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FMEA



An FMEA (Failure Mode and Effect Analysis) is a systematic method of identifying and preventing product and process problems before they occur. FMEAs are focused on preventing defects, enhancing safety, and increasing customer satisfaction. Ideally, FMEAs are conducted in the product design or process development stages, although conducting an FMEA on existing products and processes can also yield substantial benefits.



The objective of an FMEA is to look for all of the ways a process or product can fail. A product failure occurs when the product does not function as it should or when it malfunctions in some way. Even the simplest products have many opportunities for failure. For example, a drip coffeemaker—a relatively simple household appliance—could have several things fail that would render the coffeemaker inoperable. Here are some possible ways the coffeemaker can fail:

- The heating element does not heat water to sufficient temperature to brew coffee.
- The pump does not pump water into the filter basket.
- The coffeemaker does not turn on automatically by the clock.
- The clock stops working or runs too fast or too slow.
- Calcium deposits from impure water clog up the brewing process.
- There is either not enough or too much coffee used.
- There is a short in the electrical cord.



Evaluating the Risk of Failure

The relative risk of a failure and its effects is determined by three factors:

- **Severity**—The consequence of the failure should it occur.
- **Occurrence**—The probability or frequency of the failure occurring.
- **Detection**—The probability of the failure being detected before the impact of the effect is realized.



Using the data and knowledge of the process or product, each potential failure mode and effect is rated in each of these three factors on a scale ranging from 1 to 10, low to high.

By multiplying the ranking for the three factors (severity \times occurrence \times detection), a risk priority number (RPN) will be determined for each potential failure mode and effect.

The risk priority number (which will range from 1 to 1,000 for each failure mode) is used to rank the need for corrective actions to eliminate or reduce the potential failure modes. Those failure modes with the highest RPNs should be attended to first, although special attention should be given when the severity ranking is high (9 or 10) regardless of the RPN.



It is important that the FMEA team has clearly defined boundaries within which they are free to conduct the FMEA and suggest and implement improvements. For example:

- Is the team responsible only for conducting the analysis, are they to make recommendations for improvements, and/or are they to implement the improvements?
- What is their spending budget?
- What other resources do they have at their disposal?
- Does the team face a deadline or other time constraints?
- What process must they follow if they need to expand beyond the defined boundaries?
- What and how should they communicate the FMEA process and results to others in the organization?



The scope of the FMEA must be well defined. This definition usually comes from the leader of the function responsible for the FMEA. If the FMEA is focused on the design of a product, the head of the design function should clearly define the scope of the project. For a process FMEA, the leader of the manufacturing or manufacturing-engineering function would most likely define the scope.

A specific and clear definition of the process or product to be studied should be written and understood by everyone on the team. Team members should have an opportunity to clarify their understanding of the scope, if necessary, and those clarifications should be documented. This will help prevent the team from focusing on the wrong aspect of the product or process during the FMEA.



FMEA Team Start-Up Worksheet			
FMEA Number:	_____	Date Started:	_____
Team		Date Completed:	_____
Members:	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
Leader:	_____		
Who will take minutes and maintain records? _____			
1. What is the scope of the FMEA? Include a clear definition of the process (PFMEA) or product (DFMEA) to be studied. (Attach the Scope Worksheet.)			



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2. Are all affected areas represented? (circle one)		
YES	NO	Action: _____
3. Are different levels and types of knowledge represented on the team? (circle one)		
YES	NO	Action: _____
4. Are customers or suppliers involved? (circle one)		
YES	NO	Action: _____
Boundaries of Freedom		
5. What aspect of the FMEA is the team responsible for? (circle one)		
FMEA Analysis	Recommendations for Improvement	Implementation of Improvements
6. What is the budget for the FMEA?		
7. Does the project have a deadline?		
8. Do team members have specific time constraints?		
9. What is the procedure if the team needs to expand beyond these boundaries?		
10. How should the FMEA be communicated to others?		



Product/Design

- The objective for a product or design FMEA is to uncover problems with the product that will result in safety hazards, product malfunctions, or a shortened product life. As consumers, we are all too familiar with examples of these types of problems, such as an air bag in a car that may not work properly or a paint job that cracks and dulls within the first three or four years that you own the car.
- Product FMEAs can be conducted at each phase in the design process (preliminary design, prototype, or final design), or they can be used on products that are already in production. The key question asked in design FMEAs is: How can the product fail?



