# Failure Modes & Effects Analysis for Processes

Manufacturing Excellence

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# What is a pFMEA?

A systematic approach for identifying, quantifying and ranking the risk of failure modes and prioritize efforts to mitigate risk.

- Identifies potential failure modes and severity
- Facilitates process improvement
- Identifies & eliminates concerns early in process development
- Stimulates the interchange of ideas between people
- Documents the actions taken to reduce risk
- Improves “bottom line”
- Improves process reliability

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# pFMEA Conceptualized

What can go wrong with a process?

Where is the biggest risk?


What actions will we take to reduce the risk?

pFMEA's help us focus on the cause of the problems

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# pFMEA Conceptualized

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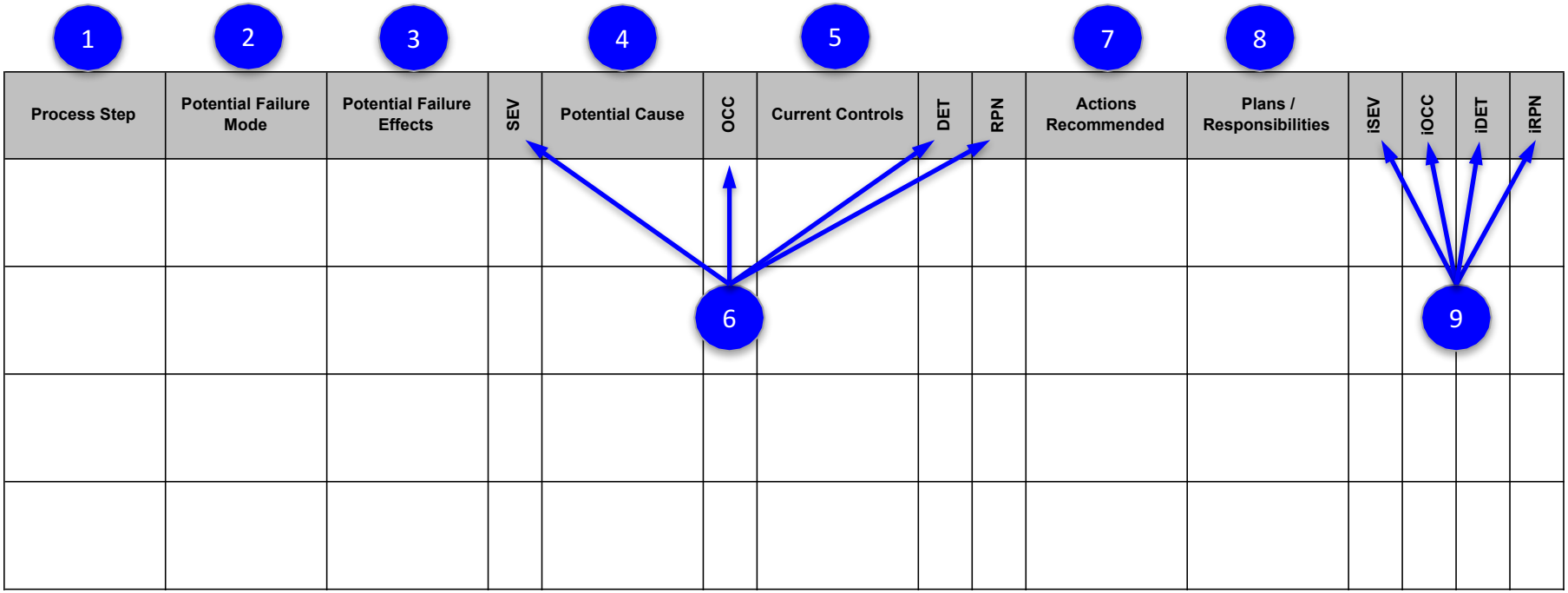
# pFMEA Steps




1. List the Process Steps
2. Identify Potential Failure Modes
3. Describe the Effects of Failures
4. Determine Causes
5. Describe Controls
6. Rate Severity, Occurrence, Detectability and Calculate RPN
7. Recommend Actions
8. Define the Plan and Responsibility for Action
9. Assess Actions

