Six Sigma Improvement Process
FMEA

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Introduction

“Anything that can go wrong will go wrong.”

Original Murphy's Law

“You never run out of things that can go wrong.”

Addendum to Murphy's Law

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Introduction

FMEA is **Potential Failure Mode, Effect, and Criticality Analysis**.

FMEA is essentially a cause-and-effect analysis which guides teams to:

- Thoroughly and systematically examine all potential failures, their potential causes, and their potential effects on the customer;
- Prioritize projects objectively based upon a risk assessment;
- Document all of the teams efforts, conclusions, and results;
- Document all proposed corrective actions to prevent failures; and
- Implement proposed corrective actions.

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Introduction

There are two primary flavors of FMEA used within manufacturing:

Design FMEAs are used during product design and development.

The primary objective is to uncover problems that will result in potential safety issues or product failures.

Process FMEAs are used to uncover problems related to the manufacture of product.

These tend to concentrate on factors related to manpower, machinery, methods, measurements and the environment.

Although the objectives of design and process FMEAs may appear different, both follow the same basic steps and the approaches are often combined.

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Introduction

Why FMEA?

"After the fact" failure analysis happens all the time in most industries.

After a significant failure(s), we hunt for the cause and a way to prevent future occurrences.

Attempting to find true causes after the fact is costly, time consuming, and an unbudgeted expense.

In addition, since causes and effects are usually separated in time, it is often difficult to connect an observed failure with an exact cause.

FMEA allows for the identification of potential product or process failures, and attempts to prevent failures from happening in the first place

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Introduction

FMEA drives systematic thinking about a product or process by asking and attempting to answer three basic questions:

- **What could go wrong** (failure) with a product or process?
- **How bad can it get** (risks), if something goes wrong (fails)?
- **What can be done** (corrective actions) to prevent things from going wrong (failures)?

FMEA attempts to identify and prioritize potential product or process failures. The failures are rated on three criteria:

- The impact of a failure - ***severity*** of the effects.
- The frequency of the causes of the failure - ***occurrence***.
- How easy is it to detect the causes of a failure - ***detectability***.

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Cause-and-Effect in FMEA

Notice that only the causes and effects are rated - failure modes themselves are not directly rated in the FMEA analysis.

FMEA is Cause-and-Effect analysis by another name – avoid being hung up on the failure mode.

The **failure mode** simply provides a convenient model, which allows us to link together multiple causes with multiple effects.

It is easy to confuse failures, causes, and effects, especially since causes and effects at one level can be failures at a lower level.

Effects are generally observable, and are the result of some cause. Effects can be thought of as *outputs*.

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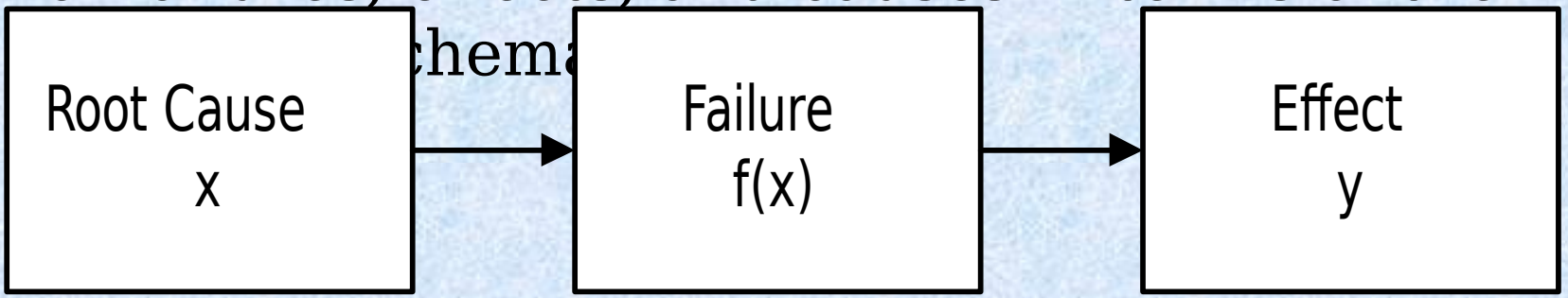
Cause-and-Effect in FMEA

Effects are usually events that occur downstream that affect internal or external customers.

Root causes are the most basic causes within the manufacturer's control. Causes, and root causes, are in the background; they are an *input* resulting in an effect.

