ChecklistGuro

FMEA (Failure Mode And Effects Analysis) Checklist

Show only Checklist

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Default

Process Definition & Scope

Ensures the process being analyzed is clearly defined and the scope is appropriate for the analysis. This includes understanding inputs, outputs, and key process steps.

Process Name

Write something...

Brief Process Description

Write something...

Process Boundaries (Start & End Points)

Write something...

Process ID / Part Number (if applicable)

Enter a number...

List of Key Inputs to the Process

Write something...

List of Key Outputs from the Process

Write something...

Stage of Process (e.g., Design, Setup, Operation, Inspection)

- [ ] Design
- [ ] Setup
- [ ] Operation
- [ ] Inspection
- [ ] Maintenance

Departments/Teams Involved

- [ ] Engineering
- [ ] Manufacturing
- [ ] Quality
- [ ] Maintenance
- [ ] Supply Chain

Process Flow Diagram & Step Identification

Confirms a clear and accurate process flow diagram exists and each process step is distinctly identified and numbered for consistent referencing.

Process Flow Diagram (PDF, PNG, JPEG)

Upload File

Brief Description of the Process

Write something...

Total Number of Process Steps Identified

Enter a number...

Step 1: Process Step Description

Write something...

Step 1: Process Step Number

Write something...

Step 2: Process Step Description

Write something...

Step 2: Process Step Number

Write something...

Notes on Step Definition and Boundaries

Write something...

Process Flow Diagram Accuracy Assessment (Initial Review)

- [ ] Accurate and Complete
- [ ] Requires Minor Adjustments
- [ ] Requires Significant Revision

Potential Failure Modes

Focuses on identifying all possible ways a process step could fail, considering different conditions and error sources.

Failure Mode 1: Describe the specific way the process step could fail.

Write something...

Failure Mode 2: Describe the specific way the process step could fail.

Write something...

Failure Mode 3: Describe the specific way the process step could fail.

Write something...

Failure Mode 4: Describe the specific way the process step could fail.

Write something...

Failure Mode 5: Describe the specific way the process step could fail.

Write something...

Failure Mode 10: Describe the specific way the process step could fail.

Write something...

Potential Effects of Failure

Evaluates the impact of each failure mode – what consequences arise for the product, process, or customer.

Immediate Impact on Product Quality

Write something...

Impact on Subsequent Processes

Write something...

Impact on Customer Satisfaction

Write something...

Impact on Safety (Operator or Environment)

Write something...

Impact on Regulatory Compliance

Write something...

Potential for Product Recall or Warranty Claims

Write something...

Impact on Production Schedule or Throughput

Write something...

Potential Causes of Failure

Identifies the root causes that could lead to each failure mode. This includes materials, equipment, methods, environment, and manpower.

Material Supplier Quality Issues

Write something...

Equipment Maintenance Deficiencies

- [ ] Lack of Preventative Maintenance
- [ ] Incorrect Lubrication
- [ ] Calibration Errors
- [ ] Worn Components

Process Parameter Drift (e.g., Temperature)

Enter a number...

Operator Training Gaps

Write something...

Design Error (if applicable)

- [ ] No Error
- [ ] Material Specification Error
- [ ] Dimensional Error
- [ ] Process Instruction Error

Environmental Factors (e.g., Humidity, Vibration)

Write something...

Cycle Time Variation

Enter a number...

Tooling Wear/Damage

- [ ] No Wear/Damage
- [ ] Minor Wear
- [ ] Significant Wear
- [ ] Damage

Severity Rating (S)

Assesses the seriousness of the effect of failure. Uses a pre-defined scale to quantify the impact.

Define Severity Scale

Write something...

Severity Rating (S) - Product Impact

- [ ] 1 - No Effect
- [ ] 2 - Minor Defect (Cosmetic)
- [ ] 3 - Moderate Defect (Functional, Repairable)
- [ ] 4 - Major Defect (Non-Functional, Significant Repair Required)
- [ ] 5 - Catastrophic Failure (Unsafe, Total Loss)

Justification for Selected Severity Rating

Write something...

Severity Rating (S) - Customer Impact

- [ ] 1 - No Impact
- [ ] 2 - Minor Inconvenience
- [ ] 3 - Moderate Dissatisfaction
- [ ] 4 - Significant Dissatisfaction/Complaint
- [ ] 5 - Safety Risk/Legal Action

Numerical Severity Value (for Calculation)

Enter a number...

Documentation of Assessment

Write something...

Occurrence Rating (O)

Estimates the likelihood of the failure mode occurring. Uses a pre-defined scale based on historical data or experience.

Define Occurrence Rating Scale

- [ ] 1: Remote
- [ ] 2: Occasional
- [ ] 3: Low
- [ ] 4: Moderate
- [ ] 5: High
- [ ] 6: Very High

Occurrence Rating

Enter a number...

