ISO/IEC 17025:2017 Section 8.7 "Corrective Action"

Thursday, February 21 – 1:00pm EST

Presented by:

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ISO/IEC 17025:2017 Section 8.7 "Corrective Action

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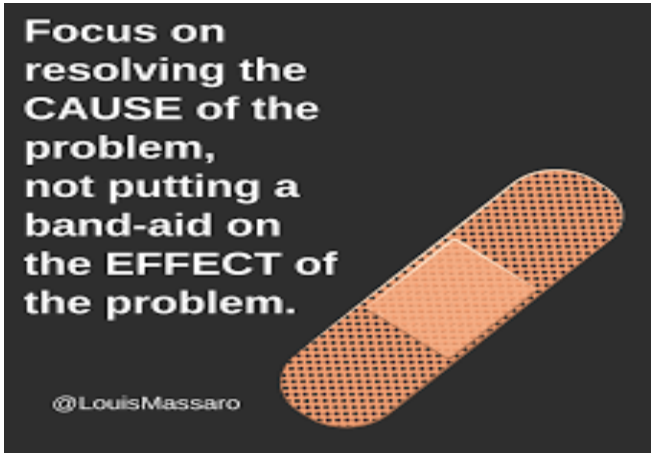
Duration of webinar is set for one hour.

You can type any questions directly into your webinar box; We will review them at the conclusion of today's session; Please keep question presented related to the topic of today's webinar.

Corrective Action

Background

- 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.



Corrective Action - Identification of changes

The writing of the clause has been modified, and some further items have been included:

- b) determining if similar nonconformities exist, or could potentially occur
- e) update risks and opportunities determined during planning, if necessary

Additional internal audits have been erased

From ISO/IEC 17025:2005 “4.11.5 Additional audits”

Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible

Corrective Action - Identification of changes

The 2005 Standard was specific to a procedure;

4.11.1 General

The laboratory shall establish a policy and a procedure.

The 2017 Standard is does not require a procedure;

8.7.1 When a nonconformity occurs, the laboratory shall react to the nonconformity and, as applicable.

A procedure can still be utilized to ensure that the requirements in the Standard are being met. A lab should revise it's procedure if in use to reflect the requirements in the 2017 Standard.

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.

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;

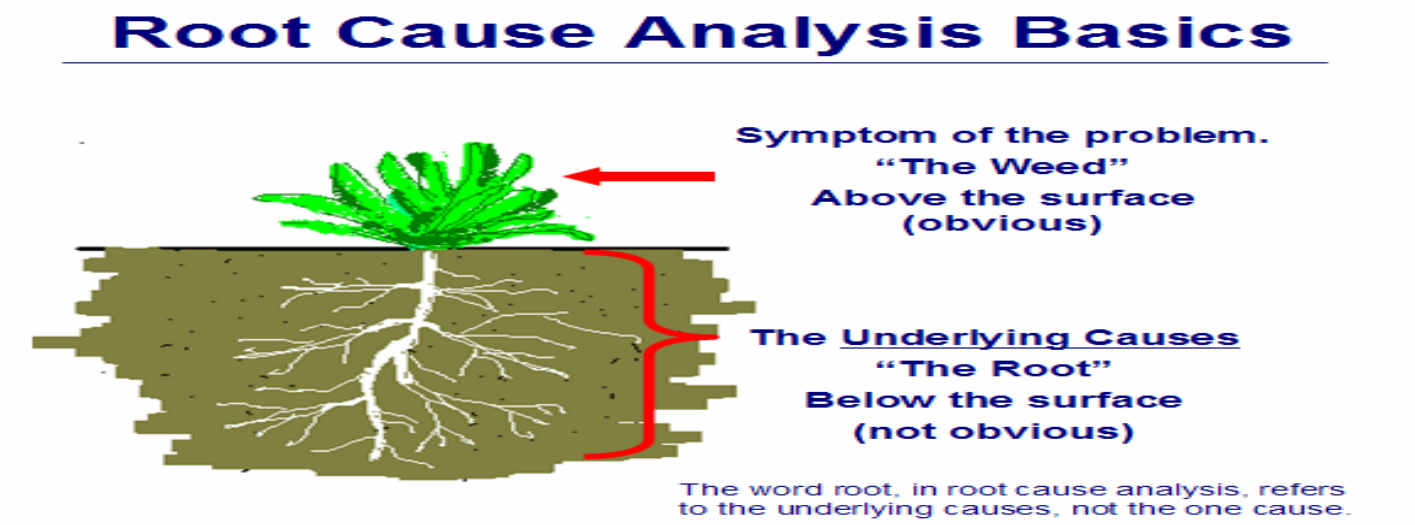
— determining if similar nonconformities exist, or could potentially occur