Failures are what transform a cause to an effect; they are often unobservable. So, one can think of failures, effects, and causes in terms of the schema



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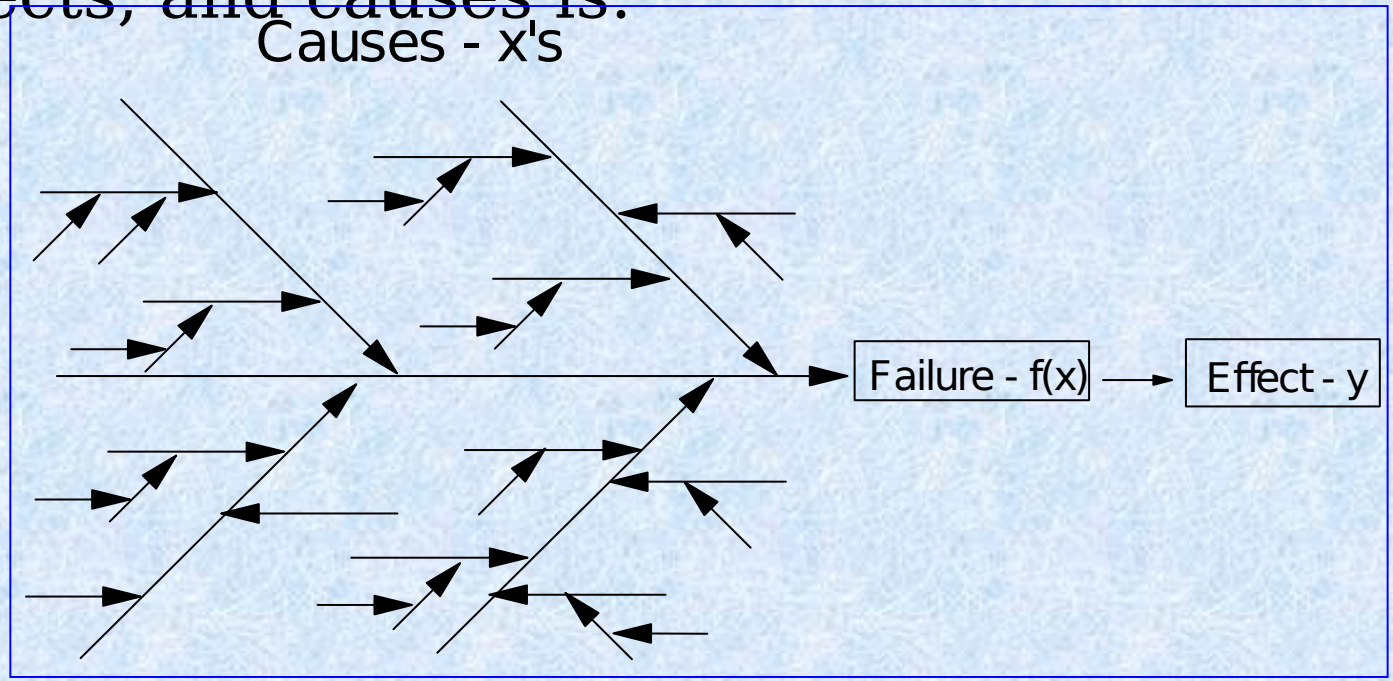
Cause-and-Effect in FMEA

Note that a failure mode can have numerous distinct effects, and that each effect has its own system of root causes.

With this in mind, another way to think of failures, effects, and causes is:



