FMEA: The Good, The Bad, and The Ugly
April ASQ Spokane Section Meeting

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Instructor Biography

- Cheryl Tulkoff has over 15 years of experience in electronics manufacturing with an emphasis on failure analysis and reliability. She has worked throughout the electronics manufacturing life cycle beginning with semiconductor fabrication processes, into printed circuit board fabrication and assembly, through functional and reliability testing, and culminating in the analysis and evaluation of field returns. She has also managed no clean and RoHS-compliant conversion programs and has developed and managed comprehensive reliability programs.

- Cheryl earned her Bachelor of Mechanical Engineering degree from Georgia Tech. She is a published author, experienced public speaker and trainer and a Senior member of both ASQ and IEEE. She holds leadership positions in the IEEE Central Texas Chapter, IEEE WIE (Women In Engineering), and IEEE ASTR (Accelerated Stress Testing and Reliability) sections. She chaired the annual IEEE ASTR workshop for four years and is also an ASQ Certified Reliability Engineer.

- She has a strong passion for pre-college STEM (Science, Technology, Engineering, and Math) outreach and volunteers with several organizations that specialize in encouraging pre-college students to pursue careers in these fields.
FMEA: Failure Modes and Effects Analysis

1) Introductions & Webinar Instructions
2) “Common Sense” Reliability Engineering
3) Introduction to FMEAs
4) FMEA Process
   - Roles & Responsibilities
5) Common Mistakes & Traps
6) Examples
Introduction

THE MARKETING DEPARTMENT HAS ASKED US TO MAKE OUR PRODUCTS MORE ROBUST.

NONE OF US KNOWS WHAT THAT MEANS.

SO WE CAN EITHER CANCEL THIS MEETING AND GO ASK THEM...

OR WE CAN PRETEND THAT ARGUING WITH EACH OTHER ABOUT THE TRUE MEANING OF "ROBUST" IS JUST AS GOOD.

WHILE THAT OPTION IS STUPID, IT WOULD GIVE US THE ILLUSION OF DOING SOMETHING USEFUL RIGHT NOW.

WOULD IT BE ETHICAL TO IGNORE THE LONG-TERM INTERESTS OF STOCKHOLDERS JUST TO FEEL GOOD ABOUT OURSELVES FOR A FEW MINUTES?

I THINK ROBUST MEANS IT HAS LOTS OF FEATURES.

IT MEANS STURDY!
Common Sense Reliability Engineering

"Unfortunately, reliability engineering has been afflicted with more nonsense than any other branch of engineering." - Pat O'Connor (Author Practical Reliability Engineering).

Reliability engineering as a discipline often fails because:

- Incorrect activities, incorrect people and incorrect timing.
- Performing tasks just to do them but not really fulfill them.
- Reliability activities focused excessively on maintenance or logistics issues instead of product optimization, problem/defect prevention & risk reduction.
- Prediction based on fundamentally flawed methods & assumptions
  - Obscure or Excessive Statistical / Probabilistic Methods.
  - Playing “Number Games” to “Look Good” of “Justify Good Enough”
    - To avoid extra effort, to meet schedule, to meet budget.
Common Sense Reliability Engineering

- **Common sense dictates that:**
  - Reliability should be defined as the absence of failures during the intended usage life of product & services.
  - Reliability Efforts Should Focus On Ensuring The Absence Of Failure.
    - Focus Product Development on FINDING & PREVENTING ALL FAILURES THAT MIGHT AFFECT THE END CUSTOMER
    - Follow by Prevention of defects in production, assembly and fabrication
    - Up front efforts for problem prevention / doing it right the first time
      - Reduces the need / cost of correcting problems found in test or problems reported by customers in the field.

- **Failure prevention can achieved by**
  - Understand why failures happen
  - Analysis to identify risks followed by risk elimination/mitigation
  - Optimizing activities designed to identify and eliminate both design and process deficiencies.
Introduction to FMEA: Failure Modes & Effects Analysis
What FMEA IS NOT...

- FMEA is just one of many tools in your tool box.
  - It is not the only tool or best tool for every problem or every situation.

- It can be used across a wide range of fields and disciplines
  - Not limited to “hardware”
    - Manufacturing
    - Software
    - Business Processes
    - Healthcare
    - Service Industries
    - Regulated industries – automotive, medical devices, NASA..
    - Any place where you need to reduce risk and prevent failure!
What FMEA is....

- FMEA
  - A systematic group of activities designed to:
    - Recognize and evaluate potential failures of systems, products, or processes
    - Identify the effects and outcomes of the failures
    - Identify actions that could eliminate or mitigate the failures
    - Provide a historical written record of the work performed
A study has found that fatal medication errors spiked by 10 percent in July, the month that graduates fresh out of medical school report to residencies, in counties with a high number of teaching hospitals, but stayed the same in areas without teaching hospitals.

Industry watchers contend a manufacturing error was likely the culprit. "It means the assembly was wrong, it means the wrong tools were used, it means they were careless in drilling the holes, and maybe the drill was dull,"

FMEA in the News

Japan’s Fukushima Daiichi nuclear plant

Tear in Boeing Jet

Medication Errors
Japan Quake & Tsunami points out both strengths and limitations of FMEA

- Key issues were detailed and identified
  - The plants were built to withstand an earthquake of 7.0.
  - There was a seawall around the facility in case of a tsunami.
  - In an earthquake, the plants had a **SCRAM procedure**, which executed an emergency shutdown of the nuclear reactors.
  - Electrical pumps were designed to pump cool water to the container to keep the rods submerged (the rods are hotter AFTER the shut down than during regular operation of the plant).
  - There were back-up batteries for running the pumps in an emergency that were designed to last about an hour or so.
  - There were diesel fuel pumps that were available to take over the pumping when the batteries ran out of juice.
  - There are vents built into the system to release steam from the reactors if the pressure inside got too high

- But many were considered low probability and/or excessively expensive to consider or the risk was underestimated
Boeing engineers underestimated the risk of cracks in the aluminum, they assumed it would be fine for 60,000 flights (pressure cycles) but have now reduced the expected life to 30,000 with inspections recommended every 500 flights after reaching 30,000....