In the report reissue example may need to go further and look into the review, and authorization of reports.

From 2005 Standard - The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

Corrective Action

ISO 17025 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

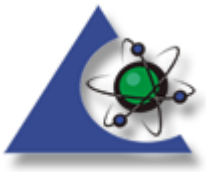
8.7.1 When a nonconformity occurs, the laboratory shall

d) review the effectiveness of any corrective action taken;

The result of the corrective actions shall be recorded and 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 .

Monitoring may also requires additional audits if identified non-conformities cause serious doubts about a laboratory's compliance with standards, its own policies and its own procedure



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. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects

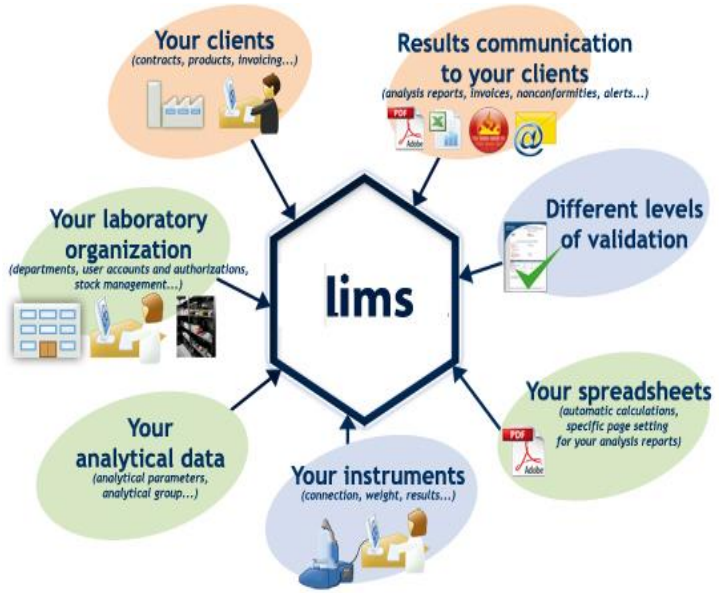
Lab should incorporate asking itself:

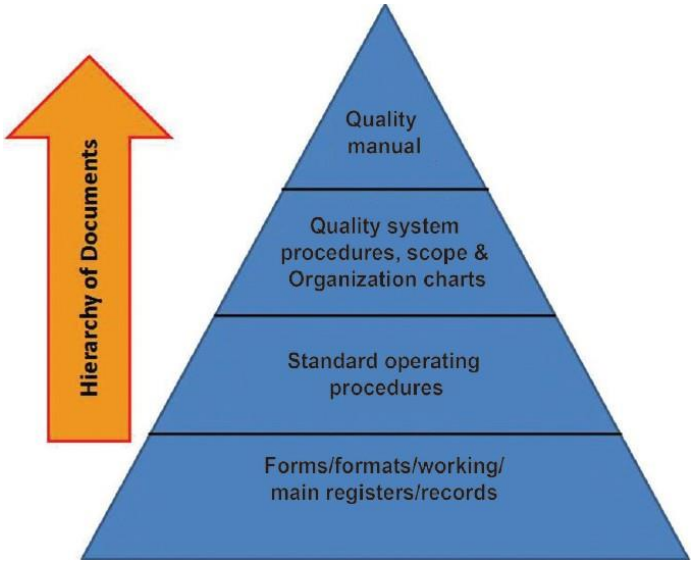
Are there any risks are opportunities?

