

Standard Operating Procedure

Title: Root Cause Analysis Investigation Procedure

Department	Quality Management	Document no	QMS-140
Title	Root Cause Analysis Investigation Procedure		
Prepared by:		Date:	
Checked by:		Date:	
Approved by:		Date:	

A. Purpose

This SOP describes the procedure for initiating, communicating, conducting and documenting Root Cause Investigation related to process, system, [raw material](#), product, facility and laboratory deviations. A detail Investigation is required to identify Root Cause of a deviation or quality trends.

B. Scope

This SOP covers the use and management of the Root Cause Investigation Tool designed on the principles of [DMAIC \(Root Cause Investigation Template TEM-315\)](#), annexed in this SOP) which may be raised in association of a deviation that needs further investigation or there is a trend in the product complaints, periodic product quality review or trend observed in any other quality aspect. Root Cause Investigation Tool is used if the root cause of a deviation is not known and there is a necessity to perform an in-depth investigation with an effort to identify root cause(s).

Root Cause Investigation tool does not need to be used in every unplanned deviation situation.

Business Rules:

[A Root Cause investigation](#) can be raised when one or more of the following occur:

- The cause of the unplanned deviation cannot be determined.
- There is a probable cause or set of causes based on available evidence but the causes are not confirmed as the root cause.
- A number of unplanned deviations that indicates repeated trends or when there are repeated trends indicated by other quality systems, such as complaints, periodic product quality review.

A Root Cause investigation process should follow the DMAIC process, which is described in the 'Root Cause Investigation Template in attachment A.

A Root Cause investigation is not a substitution of usual unplanned deviation investigation. Rather, the tool should be used as an extended investigation and findings are attached with corresponding deviation.

As the root cause is determined, corrective and preventative actions are assigned in the respective deviation investigation.

Summary and recommendations should be presented periodically at the Site Quality meeting.

C. Responsibility

Department Manager:

1. The Department Managers are responsible to determine the need for a Root Cause Investigation.

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and true root cause. The DMAIC investigation process includes the following sections in chronological order:

- **Step 1: DEFINE (problem definition)**
This is the first section of the Root Cause investigation. The section is designed with series of questions to define the problem, its history and to outline any work that has been done so far
- **Step 2: DEFINE / MEASURE (understanding the process)**
This step has a grid line space to draw a brief process map to understand the sequential activities involved in the process. As the outline of the process is complete, the participants mark possible area/s where the deviation / incident discovered.
- **Step 3a: ANALYSIS (process analysis)**
This section is designed to list if there were significant changes to process which might have contributed to repetitive incidents. The participants also need to identify and list the process controls and possible non value adding steps.
- **Step 3b: ANALYSIS (cause and effect analysis)**
This section is designed to perform a cause and effect analysis. The participants brain storm on each of six broad areas or systems such as machine, methods, measurements, materials, people and environments which are related to the defined problem. The process starts from adding the effect (defined problem) at the front of the fish – bone diagram and create branches of possible causes from the six process areas and systems.
- **Step 3c: ANALYSIS (5 WHYS, Pareto Chart)**
In this section the participants picks the possible causes of the problem. Each of the potential cause is than spread down by asking the question “WHY” up to five successive occasions or up to the point the participants feel the best possible effect / solution is already attained.
- *** This is an optional step**
If found beneficial include a Pareto analysis separately to show the fewest (20%) most significant causes which have been causing the highest (80%) level of effects.
- **Step 4: IMPROVE (Evaluate solutions)**
As the solutions are identified in the analysis step 3c, each of the solution is placed within a matrix which is best suited based on their weights measured with the degree of benefit and degree of difficulty during the implementation stage. The solutions are grouped into four possible placements within the matrix which are:
 - i. **Stars (High benefit, Low difficulty)**
These solutions should be implemented with reasonable efforts which can contribute highly to stop recurrence of the incident.
 - ii. **Quick Wins (Low benefit, Low difficulty)**
These solutions should be implemented readily which may contribute to stop recurring incident.
 - iii. **Extra Effort needed (High benefit, High difficulty)**
These solutions are relatively hard and lengthy to implement. However, once implemented, these can effectively prevent such incidents.
 - iv. **Forget It (Low benefit, High difficulty)**
These solutions are perceivably the least effective but harder to implement. These possible solutions can be discarded.
- **Step 5: IMPROVE / CONTROL (Implement solutions)**

DMAIC - Root Cause Investigation Template

Investigation Ref #:		Lot No./s:		Date:		Place:	
Item Code:		Process/Area Name:		Participants (SMEs):			

Step 1: DEFINE (PROBLEM DEFINITION)

Use the following questions to define the problem, its history and to outline any work that has been done.

