ISO/IEC 17025:2017 Requirements for Corrective Action

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ISO/IEC 17025:2017 Requirements for Corrective Action

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- All attendees are muted. However, feel free to utilize the questions tab and they will be answered at the end of the session.

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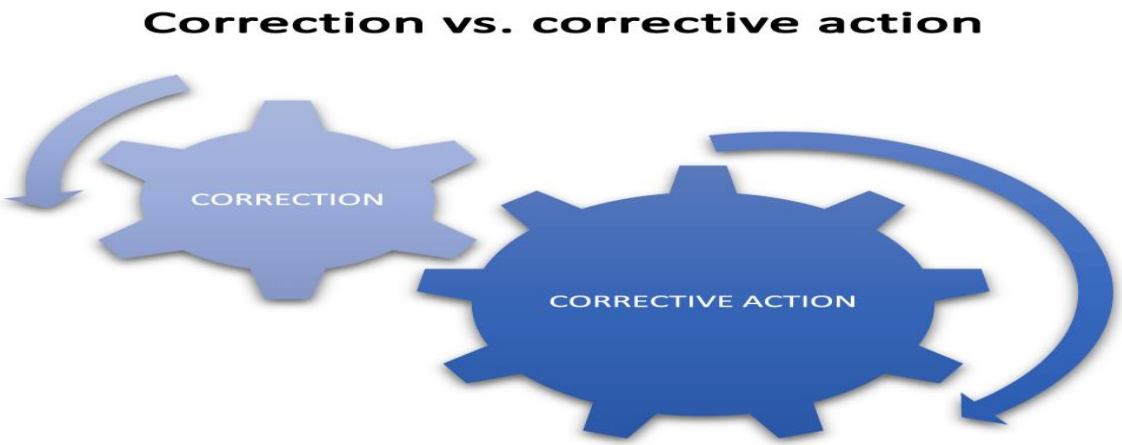
Corrective Action

Corrective action is an activity that shall be used to stop **the re-occurrence** of non-conformities

Corrective action has to be initiated when a problem exists. Remedial action can easily be confused with corrective action. Remedial action or correction is taken to rectify the mistake. Corrective action is an action to eliminate defined non-conformities and prevent reoccurrences.



Sources of Corrective Action

- Internal Audits
- External Audits
- Complaints
- Nonconforming Work
- Internal Sources to your Organization
- Customer Feedback

Corrective Action

8.7.1 When a nonconformity occurs, the laboratory **shall:**

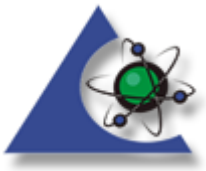
a) react to the nonconformity and, as applicable:

— take action to control and correct it;

— address the consequences

Example: To recall a test report and make necessary changes is a remedial action or correction because making changes in the report does not help to prevent ***re-occurrence*** *of non-conformities.*

If this is an isolated instance, then correction may be sufficient.



Corrective Action

8.7.1 When a nonconformity occurs, the laboratory shall

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

— reviewing and analyzing the nonconformity;

