Developing an Efficient Process FMEA

Planning For FMEA

**Gather:**
- Design Input Special Characteristics
- Surrogate Process Flow
- Team:
  - Process Owner
  - Design Representative
  - PVT-Problem Data Person
  - Supplier
  - Process Contraries

**Medium:**
- New Technology
- Past Concerns
- Design Characteristics Affected

**High:**
- Safety to Operator
- Safety in Use
- Regulatory Requirement

**Link Design Characteristics to Process Steps**

**Review Update/Process Flow**

**Determine Which Steps require analysis**
High / Med / Low

**Enter all Process Steps and a description into far left Column**

**Note the low risk items and give reason why no analysis was necessary**

**Enter all Failure Modes one after another**

**Enter Effects of Failure and Select Severity**

**Types of Failures:**
- Characteristics from Matrix (if applicable)
- Full Failure
- Partial
- Intermittent
- Unintended

**List up to 5 in the same box (grouped) per each failure mode**
- Place severity # beside each effect in parenthesis ex: (4)
- Place largest severity of the group into severity column

**Refer to Severity Chart for Scale**
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IF

B

Severity is 9 or 10?

Yes

No

Take Action to Reduce Severity / Occurrence

Review Severity, start at highest and go to lowest

Determine: What are the causes for the Failure Mode?

Enter the Causes Into FMEA Form

Fault Tree Analysis

Root Causes For 9/10 SEV

Types of Causes:
- Man
- Method
- Material
- Environment
- Machine
- Noises

Note: Typically there are numerous Causes, be sure to allow for space if Completing FMEA on paper.

IF

Failure Mode be eliminated?

Yes

No

Add to Action Column
- Responsible Person
- Date of Completion

IF

Failure Mode be eliminated?

Yes

No

Add to Action Column
- Responsible Person
- Date of Completion

Consider Process Controls

Detection/Prevention
- D - Visual Inspection
- P - Mistake Proofing
- P - Proximity Switch
- P - Lock outs
- P - Line Interlock
- D - D & R chart

List Process Controls:
- Multiple Controls are likely
- Determine Detection value for each item record it in parenthesis ex: (5)
- Move the smallest item into Detec. column

IF

SEV is 5 - 8 & OCC > 4 ?

Yes

No

IF

SEV is 9/10 & OCC > 1, DET > 1 ?

Yes

No

Determine Action to Reduce Occur. or Improve Controls

Calculate RPN
Risk Priority Number
SEV x OCC x DET
Pareto RPN

Top 20% of Failure Modes by RPN

Warning!
Do not select arbitrary RPN to be below Based on 80/20 Rule

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