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Design FMEA Scope Worksheet		
Product:	Date:	Scope defined by:
Part 1: Who is the customer?		
Part 2: What are the product features and characteristics?		
Part 3: What are the product benefits?		
Part 4: Study the entire product or only components or subassemblies?		
Part 5: Include consideration of raw material failures?		
Part 6: Include packaging, storage, and transit?		
Part 7: What are the operational process requirements and constraints?		



Process

- Process FMEAs uncover process problems related to the manufacture of the product. For example, a piece of automated assembly equipment may misfeed parts, resulting in products not being assembled correctly. Or, in a chemical manufacturing process, temperature and mixing time could be sources of potential failures, resulting in an unusable product.
- It is helpful when conducting a process FMEA to think in terms of the five elements of a process: people, materials, equipment, methods, and environment. With these five elements in mind, ask: How can process failure affect the product, processing efficiency, or safety?



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Process FMEA Scope Worksheet		
Process:	Date:	Scope defined by:
Part 1: What process components are to be included in the investigation?		
Part 2: Who is the customer?		
Part 3: What process support systems are to be included in the study?		
Part 4: To what extent should input materials be studied?		
Part 5: What are the product material requirements and constraints?		
Part 6: Should packaging, storage and transit be considered part of this study?		



Table 8.1 10 Steps for an FMEA

Step 1	Review the process or product.
Step 2	Brainstorm potential failure modes.
Step 3	List potential effects of each failure mode.
Step 4	Assign a severity ranking for each effect.
Step 5	Assign an occurrence ranking for each failure mode.
Step 6	Assign a detection ranking for each failure mode and/or effect.
Step 7	Calculate the risk priority number for each effect.
Step 8	Prioritize the failure modes for action.
Step 9	Take action to eliminate or reduce the high-risk failure modes.
Step 10	Calculate the resulting RPN as the failure modes are reduced or eliminated.



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Failure Mode and Effects Analysis Worksheet																	
Process or Product: _____										FMEA Number: _____							
FMEA Team: _____										FMEA Date: (Original) _____							
Team Leader: _____										(Revised) _____							
FMEA Process												Action Results					
Line	Component and Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurrence	Current Controls, Prevention	Current Controls, Detection	Detection	RPN	Recommended Action	Responsibility and Target Completion Date	Action Taken	Severity	Occurrence	Detection	RPN
1																	
2																	
3																	
4																	
5																	



Table 8.2a (Generic) Design FMEA Severity Evaluation Criteria

Effect	Criteria: Severity of Effect on Product (Customer Effect)	Rank
Failure to Meet Safety and/or Regulatory Requirements	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulations without warning.	10
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulations with warning.	9
Loss or Degradation of Primary Function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation).	8
	Degradation of primary function (vehicle operable, but at reduced level of performance).	7
Loss or Degradation of Secondary Function	Loss of primary function (vehicle inoperable, but comfort/convenience functions inoperable).	6
	Degradation of primary function (vehicle inoperable, but comfort/convenience functions at reduced level of performance).	5
Annoyance	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by most customers (>75%).	4
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by many customers (50%).	3
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by discriminating customers (<25%).	2
No effect	No discernible effect.	1



Table 8.2b (Generic) Process FMEA Severity Evaluation Criteria

Effect	Criteria: Severity of Effect on Product (Customer Effect)	Rank	Effect	Criteria: Severity of Effect on Process (Manufacturing/Assembly Effect)
Failure to Meet Safety and/or Regulatory Requirements	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulations without warning.	10	Failure to Meet Safety and/or Regulatory Requirements	May endanger operator (machine or assembly) without warning.
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulations with warning.	9		May endanger operator (machine or assembly) with warning.
Loss or Degradation of Primary Function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation).	8	Major Disruption	100% of product may have to be scrapped. Line shutdown or stop ship.
	Degradation of primary function (vehicle operable, but at reduced level of performance).	7	Significant Disruption	A portion of the production run may have to be scrapped. Deviation from primary process including decreased line speed or added manpower.
Loss or Degradation of Secondary Function	Loss of secondary function (vehicle inoperable but comfort/convenience functions inoperable).	6	Moderate Disruption	100% of production run may have to be reworked off line and accepted.
	Degradation of secondary function (vehicle inoperable but comfort/convenience functions at a reduced level of performance).	5		A portion of the production run may have to be reworked off line and accepted.
Annoyance	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by most customers (>75%).	4	Moderate Disruption	100% of production run may have to be reworked in-station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by many customers (50%).	3		A portion of the production run may have to be reworked in-station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by discriminating customers (<25%).	2	Minor Disruption	Slight inconvenience to process, operation, or operator
No effect	No discernible effect.	1	No effect	No discernible effect.



