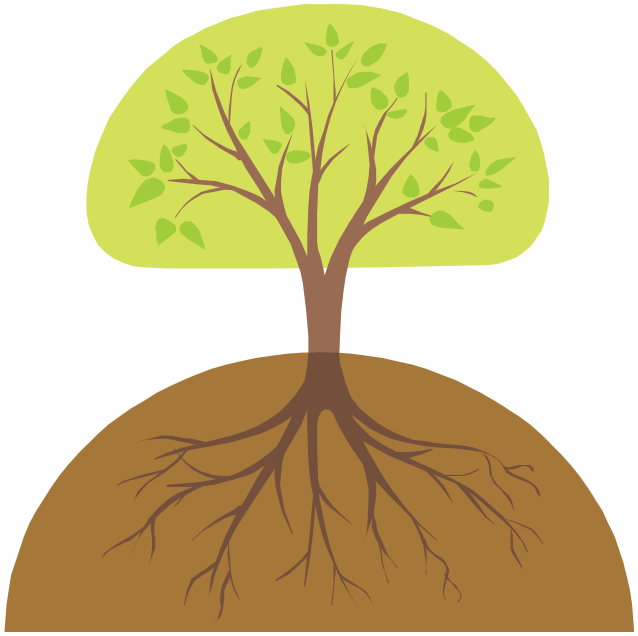
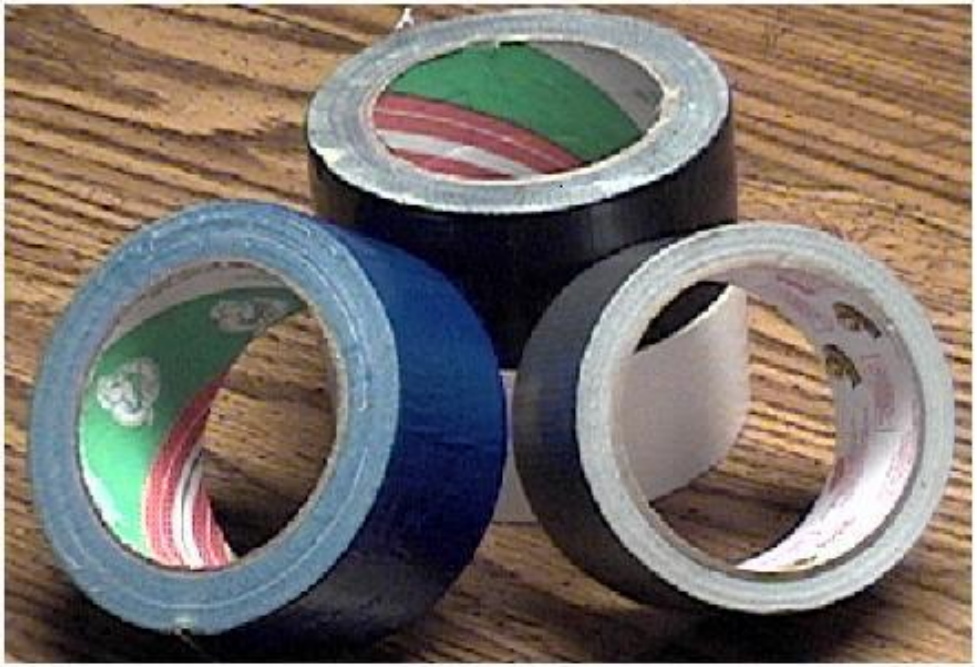
Root Cause Analysis

Why Blaming the Individual Misses the Point

Quality Matters™



I can fix anything

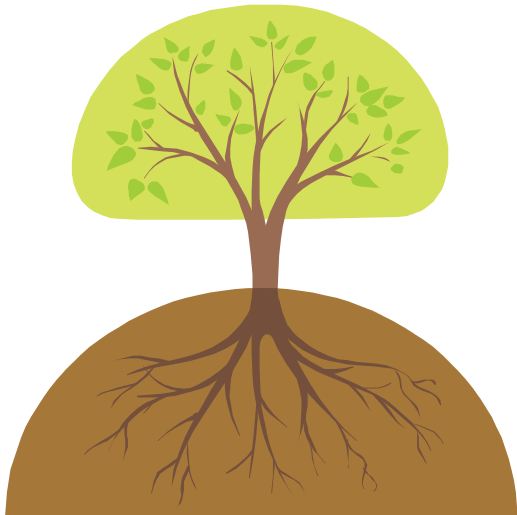


Where's the duct tape?

blog.beaumontenterprise.com

Presentation Overview

- Things to avoid
- RCA Concepts
  - Philosophy
  - Definition and Purpose
  - Benefits and Applications
- When to do RCA
- Where to begin?
- Steps of RCA



http://www.cartoonstock.com/directory/k/knee_jerk.asp

Things to AVOID!

- The “Knee Jerk Reaction”

“Reflexes seem normal. You kept him waiting over two hours.”

Things to AVOID!

- The "Knee Jerk Reaction"
  - The "Blame Game"

Things to AVOID!

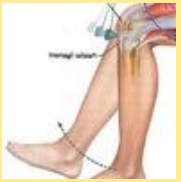
- The “Knee Jerk Reaction”
- The “Blame Game”
- The “Quick Fix”

Blame Game Culture

Un-Accountable Culture

Problem

Investigation (i.e. RCA)