FMEA: The Cure for Medical Errors

Why perform an FMEA?

- Purpose of an FMEA Study is to analyze:
  - What might go wrong?
  - How bad might the effect be?
  - How might it be prevented, mitigated or detected at the earliest possible moment?
    - With lowest cost, impact, safety risk....
  - Develop a Design FMEA process for use in future programs.
Typical FMEA Uses

- FMEA are often stored and kept to prove due engineering diligence in case of a product liability law suit or government safety investigation.

- Worst use is when a “FMEA Specialist” generates the analysis alone or to simply fulfill a contract requirement, and the report is not even read by the product team.

- FMEA are extremely powerful QRD (Quality, Reliability, Durability) analysis techniques
  - Best for total new products, new technologies and challenging design issues.
  - But the high degree of detail and repetition in a FMEA can be grueling, costly and time intensive to create especially for complex designs.
    - FMEA’ing everything can lead to
      - Overwork
      - Non Value Added work
      - FMEA fatigue!
    - Try to re-use FMEA “building blocks” or use as a check list on new versions of similar products.
FMEA Basics - Failure Mode And Effect Analysis

- FMEA is a widely used and powerful analysis/design review technique.
  - An extremely comprehensive element by element review of:
    - What can go wrong
    - What will happen
    - How the situation can be improved
  - For improving a design or process
  - For each component, element or process step:
    - List how failures can occur (Failure Mode, what can go wrong, how the failure manifests itself)
    - List what could happen (Failure Effect, consequences of the mode).
    - List how processes or the system itself can detect & prevent the problem
    - Generate Recommendations for Improvements.
Calculate a Risk Priority Number (RPN) for Each Line Item using 3 Criteria,
- Severity of the Failure Effect “S” (Scale of 1 (Low) - 10 (High)).
- Frequency of Failure Occurrence “O” (Scale of 1 (Infrequent) - 10 (Frequent)).
- Detectability/Preventability/Warning “D” (Scale or 1 (Very Detectable) - 10 (Not Detectable)).
- RPN = S x O x D, range (1 (good) to 1000 High Risk).
- An unacceptable range is defined.
  - Example: RPN’s > 150 are unacceptable and require a corrective action redesign.
  - Often a Pareto Ranking of the RPN is performed and used to prioritize corrective action efforts.
FMEA - Failure Mode And Effect Analysis

- Many FMEA Versions.
  - Design and Process Version - DFMEA & PFMEA.
  - Can be Performed at that Component, Subsystem, System and Software level
  - FMECA - Failure Mode, Effect and Criticality Analysis
    a version that further emphasizes & highlights “Safety Critical” issues
  - Initially, the FMECA was called FMEA (Failure modes and effects analysis). The C in FMECA indicates that the criticality (or severity) of the various failure effects are considered and ranked.
  - Today, FMEA is often used as a synonym for FMECA. The distinction between the two terms has become blurred.
Some Key FMEA Terms

- Failure: The loss of expected or intended function under stated conditions
- Failure mode: The way in which a failure is observed; generally describes the way the failure occurs.
- Failure effect: The immediate consequences of a failure on operation, function or functionality
- Failure cause: Defects in design, system, process, quality, or part application, the underlying cause of the failure or things which initiate a process which leads to failure.
- Severity: The consequences of a failure mode. Severity considers the worst case outcome of a failure as determined by the degree of injury, property damage, or harm that could ultimately occur.
FMEA – Use a Team Approach!

Core-team

Support-team
Product FMEA – Typical Team Example

Quality or Reliability Facilitator

Support team

Representatives from:
- Development
- Production
- Supplier Quality
- Purchasing
- Validation
- ...

Core-team

Systems Enrg
HW Design
SW Design

Production/process-engineer

Product FMEA – Typical Team Example
The FMEA Process in Detail....

1) Define the system of interest
2) Define the problems of interest for the analysis.
3) Choose the type of FMEA approach for the study
4) Divide the system for analysis & Create Teams
5) Create block diagrams that illustrate all subsystem elements, interfaces and interactions - Select Ranking System
6) Create FMEA Outlines based on the block diagrams. Subsystem elements, interfaces and interactions become the FMEA subsections
7) Performing the FMEA to Identify potential failure modes, & Their Severity, Probability of Occurrence, Detectability & Calculate RPNs for the sub-system
8) Complete the Initial Evaluation Phase Identify Excessive Risks, Develop Corrective Action Proposals & Assign Resolution Lead
9) Team Reports To Example Management
10) Mitigation Phase Example Follow Up Evaluate C.A. Effectiveness & Implementation Plans Update FMEA with Finding & Revise RPN’s
11) If new RPN are Satisfactory, Implement C.A.s
   IF Unsatisfactory Dev & Evaluate New C.A.s or Escalate to Mgmt
Information Flow

Customer Requirements:
- Functions with Req’s/Tech Specs
- System Technical Specs

Product Definition:
- Key Product Characteristics, DFMEA

Process Definition:
- Process Flow Diagram (PFD),
- Product and Process Characteristics

