

Step 4:

ISO9001:2015 -Risk Based Planning

**Cont. Methodology used to
Prioritise and Control Risk**

Introduction

In this forth workshop module we will continue defining and applying the methodology used to prioritise and control risk

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

Define the causes against each failure mode.

List the existing controls

Establish a risk rating scale against severity

Establish a risk rating scale against occurrence

Establish a risk rating scale against detection

Calculate and prioritise the RPN

Step J - Example Rating Scales

Below are examples of a Severity, Occurrence and Control Risk Rating Scales. It is critical that a common language and the rating scale is tailored to the project and is understood before attempting to assign ratings.

| Rating | Effect (Severity of Consequences to Process or Customer) | Cause (Occurrence) | Control (Difficulty of Detection or Likelihood of "Escape") |
|--------|------------------------------------------------------------------------|-------------------------------------------|----------------------------------------------------------------|
| 10 | Serious Risk – Occurs without Warning | Very high Failure is almost inevitable | More than 40% No control in place |
| 9 | Serious Risk Occurs with Warning | | More than 35% No control in place |
| 8 | Major Disruption; Scrap Customer Highly Dissatisfied | High Repeated failures | More than 30% Check for expected results |
| 7 | Major Disruption; Some Scrap Customer Dissatisfied | | More than 25% Check for expected results |
| 6 | Minor Disruption; Rework Customer Inconvenienced | Moderate: Moderate Occasional failures | More than 20% Detect failure mode |
| 5 | Minor Disruption; Some Rework Customer Slightly Inconvenienced | | More than 15% Detect failure mode |
| 4 | Minor Disruption; Minimal Rework All Customers Notice Defect | | More than 10% Detect direct cause |
| 3 | Minor Disruption; Rework by Operator; Average Customer Notices | Low: Low: Relatively few failures | More than 5% Prevent direct cause |
| 2 | Very Minor Disruption; Minor Rework Discriminating Customer Notices | | More than 1% Detect root cause |
| 1 | Virtually No Effect | Remote: Failure is unlikely | Less than 1% Prevent root cause |

Step K - Calculate and Prioritise the RPN

We will now establish a risk priority (or potential) number (RPN); this is a measure of the risk.

The RPN is the product of the Severity, Occurrence and Detection.

You may choose to rank the RPNs on a Pareto chart. This will provide a priority of the failure mode.

Even if the RPN is low, action must be taken if the severity is high.

CALCULATE RISK



| Process Step/Item Function | Potential Failure Mode | Potential Failure Effects | SEVERITY | Potential Causes | OCCURRENCE | Current Controls | DETECTION | RPN | Actions Recommended | Resp. | Actions Taken | PSEV | POCC | PDET | PRPN |
|-------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|-------------------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|-----------------------------------------------------------------------------------------------------------------|------|------|------|------|
| 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? Should include an SOP number. | How well can you detect cause or FM? | | What are the actions for reducing the occurrence of the Cause, or improving detection? Should have actions only on high RPN's or easy fixes. | Whose Responsible for the recommended action? | What are the completed actions taken with the recalculated RPN? Be sure to include completion month/year | | | | |
| Fire | Projectile Short of Target | Enemy not Destroyed | 7 | Wrong Projectile Type | 1 | None | 10 | 70 | | | | | | | |

Step L - Develop Actions, Assign Responsible and Take Actions

When the RPNs have been calculated and failure modes ranked in order. Corrective actions must be initiated for the highest priorities.

