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

- Process Flow Diagram

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

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

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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Severity is 9 or 10?
- Yes
  - Review Severity, start at highest and go to lowest
  - Fault Tree Analysis
  - Enter the Causes Into FMEA Form
  - Root Causes
    - For 9/10 SEV
  - Types of Causes:
    - Man
    - Material
    - Machine
    - Noises
  - Note: Typically there are numerous Causes, be sure to allow for space if Completing FMEA on paper.
- No
  - Failure Mode be eliminated?
    - Yes
      - SEV is 5 - 8 & OCC > 4?
        - Yes
          - IF
        - No
    - No
      - Review Severity, start at highest and go to lowest

Add to Action Column
- Responsible Person
- Date of Completion

Take Action to Reduce Severity / Occurrence

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

SEV is 9/10 & OCC > 1, DET > 1?
- Yes
  - Determine Action to Reduce Occur. or Improve Controls
- No

SEV is 5 - 8 & OCC > 4?
- Yes
- No

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

Top 20% of Failure Modes by RPN

Failure Modes

Determine: How probable is each cause as it contributes to the failure mode?
- Enter into Occur. Column

Refer to Occurrence Chart for Scale

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