Failure Mode Analysis:
- PFMEA

Control Strategy:
- Control Plan,
- Error proofing

Manufacturing:
- Work Instructions & Process Monitoring
FMEAs are “continuous steps” in the development process (mind set)
DFMEA & PFMEA are related, but separate tasks
Whenever changes are made for: FTQ or other issues, **ALL the process documentation should be reviewed & updated as required.**
FMEA – Teamleaders & Facilitators

- Team Leaders are often from a Product/Systems Group and facilitators are from a Quality/Reliability Organization but no hard and fast rules!
- Team Leader Preparation for the FMEA session:
  - Focuses on the project/product and accessing, distributing, & displaying important product information:
  - Defines and assigns tasks of the team-members:
  - Accesses support personnel when needed
  - Gathers technical solutions, subject matter expertise
FMEA – Facilitator Tasks

- Facilitator Preparation of the FMEA session
  - Works/prepares together with the team-leader
  - Helps define agenda for each meeting
    - Product-FMEA: creates block diagram
    - Process-FMEA: creates flows diagram
  - Creates the FMEA starter outline from the diagram
  - Helps select participants with team leader (4-6 persons ideal).
  - Ensures the FMEA-worksheet is completely & accurately filled-in (actions, responsible person, date)
    - Functions are correctly written down (verb/noun)
    - All known failure modes are listed
    - Failure modes effects are correct (no confusion between causes and effects).
  - Keeps the process moving don’t loose time with long discussions about severity and probability.
  - In case of doubt, take the ‘worst case’ and move on.
<table>
<thead>
<tr>
<th>Item</th>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Cause(s)/Mechanism(s) of Failure</th>
<th>Occur</th>
<th>Current Design Controls Prevention</th>
<th>Current Design Controls Detection</th>
<th>R. P. N.</th>
<th>Recomended Action(s)</th>
<th>Responsibility &amp; Target Completion Date</th>
<th>Action Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>Front Door L.H H8HX-0000-A</td>
<td>Corroded interior lower door panels</td>
<td>7</td>
<td>6</td>
<td>Vehicle general durability test veh.</td>
<td>T-118</td>
<td>Add laboratory accelerated corrosion testing</td>
<td>A Tate-Body Engrg BX 09 30</td>
<td>Based on test results (Test No. 1481) upper edge spec raised 125mm</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>- Ingress to and egress from vehicle</td>
<td>Deteriorated life of door leading to: Unsatisfactory appearance due to rust through paint over time Impaired function of interior door hardware</td>
<td>7</td>
<td>4</td>
<td>Vehicle general durability testing as above</td>
<td>T-109</td>
<td>Add laboratory accelerated corrosion testing</td>
<td>A Tate Body Engrg BX 01 15</td>
<td>Test results (Test No. 1481) show specified thickness is adequate. DOE shows 25% variation in specified thickness is acceptable</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>- Occupant protection from weather, noise, and side impact</td>
<td>Inappropriate wax formulation specified</td>
<td>2</td>
<td>2</td>
<td>Physical and Chem Lab test Report No.1265</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>- Support anchorage for door hardware including mirror, hinges, latch and window regulator</td>
<td>Entrapped air prevents wax from entering comer/edge access</td>
<td>5</td>
<td>8</td>
<td>Design aid investigation with non-functioning spray head</td>
<td>T-301</td>
<td>Add team evaluation using production spray equipment and specified wax</td>
<td>Body Engrg &amp; Assy Ops BX 11 15</td>
<td>Based on test, 3 additional vent holes provided in affected areas</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>- Provide proper surface for appearance items</td>
<td>Insufficient room between panels for spray head access</td>
<td>4</td>
<td>4</td>
<td>Drawing evaluation of spray head access</td>
<td>None</td>
<td>Add team evaluation using design aid buck and spray head</td>
<td>Body Engrg &amp; Assy Ops BX 09 15</td>
<td>Evaluation showed adequate access</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>- Paint and soft trim</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
FMEA Worksheet Sections

1. FMEA #: 
   - Enter the FMEA document number, used for tracking.

2. FMEA Type & Name: 
   - System, Subsystem or Component, 
   - Item Name and Number.

3. Design Responsibility Department or Group

4. Prepared By: 
   - The name, phone, e-mail & company of the person who led or prepared the FMEA.

5. Program/Model 
   - List the program/project of system the item is used in and the introductory model year of the item.

6. Key (Due) Date 
   - Target FMEA completion date.

7. FMEA (Revision) Date 
   - Revision Date of this version of the FMEA worksheet
FMEA Worksheet Sections

8. Core Team:
   - List the names, contact info & departments of the FMEA team members

9. Item/Function
   - Concisely list the name and pertinent info of the line item/section being analyzed.
   - Correlate the FMEA item/function number to the number on FMEA block diagram/engineering drawing.

10. Potential Failure Mode
    - Sequentially and concisely list the manner in which the item (component, subsystem or system) could potentially fail to perform the intended function described in the item/function column. The potential failure mode could cause a potential failure in a higher level item, or be the effect of lower level item.
    - List each potential failure mode associated with the particular item or function.

11. Potential Effect(s) of Failure
    - Sequentially and concisely list the potential effects of the each failure mode on the function, as perceived by the customer. Document if the failure could impact safety or result in noncompliance to regulation.
12. **Severity Ranking:**

- List the team's assessment of the Severity rank associated with the most serious potential effect of each identified failure mode. Severity is a relative ranking based on the predefined severity evaluation criteria and ranking system.