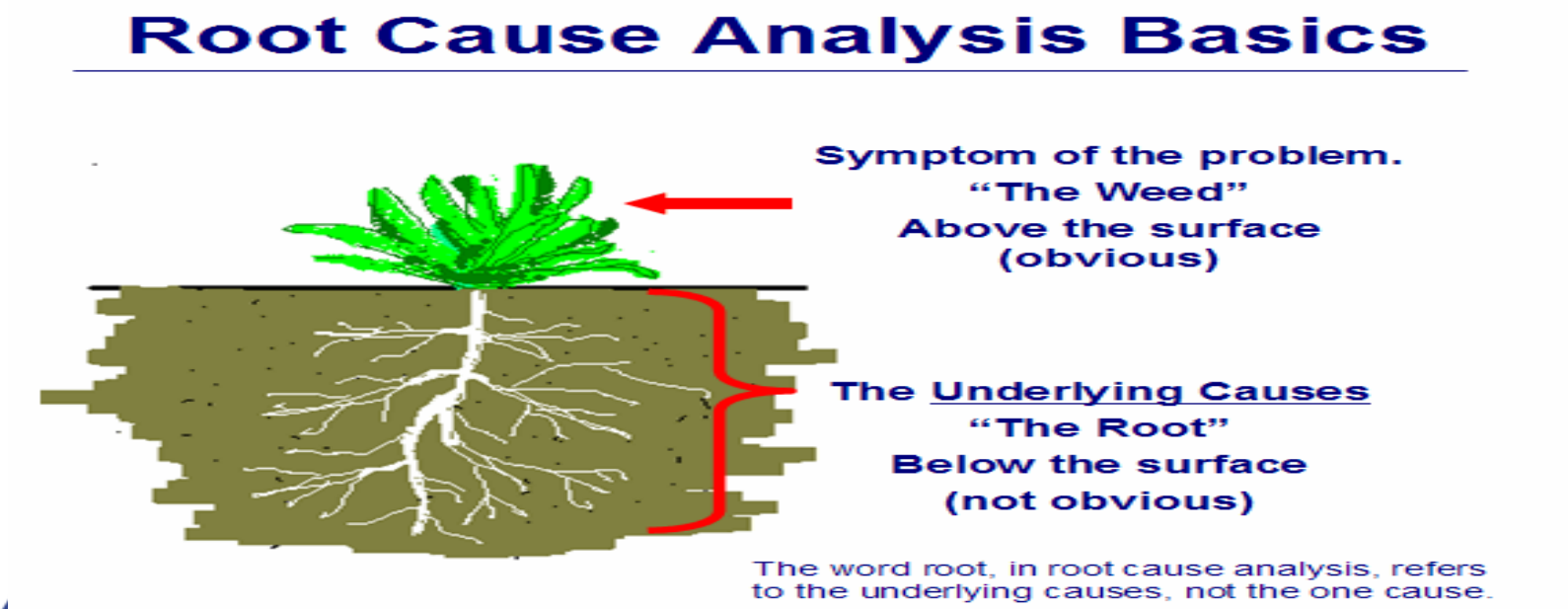
— determining the causes of the nonconformity;

— determining if similar nonconformities exist, or could potentially occur

As in the report example, if this is the third correction this month due to errors then may need to take it futher and look into the review, and authorization of reports.

Corrective Action

ISO/IEC 17025: 2017 Standard indicates that in the corrective action process the causes need to be evaluated.. Cause analysis is the important and most difficult step in the process. Any kind of mistake in this step may cause the implementation of wrong corrective action and does not avoid re-occurrence of non-conformities.

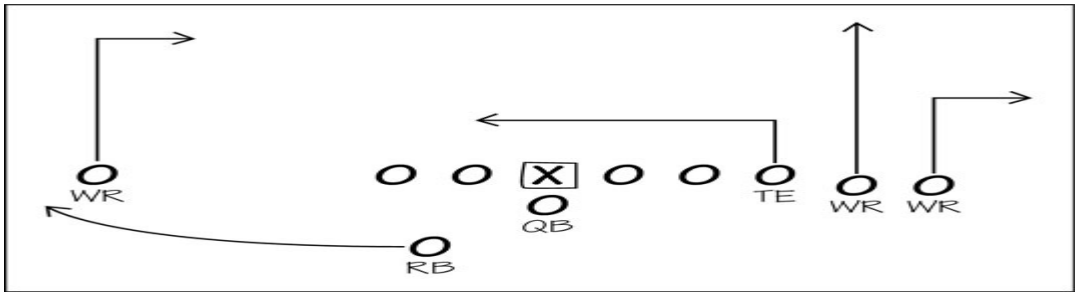


Corrective Action

8.7.1 When a nonconformity occurs, the laboratory shall:

c) implement any action needed

Necessary conditions for corrective action should be clearly defined. The laboratory management should be confident about the effectiveness and the performance of the corrective action.



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Corrective Action

8.7.1 When a nonconformity occurs, the laboratory shall:

d) review the effectiveness of any corrective action taken;

The result of the corrective actions shall be monitored for determining the effectiveness of the corrective actions. Monitoring should verify the successful completion of the identified actions and assess the effectiveness of the actions taken.

Time needs to pass to determine the effectiveness

Corrective action is a required input for the

management review.

Has corrective action taken bee effective?

