Root Cause Analysis

D. Jody Koehler, M.S.
Program Manager, TCEQ Accreditation Program
Section Manager, Laboratory/Quality Assurance

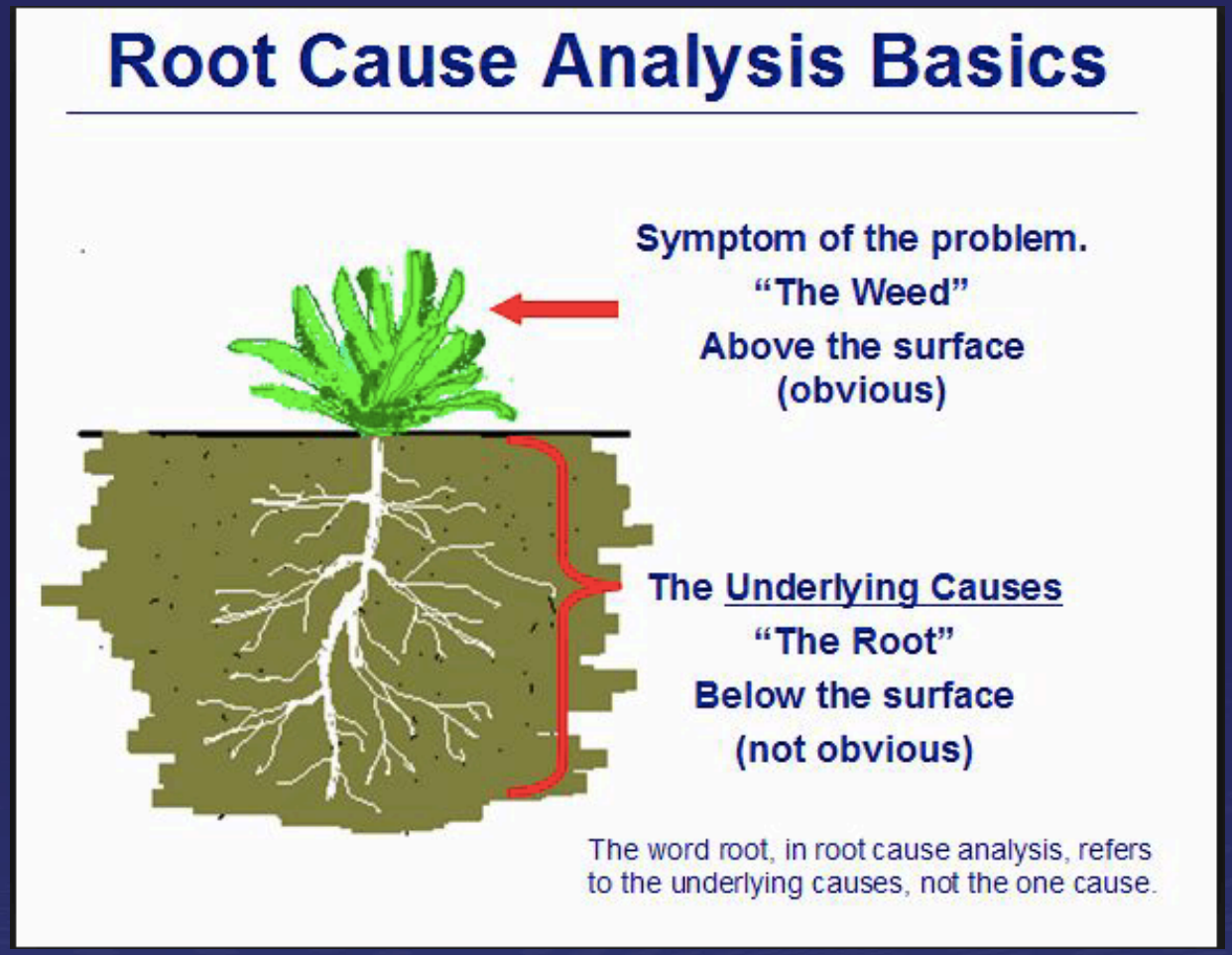
Defining Root Cause Analysis

- What is Root Cause Analysis?

