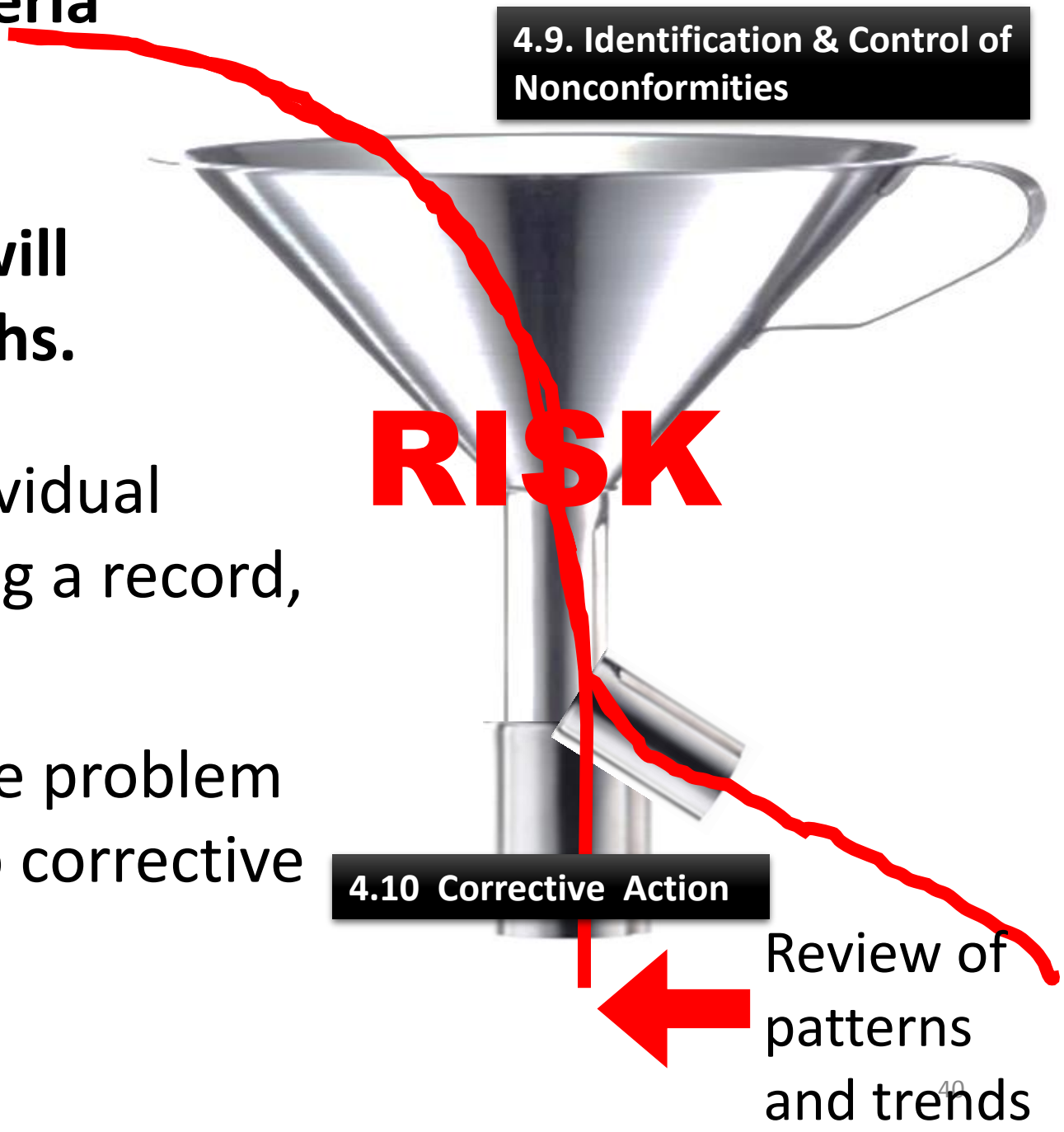
Solution

Risk assessment will guide the activities along different paths. If the risk is high, the process may differ from nonconforming events (NCEs) with lower risk.

Risk-based criteria that had been established by management will results in 2 paths.

1. Fixing the individual problem, keeping a record, and moving on.

2. Containing the problem and moving it to corrective action.

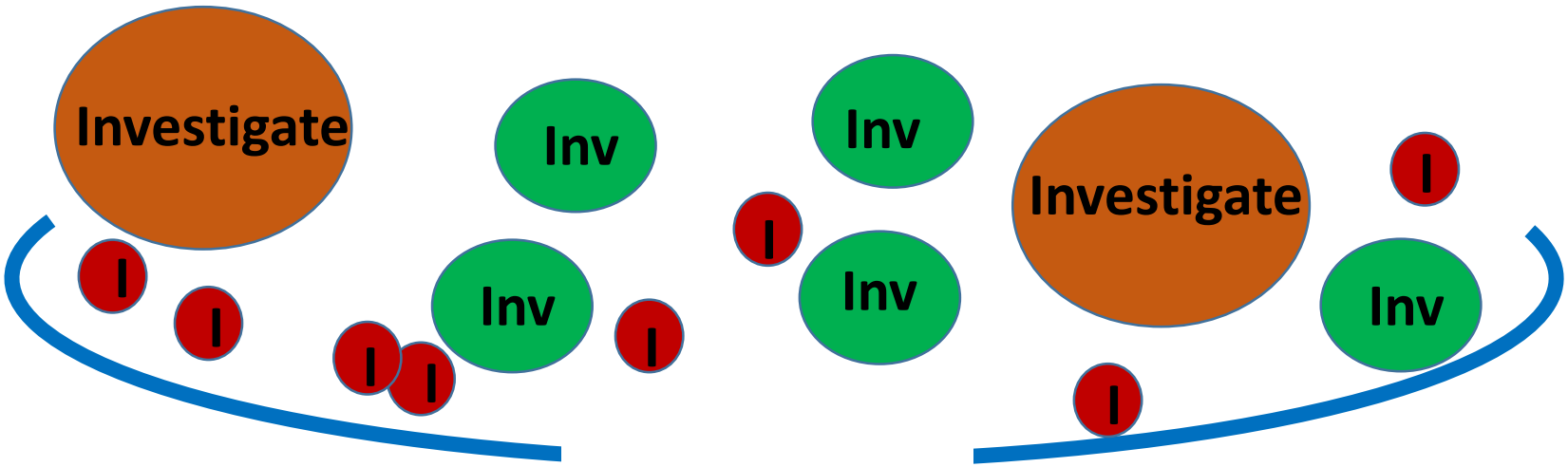


Resources are limited.

