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| --- |
| **Failure Mode Effects Analysis (FMEA)** |
| Process:  |    | Responsibility:  |    | FMEA number:  |    |
|   Core Team:  |    | Prepared by:  |    | Page | Page **1** of **3** |   |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Function | Potential Failure Mode | Potential Effect(s) of Failure | S  | Potential Cause / Mechanism of Failure | O | Current Process Controls | D | Risk Priority Number | Recommended Action(s)Assigned CAPA numbers | Responsibility & Target Completion Date | Action Results |
|
| Mitigation Actions Taken | S | O  | D  | Risk Priority Number  |
|    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |

**Document approval**

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| --- | --- | --- | --- |
| **Risk Assessment Team** | **Name** | **Date** | **Signature** |
| **Designation** |  |  |  |
| **Designation** |  |  |  |
| **Designation** |  |  |  |

FMEAs include but are not limited to the following identifying information (other functions specific to the assessment may be added where needed):

1. Fill in the identifying information on the top of your FMEA.
2. Identify function: Describes the function of the system being assessed.
3. Potential Failure mode: For each function, identify all the ways it could fail.
4. Potential effects of Failure: For each Failure mode, identify all the consequences on the system, related systems, process, related processes, product, service, customer, or regulations.
5. Determine how serious each effect is. Give Severity rating:

|  |  |
| --- | --- |
| **Severity = The severity of the effects of the failure** | **S rank** |
| **Critical** - Potential of resulting in death or serious injury requiring professional medical intervention | **3** |
| **Major** - Potential of resulting in injury not requiring professional medical intervention  | **2** |
| **Minor** - Inconvenience or temporary discomfort  | **1** |

1. For each failure mode, determine all the potential root causes.
2. For each cause, determine the occurrence rating:

|  |  |
| --- | --- |
| **Occurrence = The likelihood and frequency that the failure will occur**  | **O Rank** |
| **Certain** - 1 failure per day / hour  | **3** |
| **Moderate** – 1 failure per month / week  | **2** |
| **Remote** – 1 failure per year  | **1** |

1. For each cause, identify current process controls.
2. For each control, determine detection rating:

|  |  |
| --- | --- |
| **Detection = The chance that the failure will be detected (e.g. controls in place)**  | **D Rank** |
| **Slight** – Will rarely detect  | **3** |
| **Adequate** - Will usually detect  | **2** |
| **Excellent** - Will always detect  | **1** |

1. Calculate the Risk Priority Number:

$$RPN=S×O×D$$

|  |  |
| --- | --- |
| RPN | Interpretation |
| 1-7 | Risk is acceptable. No actions required. |
| 8-27 | Risk isn’t acceptable. Mitigation actions are required to reduce risk level. |

1. Identify recommended actions
2. Recommended controls or testing; action items to mitigate risk
3. Perform Severity, Occurrence, Detection, and Risk Priority Number again after implementation of the actions taken.