  "…a wide range of approaches, tools, and techniques used to uncover **causes** of problems."

http://asq.org/learn-about-quality/root-cause-analysis/overview/overview.html

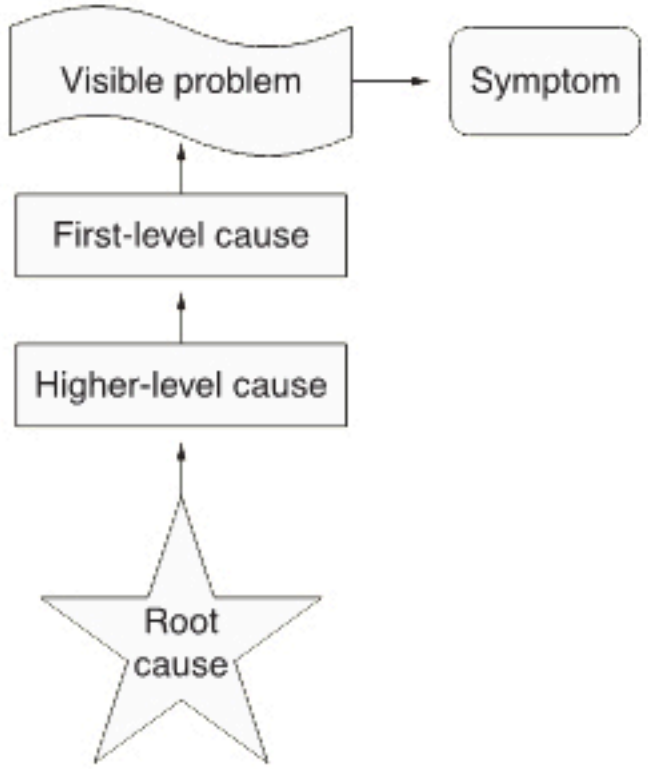
Root Cause Analysis



https://www.slideshare.net/geoffreyawalker/eus2-root-causeanalysis

Root Cause Analysis

The highest-level cause of a problem is called the root cause:



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Root Cause Analysis

- Root cause analysis (RCA) requires the investigator(s) to look beyond the solution to the immediate problem and understand the fundamental or underlying cause(s) of the situation and put them right, thereby preventing recurrence of the same issue.

Favorite Oversimplifications

- Human error
- Equipment failure
- Procedure not followed
- Inadequate training
- Design error
- Poor communication

Don’t stop at these! These are too general to take action.

Need to ask “WHY?”

Root Cause Analysis Applications

- Can be used for
  - Single or recurring problems
  - Potential problems
  - Big and small issues
  - Things that did or could happen
  - Things that went poorly or things that went well

Root Cause Analysis Applications

- The better an organization becomes at performing root cause analysis, the fewer problems they will have to investigate
- The following questions are answered during complete root cause analysis:
  - What were we doing before?
  - What is the problem?
  - Why did it happen?
  - What action is going to be taken?
  - What are our work processes to prevent recurrence of non-conforming work?

Root Cause Analysis Requirements

Required by ISO 17025:2005/TNI V1M2-2016

4.11 Corrective action

4.11.1 General

The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.

NOTE A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from customers and from staff observations.

4.11.2 Cause analysis

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

NOTE Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.

Root Cause Analysis- Requirements

Required by ISO 17025:2005/TNI V1M2-2016

4.11 Corrective action

4.11.3 Selection and implementation of corrective actions

Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence. Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem. The laboratory shall document and implement any required changes resulting from corrective action investigations.

4.11.4 Monitoring of corrective actions

The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

Methods of Root Cause Analysis

- The ‘5 Whys’:
- Fishbone Diagrams
- Others

The “5 Whys”

