ETI GROUP

Six Sigma / Lean Six Sigma
Lean Enterprise
Business Management Systems
Strategic Planning
Integrated Performance Measurement

Failure Mode And Effects Analysis (Process)

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Performing Failure Mode and Effects Analysis Effectively for Processes

"Logic will take you from A to B, but imagination will take you everywhere."

Albert Einstein

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Learning Objectives

- Design and implement a process to perform Failure Mode and Effects Analysis.
- Identify and select the appropriate participants for an FMEA Team.
- Explain the different types of FMEAs and be able to choose the appropriate type.
- Identify potential failure modes and rank them using risk priority numbers.
- Develop a Process FMEA through hands-on activities and workshop exercises.

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Introductions

- Please introduce yourself.
- Where do you work?
- What are your expectations for today?

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What is an FMEA?

A Potential Failure Modes and Effects Analysis is a systematic group of activities intended to:

- Recognize and evaluate potential failures of a product or process.
- Evaluate the effects of failures.
- Identify actions which could eliminate or reduce the chance of potential failure.
- Document the process & record decisions.

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History

- Reliability Analysis technique invented by the DoD in late 1940's to determine the effect of system and equipment failures in terms of impact on mission success and personnel/equipment safety.
- Became popular during 1960's in aerospace industry
- Initial use was on improving safety – prevent accidents
- Spread to many different industries:
  - Automotive
  - Defense
  - Electronics
  - Manufacturing
  - Medical Devices
  - Transportation

Automotive Industry

- Adopted and adapted by automotive industry for quality improvement (in addition to safety)
- Ford, GM, Chrysler developed standard format and approach
- Integral tool used as part of the Advanced Product Quality Planning process
- Guidelines published in Potential FMEA Reference Manual provided by the AIAG

Terminology Note: "Potential FMEA" and "FMEA" are used interchangeably.

FMEA: Design vs. Process

- Principles and steps are the same
- Purpose and objectives differ
- Rating scale definitions will differ
- Design
  - ✓ Discover potential problems with the design of the product that will result in safety concerns, malfunctions, or shortened life
- Process
  - ✓ Discover potential problems related to the manufacture of the product that will affect the product, safety, or processing efficiency

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Design FMEA

- Considers potential design failures (should consider technical/physical limits of manufacturing/assembly processes)
- Does not rely on process controls to overcome design weaknesses

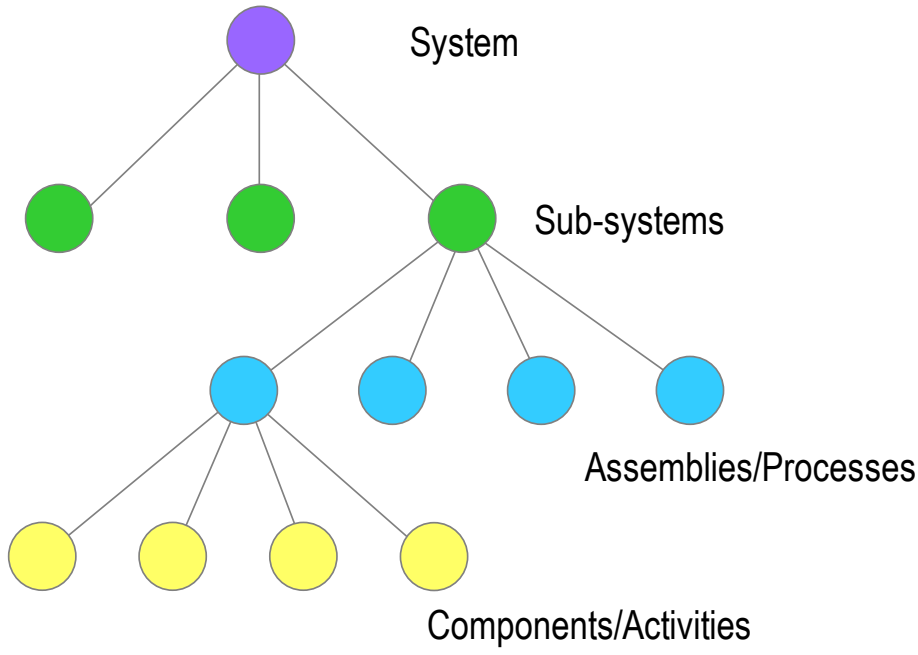
Terminology Note:

The terms "Design FMEA" and "Product FMEA" are often used interchangeably.

Process FMEA

- Assumes product as designed, will meet the design intent
- Does not rely on product design changes to overcome process weaknesses (but does consider product's characteristics)

FMEA Levels



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Results of a Design FMEA can be helpful in formulating a Process FMEA, and vice versa.

Processes can include those for Service (such as customer/technical service, field service, call center service, etc.).

Sketch an example of different levels for a Process FMEA in your application:

FMEA Applications

- Product Design (DFMEA)
- Manufacturing and Assembly Planning (PFMEA)
- Advanced Product Quality Planning (ISO/TS 16949)
- Risk Management (ISO 9001, ISO 13485, etc.)
- Safety
- Reliability-centered Maintenance
- Environmental hazard avoidance
- Problem solving (corrective actions)
- Improvement tool (preventive actions)

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ISO/TS 16949 is an International Standard used by the automotive industry.

ISO 9001 is used by a variety of industries and serves as a basis for several industry-specific standards such as AS9100 in aerospace.

ISO 13485 is an International Standard used by medical device manufacturers.

PFMEAs should include all operational production/service delivery processes from the component level up through assemblies, sub-systems and system as applicable to the organization. Other areas to include are Shipping/Receiving, material transport/conveyers, labeling, repair/rework, service/installation, etc.
It is also recommended that the operational processes that "feed" the production/service delivery processes undergo PFMEA — these may include sales, design, supply chain management/purchasing, planning, etc. Support processes such as document control, training and metrology will also benefit from PFMEA analysis.

When to Use FMEA?

Proactive tool meant to be used when there is a:

- New design/technology/process.
- Modification to an existing design/process.
- Change in the environment, location, application or usage profile of the design/process.
- Change in a Regulation affecting the design/process.

Should be a “before-the-event” action — not an “after-the-fact” analysis

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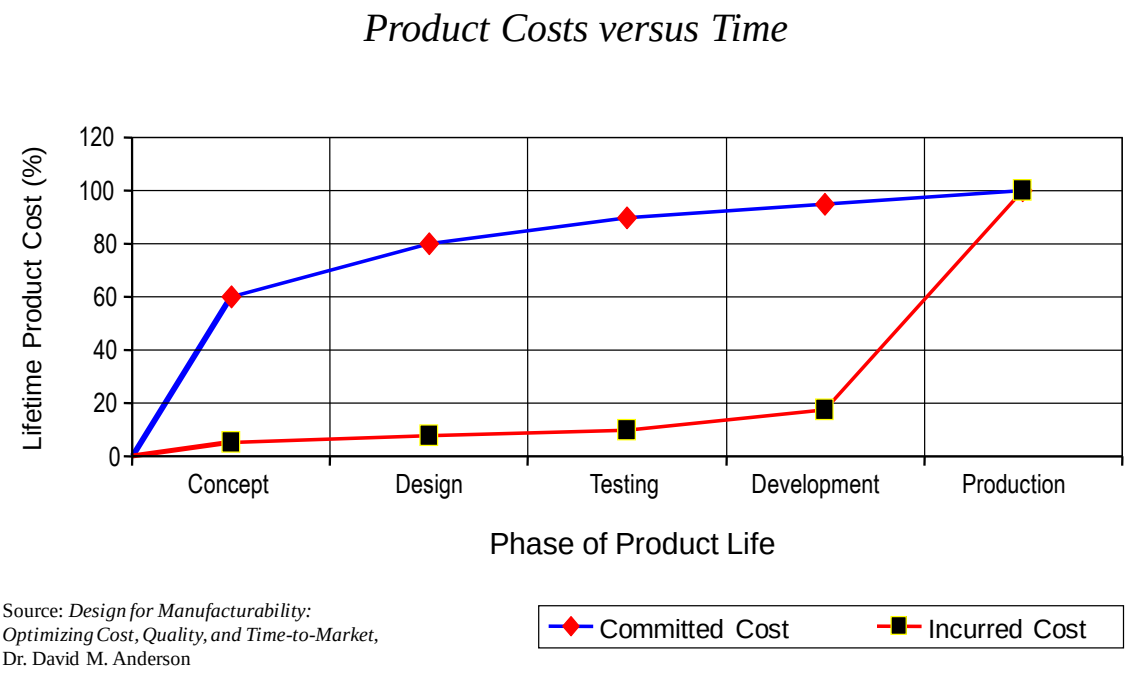
FMEA is meant as a prevention tool, and thus is ideally performed during the design planning and review stage (and here, “design” could be the design of a product, service or process). The goal is to prioritize development of product and process features that can eliminate or reduce the risk of potential failures.

An FMEA is not a “one-time-event” but rather a dynamic process and learning commitment.

FMEA can be used post mortem on actual failures (NASA performed one when the Mars Orbiter was lost).

Why Use FMEA?



Source: *Design for Manufacturability: Optimizing Cost, Quality, and Time-to-Market,* Dr. David M. Anderson

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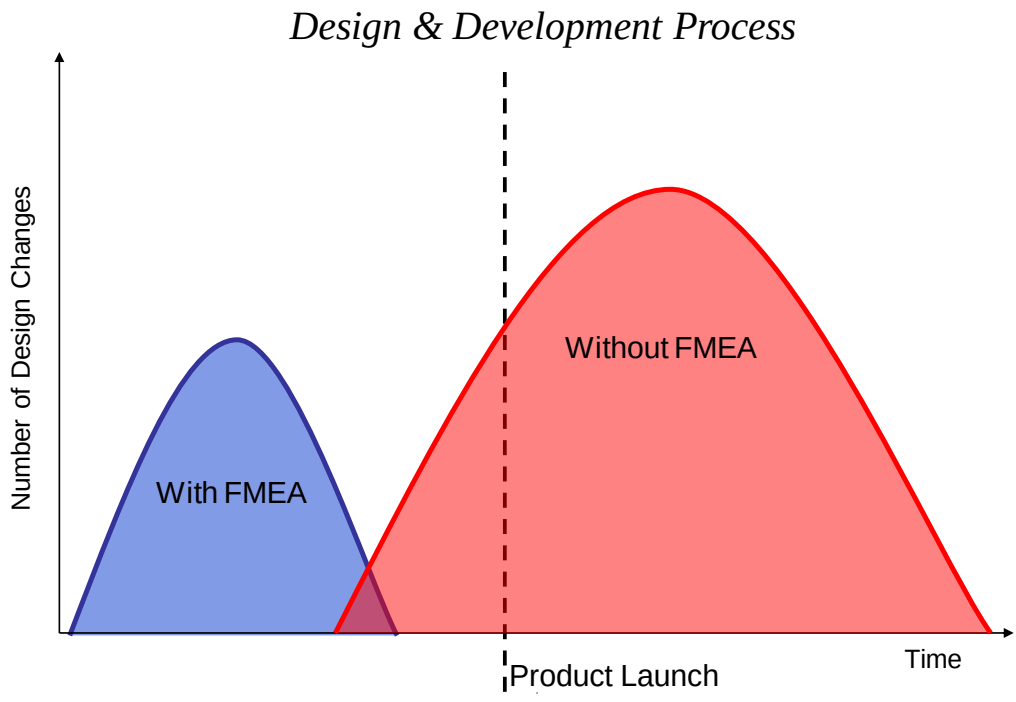
The choices made early in the Design process will determine the final cost to produce the product. Once the product reaches Production, there is very little that can be done to impact this cost.

Why Use FMEA?