Corrective Action

8.7.1 When a nonconformity occurs, the laboratory **shall**

e) update risks and opportunities determined during planning, if necessary;

ISO/IEC 17025:2017 requires the laboratory to plan and implement actions to address risks and opportunities.

Lab should incorporate asking itself: Are there any risks are opportunities presented during the course of implementing this corrective action?

Corrective Action

A lab may choose to have different processes for assigning risk levels of corrective actions, depending on their severity.

Single Lapse vs Total Breakdown, Major NCR vs Minor NCR

Corrective actions should be implemented accordingly

Corrective Action

8.7.1 When a nonconformity occurs, the laboratory shall

f) make changes to the management system, if necessary;

Corrective Action

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

What was the impact on laboratory results???

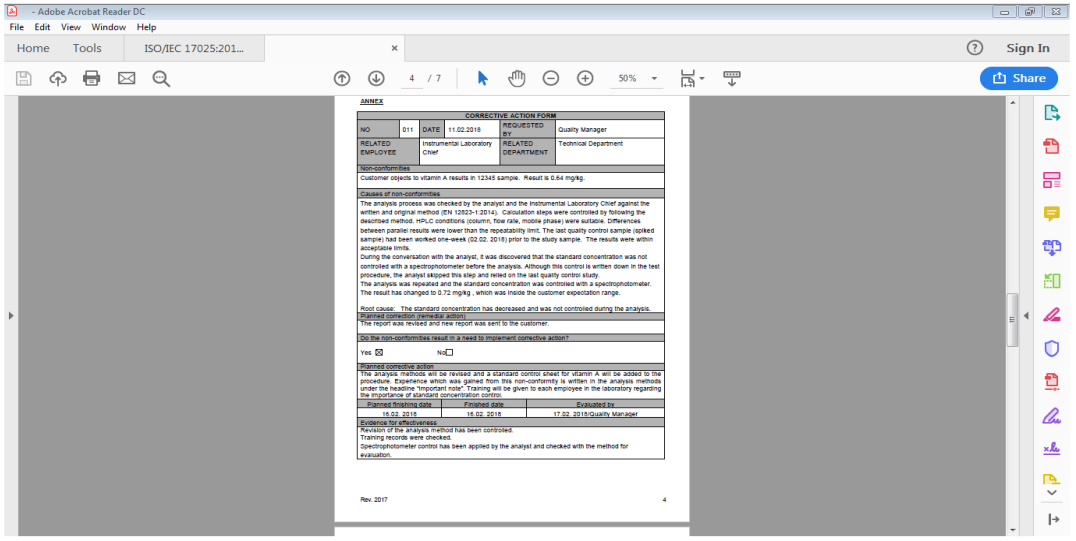
Corrective Action

8.7.3 The laboratory shall retain records as evidence of:

a) the nature of the nonconformities, cause(s) and any subsequent actions taken;

b) the results of any corrective action.

