PURPOSE OF DFMEA (DESIGN FAILURE MODE EFFECTS ANALYSIS)

- Define and guide a logical design process
- Identify, quantify, and reduce design risk
- Provide a traceable document for design and development
- Justify design activities
- Provide a means for continuous product improvement

RESPONSIBILITY AND SCOPE OF THE DFMEA

- The DFMEA is a **team** function
 - All team members must participate
 - Multi-disciplinary expertise and input is beneficial
 - Input from all engineering fields is desirable
 - Representatives from all areas (not just technical disciplines) are generally included as team members
- The DFMEA is **not** a one meeting activity
 - The DFMEA will be refined and evolve with the product
 - Numerous revisions are required to obtain the full benefit of the DFMEA
- The DFMEA should include all systems, sub-systems, and components in the product design

DFMEA INPUTS

- Product Design Requirements
 - Design requirement document (if available from customer)
 - Legal and technical regulations
- Bill of Materials (BOM) and Specific Hardware
 - List of components
 - Components and/or samples as supplied by the customer
- Product Definition
 - Drawings, sketches, animations, and simulations
 - Description of systems and components
 - What are the functions of the components listed on the BOM?
- Previous Experience (Lessons Learned from Others)
 - Experience with similar concepts, designs, and DFMEA
 - Customer and supplier inputs
 - Design guides and design standards (for example ASME codes)

DFMEA OUTPUTS

- RPN: Risk Assessment Number
 - RPN = (Severity) x (Occurrence) x (Detection)
 - Identification of both systems and components with high RPN values represents a summary of high risk items.
 - Ranking of RPN to provide guidance on critical design issues
 - Address the highest RPN items first!
- Identification of Critical and Significant Characteristics
 - This is also normally required by a customer
- The DFMEA is An Output to Your Customer
 - Be aware that your customer may be internal or external
 - Internal customers may include other engineering groups or nontechnical groups such as procurement, manufacturing, safety, etc.

DFMEA METHODOLOGY

- (1.) Complete the top of the form
 - Project, year, team members, date, and DFMEA iteration
- (2.) List items and functions
 - Start with the system, then subsystems, and finally components
- (3.) Document potential failure modes
 - How <u>could</u> the design potentially fail to meet the design intent
 - Note: this might be the cause of failure at a higher level (i.e. component to subsystem) or the effect of a failure at a lower level.
 - Consider all types of failure
- (4.) Document the potential effects of failure
 - How would the design potentially fail to meet the design intent.

- (5.) Rate the severity of the failure effect
 - See attached page for ranking guidelines
 - Severity ranking is linked to the <u>effect</u> of the failure
- (6.) Document potential causes and mechanisms of failure
 - Failure causes and mechanisms are an indication of design weaknesses
 - Potential failure modes are the <u>consequences</u> of the failure causes
 - A single failure mode may have multiple failure mechanisms
 - Use group brainstorming sessions to identify possible failure mechanisms
 - Don't be afraid to identify as many potential causes as you can
 - This section of the DFMEA will help guide you in necessary design changes
 - The output of the DFMEA will indicate on which item to focus design efforts

- (7.) Rate the occurrence
 - See attached page for ranking guidelines
 - Things that may help you rate the occurrence
 - Are any elements of the design related to a previous device or design?
 - How significant are the changes from a previous design?
- (8.) List the design controls
 - Design controls are intended to:
 - Prevent the cause of the failure mode (1st choice solution)
 - Detect the cause of the failure mode (2nd choice solution)
 - Detect the failure mode directly (3rd choice solution)
 - Applicable design controls include
 - Predictive code analysis, simulation, and modeling
 - Tolerance "stack-up" studies
 - Prototype test results (acceptance tests, DOE's, limit tests)
 - Proven designs, parts, and materials

- (9.) List any critical or special characteristics
 - Critical characteristics: Severity > 8 and Occurrence >1
 - Special characteristics: Severity > 6 and Occurrence >2
- (10.) Detection rate
 - See ranking guidelines (consider making your own)
- (11.) Calculate the RPN of each potential failure effect
 - RPN = (Severity) x (Occurrence) x (Detection)
 - What are the highest RPN items?
- (12.) Define recommended actions
 - What tests and/or analysis can be used to better understand the problem to guide necessary design changes?