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.

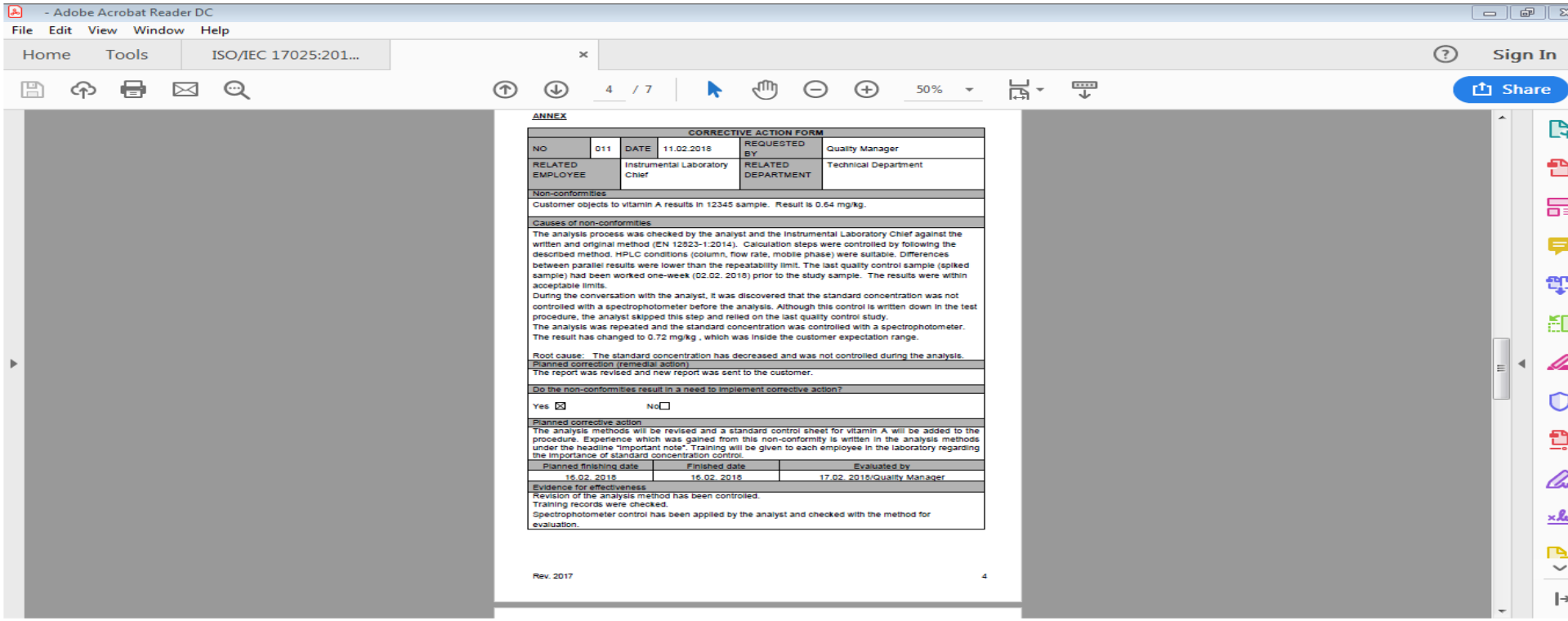
What was the impact on laboratory results???

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.



ANNEX

CORRECTIVE ACTION FORM

NO	011	DATE	11.02.2018	REQUESTED BY	Quality Manager
RELATED EMPLOYEE	Instrumental Laboratory Chief			RELATED DEPARTMENT	Technical Department

Non-conformities

Customer objects to vitamin A results in 12345 sample. Result is 0.64 mg/kg.