Table 8.3a (Generic) Design FMEA Occurrence Evaluation Criteria

Likelihood of Failure	Criteria: Occurrence of Causes – DFMEA (Design life/reliability of item/vehicle)	Incidents per item/vehicle	Rank
Very High	New technology/new design with no history.	≥ 100 per thousand ≥ 1 in 10	10
High	Failure is inevitable with new design, new application, or change in duty cycle/operating conditions.	50 per thousand 1 in 20	9
	Failure is likely with new design, new application, or change in duty cycle/operating conditions.	20 per thousand 1 in 50	8
	Failure is uncertain with new design, new application, or change in duty cycle/operating conditions.	10 per thousand 1 in 100	7
Moderate	Frequent failures associated with similar designs or in design simulation and testing.	2 per thousand 1 in 500	6
	Occasional failures associated with similar designs or in design simulation and testing.	0.5 per thousand 1 in 2,000	5
	Isolated failures associated with similar designs or in design simulation and testing.	0.1 per thousand 1 in 10,000	4
Low	Only isolated failures associated with almost identical design or in design simulation and testing.	0.01 per thousand 1 in 100,000	3
	No observed failures associated with almost identical design or in design simulation and testing.	≤ 0.001 per thousand 1 in 1,000,000	2
Very Low	Failure is eliminated through preventive control	Failure is eliminated through preventive control.	1



Table 8.3b (Generic) Process FMEA Occurrence Evaluation Criteria

Likelihood of Failure	Criteria: Occurrence of Causes – DFMEA Incidents per item/vehicle	Rank
Very High	≥ 100 per thousand ≥ 1 in 10	10
High	50 per thousand 1 in 20	9
	20 per thousand 1 in 50	8
	10 per thousand 1 in 100	7
Moderate	2 per thousand 1 in 500	6
	0.5 per thousand 1 in 2,000	5
	0.1 per thousand 1 in 10,000	4
Low	0.01 per thousand 1 in 100,000	3
	≤ 0.001 per thousand 1 in 1,000,000	2
Very Low	Failure is eliminated through preventive control	1



Table 8.4a (Generic) Design FMEA Prevention/Detection Evaluation Criteria

Opportunity for Detection	Criteria: Likelihood of Detection by Design Control	Rank	Likelihood of Detection
No detection opportunity	No current design control; Cannot detect or is not analyzed.	10	Almost Impossible
Not likely to detect at any stage	Design analysis/detection controls have a weak detection capability; Virtual Analysis (e.g., CAE, FEA, etc.) is not correlated to expected actual operating conditions.	9	Very Remote
Post Design Freeze and prior to launch	Product verification/validation after design freeze and prior to launch with pass/fail testing (Subsystem or system testing with acceptance criteria such as ride and handling, shipping evaluation, etc.).	8	Remote
	Product verification/validation after design freeze and prior to launch with test to failure testing (Subsystem or system testing until failure occurs, testing of system interactions, etc.).	7	Very Low
	Product verification/validation after design freeze and prior to launch with degradation testing (Subsystem or system testing after durability test, e.g., function check).	6	Low



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Prior to Design Freeze	Product validation (reliability testing, development or validation tests) prior to design freeze using pass/fail testing (e.g., acceptance criteria for performance, function checks, etc.).	5	Moderate
	Product validation (reliability testing, development or validation tests) prior to design freeze using test to failure (e.g., until leaks, yields, cracks, etc.).	4	Moderately High
	Product validation (reliability testing, development or validation tests) prior to design freeze using degradation testing (e.g., data trends, before/after values, etc.).	3	High
Virtual Analysis – Correlated	Design analysis/detection controls have a strong detection capability; Virtual Analysis (e.g., CAE, FEA, etc.) is highly correlated with actual or expected operating conditions prior to design freeze.	2	Very High
Detection not applicable; Failure Prevention	Failure cause or failure mode cannot occur because it is fully prevented through design solutions (e.g., proven design standard, best practice or common material, etc.).	1	Almost Certain



