

The American Association for Laboratory Accreditation

A2LA



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2011 Plenary Session Root Cause Analysis

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What is a Root Cause Analysis (RCA)

- A system of problem solving methods aimed at identifying the root causes of problems or incidents.
- Predicated on the belief that problems are best solved by attempting to correct or eliminate root causes, as opposed to merely addressing the immediately obvious symptoms.
- By directing corrective measures at root causes, it is hoped that the likelihood of problem recurrence will be minimized.



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Where is this Required?

- ISO/IEC Section 4.11
 - 4.11.1 The laboratory shall establish a policy and procedure for implementing corrective action.
 - 4.11.2 The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

- I102-Instructions for Responding to the Assessor Deficiency Report
 - “Per ISO/IEC 17025:2005, clause 4.11.2, your corrective action must start with an investigation to determine the root cause of the deficiency. ***Therefore the corrective action response must also include the documented results of the root cause analysis and the objective evidence (e.g. revised/updated lab procedures, paid invoices, packaging slips, training records, etc.) to indicate that the corrective actions have been implemented/completed to address the root cause.***”



Reactive vs. Proactive

- RCA, initially is a reactive method of problem detection and solving.
- By gaining expertise in RCA it becomes a pro-active method.
- RCA is able to *forecast* the possibility of an incident even *before* it could occur.



How do I Start a RCA



“To address this mistake we must use root-cause analysis. I’ll begin by saying it’s not my fault.”

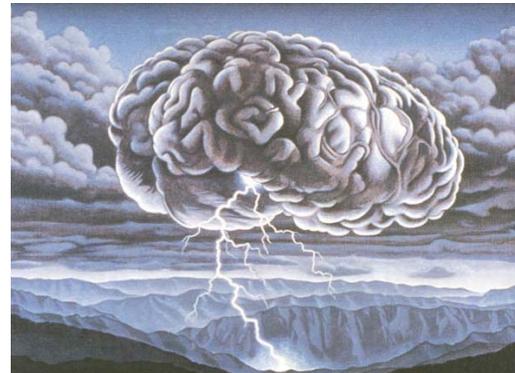
Start with a New Mindset

- People are generally not the ultimate causes of problems.
- People implement processes.
- Most people don't come to work each day planning to sabotage their own work.
- Don't want to waste all your energy fighting the surface issues.
- Passive voice is preferred to avoid casting blame.
 - Bob didn't complete form A21 correctly.
 - Form A21 lacked necessary review and approval.



Principles of RCA

- Must be performed systematically as an investigation.
 - Not a blame game
 - Not looking for the immediate fix
 - Dig deeper
 - Establish a sequence of events or timeline
 - Understand the relationships between contributory factors



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Identify the Types of Causes

Cause (Causal Factor): Event or condition that results in an effect.
Anything that shapes or influences the outcome.

Proximate Cause: The event(s) that occurred, including any condition(s) that existed immediately before, which directly resulted in its occurrence and, if eliminated or modified, would have prevented the undesired outcome. Also known as the direct cause(s). Can be both equipment and human based.

Root Cause: One of multiple factors (events, conditions or organizational) that contributed to or created the proximate cause and subsequent undesired outcome and, if eliminated, or modified would have prevented the undesired outcome. Typically multiple root causes contribute to an undesired outcome.





General Process for Performing a RCA

1. Define the problem.
2. Gather data/evidence.
3. Ask why and identify the true root cause associated with the defined problem.
4. Identify corrective action(s) that will prevent recurrence of the problem.
5. Implement the corrective action(s).
6. Observe the corrective actions to ensure effectiveness.
7. If necessary, reexamine the RCA.



Our Disaster Recovery Plan Goes Something Like This...



Tools and Techniques for RCA

- Flow Charts
- Records
- Documents
- Interviews
- Five Whys
- Cause and Effect
- Diagramming
- Checklists