Having a need does not create a resource.

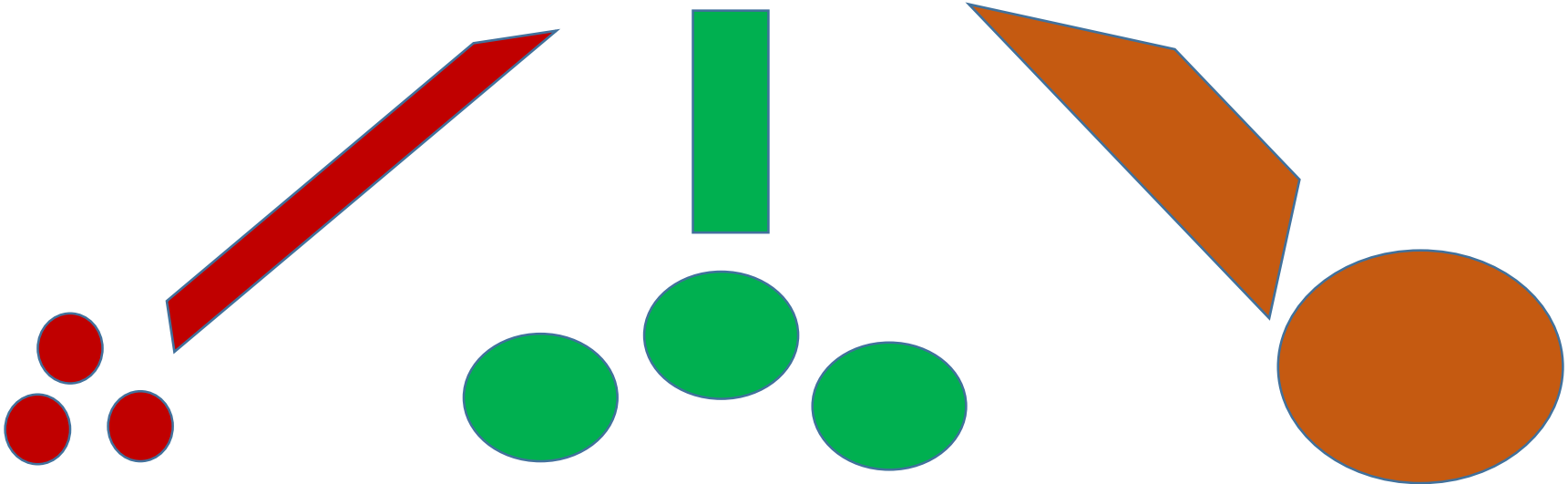
Laboratory management must prioritize problems so that the limited resources can be used wisely.

When determining the extent of the nonconformity,



RISK

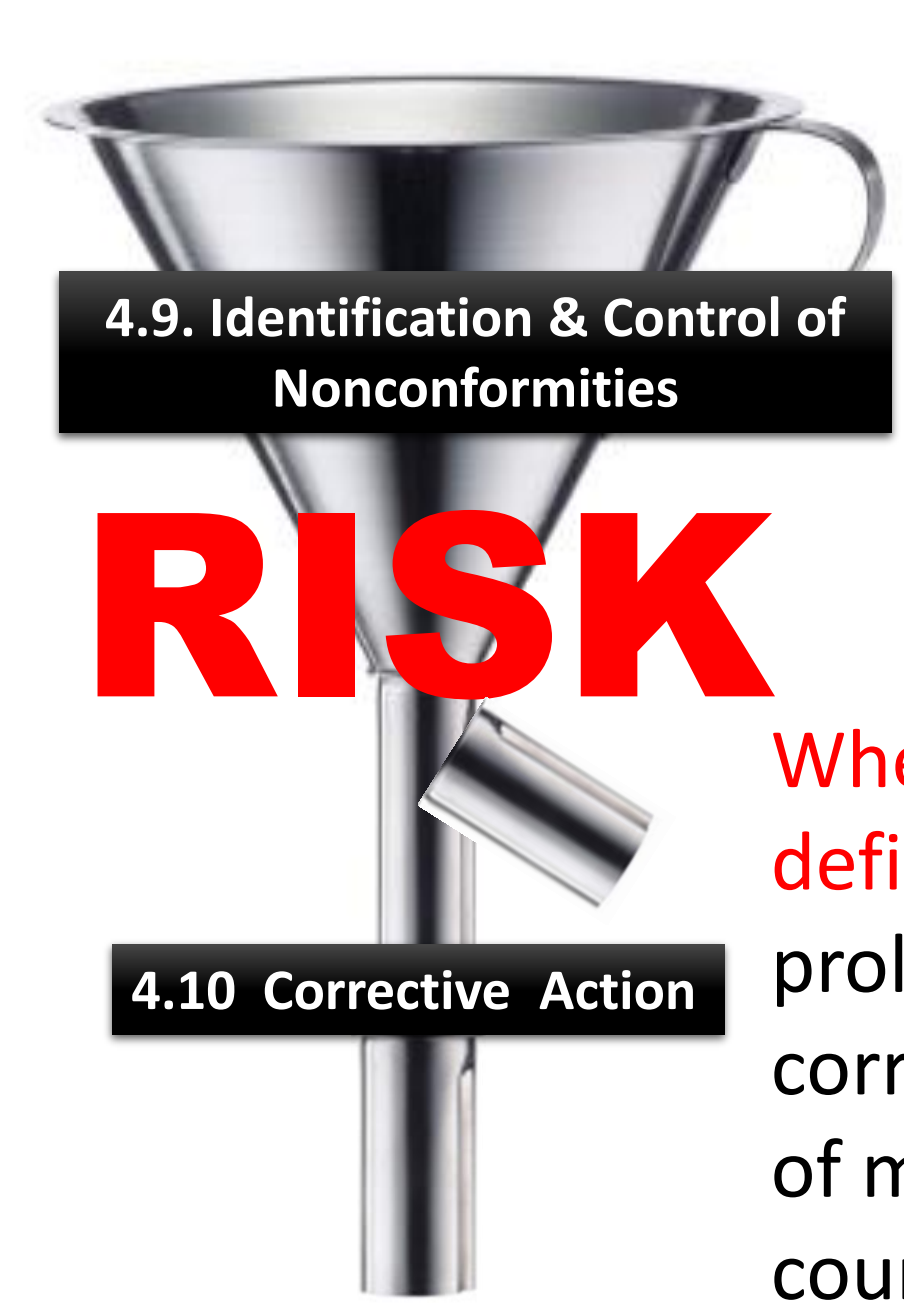
the course of action should be consistent with the risk it presents.