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Effect</th>
<th>Customer Effect</th>
<th>Manufacturing Effect</th>
<th>Equivalent to CAPA Scale Reference HTXPROC-000008S</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Hazardous without warning</td>
<td>Very high severity ranking when a potential failure mode poses a high threat to a patient safety without warning, or would likely lead to an MDR reportable event.</td>
<td>May endanger operator without warning</td>
<td>Critical Incident: Incidents that have or would likely result in an MDR reportable failure or threat to Patient Safety</td>
</tr>
<tr>
<td>9</td>
<td>Hazardous with warning</td>
<td>High severity ranking when a potential failure mode poses a potential threat to patient safety with warning, or could possibly lead to an MDR reportable event.</td>
<td>May endanger operator with warning</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Very High</td>
<td>Device inoperable (loss of primary function).</td>
<td>100% of product may have to be scrapped, or the high probability of issuance of a regulatory observation.</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>High</td>
<td>Device operable but at a reduced level of performance. Customer very dissatisfied.</td>
<td>Product may have to be sorted and portion (less than 100%) scrapped, or the possibility of issuance of a regulatory observation.</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Moderate</td>
<td>Device operable but Comfort/Convenience inoperable. Customer dissatisfied.</td>
<td>A portion (less than 100%) of the product may have to be scrapped, or a GMP violation which, alone, may not result in a regulatory inspection observation.</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Low</td>
<td>Device operable but Comfort/Convenience operable at a reduced level of performance.</td>
<td>0% of the product may have to be reworked, or a GMP violation which, alone, would not result in a regulatory inspection observation.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Very Low</td>
<td>Visual defect. Does not conform. Defect noticed by most customers (greater than 75%).</td>
<td>The product may have to be sorted, with no scrap, and a portion (less than 100%) reworked.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Minor</td>
<td>Visual defect. Does not conform. Defect noticed by 50% customers.</td>
<td>A portion (less than 100%) of the product may have to be reworked, with no scrap, not in-house.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Very Minor</td>
<td>Visual defect. Does not conform. Defect noticed by discriminating customers (less than 25%).</td>
<td>A portion (less than 100%) of the product may have to be reworked, with no scrap, in-house.</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>None</td>
<td>No discernible effect.</td>
<td>Slight inconvenience to operation or operator, or no effect.</td>
<td>None</td>
</tr>
</tbody>
</table>

Sample Process Severity Ranking Table

To be adapted for Design FMEA
FMEA Worksheet Sections

13. **Classification**
   - An non standardized adhoc column that can be used to classify special product characteristics (i.e. critical, key, major, significant). May also be used to highlight high-priority failure modes or specific company policy issues.

14. **Potential Cause(s) / Mechanism(s) of Failure**
   - Sequentially and concisely list all potential causes and/or failure mechanisms that might trigger or result in each failure mode. So that preventative or mitigation efforts can be identified.
15. Probability or Potential Frequency of Occurrence.
- Rank the likelihood that a specific failure cause/mechanism will occur during the intent design life or usage situation. The likelihood of occurrence ranking number is a relative meaning rather than an absolute value. Preventing or controlling the causes/mechanisms of the failure mode through a design or process change (i.e. design checklist, design review, design guide) is the only way a reduction in the occurrence ranking can be effected. Estimate the likelihood of occurrence of potential failure cause/mechanisms on a 1 to 10 scale.

Sample Process Occurrence Ranking Scale

<table>
<thead>
<tr>
<th>Probability</th>
<th>Estimated Failure Rate</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persistent Failures</td>
<td>&gt;= 100 per thousand pieces</td>
<td>6</td>
</tr>
<tr>
<td>Frequent Failures</td>
<td>50 per thousand pieces</td>
<td>5</td>
</tr>
<tr>
<td>Moderate Failures</td>
<td>10 per thousand pieces</td>
<td>4</td>
</tr>
<tr>
<td>Relatively Few Failures</td>
<td>1 per thousand pieces</td>
<td>3</td>
</tr>
<tr>
<td>Remote</td>
<td>.1 per thousand pieces</td>
<td>2</td>
</tr>
<tr>
<td>Unlikely</td>
<td>&lt;= .01 per thousand pieces</td>
<td>1</td>
</tr>
</tbody>
</table>

To be adapted for Design FMEA
16. Current Design Controls

- List the prevention, design validation/verification, quality controls, self diagnostics, fail safe features or other activities that have incorporated into the product or process to assure the design adequacy for the failure mode and/or cause/mechanism being considered. The team should always be focused on improving or optimizing design controls; for example, creating better tests or creating new system algorithms. There are two types of design controls to consider:

- Prevention: Prevent the cause/mekanism of failure or the failure mode from occurring, or reduce their rate of occurrence.

- Detection: Detect the cause/mekanism of failure or the failure mode, either by analytical or physical methods, before the item is released to production or by self diagnostics with fail safe features in the field. The FMEA form has separate columns for Prevention Controls and Detection Controls) to assist in distinguishing between the two types of design controls. This allows for a quick visual determination that both types of design controls are being used.
### FMEA Worksheet Sections