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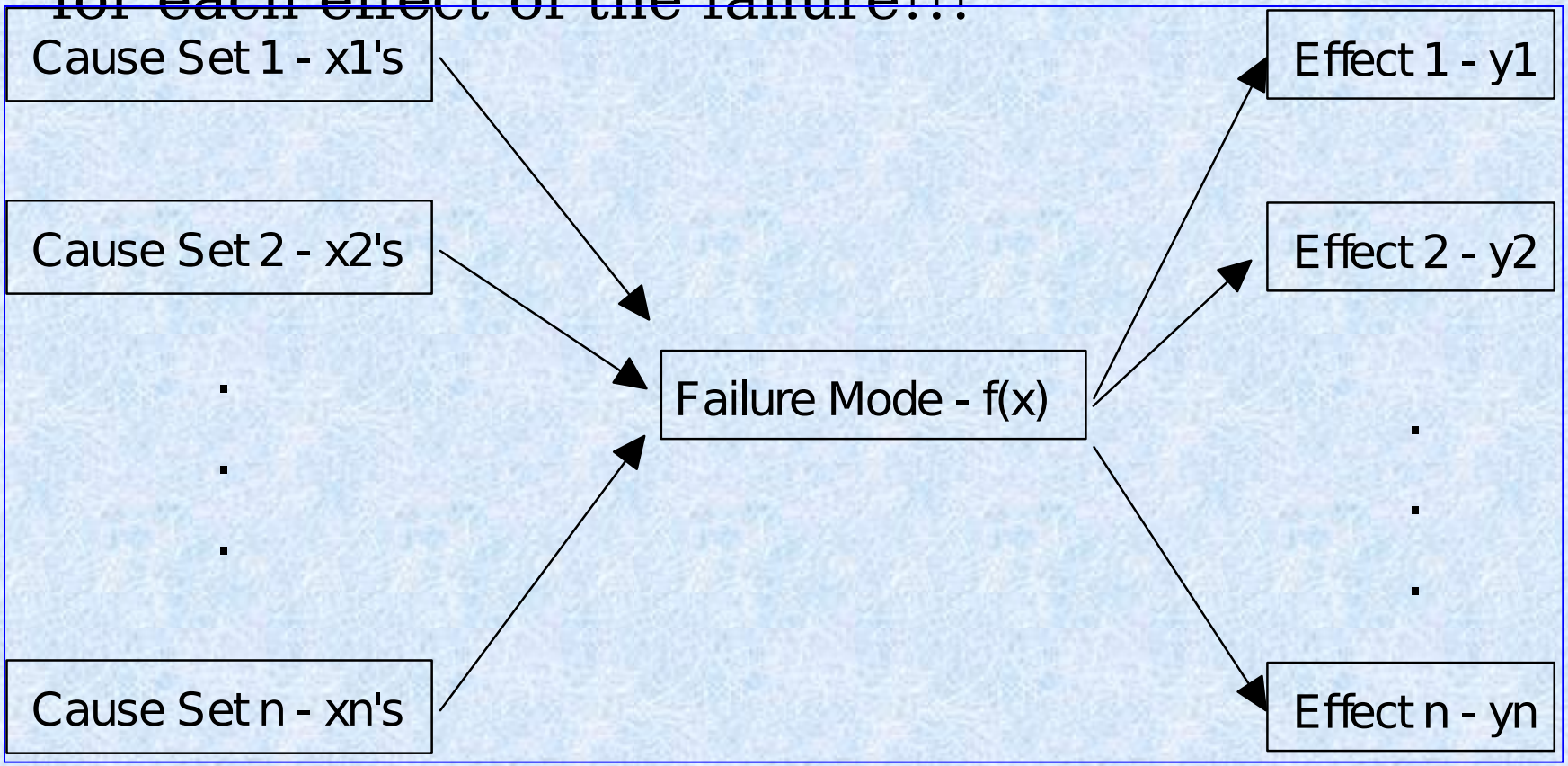
Cause-and-Effect in FMEA

Keep in mind that a single failure mode can have several effects, and that the cause-and-effect diagram on the previous slide should be repeated for each effect of the failure!!!



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Cause-and-Effect in FMEA

FMEA does not work at a system level, or if applied at too high a level in a process or design.

Process FMEA is only effective when it is applied to individual steps or substeps (perhaps sub … sub … substeps) in a process.

Design FMEA is likewise only effective when applied to individual components, subassemblies, etc., of a system or complicated device design.

Why? The roles of causes and effects actually depend upon the level within the system and upon the scope or boundary of the FMEA.

Effects at a lower level change roles to become causes at a higher level (the root cause lies at the

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Cause-and-Effect in FMEA

If one skips over important levels in the hierarchy and works at too high a level, then the team will become bogged down trying to define and sort out causes from effects.

If cause-and-effect is confusing the team, then the team should move down one or more levels and restart the FMEA process.

The **bottom-up approach** to FMEA is the best approach. Start at the lowest level of the hierarchy and sequentially work your way up through the process or design.

The rule is: Apply FMEA at all important sub-levels of a design or process. The collective