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# Preparation for a pFMEA

- Complete a PMAP that includes:
  - Process Steps
  - Process Outputs
  - Process Inputs
- Compile a team with knowledgeable representation from:
  - Manufacturing Engineering
  - Quality Engineering
  - Project Engineering
  - Manufacturing
- Schedule meetings
  - Avoid scheduling any meetings for longer than 3-hours

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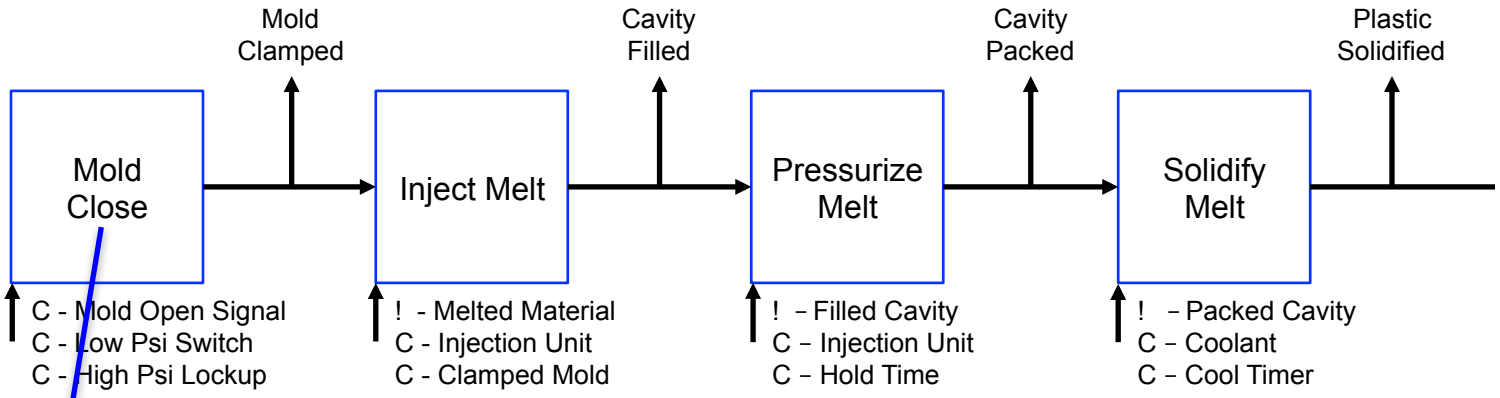
# Step 1: List the Process Step




| Process Step (1) | Potential Failure Mode (2) | Potential Failure Effects (3) | (6) SEV | Potential Cause (4) | (6) OCC | Current Controls (5) | (6) DET | (6) RPN |
|---|---|---|---|---|---|---|---|---|
| Mold Close | | | | | | | | |