Knee Jerk Reaction

Blame

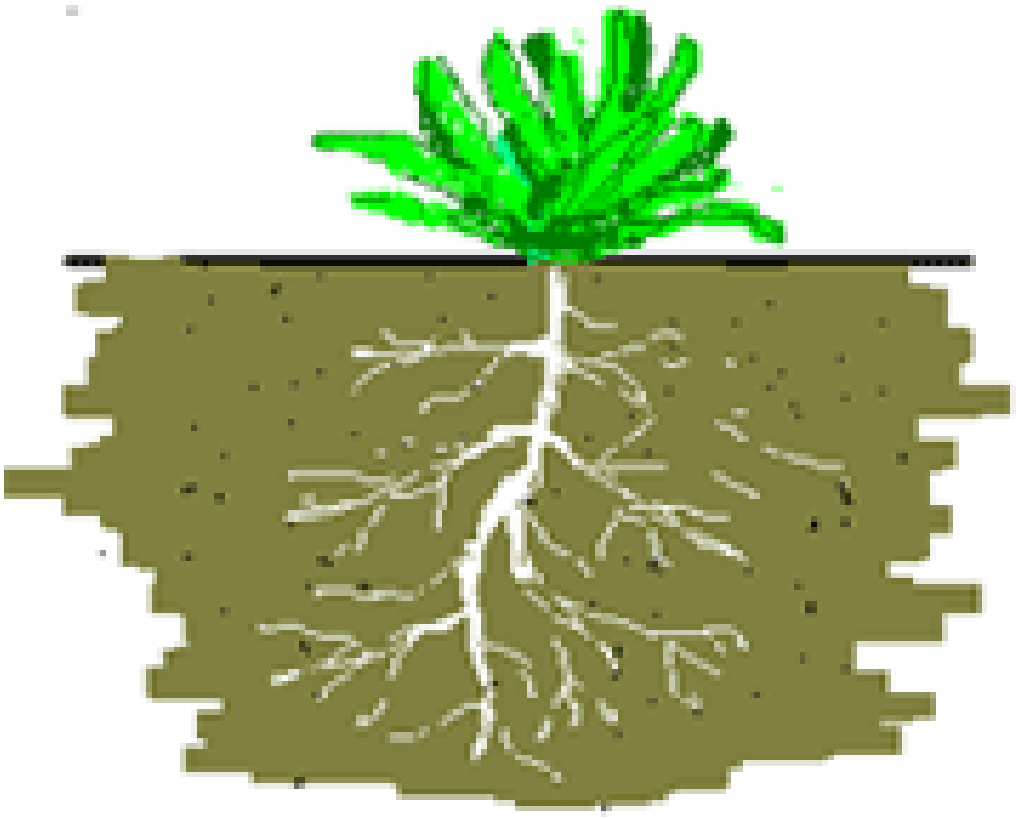
CYA

Problem Deflected

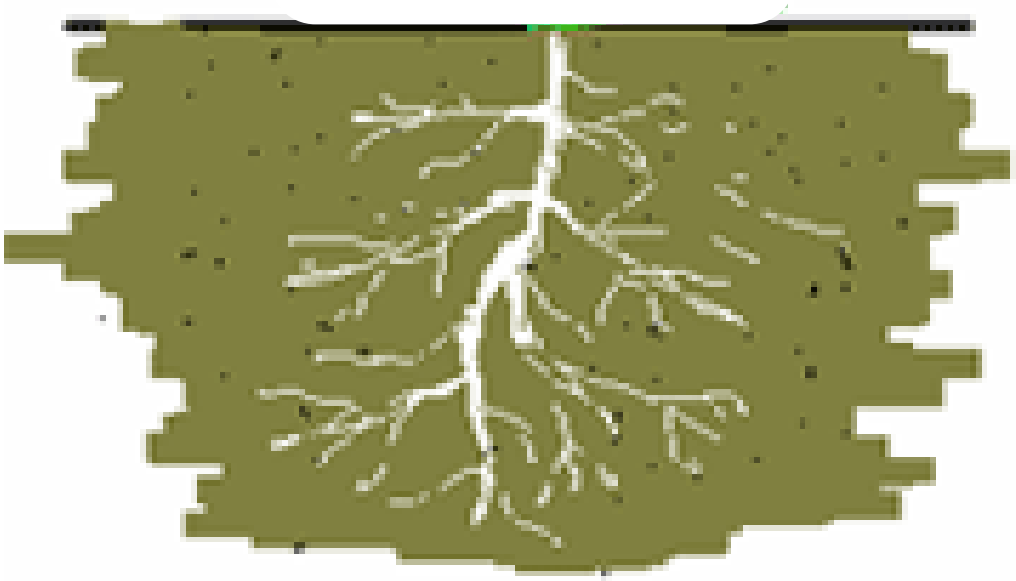
Band Aid Approach

Frustration

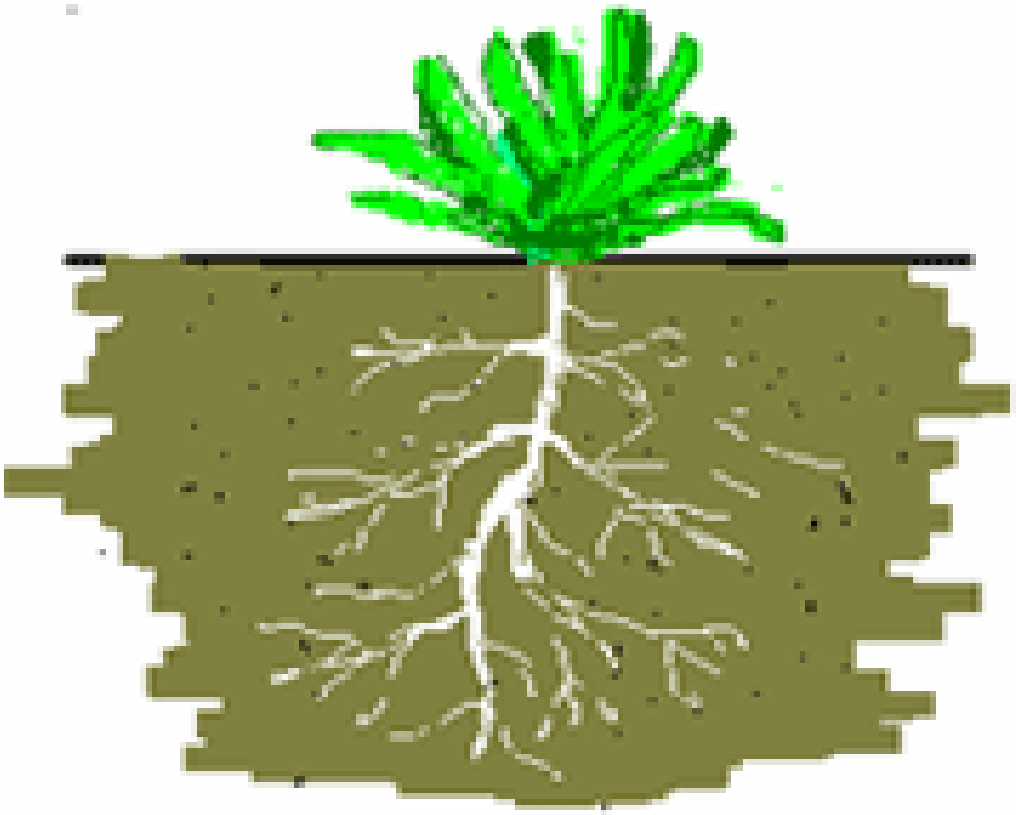
RCA Philosophy



Remove tops

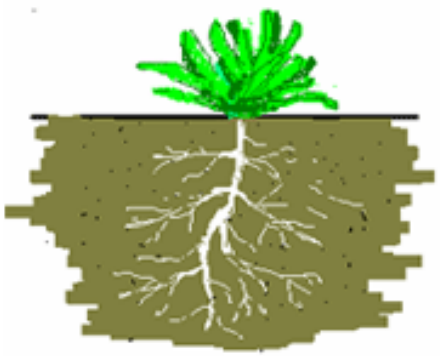


Dandelions come back!



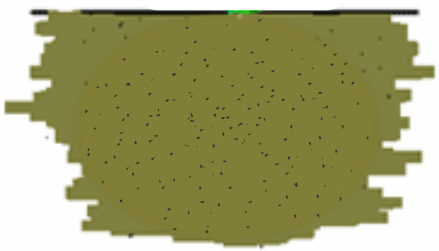
Weeds be gone!

Problem



Dig down to the roots to get to the reason

Problem effectively addressed



RCA Philosophy

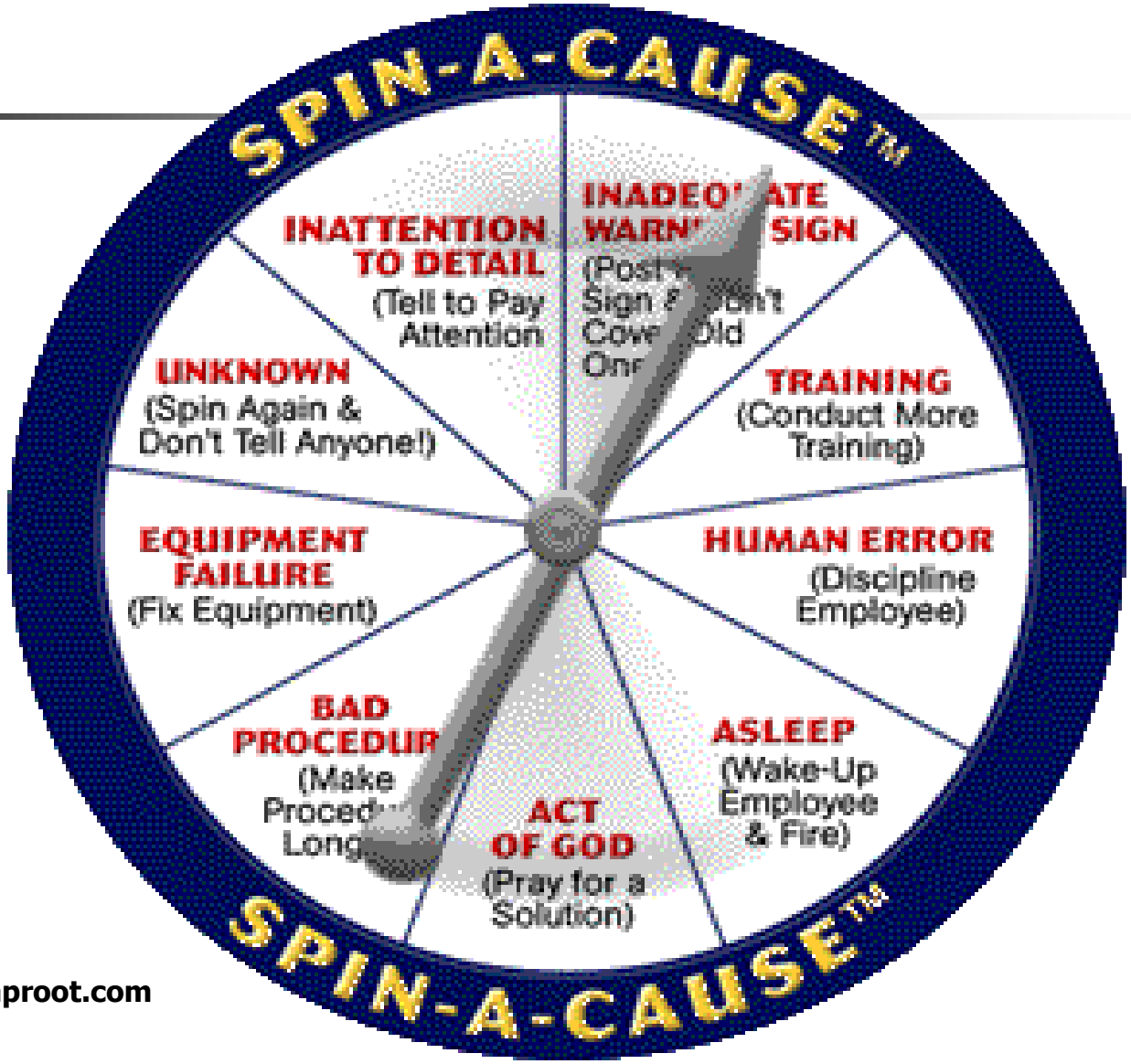
- Every nonconformity is an opportunity for quality improvement
  - Nonconformity = non-fulfillment of a requirement
  - Departure from ideal state
- Provides a mechanism for identifying and understanding the underlying reason(s) for a problem