It's far better to effectively solve a few problems than poorly solve many.

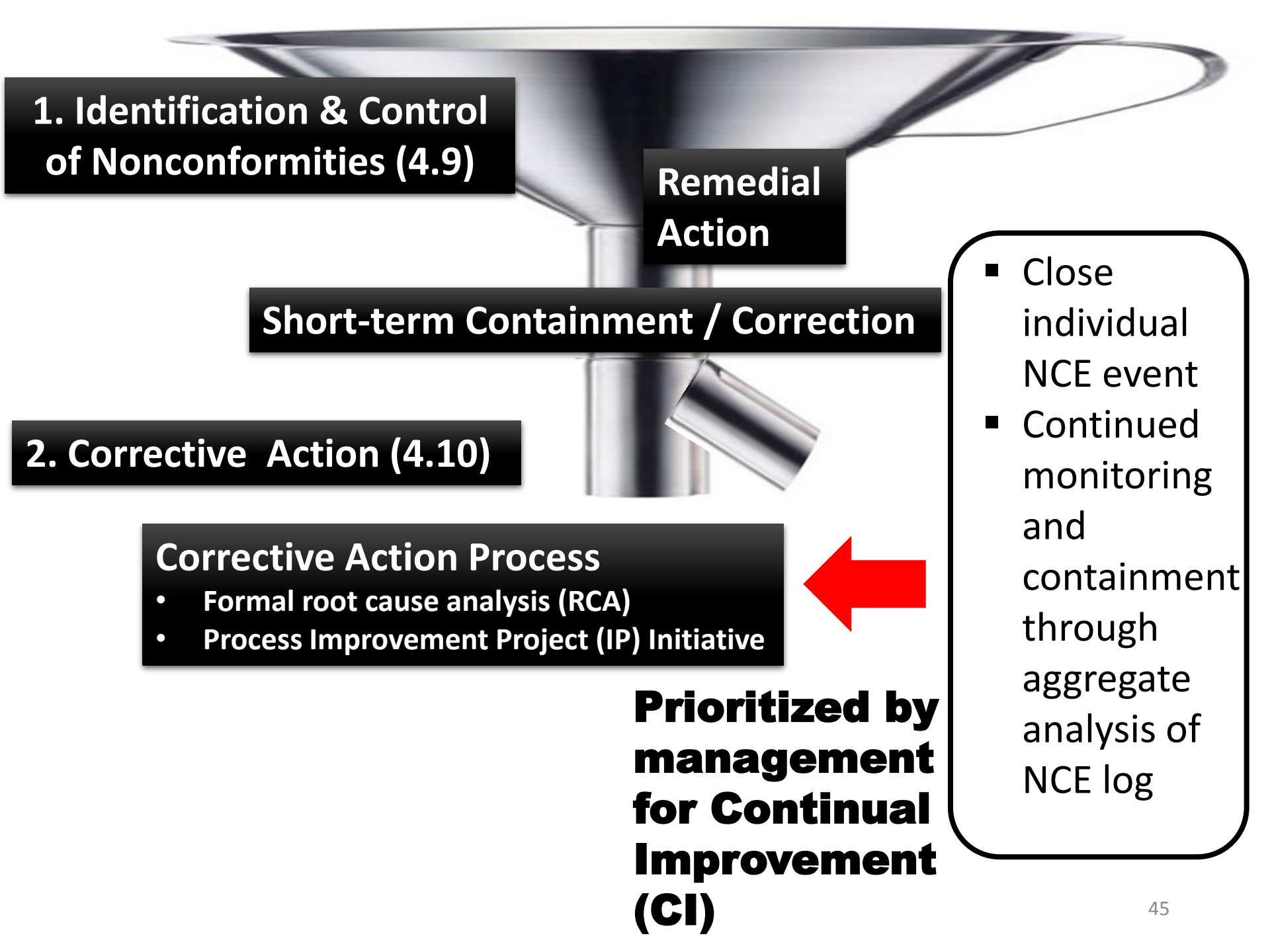
Craig Cochran,

author of Problem Solving in Plain English,
ISO 9001 in Plain English, and ISO 9001:2015 in Plain English