Justification for Occurrence Rating

Write something...

Contributing Factors to Occurrence

- [ ] Operator Error
- [ ] Equipment Malfunction
- [ ] Material Variation
- [ ] Process Parameter Drift
- [ ] Environmental Conditions
- [ ] Maintenance Issues
- [ ] Design Flaw

Data/Source Used for Rating

Write something...

Historical Occurrence Data (if available)

Write something...

Rating Confidence Level

- [ ] High
- [ ] Moderate
- [ ] Low

Detection Rating (D)

Evaluates the ability to detect the failure mode *before* it impacts the customer. Assesses existing controls and inspection methods.

Existing Control/Inspection Method?

- [ ] Yes, Formal Inspection
- [ ] Yes, Informal Observation
- [ ] Yes, Automated System
- [ ] No, None Currently Exists

Detection Rating (D) - Scale 1-10 (10=Perfect Detection)

Enter a number...

Justification for Detection Rating (D)

Write something...

Type of Control/Inspection

- [ ] Visual Inspection
- [ ] Measurement
- [ ] Testing
- [ ] Statistical Process Control (SPC)
- [ ] Other

Describe the Current Detection Method in Detail

Write something...

Effectiveness of Current Detection Method?

- [ ] Highly Effective
- [ ] Moderately Effective
- [ ] Minimally Effective
- [ ] Not Effective

Potential Improvements to Current Detection Method

Write something...

Risk Priority Number (RPN) Calculation

Calculates the RPN (Severity x Occurrence x Detection) for each failure mode. This prioritizes areas for improvement.

Severity Rating (S)

Enter a number...

Occurrence Rating (O)

Enter a number...

Detection Rating (D)

Enter a number...

RPN (S x O x D)

Enter a number...

RPN Justification/Notes

Write something...

Is RPN > Threshold?

- [ ] Yes
- [ ] No

Threshold Value (If Applicable)

Write something...

Recommended Actions

Defines specific actions to eliminate or mitigate the failure modes with high RPN values. Includes assigned responsibility and deadlines.

Detailed Description of Recommended Action

Write something...

Estimated Cost of Action (USD)

Enter a number...

Action Priority (High, Medium, Low)

- [ ] High
- [ ] Medium
- [ ] Low

Target Implementation Date

Enter date...

Responsible Department

- [ ] Engineering
- [ ] Manufacturing
- [ ] Quality
- [ ] Maintenance
- [ ] Procurement

Responsible Person/Team

Write something...

Supporting Documentation (e.g., Drawings, Specifications)

Upload File

Action Type (Select all that apply)

- [ ] Process Change
- [ ] Equipment Modification
- [ ] Training
- [ ] Design Change
- [ ] Supplier Change

Justification for Selected Action

Write something...

Action Implementation & Verification

Confirms that recommended actions have been implemented and their effectiveness in reducing risk has been verified.

Planned Completion Date for Action

Enter date...

Estimated Cost of Action Implementation (USD)

Enter a number...

Detailed Description of Action Implementation

Write something...

Person Responsible for Action Implementation

- [ ] John Doe
- [ ] Jane Smith
- [ ] David Lee

Supporting Documentation (e.g., SOP changes, training records)

Upload File

Date of Verification/Validation

Enter date...

Description of Verification Method (how was the action verified)

Write something...

Verification Result (Pass/Fail)

- [ ] Pass
- [ ] Fail

Comments/Notes on Verification Results

Write something...

Re-Evaluation & RPN Update

Updates the RPN after implementing corrective actions to demonstrate risk reduction and ongoing process improvement.

Date of Re-evaluation

Enter date...

Summary of Changes Made (Brief Description)

Write something...

New Severity Rating (S) for each failure mode

Enter a number...

New Occurrence Rating (O) for each failure mode

Enter a number...

New Detection Rating (D) for each failure mode

Enter a number...

New RPN Calculated (S x O x D)

Enter a number...

Did the action effectively reduce the risk?

- [ ] Yes
- [ ] No
- [ ] Partially

Explanation/Justification for any rating changes.

Write something...

Supporting Documentation (e.g., test results, inspection reports)

Upload File

Next Review Date

Write something...

Documentation & Review

Ensures the FMEA document is complete, accurate, and readily available for review and updates. Includes revision history.

FMEA Document Revision History

Write something...

Date of Last FMEA Review

Enter date...

FMEA Document Version Number

Enter a number...

Review Status

- [ ] Not Reviewed
- [ ] Review Complete
- [ ] Revision Required

Summary of Review Findings/Comments

Write something...

Supporting Documentation (e.g., revised process maps)

Upload File

Reviewer Signature

Reviewer Name (Printed)

Write something...