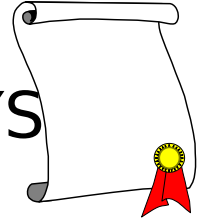




Failure Modes and Effects Analysis

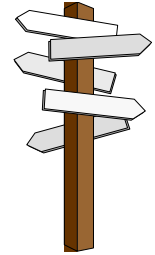
PROCESS FAILURE MODE AND EFFECTS ANALYSIS



PFMEA Defined:

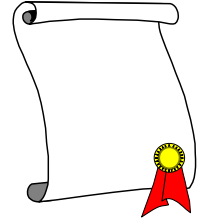
- A detailed document which identifies ways in which a process or product can fail to meet critical customer requirements (KPOVs).
- A living document which lists all possible causes (failed KPIVs) of failure from which a list of items for the control plan can be generated.
- A document which allows the team to track and prioritize the actions required to improve the process.

PFMEA Vocabulary:



- **Failure Mode:**
 - a description of a “non-conformance” at a particular process step.
- **Failure Effect:**
 - the effect a particular failure mode will have on the customer (attempt to quantify with respect to KPOVs).
- **Severity:**
 - an assessment of the seriousness of the failure effect on the customer. The customer can be the end customer and / or the next process operation.
- **Failure Cause:**
 - something which can be corrected or controlled (KPIV) that describes “how the failure mode could have occurred”.
- **Occurrence (of failure cause, scale 1-10):**
 - an assessment of the frequency with which the failure cause occurs. “How often does this KPIV fail in a specific way”.
- **Detection (of failure cause or failure mode, scale 1-10):**
 - an assessment of the likelihood (or probability) that your current controls will detect 1) when the KPIV fails or 2) when the failure mode occurs.
- **Risk Priority Number:**
 - = Severity X Occurrence X Detection.
 - used to prioritize recommend actions. Special consideration should be given to high **Severity** ratings even if **Occurrence** and **Detection** are low.

How To Create a Useful PFMEA:



Step 1: List potential failure modes.

Step 2: List potential failure effects.

Step 3: Assign severity of each effect.

Step 4: Classification

Step 5: List potential failure causes.

Step 6: Assign occurrence level to each cause.

Step 7: List current process controls for the prevention / detection of failure modes.

Step 8: Assign detection level to failure modes.

Step 9: Calculate the risk priority number.

Step 10: Recommend Actions.

Step 11: Assign responsibility.

Step 12: Assign actions to be taken.

Step 13: Recalculate Risk Priority Number.



PFMEA: SEVERITY RANKING GUIDELINES

Effect	Criteria: Severity of Effect Defined	Ranking
Hazardous: no warning	May endanger operator or others. Failure mode affects safe operation and / or does not comply with Govt. regulation. Fails with NO warning.	10
Hazardous: with warning	May endanger operator or others. Failure mode affects safe operation and / or does not comply with Govt. regulation. Fails WITH warning.	9
Very High	Major disruption to production line. 100% of product might have to be scrapped. Product inoperable. Customer very dissatisfied.	8
High	Minor disruption to production line. Part of the product may have to be scrapped. Reduced product performance. Customer dissatisfaction.	7
Moderate	Minor disruption to production line. Part of the product might have to be scrapped. Customers have discomfort.	6
Low	Minor disruption to production line. 100% of product may have to be reworked. Some Customer dissatisfaction.	5
Very Low	Minor disruption to production line. Part of the product may have to be reworked. Fit / finish does not conform. Most Customers notice.	4
Minor	Minor disruption to production line. Part of the product may have to be reworked on-line, but out-of-station. Average Customers notice.	3
Very Minor	Minor disruption to production line. Part of the product may have to be reworked on-line, but out-of-station. Discriminating Customers notice.	2
None	No Effect .	1

PFMEA: OCCURENCE RANKING GUIDELINES

Probability of Failure	Possible Failure Rates	Cpk	Ranking
Very High: Failure is almost inevitable	> 1 in 2	< 0.33	10
	1 in 3	> 0.33	9
High: Generally associated with processes similar to previous processes that often failed.	1 in 8	> 0.51	8
	1 in 20	> 0.67	7
Moderate: Generally associated with processes similar to previous processes which have experienced occasional failure but not in major proportions.	1 in 80	> 0.83	6
	1 in 400	> 1.00	5
	1 in 2,000	> 1.17	4
Low: Isolated failures associated with similar processes.	1 in 15,000	> 1.33	3
Very Low: Only Isolated failure associated with almost identical processes.	1 in 150,000	> 1.5	2
Remote: Failure is unlikely. No failures ever associated with almost identical processes.	< 1 in 1,500,000	> 1.67	1



