Failure Mode and Effects Analysis (FMEA)

UNDERSTANDING THE FUNDAMENTAL DEFINITIONS AND CONCEPTS OF FMEAS

Definition of FMEA

Failure Mode and Effects Analysis (FMEA) is a method designed to:

- Identify and fully understand potential failure modes and their causes, and the effects of failure on the system or end users, for a given product or process.
- Assess the risk associated with the identified failure modes, effects and causes, and prioritize issues for corrective action.
- Identify and carry out corrective actions to address the most serious concerns.

What is FMEA?

An FMEA is an engineering analysis

- done by a cross-functional team of subject matter experts
- that thoroughly analyzes product designs or manufacturing processes
- early in the product development process.
- Finds and corrects weaknesses before the product gets into the hands of the customer.

What is FMEA?

An FMEA should be the guide to the development of a complete set of actions that will reduce risk associated with the system, subsystem, and component or manufacturing/assembly process to an acceptable level.

What is FMEA?

- Performing an FMEA just to fill a checkbox in the Product Development Process and then filing it away, never to be seen again, is a waste of time and adds no value.
- If not for use as guidance through the development process, why waste the time and resources to do it in the first place?
- If effectively used throughout the product life cycle, it will result in significant improvements to reliability, safety, quality, delivery, and cost.

Primary Objective of FMEA

The primary objective of an FMEA is to improve the design.

- For System FMEAs, the objective is to improve the design of the system.
- For Design FMEAs, the objective is to improve the design of the subsystem or component.
- For Process FMEAs, the objective is to improve the design of the manufacturing process.

Primary Objective of FMEA

There are many other objectives for doing FMEAs, such as:

- identify and prevent safety hazards
- minimize loss of product performance or performance degradation
- improve test and verification plans (in the case of System or Design FMEAs)
- improve Process Control Plans (in the case of Process FMEAs)
- consider changes to the product design or manufacturing process
- identify significant product or process characteristics
- develop Preventive Maintenance plans for in-service machinery and equipment
- develop online diagnostic techniques

Types of FMEAs

The three most common types of FMEAs are:

- System FMEA
- Design FMEA
- Process FMEA

System FMEA

Analysis is at highest-level analysis of an entire system, made up of various subsystems.

The **focus** is on system-related deficiencies, including

- system safety and system integration
- interfaces between subsystems or with other systems
- interactions between subsystems or with the surrounding environment
- single-point failures (where a single component failure can result in complete failure of the entire system)

System FMEA

The **focus** (continued)

- functions and relationships that are *unique* to the system as a whole (i.e., do not exist at lower levels) and could cause the overall system not to work as intended
- human interactions
- service

Some practitioners separate out human interaction and service into their own respective FMEAs.

Design FMEA

Analysis is at the subsystem level (made up of various components) or component level.

The **Focus** is on product design-related deficiencies, with emphasis on

- improving the design
- ensuring product operation is safe and reliable during the useful life of the equipment.
- interfaces between adjacent components.

Design FMEA usually assumes the product will be manufactured according to specifications.

Process FMEA

Analysis is at the manufacturing/assembly process level.

The **Focus** is on manufacturing related deficiencies, with emphasis on

- Improving the manufacturing process
- ensuring the product is built to design requirements in a safe manner, with minimal downtime, scrap and rework.
- manufacturing and assembly operations, shipping, incoming parts, transporting of materials, storage, conveyors, tool maintenance, and labeling.