What is **R**oot **C**ause **A**nalysis?

http://farm3.staticflickr.com/2463/3690914949_cfea954aec.jpg

- A.K.A. RCA
  - (not Radio Corporation of America)

- A process used to define, evaluate and systematically analyze <u>"a problem"</u> to determine the underlying factor(s) or reason(s) for the problem



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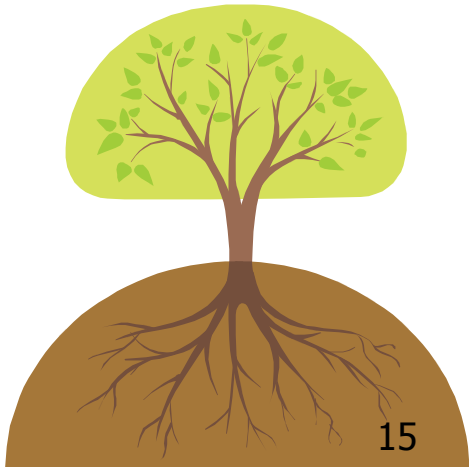
Root Cause Analysis

ISO/IEC 17025:2005 (4.11.2)

- The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

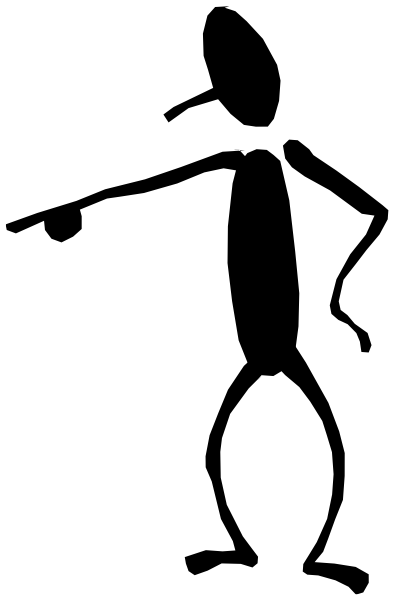


Purpose of RCA

- Identify underlying factor(s), reason(s) or cause(s) of a problem to:
  - implement corrective action to eliminate and prevent the problem from recurring
  - One or more “best” solutions

Benefits and Applications

- Evaluates the cause and effect relationship of the system or process
- Takes emphasis off the person and doesn’t point blame
- Focuses on prevention and continued improvement
- Works for minor or major issues



Benefits and Applications

WHEN DO YOU DO A ROOT CAUSE ANALYSIS?

Evaluation of Significance

- Can the nonconformity recur or does it raise doubt about compliance of the laboratory's operations with its own policies and procedures? (ISO/IEC 17025, Clause 4.9.2)
- What criteria is utilized to determine significance? (ISO/IEC 17025, Clause 4.9.1.b)

Relevant & Useable

- You don't need a cannon to kill a mosquito!

Confucius

DEFCON SYSTEM

1
Max readiness

2

3

4

5
Normal readiness

Criteria & Significance Matrix

- Define significance
  - Work product
  - Integrity of evidence
  - Customer
  - Organization's goals/ performance measures

Potential Impact				
	HIGH	Level 1	Level 1	Level 1
	MEDIUM	Level 2	Level 2	Level 1
	LOW	Correction	Level 2	Level 1
		LOW	MEDIUM	HIGH
	Frequency of Occurrence			

Define Roles

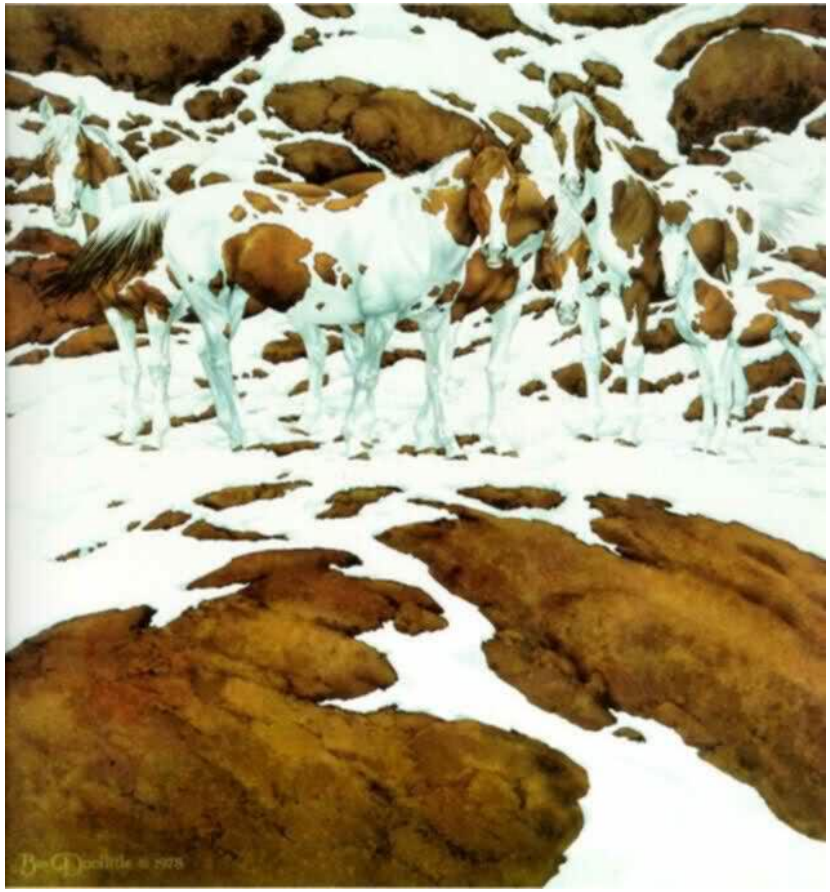
- Who will:
  - Halt work
  - Evaluate and determine significance
  - Take Correction
  - Determine to implement RCA
  - Communicate to customer (if necessary)
  - And later….Authorize resumption of work

ISO/IEC 17025, Clause 4.9.1 a – e and 4.9.2

Where to Begin?

Define Roles

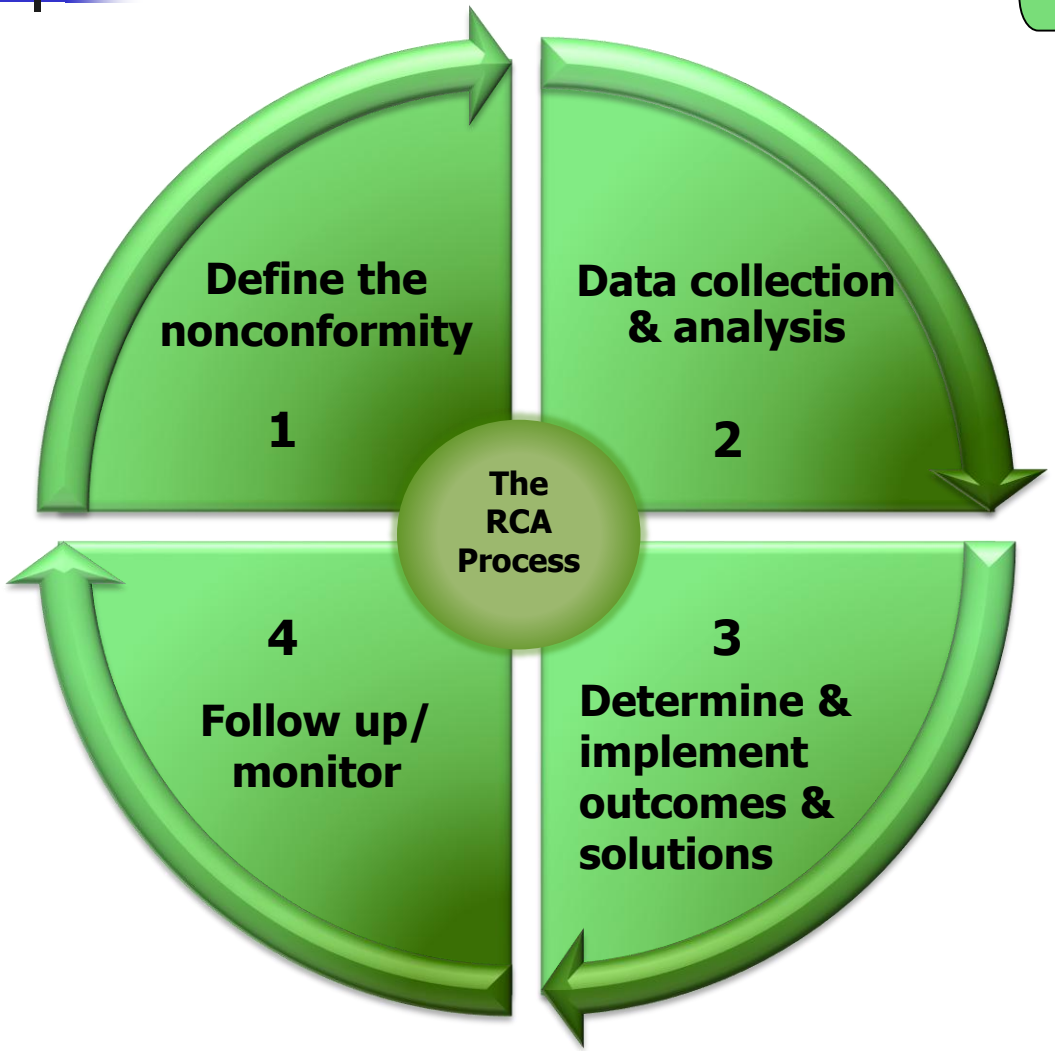
- Who will:
  - Facilitate the RCA process
  - Collect and analyze data/information
  - Organize, store the information