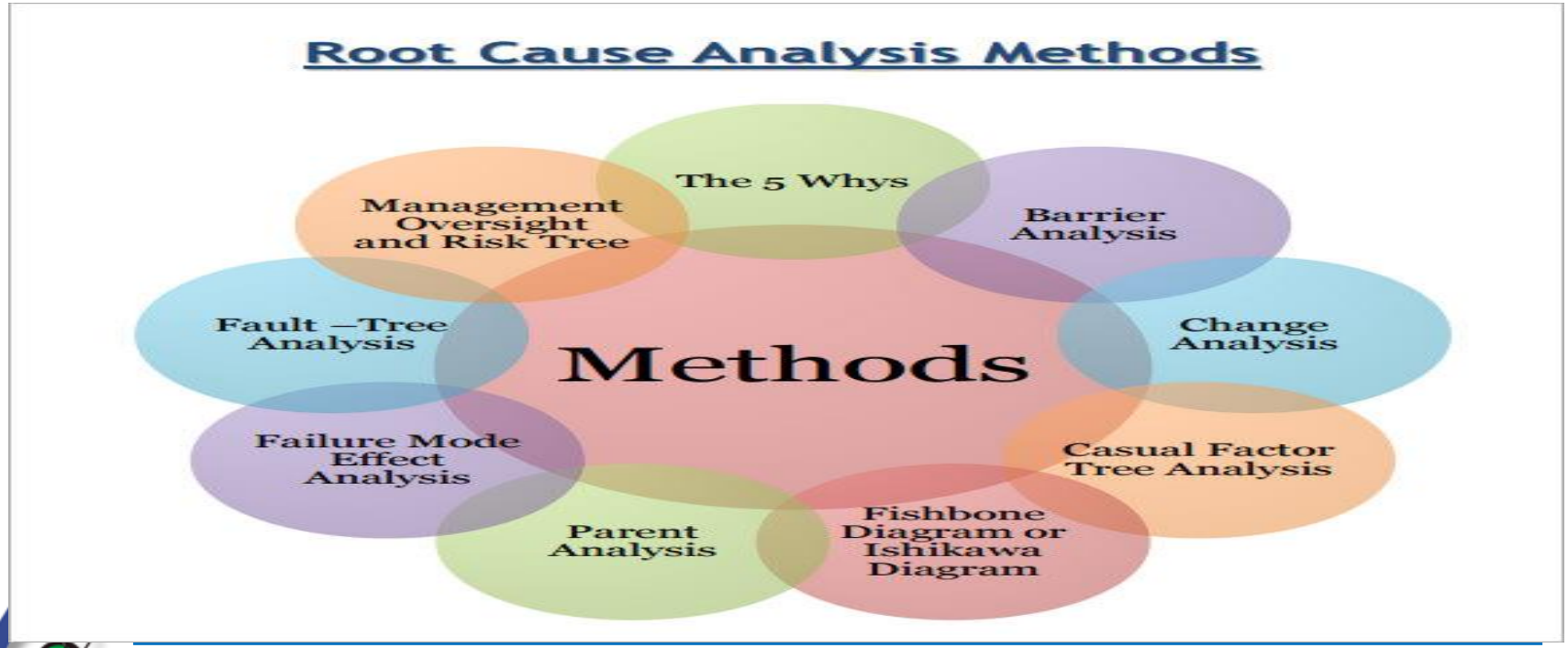
Records are needed to support compliance. This should support that a nonconformance was identified, cause analysis completed, potential corrective action identified, selected, and implemented and that the corrective action was monitored.



