

Investigation of Deviation using DMAIC

Step 1: Define

Identify the deviation and create a problem statement, define who will be working on the problem and the scope of the issue.

What is the issue or deviation that has occurred?

How was the problem identified?

Create a problem statement that describes the issue in detail and what exactly needs to occur for the problem to be considered remediated:

What is the scope of the problem and who will be assigned to the investigation?

Step 2: Measure

Set up measurement systems to collect the necessary data to determine the root cause

What metric(s) will be used to help identify the cause of the deviation?

Has a detailed process flow chart been created to help identify all the potential sources to the deviation?

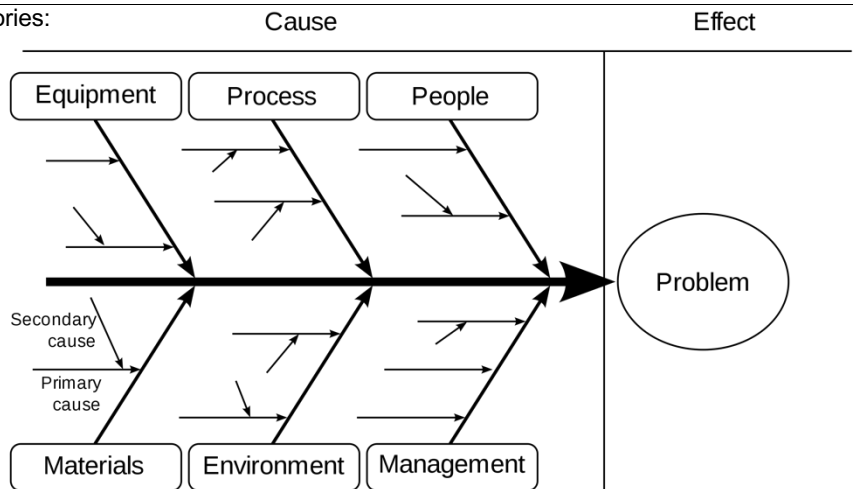
What graphical display methods (if necessary) will be used to plot the data collected?

Step 3: Analyze

Utilize analysis tools such as the 5 Why's and Fishbone diagram to figure out all the possible causes and the root cause

1. Why did this deviation occur?
2. Why did this happen?
3. Why did this happen?
4. Why did this happen?
5. Why did this happen? (Root Cause)

Write the potential causes for each of the categories:



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Step 4: Improve

Decide on one or several of the causes to “test” to see which is causing the deviation

Which causes will be tested to improve and remediate the deviation?

- The solution has passed the test of feasibility, practicality and cost-effectiveness
- The solution is robust and capable of preventing the deviation from re-occurrence
- The action plan for this deviation will be:

Step 5: Control

Once the solution has been selected, use metrics to verify that the solution has prevented the re-occurrence of the deviation

- The solution has been verified to work using what metric:
- Action plan results have been documented

The results are:

- Policies and procedures have been updated to prevent re-occurrence
- Regular audits have been established for continued monitoring to ensure the results of the action plan (and solution) have held and maintained control over the initial problem

How often will the audits occur to re-check the solution?

- Other/details:

QA Performed By	Operations Reviewed By
Name:	
Signature:	
Date:	