Process FMEAs most often assume the design is sound

FMEA Definitions and Examples

Generic FMEA Worksheet

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

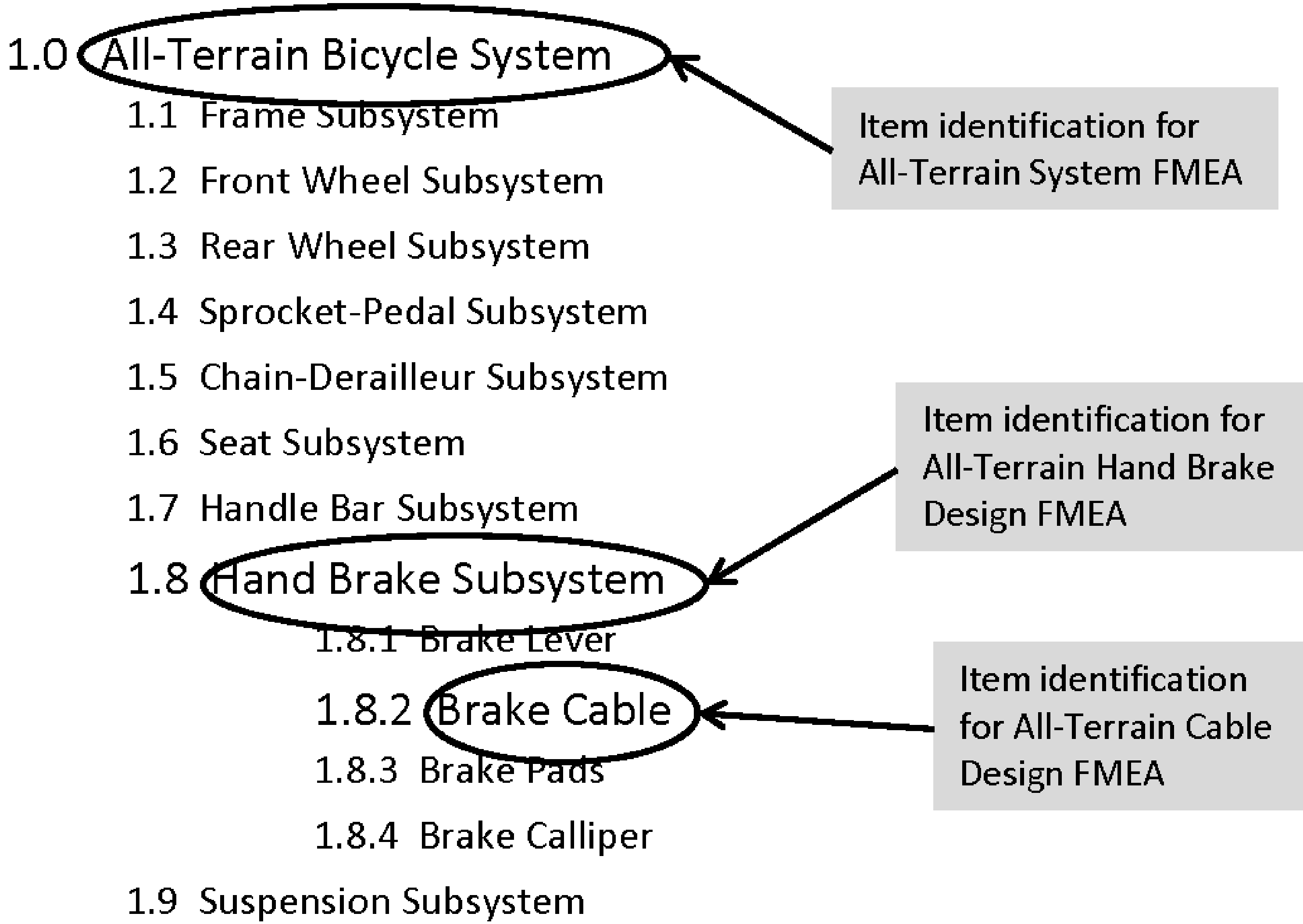
Item ①

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)



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.

TRUNCATED

TRUNCATED

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

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.

TRUNCATED

TRUNCATED

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

TRUNCATED

TRUNCAATED

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	SEV	Potential Cause(s) of Failure	OCC
Bicycle System: The bicycle must	Does not stop in d e	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

TRUNCATED

TRUNCATED

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

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 deficienc*y 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

TRUNCATED

TRUNCATED

Occurrence

"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

TRUNCATED

TRUNCATED

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

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

TRUNCATED

TRUNCATED

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

TRUNCATED

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

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

Risk Priority Number (RPN)

"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

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

Actions Taken (12)