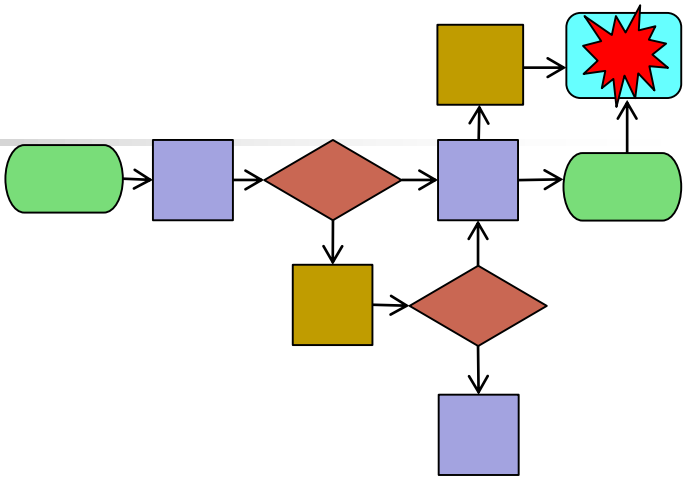


Responsibilities

- Integrity
- Confidentiality
  - Sensitive information (potential negligence or misconduct)
- Due professional care
- Fair presentation
- Independence
- Evidence-based approach

Steps of RCA

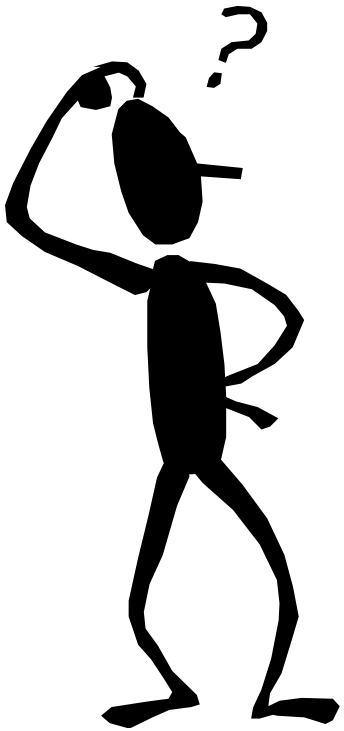




1. What's the problem?
2. Why did it happen?
3. What will be done?
4. Is it effective?

What's The Problem?

- Nonconformity
- Discrepancy
- Non-compliance
- Incident
- Error, mistake



Problems

- May be identified through a variety of activities
  - Internal audits, external assessments
  - Management reviews
  - Customer feedback, complaints
  - Staff observation
  - Technical review, administrative review
  - Verification

Step 1. What's The Problem?

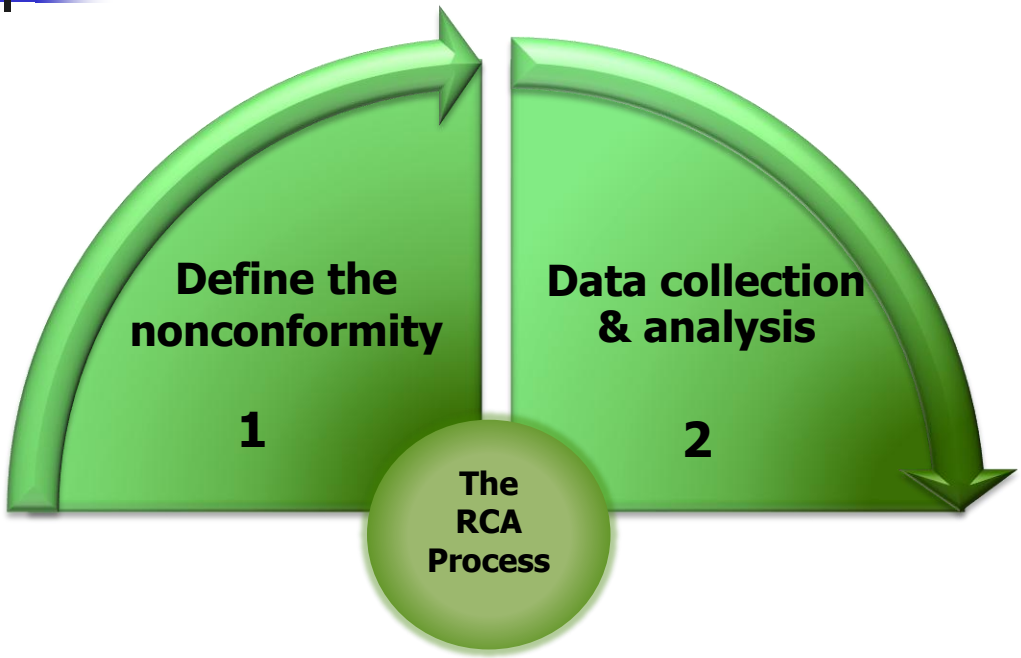
"A problem well-defined, is a problem half solved." Charles Kettering

- Focuses on the departure (or noncompliance) to policy or procedure or the nonconforming work, **<u>not the who</u>**
- Simply states or describes what is wrong, **<u>not the why</u>**

Define The Problem

- For a well-defined problem, identify & describe:
  - **What** happened?, what equipment, what method?
  - **When** – when did it occur? Date and time
  - **Where** – physical location and/or where in the process/procedure?
  - **How** much, how often? – How many times did the incident occur? How many cases affected?
  - **Impact** to organization's goals, customer, work product, performance measures
  - Important to document **who** was involved.

RCA Step 2



1. What's the problem? - Define the problem, write problem statement

2. Why did it happen? - a) fact finding, data collection & b) data analysis to determine the causal relationships and identify root cause(s)

Step 2: Why did it happen?

2a. Data collection or fact finding

1) Review documents
   - Understand process/procedure (Process mapping)
   - Narrow focus – identify potential causal factors
     - Flow chart or Fishbone diagram
     - Change & barrier analysis
2) State hypothesis & develop data collection plan
3) Data collection
   - Review records
   - Interviews and/or witnessing
4) Generate a timeline

Identify Potential Causal Factors

- An element or activity that has an influence on the result
  - Physical item or material used
  - Actual step or activity
  - Intangible surrounding elements that can influence the activity
- Think about all the items/materials used, turned on, touched, involved in or part of the activity

Keep in mind

- Changes
  - What changes have occurred during the timeframe?
  - People, methods, equipment, policies, etc.
- Barriers
  - Evaluates implemented quality control measures to prevent or detect nonconformity

Potential Causal Factors

http://web.nmsu.edu/~kburke/Instrumentation/Agilent5973GC_MS.jpg

Instruments/Equipment

- Maintenance/Calibration
- Performance
- Application/Method

Procedure/Method

- Is there a procedure/method?
- Was the method validated/approved?
- Is the method clear/sufficient detail?
- Any deviations from the test method?
- Proper controls used?

