

## **Step 3:**

# **ISO9001:2015 -Risk Based Planning FMEA and Failure Modes**

# Introduction

Having identified your process inputs risks and your outputs impacts.

It this step we will define the concept of cause and effect and a methodology to prioritise what are the key process risk enablers and the actions required to remove, reduce or control them, by using a basic Failure Modes and Effects Analysis (FMEA) tool

By the end of this workshop session you will be able to complete the following:

1. Define what is an FMEA.
2. Define when to use an FMEA
3. Types of FMEA
4. The application of a FMEA.

# Process FMEA Basics Definition and Purpose



## FMEA

A systematic method and a documented process to:  
Recognize, evaluate, and prioritize potential failures and their effects. Identify the actions which could eliminate or reduce the chance of potential failure occurring



## Failure Mode

The way in which the systems, process, component, subassembly or product could fail to perform its intended function.

Failure modes may be the result of upstream operations or may cause downstream operations to fail.

# Definition and Purpose (cont.)

## Why use an Process FMEA?

- Identify potential failure modes and rate the severity of their effects
- Rank order of potential deficiencies
- Focus on prevention – Stop the risk before it stops you.



### Failure Effects

The outcome of the occurrence of the failure mode on the system, product, or process. The “IMPACT” on the customer.

# FMEA Example

<div style="border: 1px solid black; padding: 5px; display: inline-block;"> <b>Process/Product Failure Modes and Effects Analysis (FMEA)</b> </div>															
Process or Product Name: Statapult Firing Process					Prepared by: Sir George			Page <u>1</u> of <u>1</u>							
Responsible: King William					FMEA Date (Orig) <u>Jan 5, 1280</u> (Rev) <u>A</u>										
Process Step/Item Function	Potential Failure Mode	Potential Failure Effects	S F V	Potential Causes	O C C	Current Controls	D E T	R P N	Actions Recommended	Resp.	Actions Taken	P S E V	P O C C	P D E T	P R P N
What is the process step/item function under investigation?	In what way could the process step/function potentially fail to meet process requirements or intent?	What is the impact on the Key Output Variables (Customer Requirements) or internal requirements?	How Severe is the effect to the customer?	What are the causes of this Failure Mode? Typical failure cause result from process inputs.	How often does cause or FM occur?	What are the existing controls and procedures (inspection and test) that prevent the cause or the Failure Mode? <b>Should include an SOP number.</b>	How well can you detect cause or FM?		What are the actions for reducing the occurrence of the Cause, or improving detection? <b>Should have actions only on high RPN's or easy fixes.</b>	Whose Responsible for the recommended action?	What are the completed actions taken with the recalculated RPN? <b>Be sure to include completion month/year</b>				

Identify output failures and impacts

Assess inputs

Prioritize

Determine actions and impact

# When to Use an FMEA

- Early in the process improvement investigation, after a process map has been developed.
- When new systems, processes and products are being designed.
- When existing designs or processes are being changed.
- When carry-over designs are used in new applications.
- After system, product, or process inputs and outputs functions have been defined, but before specific hardware is selected or released to manufacturing (ideally).

# Types of FMEA's

- **Strategic** - used to develop contingency plans for new business or operating strategies. Focuses on risk elements including: markets; competition; technology; Health, Safety and Environmental
- **System** - used to analyze systems and sub-systems in the early concept and design stages. Focuses on potential failure modes associated with the functions of a system caused by the design.
- **Design** - used to analyze product designs before they are released to production. Focuses on product function.
- **Process** - used to analyze our operations. Focuses on process steps and inputs.
- **Defects** - used to error proof processes. Focuses on process steps and errors.