17. Detection is a relative ranking of the intended design controls.

**Sample Process Detection Scale**

<table>
<thead>
<tr>
<th>Detection</th>
<th>Criteria</th>
<th>Inspection Types *</th>
<th>Suggested Range of Detection Methods</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Almost Impossible</strong></td>
<td>Absolute certainty of non-detection.</td>
<td>X</td>
<td>Cannot detect or is not checked.</td>
<td>10</td>
</tr>
<tr>
<td><strong>Very Remote</strong></td>
<td>Controls will probably not detect.</td>
<td>X</td>
<td>Control is achieved with indirect or random checks only.</td>
<td>9</td>
</tr>
<tr>
<td><strong>Remote</strong></td>
<td>Controls have poor chance of detection.</td>
<td>X</td>
<td>Control is achieved with visual inspection only.</td>
<td>8</td>
</tr>
<tr>
<td><strong>Very Low</strong></td>
<td>Controls have poor chance of detection.</td>
<td>X</td>
<td>Control is achieved with double visual inspection only.</td>
<td>7</td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>Controls may detect.</td>
<td>X</td>
<td>Control is achieved with charting methods, such as SPC (Statistical Process Control).</td>
<td>6</td>
</tr>
<tr>
<td><strong>Moderate</strong></td>
<td>Controls may detect.</td>
<td>X</td>
<td>Control is based on variable gauging after parts have left the station, or Go/No-Go gauging performed on 100% of the parts after parts have left the station.</td>
<td>5</td>
</tr>
<tr>
<td><strong>Moderately High</strong></td>
<td>Controls have a good chance to detect.</td>
<td>X</td>
<td>Error detection in subsequent operation, or gauging performed on setup and first-piece check (for set-up causes only).</td>
<td>4</td>
</tr>
<tr>
<td><strong>High</strong></td>
<td>Controls have a good chance to detect.</td>
<td>X</td>
<td>Error detection in-station, or error detection in subsequent operations by multiple layers of acceptance: supply, select, install, verify. Cannot accept discrepant parts.</td>
<td>3</td>
</tr>
<tr>
<td><strong>Very High</strong></td>
<td>Controls almost certain to detect.</td>
<td>X</td>
<td>Error detection in-station (automatic gauging with automatic stop feature). Cannot pass discrepant part.</td>
<td>2</td>
</tr>
<tr>
<td><strong>Very High</strong></td>
<td>Controls certain to detect.</td>
<td>X</td>
<td>Discrepant parts cannot be made because item has been error-proofed by process/product design.</td>
<td>1</td>
</tr>
</tbody>
</table>
18. RPN - Risk Priority Number
   - The RPN is the product of the severity (S), occurrence (O), and detection (D) rankings: \((S) \times (O) \times (D) = \text{RPN}\). The RPN is used to prioritize the risk related to each failure mode and mechanism.

19. Recommended Corrective Action.
   - Engineering efforts for preventive/corrective action should be first directed at high severity, high RPN, items identified by the team. The objective is to recommended action that reduce severity, occurrence and detection risks rankings.

   9 or 10 severity issues require special attention to ensure that the risk is addressed through design controls or preventive/corrective action(s) regardless of the RPN value. After special attention has been given to severity rankings of 9 or 10, other failure modes can then be addressed.

   The primary objective of recommended actions is to reduce risks AND increase customer satisfaction by improving the design.

20. Responsibility & Target Completion Date
   - Enter the name of the organization and the individual responsible for evaluating and implementing each recommended corrective action and the target completion date.
FMEA Worksheet Sections

21. Action Taken
   - After the recommended corrective action has been evaluated and implemented briefly describe the final outcome and effective date.

22. Corrective Action Results.
   - After the preventive/corrective action has been identified, estimate and record the revised resulting severity, occurrence, and detection rankings. Calculate and record the resulting RPN. If no actions are taken, leave these columns blank. All revised ratings should be reviewed. If further action is considered necessary, repeat the analysis. The focus should always be on continuous improvement.

The design-responsible engineer is responsible for ensuring that all recommended actions have been adequately addressed and implemented. The FMEA is a living document throughout the product development process and should always reflect the latest design level and latest relevant.
Common Mistakes and Traps

- “Fill in the blanks” only.
  - *Don’t understand the scope and objective of FMEA*
- Day dreaming
  - *Didn’t go through the self-challenge process of design control*
- Couldn’t separate Failure Mode, Cause, Effect
  - *Mixed everything together. Argument for the sake of argument.*
Common Mistakes and Traps

- Repeated itself
  - Dog chases its own tail.
- Mitigation is not truly challenged
- Ranking criteria too loose
- Only identifying the problems but not the solutions. Or, couldn’t control it, even if there is a solution. Control plan not in place.
- Do once, then keep in file
  - Leaving Document rather than Living Document
- Lack of consistency
1. Develop a sub-system or component by component system block diagram, mechanization or schematic of the device/system to be analyzed.

2. For each subsystem or component, identify and list the:
   Potential Failure Modes (i.e. how failures might be observed or experienced) and the Potential Effect(s) of the Failure
   - Then rate their severity on a predetermined scale (typically 1-5 or 1-10) where a low value indicates a low severity

3. Identify Potential Cause(s) or Mechanisms of Failure for each Failure mode
   - Then rate their potential probability or frequency of occurrence on another predetermined 1-5 or 1-10 scale.

4. Identify the Design Controls, prognostics or Fail Safe features incorporated into design to detect, prevent and/or mitigate the failure so that safety and/or hazardous conditions are adverted.
   - Then rate the expected effectiveness of the design controls on another 1-5 or 1-10 scale.

5. Calculate the risk factor for each item by multiply the value of the Severity Scale by the Probability Scale & the Effectiveness Scale values.
   The risk factor value often called the Risk Priority Number (RPN) is then used to quantify, rank and access the risk of each element and feature of the design as well as the overall design, where small RPN values indicate low risk and large values indicate higher risk.
   - Different industry and companies have developed standards that defined various evaluation scales and acceptable RPN values related to the criticality of their products.