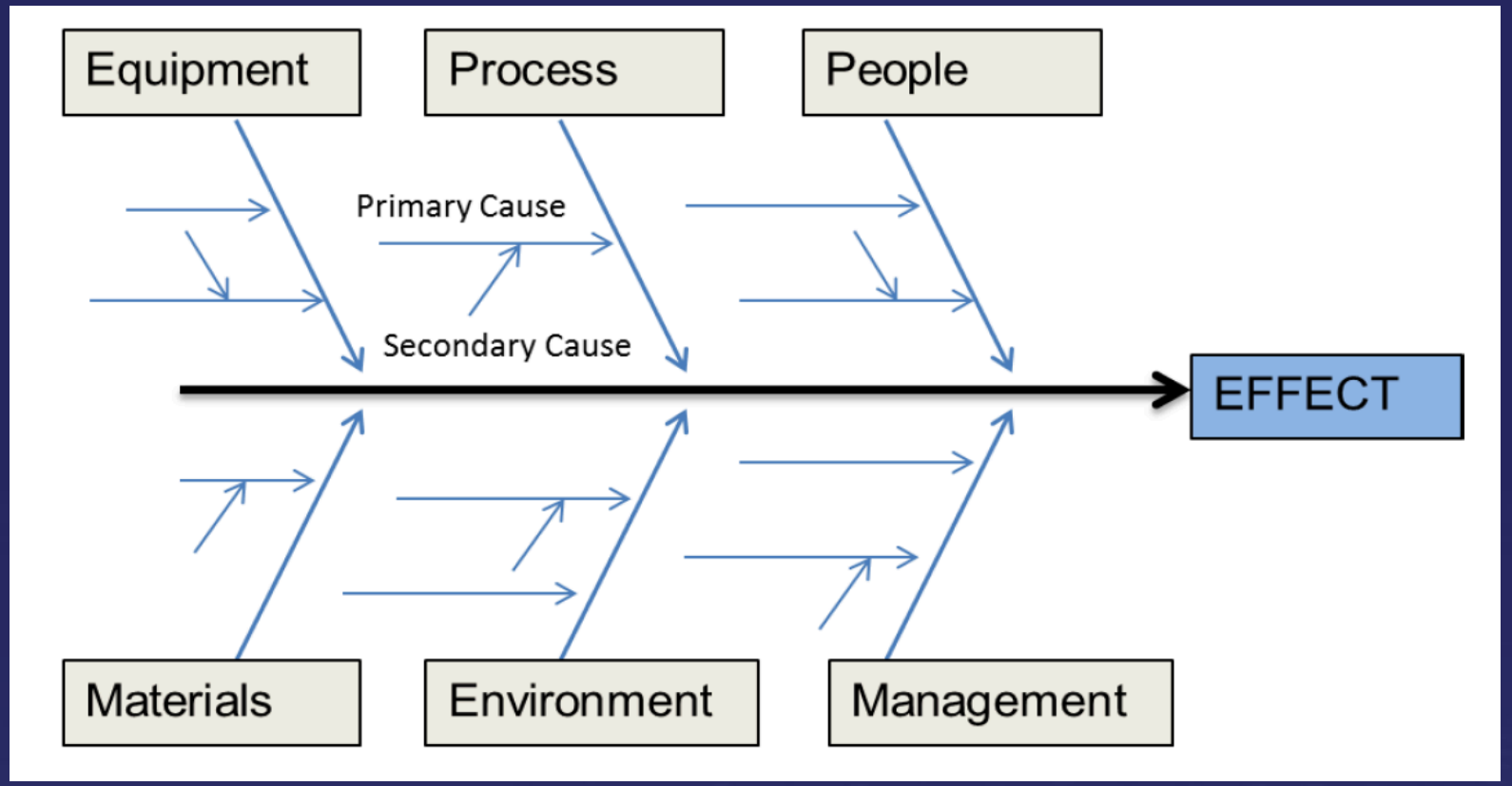
- The ‘5 Whys’ is the simplest method for structured root cause analysis.
- It is a question asking method used to explore the cause/effect relationships underlying the problem. The investigator keeps asking the question ‘Why?’ until meaningful conclusions are reached.

https://www.scribd.com/document/169089812/BRC026-Understanding-Root-Cause-Analysis

The “5 Whys”

- It is generally suggested that a minimum of five questions need to be asked, although sometimes additional questions are required or useful, as it is important to ensure that the questions continue to be asked until the real cause is identified rather than a partial conclusion.
- As previously mentioned, it is usually necessary to obtain information or objective evidence at each stage of the process, it is also sometimes necessary to re-phrase a question or make it more specific to obtain meaningful data, for example, instead of simply asking ‘why?’, ask ‘why was the operator not trained?’ or ‘why did the training process fail?’ or ‘why was the training process not effective on this occasion?’