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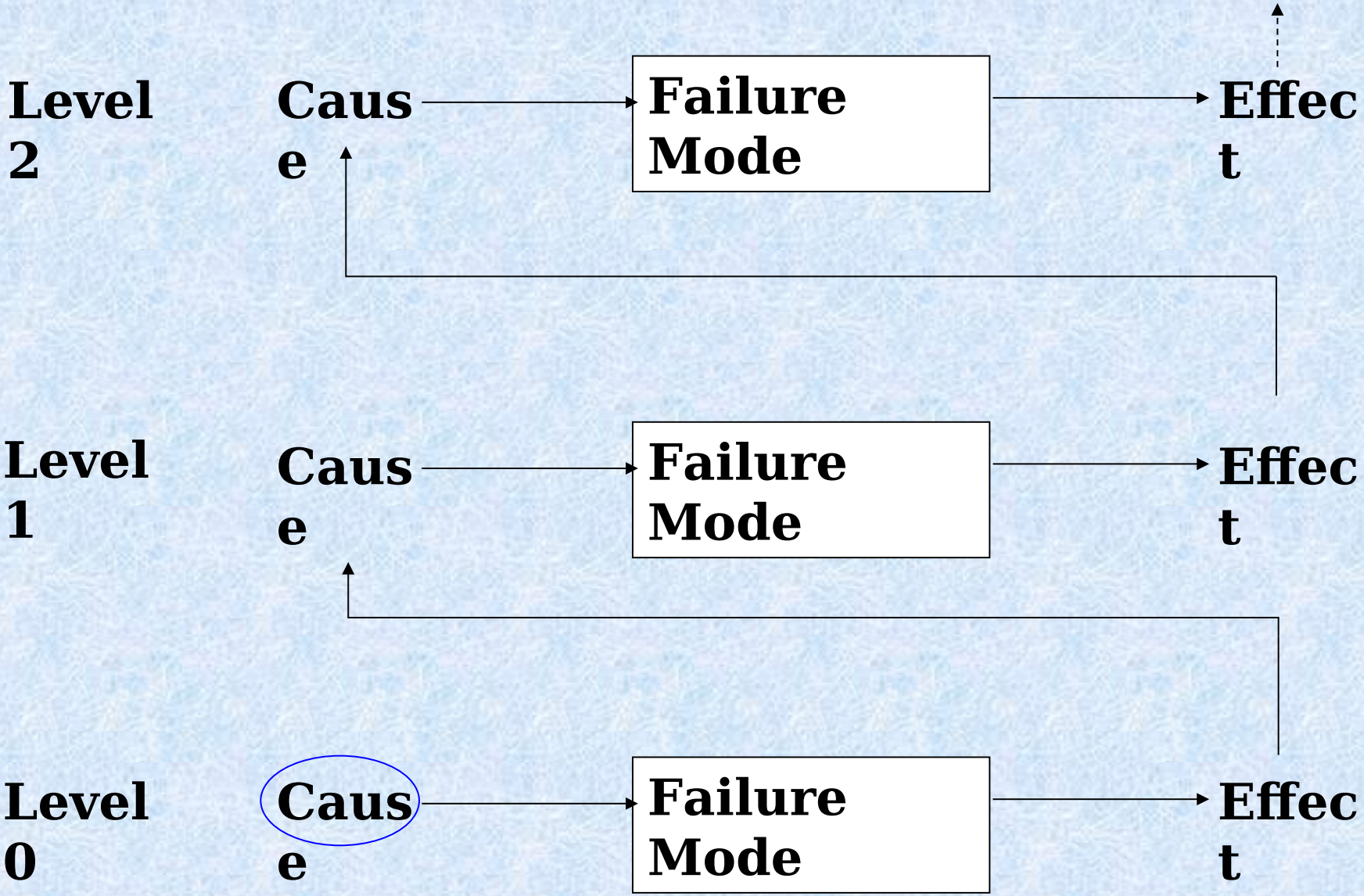
Cause-and-Effect in FMEA



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Cause-and-Effect in FMEA

Example: A manufacturer makes high strength steel pins that hold the wing onto the fuselage of a fighter aircraft. The pin is safety critical since pin failure would result in the wing detaching from the aircraft.

As a matter of interest the pins cost around a thousand dollars apiece, but the aircraft itself sells for around $40 million.

The next slide contains a hypothetical cause-and-effect trace through the hierarchy from manufacture of the pin to aircraft failure.

The example, which is based on an actual incident, has been simplified to emphasize the concept of cause-and-effect roles as one moves up through the hierarchy of a system.