Causes of non-conformities

The analysis process was checked by the analyst and the Instrumental Laboratory Chief against the written and original method (EN 12823-1:2014). Calculation steps were controlled by following the described method. HPLC conditions (column, flow rate, mobile phase) were suitable. Differences between parallel results were lower than the repeatability limit. The last quality control sample (spiked sample) had been worked one-week (02.02. 2018) prior to the study sample. The results were within acceptable limits.
During the conversation with the analyst, it was discovered that the standard concentration was not controlled with a spectrophotometer before the analysis. Although this control is written down in the test procedure, the analyst skipped this step and relied on the last quality control study.
The analysis was repeated and the standard concentration was controlled with a spectrophotometer.
The result has changed to 0.72 mg/kg , which was inside the customer expectation range.

Root cause: The standard concentration has decreased and was not controlled during the analysis.

Planned correction (remedial action)

The report was revised and new report was sent to the customer.

Do the non-conformities result in a need to implement corrective action?

Yes ☒ No☐

Planned corrective action

The analysis methods will be revised and a standard control sheet for vitamin A will be added to the procedure. Experience which was gained from this non-conformity is written in the analysis methods under the headline "Important note". Training will be given to each employee in the laboratory regarding the importance of standard concentration control.

Planned finishing date	Finished date	Evaluated by
16.02. 2018	16.02. 2018	17.02. 2018/Quality Manager

Evidence for effectiveness

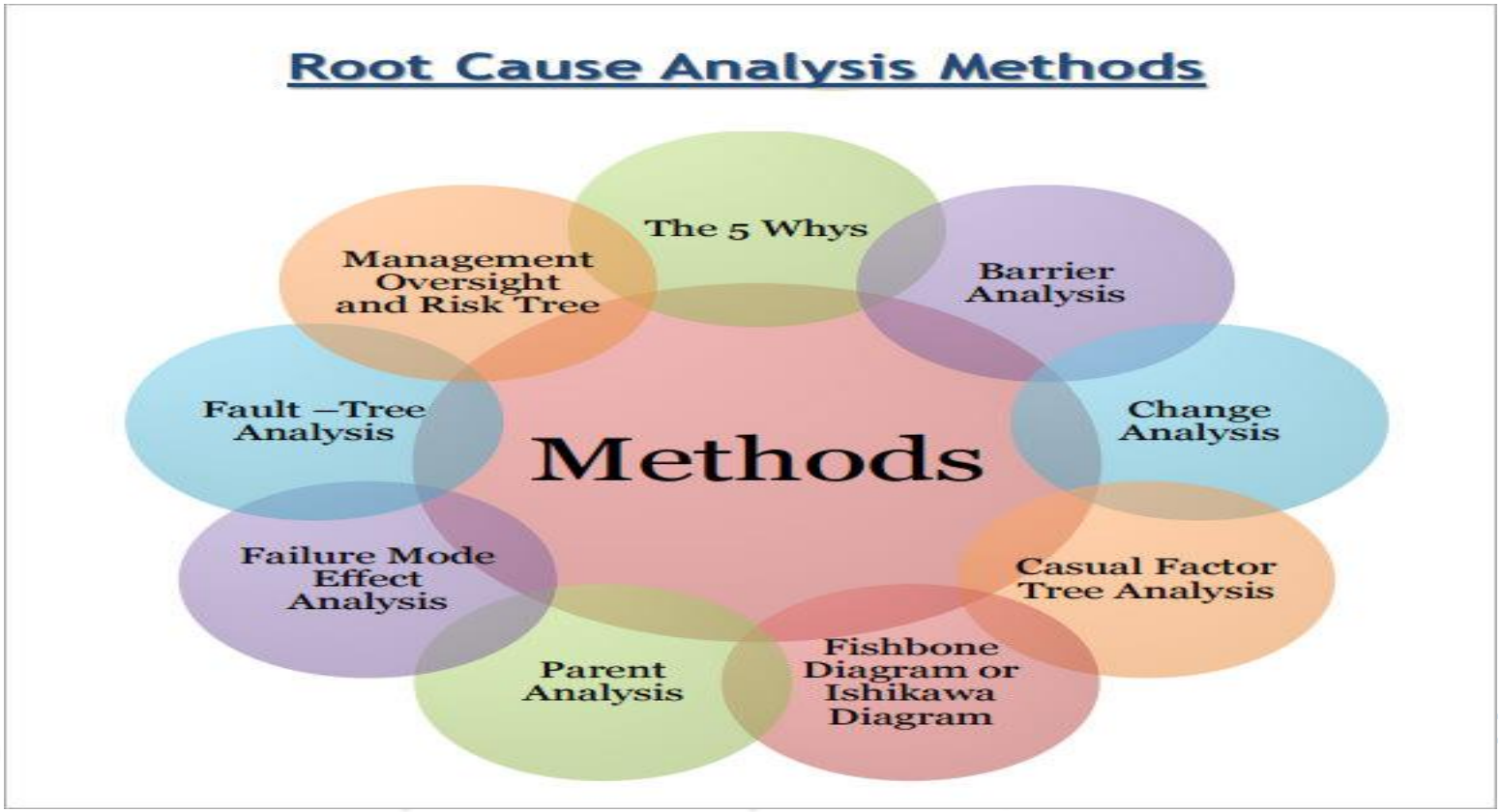
Revision of the analysis method has been controlled.
Training records were checked.
Spectrophotometer control has been applied by the analyst and checked with the method for evaluation.