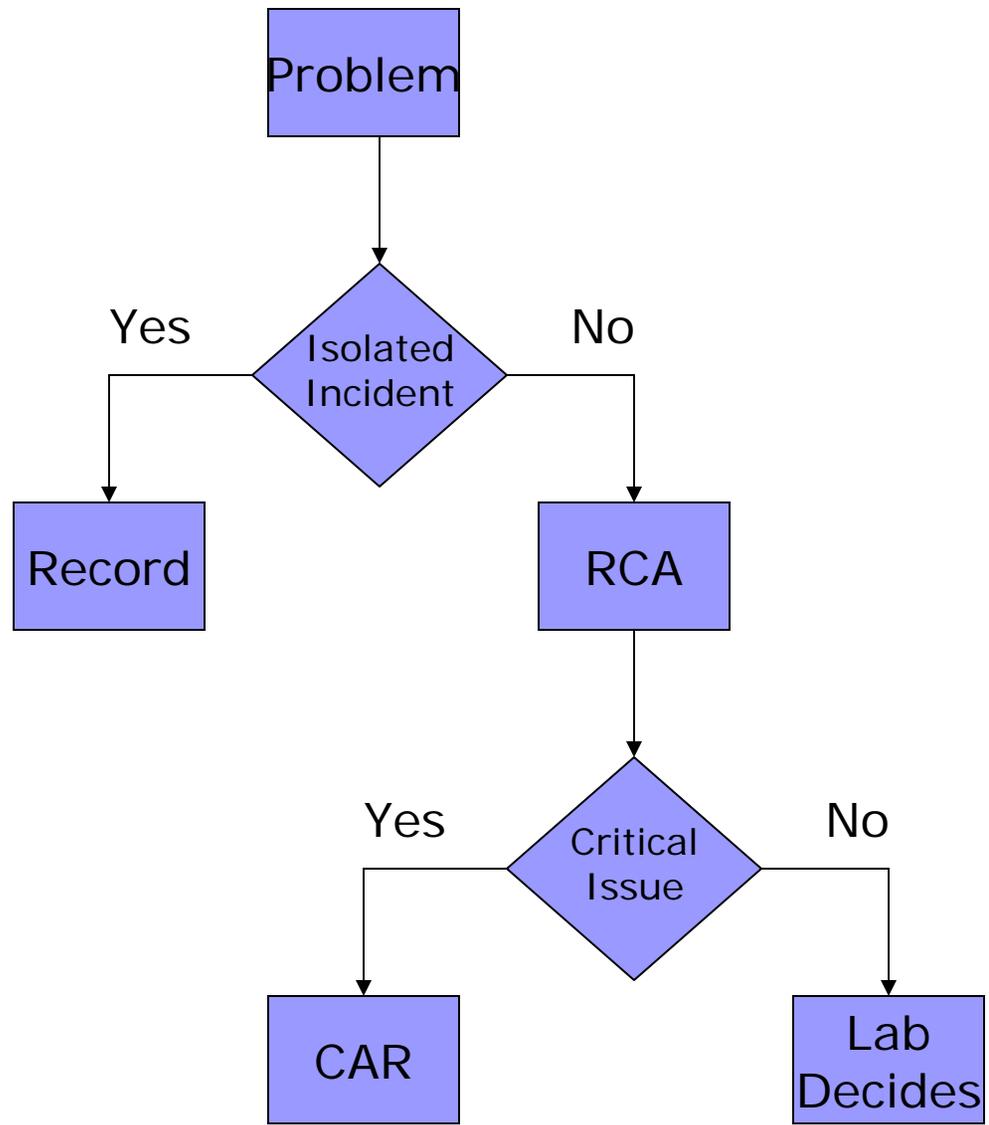




Flow Charts

- Process flow presented in graphical format starting from beginning of task.
- Easy-to-follow picture.
- Identifies linkages between subjects.
 - Boxes connected by lines show workflow.
 - Diamonds signal yes/no decision points.
- Lack the detail of procedures and documents.
- May be of limited use to complex system failures.





RCA May Lead to Determination of an “Isolated Incident”

- Not process problem or training.
- Examples: sample not injected into GCMS instrument, liquid media or slant tube not inoculated with loop, glass rod too hot from Bunsen burner when making spread plates, etc.
- Laboratory discretion on how to proceed based upon their knowledge and procedures.
- Keep in mind 4.9.2.



Records

- Verify compliance with requirements.
- Entire RCA process depends on available and reliable records.
- Patterns in remedial action records.
- System must control records properly.
- Objective evidence of system breakdowns.
- May not be complete or readily available (could be a nonconformance in its own regard).



Documents

- Can outline requirements of a process.
- Explains what should happen.
- Don't need to rely on memory; adds consistency.
- Describes the characteristics of a positive outcome.
- May not be understandable or may not exist.



