

FMEA to Identify Potential Failure Modes



Major Steps in FMEA Process

Failure Modes and Effects Analysis (FMEA) is a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change. It includes 10 crucial steps that everyone should be familiar with before beginning the process.



FMEA is used during design to prevent failures. Later it's used for control, before and during ongoing operation of the process. Ideally, FMEA begins during the earliest conceptual stages of design and continues throughout the life of the product or service.



Failure modes and effects analysis documents current knowledge and actions about the risks of failures, for use in continuous improvement. It is **used during design to prevent failures**



When to Use FMEA



At the time of designing or redesigning of a process, product, or service, after quality function deployment (QFD)



In case of restructuring of a process



Prior to developing control plans for a new or modified process



When improvement goals are planned for an existing process, product, or service



When there is major failure detected in the existing process, product, or service



Periodically throughout the life of the process, product, or service



It is crucial for the entire team to understand the key elements and techniques of the FMEA for an effective analysis. Therefore it's important to guide the team on method, it's description, reason to choose them.



Method

Description

Reason to Choose

Comment

Cause-Consequence Analysis

An analytical technique used in risk management for a better understanding of failures by assessing the probability of failures of systems with a focus on their causes

- Analyse both causes and the consequences
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Event Tree Analysis

A forward, top-down, logical modeling technique for both success and failure that explores responses through a single initiating event and lays a path for assessing probabilities of the outcomes and overall system analysis

- Analyse all the events in the process
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Failure Modes & Effects Analysis (FMEA)

A process of reviewing as many components, assemblies, and subsystems as possible to identify potential failure modes in a system and their causes and effects

- Analyse all the processes
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Hazard & Operability Analysis (HAZOP)

A structured and systematic examination of a complex planned or existing process or operation in order to identify and evaluate problems that may represent risks to personnel or equipment

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Preliminary Hazard Analysis (PHA)

A process to identify and categorize hazards or potential hazards associated with the operation of a proposed system, process, or procedure

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A preliminary risk analysis (PRA) is a high-level exercise conducted at the initiation of a new system or project. A preliminary risk analysis, while being a relatively quick-and-painless process, should still consider all variables that can affect a situation – all technical, operational, administrative, physical and personnel variables that may exist. With these variables, you can then brainstorm possible threats.

Preliminary Risk Assessment for New Trail Bike Design

1 Lower Risk

2 Moderate Risk

3 Higher Risk

System Hierarchy

Safety Concerns	New Technology	Degree of Change	Field Concerns	Regulation Concerns	Supplier Concern	Prioritization Metric
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Frame Subsystem	2	2	3	1	1	1	12
Front Wheel Subsystem	1	1	1	1	1	1	1
Rear Wheel Subsystem	1	1	1	1	1	1	1
Sprocket Subsystem	1	1	1	1	1	2	2
Chain Subsystem	2	1	1	1	1	2	4
Seat Subsystem	2	1	1	1	1	1	2
Handle Bar Subsystem	1	1	1	1	1	1	1
Hand Brake Subsystem	2	1	1	3	1	2	12
Suspension Subsystem	2	2	2	1	1	1	8



In many cases, specific changes to a design or manufacturing process are being considered



The changes includes changes in design, material, manufacturer, supplier, supplier design or process, usage environment, interfaces, specifications, performance requirements, or any other changes



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FMEA - Risk Assessment Scoring Matrix



A risk assessment matrix, also known as a Probability and Severity risk matrix, is a visual tool that depicts the potential risks affecting a business. The risk matrix is based on two intersecting factors: the likelihood that the risk event will occur, and the potential impact that the risk event will have on the business. In other words, it's a tool that helps you visualize the probability vs. the severity of a potential risk.

Certain	10	20	30	40	50	60	70	80	90	100
Almost Certain	9	18	27	36	45	54	63	72	81	90
Very Likely	8	16	24	32	40	48	56	64	72	80
Probable	7	14	21	28	35	42	49	56	63	70
Likely	6	12	18	24	30	36	42	48	54	60
Likely	5	10	15	20	25	30	35	40	45	50
May Happen	4	8	12	16	20	24	28	32	36	40
Improbable	3	6	9	12	15	18	21	24	27	30
Unlikely	2	4	6	8	10	12	14	16	18	20
Very Unlikely	1	2	3	4	5	6	7	8	9	10
	Insignificant Injury	Minor Injury	Minor Injury	Illness-Injury	Illness-Injury	Major Injury	Major Injury	Single Fatality	Fatality	Multiple Fatalities
Key Significant		0 to 3		May be ignored, no further action required			SEVERITY			
Very Low		4 to 12								
Low		13 to 25		Ensure safe working						
Moderate		26 to 42		Refer to risk assessment, safe working procedures						
High		43 to 67		Monitor control measures						
Very High		68 to 100		Avoid if possible, full method statement if not						

