Failure Modes & Effects Analysis (FMEA)

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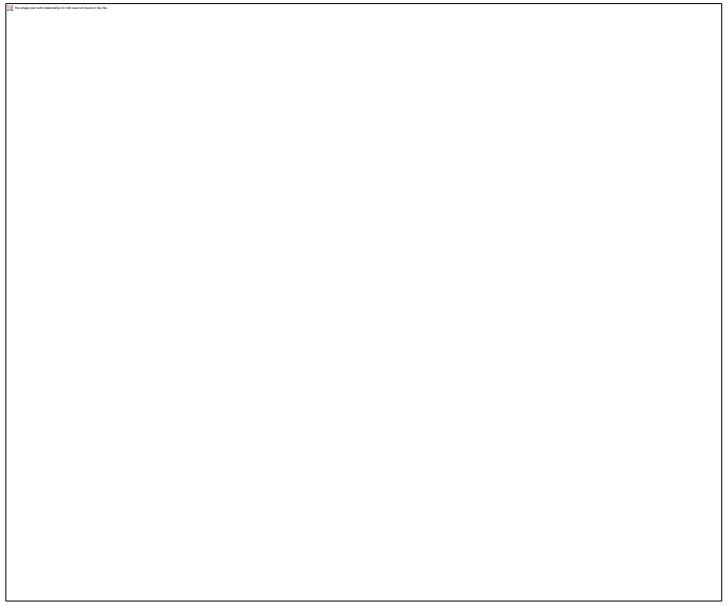
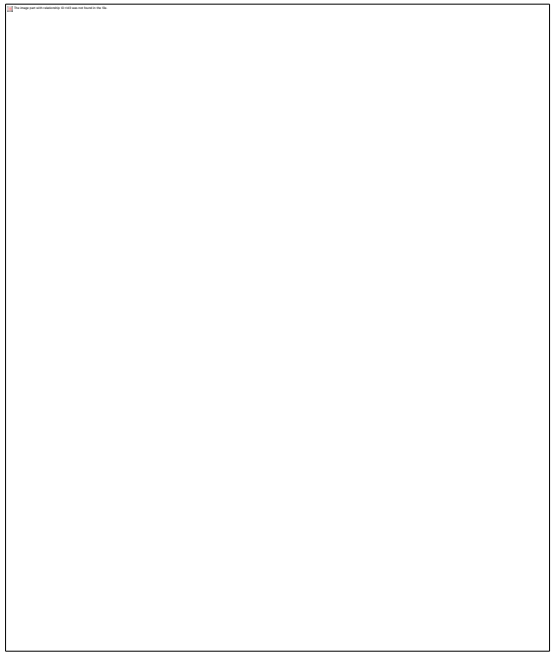
The Bigger Picture

FMEA is a tool which fits into a wider approach called:





The Bigger Picture

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“Catastrophic failures in operational risk management are rarely caused by a single and major point of failure. Rather they are the cumulative effect of smaller and inter-related failures. …FMEA is the tool of choice to address these complex operational risk failures at any level of an organization, whether tactical, strategic, or enterprise-wide. It works in every type of organization.”

A leading Operational Risk Authority

“To me Failure Modes and Effects Analysis (FMEA) is a versatile, powerful, process centered tool that belongs in every Process Owners’ and Six Sigma practitioners’ toolbox.“

A leading Six Sigma Authority

The Scope of this Lecture

The objectives for this session include:

- Understand what a FMEA is, why it is used, and when it can it be deployed
- Understand the different components, definitions, and calculations used in an FMEA
- Learn the steps to developing an FMEA

History of the FMEA

- 1940s - First developed by the US military in 1949 to determine the effect of system and equipment failures
- 1960s - Adopted and refined by NASA (used in the Apollo Space program)
- 1970s – Ford Motor Co. introduces FMEA after the 'Pinto affair'. Soon adopted across automotive industry
- Today – FMEA used extensively in both the manufacturing and service industries

Defining Reliability

Product reliability is one of the qualities of a product. Quite simply, it is the quality which measures the probability that the product or device "will work."

As a definition:

- Product reliability is the ability of a unit to perform a required function under stated conditions for a stated period of time.

And, correspondingly, quantitative reliability, as a definition, is:

- Quantitative reliability is the probability that a unit will perform a required function under stated conditions for a stated time.

Source: Fergenbaum, A. V. (1991). Total Quality Control. New York: McGraw-Hill, Inc.

When Reliability is Lacking - *Categories of Failure Mode*

Safety

Any failure mode that directly affects the ability of a product to meet Safety Standards, or creates a potential product liability issue, or can result in death or extensive property damage.

Major (Hard)

Any failure mode that stops the operation of a product or system which requires immediate repair.

Evidenced by a catastrophic event, i.e, TEPCO Nuclear Plant Meltdown

Failure mechanism might be due to a "shock" to the system or an accumulation of shocks to the system

Minor (Soft)

Any failure mode that results in a product not meeting one of its intended functions, but does not preclude it from satisfying its most important functions.

Any failure mode which results in a gradual but not complete ability of the product to meet its intended function.

Degradation of performance over time, wear are examples of soft failures.

FMEA Defined

What is a Failure Modes & Effects Analysis?

- An FMEA is a systematic method to:
  1. Recognize, evaluate, and prioritize (score) potential failures and their effects
  2. Identify actions which could eliminate or reduce the chance of potential failure occurring
  3. Document and share the process
- FMEA generates a ***living*** document that can be used to anticipate and prevent failures from occurring.
- In DMAIC and Design For Sigma Projects, FMEA's can be used in various stages and revised as the project moves forward.

Why Use a FMEA?

- Use of quality tools such as Statistical Process Control (SPC) encourage the use of FMEA(s) to help problem-solve quality problems
- ISO/QS 9000 and product liability directives of the EC 1985 strongly encourage its use.
- Helps select alternatives (in system, design, process, and service) with high reliability and high safety potential during the early phases *(Blanchard 1986)*
- Ensures that all conceivable effects on operational success have been considered.
- Many risk management regimens and standards, such as ISO 31000/31010 used in finance and operations are based on FMEA logic – probability vs. severity scoring and matrix.