Benefits of FMEA

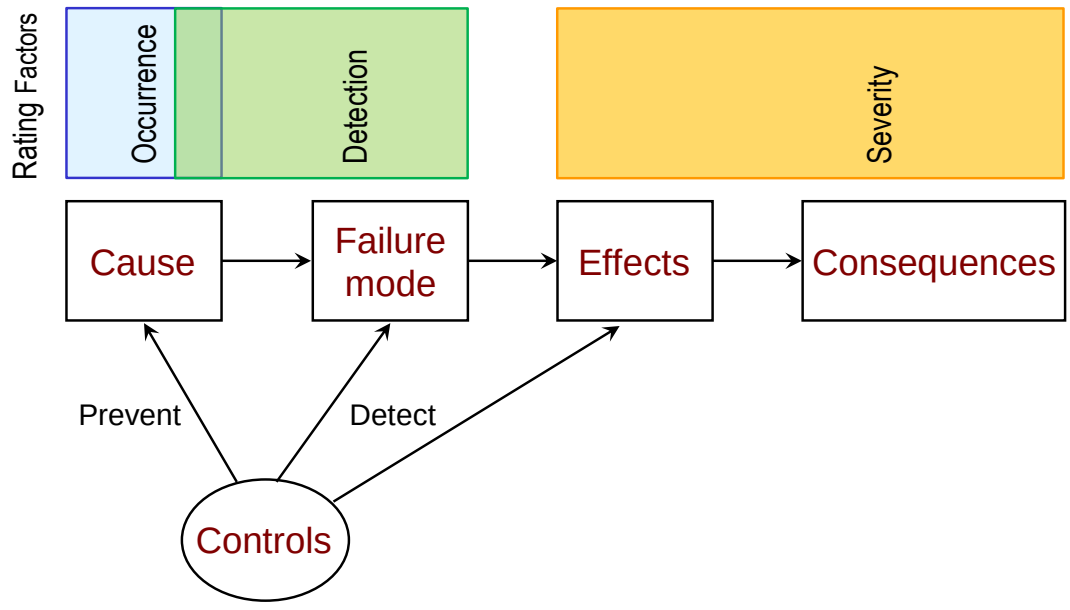
- Improved knowledge of the product & process
- Promotes a focus on customer requirements and consequences of failure
- Time savings, improved productivity
- Cost savings
- Reduced warranty repairs and recalls (i.e., improved reliability)
- Improved quality
- Better maintainability
- Provides documented planning history for future changes, new product and/or process designs
- Prioritizes corrective & preventive actions for product design and process controls

⇩

Increased Customer Satisfaction

The FMEA Process

Terms & Definitions



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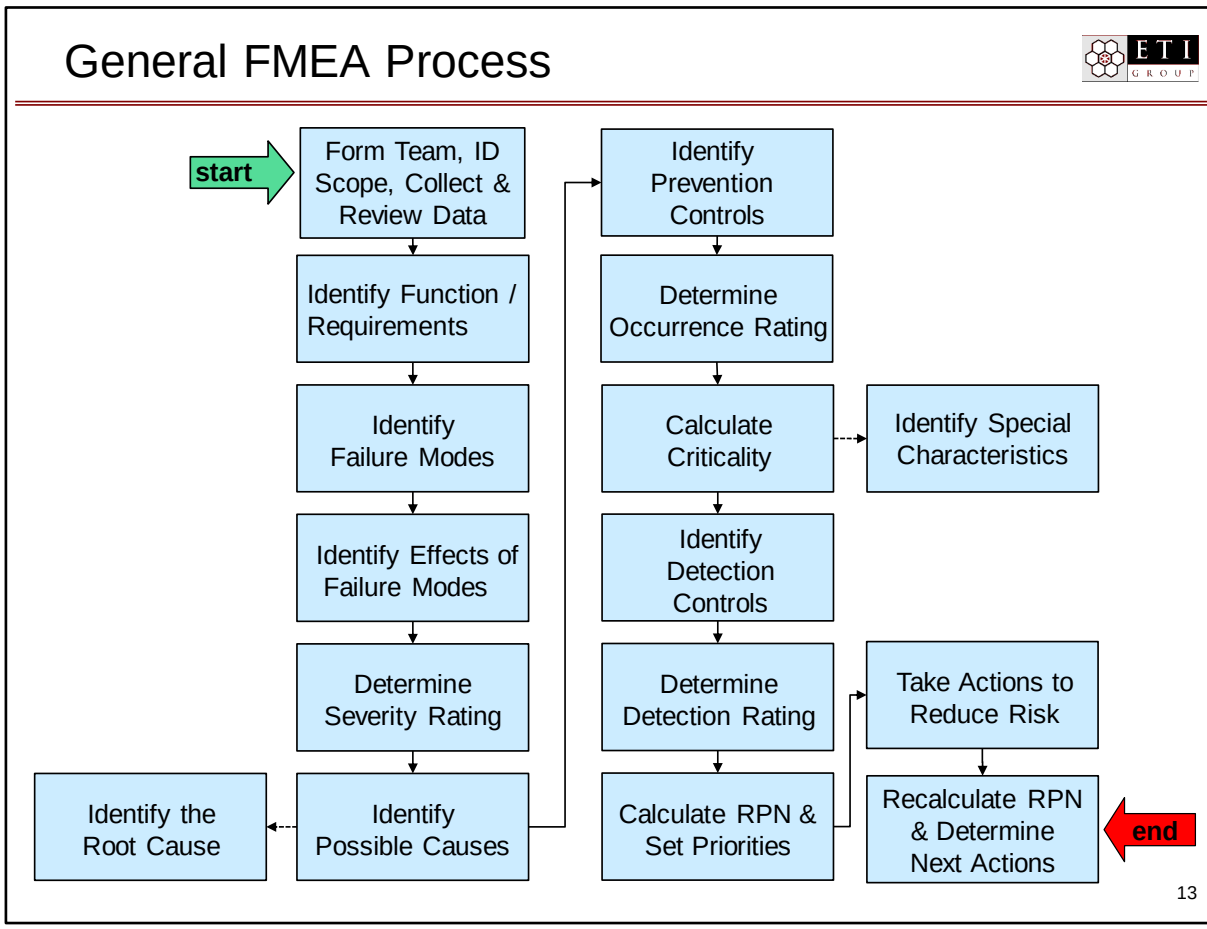
Customer:	Internal or external departments, people, and processes that will be adversely affected by failure.
Function/Requirement:	Intended purpose of a product or process.
Cause:	Means by which a particular element results in a failure mode.
Failure Mode:	Way in which a product or process could fail to perform its desired function.
Effect(s):	Symptom(s) the customer will see or experience.
Consequence:	What occurs in the customers' process, system, etc. as a result of the effects.
Controls:	Mechanisms that prevent the Cause from occurring or which detect the Failure Mode or Effect.
Severity:	Assessment of how serious the consequences of the Effect will be on the Customer.
Occurrence:	Assessment of the likelihood that a particular cause will happen and result in the failure mode.
Detection:	Assessment of the likelihood that current controls will detect the cause/mechanism of failure or the failure mode.



RPN = Risk Priority Number

FMEA Team

- "Preparation" of the document—assign to an individual
- FMEA input, review and analysis is a TEAM effort
- Non-permanent team with representatives from:
  - Process Engineering
  - Procurement
  - Quality
  - Planning
  - Finance
  - *The CUSTOMER*
  - Production Support
  - Service Delivery
  - Production/Service
  - Sales/Marketing/Program Management
  - Customer Service/Support
  - Design & Development
- Best size: 4 to 6 people
- Goal: use FMEA as a tool to stimulate discussion & exchange of ideas
- Multiple FMEA Teams—ensure there is some overlap between teams for coordination

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Software can speed up the FMEA process, but it is still important to keep the output visible to all participants during a session.

Don't let the typing in of information slow down the group process.

Consider using a combination of flip charts and sticky notes with the whole group, and have someone type it into a spreadsheet later.

FMEA Team

- Want cross-section of people:
  - ✓ Some who are minimally knowledgeable – bring fresh perspective, more critical
  - ✓ Some who are knowledgeable—bring understanding
- FMEA, by its nature, is critical — "Let's find everything that can go wrong" — some may take this personally!
  - ✓ Owner may tend to become defensive ("how dare you say my baby is ugly!")
  - ✓ May disregard or overlook possibilities ("that could never occur")
  - ✓ May lead to forming a Team that does not include owner of what is being analyzed

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FMEA Team

- Management needs to clearly define boundaries.
- FMEA team needs to understand boundaries—should not begin without them!
- Answer following questions:
  - ✓ What is Team responsible to do?
  - ✓ What is the budget?
  - ✓ What other resources are available or are not available?
  - ✓ Is there a time constraint?
  - ✓ How does the Team expand the boundaries (if need be)?
  - ✓ What and how should the results be communicated? To whom?
- Should have a procedure for performing FMEA.
  - ✓ Standing guidelines on boundaries
  - ✓ Company's defined process

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A FMEA Team Start-up Worksheet is given in the Appendix.

FMEA Worksheet

- Forms backbone of FMEA process.
- Can record actions using worksheet.
- Several versions — pick one you like or create your own (or use one customer says to use).
- Worksheet should:
  - ✓ Capture all important information/data
  - ✓ Serve as a communication tool and record
  - ✓ Be numbered (# should have some significance)
  - ✓ Be changed as process design or plan progresses
  - ✓ Be retained as a quality record (known location and retention period)
- Typically — read and work with worksheet from left to right.

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See Appendix for examples of completed PFMEAs.

PFMEA Worksheet

Item/Operation Area: _____

Level: ☐ System ☐ Sub-System ☐ Process ☐ Activity

Description: _____

Scope: _____

Core Team: _____

PFMEA Number: _____

Page ____ of ____

Prepared by: _____

PFMEA Date (Original): _____

PFMEA Date (Revised.): _____

Process Step / Function	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Current Process Controls: Prevention	Occurrence	Current Process Controls: Detection	Detection	CN	RPN	Recommended Action(s)	Responsibility & Target Completion Date	Action Results: Actions Taken & Completion Date	Severity	Occurrence	Detection	CN	RPN

Total RPN (before action): ☐

Total RPN (after action): ☐

Microwave Popcorn Exercise

1. We will create a high-level Flow Diagram of the process in the Large Group.
2. We will identify each Process Step's Function and Requirements in the Large Group.
3. Small groups will then be assigned to identify Potential Failure Modes and Effects for one Process Step and linked Function-Requirements.

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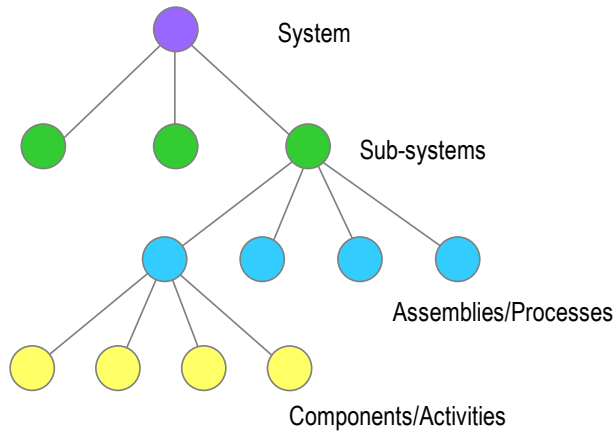
Where to Focus?

Proactive Design Approach

Start at System level to prioritize where to dig deeper in lower levels.



Start at Activity level and work bottom-up to address design issues.

Reactive Debug Approach

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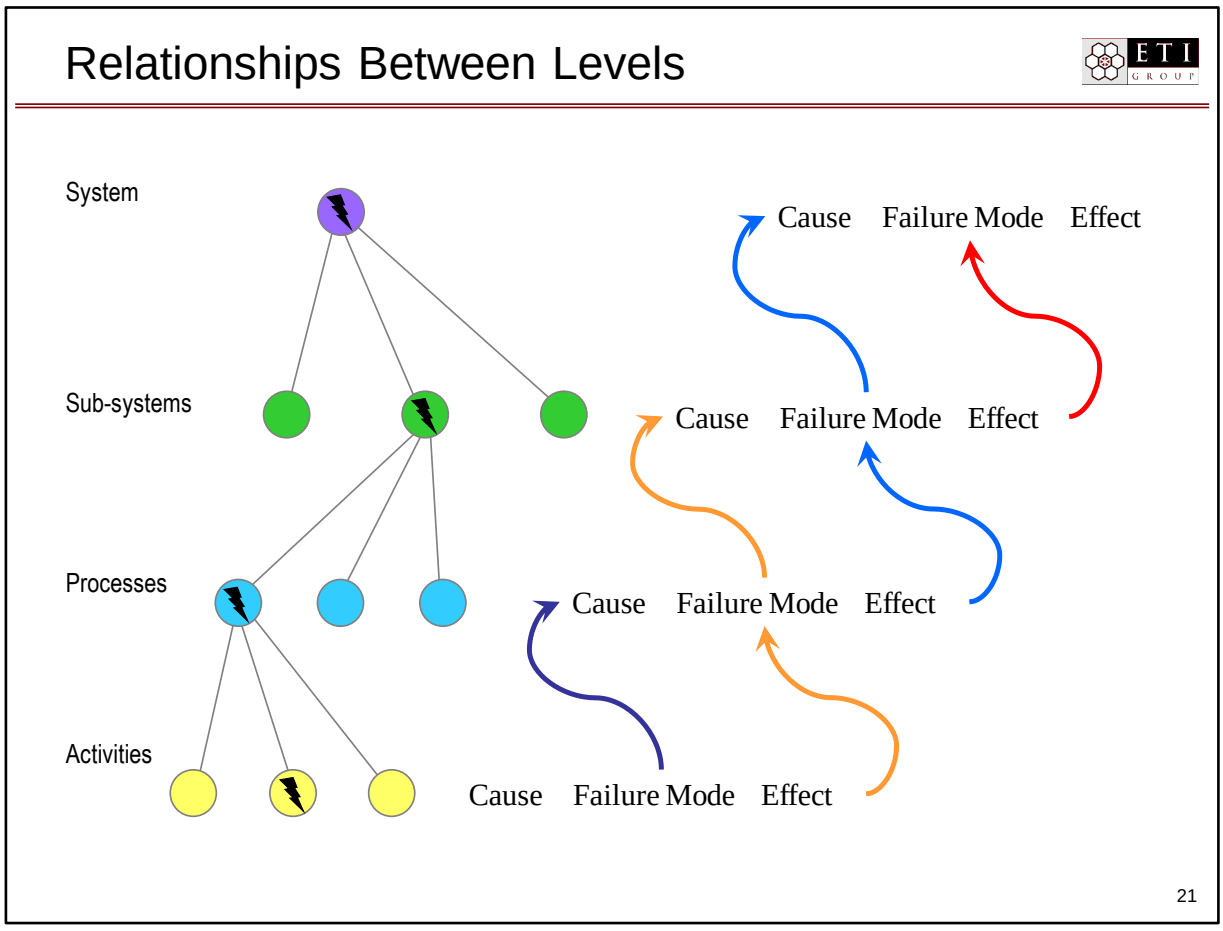
Each level relates to the others, especially for products manufactured with components nested within assemblies, which are then nested within sub-systems, which are then grouped together to form the system.