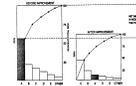
The objective of the corrective actions is to reduce any one or all of the Severity, Occurrence and Detection Ratings. This can be done by change of design, FTA's to better understand causes, improved control plans, improved processes, etc. The Ratings can be reduced by:

| Process Step/Item Function | Potential Failure Mode | Potential Failure Effects | SEV | Potential Causes | OCC | Current Controls | DET | RPN | Actions Recommended | Resp. | Actions Taken | PSEV | POCC | PDET | PRPN |
|-------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|-------------------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|-----------------------------------------------------------------------------------------------------------------|------|------|------|------|
| 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? Should include an SOP number. | How well can you detect cause or FM? | | What are the actions for reducing the occurrence of the Cause, or improving detection? Should have actions only on high RPN's or easy fixes. | Whose Responsible for the recommended action? | What are the completed actions taken with the recalculated RPN? Be sure to include completion month/year | | | | |
| Fire | Projectile Short of Target | Enemy not Destroyed | 7 | Wrong Projectile Loading | 7 | Assembly Check List | 6 | 294 | Develop Instructions Revise Check List Operator Training/Test | Sir George | Practiced from Jan 10 to Jan 15, 1280 | | | | |
| | | Enemy not Destroyed | 7 | Wrong Arm Grasp Point | 6 | Inspector | 4 | 168 | Add Grasp to Statapult Operator Training/Test | Sir George | Trained Jan 9, 1280 | | | | |

Step M

Assign the Appropriate Severity, Occurrence, and Detection Levels and Compare RPNs and PRPN's

When the recommended action has been identified, predict and record the subsequent severity, occurrence, and detection ratings are re-calculated



| Process Step/Item Function | Potential Failure Mode | Potential Failure Effects | SEV | Potential Causes | OCC | Current Controls | DET | RPN | Actions Recommended | Resp. | Actions Taken | PSEV | POCC | PDET | PRPN |
|-------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|-------------------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|-----------------------------------------------------------------------------------------------------------------|------|------|------|------|
| 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? Should include an SOP number. | How well can you detect cause or FM? | | What are the actions for reducing the occurrence of the Cause, or improving detection? Should have actions only on high RPN's or easy fixes. | Whose Responsible for the recommended action? | What are the completed actions taken with the recalculated RPN? Be sure to include completion month/year | | | | |
| Fire | Projectile Short of Target | Enemy not Destroyed | 7 | Wrong Projectile Loading | 7 | Assembly Check List | 6 | 294 | Develop Instructions Revise Check List Operator Training/Test | Sir George | Practiced from Jan 10 to Jan 15, 1280 | 7 | 3 | 4 | 84 |
| | | Enemy not Destroyed | 7 | Wrong Arm Grasp Point | 6 | Inspector | 4 | 168 | Add Grasp to Statapult Operator Training/Test | Sir George | Trained Jan 9, 1280 | 7 | 2 | 4 | 56 |

Catapult FMEA

When the failure mode causes has been identified and their RPN calculated; move on to the next failure mode and repeat the process until all process steps have been completed.

Process or Product Name: Statapult Firing Process
 Responsible: King William

Prepared by: Sir George Page 1 of 1
 FMEA Date (Orig) Jan 5, 1280 (Rev) A

| Process Step/Item Function | Potential Failure Mode | Potential Failure Effects | SEV | Potential Causes | OCC | Current Controls | DET | RPN | Actions Recommended | Resp. | Actions Taken | PSEV | POCC | PDET | PRPN |
|--------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|-------------------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|-----------------------------------------------------------------------------------------------------------------|------|------|------|------|
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| Fire | Projectile Short of Target | Enemy not Destroyed | 7 | Wrong Projectile Type | 1 | None | 10 | 70 | | | | | | | |
| | | Enemy not Destroyed | 7 | Wrong Projectile Loading | 7 | Assembly Check List | 6 | 294 | Develop Instructions Revise Check List Operator Training/Test | Sir George | Practiced from Jan 10 to Jan 15, 1280 | 7 | 3 | 4 | 84 |
| | | Enemy not Destroyed | 7 | Wrong Arm Grasp Point | 6 | Inspector | 4 | 168 | Add Grasp to Statapult Operator Training/Test | Sir George | Trained Jan 9, 1280 | 7 | 2 | 4 | 56 |
| | | Enemy not Destroyed | 7 | Wrong Arm Pull Back Rate | 2 | Grasp "Feel" | 5 | 70 | | | | | | | |

Step 5

In Step 5 we will define the following:

1. What is a Preventive Control
2. What is a Detection Control
3. When and Where to Apply them