Why Use a FMEA - Continued

- Improves the quality, reliability and safety of products and processes in a proactive manner.
- Helps to increase customer satisfaction, by proactively addressing failures that keep us from meeting critical customer requirements in processes or products.
- Reduces product development timing and cost
- Reduces operational risk
- Documents and tracks actions taken to reduce risk; Prioritize areas of focus

FMEA is a Team Process (Ideally)

Team Formation

- Product Development
- Design
- Manufacturing
- Quality
- Sales/Marketing
- Suppliers
- Reliability and testing

Team Roles

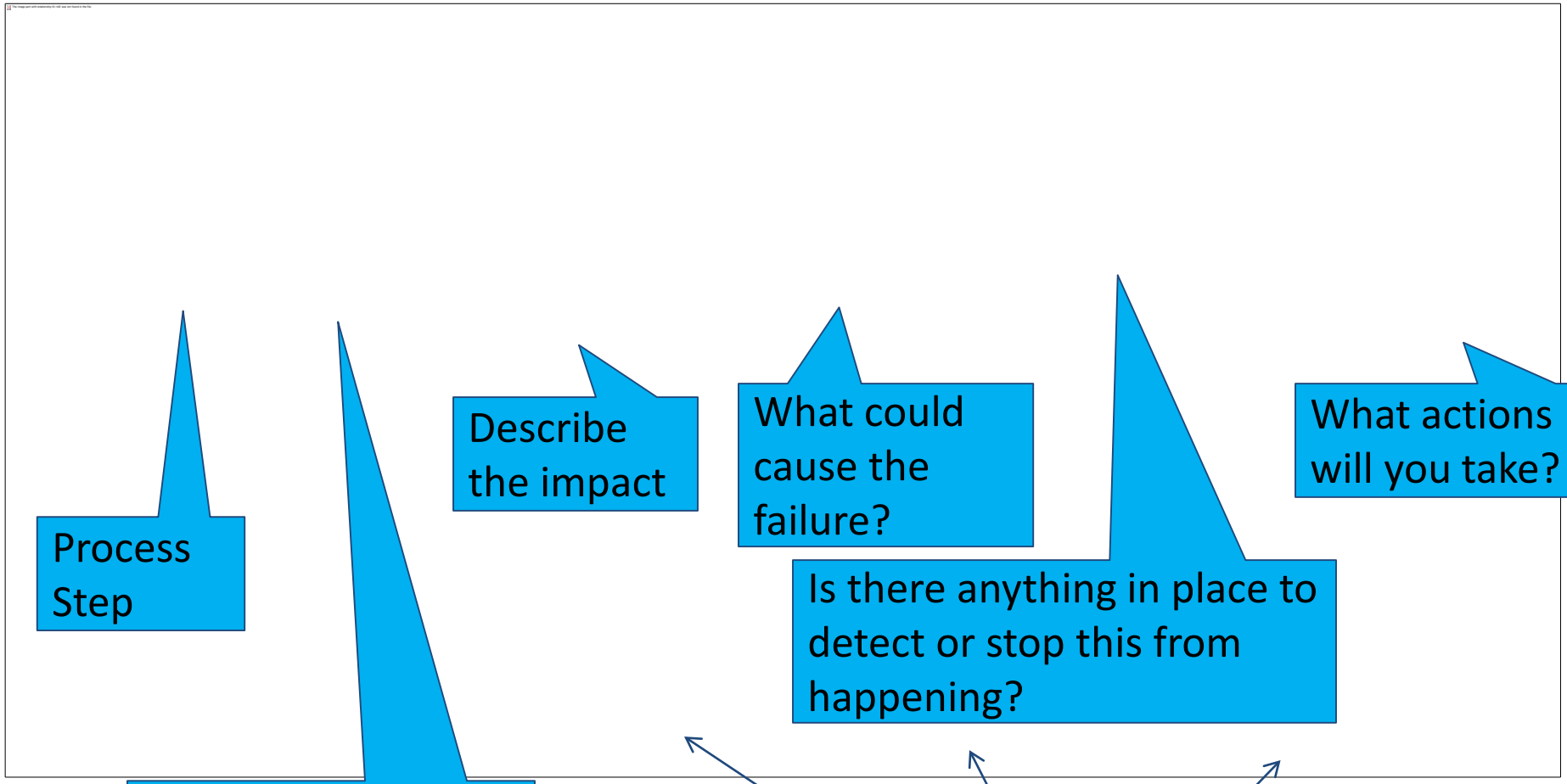
- Facilitator
- Champion
- Recorder/librarian

6-10 members is optimal

Elements of a Successful FMEA

1. **All problems are not the same**. This is perhaps the most fundamental concept in the entire FMEA methodology. Unless a priority of problems (as a concept) is recognized, workers are likely to be contenders for chasing fires. They will respond to the loudest request and/or the problem of the moment. (In other words, they will manage by emergency.)
2. **The customer must be known**. Acceptance criteria are defined by the *customer, not the engineer.*
3. **The function must be known.**
4. **One must be prevention (proactively) oriented.** Unless continual improvement is the force that drives the FMEA, the efforts of conducting FMEA will be static. The FMEA will be conducted only to satisfy customers and/or market requirements to the letter rather than the spirit of the requirements. Unfortunately, this is a common problem in implementation of an FMEA program.)

Sample FMEA Form



Process Step

Describe how the process step could go wrong

Describe the impact

What could cause the failure?

Is there anything in place to detect or stop this from happening?

What actions will you take?

Rankings (1-10)