To use time most efficiently, create a hierarchy diagram as above to define context and relationships before diving into the details of the FMEA. And, consider whether to focus "top down" or "bottom up."

- The top down approach to FMEA is from a process design standpoint, looking forward and considering all possible failure modes in order to try to design them out or at least minimize their effects. As said in the slide, beginning at a higher level will help prioritize what to focus on in the process design/planning effort. Imagine if at the initial design/planning of a system, an FMEA was performed for all activities in all processes in all sub-systems…there could be an infinite number of possible failure modes identified! The analysis process would quickly become overwhelming and unmanageable.
- When "debugging" from the bottom up, there are typically data on actual errors to work from, either at the activity level or higher. What is learned here about process causes can inform the design of the next generation of processes, or trigger changes to existing ones.

Both approaches are needed. If only actual failures were used in a FMEA, other potential failures might get overlooked in the design/planning process.



Looking from the bottom up, the slide shows how a failure at a lower level may propagate up through the various levels and ultimately impact the system, with an effect on the customer.

The cause–failure mode–effect relationship between levels: the effects of failure modes at lower levels become the failure modes at the next level up; the failure modes at lower levels become the causes at the next level up.

As explained previously, the top down approach is used in a broader design sense. The particular failure mode shown propagating up here could certainly be identified at the beginning of a system level PFMEA. The difference being, it would likely be one of several possibilities considered.

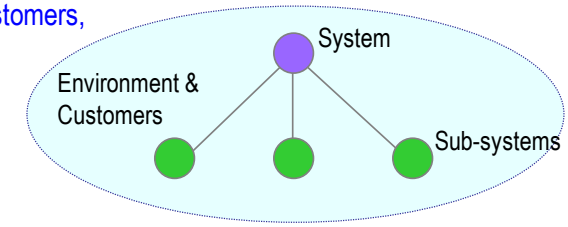
Where to Start?

Each level has functions and relationships unique to that item as a whole — its "emergent properties" — which are not present at lower levels.

Choosing a level (as opposed to jumping between levels in the same FMEA), provides an opportunity to identify failure modes unique to the interactions and interfaces that appear at that level alone.

A System level FMEA considers failure modes due to the interaction and interfaces between:

- ✓ the system and its environment and customers;
- ✓ the sub-systems within the system;
- ✓ the sub-systems and the environment and customers,
- ✓ as well as single-point failures.



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For any level, the above statement is true. For example, if a sub-system is chosen for analysis, it will have emergent properties not present in the individual processes. The interactions and interfaces of the sub-system with the environment/customers, of the processes within the subsystem, the processes with the environment/customer and single point failure will need to be considered (and so on down through the levels).

The idea is to set a *practical* boundary which will help in defining the Scope of the FMEA. Depending on an organization's role in the chain of design and/or manufacture and the associated "field of view," any operation could be considered a system, sub-system, process or activity. Take for example a powder-coating process: it could be an outsourced process in a higher level manufacturing flow, or the system itself if you are the Powder Coater.

In a Process FMEA, the interfaces and interactions to be considered are between the "6 M's" of the process: Machine, Method, Material, Measurement, Members, Mother Nature (aka Environment). For non-manufacturing processes, some equivalents for the 6 M's are: equipment (e.g., computer/IS system) for machine, inputs/information for material, feedback/reports for measurement, and work environment instead of physical environmental factors.

FMEA Scope

The Scope sets the boundary of analysis.

A clear scope needs to be written and understood by the FMEA team and Management.

It should answer the following questions:

- ✓ Is the focus design or debug (where is the product and/or process on the development–to–launch timeline)?
- ✓ What operation or area is to be covered by this FMEA (system, sub-system, etc.)?
- ✓ What is triggering the FMEA (new product/process, changed environment, etc.)?
- ✓ Who is the customer and what are the customer requirements?

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A FMEA can build on a previous one, especially for similar products, technologies, etc. Design and Process FMEAs will also inform each other.

If the FMEA is in response to a change, the scope can just focus on the particular change. For example, in the case of a machine or tooling modification, the FMEA could look at possible interactions resulting from the modification. An FMEA could be performed to assess the impact of a particular regulatory change; how a different operating environment could affect a process; how using an existing process on a new product could fail, etc.

The customer (and associated requirements) to be considered should follow from the purpose of the FMEA. For example: End User/Distributor (reliability or on-time delivery), OEM, Hub Sites or Supply Chain Assembly/Manufacturing Centers (downstream manufacturability), Regulators (environmental and safety compliance), Field Service (serviceability), etc.

It is also important to ask what is to be excluded from the Scope.

Diagramming the hierarchy (as shown previously) will be useful for initial scoping or refining scope once a team is assigned. Other helpful tools are: DFMEAs for product to be manufactured, Assembly Drawings, Process Flow Diagrams, Bills of Process (e.g., tooling and fixture lists), Interrelationship/Characteristic Matrices, etc.

Process Step/Functions

Definition: *Function is the intended purpose for a step which relates to a product/customer need or expectation.*

- This work starts off the analysis portion of the FMEA worksheet and is dependent on a clear Scope.
- List steps and interfaces with an amount of detail appropriate to the level being analyzed.
- May need to create a more detailed flow diagram of operation being analyzed.
  - ✓ Can also indicate flow of information, product
  - ✓ Use to understand inputs, function performed, outputs, interfaces
  - ✓ Identify product/process characteristics and sources of variation associated with each operation
  - ✓ Walk the process!

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The PFMEA worksheet uses the term "process step." Depending on scope, it could refer to a step on a system level, sub-system, process or activity.

The format here should follow from what is currently used for process documentation in order to link FMEA results to existing documentation. For example, an existing procedure may have numbered process steps that correspond to a text description of the function, or a flow diagram (aka process map) may show a process step with wording that adequately describes the function (e.g., clean part in degreaser).

Identify Functions

- Give a simple description of the step and its purpose
  - ✓ Apply surface coat to retard metal corrosion
  - ✓ Tighten bolt using torque wrench
- If there are multiple functions for a step, list each separately
- Perform a risk assessment on the process
  - ✓ Use knowledge of process, DFMEAs, past data to decide which steps need to be analyzed
  - ✓ Higher risk steps require PFMEA

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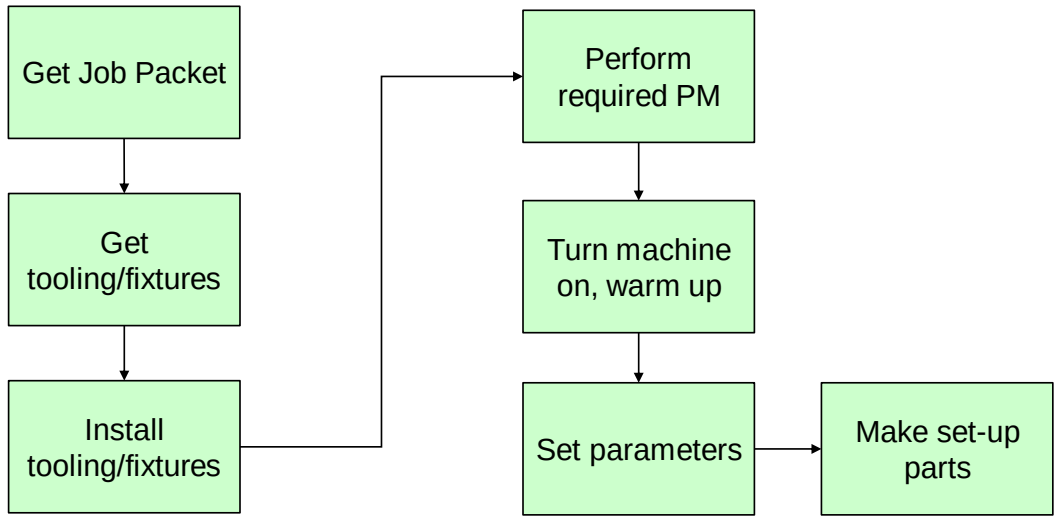
See Appendix for an example process flow diagram.

Example Flow Diagram



Risk Assessment — Example for Equipment Set-up

Process Step	Relative Risk
Get Job Packet	Low Risk
Get tooling/fixtures	Medium Risk
Install tooling/fixtures	High Risk
Perform required Preventive Maintenance	Medium Risk
Turn machine on, warm up	Low Risk
Set parameters	High Risk
Make set-up parts	Medium Risk

Requirements

Definition: *Necessary inputs/outcomes of a step which relate to product design intent and customer requirements.*

- List requirements for each function of the step being analyzed.
- If there are multiple requirements, write each one separately since they may have different failure modes.

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Requirements — Example for Equipment Set-up

Process Step	Relative Risk	Requirement
Get Job Packet	Low Risk	—
Get tooling/fixtures	Medium Risk	Specified tooling/fixture for job
Install tooling/fixtures	High Risk	Correctly place and align tooling/fixtures
Perform required Preventive Maintenance	Medium Risk	Daily PM (coolant fill, lubrication) Weekly/Monthly PM as required
Turn machine on, warm up	Low Risk	—
Set parameters	High Risk	Specified speed, pressure, feed rate
Make set-up parts	Medium Risk	Specified material per Bill of Material, Make per Assembly Drawing

Project Application Exercise #1

1. Choose a Focus for your FMEA — either Design (looking forward for a new process) or Debug (existing process with known issues, looking backward at process design).
2. Choose a Level for your FMEA — System, Sub-system, Process or Activity.
3. Name the operation you will analyze .
4. List a few steps in the operation along with their Functions.
5. For at least one of the steps, list Requirement(s) for each Function(s).

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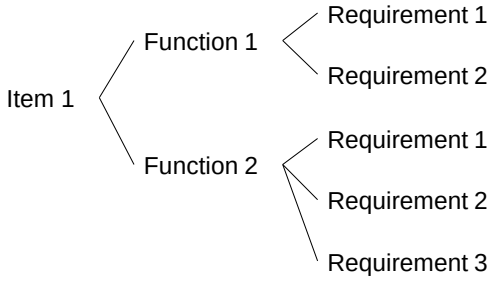
For system or sub-system level, the “steps” could be a few linked hand-offs between functional groups and/or processes.

PFMEA Tree for Exercise #1



Potential Failure Modes

Definition: *The manner in which a step could potentially fail to meet the requirements.*

- If requirements are well-defined, the Failure Modes will follow easily.
- Use a technical statement: think in terms of an observable physical event that could interfere with the process intent.
- For purposes of the analysis, assume that failure could occur ("potential" means it won't necessarily happen).
- Think about failure modes in terms of the Scope.
- List potential failure modes of each function/requirement.

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One assumption used is that the basic product design is correct, although the PFMEA may identify design changes that could eliminate or reduce a failure mode (e.g., consideration of tooling access, error proofing component placement, etc.).

Another assumption is that incoming materials are correct, unless historical data proves otherwise, and a consistent lack of capability must be considered.

Potential Failure Modes — Example for Equipment Set-up

Process Step	Relative Risk	Requirement	Potential Failure Mode
Get tooling/fixtures	Medium Risk	Specified tooling/ fixture for job	Wrong tool/fixture(s)
Install tooling/fixtures	High Risk	Correctly place and align tooling/ fixtures	Incorrect Install
Set parameters	High Risk	Specified speed, pressure, feed rate	Wrong parameters

Potential Failure Modes

- Types of failure mode:
  - ✓ Complete failure
  - ✓ Partial failure
  - ✓ Intermittent failure
  - ✓ Failure over time
  - ✓ Over-performance of function
- Categories help us avoid overlooking potential failure modes — consider each type.
- May also help point out if Functions are poorly defined.

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A large number of failure modes for a single function/requirement may be another clue that better definition is needed.

Brainstorming and Affinity Diagrams can be useful tools for coming up with failure modes.

Afterward, it can be helpful to review historical information for the operation (or a similar one) to validate the identified failure modes. Info can include past quality & reliability reports, field service reports, process control reports, test results, customer complaints, warranty data, etc.

Failure modes—Example

Initial Function Definition:

"Apply surface coat to retard metal corrosion."