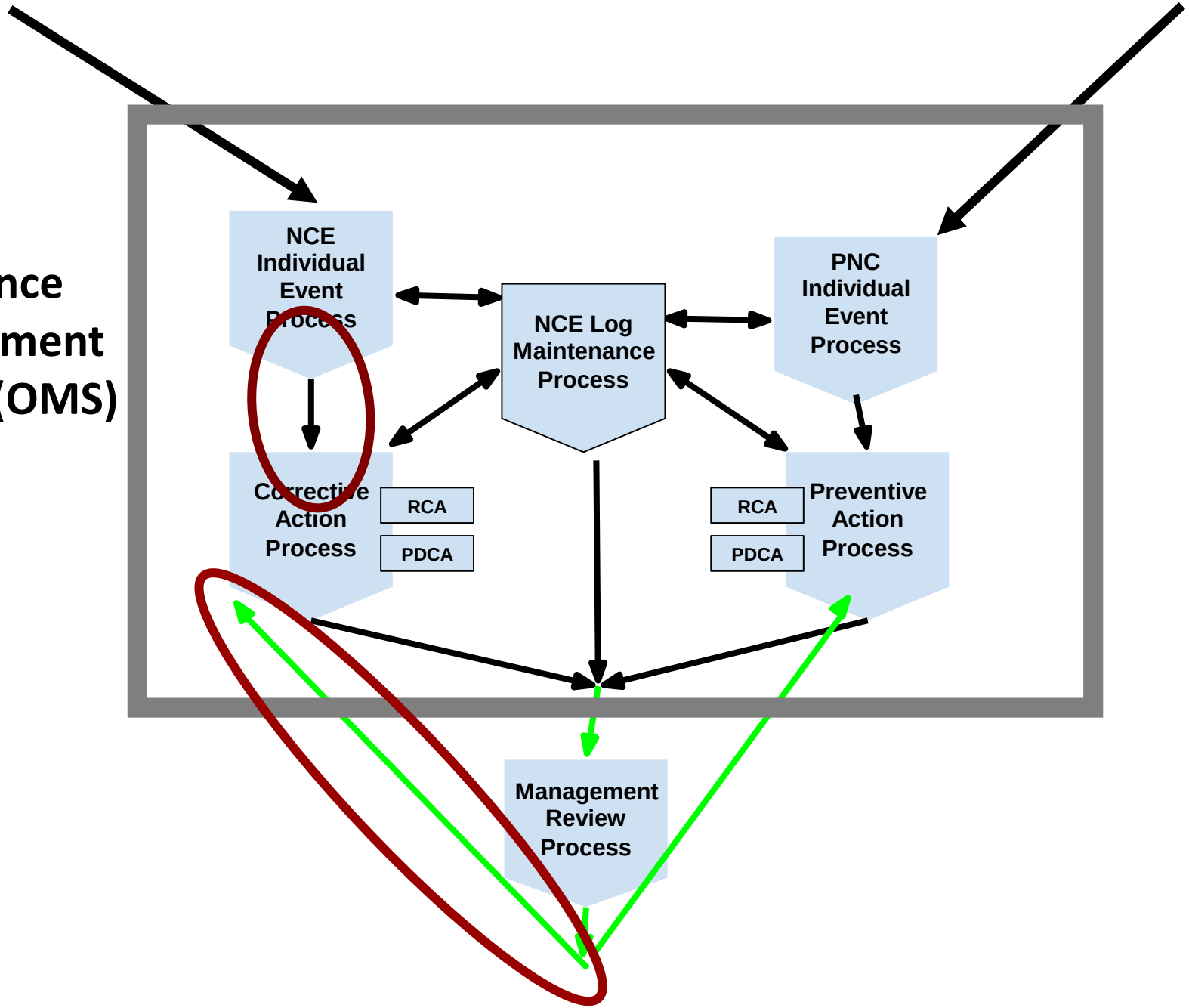


Without defined criteria, you are stuck enacting corrective action in all cases, even when it's not the best option.

When management does **not** define criteria, it can result in a proliferation of unwarranted corrective actions that are often of marginal value or even counterproductive to the organization.


1. Identification & Control of Nonconformities (4.9)
Remedial Action
Short-term Containment / Correction
2. Corrective Action (4.10)
Corrective Action Process
• Formal root cause analysis (RCA)
• Process Improvement Project (IP) Initiative
Prioritized by management for Continual Improvement (CI)
▪ Close individual NCE event
▪ Continued monitoring and containment through aggregate analysis of NCE log

Occurrence Management System (OMS)



ISO 15189: 4.9 Identification and control of nonconformities

The laboratory shall have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination, or post examination processes.

……

When it is determined that nonconformities in pre-examination, examination and post-examination processes could recur or that there is doubt about the laboratory's compliance with its own procedures, the laboratory shall take action to identify, document and eliminate the cause(s). Corrective action to be taken shall be determined and documented (see 4.10).

NCE Requirements

ISO 15189: 4.9(h) Each episode of nonconformity is documented and recorded,

- Identify, report and record NCEs
- Investigate and take appropriate action on NCEs

---

with these records being reviewed at regular specified intervals to detect trends and initiate corrective action.

- Classify, analyze, and present NCE data and information
- Identify underlying causes of process problems
- Report NCE information for management review.

Requirements modified from CLSI:GP26-A4

ISO 15189: 4.10 Corrective action

The laboratory shall take corrective action to eliminate the cause(s) of nonconformities.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

Who decides what is *appropriate*?

Corrective Action Process

- Identify the need for CA as an output from the NCE process
- Document and assign project leader
- Contain problem as needed
- Track progress
- Update progress to management
- Submit Close-out report
- Celebrate with staff

RCA Process

- Identify possible causes
- Collect and analyze data
- Determine actual causes(s)

(problem statement)

PDCA Process

- Identify solutions
- Implement solutions
- Evaluate results

(aim statement)

Root Cause Analysis (RCA)

- Method of problem solving that works to identify the root causes of problems.
- Powerful approach to solving problems
- A process to systematically detect and analyze the possible causes (the WHY) of a problem in order to determine corrective action(s) to be taken

How to solve a problem

Beneath every problem lies a cause for that problem

Step # 1 Identify the cause of the problem

RCA Process

Step # 2 Find ways to eliminate the cause and prevent it from recurring

PDCA Process

The purpose of RCA is intended to provide a framework for identifying issues buried beneath layers of documents, records, practices, excuses, and confusion to discover **what really went wrong.**

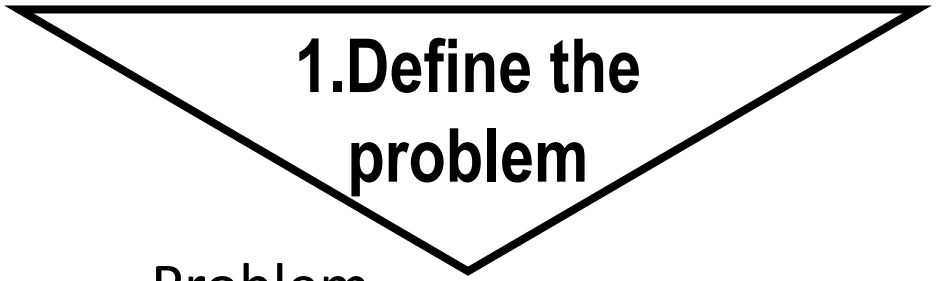
No more QUICK FIXES

RCA Process Map

image adapted from Okes, (2009), Fig. 1.2

Decision to do RCA has been met

Diagnostic Phase
(Find It)



Problem Statement

Solution Phase
(Fix It)

RCA Step #1 :Define the Problem

In order to define the problem, you must have some initial information.