Corrective Action

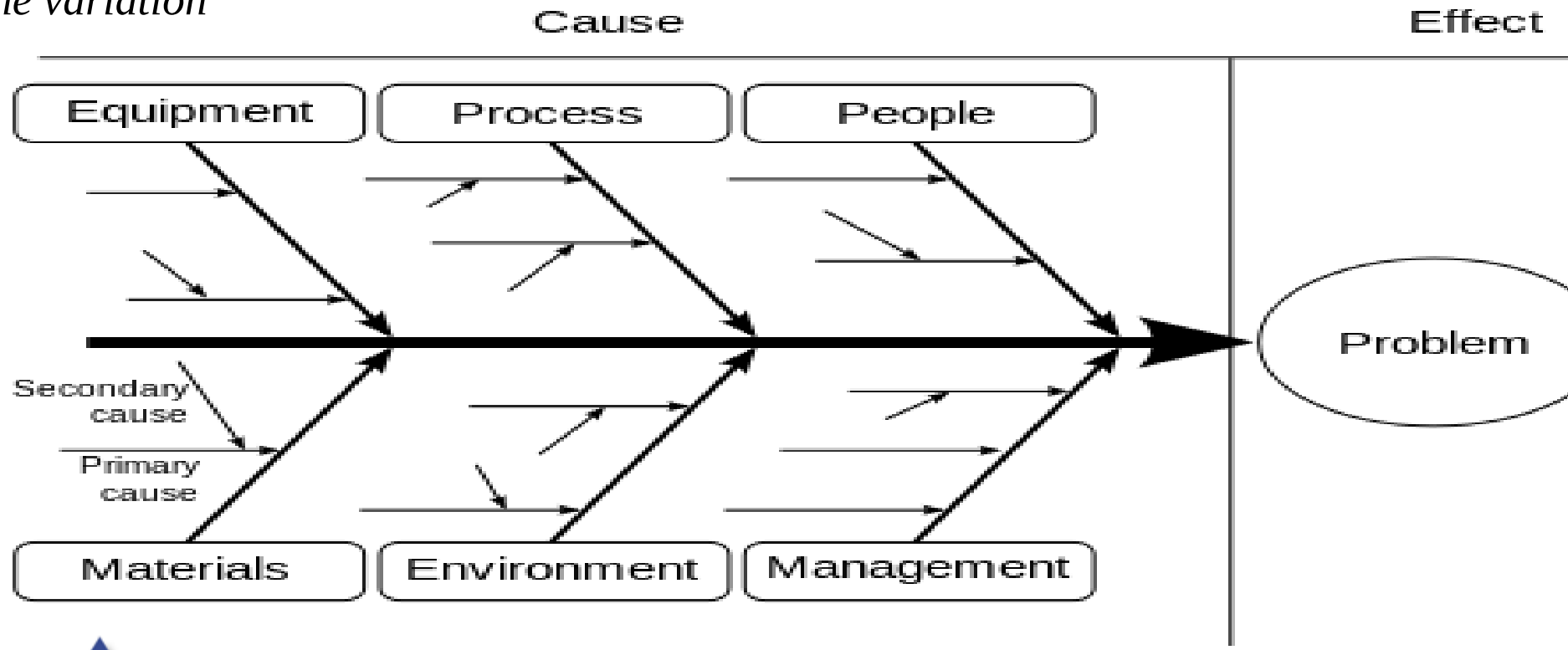
Techniques for Root Cause Analysais

A root cause analysis should be performed as soon as possible after the error or variance occurs. otherwise, important details may be missed. All of the personnel involved in the error should be involved in the analysis. Without all parties present, the discussion may l lead to fictionalization or speculation that will dilute the facts



Fishbone or Ishikawa or Cause-and-Effect Diagrams

This will group causes into categories. This may include people, measurements, methods, materials, environment and machines. The fishbone diagram forces you to consider all possible causes of a problem instead of focusing on the most obvious one. Here causes are grouped into several categories to easily identify the correct source of the variation



Fishbone or Ishikawa or Cause-and-Effect Diagrams

Categories are very broad and might include things like "People" or "Environment." After grouping the categories, we break those down into the smaller parts. For example, under "People" we might consider potential root cause factors like "leadership," "staffing," or "training."

As we dig deeper into potential causes and sub-causes, questioning each branch, we get closer to the sources of the issue. We can use this method eliminate unrelated categories and identify correlated factors and likely root causes. For the sake of simplicity, carefully consider the categories before creating a diagram.

Brainstorming

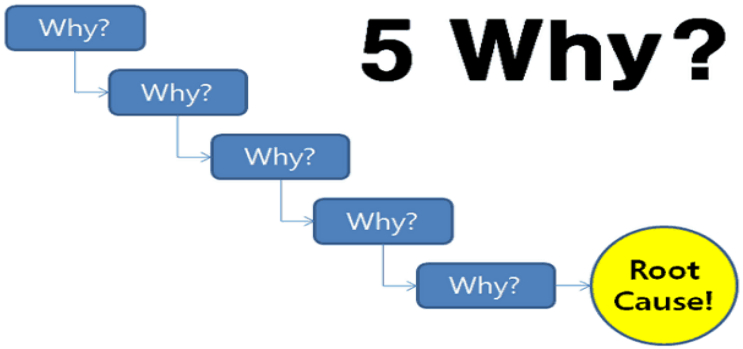
The person facilitating the meeting has two roles; first, to assure that the steps are properly executed and second, help assure the discussion stays on topic in regard to finding the root cause of the problem you are trying to solve.

In addition to all the great ideas you can get from a Brainstorming session, it can also benefit you with regard to company politics. This is the case because the people involved in the **brainstorming session** will be more likely to support the resulting action items because they were involved the process that created the solution.