Failure Mode categories:

Complete:	No coating
Partial:	Insufficient coating coverage
Intermittent:	One part has coating, next doesn't
Failure over time:	Gradual decrease/increase in coating thickness
Over-performance:	Too much coating

Poorly defined function:

- ✓ If there is too much coating, it over-performs but still meets the initial Function definition.
- ✓ Change definition to "Cover surface with minimum coating thickness to retard corrosion."

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Be specific—operator fails to connect tab vs. operator error; bearing fails vs. machine malfunction.

Examples of descriptors for failure modes:

– Bent	– Cracked	– Tool Worn	– Open circuit
– Short circuited	– Grounded	– Handling Damage	– Binding
– Improper Set-up	– Deformed	– Burred	– Dirty

Let's look at how a Failure Mode identified for the Equipment Set-up example could be expanded to include these 5 Failure Mode categories:

Potential Failure Modes — Example for Equipment Set-up

Process Step	Requirement	Initial Potential Failure Mode	Expanded Potential Failure Modes
Install tooling/ fixtures	Correctly place and align tooling/ fixtures	Incorrect Install	Complete: Partial: Intermittent: Failure over time: Over-performance:

Project Application Exercise #2

1. For the step you chose in Exercise #1, pick one of your identified function/requirements to use for this exercise.

2. Identify Potential Failure Modes of the function/requirement; consider all 5 types of Failure Modes:

   - Complete
   - Partial
   - Intermittent
   - Failure over time
   - Over-performance

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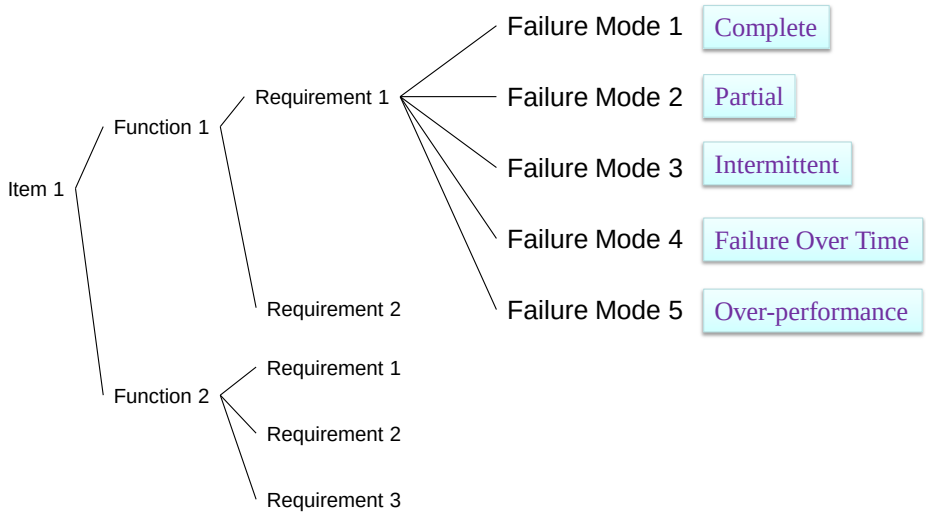
PFMEA Tree for Exercise #2



Potential Effects & Consequences

Definition: *Effects of the failure mode as perceived by the customer.*

- Non-technical statements that describe symptoms of the failure mode.
- List effects (and consequences) for each failure mode.
- Consider various levels of customers leading up to the End-user.
- Regardless of design specifications, consider what would be objectionable to the customer.
- Identify any safety or regulatory/legal impacts

Process Step	Failure Mode	Effect	Consequence to Customer
Apply surface coat	Gaps in surface coat	Unsatisfactory surface finish	Mfg: If detected, sorting & reworking needed End-user: Parts rejected or if used, later corrosion damage risk
Tighten bolt	Bolt too loose	Mechanical instability (part can swing on frame)	Mfg: Difficult to attach next part End-user: Parts can vibrate, will loosen over time and come apart causing product failure.

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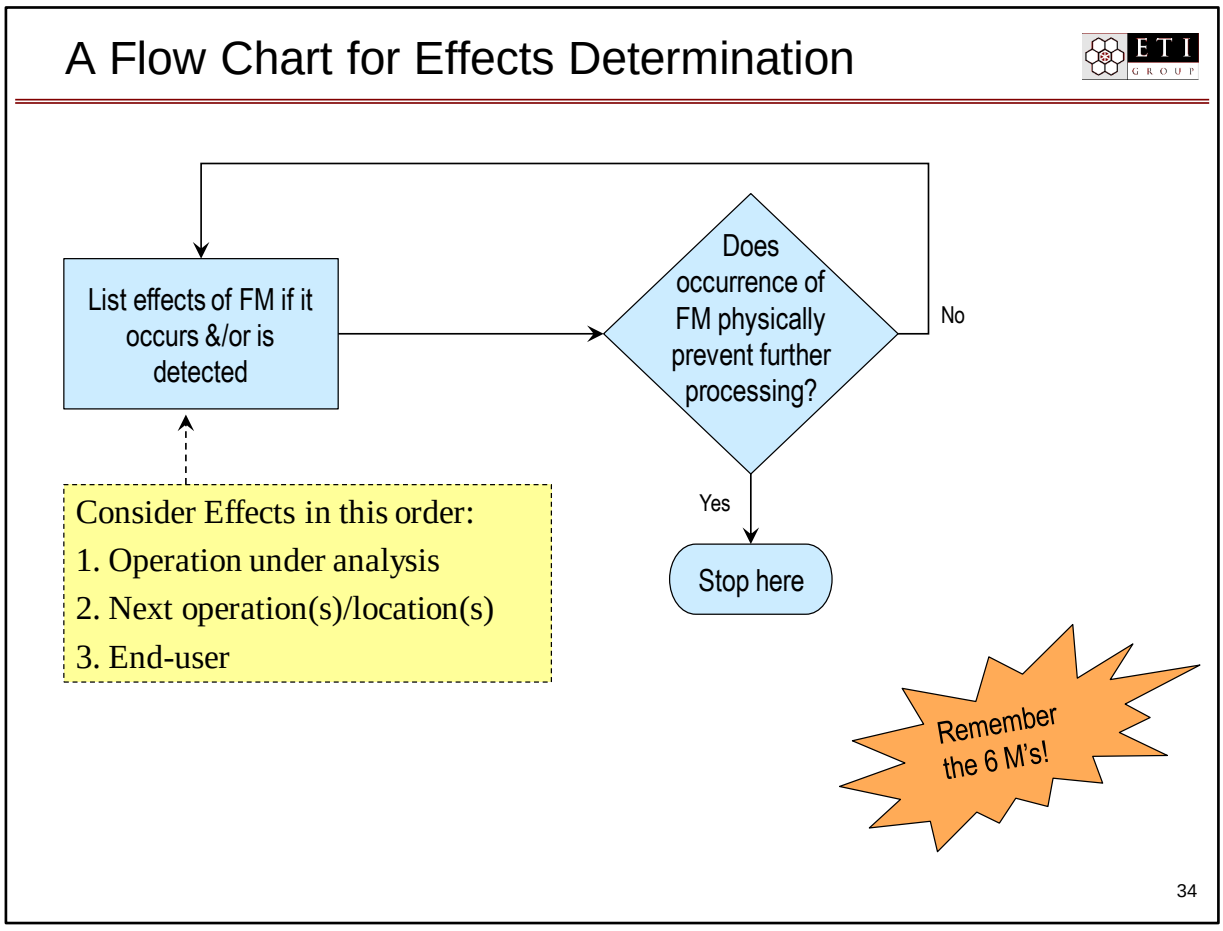
There can be multiple effects for each potential failure mode; list all effects and consequences.



FM = Failure Mode

The description of effects for the operation under analysis and any next operations (downstream assembly in-house or at other locations) should be stated in terms of process operation and performance.

End-user effects should be stated in terms of product effects, i.e., the consequences experienced with the product.

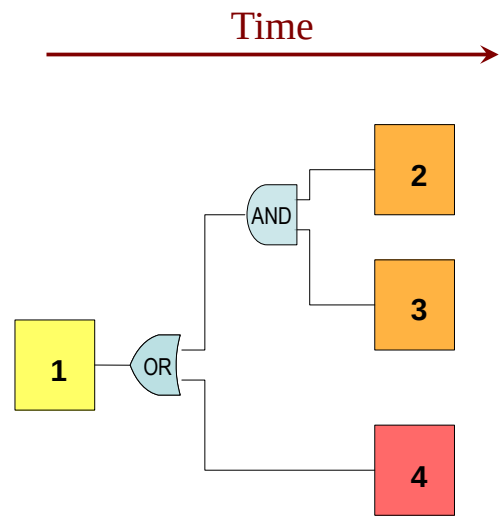
What might be some effects and consequences for the previously identified Failure Modes for the Equipment Set-up example?

Effects & Consequences — Example for Equipment Set-up

Process Step	Potential Failure Mode	Effects & Consequences
Get tooling/fixtures	Wrong tool/fixture(s)	
Install tooling/fixtures	Incorrect Install	
Set parameters	Wrong parameters	

Related Tool: Event Tree Analysis

- Visual representation of all the events that can occur in a system.
- Starts at a root event and follows what happens because of that event.
- Good tool to trace linking events to see consequences.
- Goal is to determine probability of a future event based on outcomes of prior events in the chronological sequence leading up to the event being considered.



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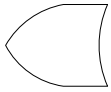

OR Gate: events 2 AND 3 OR event 4 will occur as a result of event 1.

AND Gate: events 2 AND 3 will happen together as a result of event 1.

Assigning Ratings

- Severity, Occurrence & Detection all based on 10 point scale.
- 1 is best case, 10 is worst case.
- Need clear, concise definitions for rating scale—as descriptive as possible.
- Establish before beginning rating process.
- Organization can customize rating scales or use industry standard scales:
  - ✓ Best to have company standards
  - ✓ Scales should be specific to product or process

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A five point scale may also be used.

Always “round” to higher value for rating numbers.

Any information on past nonconformities and lessons learned, data on quality, reliability, capability, customer complaints, warranty returns, etc. will be helpful in determining ratings. A survey of information available on best practices (such as guidelines and standards for manufacturing, identification and traceability, error proofing, etc.) will also help.

Severity Rating

Definition: *Value assigned to the most serious effect for a given failure mode.*

- First step in analyzing risk is to rank severity of effect and resulting consequences to the customer.
- Assume that effects will result given that failure mode has occurred
- Effects/consequences are rated as a group—most serious consequence establishes the rating ("worst case")
- Use experience, knowledge, expertise to decide.
- Rank is relative within the scope of the FMEA

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Severity ratings should be considered as appropriate for the various customer effects, both for in-house operations and the End-user. The final Severity rating will be the overall highest number.

Severity Rating—Manufacturing

	Rating	Description	Consequence	
5	10	Hazardous – no warning	Failure affects safe process operation (may endanger personnel or equipment) or involves noncompliance with government regulation. No warning of failure provided.	Failure to meet Safety &/or Regulatory Requirements
	9	Hazardous – with warning	Ditto above except failure occurs with a warning.	
4	8	Very High	100% of product may have to be scrapped. Line or shipment stoppage.	Major Disruption
	7	High	Portion of product may have to be scrapped. Deviation from primary process needed (change to process parameters/conditions, decreased production rate, additional resources required).	Significant Disruption
3	6	Moderate	100% of product may have to be reworked off-line and reverified.	Moderate Disruption
	5	Low	Ditto above except only a portion of product is affected.	
2	4	Very Low	100% of product may have to be reworked in-station before continuing processing.	Minor Disruption
	3	Minor	Ditto above except only a portion of product is affected.	
	2	Very Minor	Slight inconvenience during process operation.	Slight Disruption
1	1	None	No discernible effect.	No Effect

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When a portion of the product has to be reworked or scrapped, this action also implies sorting.