2 parts to Step #1

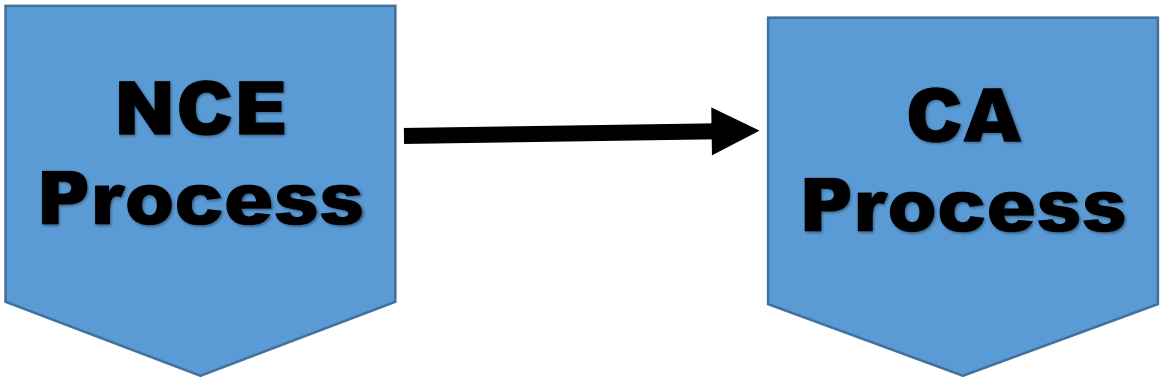
A. Collect data to determine or confirm the facts.

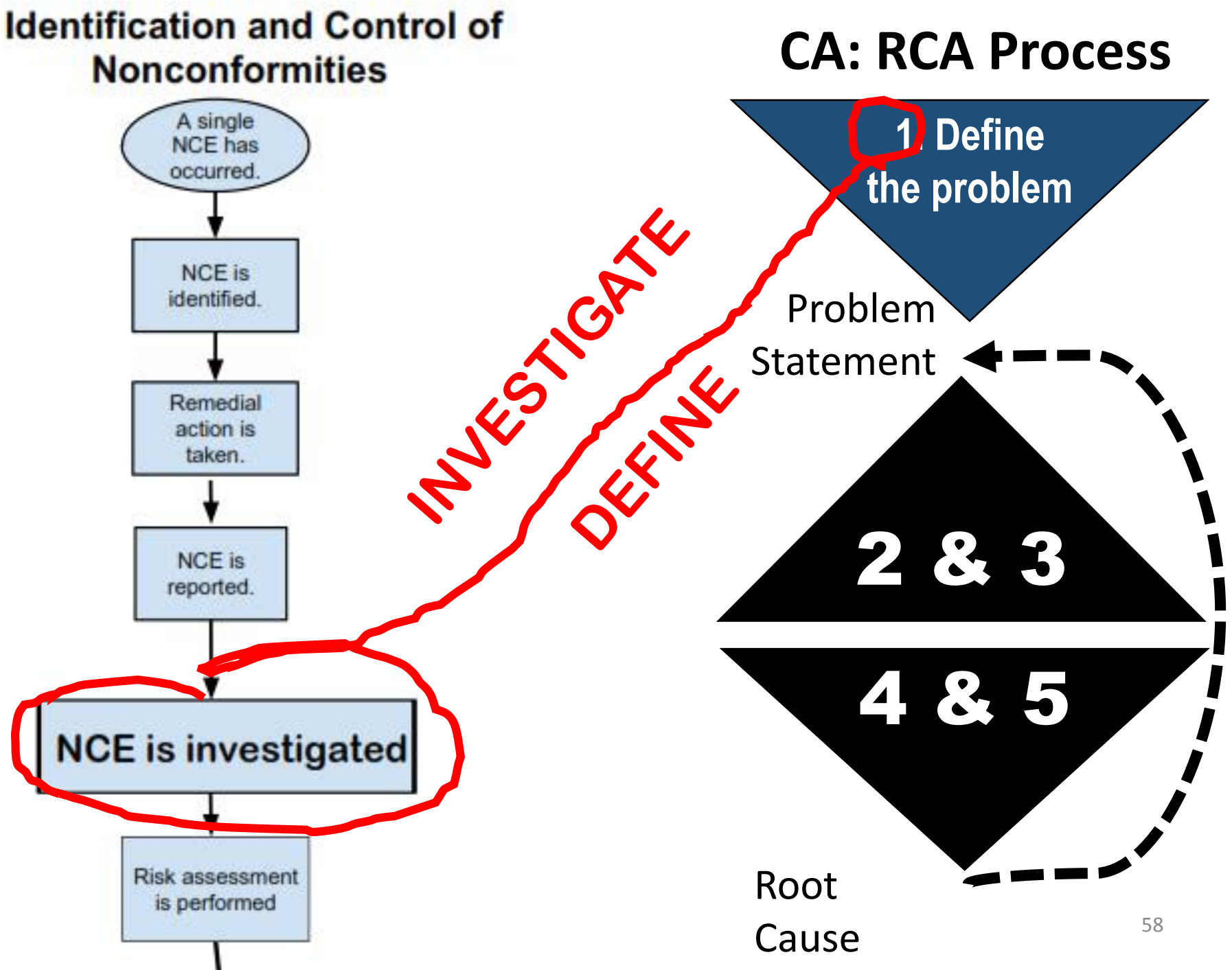
B. Define the problem to solve.

A problem well stated is a problem half solved Charles Kettering

In order to define the problem, you must have some initial information.

Effective RCA starts with a good NCE report.




Identification and Control of Nonconformities
A single NCE has occurred.
NCE is identified.
Remedial action is taken.
NCE is reported.
NCE is investigated
Risk assessment is performed
INVESTIGATE
DEFINE
CA: RCA Process
1 Define the problem
Problem Statement
2 & 3
4 & 5
Root Cause

WHAT exactly is the problem? (Move one step beyond the symptoms)
WHERE does it occur?
WHEN does problem happen?
WHO experiences the problem?
HOW MUCH does it occur?
WHY DOES IT MATTER? (i.e., what requirements are violated by the problem?)