Rev. 2017 4

Corrective Action

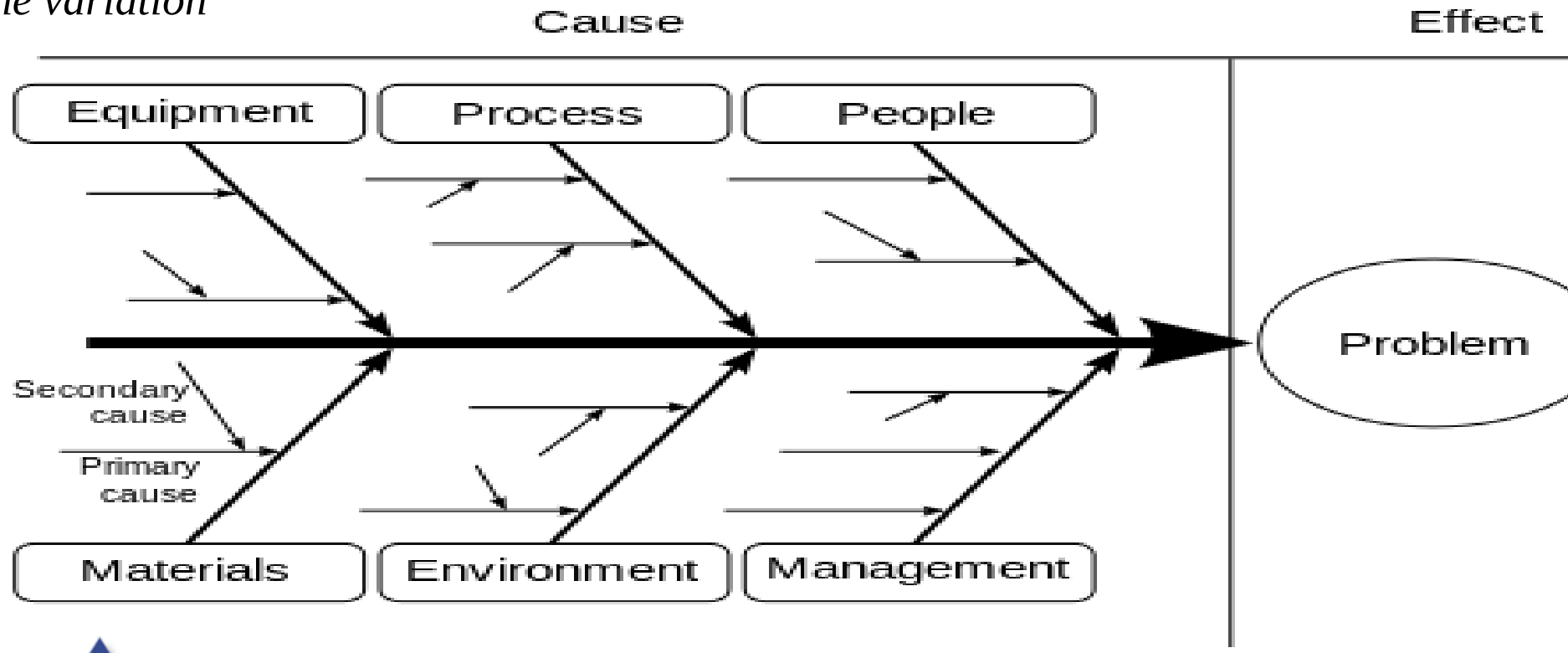
Techniques for Root Cause Analysais

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 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

Fishbone or Ishikawa or Cause-and-Effect Diagrams

Common categories to consider in a Fishbone diagram:

Machine (equipment, technology), Method (process), Material (includes raw material, consumables, and information), Man/mind power (physical or knowledge work), Measurement (inspection), Mission (purpose, expectation), Management / money power (leadership), Maintenance, Product (or service), Price, Promotion (marketing), Process (systems), People (personnel), Physical evidence, Performance, Surroundings (place, environment), Suppliers, Skills

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

Brainstorming

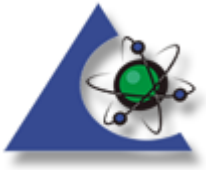
The brainstorming process brings together a group of people to discuss the issue in a question in a facilitated environment. The basic premise is that a group of people working collectively to find a solution is more productive and innovative than if each person tried to come up with a solution individually.

Basic steps of the brainstorming process include: scheduling a meeting, informing the participants of the topic to be discussed, assigning a specific person in the meeting who will write down people's thoughts, with all participants having equal opportunity to participate. The resulting discussion should identify the root cause of the problem and try to resolve it.

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. Remember this point when trying to decide who to invite to the meeting. After all, the people who are not part of the solution, may in turn become part of the problem