Severity Rating—End-user

	Rating	Description	Consequence	
5	10	Hazardous – no warning	Failure affects safe product operation or involves noncompliance with government regulation. No warning provided when failure occurs.	Failure to meet Safety &/or Regulatory Requirements
	9	Hazardous – with warning	Failure affects safe product operation or involves noncompliance with government regulation. Failure occurs with a warning.	
4	8	Very High	Product is inoperable with loss of Primary Function.	Loss or Degradation of Primary Function
	7	High	Product is operable but at a reduced level of performance.	
3	6	Moderate	Product is operable but convenience item(s) are inoperable.	Loss or Degradation of Secondary Function
	5	Low	Product is operable but convenience item(s) operate at a reduced level of performance.	
2	4	Very Low	Fit and finish or squeak and rattle item does not conform. Most customers notice defect.	Annoyance
	3	Minor	Fit and finish or squeak and rattle item does not conform. Average customers notice defect.	
	2	Very Minor	Fit and finish or squeak and rattle item does not conform. Discriminating customers notice defect.	
1	1	None	No discernible effect.	No Effect

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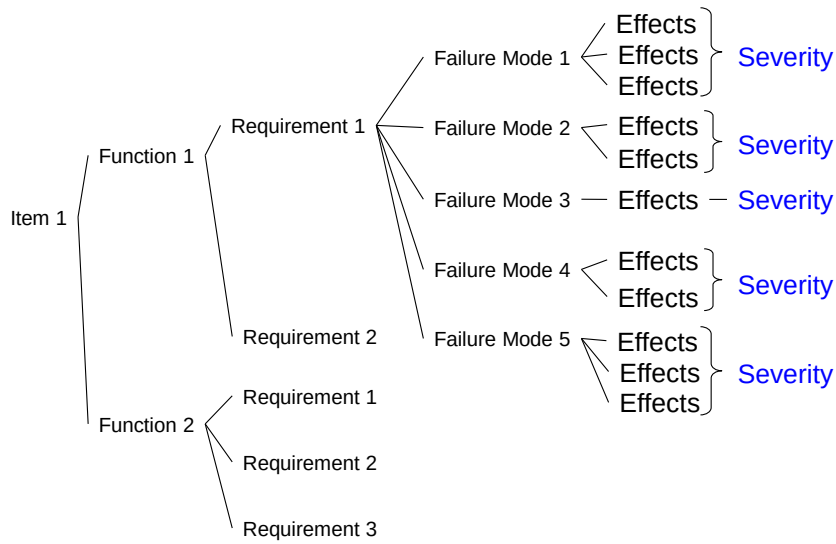
For service delivery applications, the “End User” rating scale is most appropriate; just think “service” for product and “deliverable” for “operable.”

Project Application Exercise #3

1. For each of the failure modes identified in Exercise #2, list the Effects. Consider effects for each of the different levels of customers leading up to the End-user.
2. For each linked Failure Mode and Effects chain (do at least 3), give a Severity Rating for both the manufacturing and End-user Effects.
3. Assign an *overall* Severity rating for each linked Failure Mode and Effects chain.
4. Use the Severity rating scales provided on the previous pages.

PFMEA Tree for Exercise #3



Potential Cause

Definition: *The condition that makes it possible for a failure mode to occur.*

- Real world failure modes often have multiple potential causes; list each one separately.
- Causes are potential — may or may not occur.
- Describe in terms that allow correction or control.
- Consider variation sources (remember the 6 M's).
- Begin with Failure Modes that have the highest Severity rating.

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Initially, focus on the immediate cause of the failure. The purpose at this point is to be able to determine Occurrence rating.

Deeper root cause analysis will be performed later on high priority causes (during the "Recommended Action" step).

The same assumptions regarding product design and incoming material/components used when determining failure modes apply here.

Potential Cause

- Be as concise and complete as possible.
- Good tools to use – Cause & Effect Diagram or Fault Tree Analysis.
- Example Causes:
  - ✓ Improper torque—over or under
  - ✓ Improper weld—current, time, pressure
  - ✓ Inaccurate gauging
  - ✓ Improper heat treat—time, temperature
  - ✓ Inadequate gating or venting
  - ✓ Inadequate or no lubrication
  - ✓ Part missing or wrong location
  - ✓ Wrong tooling/fixture

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Avoid generic, ambiguous phrases like “poor processing” or “operator error.”

See Appendix for an example Cause and Effect Diagram

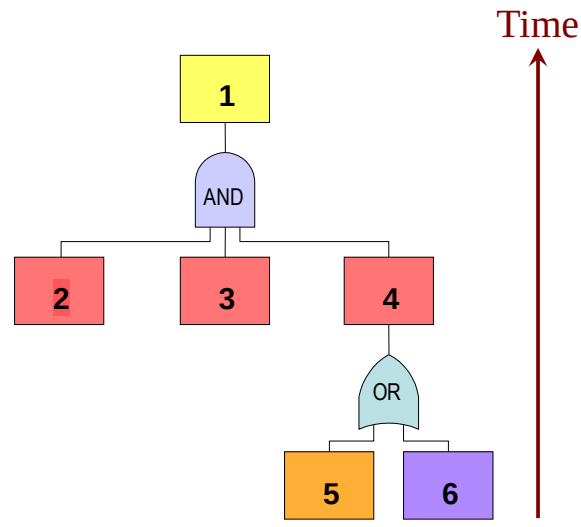
What might be some potential causes for the previously identified Failure Modes for the Equipment Set-up example?

Potential Causes — Example for Equipment Set-up

Process Step	Potential Failure Mode	Potential Causes
Get tooling/fixtures	Wrong tool/fixture(s)	
Install tooling/fixtures	Incorrect Install	
Set parameters	Wrong parameters	

Related Tool: Fault Tree Analysis

- Deductive, top-down method.
- Analyzes system design and performance.
- Specify top event to analyze and determine everything that would have to happen for event to occur.
- Makes use of logical AND and OR gates.
- Should analyze entire system as well as human interactions.



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AND Gate: events 2 AND 3 AND 4 have to happen for event 1 to occur.

OR Gate: event 5 OR 6 has to happen in order for event 4 to occur.

See Appendix for more details on FTA

Project Application Exercise #4-a

1. Choose a failure mode with a high Severity rating from Exercise #3.
2. Brainstorm potential Cause(s) of the Failure Mode(s).

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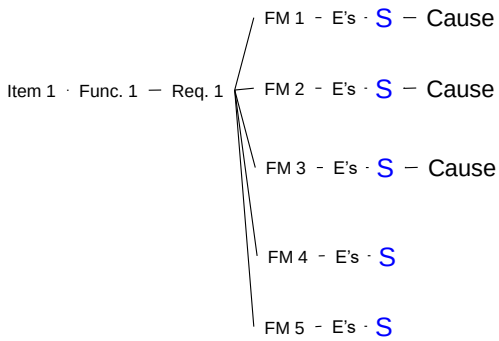
PFMEA Tree for Exercise #4-a



Current Process Controls — Prevention

Definition: *Process–level controls that eliminate (or reduce the rate of) the occurrence of a cause of a failure mode.*

- The occurrence rating will be affected by the preventive process controls.
- "Current" means have been used on same or similar process.
- Some Prevention Process Control Examples:
  - ✓ Statistical process control (SPC) charts
  - ✓ Error proofing of tooling/fixtures
  - ✓ Error proofing of data entry
  - ✓ Set-up sheets
  - ✓ Preventive and predictive maintenance
  - ✓ Operator training/qualification
  - ✓ Built-in equipment controls/protection features

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SPC can be considered a prevention control for a particular cause only if it is used real-time and can predict the occurrence of the *cause* before nonconforming parts are made (e.g., tool wear). This ability requires a thorough understanding of how process variation relates to product characteristics.

Occurrence Rating

Definition: *Likelihood that a particular cause will occur and result in the failure mode.*

- Occurrence rating is relative within the scope of the FMEA; it should not be confused with actual likelihood.
- Do not evaluate causes as a group—each cause gets its own occurrence rating.
- Consider:
  - ✓ Failure rates, service history, field experience with similar process
  - ✓ Whether item is a carryover from or similar to a previous process
  - ✓ If operation is new, significantly changed/different from previous process
  - ✓ Changes to application/operating environment, etc.
  - ✓ Results of reliability or other Engineering analysis

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Occurrence Rating

	Rating	Description	Failure Rate	C_{pk}	Likelihood of Failure
5	10	New technology/process with no history; failure is inevitable.	≥ 1 in 10	≥ 0.43	Very High
4	9	Significant failures associated with similar processes.	1 in 20	≥ 0.55	
	8	Regular failures associated with similar processes.	1 in 50	≥ 0.69	High
	7		1 in 100	≥ 0.78	
3	6	Frequent failures associated with similar processes.	1 in 500	≥ 0.96	Moderate
	5	Occasional failures associated with similar processes.	1 in 2,000	≥ 1.1	
	4	Isolated failures associated with similar processes.	1 in 10,000	≥ 1.24	
	3	Only isolated failures associated with almost identical processes.	1 in 100,000	≥ 1.42	Low
2	2	No observed failures associated with almost identical processes.	1 in 1,000,000	≥ 1.58	Very Low
1	1	Failure is eliminated through preventive process control.	cannot happen	NA	Remote

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Note: A C_{pk} value for a defect rate of zero is mathematically impossible, but for reference, a $C_{pk} = 2$ will give an estimate of 1 part per billion defective.

Project Application Exercise #4-b

1. Use the potential Cause(s) identified in Exercise #4-a.
2. List Preventive Process Controls for each potential Cause.
3. Give each Cause a likelihood of Occurrence using the rating scale provided on the previous page.

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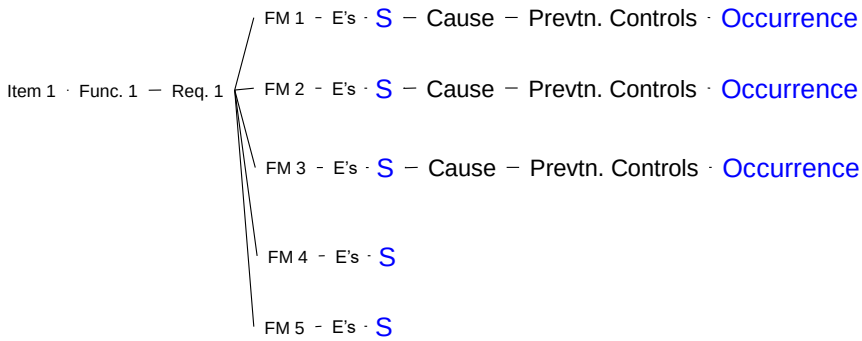
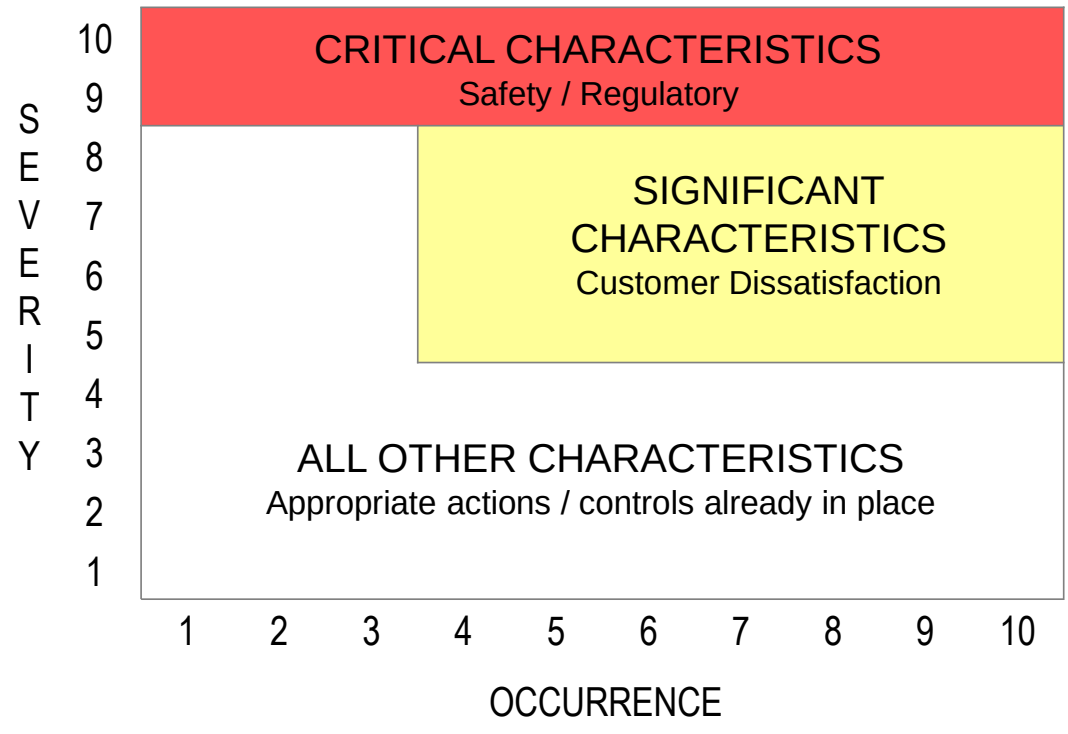
PFMEA Tree for Exercise #4-b



Identifying Special Characteristics



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Special Characteristic Definition:

Product characteristic or operational process parameter which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.

Implementation of Special Characteristics:

- Could be addressed as part of Risk Management activities
- May get identified with a designated symbol on drawings (e.g., functionally critical, automation/assembly critical, etc.)
- Could be added to plans for process control and test/inspection

General rule of thumb:

- Values of 9 & 10 (highest numbers) must be addressed
- Value of 1 should result in no further action

Project Application Exercise #5

1. Plot the Severity and Occurrence Ratings from previous exercises on the Severity x Occurrence Chart on the "Identifying Special Characteristics" slide.

2. Would your plots lead to the identification of any Critical &/or Significant Characteristics?

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Note: If using a 1 to 5 scale, first multiply ratings by 2.