A very basic, process example…

Sample FMEA Process - Adding Milk to a Cake Mix

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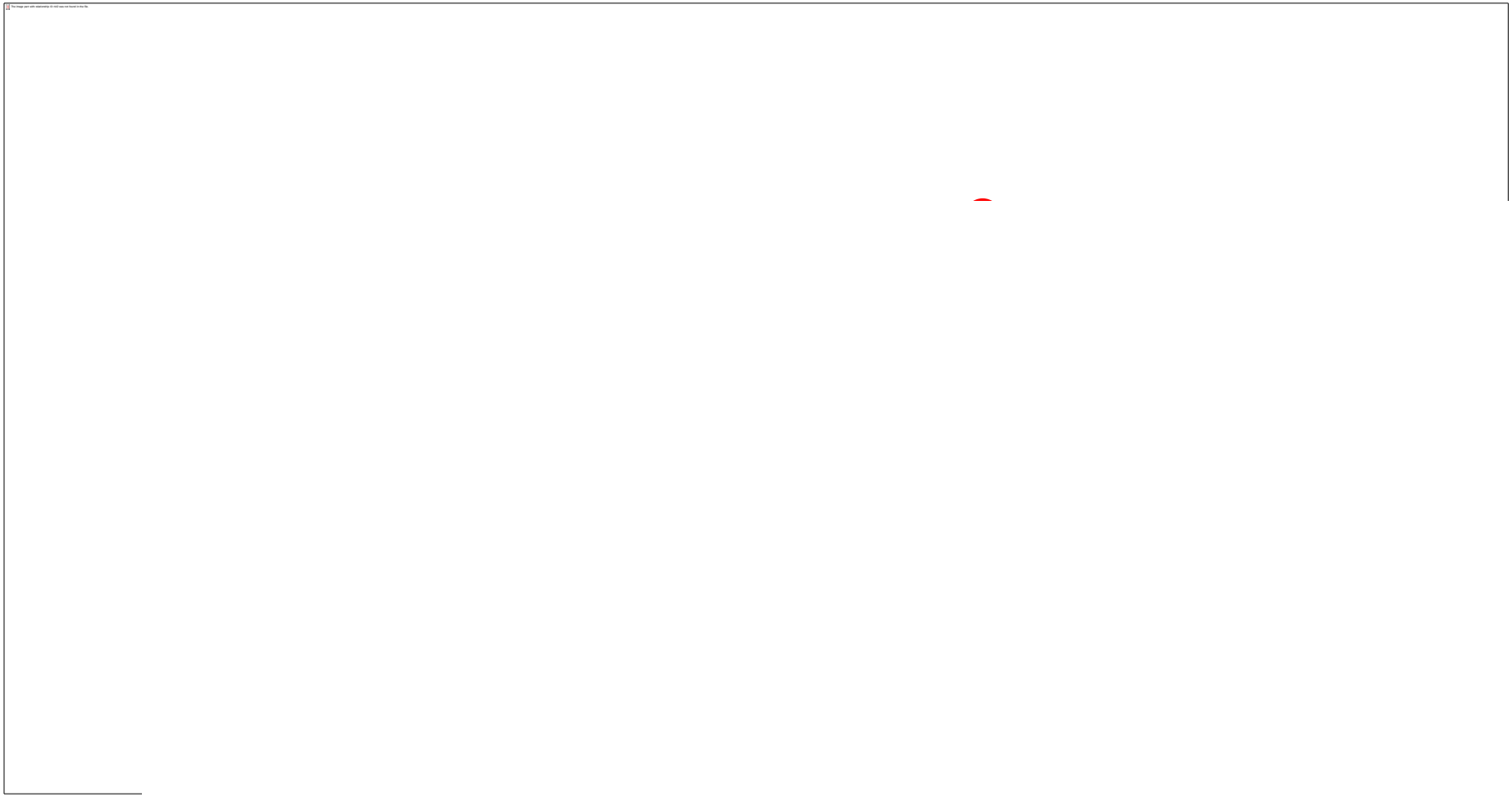
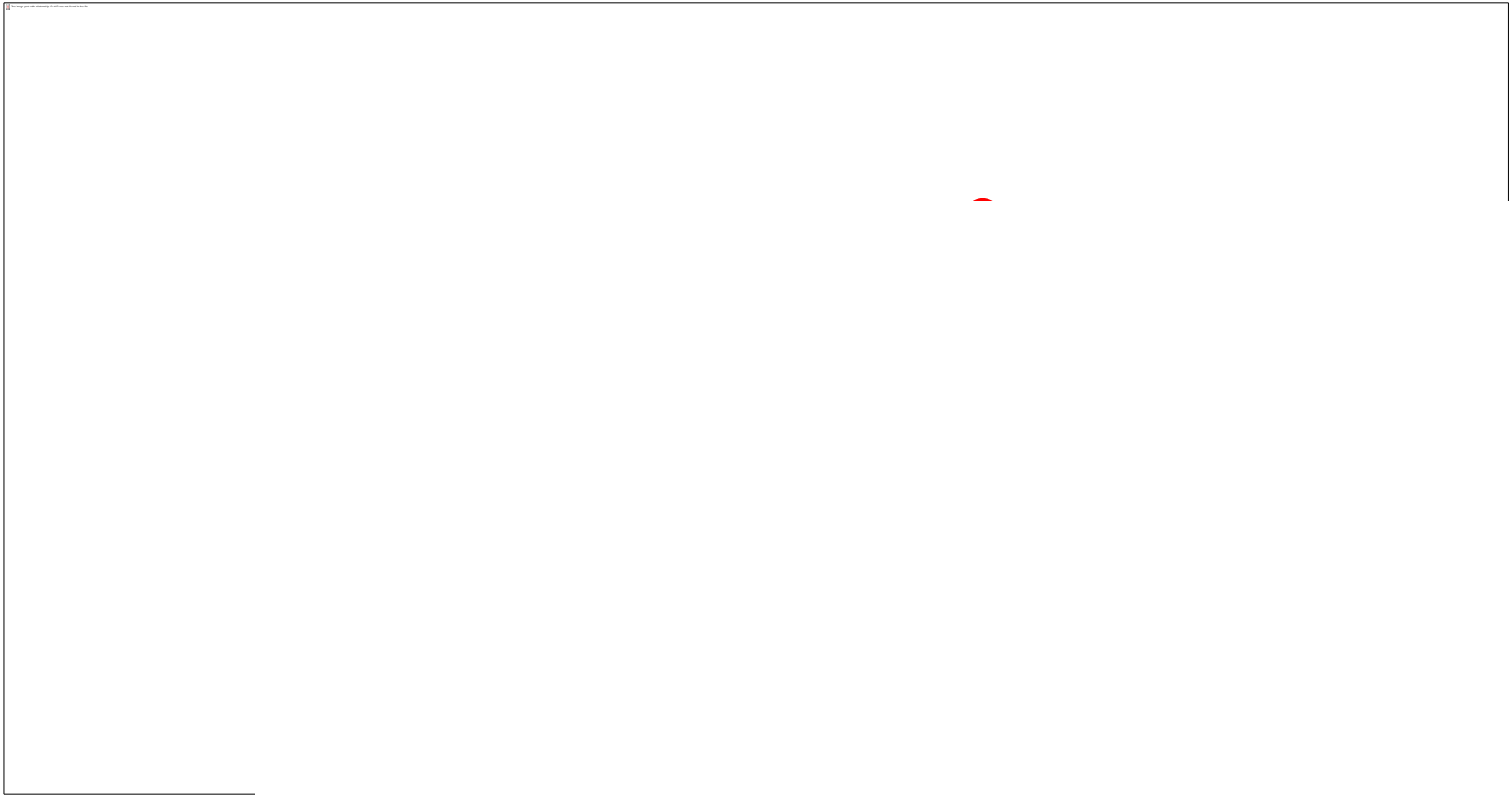
Sample FMEA Process - Adding Milk to a Cake Mix