PFMEA: DETECTION RANKING GUIDELINES

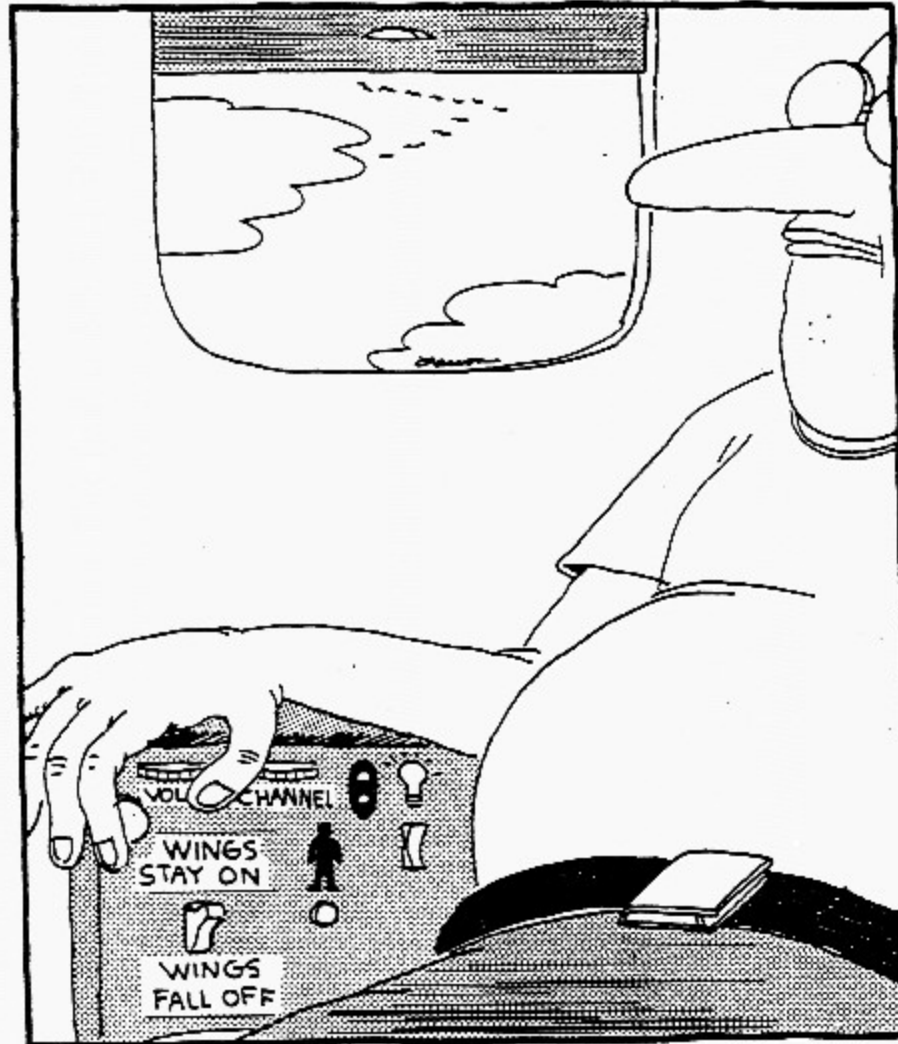
Detection	Criteria: Likelihood the existence of a def will be detected by test content before pro advance next or subsequent process	Ranking
Almost Impossible	Test content detects < 80% of failures	10
Very Remote	Test content must detect 80% of failures	9
Remote	Test content must detect 82.5% of failures	8
Very Low	Test content must detect 85% of failures	7
Low	Test content must detect 87.5% of failures	6
Moderate	Test content must detect 90% of failures	5
Moderately High	Test content must detect 92.5% of failures	4
High	Test content must detect 95% of failures	3
Very High	Test content must detect 97.5% of failures	2
Almost Certain	Test content must detect 99.5% of failures	1



PFMEA: EXAMPLE

#	Process Function (Step)	Potential Failure Modes	Potential Failure Effects	SEV	Potential Causes of Failure (KPIVs)	OC C	Current Process Controls	DET	RPN	
1	Load Brckt1 into Fixture A	Parts do not fit	Delay in Process	2	Incoming part dim Out of print	3	Receiving Inspection	6	36	
2		Part is loaded incorrectly	Final Assembly W / L out of print	8	Operator Error	5	100% final Dim Gauge / 100% Visual Inspect.	4	160	#2
3	Fixture A: Start Cycle	Machine will not cycle	Delay in Process	2	Power off, Sensor out	2	1 / month P M	7	28	
4	Fixture A: Clamps	Machine will not clamp	Delay in Process	2	Low Air Pressure Sensor out	2	1 / month P M	7	28	
5			Delay in Process	2	Part loaded wrong	2	Sensor installed	2	8	
6	Fixture A: Welds	Machine will not weld	Delay in Process	2	Not enough voltage supplied	1	Voltage regulator visual alarm	2	4	
7		Welds appear small or light	Airbag housing will not sustain deployment	10	Weld schedule out of adjustme	5	100% visual inspection 2/ destructive tests	4	200	#1
8	Fixture A: unclamps	Machine will not unclamp	Delay in Process	2	Pressure release valve broken	2	1/ month P M	7	28	
9	Remove and Transport SubA	Dropped / Damaged SubA	Final Assembly W/L out of print	8	Operator Error	2	100% Final Dir Visual inspectio	4	64	#3

WHY FMEA?





FMEA Exercise

- ➔ One Team Perform an FMEA on a Typical Production Process.
- ➔ One Team Perform an FMEA on a Typical Administrative Process.