Potential Causal Factors

Materials/Supplies

- Appropriate grade/quality?
- Reagents verified?
- Proper handling/storage
- Contamination

Evidence Samples

- Matrix effects
- Sufficient sample
- Submitted, received
- Handling, storage, controlled

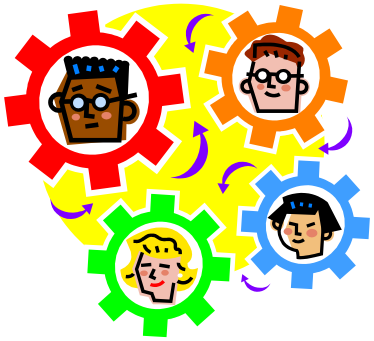
Potential Causal Factors

Work Environment

- Space, workflow, ergonomics
- Lighting, ventilation

Personnel

- Training, qualifications, experience
- Work practices, organization
- Planning, scheduling
- Communication, distractions
- Physical, mental well being



Personnel

- Blame can distract you from identifying the real cause(s) of the problem

"To address this mistake we need to utilise our thorough system of root cause analysis. I will begin, if I may, by pointing out that it's not my fault"

www.roystonrobertson.co.uk

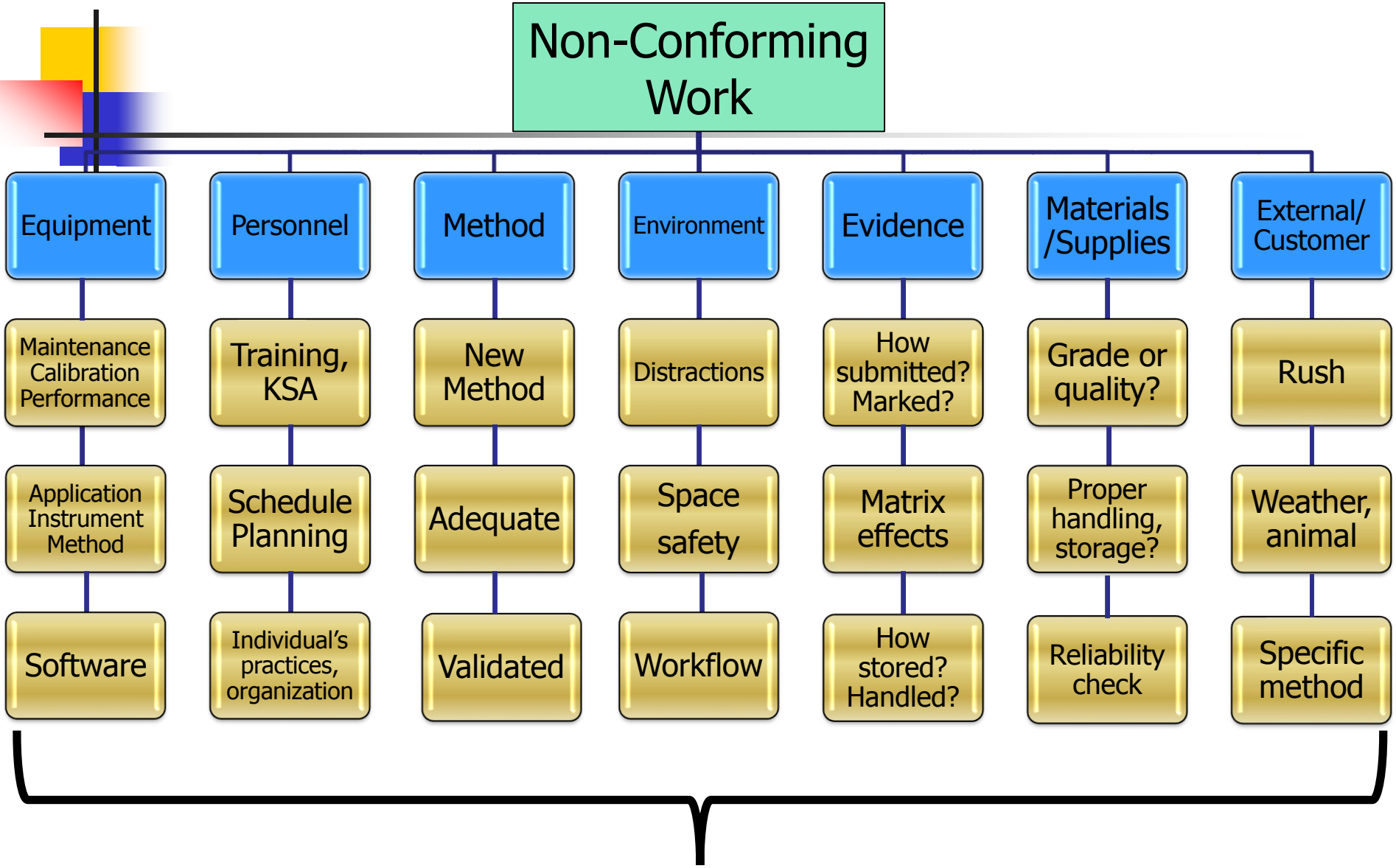
External & Customer Requirements

External factors

- human and non-human factors beyond the control of the laboratory
- Weather
- Animal interference

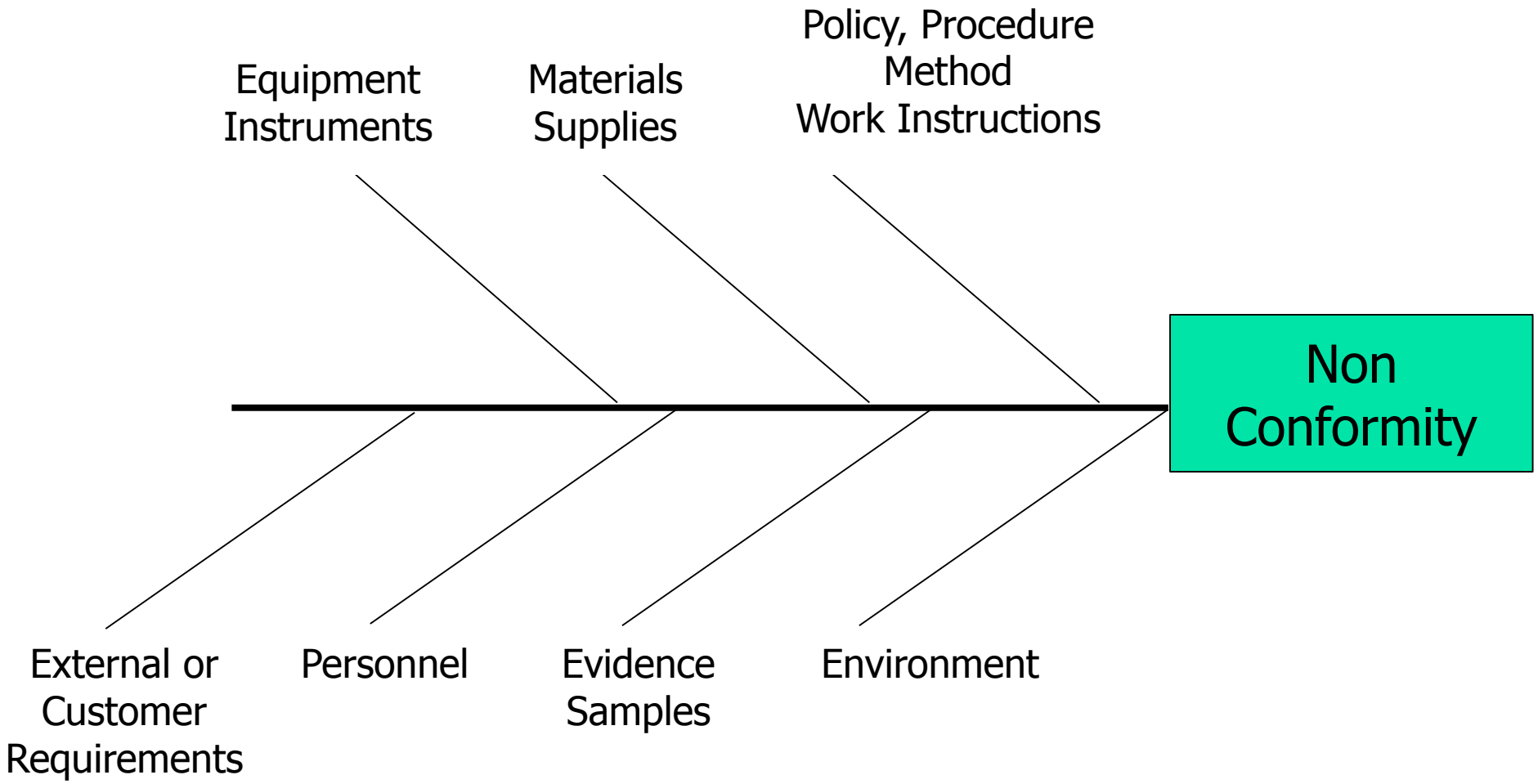
Customer Requirements

- Rush
- Specific testing requested
- Other?



Potential Causal Factors

Fishbone Diagram



Formulate a Hypothesis

- State the potential cause(s) of the non-conformity
- Develop a data collection plan
  - List and assign tasks
  - Designate how information recorded
  - Set a due date(s)
- Start review of records and data collection
  - Keep good records

"In God we trust. All others must have data."