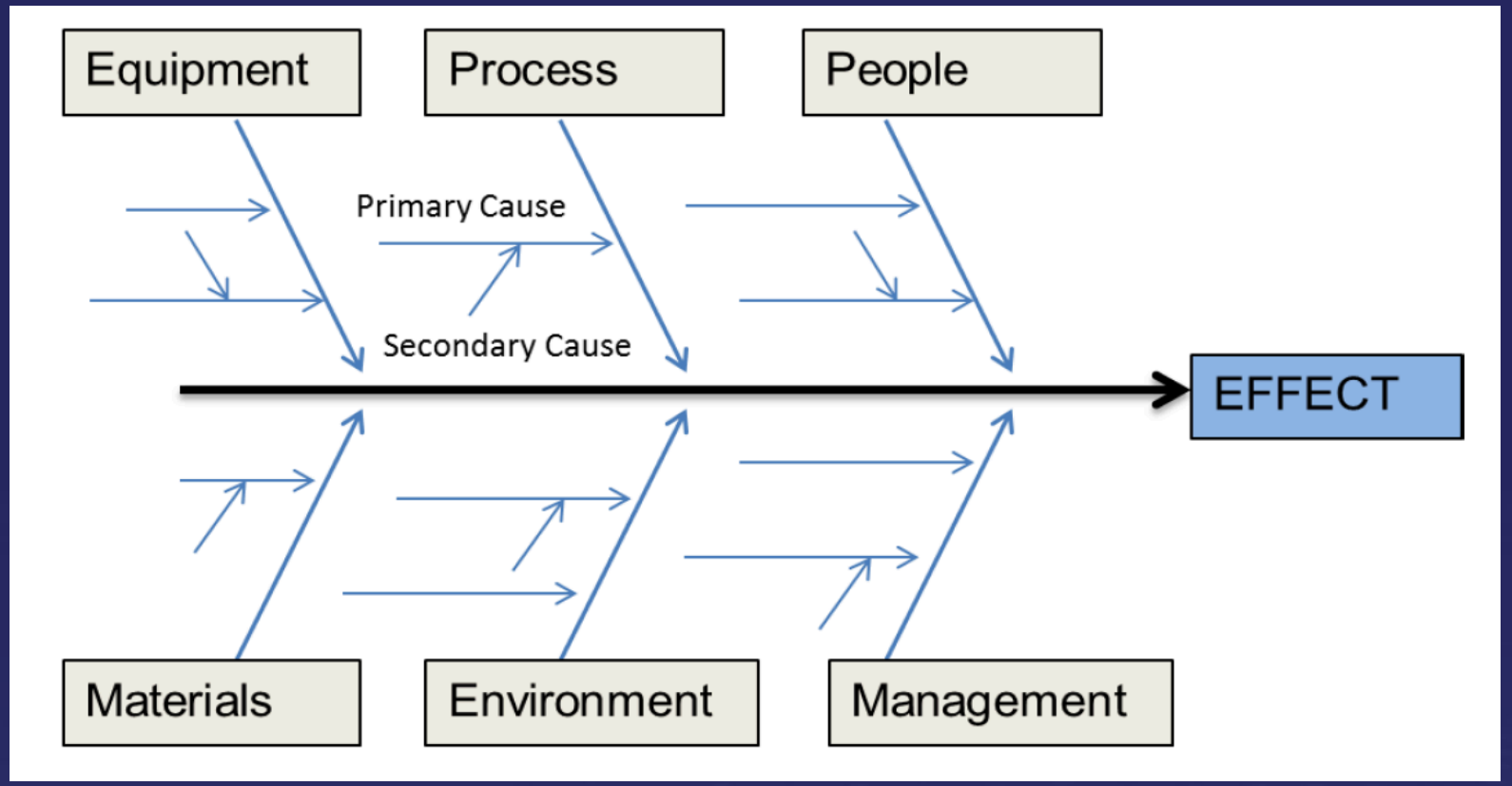
Fishbone Diagram



They are most useful when the ‘5 whys’ is too basic, for example, where a complex issue needs to be considered in bite size pieces or where there is a lot of data that needs to be trended.

https://www.scribd.com/document/169089812/BRC026-Understanding-Root-Cause-Analysis

Fishbone Diagram



The various causes are grouped into categories (such as equipment, materials or processes) and the arrows in the image indicate how the causes cascade or flow toward the non-conformity.

Fishbone Diagram

- Common categories include:
  - Equipment – this should include consideration of all equipment that could have a role in the non-conformity, for example, production line, facilities, computers or tools
  - Processes or Methods – how work is performed, policies, procedures, rules or work instructions
  - Measurements – any data collection or measurement, either from a process or subsequent to the non-conformity, for example metal detection records, check weights or final product analysis
  - Materials – any information relating to raw materials or final products, for example raw material specification or goods receipt checks for a specific batch of ingredient.
  - Environment – The location, time, temperature, culture, standards of cleanliness or available time, for an activity.
  - People – Any role involved in the implicated process.