Problem Statements

- Should contain specific **facts** (e.g. What, Who, When, Where, Why does it matter) obtained through investigation and research.
- Take nothing for granted; all **facts** are verified, if possible
- Do not speculate on causes, but define the problem as **factually** as possible

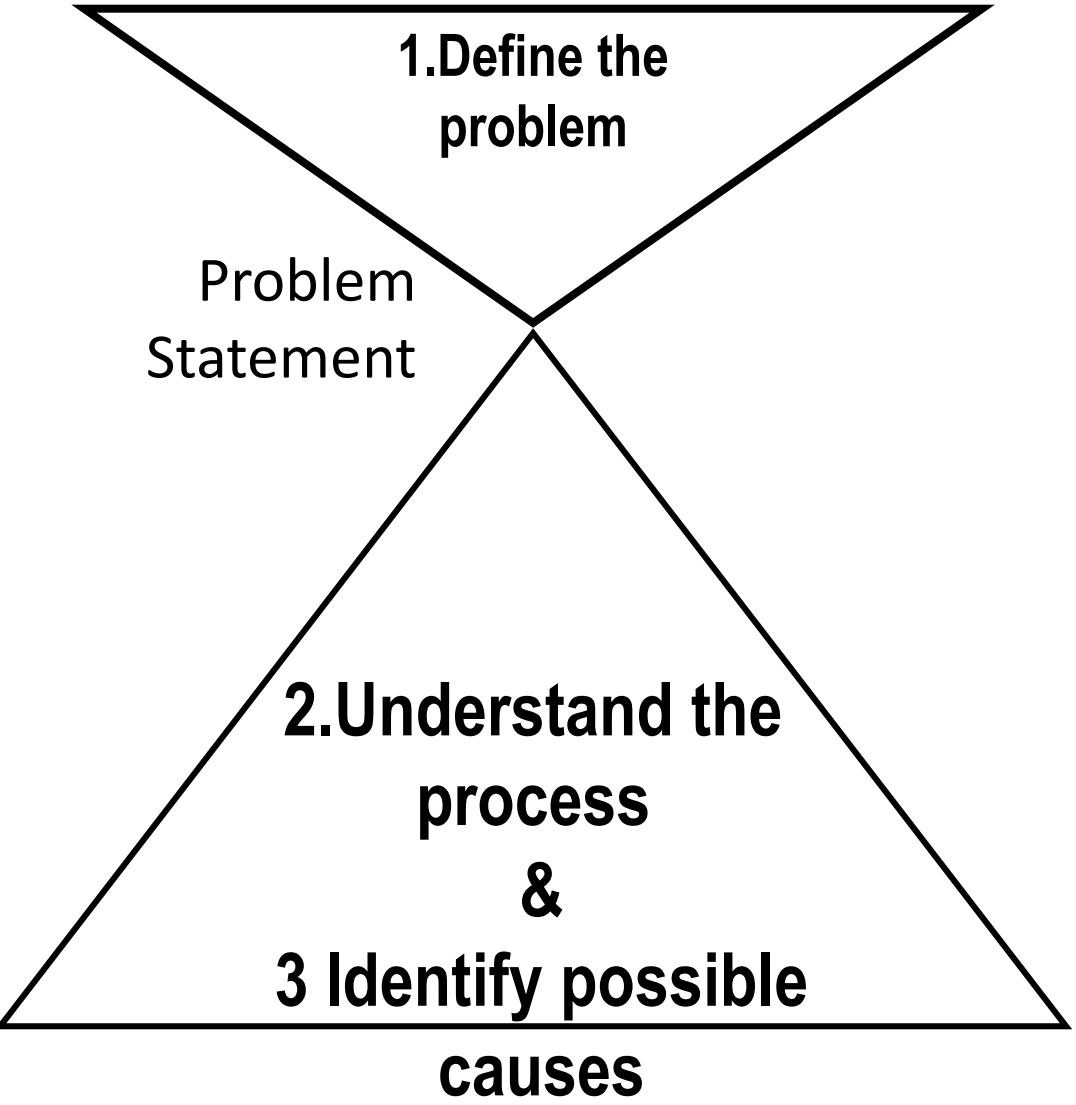
RCA Process Map

Decision to do RCA has been met

image adapted from Okes, (2009), Fig. 1.2

Diagnostic Phase (Find It)

Solution Phase (Fix It)



Understand the process first,

then ask **WHY.**

RCA Process Map

image adapted from Okes, (2009), Fig. 1.2

Decision to do RCA has been met

Diagnostic Phase (Find It)

1.Define the problem

Problem Statement

2.Understand the process & 3 Identify possible causes

4. Collect evidence to confirm or deny each cause & 5. Determine the root cause(s)

Root Cause Statement

Solution Phase (Fix It)

6. Identify possible solution(s)

7. Select solution(s) to be implemented

Preferred Solution(s)

8. Implement Solution(s)

9. Evaluate effects

NO

YES

Measure of Effectiveness

Quality·Improvement·Project·Plan XC30¶

PLAN¶

Use·all·the·resources·available·to·you·to·try·and·understand·the·problem,·propose·solutions·and·develop·an·action·plan.¶

SECTION·A--Identifying·the·problem¶

I.·State·the·apparent·problem:¶

_____ →

II.·Collect·Baseline·Data:¶

What·data·will·be·collected?· _____

Method·--How·will·the·data·be·collected?· _____

Who·is·responsible·for·collecting·data?· _____

What·are·the·tools/forms/checklists·to·be·used?· _____

Over·what·period·of·time·will·the·data·be·collected?· _____

When·will·the·data·be·reviewed?· _____

¶

III.·Analyze·the·baseline·data:¶

What·is·wrong?· _____

SECTION·B:·Action·Plan¶

I.·Identified·problem:· _____ →

II.·AIM·Statement·(overall·goal·of·this·project)· _____ →

III.·Actions·to·be·implemented·(following·brainstorming·of·possible·solutions).¶

Action·item¤	Responsible·Person¤	Timeline¤	Signature¤
¤	¤	¤	¤

¶

IV.·Select·and·Define·ELEMENT·TO·BE·MEASURED·(to·monitor·effectiveness·of·implemented·actions) _____ →