Deming

Data Collection Plan				CAR/RCA#: EX2-COC
Causal Factors or hypotheses	**Records Data Source**	**Sample Size**	**Time frame**	**Assigned to**

Records, Records and More Records

- Case file records
  - Notes, photos, diagrams
  - Communication logs
  - COC, LIMS entries
  - Other cases of similar type
  - Technical review records
  - Evidence information
- Methods/work instructions
  - Validation records
  - Deviation records
  - Document approval records
- Materials/Supplies
  - Chemical and Reagent logs
  - Purchasing records
  - Reference material records
  - Vendor records
- Instrument records
  - Maintenance records
  - Intermediate check records
  - Calibration records
  - Validation records

Even More Records

- External Factors
  - What was happening outside during this timeframe? Weather, animal issues?
  - Grounds maintenance records
- Customers
  - Communication log
  - Request for service record
- Other records
  - QC trend data
  - Complaint logs
  - CAR/PAR logs
  - Correction records
  - Audit records
- Work Environment
  - Temperature logs
  - Building maintenance logs
  - Refrigerator/freezer logs
  - Safety records
- Personnel
  - Training records
  - Work/leave schedule
  - Distractions (notebook, testimony, other duties)
  - Proficiency test records

Interviewing/Witnessing

- Interviewing
  - Personnel involved and/or impacted
  - Technical Leader
  - Supervisor
  - Customer
  - Suppliers
- Witnessing
  - Procedure, method
  - Activity, task

Don’t Make Assumptions

- Can follow procedures and still have a failure
- Can veer from procedures and have an acceptable outcome

Acceptable outcome			
	Yes	Possible	Assumed
	No	Assumed	Possible
		No	Yes
		Procedure Followed	

Develop a Timeline

March 1, 2013
Evidence submitted by KPD Case #2013-TCL-00100, placed in evidence locker

March 29, 2013
analyst gets evidence from locker

April 1, 2013
Analyst Corrects evidence COC, notifies office staff and supervisor

April 3, 2013 –
Initiated RCA and immediate review of COC on cases before and after

Evidence submitted → Nonconformity Identified → Correction & CAR → RCA

March 6, 2013
2013-TCL-00100 Evidence logged into LIMS

April 1, 2013
analyst identified a nonconformity with the evidence COC for item DBM-004

April 2, 2013 –
supervisor calls QA Manager. Moved to CAR

April 5, 2013 –
Problem defined, potential causes identified, DCP developed & data collection initiated

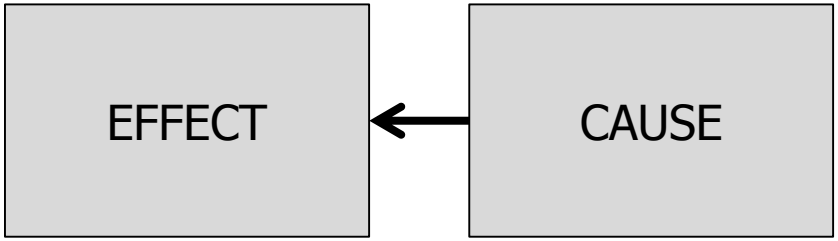
http://office.microsoft.com/en-us/templates/results.aspx?qu=timelines&ex=2&av=zpp150

Step 2b. Data Analysis

- Data review and analysis
- Delineate causal relationships to identify cause(s)
  - Cause and effect
  - Ask at least 5-Whys
  - Cause mapping
- Logical systematic process
- Objective data to support cause

Cause and Effect Relationship

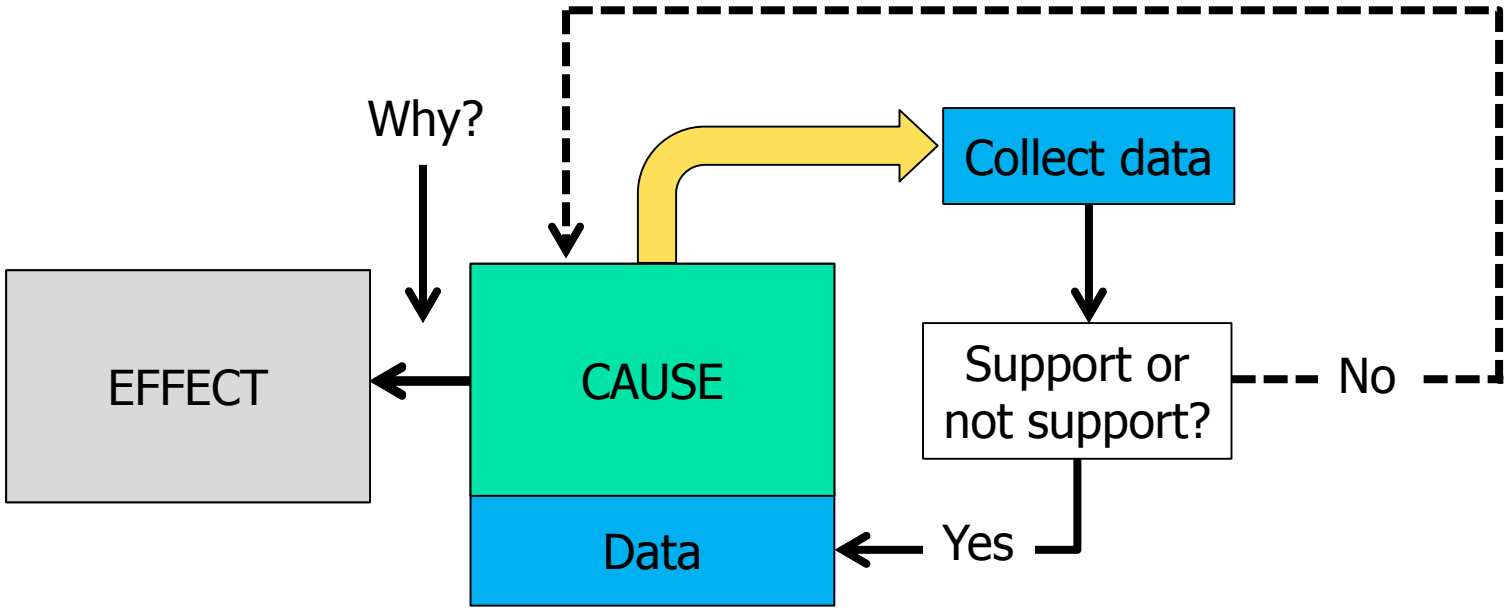
- Cause
  - Produces an effect
  - Supported by data/evidence
- Possible cause (apparent, probable, likely, potential)
  - Missing evidence/data for support
  - Can’t substantiate, untested



Cause and Effect Relationship

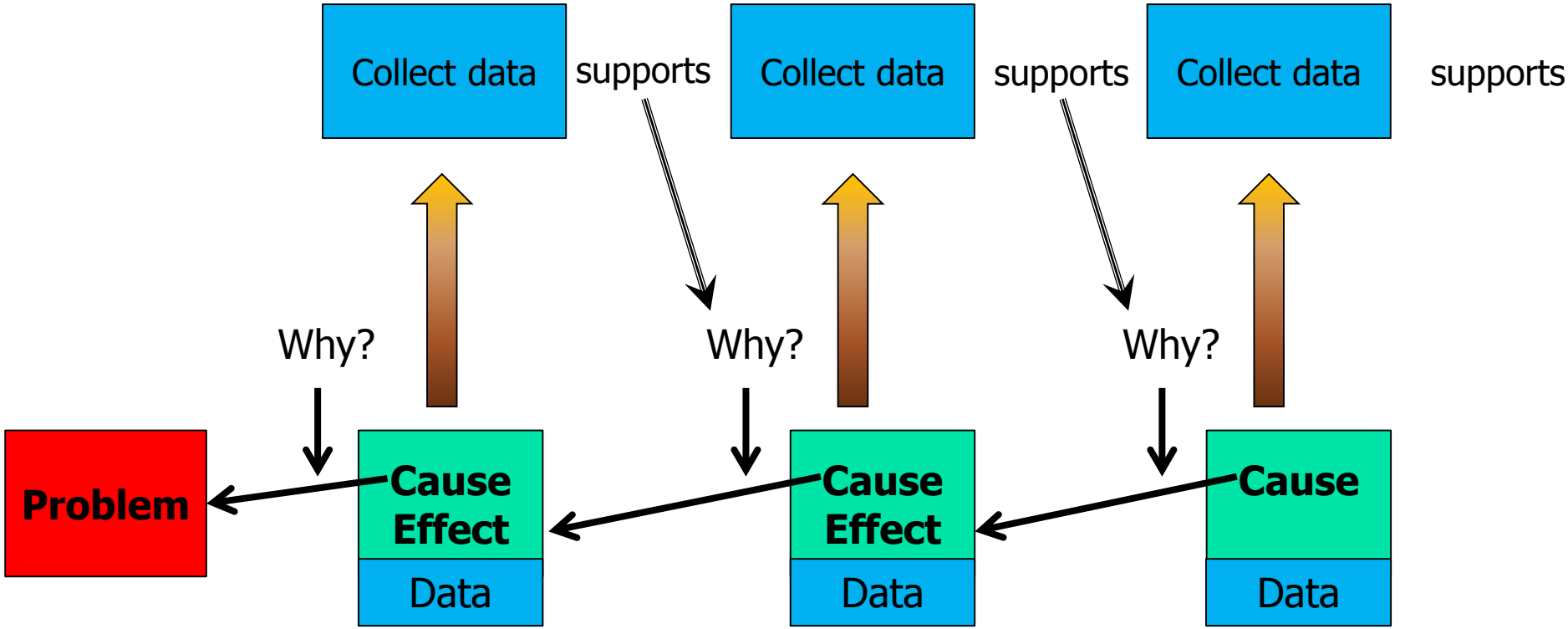
Cause and Effect Process

- The initial effect is the problem
- Ask why, ID potential causal factors – State hypothesis
- Review records: collect and analyze data
  - Does data support or not support hypothesis?