6. DFMEA PART 2: Once all the RPN values are determined for each aspect of the design. The FMEA team evaluates the over all and individual risks of the design to determine if the design risks are acceptable or if failure risks are excessive and the design need to be revised to reduce the failure risks. This leads to the second phase of the FMEA where Recommended Corrective Action(s), Implementation Responsibility, & Target Completion Date and define and tracked.

7. DFMEA PART 3: As corrective actions are implemented the FMEA team reviews the corrective action revision and re-evaluates the severity, probability and effectiveness of each revised design element and recalculates a new RPN base on the improvements. If the risk is still not determined to be acceptable further corrective action design revisions may be required.
   - In this way the FMEA is used as a risk evaluation and control process throughout the design-development phase of a program and used to evaluate if quality, reliability and safety was designed in to the product. The FMEA also serves to document that due diligence was applied for quality, reliability, safety and risk management during the design-development program.

8. Another use for FMEA is that many companies will require a new project team to review older FMEA for similar products, at the start of a new project, so that the lessons learn in the past are identified and reused at the beginning of the design. In this way a new project team should get started at a higher point on the learning curve and not need to relearn past lessons on their own.
<table>
<thead>
<tr>
<th>EFFECT</th>
<th>SEVERITY EVALUATION CRITERIA: Severity of Effect</th>
<th>RNK.</th>
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<tbody>
<tr>
<td><strong>Hazardous-without warning</strong></td>
<td>Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning</td>
<td>10</td>
</tr>
<tr>
<td><strong>Hazardous-with warning</strong></td>
<td>Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning</td>
<td>9</td>
</tr>
<tr>
<td><strong>Very High</strong></td>
<td>Vehicle/item inoperative (loss of primary function).</td>
<td>8</td>
</tr>
<tr>
<td><strong>High</strong></td>
<td>Vehicle/item operable but at a reduced level of performance. Customer very dissatisfied.</td>
<td>7</td>
</tr>
<tr>
<td><strong>Moderate</strong></td>
<td>Vehicle/item operable but Comfort/Convenience item(s) inoperative. Customer dissatisfied.</td>
<td>6</td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>Vehicle/item operable but Comfort/Convenience item(s) operable at a reduced level of performance. Customer somewhat dissatisfied.</td>
<td>5</td>
</tr>
<tr>
<td><strong>Very Low</strong></td>
<td>Fit &amp; Finish/Squeak &amp; Rattle item does not conform. Defect noticed by most customers (greater than 75%).</td>
<td>4</td>
</tr>
<tr>
<td><strong>Minor</strong></td>
<td>Fit &amp; Finish/Squeak &amp; Rattle item does not conform. Defect noticed by 50% of customers.</td>
<td>3</td>
</tr>
<tr>
<td><strong>Very Minor</strong></td>
<td>Fit &amp; Finish/Squeak &amp; Rattle item does not conform. Defect noticed by discriminating customers (less than 25%).</td>
<td>2</td>
</tr>
<tr>
<td><strong>None</strong></td>
<td>No discernable effect.</td>
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# Occurrence Evaluation Criteria

## Suggested Occurrence Evaluation Criteria

<table>
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<tr>
<th>Probability of Failure</th>
<th>Likely Failure Rates Over Design Life</th>
<th>Ranking</th>
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<tbody>
<tr>
<td>Very High: Persistent failures</td>
<td>$\geq 100$ per thousand vehicles/items</td>
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<tr>
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<td>$50$ per thousand vehicles/items</td>
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</tr>
<tr>
<td>High: Frequent failures</td>
<td>$20$ per thousand vehicles/items</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>$10$ per thousand vehicles/items</td>
<td>7</td>
</tr>
<tr>
<td>Moderate: Occasional failures</td>
<td>$5$ per thousand vehicles/items</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>$2$ per thousand vehicles/items</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>$1$ per thousand vehicles/items</td>
<td>4</td>
</tr>
<tr>
<td>Low: Relatively few failures</td>
<td>$0.5$ per thousand vehicles/items</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>$0.1$ per thousand vehicles/items</td>
<td>2</td>
</tr>
<tr>
<td>Remote: Failure is unlikely</td>
<td>$\leq 0.01$ per thousand vehicles/items</td>
<td>1</td>
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</table>

*Note: Zero (0) rankings for Severity, Occurrence or Detection are not allowed*
## Detection Rating

### Suggested Detection Evaluation Criteria

<table>
<thead>
<tr>
<th>Detection</th>
<th>Criteria</th>
<th>Rank</th>
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</thead>
<tbody>
<tr>
<td><strong>Absolute Uncertainty</strong></td>
<td>Design Control will not and/or cannot detect a potential cause/mechanism and subsequent failure mode; or there is no Design Control.</td>
<td>10</td>
</tr>
<tr>
<td><strong>Very Remote</strong></td>
<td>Very Remote chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.</td>
<td>9</td>
</tr>
<tr>
<td><strong>Remote</strong></td>
<td>Remote chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.</td>
<td>8</td>
</tr>
<tr>
<td><strong>Very Low</strong></td>
<td>Very Low chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.</td>
<td>7</td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>Low chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.</td>
<td>6</td>
</tr>
<tr>
<td><strong>Moderate</strong></td>
<td>Moderate chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.</td>
<td>5</td>
</tr>
<tr>
<td><strong>Moderately High</strong></td>
<td>Moderately High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.</td>
<td>4</td>
</tr>
<tr>
<td><strong>High</strong></td>
<td>High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.</td>
<td>3</td>
</tr>
<tr>
<td><strong>Very High</strong></td>
<td>Very High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.</td>
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</tr>
<tr>
<td><strong>Almost Certain</strong></td>
<td>Design Controls will almost certainly detect a potential cause/mechanism and subsequent failure mode.</td>
<td>1</td>
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</table>
Questions & Discussion

Please feel free to contact me anytime for questions!

culkoff@dfrsolutions.com

www.dfrsolutions.com
Your Partner Throughout the Product Life Cycle

DfR lends a guiding hand on quality, reliability and durability (QRD) issues through our expertise in the emerging science of Reliability Physics, providing crucial insights and solutions early in product design, development and test throughout manufacturing, and even into the field.
Your Needs...