Fishbone Diagram

- This type of root cause analysis is a causal process, it seeks to understand the possible causes by asking ‘what actually happened?’, ‘When?’, ‘Where?’ ‘Why?’, ‘How?’ and ‘So what?’ in other words, a possible cause is identified, and the consequences and significance is investigated for each of the group categories.
- For example:
  - What happened? - Procedure was not followed correctly
  - Why? - Staff member was untrained in the procedure
  - When? - Monday morning
  - Where? - Line 2
  - How? - Staff shortages
  - So what? (i.e., is this important?) - The safety of the product could be implicated if the procedure is not followed correctly. Training processes have not been followed correctly.

Conclusions from Root Cause Analysis

- The root cause should be something that can be managed or changed, which means that it normally relates to a system or process and occasionally an alterable behavior.
- For example, it is often tempting to reach a conclusion such as ‘they forgot’, ‘not enough time’, ‘not enough money’, ‘not enough staff’, ‘staff sickness’ or ‘made a mistake’, these answers may be true, but in most cases, they are out of our control, whereas **root cause analysis should lead to controllable, manageable or adjustable processes.**

Non-conformity Correction

- It is important that immediate action is taken to correct a non-conformity. However, this is separate from the root cause analysis and proposed action plan.
- The purpose of root cause analysis is to look beyond the immediate non-conformity, to investigate what system or process allowed the non-conformity to occur.
- Once this is established, the proposed action plan can focus on ensuring that the system or process is amended such that the fault cannot occur in future.
- Therefore, the proposed action plan should not be a repeat of the immediate corrective action.

When Corrective Action Doesn't Work

- Occasionally, despite root cause analysis and the implementation of a proposed action plan, the non-conformity reoccurs. There are many potential reasons why this might happen, including:
  - Incomplete initial root cause analysis
  - Incorrect root cause conclusions (i.e., the true root cause was not established)
  - Multiple root causes (the proposed action plan needs to manage every root cause)
  - Proposed action plan not fully implemented or trained to staff
- In these situations, it may be necessary to revisit the root cause analysis and identify additional causes and appropriate controls.

When Corrective Action Doesn't Work

- Affirms the importance of evaluating the effectiveness of implemented corrective actions to ensure there isn't a recurrence of the non-conforming work

Evaluating the Effectiveness of Corrective Actions

- Purpose: ensure that non-conformities don't recur
- Effectiveness should be monitored for a specified time period
- If ineffective, begin the corrective action cycle again

Deming's Wheel

Non-Conformity Documentation

- Documentation of non-conformities is required by accreditation standards
- Best practice to keep a log of non-conformities outside of case records for tracking purposes
  - If there's a log, the laboratory can look at trends in the types of non-conformities and make proactive preventative action plans

Communication About Non-Conformities

- Who needs to know when an error occurs?
  - Stakeholders- this may include customers, depending upon the severity of the non-conformity
  - Technical laboratory management
  - Non-technical laboratory management

“Near Miss”

- Definition: Nonconformity with potential to cause damage; damage prevented through a fortuitous intervention
- Should be evaluated as if a damaging non-conformity had occurred
- Can be utilized as a teaching moment for involved staff

Preventative Actions

- Definition: change implemented to address a weakness in a system that is not yet responsible for causing non-conforming work
- Advantage: Ability to make changes before products are negatively impacted
- Required to be documented

Preventative Actions

- Can arise from:
  - Customer complaints
  - Employee suggestions
  - Corrective actions in other disciplines
  - Customer or employee surveys
  - In depth review of processes/procedures

Just Culture

- **What is Just Culture?**
  - **Culture** in which front-line operators and others are not punished for actions, omissions or decisions taken by them which are commensurate with their experience and training, but where management seeks to learn whether and to what extent the system contributed to the mistake.

Just Culture

- It is sometimes tempting to reach a conclusion such as; ‘oversight’, ‘misunderstood’, or ‘forgot’, however, people are rarely the true root cause, and the investigator will need to establish what system, policy or process allowed the human error to occur.
- Throughout the process it must be noted that root cause analysis is not designed to establish who is to blame for a non-conformity, but to correct the underlying cause and prevent recurrence.
- This does not mean misconduct or incompetence is tolerated.

Just Culture-Advantages

- By creating a “safe harbor” people are more likely to come forward when errors occur
- Promotes transparency
- Encourages a culture of constant quality improvement which will improve the robustness of the laboratory’s quality system

Questions?

Contact Information:

D. Jody Koehler, M.S.

512-239-1990

Jody.Koehler@tceq.texas.gov