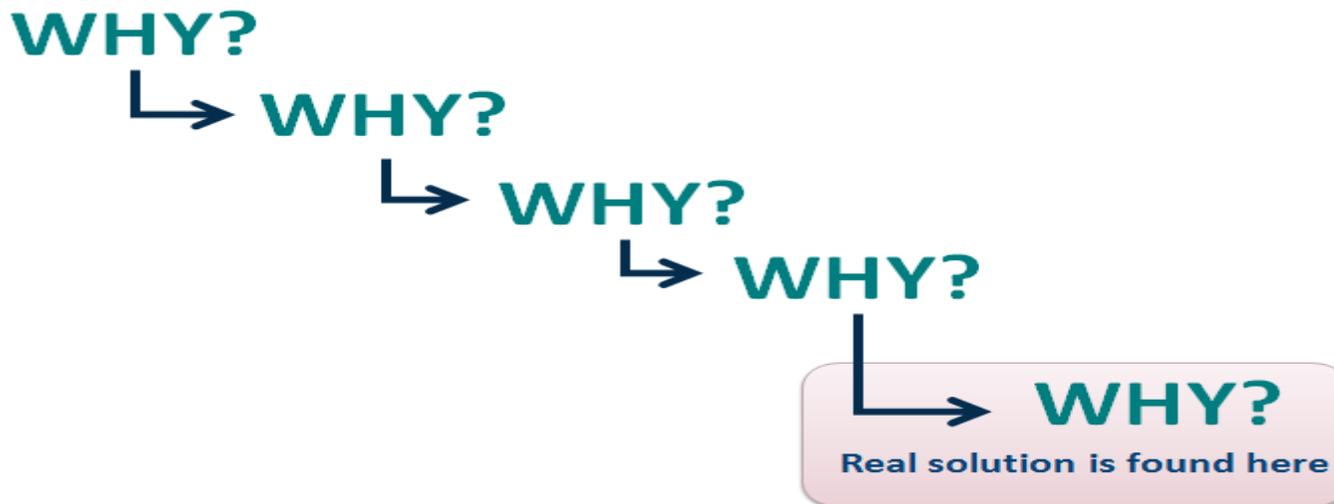
Interviews



- Have staff (and others) explain their documents and actions.
- Have the problem explained.
- May be the only source of information.
- Helps to understand work flow.
- Can be subjective or associated with blame.

Five Whys

- Helpful in tracing the chain of events (starting with the nonconformance and working backwards)



Example

- CAB did not complete action items from Management Review within the agreed upon timescale.
 - Why—Action items were assigned and then became less important as everyone was busy.
 - Why – There was no follow up to ensure that action items were complete.
 - Why – Action items were not entered into our tracking system.
 - Why– That was not in our Management Review SOP.
 - Why– Inadequate review of SOPs for compliance to ISO 17025.
 - Solution– Revise SOP to place action items in tracking system to ensure timely follow up.