- The company need to be more focused on the risks with the score of over 68. These should be mitigated on the priority basis
- For the high risks (score between 43 and 67), the company needs to set proper control measures to avoid these risks
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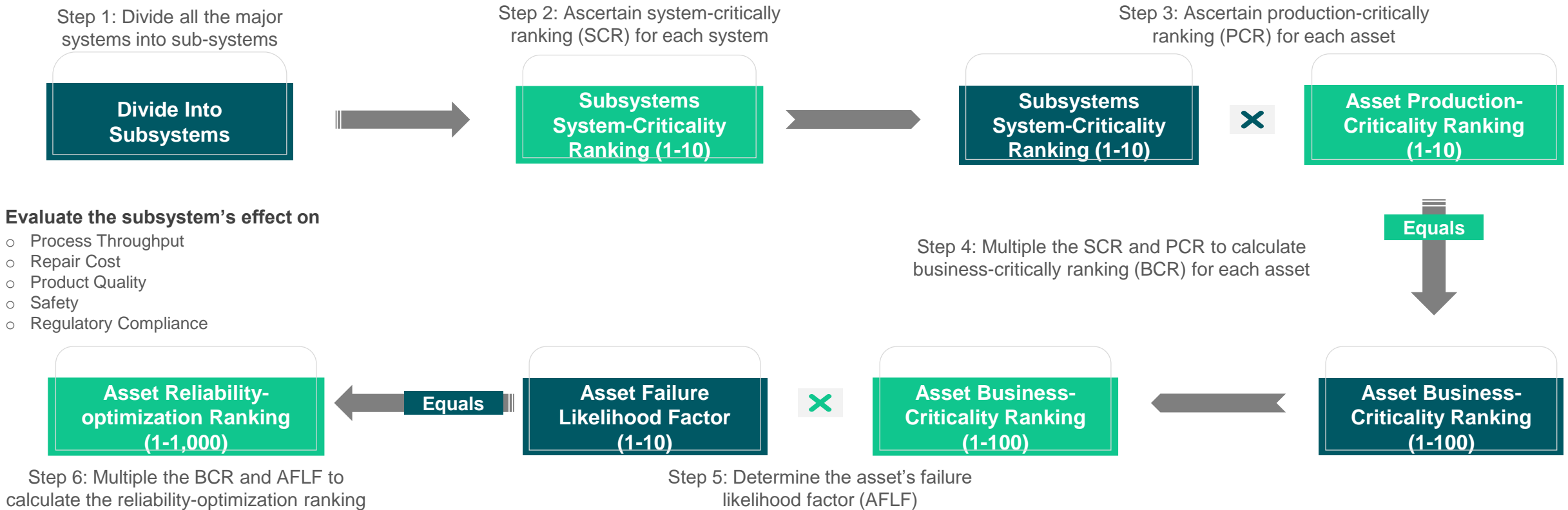
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Action Plan – Prioritize Plant Assets



An Action Plan is a list of tasks that you need to do to complete a simple project or objective. To draw one up, simply list the tasks that you need to complete to deliver your project or objective, in the order that you need to complete them.