- ...faster time to market
- ...find, incorporate new technologies
- ...extend warranty period
- ...reduce warranty costs
- ...technically manage suppliers
- ...improve employee skills
- ...out perform your competition
DfR uses Physics-of-Failure (PoF) and Best Practices expertise to provide knowledge-based strategic quality and reliability solutions to the electronics industry

- Technology Insertion
- Design
- Manufacturing and Supplier Selection
- Product Validation and Accelerated Testing
- Root-Cause Failure Analysis & Forensics Engineering

Unique combination of expert consultants and state-of-the-art laboratory facilities

- Capabilities at package, board, product, and system-level
How Do Companies Use DfR?

- Work overflow
  - Maximize the efficiency of your current staff
- Independent party on critical design reviews
- Supplier benchmarking (commodity / custom)
- Test plan development and execution
- Reliability predictions
- Root-Cause Analysis
- Continuing education
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<td><strong>Who Uses DfR?</strong></td>
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DfR Solutions – Senior Experts

- **Dr. Craig Hillman, CEO and Managing Partner**
  - **Expertise:** Design for Reliability (DfR), Pb-free Transition, Supplier Benchmarking, Passive Components, Printed Circuit Board
  - PhD, Material Science (UCSB)

- **Dr. Nathan Blattau, Vice President**
  - **Expertise:** Power Devices, DfR, Nonlinear Finite Element Analysis (FEA), Solder Joint Reliability, Fracture, Fatigue Mechanics.
  - PhD, Mechanical Eng. (University of Maryland)

- **Cheryl Tulkoff, CRE**
  - **Expertise:** Pb-Free Transition, PCB and PCBA Fabrication, IC Fabrication, RCA (8D and Red X)
  - B.S., Mechanical Engineering (Georgia Tech)

- **Dr. Ron Wunderlich**
  - **Expertise:** Design for EMI/EMC, Power Supply Design, Analog Circuit Design, Spice Model Development, Monte Carlo Circuit Simulation
  - PhD, Electrical Engineering (SUNY – Binghamton)

- **Greg Caswell**
  - **Expertise:** Nanotechnology CMOS, CMOS/SOS, Input Protection Networks / ESD, SMT, Pb-free
  - B.S., Electrical Engineering (Rutgers)

- **Dr. Randy Schueller**
  - **Expertise:** IC Fabrication, IC Packaging, Pb-Free Transition Activities, Supplier Benchmarking, Corrosion Mechanisms
  - PhD, Material Science (University of Virginia)

- **Dr. Gregg Kittlesen**
  - **Expertise:** Semiconductor Lasers, Microprocessors, Memory Components, Photonic and RF Technologies, Supply Chain Management
  - PhD, Inorganic Chemistry (MIT)

- **James McLeish, CRE**
  - **Expertise:** FMEA, Root-Cause Analysis, Warranty Analysis, Automotive Electronics, Physics of Failure, Battery Technology
  - M.S., Electrical Eng. (Wayne State University)

- **Norm Anderson**
  - **Expertise:** Avionics, Product Qualification, Safety Criticality Assessment, FTA, FMEA, Component Uprating, Obsolescence
  - B.S., Electrical Engineering (Iowa State University)

- **Anne Marie Neufelder**
  - **Expertise:** Software Reliability Prediction, Best Practices in Software Risk Management
  - B.S., Systems Engineering (Georgia Tech)

- **Walt Tomczykowski, Vice President, CRE**
  - **Expertise:** Systems Eng., Life Cycle Management (including obsolescence), Spares Analysis, Counterfeit Mitigation, Failure Analysis
  - M.S., Reliability Eng. (University of Maryland)
DfR
Locations (North America)

Austin, TX
512-913-8624

Rochester Hills, MI
248-726-7600

Binghamton, NY
607-754-0347

Minneapolis, MN
320-433-4075

Corporate Headquarters
College Park, MD
301-474-0607
DfR Resources and Equipment

Electrical
- Oscilloscopes (Digital and Analog)
- Curve Tracers (Digital and Analog)
- Capacitance Meters
- Low/High Resistance Meters
- High Voltage Power Supplies (Hi-Pot)
- Network Analyzer (up to 3 GHz)

Testing
- HALT / HASS
- Temperature Cycling
- Thermal Shock
- Temperature/Humidity
- Vibration
- Mechanical Shock / Drop Tower
- Mixed Flowing Gas
- Salt Spray
- Capacitor Testing (Ripple Current, Step Stress, Partial Discharge)
- Bend Testing (Cyclic and Overstress)
- Mechanical Testing

Material Analysis
- X-ray
- Acoustic Microscopy
- Infrared Camera
- Metallographic Preparation
- Stereoscope
- Optical Microscope
- Scanning Electron Microscope
- Energy Dispersive Spectroscopy
- Ion Chromatography
- FTIR (Solid / Film / Liquid)
- Thermomechanical Analyzer
- Mechanical Testing (Tension, Compression, Shear, etc.)
- SQUID Microscopy

Other
- Circuit Simulation
- Finite Element Analysis (FEA)
- Computational Fluid Dynamics
- Reliability Prediction (Physics of Failure)
DfR has developed a revolutionary tool that allows for an early-stage assessment of hardware design

- Easy-to-use + Comprehensive
- Identification of high risk design elements
- Tradeoff analysis
- Faster time-to-market through guarantee of test success
- Physics-based reliability prediction
- Warranty reduction
"The notion that a transistor ages is a new concept for circuit designers," … aging has traditionally been the bailiwick of engineers who guarantee the transistor will operate for 10 years or so…But as transistors are scaled down further and operated with thinner voltage margins, it’s becoming harder to make those guarantees… transistor aging is emerging as a circuit designer’s problem.