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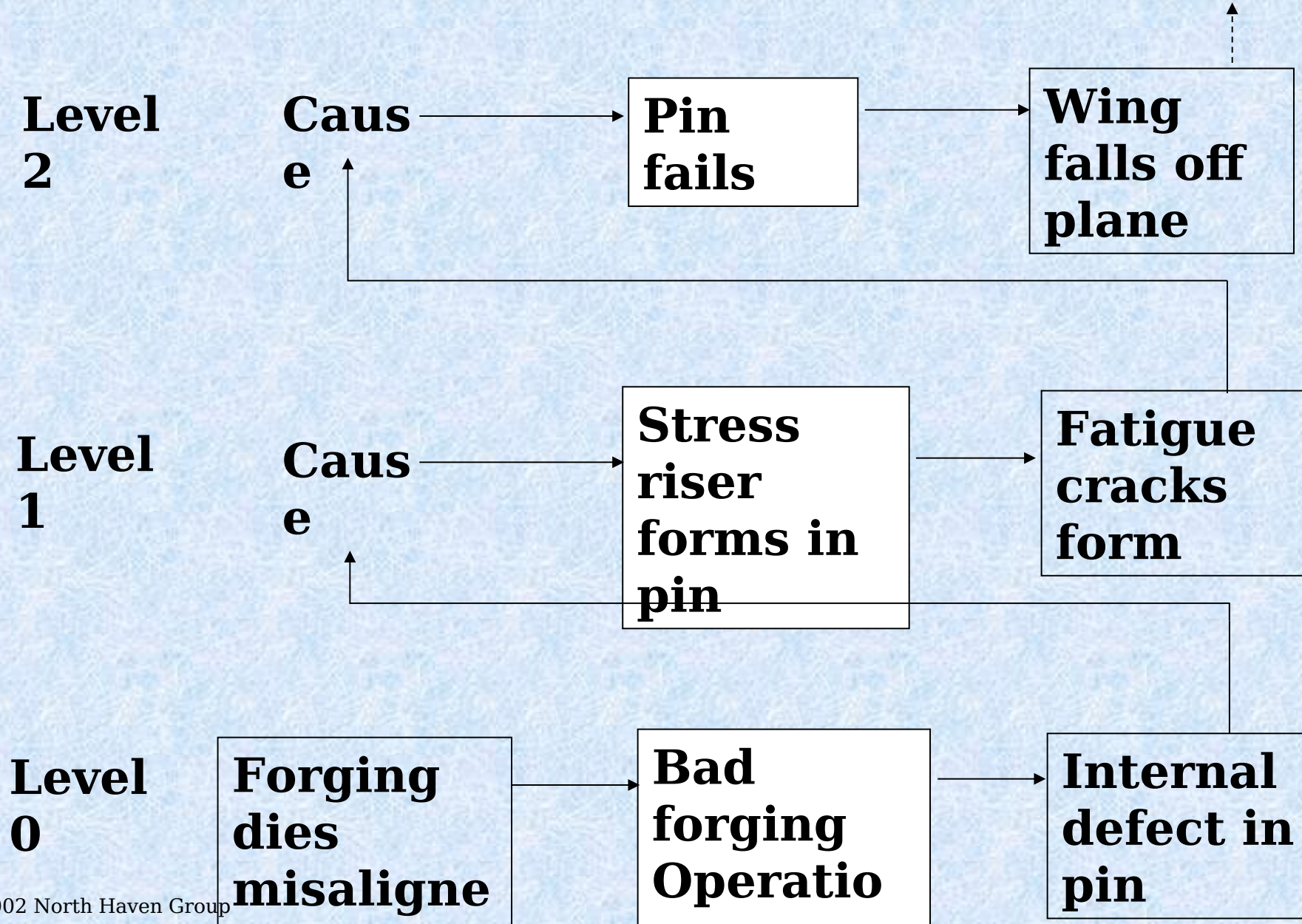
Cause-and-Effect in FMEA



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Risk Priority Numbers

The failures identified by the team in an FMEA project are prioritized by what are called **Risk Priority Numbers**, or RPN values.

The RPN values are calculated by multiplying together the Severity, Occurrence, and Detection (SOD) values associated with each cause-and-effect item identified for each failure mode.

We reiterate that the failure mode itself is not rated and only plays a conceptual role in linking causes with their effects on the product, process, or system.

For a given cause-and-effect pair the team assigns SOD values to the effects and causes. Then an RPN is calculated for that pair: **RPN = Severity x Occurrence x Detection**.

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Risk Priority Numbers

Once the RPN values are assigned to each of the cause-and-effect pairs identified by the team, the pairings are prioritized.

The higher the RPN value, the higher the priority to work on that specific cause-and-effect pair.

Note: If an effect is safety critical, then the associated pair is automatically given high priority because the effect carries a very high risk if a failure were to occur.

The measurement scale for the SOD values is typically a 5 or 10 point Likert scale (an ordinal rating scale).

The exact criteria associated with each level of each rating scale is dependent upon either a company designed rating criteria or a specified rating criteria from an industry specific guideline.

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Risk Priority Numbers

The Automotive Industry Action Group (AIAG), for example, requires the use of 10 point Likert scale for each of the SOD items.

The AIAG rating criteria are well-defined and those performing FMEA for an automotive application may be required to use the AIAG guideline. Be certain to confirm whether or not an FMEA guideline is required before proceeding.

We recommend the use of a 5 point Likert scale for each of the three rating criteria: Severity, Occurrence, and Detection.

Note: The 5 point scale facilitates the ability of the team to assign ratings in a timely fashion. Too many levels can lead to a false sense of precision and a lot of agonizing over the exact rating to be assigned for each item.

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Risk Priority Numbers

Severity rates the seriousness of the effect for the potential failure mode - how serious is the effect if the failure did occur?

The more critical the effect, the higher the severity rating.

The rating system should be developed to reflect the [illegible] of a rat[illegible]

Severity	Rating	Criterion
None	1	No effect.
Minor	2	Customer annoyed. Minor effect on product performance. Fault noticed occasionally.
Significant	3	Customer dissatisfied. Noticeable effect on product performance. Product requires repair.
Extreme	4	Customer very dissatisfied. Product inoperable, but safe. Must replace product.
Hazardous	5	Product unsafe to use or operate. Not in compliance with governmental regulations.