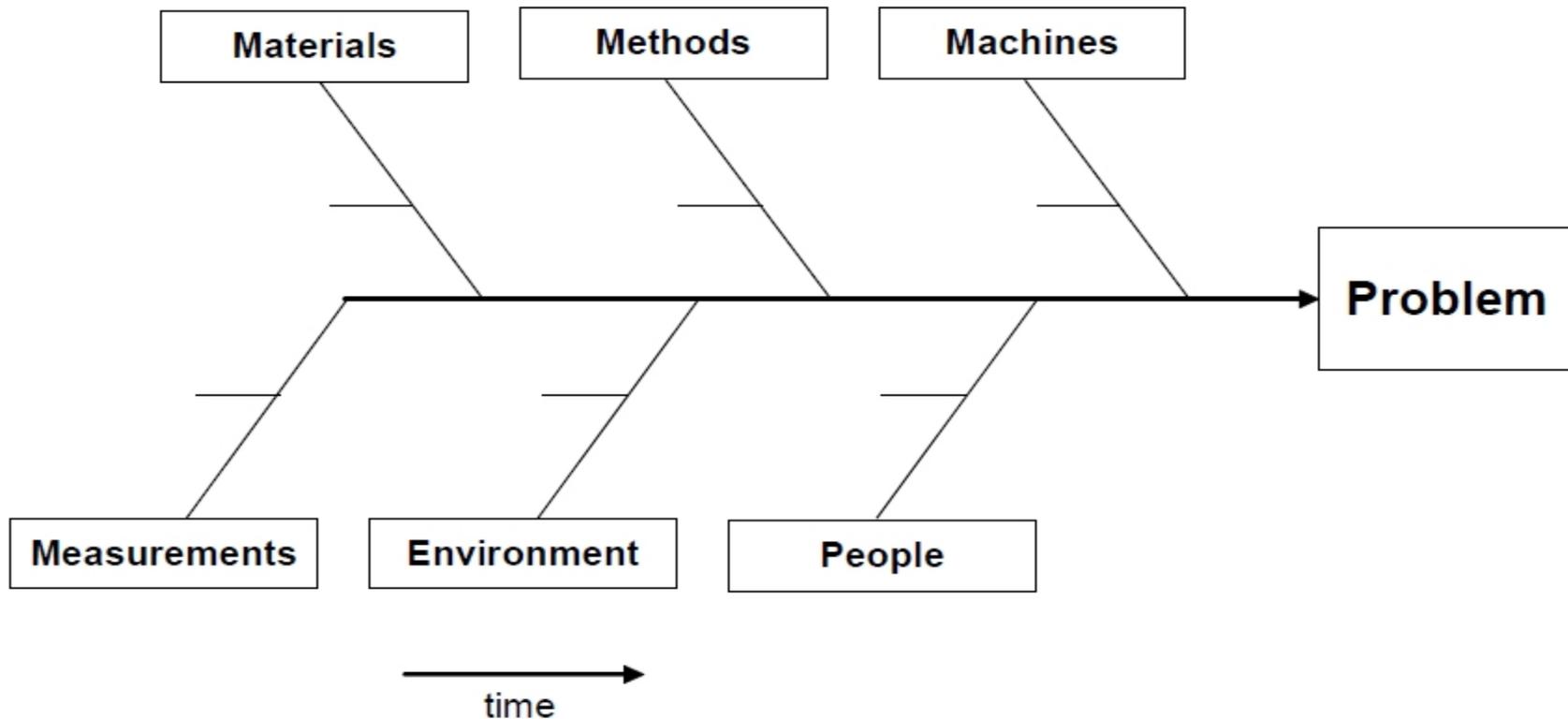
Cause and Effect

- Presents an accessible picture / diagram.
- Use headings to organize the RCA.
- Categorize questions below appropriate heading.
- Makes the potential causes more apparent by framing situation into “macro view”.



"What do you mean 'it just happened'?
Didn't we discuss cause and effect?"