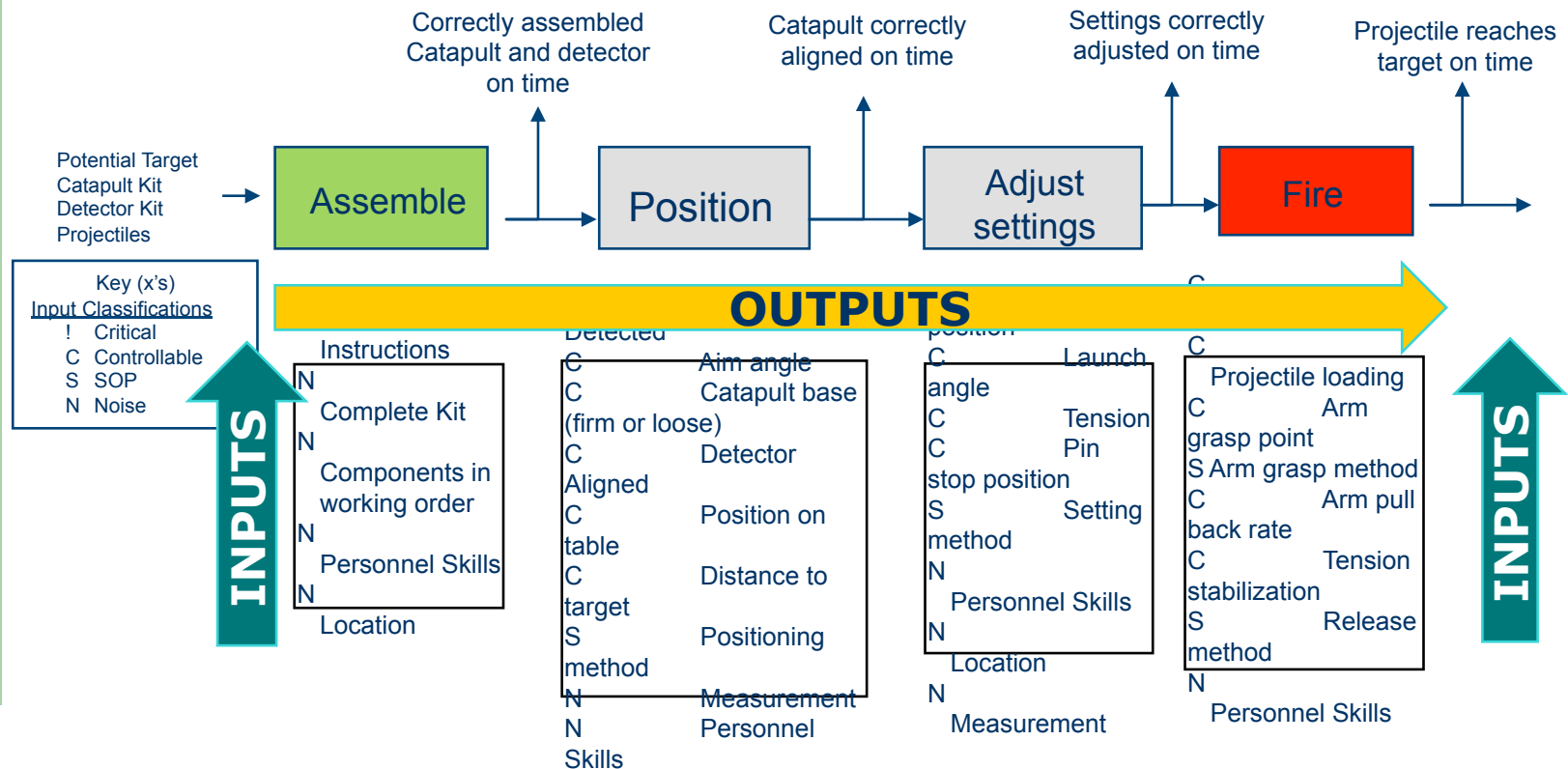
# FMEA Examples

- **Design:** A designer needs to design a brake pad for a new caliper assembly. How do we identify the effect the new brake pad will have on the caliper assembly?
- **New Manufacturing:** A new lifting machine with improved capability is going to be added to the final assembly. What effect will this have?
- **Process** A customer has added a requirement for particulate air test to be carried out. How do we plan to measure and control it?
- **Logistics:** A logistics manager needs to determine how a new kanban process will impact the movement of parts to line side storage and buffer stock. How would he know what factors to identify that would impact customer deliveries?
- **Administrative:** A HR manager needs to determine how a change from a weekly payment to monthly payment will have an impact on contract staff. How would he know what factors to identify?



# The Misfired Catapult

When a catapult misfired and struck the right tower of the castle. The king demanded an investigation as to the cause. To help determine the root cause a process FMEA was used. A process map was first produced listing the outputs and the different inputs types. See below.











# Step 4

Step 4 is where we start to list the causes of the failure modes and what controls are in place and we start the risk scoring process.

List the Causes of Each Failure Mode.

List Existing Controls

Establish a Risk Score Rating Scale for Probability of Causes

Establish a Risk Score Rating Scale for Severity

Establish a Risk Rating Scale for Effectiveness of Control