Table 8.4b (Generic) Process FMEA Detection Evaluation Criteria

Opportunity for Detection	Criteria: Likelihood of Detection by Process Control	Rank	Likelihood of Detection
No detection opportunity	No current process control; Cannot detect or is not analyzed.	10	Almost Impossible
Not likely to detect at any stage	Failure Mode and/or Error (Cause) is not easily detected (e.g., random audits).	9	Very Remote
Problem Detection Post Processing	Failure Mode detection post-processing by operator through visual/tactile/audible means.	8	Remote
Problem Detection at Source	Failure Mode detection in-station by operator through visual/tactile/audible means or post-processing through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.).	7	Very Low
Problem Detection Post Processing	Failure Mode detection post-processing by operator through use of variable gauging or in-station by operator through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.).	6	Low
Problem Detection at Source	Failure Mode or Error (Cause) detection in-station by operator through the use of variable gauging or by automated controls in-station that will detect discrepant part and notify operator (light, buzzer, etc.). Gauging performed on setup and first-piece check (for set-up causes only.)	5	Moderate



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Problem Detection Post Processing	Failure Mode detection post-processing by automated controls that will detect discrepant part and lock part to prevent further processing.	4	Moderately High
Problem Detection at Source	Failure Mode detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing.	3	High
Error Detection and/or Problem Prevention	Error (Cause) detection in-station by automated controls that will detect error and prevent discrepant part from being made.	2	Very High
Detection not applicable; Error Prevention	Error (Cause) prevention as a result of fixture design, machine design or part design. Discrepant parts cannot be made because item has been error-proofed by process/product design.	1	Almost Certain



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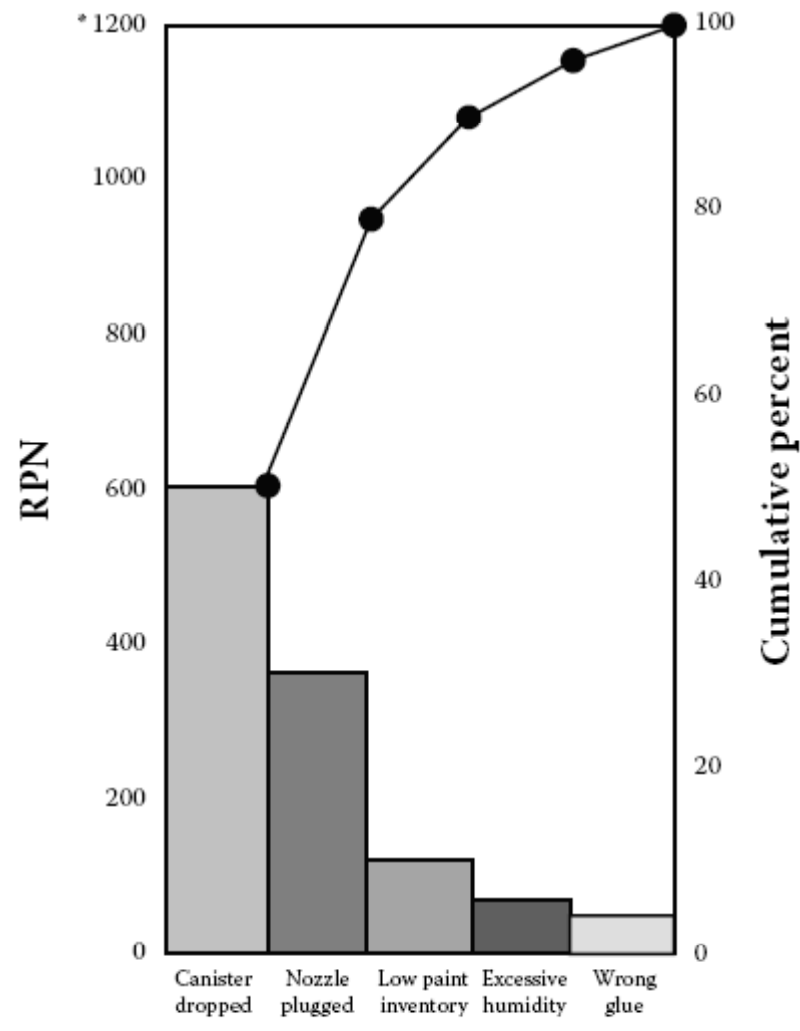