Sample FMEA Process - Adding Milk to a Cake Mix



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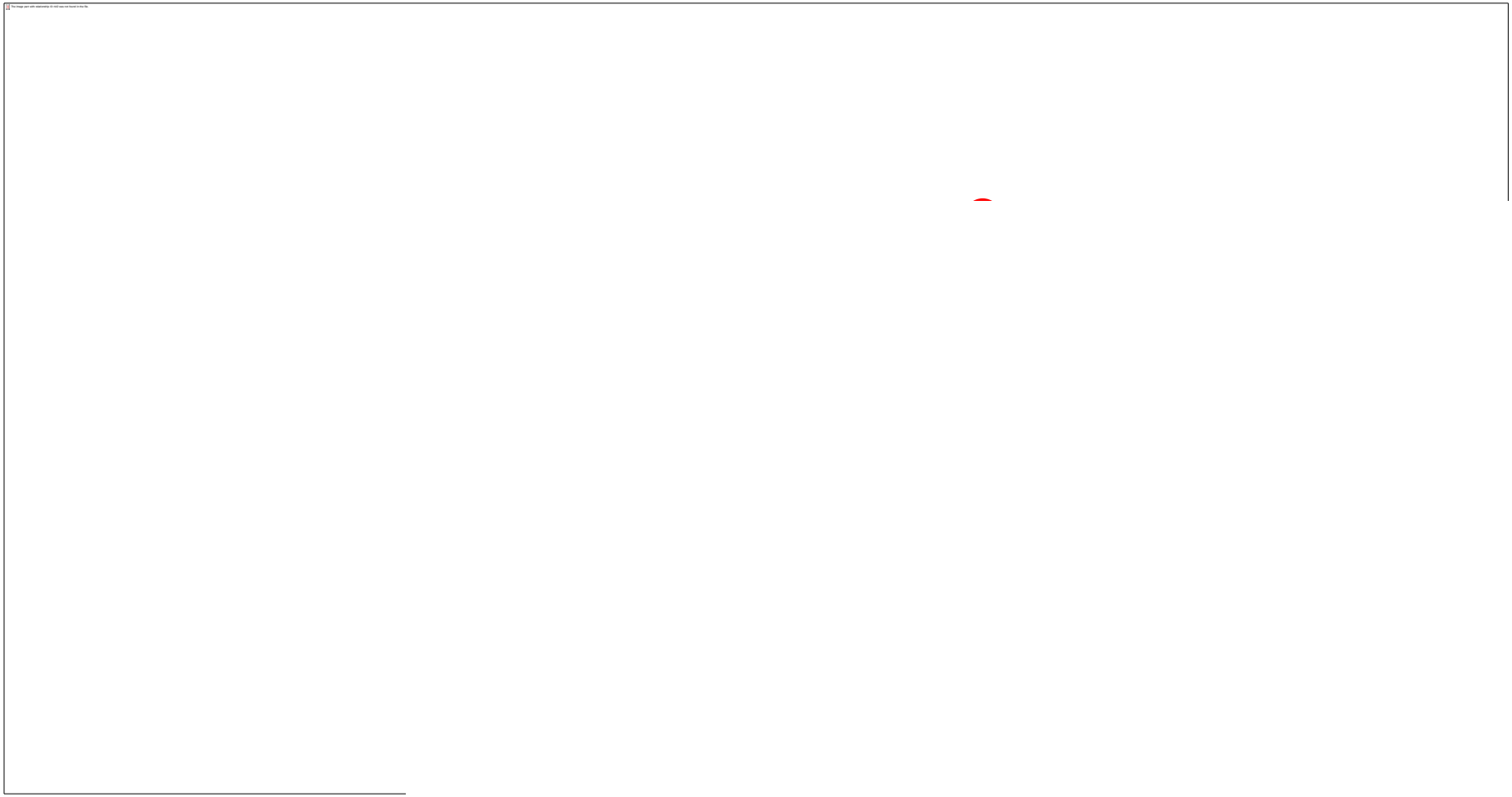

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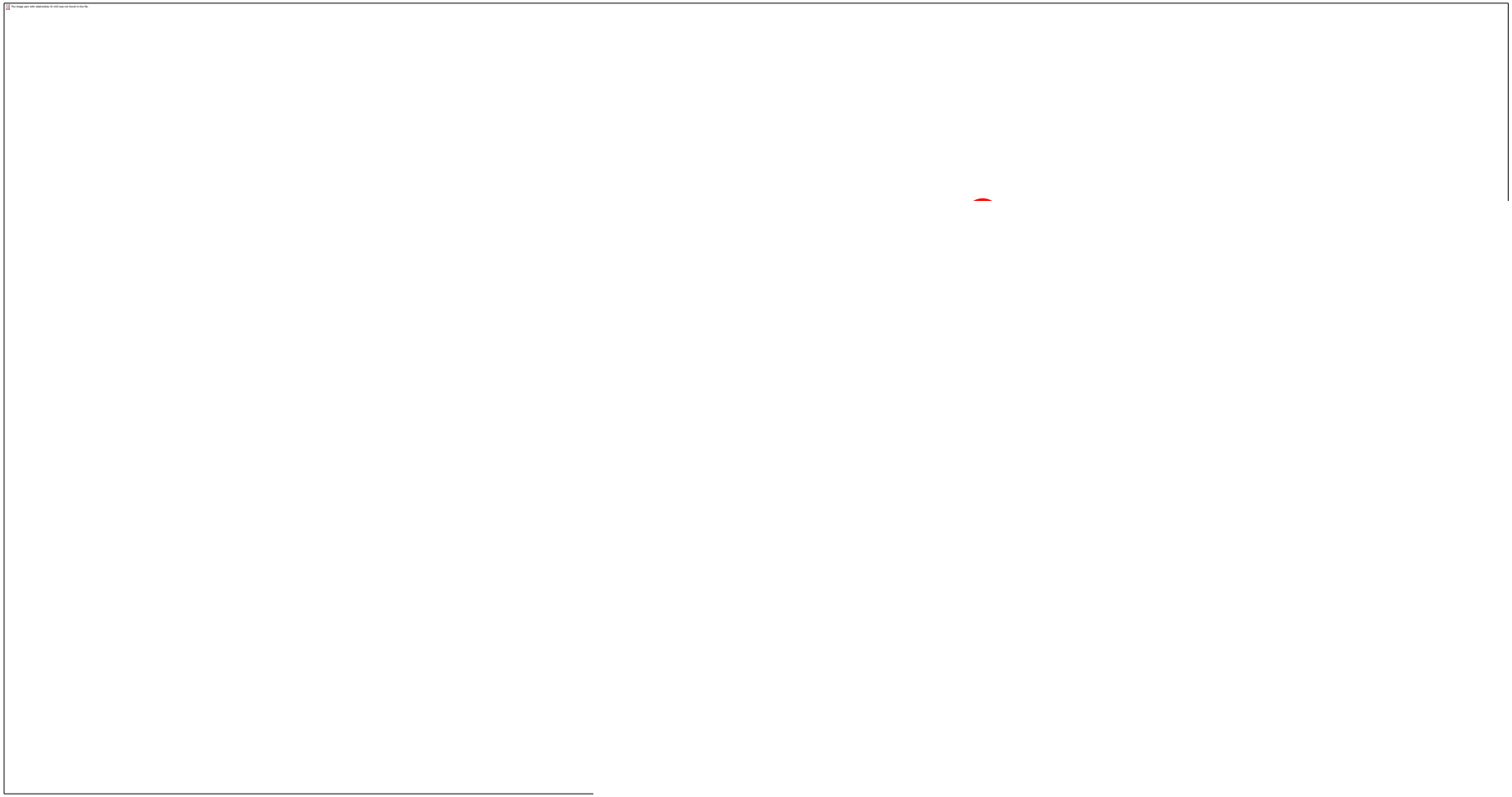