- (13.) Assign action items
 - Assemble team
 - Partition work among different team members
 - Assign completion dates for action items
 - Agree on next team meeting date
- (14.) Complete "Action Results" Section of DFMEA
 - Note any work not accomplished (<u>justify</u> incomplete work)
 - Change ratings if action results justify adjustment, but the <u>rules</u> are:
 - Severity: May only be reduced through elimination of the failure effect
 - Occurrence: May only be reduced through a design change
 - <u>Detection</u>: My only be reduced through improvement and additions in design control (i.e. a new detection method, better test methodology, better codes)
 - Include test and analysis results with with DFMEA to validate changes!!

• (15.) Repeat: undertake the next revision of the DFMEA

Your DFMEA is an evolving document!

Revise your DFMEA frequently!

Diligence will eliminate design risk!

Include documentation of your results!

SEVERITY CRITERIA

Score	<u>Rank</u>	Comments
1	None	No Effect
2	Very Minor	Fit/Finnish Do Not Conform. Defect Noticed By
	·	Discriminating Customer. Performance Nominal.
3	Minor	Fit/Finnish Do Not Conform. Defect Noticed By Average
		Customer. Performance Nominal.
4	Very Low	Fit/Finnish Do Not Conform. Defect Noticed By Most
	·	Customers. Performance Nominal.
5	Low	Device Operable, But Convenience Options Operate At
		Reduced Performance Levels. Customer Experiences
		Some Dissatisfaction.
6	Moderate	Device Operable, But Convenience Options Inoperable.
		Customer Experiences Some Dissatisfaction.
7	High	Device Operable, But At Reduced Performance Levels.
		Customer Dissatisfied.
8	Very High	Device Inoperable With Loss Of Primary Function
9	Hazardous	A Potential Failure Mode Makes Operation Unsafe To
	(With Warning)	Operator And/Or Involves Non-Compliance With
		Government Regulations With Warning
10	Hazardous	A Potential Failure Mode Makes Operation Unsafe To
	(Without Warning)	Operator And/Or Involves Non-Compliance With
		Government Regulations With Warning

OCCURRENCE CRITERIA

<u>Score</u>	<u>Rank</u>	Comments	Failure Rate
1	Remote	Failure Is Unlikely	<1 in 1,000,000
2	Very Low	Relatively Few Failures	1 in 150,000
3	Low	Not Uncommon	1 in 15,000
4	Moderate	Occasional Failures	1 in 2,000
5	Moderate	Frequent Failures	1 in 500
6	Likely	Frequent Failures	1 in 100
7	High	Failure Is Typical	1 in 25
8	Very High	Repeated Failures	1 in 10
9	Severe	Failure Is Almost Inevitable	1 in 5
10	Extreme	Failure Is Normal	> 1 in 2

DETECTION CRITERIA

Scor	<u>re</u> <u>Rank</u>	Comments		
1	Almost Certain	Design controls will almost certainly detect a potential cause/mechanism and subsequent failure mode.		
2	Very High	Very high chance the design control will detect a potential cause/mechanism and subsequent failure mode.		
3	High	High chance the design controls will detect a potential cause/mechanism and subsequent failure mode.		
4	Moderately High	Moderately high chance the design controls will detect a potential cause/mechanism and subsequent failure mode.		
5	Moderate	Moderate chance the design controls will detect a potential cause/mechanism and subsequent failure mode.		
6	Low	Low chance the design controls will detect a potential cause/mechanism and subsequent failure mode.		
Very Low Very low chance the design controls will detect a potential cause/mechanism and subsequent failure mode.				
8	Remote	Remote chance the design controls will detect a potential cause/mechanism and subsequent failure mode.		
9	Very Remote	Very remote chance the design controls will detect a potential cause/mechanism and subsequent failure mode.		
10 A	Absolute Uncertainty	No Control. Design control will not and/or can not detect a potential cause/mechanism and subsequent failure mode.		

• Links de interes

http://quality-one.com/fmea/

Design R	esponsibility		Sc	utside Suppliers heduled Produc am Members	ctRele					:
Function of part	Potential Failure Mode	Potential Effect of Failure Mode		Potential Cause(s) of Failure Mode	Occ.	Current Design Controls	Det.	RPN	Corrective/ Preventive Actions	Responsibl Party & Dat
What are the part's basic functions?	What can go wrong re: the basic functions?	L a	low bi	?	How often does it napper	12	low go are the metho ait pre- venting detect it?	se ds g or	What are the specific actions that can be done about it?	