V.·Results·of·element·measured·at·baseline· _____ →

VI.·Acceptable·results·(target·for·this·measure)· _____ →

VII.·Data·Collection¶

How·will·the·data·be·collected?· _____ →

Who·is·responsible·for·collecting·data?· _____ →

RCA Process Map

image adapted from Okes, (2009), Fig. 1.2

Decision to do RCA has been met

Diagnostic Phase (Find It)

1.Define the problem

Problem Statement

2.Understand the process & 3 Identify possible causes

4. Collect evidence to confirm or deny each cause & 5. Determine the root cause(s)

Root Cause Statement

Solution Phase (Fix It)

6. Identify possible solution(s)

7. Select solution(s) to be implemented

Preferred Solution(s)

8. Implement Solution(s)

9. Evaluate effects

NO

YES

10. Institutionalize the change

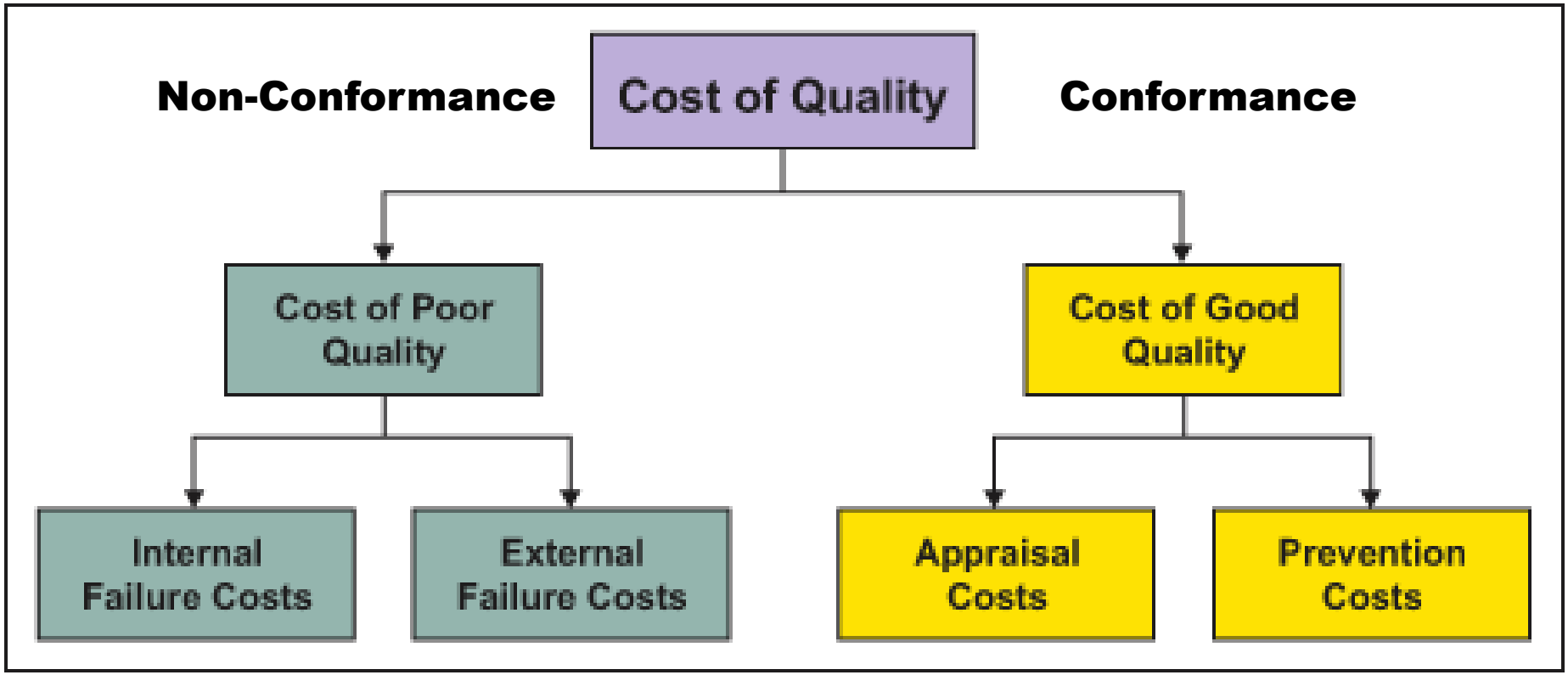
Laboratories should have a methodology that will allow their staff to do an investigation using a repeatable process to uncover cause every time. They can then go from problem to problem to problem. The data will change, the content will change, and the customer will change, but the process is so good that it will get them to the appropriate answer every time.

No studies have shown that NCE management is a more effective way to promote quality than up-front quality planning and design.

Quality planning and design keeps problems out of RCA.

How Much Does Failure Cost Us?