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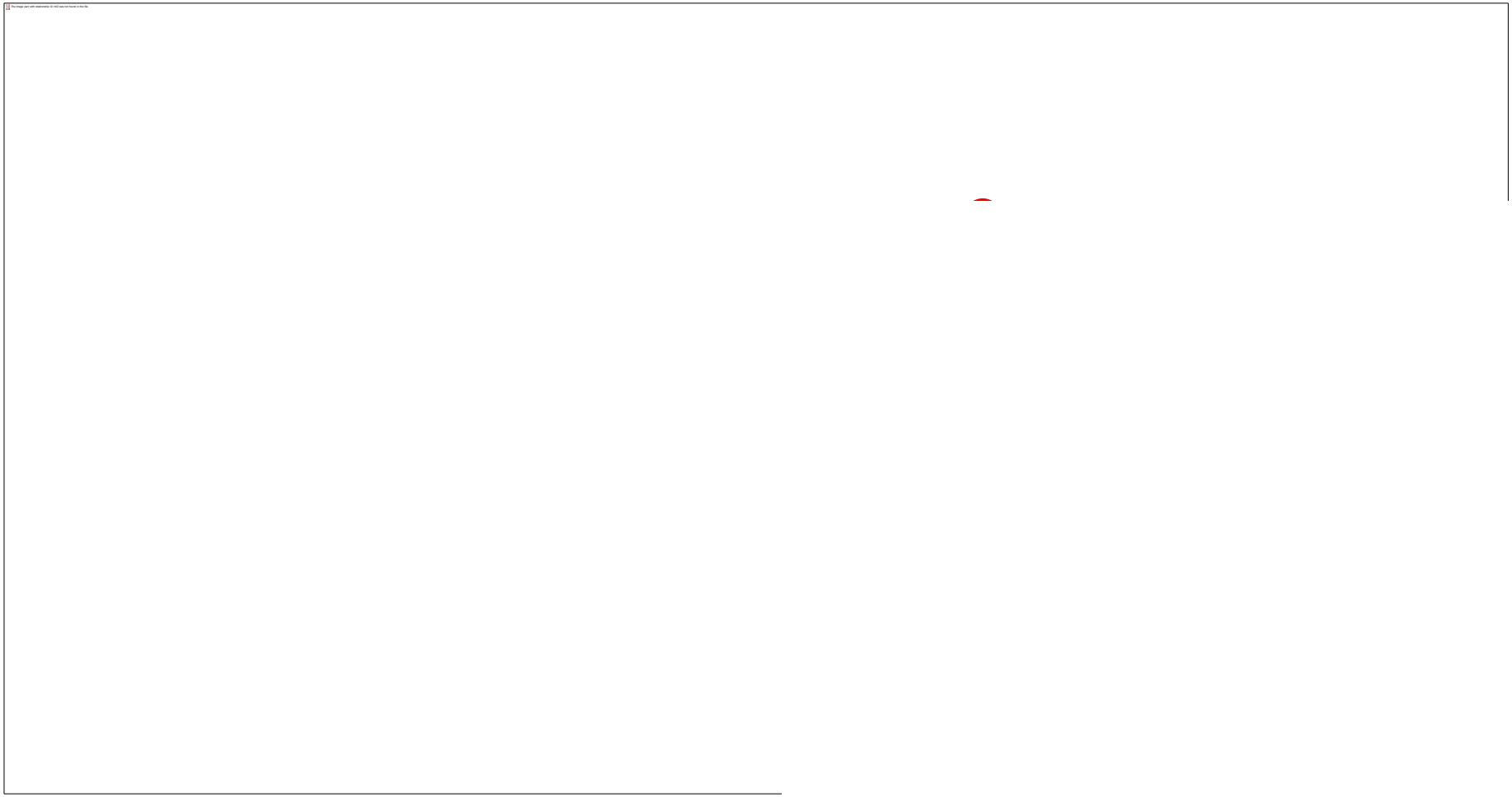

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Types of FMEAs

- **Design FMEA** - examines the functions of a component, subsystem or main system.
  - Potential Failures: incorrect material choice, inappropriate specifications.
  - Example: Air Bag (excessive air bag inflator force).
- **Process FMEA** - examines the processes used to make a component, subsystem, or main system.
  - Potential Failures: operator assembling part incorrectly, excess variation in process resulting in out-spec products.
  - Example: Air Bag Assembly Process (operator may not install air bag properly on assembly line such that it may not engage during impact).

Definitions

Failure Mode

- The way in which the product or process could fail to perform its intended function.
- Failure modes may be the result of upstream operations or inputs, or may cause downstream operations or outputs to fail.

Failure Effects

- The outcome of the occurrence of the failure mode on the system, product, or process.
- Failure effects define the impact on the customer.
- Ranking is translated into "**Severity**" score

Definitions

Failure Causes

- Potential causes or reasons the failure mode could occur
- Likelihood of the cause creating the failure mode is translated into an "**Occurrence**" score

Current Controls

- Mechanisms currently in place that will detect or prevent the failure mode from occurring
- Ability to detect the failure before it reaches the customer is translated in "**Delectability**" score

Calculations
Risk Priority Number

The Risk Priority Number (RPN) identifies the greatest areas of concern.