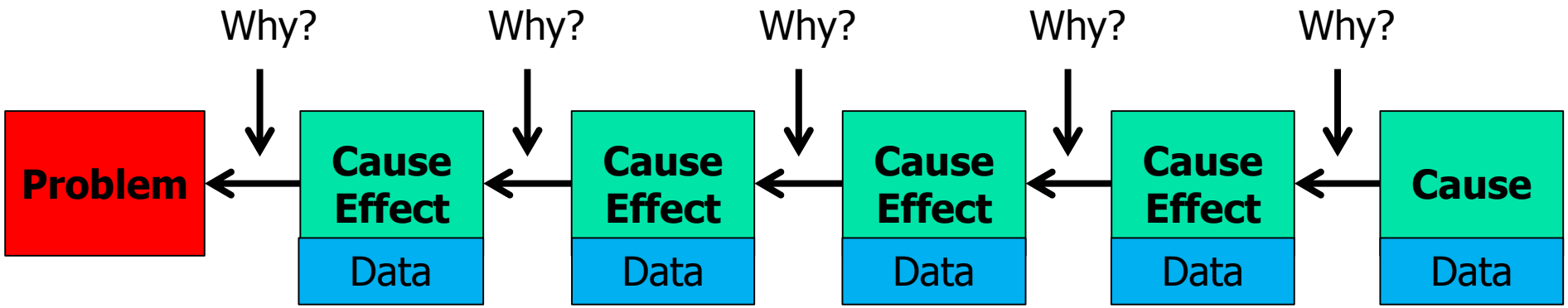
Iterative Process

- Ask why, state potential cause (hypothesis), collect data, draw conclusion, ask why, …….



Cause Mapping

- A tool used to visualize the cause and effect relationships



- To be effective it must be:
  - Systematic
  - Verified with data

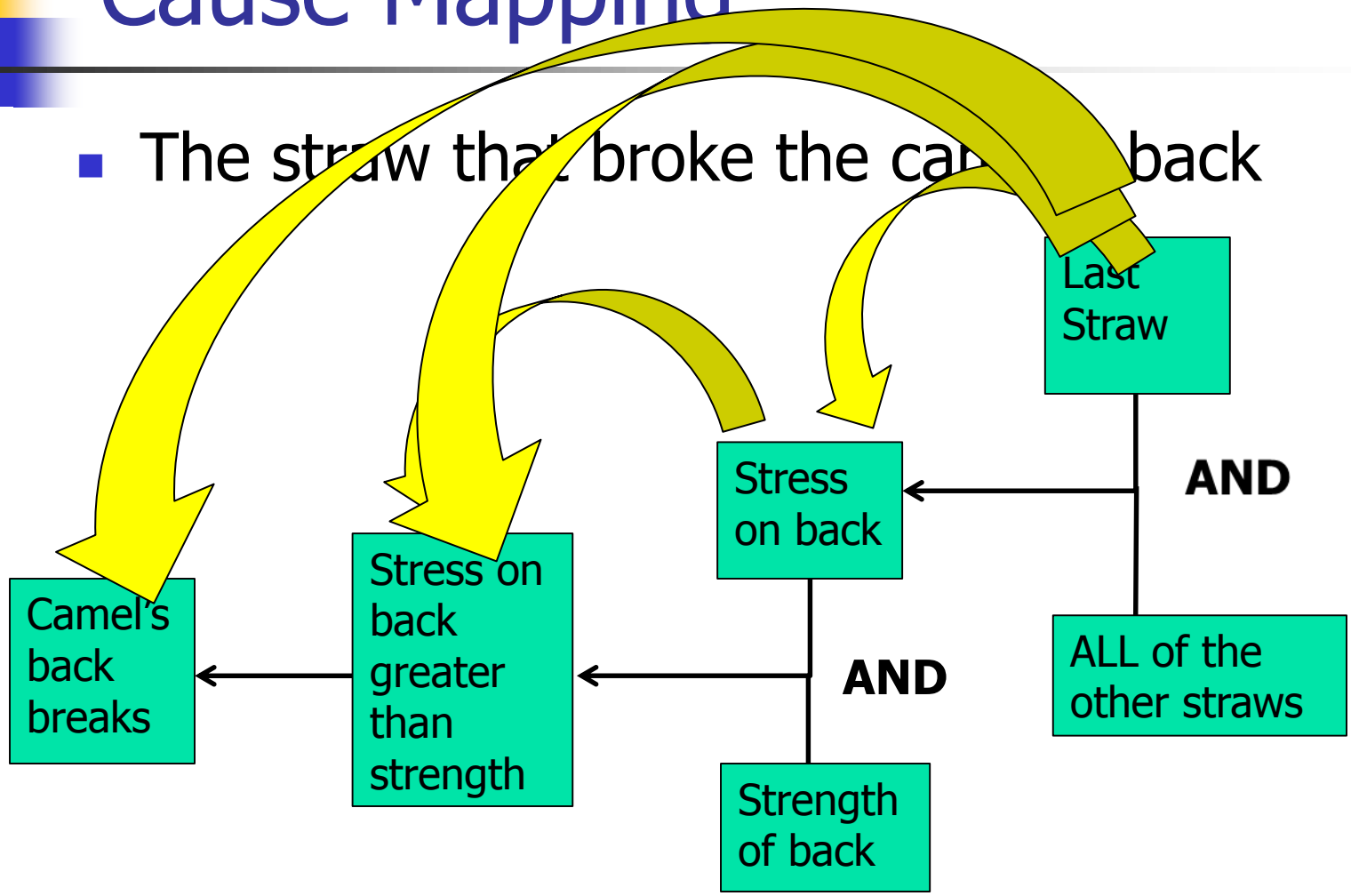
How Far Do You Have To Go?

- Favorite Oversimplifications
  - Human Error
  - Equipment Failure
  - Procedure Not Followed
  - Training Inadequate
  - Design Error
  - Poor Communication

Don't stop at these! They are too general to take action. Ask "Why?" again!