List the process steps from your PMAP in the pFMEA

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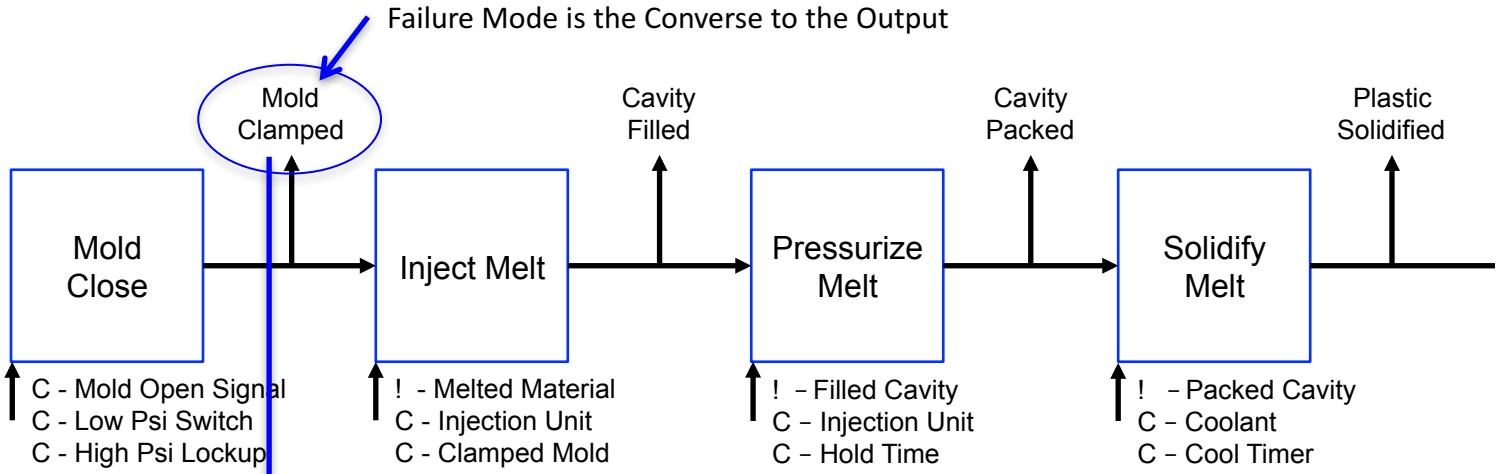
# Step 2: Identify Potential Failure Modes




| Process Step (1) | Potential Failure Mode (2) | Potential Failure Effects (3) | (6) SEV | Potential Cause (4) | (6) OCC | Current Controls (5) | (6) DET | (6) RPN |
|---|---|---|---|---|---|---|---|---|
| Mold Close | Mold Didn't Clamp | | | | | | | |

How the process could fail to conform to process requirements as described by the needs, wants, and expectations of internal & external customers. It is typically the converse to what you want to happen at a process step.

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# Step 3: Describe the Effects of the Failure

An adverse consequence that the customer might experience. The customer could be the next operation, subsequent operations, or the end user

| Process Step (1) | Potential Failure Mode (2) | Potential Failure Effects (3) | (6) SEV | Potential Cause (4) | (6) OCC | Current Controls (5) | (6) DET | (6) RPN |
|---|---|---|---|---|---|---|---|---|
| Mold Close | Mold Didn't Clamp | Cannot Inject Material | | | | | | |

There can be multiple effects for each Failure Mode!

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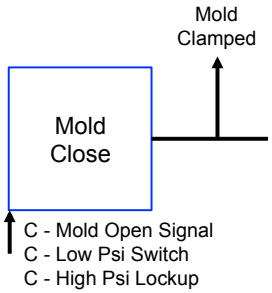
# Step 4: Determine the Cause(s)




| Process Step (1) | Potential Failure Mode (2) | Potential Failure Effects (3) | (6) SEV | Potential Cause (4) | (6) OCC | Current Controls (5) | (6) DET | (6) RPN |
|---|---|---|---|---|---|---|---|---|
| Mold Close | Mold Didn't Clamp | Cannot Inject Material | | Mold Open Signal Not Made | | | | |
| | | | | High PSI Switch not made | | | | |
| | | | | Obstruction in between mold surfaces | | | | |

The means by which a particular element of the process results in a Failure Mode, Root Causes are inputs (x's) to the process

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# Step 5: Describe the Controls

| Process Step (1) | Potential Failure Mode (2) | Potential Failure Effects (3) | (6) SEV | Potential Cause (4) | (6) OCC | Current Controls (5) | (6) DET | (6) RPN |
|---|---|---|---|---|---|---|---|---|
| Mold Close | Mold Didn't Clamp | Cannot Inject Material | | Mold Open Signal Not Made | | Documented process settings | | |
| | | | | High PSI Switch not made | | Mold Protection Set-up Training | | |
| | | | | Obstruction in between mold surfaces | | None | | |

What you are currently doing to:

- Prevent the cause from occurring
- Reduce the rate of occurrence for the cause
- Detect the cause before it results in the failure mode
- Detect the failure mode before customer experiences the effect