Current Process Controls — Detection

Definition: *Controls that detect the cause of failure or the failure mode after they have happened and which lead to controls for nonconforming product.*

- Detection controls affect the Detection rating.
- "Current" means have been used on same or similar process.
- Some Detection Process Control Examples:
  - ✓ Inspection/test at or downstream from operation
  - ✓ Final product acceptance inspection/testing
  - ✓ Measurement validation at set-up (torque, pressure, temperature, etc.)
  - ✓ On-line go/no-go sensors
  - ✓ Automated on-line visual inspection

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Detection controls may happen at an operation or any time before product is sent to an external (paying) customer.

SPC cannot be considered a detection control because it uses process sampling and is not intended for sorting nonconforming product.

Detection Rating

Definition: *Rank given to the best current detection process control.*

- Detection rating is relative within the scope of the FMEA, it is not a guarantee of performance.
- Assume that the failure mode has taken place and assess the ability of the detection process controls to find it.
- Do not evaluate causes as a group—each cause gets its own detection rating.
- If there are multiple detection process controls for a cause, list a rank next to each but record only the lowest number (best control method) in the Detection column.
- Do not presume that detection rank is low if occurrence rank is low, these are two different things!

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Detection Rating

	Rating	Description	Likelihood of Detection
5	10	No current process control; cannot detect cause/failure mode or is not analyzed.	Almost Impossible
5	9	Cause/FM is not easily detected (e.g., random audits of process conducted).	Very Remote
4	8	FM checked for by opr post-processing through visual/tactile/audible (v/a/t) technique.	Remote
4	7	FM checked for in-station by opr through v/a/t technique or post-processing through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.).	Very Low
4	6	FM checked for post-processing by opr through use of variable gauging or in-station by opr through use of attribute gauging (see examples above.).	Low
3	5	FM/Cause checked for in-station by opr through use of variable gauging or by automated controls in-station that will detect N/C part & notify opr (light, buzzer, etc.). Set-up causes only: Gauging performed on set-up & first-piece check.	Moderate
3	4	FM checked for post-processing by automated controls that will detect N/C part & lock part to prevent further processing.	Moderately High
3	3	FM checked for in-station by automated controls that will detect N/C part & automatically lock part in station to prevent further processing.	High
2	2	Cause checked for in-station by automated controls that will detect error & prevent N/C part from being made.	Very High
1	1	Cause prevented due to design of fixture/tooling/machine/part. N/C parts cannot be made because of error-proofing of process/product design.	Almost Certain

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FM = Failure Mode

Opr = Operator

"Visual/Audible/Tactile" (v/a/t) techniques could be an operator looking at parts as they come off a machine, running a hand over a surface to check for burrs, listening for a correct/incorrect sound or other "human senses" checks.

Project Application Exercise #6

1. For the same cause(s) identified in Exercise #4, list Process Controls that would Detect each failure mode or cause(s).
2. Rate each Detection Process Control with a likelihood of its ability to detect the failure mode or cause(s).
3. Use the Detection rating scale provided on the previous page.
4. If there is more than one Detection Control per cause, list each, but use lowest (best) ranking for the final Detection number.

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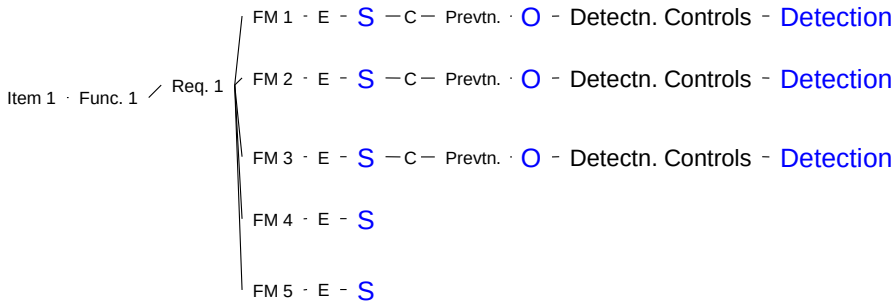
PFMEA Tree for Exercise #6



Risk Priority Number (RPN)

RPN is a *relative* measure of risk

RPN = Severity x Occurrence x Detection

Like a golf score, lower is better

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RPN Cautions

- RPN is distorted because of non-linear scales in different individual scales.
- Severity, Occurrence and Detection are weighted equally.
- Incorrect assumptions:

Incorrect Assumption	Actual Statistical Data
The average of all RPN values is roughly 500	The Average RPN value is 166
Roughly 50% of RPN values are above 500 (the median is near 500)	6% of all RPN values are above 500 (the median is 105)
There are 1000 possible RPN values	There are 120 unique RPN values

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It is important to remember that the RPN is:

- A relative number
- Not a calculated reliability metric
- Not continuous data

RPN Conclusions

- RPN should be used as a guideline to rank concerns, aid dialog and prioritize action.
- High Severity values merit special attention, especially if coupled with high Occurrence values.
- The Criticality Number (CN = S X O) is an additional tool to use.

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The Criticality Number is what gets plotted on the “Special Characteristics” chart shown earlier.

RPN vs. CN — Example

Severity	Occurrence	Detection	CN	RPN
8	6	1	48	48
1	6	8	6	48

RPN = S x O x D
CN = S x O

- RPN, alone, can be misleading.
- Should calculate both CN and RPN and use together for ranking issues.
- Use of a threshold or cutoff value for action is *not* recommended.

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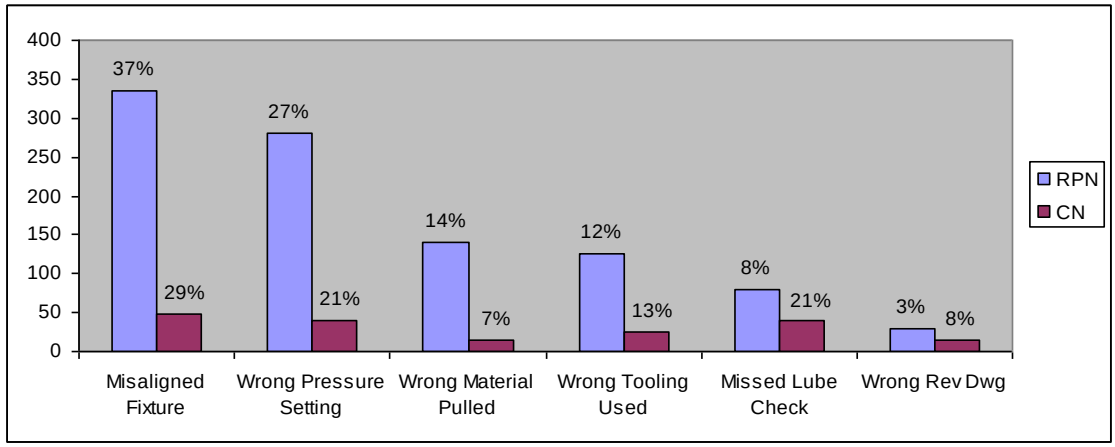
While it may seem helpful to establish a "cutoff RPN," there is a risk of driving the wrong behavior and not taking action when it is merited.

As mentioned before, RPN and CN are helpful in ranking priorities. Action should then proceed on the basis of which risks are most important to mitigate, given the time and resources available.

Prioritizing Failure Modes — Example

RPN/CN Pareto chart for Equipment Set-up



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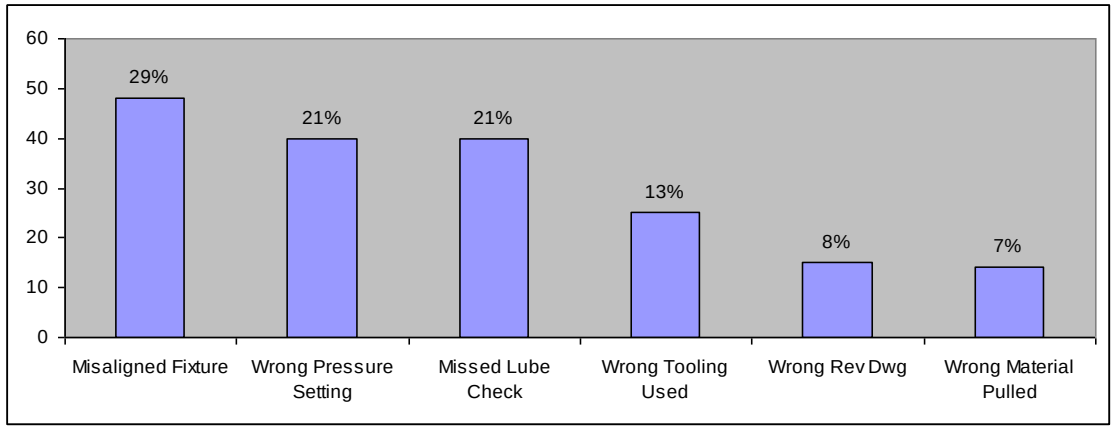
Which failure modes account for 80% of the total RPN?

Raw Data for Pareto Chart—Equipment Set-up Failure Modes

Category	Severity	Occurrence	Detection	RPN	% RPN	CN	% CN
Misaligned Fixture	8	6	7	336	37%	48	29%
Wrong Pressure Setting	8	5	7	280	27%	40	21%
Wrong Material Pulled	2	7	10	140	14%	14	7%
Wrong Tooling Used	5	5	5	125	12%	25	13%
Missed Lube Check	10	4	2	80	8%	40	21%
Wrong Rev Dwg	3	5	2	30	3%	15	8%
Total RPN				991		182	

Prioritizing Failure Modes

Pareto chart of CN Only for Equipment Set-up



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Which failure modes would be selected if the top 80% were used?

How do the top three failure modes compare between RPN and CN?

Raw Data for Pareto Chart—Equipment Set-up Failure Modes

Category	Severity	Occurrence	Detection	CN	% CN
Misaligned Fixture	8	6	7	48	29%
Wrong Pressure Setting	8	5	7	40	21%
Missed Lube Check	10	4	2	40	21%
Wrong Tooling Used	5	5	5	25	13%
Wrong Rev Dwg	3	5	2	15	8%
Wrong Material Pulled	2	7	10	14	7%
Total RPN				182	

Project Application Exercise #7

1. Calculate CN and RPN for your Ratings.
2. Calculate total CN and RPN (and sketch Pareto charts as desired).
3. What would your priorities be?

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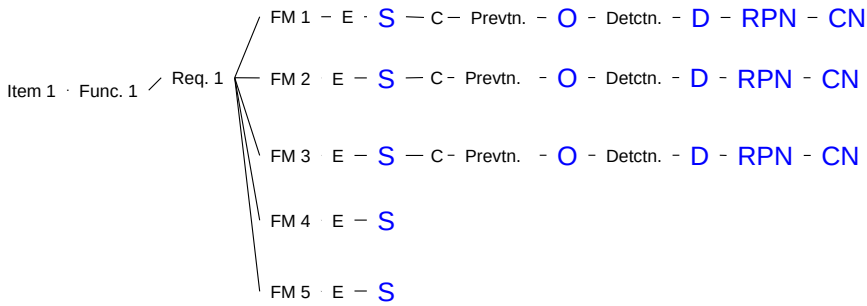
PFMEA Tree for Exercise #7



Reducing Risk

- Fundamental purpose of performing FMEAs is to recommend and take actions that reduce risk.
- Direct actions at critical items and highest ranked items.
- Can reduce risk by lowering Severity, Occurrence, or Detection rating.
- Decisions & action taken should be noted on FMEA worksheet.

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This is the time to dig deeper into the causes and the reasons they occur. Earlier work on cause determination can be revisited at this point, especially if Cause and Effect Diagrams, Fault Tree Analysis or other tools were used.

The “Five Why’s” is another helpful technique for getting to root causes. Brainstorming, Affinity diagrams and data collection/analysis can also be used both for investigating causes and generating ideas for preventing their occurrence.

If no recommended action is taken on a particular failure mode/cause/control chain, it may be helpful to future readers (and prudent in the case of external customers/regulators) to give the rationale (especially for steps with a high severity rating).

Possible Actions to Reduce Ratings

Reduce rankings in this order

Severity	Occurrence	Detection
• Design Revision to: ✓ Improve design of process/product ✓ Compensate or mitigate severity of failure • Change application &/or field environment	• Design Revision to remove or control cause: ✓ Error proof product/process ✓ Revise design geometry & tolerances ✓ Fail safe process design ✓ Increase Cpk through Design of Experiments (DOE) &/or equipment modification	• Improve knowledge of dominant causes of process variation (special & common) & interactions (DOE, reliability testing) • Ensure the measuring devices are accurate and precise (regular calibration and gauge studies) • Ensure Preventive Maintenance performed • Parts/component change to make detection easier

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Severity can often be difficult to impact, especially so once a product design has been released or a process has been implemented. Making a process/product design revision does not automatically mean severity will be reduced. For best success with reducing severity, FMEAs should be performed early in the development process.

Improving and/or increasing detection controls (e.g., inspection/test) is generally costly and not as effective as preventive controls, even though this technique is very typical in many organizations. Increased inspection/test could be used temporarily to gather sufficient data to study significant factors in process variation (but a Designed Experiment would be better!).