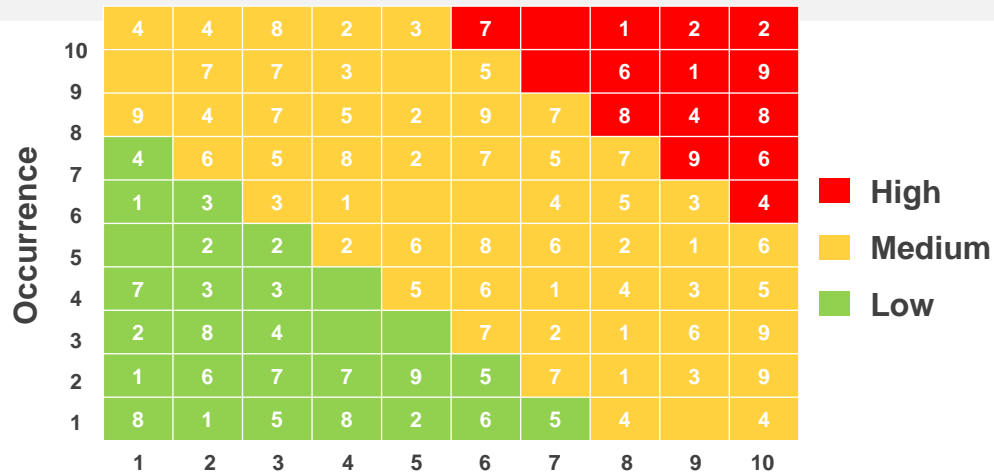


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The FMEA Dashboard provides an at-a-glance overview of your FMEA information. Combining all the data you need for quick assessment, the Dashboard offers the ability to monitor and manage your Failure Mode and Effects Analyses with efficiency and effectiveness.

DFMEA Risk Matrix
for Sample Data



Overdue Recommended Action for DFMEA
for Sample Data

RECOMMENDED ACTION

- Terminate the mission and trigger failsafe lanch
- Support redundant data storage and fault tole
- Support emergency landing functionality
- Evaluate the battery suppliers and select the
- Support emergency landing functionality

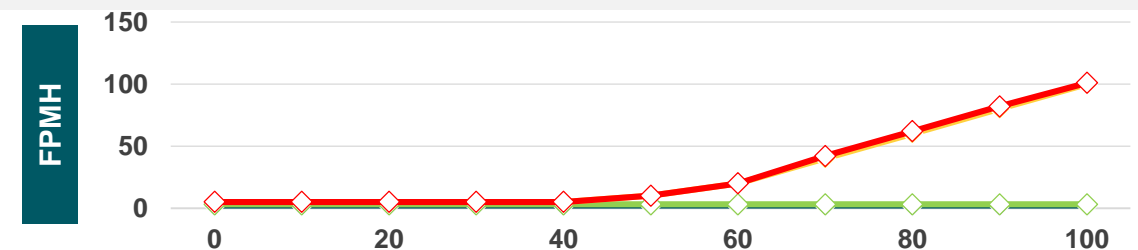
Recommended Action Complete
for DFMEA
for Sample Data



Workflow Responsibility for Problems
for Sample Data

PROBLEM ID	STATUS
Problem0001	There is a significant number of product return of the new drone model due to ph
Problem0002	Multiple instances of electrical short circuits and damage to drone and property
Problem0003	The number of customer complaints about the uncontrolled drone has increased
Problem0004	The return home and emergency failsafe landing features are not working in servers

Failure Rate VS Temperature for Sample Data



1. Is FMEA a Six Sigma tool?

Yes, FMEA is definitely a Six Sigma tool. In fact, it's one of the most commonly used tools in Six Sigma (this itself means defects are to be kept at less than 3.4 per million iterations of the process or event).

FMEA is particularly important in Six Sigma because one of the main goals of Six Sigma is to reduce process variability. By identifying potential failure points and then taking steps to address them, organizations can significantly reduce process variability and improve overall quality.

2. What are the steps to FMEA Analysis?

The first step in conducting an FMEA is to identify the potential failure modes for a process or product. A failure mode is defined as a way in which a process or product can fail to meet its intended purpose.

Once the potential failure modes have been identified, the next step is to assess the potential effects of each failure mode. The impact of a failure mode is typically classified as either major, minor, or no impact.

After the potential failure modes and their effects have been identified, the next step is to identify the causes of each failure mode. The causes of failure can be classified as either internal or external. (Contd.)



Internal causes are typically things that are within the control of the organization, such as design flaws, process deficiencies, or material defects. External causes are typically outside the organization's control, such as environmental factors or customer demands. Once this is done, we come to the corrective actions that need to be taken. There are designed to eliminate or reduce the chances of a failure mode occurring.

After the corrective actions have been identified, the final step is to implement the corrective actions and to monitor the process or product to ensure that the corrective actions are effective.

When conducting an FMEA, it is important to use a systematic and logical approach. The steps outlined above are a general guide that can be followed when conducting an FMEA.

3. What are the types of FMEA?

There are two main types of FMEA: Design FMEA and Process FMEA. Design FMEA is used to identify potential problems with a new product or system before it is manufactured or used. Process FMEA is used to identify potential problems with an existing manufacturing or assembly process.



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