5 Whys

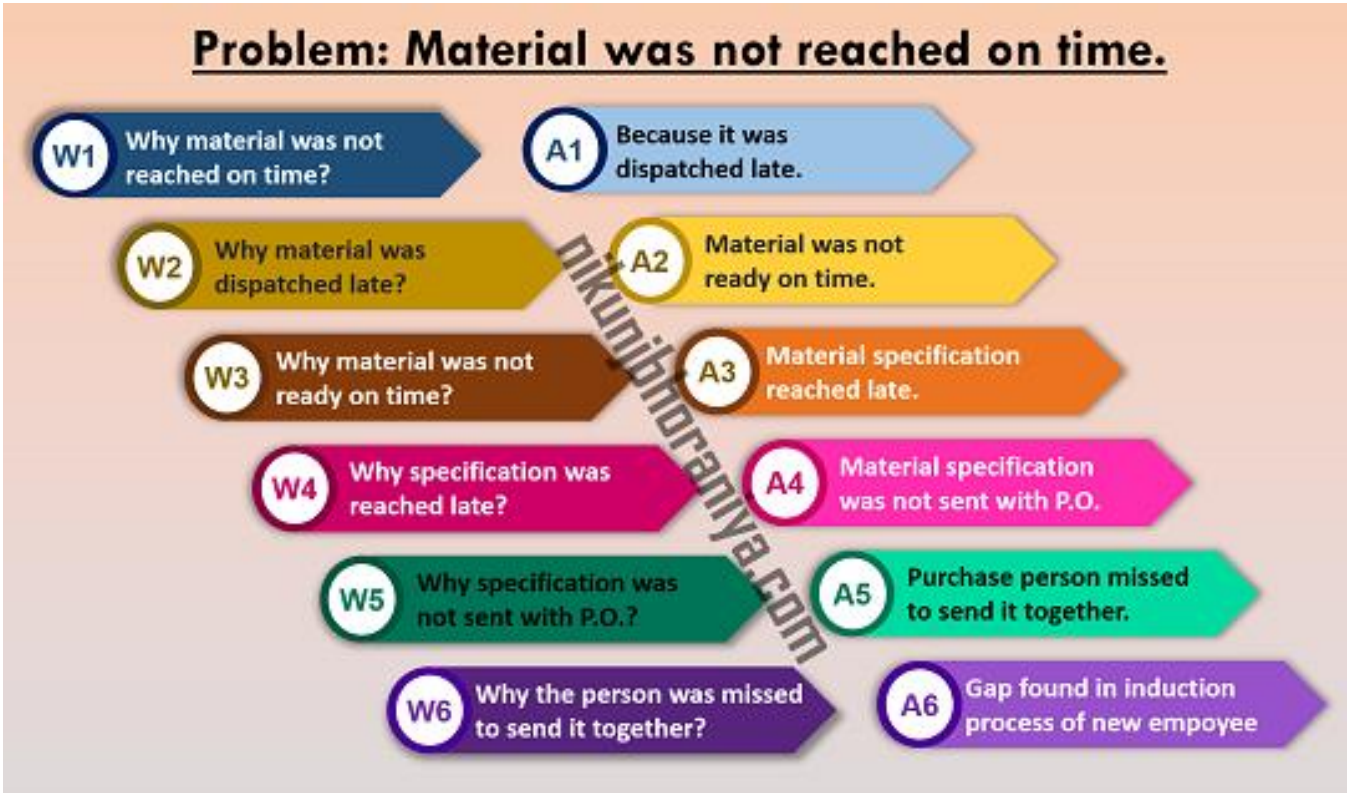
One of the more common techniques in performing a root cause analysis is the 5 Whys approach. We may also think of this as the annoying toddler approach. For every answer to a WHY question, follow it up with an additional, deeper “Ok, but WHY?” question.

Five is an arbitrary figure. The theory is that after asking why five times you will probably arrive at the root cause. The root cause has been identified when asking why doesn’t provide any more useful information.



5 Whys

Example



5 Whys

Issue – An employee fell and was injured during the first shift start up.

There was an oil spill on the floor in the machining department

Why?

A Seal in machine 2 deteriorated and began cracking and leaked oil.

Why?

The seal material was not robust to the application

Why?

Lower cost seals purchased from new supplier

Why?

Seal material not specified in service manuals so low cost seals were used

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This time is allocated for questions. You should have a space provided for submitting questions.

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If a question is not answered, please submit directly to webinar@pjlabs.com

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