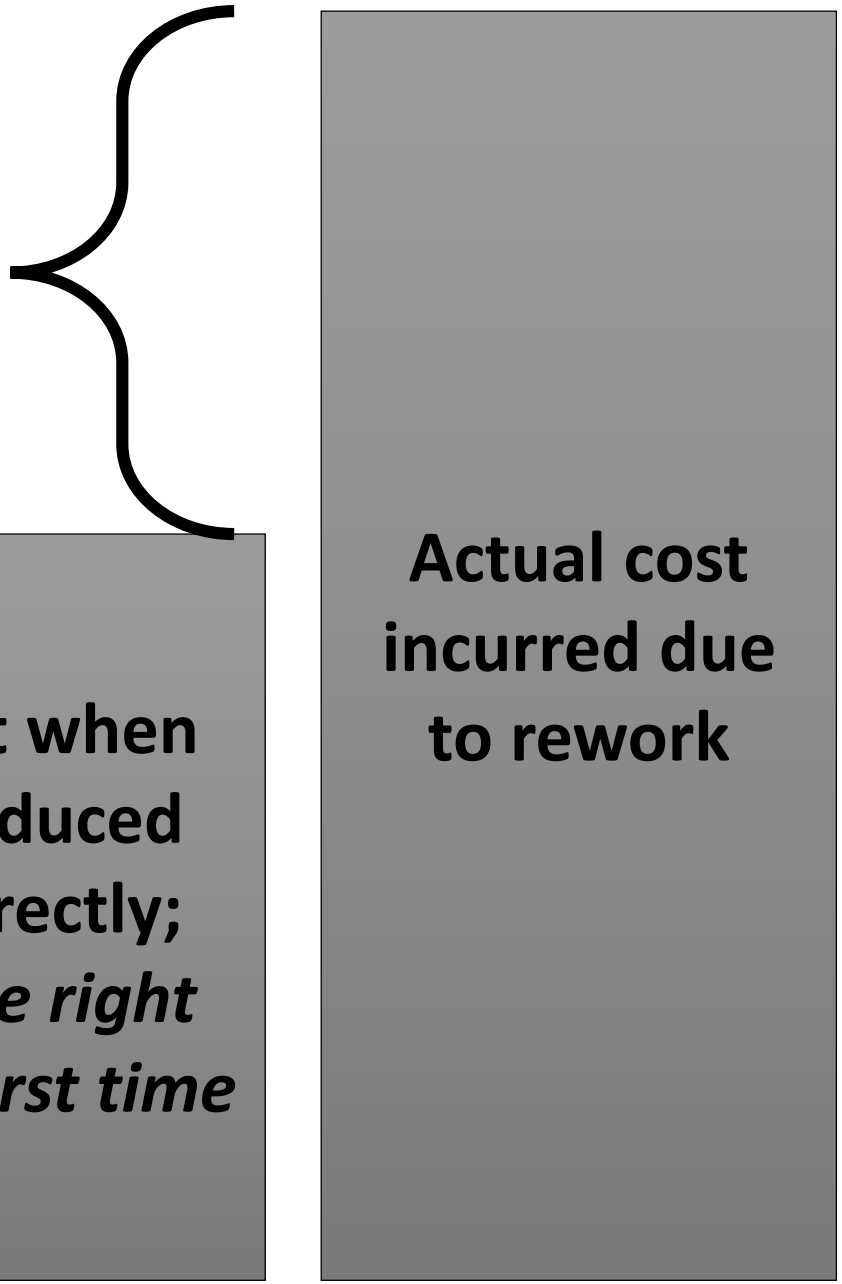
The Cost of Quality is NOT the cost of creating a quality product or service. Instead, the Cost of Quality is a FAILURE to create a quality product or service.



Every time work is redone (rework), the Cost of Quality increases.

Cost of Quality

- any cost that would not have been expended if quality was met the first time.
- also known as the Cost of Poor Quality (COPQ)



Types of Quality Costs
Costs of Good Quality

I. **Expenses for Maintaining Quality** – line items in an operating budget
   A. **Prevention Costs** – costs for laboratory activities designed to prevent poor quality in laboratory services
   B. **Appraisal Costs** – costs for activities associated with measuring, evaluating, or auditing to assure conformance to quality standards.

Types of Quality Costs
Costs of Poor Quality (CoPQ)

II. **Expenses for Rectifying Quality Problems** – causes for running over (exceeding) the budget
   A. **Internal Failure Costs** – costs for rework caught and corrected inside the laboratory (before it reaches the customer)
   B. **External Failure Costs** – costs for rework not caught by the laboratory but was detected by the customers

How to Translate Failure into a Reasonable Estimate of Cost

Cost of Supplies (Materials)

1. Create a list of supplies used for only the failed process (Remember, SLMTA Module 3: Creating a List of Supplies for a Test?).
2. Determine the cost of the supplies using purchase order information.
3. Determine the quantity wasted due to the nonconformity.

Cost of Labor

1. Determine who, by job title, does what and for how long to address this failure.
2. Determine the hourly wage for that job title.

Job Aid 3: COPQ [705]

How to ESTIMATE the Cost of Poor Quality (COPQ)

Failure Event: **Date:**

Material Costs	Material Item Description	Item Cost per 1 Item	Quantity Used	Total
	Item 1			0.00
	Item 2			0.00
	Item 3			0.00
	Item 4			0.00
	Item 5			0.00
	Item 6			0.00
	Item 7			0.00
	Item 8			0.00
	Item 9			0.00
	Item 10			0.00
			Cost of Materials Subtotal	0.00

Labor Costs	**Labor Item Description** (may include initial NCE discovery, investigation, repeated process, and follow-up of the failure)	**Hours per Task** (in tenths of an hour)	**Hourly Rate**	**Total**
	Job Title 1			0.00
	Job Title 2			0.00
	Job Title 3			0.00
	Job Title 4			0.00
	Job Title 5			0.00
		Hours of Labor 0.00	**Cost of Labor Subtotal**	0.00

spreadsheet adapted from CLSI QMS20-R, 2014, Appendix B1

Cost per Failure 0.00

Equipment Downtime incurs failure costs for:

- Alternate provision of laboratory services (i.e. sending samples to another laboratory)
- Verifying functionality after in-house service is restored
- Loss of revenues or customers during equipment downtime period

ESTIMATED Cost of Poor Quality Worksheet

Failure: 60 electrolyte test requests from pediatrics were referred due to equipment downtime — August 30 - Sept 10, 2016

Material Costs	Material Item Description	Item Cost per 1 Item	Quantity Used	Total
	gasoline for transport in liters	2.00	7.00	14.00
	referral laboratory charge per request (used their reagents)	0.25	60.00	15.00
	Item 3			0.00
	Item 4			0.00
	Item 5			0.00
	Item 6			0.00
	Item 7			0.00
	Item 8			0.00
	Item 9			0.00
	Item 10			0.00
			Cost of Materials Subtotal	29.00

Labor Costs	Labor Item Description	Hours per Task (in tenths of an hour)	Hourly Rate	Total
	Transport Courier (3 trips/day * 12 days*0.5 hours/trip)	18.00	3.00	54.00
	Referral Testing Clerk (5 min to write transfer slip and aliquot 60 specimen)	5.00	6.00	30.00
	General Laboratory Clerk (additional help with transfer log 15min/day *12 days)	4.00	5.00	20.00
	Job Title 4			0.00
	Job Title 5			0.00
	Hours of Labor	27.00	**Cost of Labor Subtotal**	133.00

Cost per Failure 162.00

Prevention is ALWAYS cheaper.

It is still easier, faster, and cheaper
to prevent errors
than to have to
find them and fix them.

Questions ????
Comments !!!!!