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Risk Priority Numbers

Occurrence, or frequency of occurrence, is a rating that describes the chances that a given cause of failure will occur over the life of product, design, or system.

Actual data from the process or design is the best method for determining the rate of occurrence. If actual data is not available, the team must estimate rates for the failure mode.

Examples:

- The number of failures per 1000 such components, or
- The average useful life of 200 similar components.

An occurrence value must be determined for every potential cause of the failure listed in the FMEA form.

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Risk Priority Numbers

The higher the likelihood of a failure, the higher the occurrence value.

Occurrence guidelines can be developed and should reflect the situation of interest, for example:

Occurrence	Rank	Criterion	Failure Rate
Remote	1	Very low number of failures	<=.000001
Low	2	Few failures likely	>.000001 - .0001
Moderate	3	Medium number of failures	>.0001 - .001
High	4	High number of failures	>.001-.01
Very High	5	Very high number of failures	>.01

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Risk Priority Numbers

The **detection** rating describes the likelihood that we will detect a cause for a specific failure mode.

An assessment of process controls gives an indication of the likelihood of detection.

If there are no current controls, the detection rating will be high. If there are controls, the detection rating will be low.

Keep in mind that 100% inspection is not 100%

"*A failure will not appear till a unit has passed final inspection.*"

Murphy's Law of Product Development

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Risk Priority Numbers

Current process controls are recorded on the FMEA form for each cause before detection ratings are assigned. Types of control strategies commonly used include:

- Mistake-Proofing,
- Statistical Process Control,
- Control Plans,
- Design of Experiments to establish causal relationships between failure modes and processing variables,
- Inspection and Test procedures at critical control points,
- SOPs and Operator Training,
- Process or Design Capability Studies,
- Measurement Capability Studies, and
- Design or Process Audits.

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Risk Priority Numbers

The higher a detection rating, the lower the likelihood we will detect a specific cause if it were to occur.

An example of detection guidelines follows:

Detection	Rank	Criterion	Detection Rate
Very High	1	Cause obvious and easily detected	>99.9%
High	2	Cause easily detected by inspection	>99.0% - 99.9%
Moderate	3	Moderate likelihood of detection	>95% - 99%
Low	4	Cause is hard to identify	>80% - 95%
Remote	5	Cause usually not detectable	0% - 80%

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FMEA Case Study

F111 Wing Attachment Pin Failure

The Department of Defense, in the 1960's, embarked upon the design and development of a new fighter aircraft that was supposed to accommodate the needs of both the Air Force and the Navy.

The new aircraft, labeled the F111, incorporated state-of-the-art engineering concepts in the design and was considered the best designed aircraft to that point in time. The aircraft was also very expensive, and as a result, the program had high political visibility.

In December of 1969 while on a training run at Nellis AFB in Nevada, a new F111 experienced a wing separation and crash. Both pilot and copilot were killed.

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FMEA Case Study

The crash was captured on film and widely shown on television, which led to a tremendous political backlash.

How could a new, well-designed, and very expensive aircraft experience a wing separation?

The cause of the wing separation was the failure of a high strength steel pin used to attach the wing to the fuselage.

Each wing had a single attachment pin, since redundancy was eliminated to reduce cost.

Theoretically, the pin was more than strong enough to withstand the maximum stresses that the pin would potentially experience during the lifetime of the aircraft.

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FMEA Case Study

Unfortunately, the attachment pin in question contained a large manufacturing defect that lead to premature failure.

The designers did not account for defects in the pin material or pin failures due to manufacturing.

The F111 disaster was a major contributing factor in the decision by the DOD to formally require FMEAs of their vendors.

The following table contains only a small portion of a simulated Design FMEA for the wing attachment pin.

Consider all of the possible FMEAs that would be required to complete a system level FMEA for the entire F111 or just the wing assembly itself.

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Function (Wing Attach Pin -- D6AC steel)	Failure Mode	Effect	Severity	Causes	Occurrence	Design Verification	Detection	RPN	Recommended Actions	Responsible Party	Action and Results				
											Status	Severity	Occurrence	Detection	RPN
Hold wing on aircraft	Pin breaks	Wing falls off -- plane crashes	5	Pin material has insufficient Strength	2	Material Specs. Review	2	20	Add mechanical testing of pin steel to quantify strength distribution for different heats	Strength Engineering Group	Based on test data, lower tolerance bound of steel strength well above upper design stress limit	5	1	1	5
			5	Pin physical design has insufficient strength	3	Design Review	2	30	Perform Designed Experiment to determine pin strength as function of design parameters	Wing Design Engineering Group	Based on test data, add extra 0.75" of stock to pin diameter	5	1	2	10
				Pin corroded by salt air on aircraft carriers	4	Design Review	3	60	Perform accelerated life testing of pins in salt fog chambers	Corrosion Engineering Group	Based on test data, add corrosion protection coating to pin	5	2	2	20

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FMEA Case Study

Note that one of the Recommended Actions resulted in a requirement for a redesign of the wing attachment mechanism.