Table 8.5 Specific Actions to Reduce Rankings

<i>Severity</i>	<i>Occurrence</i>	<i>Detection</i>
<ul style="list-style-type: none"> ■ Personal protective equipment (e.g., hard hats or bump caps, side shields on safety glasses, full face protection, cut-proof gloves, long gloves) ■ Safety stops/emergency shut-offs ■ Use different material, such as safety glass that will not cause as severe an injury should it fail. 	<ul style="list-style-type: none"> ■ Increasing the Cpk through design of experiments and/or equipment modifications. ■ Focus on continuous improvement/ problem-solving teams. ■ Engaging mechanism that must be activated for the product or process work (e.g., some lawn mowers have handles that must be squeezed in order for them to operate). 	<ul style="list-style-type: none"> ■ Statistical process control (to monitor the process and identify when the process is going out of control) ■ Ensure the measuring devices are accurate and regularly calibrated. ■ Institute preventive maintenance to detect problems before they occur. ■ Use coding such as colors and shapes to alert the user or worker that something is either right or wrong.



Table 10.1 Other Uses for FMEAs

<i>Function</i>	<i>Examples</i>
Safety	A plastics molder conducted an FMEA on a new piece of molding equipment to ensure that the safety devices on it worked and that emergency stop buttons were properly placed.
Accounting/finance	A finance department performed an FMEA on its annual budget to make sure it was realistic and accounted for potential emergency expenses.
Software design	A firm that develops CAD software used an FMEA to uncover bugs in the system prior to release for beta testing.
Information systems/technology	The information systems department conducted an FMEA to determine the security of sensitive data.
Marketing	During the development of a new corporate brochure, the marketing department incorporated an FMEA into the design process to reduce the potential of offending potential customers and miscommunicating vital information about the company.
Human resources	An HR department led an FMEA that involved senior managers from all departments during an organizational restructuring.
Purchasing	Working with the process-engineering department, a purchasing group used an FMEA to select a new piece of manufacturing equipment.



Table A.7.2 Alternative Process FMEA Worksheet

Process Failure Mode and Effects Analysis Worksheet (Alternative Version: major changes noted.)																	
Process: _____				Model Year/Program: _____				PFMEA Number: _____									
PFMEA Core Team: _____				Process Responsibility: _____				PFMEA Date: (Original) _____									
Team Leader: _____								(Revised) _____									
Page: _____ of _____																	
PFMEA Analysis Results							Action Results										
Process Step (Component) and Function	Requirement	Potential Failure Mode	Potential Effect(s) of Failure	Severity Classification	Potential Cause(s) of Failure	Current Process				Recommended Action	Responsibility and Target Completion Date	Action Taken and Completion Date	Severity	Occurrence	Detection	RPN	
						Current Controls, Prevention	Occurrence	Current Controls, Detection	Detection								

Requirements are the inputs to the process specified to meet the intent of the design and/or customer needs.

The Classification column can be used to highlight high priority failure modes and/or to classify special characteristics.

In this version of the worksheet, the Occurrence Ranking has been moved after the "Prevention Controls" column to recognize that the Occurrence Rankings can be affected by prevention controls.



Table A.7.1 Alternative Design FMEA Worksheet

Design Failure Mode and Effects Analysis Worksheet (Alternative Version: major changes noted.)																	
Product: _____				Model Year/Program: _____				DFMEA Number: _____									
DFMEA Core Team: _____				Design Responsibility: _____				DFMEA Date: (Original) _____									
Team Leader: _____								(Revised) _____									
DFMEA Analysis Results											Action Results						
Item (Component) and Function	Requirement	Potential Failure Mode	Potential Effect(s) of Failure	Severity Classification	Potential Cause(s) of Failure	Current Design				Recommended Action	Responsibility and Target Completion Date	Action Taken and Completion Date	Severity	Occurrence	Detection	RPN	
						Current Design Controls, Prevention	Occurrence	Current Design Controls, Detection	Detection								

An optional column, requirements can be used to augment analysis of a specific failure mode.