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

The 5 Whys technique was developed and fine-tuned within the Toyota Motor Corporation as a critical component of its problem-solving training. Toyota encouraged teams to dig into each problem that arose until they found the root cause. "

Here's an example Toyota offers *of a potential 5 Whys that might be used at one of their plants.*

1. **"Why did the robot stop?"**
   The circuit has overloaded, causing a fuse to blow.
2. **"Why is the circuit overloaded?"**
   There was insufficient lubrication on the bearings, so they locked up.
3. **"Why was there insufficient lubrication on the bearings?"**
   The oil pump on the robot is not circulating sufficient oil.
4. **"Why is the pump not circulating sufficient oil?"**
   The pump intake is clogged with metal shavings.
5. **"Why is the intake clogged with metal shavings?"**
   Because there is no filter on the pump.

5 Whys

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

Why did Mr. Smith fall and was injured during the first shift start up?

Why?

5 Whys

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?

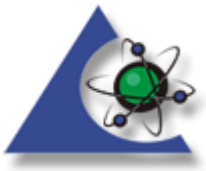
The seal material was not robust to the application

Why?

Lower cost seals purchased from new supplier

Why?

Seal material not specified in service manuals



ISO/IEC 17025:2017 Section 6.6 Externally Provided Products and Services

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

Please keep questions related to the topic covered in this webinar;

Save the Date

Next PJLA Webinar

Thursday, March 28 – 1:00pm EST

Metrological Traceability to include the requirements of ISO/IEC 17025:2017 along with those specified in PJLA Policy PL-2 "PJLA Measurement Traceability Policy"