A capability study determined that the Nondestructive Testing Methods (NDT) to detect material flaws in the pins were not capable of detecting critical flaws.

After the wing pin failure, it was indeed discovered that the NDT methods were not adequate to detect even large material flaws in the pins. The pin failed because of a large forging lap, which went undetected in numerous inspections. Too bad the capability work had not been done before the fatal crash.

The following table is a continuation of the F111 wing attachment pin example, but contains a hybrid FMEA (both Design and Process failure modes are considered).

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Function (Wing Attach Pin -- D6AC steel)	Failure Mode	Effect	Severity	Causes	Occurrence	Current Control	Detection	RPN	Recommended Actions	Responsible Party	Action and Results				
											Status	Severity	Occurrence	Detection	RPN
Hold wing on aircraft	Pin breaks	Wing falls off -- plane crashes	5	Pin Contains Surface Scratches forming stress risers	3	Visual Inspection of final machined pins prior to installation	2	30	Perform capability study to determine if Visual Inspection is capable of detecting critical scratches	Quality Assurance Mechanical Inspection Group	Based upon study Visual Inspection capable	5	1	1	5
				Pin contains internal and surface material defects (e.g., forging laps or inclusions)	3	NDT - Magnetic Particle Testing, Penetrant Testing, Ultrasonic Testing, Radiography	4	60	Perform capability studies to determine if NDT methods capable of detecting critical flaws	Quality Assurance and NDT Engineering	Based on study, NDT methods incapable -- required redesign of wing attach mechanism	5	3	4	60
				Pin machined undersize	3	Mechanical Inspection	2	30	Perform gage capability study	Quality Assurance Mechanical Inspection Group	Based on test data, improve inspector training	5	1	1	5

Conducting an FMEA

Conducting an FMEA: Basic Steps

1. Define the scope of the FMEA.
2. Review the process.
3. Brainstorm potential failure modes.
4. List potential effects and causes.
5. Assign severity, occurrence and detection ratings.
6. Calculate the risk priority number (RPN) for each cause.
7. Rank or prioritize causes.
8. Take action on high risk failure modes.
9. Recalculate RPN numbers.

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Process/Product FMEA Form

Process or Product Name _____ Date:_____

Prepared By: _____ Page ____ of ____

Step/Function	Potential Failure Mode	Potential Effects	Sever	Potential Causes	Occur	Current Control	Detect	RPN	Recommended Actions	Resp	Action and Results

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Conducting an FMEA

1. Define the scope of the FMEA.

The scope of the FMEA must be well defined before the team gets started.

Keep the scope narrow.

Narrowing the scope assures that the FMEA can be successfully completed in a timely manner.

This means that the product, process, process step(s) and/or process component(s) that will be studied need to be clearly defined and understood by every member of the team.

Defining the scope also helps to ensure that the right people are on the team, and helps the team identify ‘experts’ that can provide valuable input and information during the FMEA.

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Conducting an FMEA

2. Review the process

The target process should be reviewed to ensure that all team members have the same understanding of the process.

As we have seen, Process Maps and SIPOC Models are effective tools for defining the process and critical process steps.

Blueprints, engineering drawings, SOPs, and product 'routings' should also be used if available.

Remember that the key to understanding a process is to "*be the product*".

Team members should follow the product through each of the process steps, interviewing 'experts' and machine operators to obtain a more in depth understanding of the process.

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Conducting an FMEA

3. Brainstorm potential failure modes.

Potential failure modes are best identified via brainstorming sessions after the process has been reviewed.

Ideas are first generated by team members individually. Then, as a group, a thorough list of potential failure modes is developed using a flip chart.

At this stage, many of the problem solving tools reviewed in Block 1 are very useful, such as:

- Process Maps and SIPOC Models,
- Pareto charts and other simple data summary techniques,
- Cause-and-Effect Diagrams or Matrices, and
- Group decision techniques such as Multivoting and NGT.

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Conducting an FMEA

This list is reviewed to determine whether there are logical groupings for failure modes (component, process step, type of failure,…), and whether items on the list can be combined.

The resulting list of items and potential failure modes are then recorded on the FMEA form.

Process/Product FMEA Form

Process or Product Name _____ Date:_____

Prepared By: _____ Page ____ of ____

Step/Function	Potential Failure Mode	Potential Effects	Sever	Potential Causes	Occur	Current Control	Detect	RPN	Recommended Actions	Resp	Action and Results

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Conducting an FMEA

4. List potential effects and causes.

Within each of the failure modes listed on the FMEA form, the team identifies potential effects of the failure if the failure were to occur. These are the consequences of the failure.