Fishbone Diagram

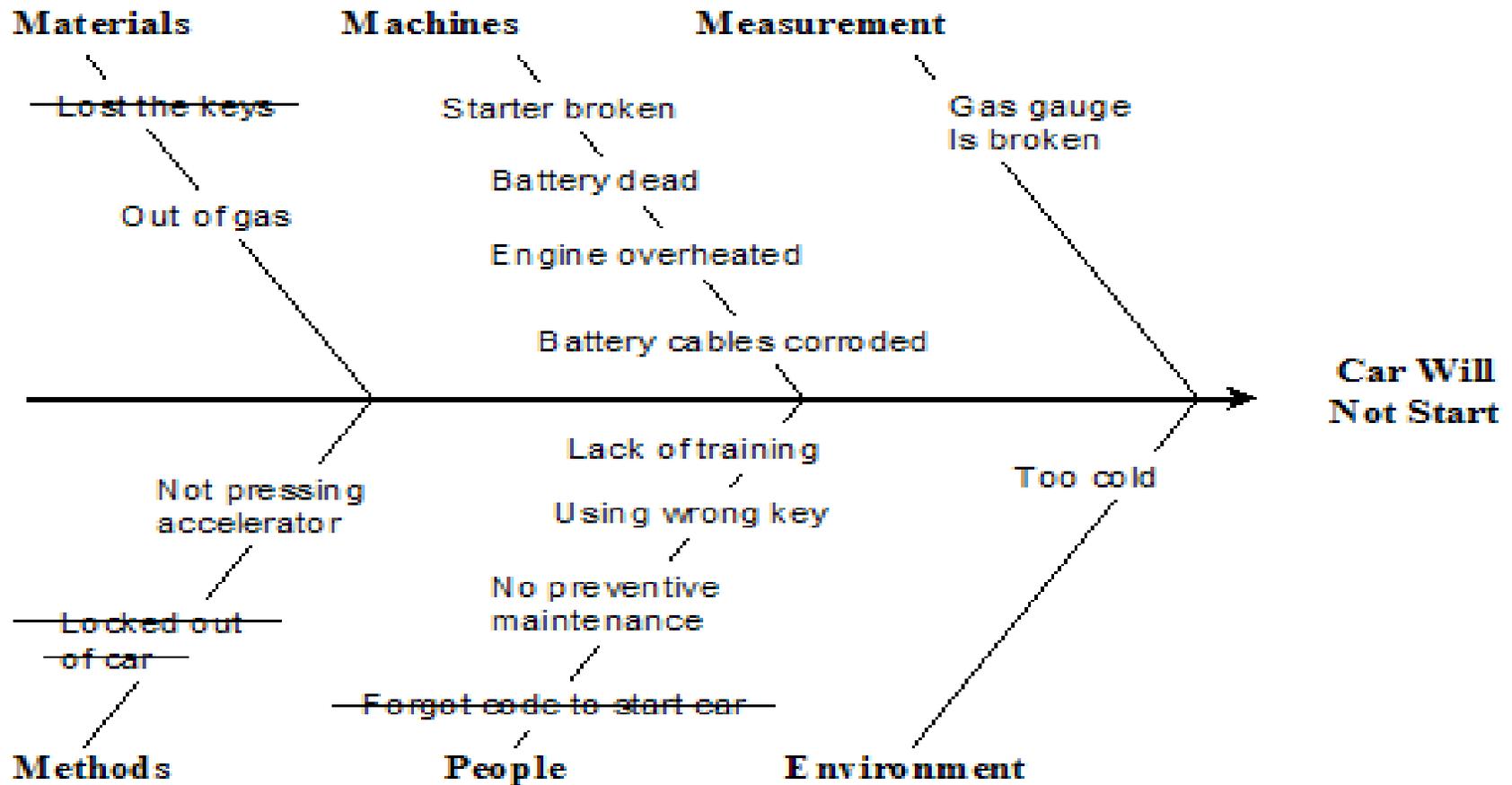


Definitions



- Material: incorrect, degradation, certificates of analysis
- People: training, verbal miscommunication, lack of communication, staff changed mid-project
- Machinery: defective, not maintained, not calibrated, overloaded
- Method: procedures, work instructions, amendments
- Measurement: calibrations, appropriate
- Environment: temperature, humidity, work area, distractions

Example

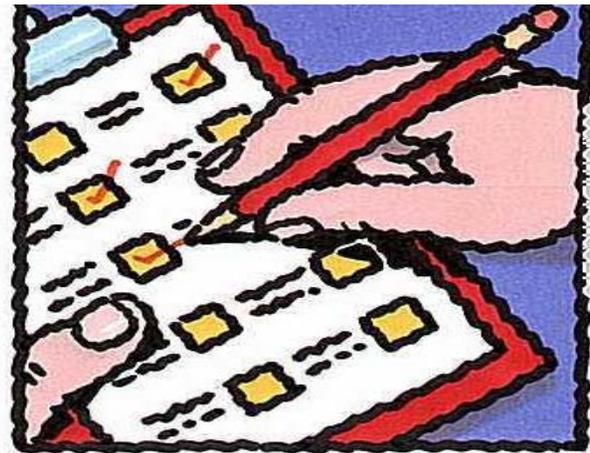


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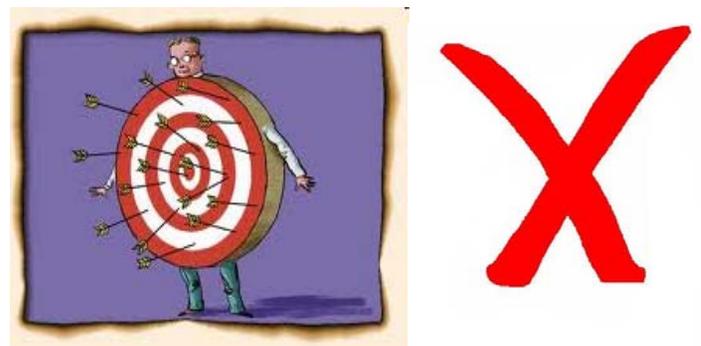
Checklists

- Can be useful to keep track of questions and potential causes.
- Helpful to organize overall process.
- Needs to be used with other tools to determine specific root cause.