What is the problem / incident? <i>[Write what actually happened]</i>	
When did it happen? <i>[Date and time]</i>	
Where did it happen? <i>[Where exactly on the process / machine, STEP - be specific]</i>	
Who was working when the incident discovered? <i>[Enter roles who found the incident]</i>	
What was done immediately to fix the problem? <i>[Include briefly the actions taken and by whom?]</i>	
How long did it take to fix the problem? <i>[Include lost time]</i>	
Has this happened before? <i>[Enter date, time, deviation ref.]</i>	
What actions were taken before? <i>[If known issue]</i>	

Step 3a: ANALYSIS (PROCESS ANALYSIS)

Think about the process according to the questions below.

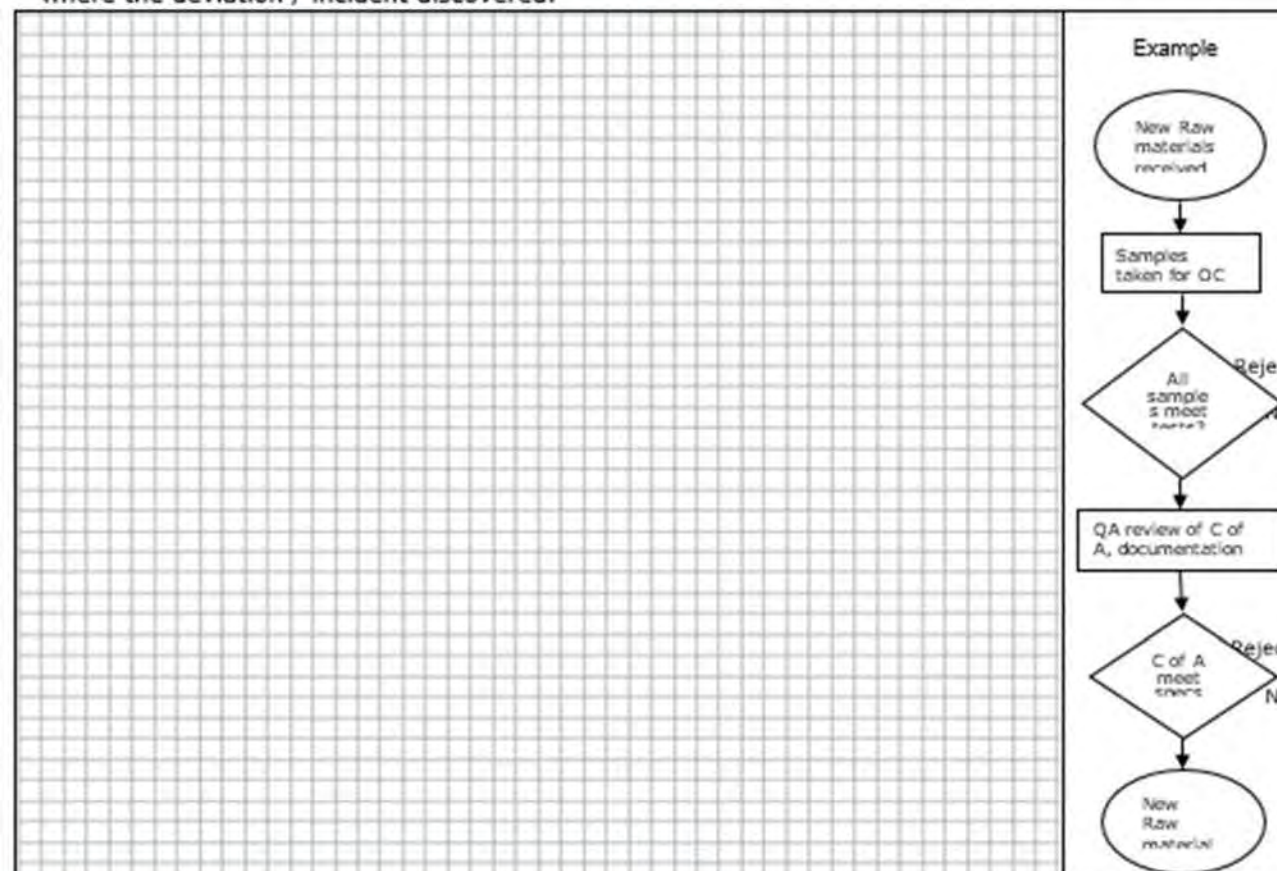
Significant changes to the process <i>[Have any change been made recently?]</i>	
List all process controls <i>[Are those effective in place?]</i>	

Prepared By:

Prepared by:	
Authorised by (Dept Manager)	

Step 1: DEFINE / MEASURE

Use the below space to draw a brief process map to UNDERSTAND activities. Mark possible areas where the deviation / incident discovered.



Step 3b: ANALYSIS (CAUSE & EFFECT)

Put the problem statement in the fish 'Head' and brainstorm possible causes.