RPN is the product of:

(1) **Severity** rating

(2) **Occurrence** rating

(3) **Detection** rating

Calculations - FMEA Variables

- **Severity**
  - A rating corresponding to the seriousness of an effect of a potential failure mode. (scale: 1-10. 1: no effect on the customer, 10: hazardous effect)
- **Occurrence**
  - A rating corresponding to the rate at which a first level cause and its resultant failure mode will occur over the design life of the system, over the design life of the product, or before any additional process controls are applied. (scale: 1-10. 1: failure unlikely, 10: failures certain)
- **Detection**
  - A rating corresponding to the likelihood that the detection methods or current controls will detect the potential failure mode before the product is released for production for design, or for process before it leaves the production facility. (scale: 1-10. 1: will detect failure, 10: almost certain not to detect failures)

Calculations - Risk Priority Number (RPN)

Severity x Occurrence x Detectability = Risk Priority Number (RPN)

For a given potential failure mode, how bad the outcome is multiplied by how likely it would actually happen multiplied by what things are in place today to prevent or notice it before it happens.

FMEA Tips

- No absolutes rules for - what is a high RPN number. Rather, FMEA often are viewed on relative scale (i.e., highest RPN addressed first)
- It is a team effort
- Motivate the team members
- Ensure cross-functional representation on the team
- Treat as a living document, reflect the latest changes
- Develop prioritization with the process owners!
- Assign an owner to the FMEA; ensure it is periodically reviewed and updated

FMEA & The DMAIC/DMADV Lifecycle

Q: At what phase can/should the FMEA be used in a DMAIC project?

A: A FMEA can be used in most phases of the DMAIC lifecycle for various purposes

How it can be used:
- Project selection
- Project scope

How it can be used:
- Understand the process (w/ process mapping)

How it can be used:
- Identify process variables / root cause analysis

How it can be used:
- Assist with new process development / understand failures in design

How it can be used:
- Manage and control the process on an ongoing basis

FMEA can also be used in each stage of Design for Six Sigma - DMADV

Generic FMEA Worksheet

Item	Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurrence	Current Design Controls (Prevention)	Current Design Controls (Detection)	Detection	RPN	Recommended Action(s)	Responsible Person / Target Completion Date	Actions Taken / Effective Completion Date	Revised Rankings			
														Severity	Occurrence	Detection	RPN
1	2	3	4	5	6	7	8	8	9	10	11		12				

Item 1

An “item” is the *focus* of the FMEA project.

- For a System FMEA this is the system itself.
- For a Design FMEA, this is the subsystem or component under analysis.
- For a Process FMEA, this is usually one of the specific steps of the manufacturing or assembly process under analysis, as represented by an operation description.

Example: Bicycle hand brake subsystem

All-Terrain System Hierarchy

(with components for Hand Brake Subsystem)

1.0 All-Terrain Bicycle System

- 1.1 Frame Subsystem
- 1.2 Front Wheel Subsystem
- 1.3 Rear Wheel Subsystem
- 1.4 Sprocket-Pedal Subsystem
- 1.5 Chain-Derailleur Subsystem
- 1.6 Seat Subsystem
- 1.7 Handle Bar Subsystem
- 1.8 Hand Brake Subsystem
  - 1.8.1 Brake Lever
  - 1.8.2 Brake Cable
  - 1.8.3 Brake Pads
  - 1.8.4 Brake Calliper
- 1.9 Suspension Subsystem

Item identification for All-Terrain System FMEA

Item identification for All-Terrain Hand Brake Design FMEA

Item identification for All-Terrain Cable Design FMEA

Function 2

A “function” is what the item or process is intended to do, usually to a given standard of performance or requirement.

- For Design FMEAs, this is the primary purpose or design intent of the item.
- For Process FMEAs, this is the primary purpose of the manufacturing or assembly operation.
- Functions are typically described in a verb-noun format.
- There can be many functions for each item or operation.

Example: Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.

Item/Function	Potential Failure Mode
Hand Brake S/S: Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.

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Failure Mode 3

The term “failure mode” combines two words that both have unique meanings.

- The Concise Oxford English Dictionary defines the word “failure” as *the act of ceasing to function or the state of not functioning*.
- “Mode” is defined as *a way in which something occurs*

Failure Mode 3
cont…

A “failure mode” is the manner in which the item or operation potentially fails to meet or deliver the intended function and associated requirements.

- may include failure to perform a function within defined limits
- inadequate or poor performance of the function
- intermittent performance of a function
- and/or performing an unintended or undesired function

Example: Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure
Hand Brake S/S: Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.	**Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.**	Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in accident.

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Effect 4

An “effect” is the consequence of the failure on the system or end user.

- This can be a single description of the effect on the top-level system and/or end user, or three levels of effects (local, next-higher level, and end effect)
- For Process FMEAs, consider the effect at the manuf. or assembly level, as well as at the system or end user.
- There can be more than one effect for each failure mode. However, typically the FMEA team will use the most serious of the end effects for the analysis.

Example: Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in accident.

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV
Hand Brake S/S: Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	**Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in accident.**	10

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Severity 5

“Severity” is a ranking number associated with the most serious effect for a given failure mode

- based on the criteria from a severity scale.
- a relative ranking within the scope of the specific FMEA
- determined without regard to the likelihood of occurrence or detection.

Example: 10

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	S E V	Potential Cause(s) of Failure	O C C
Bicycle System: The bicycle must	Does not stop in	Potential accident or injury to bicycle operator without warning.	10	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	5
				Brake system mis-adjusted by bicycle user	3

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Suggested DFMEA Severity Evaluation Criteria

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

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Cause 6

A “cause” is the specific reason for the failure, preferably found by asking “why” until the root cause is determined.

- For Design FMEAs, the cause is the *design deficiency* that results in the failure mode.
- For Process FMEAs, the cause is the *manufacturing or assembly deficiency* that results in the failure mode.
- at the component level, cause should be taken to the level of failure mechanism.
- if a cause occurs, the corresponding failure mode occurs.
- There can be many causes for each failure mode.

Example: Cable breaks

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC
Hand Brake S/S: Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in accident.	10	**Cable Binds due to inadequate lubrication or poor routing**	4
				External foreign material reduces friction	2
				Cable breaks	6

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Occurrence 7

“Occurrence” is a ranking number associated with the likelihood that the failure mode and its associated cause will be present in the item being analyzed.

- For System and Design FMEAs, consider the likelihood of occurrence during the design life of the product.
- For Process FMEAs consider the likelihood of occurrence during production.
- based on the criteria from the corresponding occurrence scale.
- has a relative meaning rather than absolute value, determined without regard to the severity or likelihood of detection.