IEEE Spectrum, June 2009

- Working with companies across the electronic supply chain to develop an online solution
IC Wearout – Value Proposition

- Tradeoff studies
- Reliability predictions
- System prognostics and self-healing
- Supplier engagement
- Meets current market needs, including
  - Accelerates time-to-market through earlier and more robust analysis
  - Mitigates risk in move to environmentally friendly materials
  - Effectively manages the original design manufacturer (ODM) supply chain
  - Meets new requirements from end-users and regulators for knowledge based assessment
- Major solder manufacturer needed to demonstrate reliability of 2nd generation Pb-free alloy

- DfR provided a turn-key solution
  - Test plan development
  - Test coupon design
  - Test execution
  - Failure analysis
  - Solder reliability model

- Results
  - Developed new test technology to meet schedule and cost constraints
  - Online calculators now available for customers world-wide
DfR has assisted numerous component manufacturers and OEMs in ensuring robustness of existing and future packaging solutions.

**Expertise**
- 1st Level Interconnects (Solder Bumps / Wire Bonds)
- Underfill Selection and Validation
- Substrate / RDL
- Design for Manufacturability (Package Level)
- Physics of Failure (PoF) Reliability Prediction
- Finite Element Analysis (FEA)

**Focus**
- Flip Chip / Ball Grid Array
- Bottom Terminated Components
- Stacked Die / System in Package (SiP)
DfR uses industry-leading design for excellence (DfX) practices to optimize design and ensure success early in new product development (NPD).

**Expertise**
- Circuit Analysis
- Power Supply Design
- Design for Reliability
- Design for Manufacturability
- Design for Testability
- Design for Environment
- Physics of Failure (PoF) Reliability Prediction
- Finite Element Analysis (FEA)

**Focus**
- Semiconductor Packaging
- Printed Circuit Board
- Circuit Card Assemblies
- Product and System-Level

DfR Solutions

5110 Roanoke Place, Suite 101, College Park, MD 20740 | 301-474-0607 | www.dfrsolutions.com
DfR offers multiple solution paths for ensuring a quality supply chain.

- Each solution is specifically tailored to each company’s production volume, design complexity, and cost requirements.

**Approaches include**

- Component-Level Testing
- Development of Supplier Qualification Documents
- Supplier Evaluations (Component, Board, Assembly)
- Construction Analysis
- Statistical Process Control Evaluations
Supply Chain: Component Qualification

- Working with major electronic OEMs on benchmarking suppliers of critical components

- Actions include
  - Developing test plans
  - Characterizing time to failure behavior
  - Developing qualification criteria based on test results
Testing: Test Plan Development

- Product test plans are critical to the success of a new product or technology
  - Stressful enough to identify defects
  - Show correlation to a realistic environment

- DfR Solutions approach
  - Industry Standards + Physics of Failure

- Results in an optimized test plan that is acceptable to management and customers

- Experience in product test plans include
  - Industrial controls
  - Process monitoring
  - Consumer appliances
  - Telecom (Class I, II, and III environments)
  - Personal computers
  - Mobile phones and other mobile products
  - Avionics (engine controls, fuselage)
  - Automotive (under-hood, passenger compartment, chassis, and trunk)
  - Down-hole oil-drilling

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Root Cause Analysis (RCA) -- Personnel

- The number one requirement in failure analysis
- DfR has all the necessary elements
  - Electrical engineers, mechanical engineers, materials scientists, inorganic chemists, etc.
- Extensive in-house expertise
  - PhD, MS, BS + industry experience
- The right background
  - Over 800 failure analyses combined
Failure Analysis: Desktop Computer

- Failures during HALT
  - Exposure to vibration
- Electrical testing indicated electrical open
  - Under BGA socket
- Validity of failure mechanism?
  - Shearing of electrolytic capacitor leads
- Dependent upon orientation of capacitors
  - Only those along the board length
- Vibration test may not have applied random loads
  - Potential issues with vibration table or fixturing
On-Die RCA

- Wireless and telecom component manufacturer
  - Issues with new silicon nitride technology in MIMCAP structure
  - Halted multi-million dollar product launch

- Identified potential root causes based on
  - Knowledge of semiconductor process technology
  - Fundamental behavior of the material

- Recommended experimental design and analytical techniques to confirm failure mechanism
  - Guided modification in process parameters for fundamentally more robust technology
Let your staff learn all day / every day

E-LEARNING

- Scholarly articles
- Technical white papers
- Case studies
- Reliability calculators
- Online presentations
Interested?

- Could your next product benefit from DfR’s extensive expertise and PoF knowledge base?
  - Bring us in as an independent party during critical design reviews

- Are you concerned with new technologies?
  - DfR’s scientists and engineers can provide comprehensive analysis to ensure risk-minimization during these difficult transitions

- Take advantage of our unique Open-Door policy!
  - See how much we already know about your current issues
  - Chances are we have already solved your problem at least once before
  - We work around the clock and around the world
  - Contact us by phone (301-474-0607) or email (askdfr@dfrsolutions.com)