Improving employee and customer (downstream, end user) training may impact all three rankings.

Example Actions

Reduce rankings in this order

Severity	Occurrence	Detection
Process design change: • Personal protective equipment (e.g., hard hats, side shields on safety glasses, full face protection, ventilators, etc.) • Safety stops or emergency shut-off's • Use of different materials (e.g., safety glass, chemical alternatives) that will not cause as severe an injury Product design change: • Choose product components/materials that won't be damaged by processing conditions	• Engaging mechanism that must be activated for machine to work (e.g., lawnmowers with handle that must be held to run) • Automated feedback loop between a product characteristic and process parameter • Total Predictive Maintenance (TPM) to replace tooling, bearing, etc. before Production parts become nonconforming • See also section on Prevention Process Controls for ideas	• Use coding (colors, shapes, sounds) to alert the operator that something is either right or wrong • See also section on Detection Process Controls & the Detection Rating Scale for ideas

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Project Application Exercise #8

1. If resources were not an issue, what would be some recommended actions for the priorities identified in Exercise #7?

2. Imagine that these actions were taken. Revisit the Severity, Occurrence and Detection Ratings and revise them as appropriate.

3. Recalculate CN and RPN.

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Following Up

RPN should be recalculated after recommended actions are taken and proven to be effective.

Evaluation could include:

- Ensuring that Process Capability goals are achieved.
- Confirmation studies (DOE, reliability) to confirm solution and assure changes have not introduced new failure modes.
- Reviewing changes made to floor layout, machine/tooling/fixture specifications, bills of process, preventive maintenance plans, etc. to confirm changes.
- Confirming changes to standards, guidelines, procedures (including process flow diagrams, work instructions, etc.), process control plans and other documentation.

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FMEA Management

Use Process FMEA recommended actions for ongoing control:

- Identify special characteristics and parameters.
- Ensure prevention and detection controls continue to be used.
- Develop process control and inspection/test plans.
- Provide feedback and ideas for product design

Periodically review FMEA:

- Validate/revise estimates through post launch data (internal and external).
- Pay special attention to occurrence and detection ratings.
- Revisit FMEA whenever a process change occurs.
- Maintain revision control.

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Think of FMEA as an iterative continuous improvement tool.

See the Appendix for more information on quality planning.

Summary of Process FMEA

- Goals:
  - ✓ Identify potential process failures
  - ✓ Assess customer effects of failure
  - ✓ Identify process causes and variables to focus controls
  - ✓ Reduce severity and/or occurrence or increase detection
  - ✓ Develop prioritized list of issues to correct/improve
  - ✓ Record thoughts, decisions and plans as product is designed
- Should include all operational and support processes
- "Customer" is End User and down-stream operations
- Parallels, formalizes and documents engineering mental disciplines
- Perform on all new processes, changed processes, and processes used in new applications or environments
- Assumes product, as designed, will meet the design intent
- Does not rely on product design changes to overcome process weaknesses (but does consider product's characteristics)

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Key Elements of FMEA

Timeliness	Performed early and continuously throughout the development cycle to reduce risk of failure and decrease product/process design changes late in the development cycle.
Teamwork	Conducted by a team of people with diverse experience and expertise (including customer representation if possible).
Knowledge	Provides a structured "living" document to be updated throughout the design and development process — records the basis for design decisions and process controls. An excellent tool for continuous improvement.

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Appendix

FMEA Team Start-up Sheet

FMEA Number: _____ Date Started: _____

Date Completed: _____

Team Members: _____ _____ _____

_____ _____ _____

_____ _____ _____

Team Leader: _____

1. Are all affected areas represented on the team?

   YES NO Action: _____

2. Are different levels and types of knowledge represented on the team?

   YES NO Action: _____

3. Is the customer involved?

   YES NO Action: _____

4. Who will take minutes and maintain records? _____

FMEA Team Boundaries of Freedom

5. What aspects of the FMEA is this team responsible for?

FMEA Analysis	Recommendations for Improvement	Implementation of Improvements

6. What is the budget for the FMEA? _____
7. Does the project have a deadline (provide if Yes)? _____
8. Do team members have specific time constraints? _____
9. What is the process to follow if the team needs to expand beyond these boundaries? _____

   _____

10. How should the FMEA results be communicated to others? _____

    _____

    _____

11. What is the scope of this FMEA? (be specific and include a clear definition of the process or product to be studied) _____

    _____

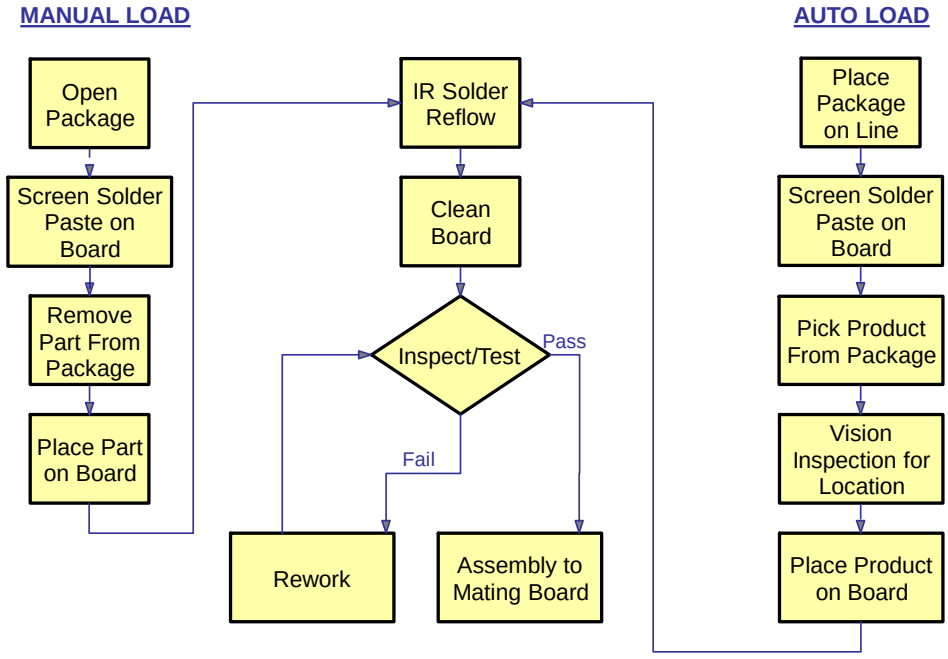
    _____

    _____

    _____

Process Flow Diagram — Example

Customer process for board-to-board SMT connector



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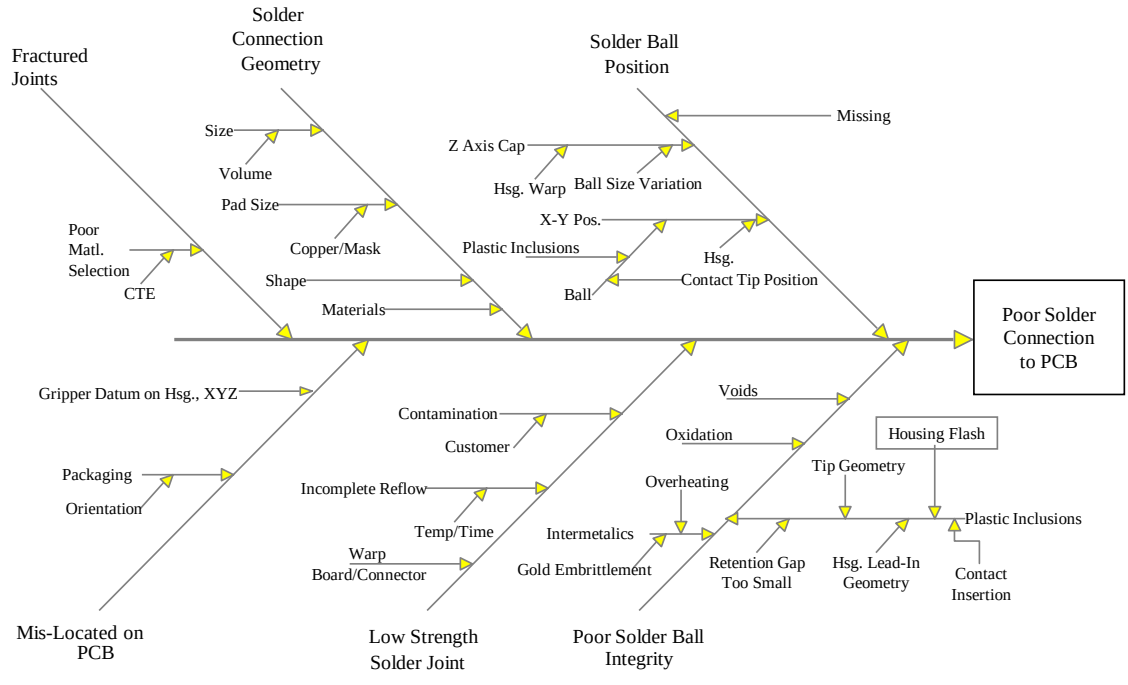
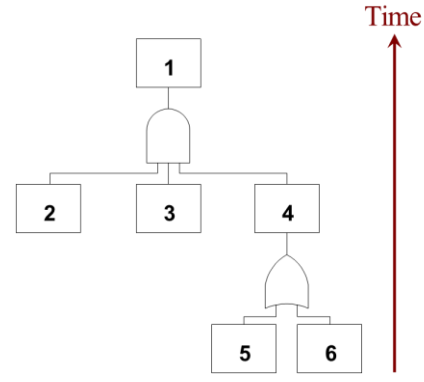
Cause-and-Effect (Fishbone) Diagram — Example



This diagram is an example of how an organization used the potential causes of a failure mode determined during an FMEA session to create a trouble-shooting guide. It is not a "classic" C & E Diagram because while it has a typical "effect" — in this case "poor solder connection to a printed circuit board" — it does not use the typical "6M" sources of process variation (Machine, Method, Material, Measurement, Members, Mother Nature/Environment). For the organization, it was a format that operators were already familiar with, so they chose to show it using the "bones" of the diagram for different cause categories. Any number of formats could be used; what's important is to consider how the results of the FMEA work can be used to assist in ongoing process control efforts.

Fault Tree Analysis

- Fault Tree Analysis originated with Bell Labs
- Element of Failure Modes & Effects Analysis
  - ✓ Used to analyze all possible causes of a particular failure mode
- In practice, it looks like a combination of tools
  - ✓ Kepner Tregoe
  - ✓ Cause & Effect Diagrams
  - ✓ The 5 Whys
- Powerful graphical tool that is easy and intuitive to use



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AND Gate: events 2 AND 3 AND 4 have to happen for event 1 to occur.

OR Gate: event 5 OR 6 has to happen in order for event 4 to occur.

Method is deductive, top down, where #1 above is the Failure Mode and subsequent numbers are possible causes.

Logical AND and OR gates are used to show everything that would have to happen for the failure mode to occur.

A systems view should be considered and include human interactions (think in terms of the 6 M's).

Where Do You Start?

Start by asking “What could cause this Failure Mode?”

- Think about causes that could occur separately (OR gates)
- Consider combinations of errors/failures that would occur together (AND gates)
- May need to “walk the process”
- Use historical data and experience
- Lay out the Fault Tree Diagram showing the possible causes in sequence to each other, starting at the top level and drilling down (sticky notes are helpful)

Example: Fault Tree — 1st Level Analysis

- What's The Problem?
  - ☑ Lathe turned part has poor surface finish in ID of wall.
- Possible Causes?
  - ☑ Wrong Material Specified (Design FMEA)
  - ☑ Wrong Tool (Process FMEA)
  - ☑ Tool Chatter (Process FMEA)

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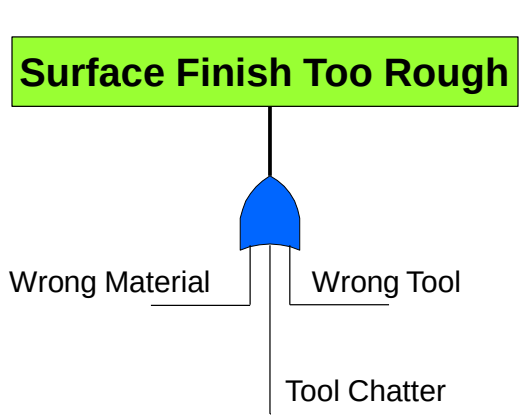
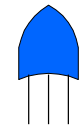
Fault Tree — 1st Level Layout





1	2	3	Fail?
T	T	T	T
F	F	F	F
T	T	F	T
F	F	T	T
T	F	F	T
F	T	F	T
T	F	T	T
F	T	T	T

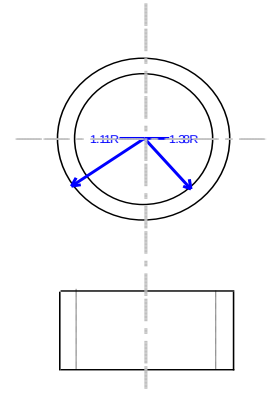
Or Gate

78

A table of possible combinations may be a helpful aid to discussion, to determine whether an “OR” and “AND” situation is present. A “T” means the condition is “true,” i.e., present. “F” means it is not present. As shown above, if situation 1, 2, or 3 is present, the Failure Mode will be present. The causes are not dependent on each other, therefore an “OR” gate is appropriate.