Cause Mapping

- The straw that broke the camel's back



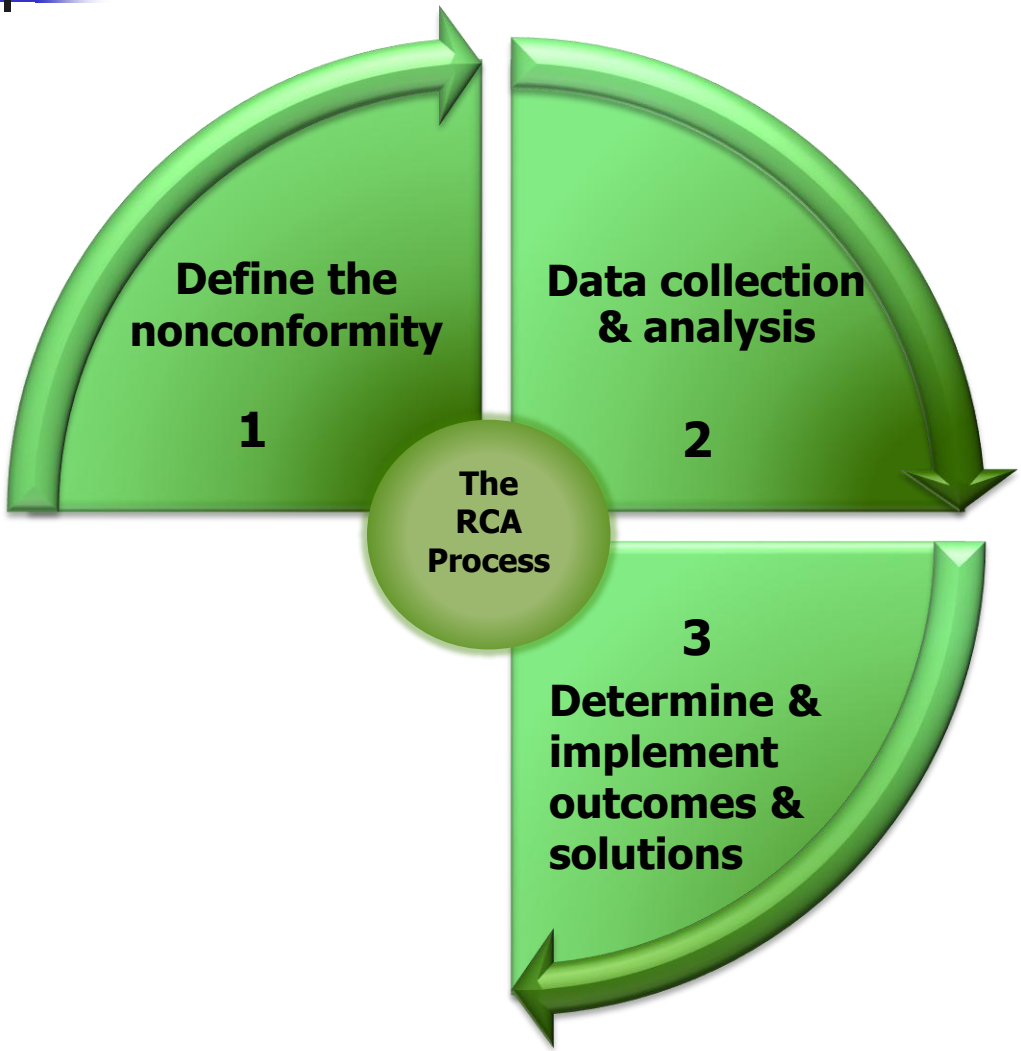
Data Analysis

- Compare and contrast
  - Written procedure to what is actually done
- Look for
  - Differences
  - Compliance
  - Gaps, missing steps, or missing data
  - Shift or change in performance
- Evaluate
  - QC data trends
  - Data correlation

Charts and Plots

- Data Analysis
  - Frequency plot
  - Histogram
  - X-Y Plot (Line graph, scatter plot)
  - Run chart
  - Contingency table
  - Pivot table
  - Is-Is Not table

RCA Step 3



1. What's the problem?
2. Why did it happen?
3. What will be done? – determine and implement outcomes and solutions

Possible Outcomes/Solutions

- Corrective actions to:
  - eliminate the cause
  - prevent the problem from recurring
- Preventive actions
  - eliminate the cause of a <u>potential</u> nonconformity
- No action
- Combination
- Communication

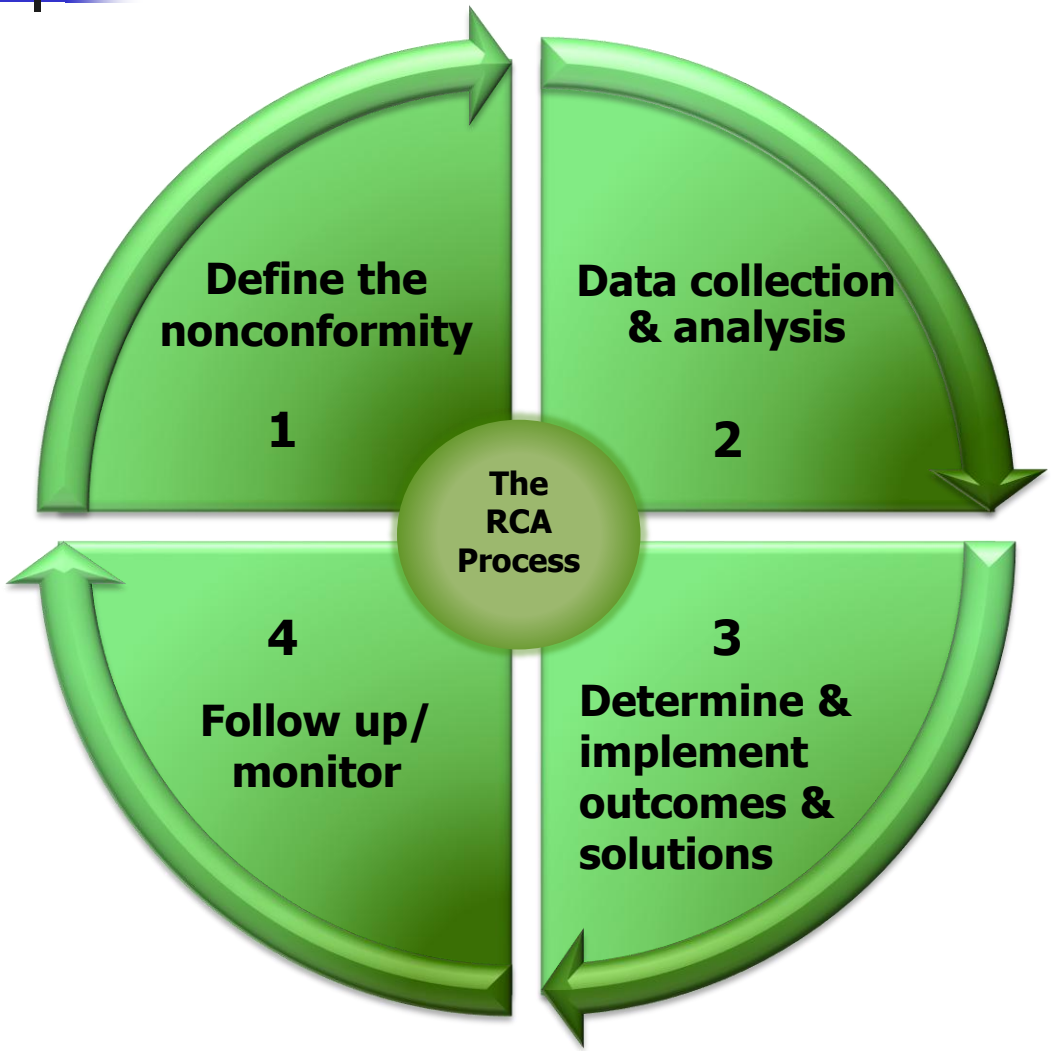
Determine Outcomes/Solutions

- Evaluate data and cause map to brainstorm and identify potential solutions
- Be thorough
- Identify multiple solutions
- Solutions should **prevent** the problem from recurring
- Develop a Corrective Action Plan

Communication

- Who will be notified?
  - Staff/employees
  - Customers
  - Accrediting Body, Commission
  - Press, Legislatures, Governing Body
- How will information be communicated?
- What will be communicated?
- When will communication take place?

RCA Step 4



1. What's the problem?
2. Why did it happen?
3. What will be done?
4. Is it effective? – Follow up, monitor and review solutions to ensure they are effective.

Step 4: Follow up/Monitor

- Monitor results to ensure that corrective actions are effective
- This is a check step to ask:
  - How's it going?
  - What's working?
  - What's not working?
  - What could be improved?
  - Are corrective actions effective?

When and What to Monitor?

- When
  - weeks/months
  - Next internal audit, Management review
- What
  - Case files
  - Interviews/witnessing
  - Correction records
  - Corrective Action Request records

Corrective Action Records

- Must keep good records because……

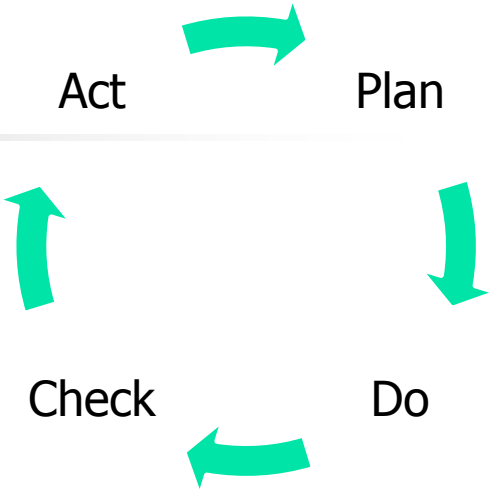
If it isn't written down,

it didn't happen.

Benefits and Applications

- Establishes quality culture by fostering a problem solving culture of open communication
- Results in a change in behavior
- Use skills to evaluate a system that is working well and carry lessons learned to other processes.

Benefits Continued



- Continuous improvement
- Accountability
- Less frustration, more involvement
- Lowers risk
- Cost savings


THOSE WHO DO NOT
REMEMBER THE PAST
ARE CONDEMNED
TO REPEAT IT.

“A bad system will beat a good person every time”

W. Edwards Deming

References

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Level 100: The Corrective Action Process

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Thank You

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