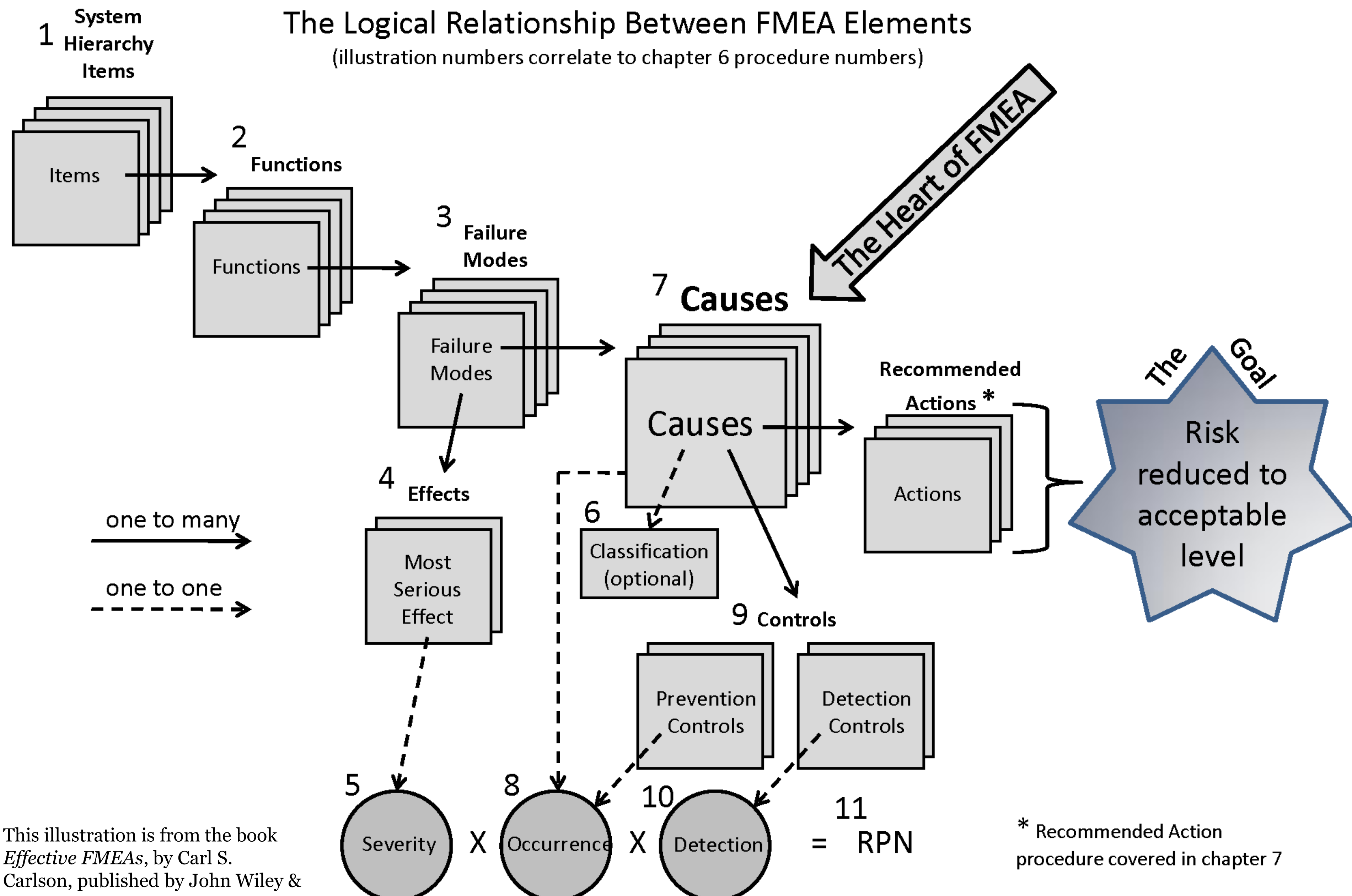
"Action Taken" is the specific action that is implemented to reduce risk to an acceptable level.

- 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)



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.

Biography

- Carl S. Carlson is a consultant and instructor in the areas of FMEA, reliability program planning and other reliability engineering disciplines, currently supporting clients of ReliaSoft Corporation.
- He has 30 years experience in reliability testing, engineering, and management positions, including manager of product reliability at General Motors.
- He co-chaired the cross-industry team that developed the commercial FMEA standard (SAE J1739, 2002 version) and was a past member of the Reliability and Maintainability Symposium (RAMS) Advisory Board.
- He holds a B.S. in Mechanical Engineering from the University of Michigan, is a senior member of ASQ and a Certified Reliability Engineer.
- He is the author of "Effective FMEAs", published by John Wiley & Sons, 2012. He can be reached at Carl.Carlson@EffectiveFMEAs.com. Information about the book and useful aids to performing FMEAs can be found on www.effectivefmeas.com.