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# Step 6: Create Severity, Occurrence and Detection Tables

| Severity Criteria | | |
|---|---|---|
| **Rank** | **Process** | **Product** |
| **5** | Product reg requirement | Loss of Function, could harm surgeon or patient and necessitate revision surgery |
| **4** | Product scrapped | Loss of function, could harm (minor) surgeon or patient |
| **3** | Product requires rework on-line | Loss of Primary Function |
| **2** | Product requires rework off-line | Degraded function / Loss of Secondary Function |
| **1** | No Effect (MRB) | No Effect (MRB) |

| Detection | |
|---|---|
| **Rank** | **Description** |
| **5** | Remote - Measurements can only be performed after assembly |
| **4** | Low - Measurement can be performed after subsequent process steps |
| **3** | Moderate - Measurements cannot be performed in-process but can be measured prior to next manufacturing step |
| **2** | High - Measurements can be performed in-process |
| **1** | Certain - Can detect failure by functional Check ??? Error-proofed process |

| Occurrence Criteria | | |
|---|---|---|
| **Rank** | **Probability of Failure** | **Description** |
| **5** | **Extremely High** | **greater than 1 in 10** |
| **4** | **High** | **greater than 1 in 100** |
| **3** | **Occasional** | **greater than 1 in 10,000** |
| **2** | **Remote** | **greater than 1 in 100,000** |
| **1** | **Improbable** | **Effective Preventative Control in place** |

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# Step 7: Rate Severity, Occurrence, Detection and RPN

| Process Step (1) | Potential Failure Mode (2) | Potential Failure Effects (3) | (6) SEV | Potential Cause (4) | (6) OCC | Current Controls (5) | (6) DET | (6) RPN |
|---|---|---|---|---|---|---|---|---|
| Mold Close | Mold Didn't Cl | ect | 3 | Mold Open Signal Not Made | 1 | Documented process settings | 2 | 6 |
| | | | | vitch not e | | | | 36 |
| | | | 3 | on in between mold surfaces | | | | 30 |

Severity is an assessment of how serious the effect is on the process or product

Occurrence is an estimate of the likelihood that a specific cause will occur and result in the failure mode

Detection is an assessment of the ability of the current control to either detect the failure mode, detect the cause, and/or prevent the cause from occurring

Note: *Potential Causes* that share the same *Potential Failure Effect* share the same *Severity*

Risk Priority Number (RPN) = Sev x Occ x Det

- This number is used to place priorities
- Items with low RPN numbers still require attention if the severity ranking is high

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# Step 8: Recommend Actions

Once RPN's are calculated:

✓ Identify high RPN items

✓ Recommend action

| High Severity Rating Generally requires a design change (Difficult to Change) | High Occurrence Rating leads to the prevention of the failure mode or the cause of the failure mode | High Detection Rating leads to design controls to detect the cause and prevent the failure from occurring (easiest to change) |
|---|---|---|

Focus on Defect Prevention

Tip: Pareto items by RPN to position all high RPN's together

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# Step 9: Recommend and Determine the Plan and Assign Responsibility

| Process Step (1) | Potential Failure Mode (2) | Potential Failure Effects (3) | (6) SEV | Potential Cause (4) | (6) OCC | Current Controls (5) | (6) DET | (6) RPN | Actions Recommended (7) | Plans / Responsibilities (8) | (9) iSEV | (9) iOCC | (9) iDET | (9) iRPN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mold Close | Mold Didn't Clamp | Cannot Inject Material | 3 | Mold Open Signal Not Made | 1 | Documented process settings | 2 | 6 | | | | | | |
| | | | 3 | High PSI Switch not made | 3 | Mold Protection Set-up Training | 4 | 36 | Perform quarterly skills assessment | CI Specialist to develop and implement skills assessment by 20May2017 | 3 | 1 | 4 | 12 |
| | | | 3 | Obstruction in between mold surfaces | 5 | None | 2 | 30 | | | | | | |

- Actions must have dates and who is responsible
- After actions are recommended, re-rate & re-calculate RPN's
- Once actions are implemented, update pFMEA with 'new' actuals to see the actual impact on the actions

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# Questions?

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