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
Things to AVOID!

- The “Knee Jerk Reaction”

http://www.cartoonstock.com/directory/k/knee_jerk.asp
Things to AVOID!

- The “Knee Jerk Reaction”
- The “Blame Game”
Things to AVOID!

- The “Knee Jerk Reaction”
- The “Blame Game”
- The “Quick Fix”
Un(Accountable

Culture

Problem

Deflected

Frustration

Blame Game

Culture

Problem

Investigation

(i.e. RCA)

CYA

Blame

Knee Jerk

Reaction

Band Aid

Approach
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 Root Cause Analysis?

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

A process used to define, evaluate and systematically analyze "a problem" to determine the underlying factor(s) or reason(s) for the problem.
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

FBI apologizes to lawyer held in Madrid bombings
Man feels he was singled out because he's Muslim

Offering a rare public apology, the FBI admitted mistakenly linking an American L...

The mother and wife of a Portland lawyer, who was arrested in connection with the Spain bombing, talk to NBC about the release of Brandon Mayfield.
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)*
You don’t need a cannon to kill a mosquito!

Confucius
Criteria & Significance Matrix

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

The RCA Process

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, **not the who**

- Simply states or describes what is wrong, **not the why**
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

**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?
Fishbone Diagram

- Equipment Instruments
- Materials Supplies
- Policy, Procedure Method Work Instructions

- External or Customer Requirements
- Personnel
- Evidence Samples
- Environment

Non Conformity
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

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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

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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 identifies a nonconformity with the evidence COC for item DBM-004

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

- **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

- **April 2, 2013**
  Supervisor calls QA Manager. Moved to CAR

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

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

![Diagram of Cause and Effect Relationship]
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?

---

**Cause and Effect Process**

- **EFFECT**
  - Why?

- **CAUSE**
  - Collect data
  - Support or not support?

- **Data**

---

No

Yes
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

Camel's back breaks

Stress on back greater than strength

Stress on back

Strength of back

Last Straw

AND

ALL of the other straws

AND
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 potential 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.

The RCA Process

Define the nonconformity

Data collection & analysis

Determine & implement outcomes & solutions

Follow up/monitor
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


- ThinkReliability – [www.thinkreliability.com](http://www.thinkreliability.com)
Level 100: The Corrective Action Process

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Quality Matters™
Thank You

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