Example: 6

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC
Bicycle System: The bicycle must provide safe and reliable	Does not stop in required distance	Potential accident or injury to bicycle	10	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	5
				Brake system mis-adjusted by bicycle user	3

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Suggested DFMEA Occurrence Evaluation Criteria

Likelihood of Failure	Criteria: Occurrence of Cause (Design Life/Reliability of Item/Vehicle)	Rank
Very High	New technology/new design with no history.	10
High	Failure is inevitable with new design, new application, or change in duty cycle/operating conditions.	9
	Failure is likely with new design, new application, or change in duty cycle/operating conditions.	8
	Failure is uncertain with new design, new application, or change in duty cycle/operating conditions.	7
Moderate	Frequent failures associated with similar designs or in design simulation and testing.	6
	Occasional failures associated with similar designs or in design simulation and testing.	5
	Isolated failures associated with similar design or in design simulation and testing.	4
Low	Only isolated failures associated with almost identical design or in design simulation and testing.	3
	No observed failures associated with almost identical design or in design simulation and testing.	2
Very Low	Failure is eliminated through preventative control.	1

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Controls 8

“Controls” are the methods or actions currently planned, or are already in place, to reduce or eliminate the risk associated with each potential cause.

- Controls can be the methods to prevent or detect the cause during product development, or actions to detect a problem during service before it becomes catastrophic.
- There can be many controls for each cause.

Prevention-type Controls

For System or Design FMEAs, prevention-type design controls describe how a cause, failure mode, or effect in the product design is *prevented* based on current or planned actions

- they are intended to reduce the likelihood that the problem will occur, and are used as input to the occurrence ranking.

Example: Cable material selection based on ANSI #ABC.

Detection-type Controls

For System or Design FMEAs, detection-type designs controls describe how a failure mode or cause in the product design is *detected*, based on current or planned actions before the product design is released to production, and are used as input to the detection ranking.

- They are intended to increase the likelihood that the problem will be detected before it reaches the end user.

Example: Bicycle system durability test # 789

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET
Hand Brake S/S: Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in accident.	10	Cable Binds due to inadequate lubrication or poor routing	4	**Hand Brake Design Guide #123**	**Bicycle system durability test # 789**	2
				External foreign material reduces friction	2			3
				Cable breaks	6	**Cable material selection based on ANSI #ABC.**	**Bicycle system durability test # 789**	4

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Detection 9

“Detection” is a ranking number associated with the best control from the list of detection-type controls, based on the criteria from the detection scale.

- considers the likelihood of detection of the failure mode/cause, according to defined criteria.
- a relative ranking within the scope of the specific FMEA
- determined without regard to the severity or likelihood of occurrence.

Example: 4

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET
Bicycle System: The bicycle must provide safe and reliable transportation, including safe	Does not stop in required distance	Potential accident or injury to bicycle operator without	10	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain	5	All-Terrain braking system design guide (document # 123)	All-Terrain bicycle stopping test # ABC	5
							1. Bicycle system durability test # 789 2. Bicycle system performance testing to design requirements	9

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Suggested DFMEA Detection Evaluation Criteria

Opportunity for Detection	Criteria: Likelihood of Detection by Design Control	Rank	Likelihood of Detection
No detection opportunity	No current design control; Cannot detect or is not analyzed.	10	Absolute Uncertainty
Not likely to detect at any stage	Design analysis/detection controls have a weak detection capability; Virtual Analysis (e.g. CAE, FEA, etc.) is **not correlated** to expected actual operating conditions.	9	Very Remote
Post Design Freeze and prior to launch	Product verification/validation after design freeze and prior to launch with **pass/fail** testing (Sub-system or system testing with acceptance criteria e.g. ride & handling, shipping evaluation, etc.)	8	Remote
	Product verification/validation after design freeze and prior to launch with **test to failure** testing (Sub-system or system testing until failure occurs, testing of system interactions, etc.)	7	Very Low
	Product verification/validation after design freeze and prior to launch with **degradation** testing (Sub-system or system testing after durability test e.g. function check).	6	Low
Prior to Design Freeze	Product validation (reliability testing, development or validation tests) prior to design freeze using **pass/fail** testing (e.g. acceptance criteria for performance, function checks, etc.)	5	Moderately
	Product validation (reliability testing, development or validation tests) prior to design freeze using **test to failure** (e.g. until leaks, yields, cracks, etc.).	4	Moderately High
	Product validation (reliability testing, development or validation tests) prior to design freeze using **degradation** testing (e.g. data trends, before/after values, etc.)	3	High

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Risk Priority Number (RPN) 10

"RPN" is a numerical ranking of the risk of each potential failure mode/cause, made up of the arithmetic product of the three elements:

- severity of the effect
- likelihood of occurrence of the cause
- likelihood of detection of the cause.

Example: 240 (10 x 6 x 4)

Limitations of RPN

RPN is not a perfect representation of the risk associated with a failure mode and associated cause.

- subjective
- not continuous

High severity must be considered regardless of RPN value

Recommended Actions 11

"Recommended actions" are the tasks recommended by the FMEA team to reduce or eliminate the risk associated with potential causes of failure. They should consider

- existing controls
- relative importance (prioritization) of the issue
- cost and effectiveness of the corrective action.
- there can be many recommended actions for each cause.

Example: Require cable DFMEA/PFMEA from cable supplier approved by All-Terrain FMEA team.

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET	RPN	Recommended Actions
Hand Brake S/S: Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in accident.	10	Cable Binds due to inadequate lubrication or poor routing	4	Hand Brake Design Guide #123	Bicycle system durability test # 789	2	80	**Redesign hand brake cable routing to reduce friction and make system insensitive to lubrication degradation** **Modify bicycle durability testing to include periodic brake cable checks for binding**
				External foreign material reduces friction	2			3	60	
				Cable breaks	6	Cable material selection based on ANSI #ABC.	Bicycle system durability test # 789	4	240	**Require cable DFMEA/PFMEA from cable supplier approved by All-Terrain FMEA team.** **Based on results of Cable DFMEA, develop cable strength test and modify cable design to improve strength**
				Brake Lever breaks	1	Hand Brake Design Guide #123	Bicycle system durability test # 789	1	10	
				Selected brake pad material does not apply required friction to wheel	2			2	40	

