Failure Mode Effects and Analysis (FMEA)

Problem How to anticipate and mitigate potential problems?

Difficulty

Some training required

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 where the process must be changed

FMEAs should be created whenever a failure can result in harm.

FMEA types include:

- Design (<u>DFMEA</u>) focuses on components and subsystems
- Process (PFMEA) focuses on manufacturing and assembly processes



Process

- Determine FMEA type: Defect (FMEA), Design (<u>D</u>FMEA), or Process (<u>P</u>FMEA) and obtain appropriate standardized tables
- 2. Identify potential failure modes.
- 3. For each failure mode, using standardized tables, assess the following on a 1-10 scale:
 - Severity rating (how bad it is, if it occurs)
 - Occurrence rating (how often it will occur)
 - Detectability rating (how likely it is to be detected, if it occurs)
- 4. For each failure mode, multiply the above three numbers (each is between 1 to 10) to obtain a **Risk Priority Number** (RPN)
- 5. For the failure modes with the **highest RPN** values, determine mitigation strategies



FMEA – Example – Giving a presentation



Automobile Industry Action Group (AIAG) created the following standards for the North American auto industry

Severity

EFFECT Hazardous - without warning	CRITERIA: SEVERITY OF EFFECT May endanger machine or assembly operator. Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation. Failure will occur without warning.		RANKING 10	Likelihood / Occurrence				
Hazardous - with warning	May endanger machine or assembly operato potential failure mode affects safe vehicle op with government regulation. Failure will occu	r. Very high severity ranking when a	9	Possible				
Very High	Major disruption to production line. 100% of provident of the second s	Probability of Failure		Failure Rates	Ppk	Ranking		
High	Minor disruption to production line. Product n (less than 100%) scrapped. Vehicle operable performance. Customer dissatisfied.	Very High: Failure almost inevitable		<u> </u>	<u><0.33</u> ≥0.33	10 9	Detectabilit	t y
Moderate	Minor disruption to production line. A portion have to be scrapped (no sorting). Vehicle/iter Comfort/Convenience item(s) inoperable. Cu	High: Generally associated with pro cesses similar to previous processe that have often failed		Criteria: Likelihood the Existence of a Defect will be Detected by Process Controls Before Next or Subsequent Process, or Before Part or				
Moderate: Generally associa processes similar to previous			ated with s pro-	Detection As Almost N	Component Leaves the Manufacturing or <u>etection</u> Assembly Location Almost No known control available to detect			Rankino 10

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FMEA – Notes

Slide 1

Slide 2

- 1. For a given process, FMEA uses a weighted decision matrix to identify the highest risk issues.
- The risks and there can be hundreds are prioritized so that only the most important ones need to be addressed.
- 3. Three values are determined that characterize each risk; they are multiplied together to obtain the RPN. The RPN values are then ordered, largest to smallest.
- 4. After risks are identified and prioritized, they can be managed. See the 6in6 presentation on "Risk Analysis & Management."

- 1. This example is for someone giving a presentation. The FMEA analysis is addressing "What can go wrong?"
- 2. It is critical to recognize that Severity and Occurrence have a reversed sense from Detection. A large Detectability is good (so the value is 1, say) while a large Severity of Occurrence is bad (so the value is 9, say).
- 3. Different industry groups have determined appropriate {S, O, D} value for their industry.
- 4. For the AIAG (Automobile Industry Action Group), the "Occurrence" value is
 - 10 if it happens more than half the time
 - 4 if it occurs 1 time in 2,000 potential occurrences.
- 5. Risks with low RPN values may not need to be mitigated.
- 6. The mitigations identified should be implemented *before* the process is rolled out.

Recommended web sites for additional information

- https://www.6sigma.us/fmea/all-about-failure-mode-and-effectsanalysis/
- https://www.sixsigma-

institute.org/Six_Sigma_DMAIC_Process_Improve_Phase_F ailure_Mode_Effect_Analysis_FMEA.php