The Classification column can be used to highlight high priority failure modes and/or to classify special characteristics.

In this version of the worksheet, the Occurrence Ranking has been moved after the "Prevention Controls" column to recognize that the Occurrence Rankings can be affected by prevention controls.



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Severity: DFMEA Custom Ranking, Customer Satisfaction Examples	
Ranking	Example
10	In-service failure that threatens safety
9	Extensive product recall
8	Unscheduled engine removal
7	Premature (unscheduled) component replacement
6	Oil leak but system still operational
5	Air-conditioning system not operating properly
4	Interior panel rattles
3	Variation in seat colors
2	Door plugs missing
1	Scratch on interior of housing



Severity: DFMEA Custom Ranking, EH&S (Environmental, Health, and Safety) Examples	
Ranking	Example
10	Catastrophic product failure causes loss of life or serious injury.
9	Product creates major hazardous environmental disposal problem.
8	Use of product under normal conditions leads to OSHA recordable injury.
7	Use of product under normal conditions leads to exposure above Permissible Exposure Limits (PEL).
6	Product creates moderate hazardous environmental disposal problem.
5	Manufacture of or use of product leads to temporary noncompliance with ISO 14001 audit.
4	Use of product under normal conditions leads to injury requiring first aid.
3	Use of product leads to spill of nonhazardous material.
2	Use of product leads to poor housekeeping.
1	Manufacture or use does not have a detectable impact on EH&S.



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Severity: DFMEA Custom Ranking, Event-Based Ranking Examples	
Ranking	Example
10	≥ 5 per design
9	≥ 2
8	≥ 1
7	$\geq 1:2$ designs
6	$\geq 1:5$
5	$\geq 1:10$
4	$\geq 1:50$
3	$\geq 1:100$
2	$\geq 1:250$
1	$< 1:250$



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Occurrence: DFMEA Custom Ranking, Piece-Based Examples	
Ranking	Example
10	$Cpk < 0.33$
9	$Cpk \approx 0.33$
8	$Cpk \approx 0.67$
7	$Cpk \approx 0.83$
6	$Cpk \approx 1.00$
5	$Cpk \approx 1.17$
4	$Cpk \approx 1.33$
3	$Cpk \approx 1.67$
2	$Cpk \approx 2.00$
1	$Cpk > 2.00$



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Detection: DFMEA Custom Ranking, Design Rule Examples	
Ranking	Example
10	No design rules used.
9	Design protocols are formalized.
8	Design rules are specified in initial design criteria.
7	Design reviews held to ensure compliance to design rules.
6	Checklist used to ensure design rules are followed.
5	Purchasing systems do not allow selection of nonstandard components.
4	Early supplier involvement so all relevant knowledge about input materials and compliance to design needs are understood.
3	Design software signals compliance issues.
2	Design software ensures compliance to the relevant industry standards.
1	Design software prevents use of nonstandard dimensions, spacing, and tolerances.



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Detection: DFMEA Custom Ranking, DFA/DFM (Design for Assembly/Design for Manufacturability) Examples	
Ranking	Example
10	No consideration given for DFA/DFM.
9	The number of components has been minimized.
8	Only standard components have been used.
7	Ergonomic assembly techniques have been incorporated.
6	Design elements such as pad sizes, wire gauge, and fasteners have been standardized throughout the design.
5	Modular designs used.
4	Easy-fastening devices (snap fits or quick fastening devices such as quarter-turn screw, twist locks, spring clips, latches) used.
3	Self-testing or self-diagnosis has been built-in.
2	Self-aligning surface, grooves, and guides used.
1	Asymmetrical features used to mistake-proof assembly.



Detection: DFMEA Custom Ranking, Simulations & Verification Testing Examples	
Ranking	Example
10	No verification testing used.
9	GO/NOGO tests used to ensure dimensional requirements.
8	Partial functionality of prototype tested before release.
7	Full Alpha tests conducted; no Beta testing.
6	Untested computer model used to simulate product performance.
5	Accelerated life testing of final design before release; lab simulation.
4	Alpha and Beta testing used before release to ensure design meets needs.
3	Product tested for full functionality in customer's application.
2	Finite element analysis to highlight stress concentrations requiring design changes early in the design stages.
1	Computer modeling to ensure form and fit of mating components.