TRUNCATED

TRUNCATED

Actions Taken 12

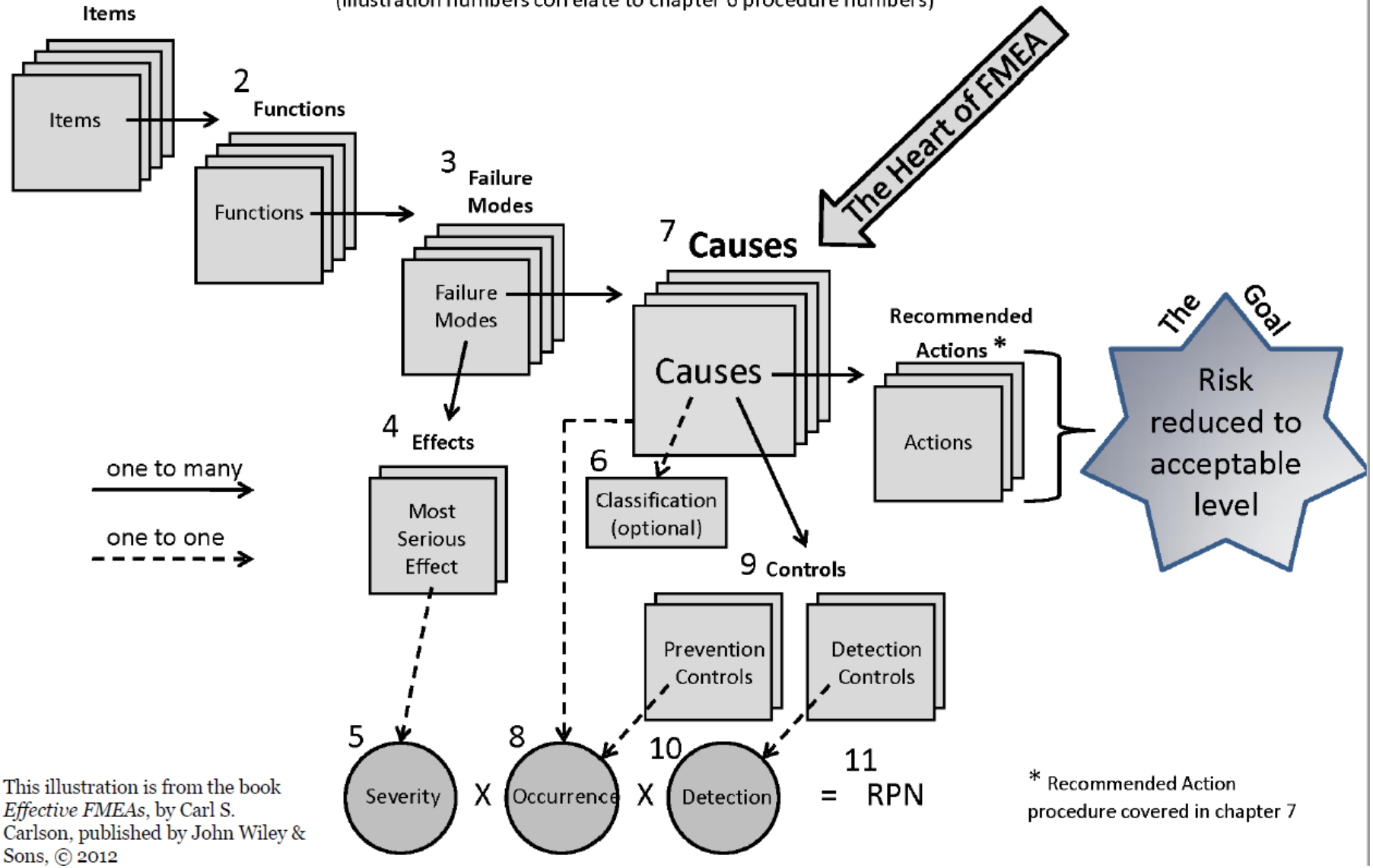
"Action Taken" is the specific action that is implemented to reduce risk to an acceptable level.

- it should correlate to the specific recommended action
- and is assessed as to effectiveness by a revised severity, occurrence, detection ranking, and corresponding revised RPN.

Example: Cable supplier completed DFMEA/PFMEA and approved by All-Terrain team

The Logical Relationship Between FMEA Elements

(illustration numbers correlate to chapter 6 procedure numbers)



This illustration is from the book *Effective FMEAs*, by Carl S. Carlson, published by John Wiley & Sons, © 2012

* Recommended Action procedure covered in chapter 7

Is that all there is to FMEA?

If FMEA were only an exercise in “filling out a form” then the definitions would be all you need to know.

- There is much more to learn about FMEAs!

What else is needed?

FMEA has the *potential* to anticipate and prevent problems, reduce costs, shorten product development times, and achieve safe and highly reliable products and processes.

- To obtain the best possible results from FMEA, companies need to focus on key success factors.

FMEA Success Factors

understanding the fundamentals and procedure of FMEAs, including the concepts and definitions

- preparation steps for each FMEA project
- applying lessons learned and quality objectives
- providing excellent facilitation
- and implementing an effective company-wide FMEA process.

Implementing FMEA success factors will uniformly ensure FMEAs achieve safe, reliable and economical products and processes.

Preparation Steps for Each FMEA Project

Determine the scope of the FMEA project

- Make the scope visible and get consensus on boundaries
- Assemble the right FMEA team (not done by one or two people)
- Establish ground rules and assumptions
- Gather information
- Prepare for the FMEA meetings

Applying Lessons Learned & Quality Objectives

Much is learned by observing the mistakes companies have made in doing FMEAs. Based on the experience of over two thousand FMEAs and working with hundreds of companies in a wide variety of applications, certain common mistakes show up repeatedly.

- What are the primary ways that FMEAs can be done wrongly (mistakes made)
- What are the leading factors that make for effective FMEAs (quality objectives)?

Providing excellent facilitation

FMEA facilitation is a different subject than FMEA methodology.

- To be successful, FMEA leaders need to develop expert facilitation skills
  - Brainstorming
  - Encouraging Participation
  - Active Listening
  - Controlling Discussion
  - Making Decisions
  - Conflict Management
  - Managing Level of Detail
  - Managing Time
  - Unleashing Team Creativity

Implementing an effective FMEA process

A *company-wide FMEA process* is the entire set of systems and tasks essential to support development of high-reliability products and processes through timely accomplishment of well-done FMEAs.

- Management support for strategy and resources
- Roles and responsibilities
- Management review of high risk issues
- FMEA quality audits
- Execution of FMEA recommended actions
- Feedback loop to incorporate lessons learned

In Summary . . .

Everyone wants to support the accomplishment of safe and trouble-free products and processes while generating happy and loyal customers.

- When done correctly, FMEA can anticipate and prevent problems, reduce costs, shorten product development times, and achieve safe and highly reliable products and processes.

FMEA Resources

This presentation is based on the book *Effective FMEAs*, by Carl S. Carlson, published by John Wiley & Sons, © 2012

- Information about the book and links to useful FMEA articles and aids can be found on www.effectivefmeas.com.
- If you have questions or comments about this presentation, the subject of FMEAs, or the book *Effective FMEAs*, please send an email to the author at Carl.Carlson@EffectiveFMEAs.com.