What to be Cautious About When Selecting Corrective Action

- Changing too many variables at once may be a problem.
- Select the one action that is MOST likely to correct the problem.
- Record the findings and observations after this adjustment is made to see if it fixes the problem.
- If the problem happens again, select another variable from the list.



Examples



The Ugly



- Deficiency—The A2LA Traceability Policy requires that calibrations be performed by an accredited calibration provider if available or that the calibration meets T9. The CAB has their balances calibrated by ABC Calibration Shop which is accredited but the lab did not get endorsed certificates.
- Root Cause—The previous assessor did not catch this.
- Solution—Tell A2LA that we will get proper certificates next time.



The Bad



- Deficiency—The A2LA Traceability Policy requires that calibrations be performed by an accredited calibration provider if available or that the calibration meets T9. The CAB has their balances calibrated by ABC Calibration Shop which is accredited but the lab did not get endorsed certificates.
- Root Cause—We were unaware of the requirement.
- Solution—Contact ABC to see if we can get proper certificates and make arrangements for future calibrations.

The Good



- Deficiency—The A2LA Traceability Policy requires that calibrations be performed by an accredited calibration provider if available or that the calibration meets T9. The CAB has their balances calibrated by ABC Calibration Shop which is accredited but the lab did not get endorsed certificates.

- Root Cause
 - Why-We did not request endorsed certificates.
 - Why-We were unaware that we had to request an accredited calibration.
 - Why-We did not know that ABC had multiple levels of service.
 - Why-We did not research our provider sufficiently.
 - Why-Our contract review and supplier evaluation did not include enough detail to ensure this level of inspection.



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The Good Continued

- Solution part 1—Revise contract review SOP to include requesting accredited calibrations from our providers.
- Solution part 2—Revise supplier evaluation form to include determination if our calibration providers are accredited and if they offer different levels of service.
- Solution part 3—Hold training on revisions and stress the importance of traceable calibrations.
- Solution part 4—Contact ABC to ensure that future calibrations will be accredited.





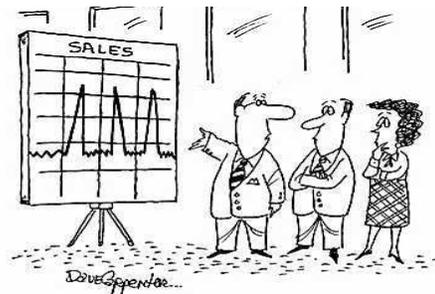
How does A2LA Evaluate RCA

- No restatement or rewording of the deficiency will be accepted.
- Evidence must show that an effort has been made to establish a root cause.
- For repeat deficiencies, evidence must show that CAB has gone beyond the original RCA. Due to the citation of a repeat deficiency, there is now objective evidence that the original corrective action did not prevent recurrence.



Assessor's Role in Evaluating RCA

- Assessors do not judge the CABs RCA.
- Assessors are fact finders—they need to see evidence that there is either no root cause or that it was ineffective (i.e. repeat problems) for there to be a deficiency written against RCA.
- Assessors need to review corrective actions and RCAs associated with complaints, internal audits, non-conforming work to ensure that the lab has a robust system in place.
- Their assessment shall not be opinion based.



"I'm not superstitious either, but those were the three days Harris wore his lucky socks."



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Assessor's Role Continued

- For each identified problem:
 - 1. Determine whether a root cause has been conducted.
 - 2. Establish that a remedial action has been initiated.
 - 3. Establish that a corrective action has been put into place to eliminate the root cause.
 - 4. Verify that the lab has followed up on the corrective action at a later date to ensure that the CA has been initiated and the root cause has been eliminated.
 - 5. If there has been a recurrence of the problem, ensure that the lab has gone back to try to establish a new root cause.



Accreditation Council's Role in Evaluating RCA

- The AC is not responsible for evaluating RCA.
- The AC is to review the deficiencies and the corrective actions to determine if the evidence provided is appropriate and complete.
- Again, the AC is not to impart opinion in their judgments.





Conclusions

- CABs often overlook the important problem solving techniques of RCA.
- RCA, if used effectively, can be a powerful tool to prevent problems from happening again.
- Can help your laboratory run more efficiently by saving time, staff resources, and money.





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