Fault Tree — 2nd Level Analysis

- Wrong material specified
  - ☑ Incorrect Alloy
  - ☑ Incorrect Temper
- Wrong Tool
- Tool Chatter
  - ☑ Wrong Feed Rate
  - ☑ Machine Problem



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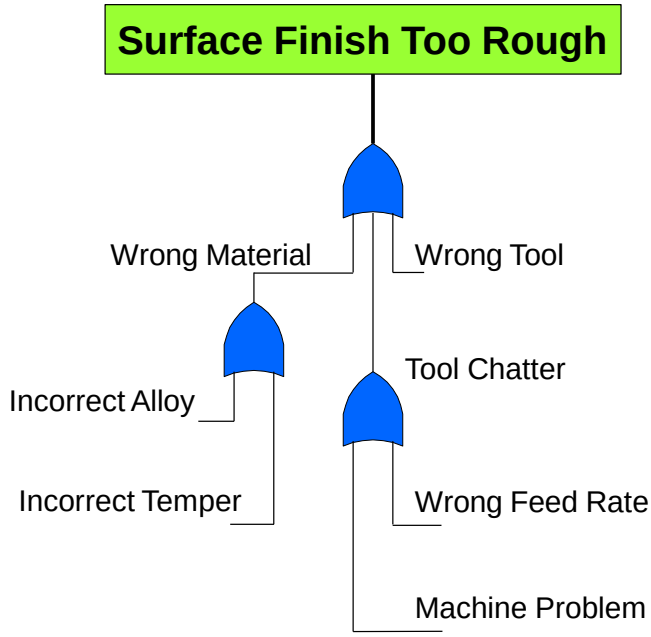
Fault Tree — 2nd Level Layout



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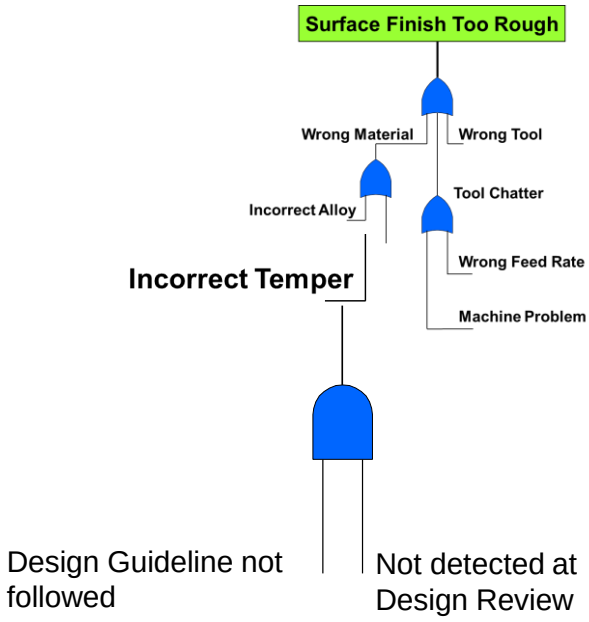
Fault Tree — 3rd Level for Wrong Material (DFMEA)



1	2	Fail?
T	F	F
F	T	F
T	T	T
F	F	F

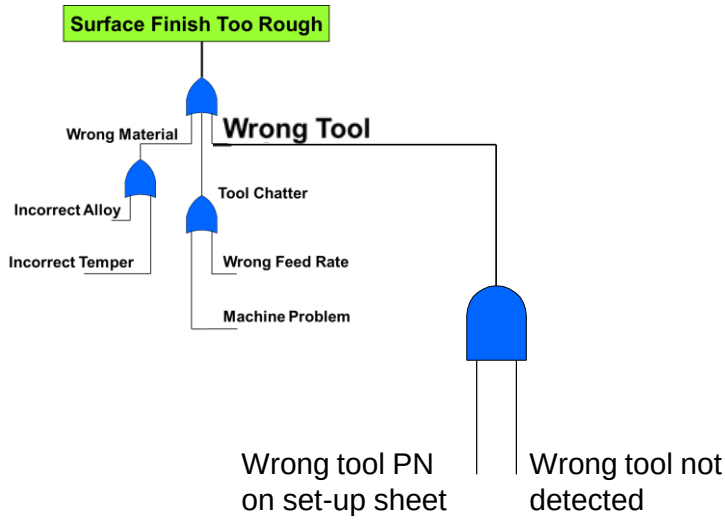
And Gate

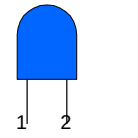
81

Here, the table for the "AND" gate shows the dependency between the two sub-causes for Incorrect Temper — both have to be true in order to result in a failure.

This example just shows one path. The analysis could continue to drill down further into causes for the path shown and the other causes.

Fault Tree — 3rd Level for Wrong Tool (PFMEA)





1	2	Fail?
T	F	F
F	T	F
T	T	T
F	F	F

And Gate

82

Here, the table for the "AND" gate shows the dependency between the two sub-causes for Wrong Tool— both have to be true in order to result in a failure.

This example just shows one path. The analysis could continue to drill down further into causes for the path shown and the other causes.

Quality Planning with FMEA

- Product & process planning and risk management:
  - ✓ Should follow a structured method
  - ✓ Define and establish the steps needed to assure product satisfies the customers' requirements
  - ✓ Should be an integrated system – design leading into process planning
  - ✓ Can use analytical techniques such as DOE, Value Engineering, simulation, Computer Aided Engineering (CAE), etc.
- Process control plan:
  - ✓ Aids in producing product that meets requirements
  - ✓ Goal is to minimize variation
  - ✓ Structured approach for design, selection & implementation of value-added control methods for total system
  - ✓ Use a team approach with people experienced on similar product/process
- Design & Process FMEAs are important tools to use as part of the planning process.

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Take advantage of the Rule of 10's!

Manufacturing Process FMEA — Example for Equipment Set-up

Item/Operation Area: Equipment Set-up

Level: ☐ System ☐ Sub-System ☑ Process ☐ Activity

Description: Set-up of the bifurculator machine used on the dimidiator product.

Scope: Will analyze process from when a job packet is pulled (although the job packet creation process will be covered by a different PFMEA) through the production of set-up parts. Set-up part inspection is excluded from this scope and will be performed as a separate PFMEA.

Core Team: B.E. Kinde (QA), T.U. Aahl (Mfg. Engr.), Y.R. Freundz (Maint.), E.V. Ridai (Mfg. Lead)

PFMEA Number: 20XX-572-002

Page 1 of 1

Prepared by: B.E. Kinde

PFMEA Date (Original): 4-8-20XX

PFMEA Date (Revised.): 6-12-20XX

	Process Step / Function	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Current Process Controls: Prevention	Occurrence	Current Process Controls: Detection	Detection	CN	RPN	Recommended Action(s)	Responsibility & Target Completion Date	Action Results: Actions Taken & Completion Date	Severity	Occurrence	Detection	CN	RPN
Low Risk	1. Get Job Packet	(not addressed in this PFMEA)																		
Medium Risk	2. Get tooling & fixtures	Specified tooling/fixture for job																		
High Risk	3. Install tooling & fixtures	Correctly place and align tooling/fixtures	Misaligned fixture	Damage to tool/fixture, product out of spec. &/or damaged, unable to process at next station	8	Inaccurate measurement of fixture to mounting plate	Operator qualification	6	Tool "crashes" as it comes down on material; Visual inspection of set-up parts	8	48	384	Automated gauging that gives a green light signal when fixture is aligned properly; update work instructions and operator training.	Gauging-T.U. Aahl, Y.R. Freundz Doc.'s & Training-E.V. Ridai	Auto'd gauging installed and validated 5-15-20XX; updated WI's released 5-17-XX; all operators trained and qualifed by 6-1-20XX	8	3	5	24	120
					8	One or more bolts too loose	Operator qualification	5	Fixture rattles upon tool impact; Visual inspection of set-up parts	8	40	320	Use a torque wrench to assure proper setting; update work instructions and operator training.	Wrench-B.E. Kinde Doc.'s & Training-E.V. Ridai	Torque wrenches purchased and calibrated by 4-30-20XX; updated WI's released 5-3-20XX; all operators trained and qualifed by 5-15-20XX	8	3	5	24	120
Medium Risk	4. Perform required PM	Daily PM (coolant fill, lubrication)																		
Low Risk	5. Turn machine on, warm up	Weekly/Monthly PM as required																		
High Risk	6. Set parameters	Specified speed, pressure, feed rate	Pressure set too high	Excessive tool/fixture wear, flaring of product edges requiring off-line grinding (MFG S= 6); won't mate to subassembly at customer location (Cust. S=8)	8	Pressure indicated by dial, difficult to interpret	Operator qualification; Pressure parameter specified on set-up sheet	7	Operator slides hand over part edge to check for flaring on set-up parts	8	56	448	Install digital pressure read-out; re-train operators; WI adequate as is	Pressure Instrumentatn-T.U. Aahl, Y.R. Freundz Training-E.V. Ridai	Pressure read-out installed and validated 5-15-20XX; all operators trained and qualifed by 5-18-20XX	8	2	5	16	80
Medium Risk	7. Make set-up parts	Specified material per Bill of Material																		
		Make per Assembly Drawing from Job Packet																		

Total RPN (before action): 1152

Total RPN (after action): 320

Transactional Process FMEA — Example for Review of Customer RFQ

Item/Operation Area: Customer Order Review

Level: ☐ System ☐ Sub-System ☑ Process ☐ Activity

Description: Process for the review of customer Request for Quote (RFQ)

Scope: Includes review of customer requirements for new RFQs
Does not include existing product or Legal/Finance review of customer contract Terms and Conc

Core Team: W.E. Kanduit (Sales Mgr.), Ona Time (Inside Sales), Noah Prablym (Inside Sales), Reina M. Ahlin, (Quality Mgr.)

PFMEA Number: 20XX-572-002
Page 1 of 1
Prepared by: W.E. Kanduit
PFMEA Date (Original): 3-8-20XX
PFMEA Date (Revised.): 6-12-20XX

	Process Step / Function	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Current Process Controls: Prevention	Occurrence	Detection	Detection	CN	RPN	Recommended Action(s)	Responsibility & Target Completion Date	Action Results: Actions Taken & Completion Date	Severity	Occurrence	Detection	CN	RPN
Low Risk	1. RFQ/PO received & confirmed	Communicate with customer																		
Medium Risk	2. File customer data package	Correctly vault data files in customer folder on network	incorrect location used	next step(s) delayed due to search; files lost	3															
Medium Risk	3. Review customer data files	Ensure all needed info is received	fail to ID missing/needed info	next step(s) delayed while info being provided	4															
High Risk	4. Review customer requirements	Determine requirements not stated but considered necessary by us.	fail to ID necessary requirements	Later discovery causes delays, extra cost, product failure	8	lack of knowledge, oversight, failure to consult more knowledgable person, in a hurry	Procedure lists things to consider and option to consult others.	6	Sales Mgr. reviews Quotes before they're sent, if time allows. Will review more often for new people.	7	48	336	Develop S/W application that guides the review and gives examples, requires sign-off by assigned "functional expert," will not allow Quote creation unless all fields completed.	Outsourced provider in consultation with internal cross-functional team that includes Product and Mfg. Engr., Production Mgr., Quality Mgr., Purchasing Mgr. 9-15-XX.	S/W App validated, procedure updated, personnel trained. Implemented 10/1/XX. Process Monitored and RPN recalculated 12/1/XX.	8	2	2	16	32
		ID applicable statutory/regulatory requirements.	fail to ID necessary statutory/regulatory requirements	compliance failure which could cause delays, extra cost, rework, lack of product acceptance, etc.	8	lack of knowledge, oversight, failure to consult more knowledgable person, in a hurry	Procedure recommends consulting Quality Mgr.	4	Same as above, sometimes customers cc Quality Mgr.	8	32	256	Same as above			8	2	2	16	32
		ID potential risks to achievement of requirements, requested quantity & delivery date, etc.	risks not identified	delays, extra cost, product failure	8	lack of knowledge, oversight, failure to consult more knowledgable person, in a hurry	Procedure lists things to consider and option to consult others.	7	Sales Mgr. reviews Quotes before they're sent, if time allows. Will review more often for new people.	7	56	392	Same as above			8	3	3	24	72
Medium Risk	5. Create Quote	Include all requirement info and any deviation requests to requirements, quantity, delivery date, etc.	Quote doesn't reflect full reality of requirements/needs	delays and extra cost	7	(assumption here is all req./dev. info available) oversight, in a hurry	Procedure has an example of a Quote format in an Appendix.	3		7	21	147	S/W application described above will populate a Quote template based on review results.			7	2	2	14	28
Low Risk	6. Send Quote to Customer																			

Total RPN (before action): 1131

Total RPN (after action): 164