The team then identifies potential root causes of

Process/Product FMEA Form

Process or Product Name _____ Date: _____

Prepared By: _____ Page ____ of ____

Step/Function	Potential Failure Mode	Potential Effects	Sever	Potential Causes	Occur	Current Control	Detect	RPN	Recommended Actions	Resp	Action and Results

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Conducting an FMEA

If the team is struggling to clearly separate causes, failures, and effects, then you are most likely trying to work at too high of level in the process or assembly.

Again, a bottom-up approach works best.

Try to remember three simple questions when doing an FMEA:

1. **What can go wrong? (failure mode)**
2. **What happens if something goes wrong? (effect)**
3. **Why did something go wrong? (cause)**

Note: FMEA and Design of Experiments work very well together!

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Conducting an FMEA

5. **Assign severity, occurrence and detection ratings.**

6. **Calculate the risk priority number (RPN) for each cause** by multiplying the severity, occurrence, and detection ratings for each cause.

7. **Rank or prioritize causes within each failure mode.**

   RPN numbers are used to rank causes from highest RPN to the lowest.

   This provides a simple method for prioritizing causes.

   Note: Items with high severity ratings, even with low or moderate RPN numbers, should be addressed.

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Conducting an FMEA

8. Take action on high risk failure modes.

Once causes with large RPNs are identified, **Recommended Actions** are identified and implemented to reduce or eliminate the potential causes of failures.

Most FMEA forms incorporate a section that identifies the individual(s) accountable for the implementation of the recommended actions, along with the target completion dates.

The goal of the FMEA is to reduce the RPN. This is done by reducing:

Severity (by redesigning the product)

Occurrence (by improving the process or requirements)

Detection (by improving detection techniques or equipment)

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Conducting an FMEA

Many companies opt for the easiest way to reduce RPN numbers: Improving the detectability of the cause.

However, reducing or eliminating the root causes, thus eliminating the need for controls or detection methods, is the best approach for improvement.

9. Recalculate RPN numbers.

Once actions are implemented, RPN numbers are typically recalculated.

This helps to evaluate the effectiveness of the recommended actions in reducing or removing the cause of the failure mode, and gives the team an understanding of the overall improvements that have been made through their efforts.

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Pitfalls and Limitations

"When working toward the solution of a problem, it always helps if you know the answer."

Murphy's Rule of Accuracy

"New systems generate new problems."

Murphy's Rule of Design

"Thinking is the hardest work there is, which is probably why so few engage in it."

Henry Ford

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Pitfalls and Limitations

Although FMEA is an effective method to uncover and remedy potential failures in a design or process, there are pitfalls and limitations.

One of the shortcomings of FMEA is that it is inherently a semi-quantitative method. The most critical failure modes, as identified by an FMEA, should be dealt with from a more quantitative and analytic perspective such as Fault Tolerance Analysis (FTA).

Inappropriate use of the FMEA method can result in unsafe products being delivered to customers.

Yet, the producers of the unsafe product may have high confidence in the quality and reliability of their product due to a faulty and misleading FMEA(s).

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Pitfalls and Limitations

Among the more common mistakes made by practitioners in the application of FMEA are:

- Lack of statistical thinking, methods, and analyses in the calculation of the SOD values or in the generation of remedies for potential failure modes.
- Not all required areas of expertise are represented on the FMEA team.

  The team composition is crucial.
- Short-circuiting the FMEA process with a less than thorough effort put forth in order to meet tight project deadlines or perhaps to meet optimistic management estimates of the time required to complete the project.

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Pitfalls and Limitations

Common mistakes (continued):

- Inability to narrow the scope of the FMEA to those potential failure modes that are truly critical.

  Too many potential failures in the FMEA usually results in a long and drawn-out FMEA process that often ends in non-results or poor results.

- Rigid application of FMEA to a scenario where it is inappropriate or the practitioners do not modify the method to their application.

- FMEA is NOT a general problem-solving tool. It has very specific applications for which it is recommended and effective.

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Summary

Definitions used throughout this section:

Failure Mode: Ways that the process can fail to complete its intended function.

Potential Causes: Causes of a failure mode.

Effects: Outputs of a failure mode.

Severity: The significance of the impact of the effect.

Occurrence: How likely the specific cause is to occur.

Detection: How likely the current system will detect the cause of a failure mode.

RPN: Severity x Occurrence x Detection.

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Summary

Again, if the team is struggling to clearly separate causes, failures, and effects, then you are most likely trying to work at too high of level in the process or assembly.

Keep repeating these three simple questions when doing an FMEA:

1. What can go wrong (what is the failure mode)?

2. What happens if something goes wrong (what is the effect of the failure)?

3. Why did something go wrong (what is the root cause of the effect)?

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