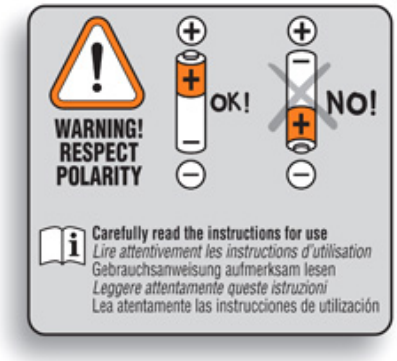
EXAMINING RISK
FAILURE MODES EFFECT ANALYSIS (FMEA)



Source: http://www.petzl.com/de/en/outdoor/headlamps/batteries

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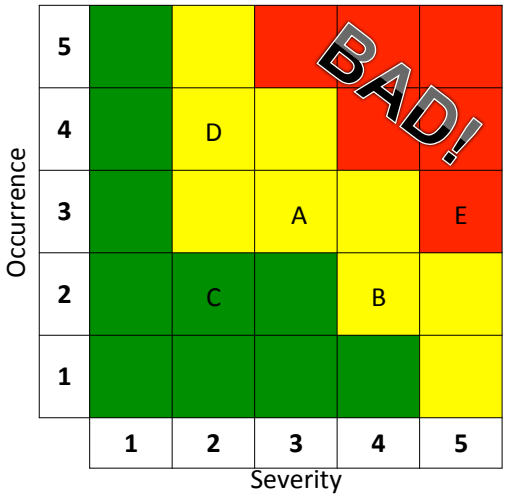
RISK IN A NUTSHELL

Risk	Description
[A]	Vibration
[B]	Communication Loss
[C]	Latency
[D]	Sensor Inaccuracy
[E]	Equipment Failure



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RATIONALE

Allows us to identify areas of our process that **most impact our customers**

Helps us identify how our design or process is **most likely to fail**

Points to process failures that are **most difficult to detect**

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TYPES

System/Concept: (Driven by system functions) A system is an organized set of parts or subsystems to accomplish one or more functions. System FMEAs are typically very early, before specific hardware has been determined.

Design: (Driven by part or component functions) A Design/Part is a unit of physical hardware that is considered a single replaceable part with respect to repair. Design FMEAs are typically done later in the development process when specific hardware has been determined.

Process: (Driven by process functions & part characteristics) A Process is a sequence of tasks that is organized to produce a product or service. A Process FMEA can involve fabrication, assembly, transactions or services.

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EXAMPLES

Manufacturing: A manager is responsible for moving a manufacturing operation to a new facility. He/she wants to be sure the move goes as smoothly as possible and that there are no surprises.

Design: A design engineer wants to think of all the possible ways a product being designed could fail so that robustness can be built into the product.

Software: A software engineer wants to think of possible problems a software product could fail when scaled up to large databases.

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Failure Mode

the way in which the component, subassembly, product, input, or process could fail to perform its intended function

Effects Analysis

studying the consequences of failures

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FMEA (FAILURE MODE EFFECTS ANALYSIS)

Why

- Methodology that facilitates process improvement
- Identifies and eliminates concerns early in the development of a process or design
- Improve internal and external customer satisfaction
- Focuses on prevention
- FMEA may be a customer requirement
- FMEA may be required by an applicable Quality System Standard

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FMEA (FAILURE MODE EFFECTS ANALYSIS)

A structured approach to:

- Identifying the ways in which a product or process can fail
- Estimating risk associated with specific causes
- Prioritizing the actions that should be taken to reduce risk
- Evaluating design validation plan (design FMEA) or current control plan (process FMEA)

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TYPES OF FMEAS

Design

- Analyzes product design before release to production, with a focus on product function
- Analyzes systems and subsystems in early concept and design stages

Process

- Used to analyze manufacturing and assembly processes after they are implemented

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SEVERITY, OCCURRENCE, DETECTION

Severity

- Importance of the effect on customer requirements

Occurrence

- Frequency with which a given cause occurs and creates failure modes

Detection

- The ability of the current control scheme to detect or prevent a given cause

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RISK PRIORITY NUMBER (RPN)

- **RPN is the product of the severity, occurrence, and detection scores.**

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FMEA PROCEDURE

1. **For each design component/process input, determine the ways in which the component/input can go wrong (failure mode)**
2. **For each failure mode, determine effects**
   - Select a **severity** level for each effect
3. **Identify potential causes of each failure mode**
   - Select an **occurrence** level for each cause
4. **List current controls for each cause**
   - Select a **detection** level for each cause

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FMEA PROCEDURE (CONT.)

5. **Calculate the Risk Priority Number (RPN)**
6. **Develop recommended actions, assign responsible persons, and take actions**
   - Give priority to high RPNs
   - MUST look at severities rated a 10
7. **Assign the predicted severity, occurrence, and detection levels and compare RPNs**

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THE FMEA FORM

Process/Product
Failure Modes and Effects Analysis Form
(FMEA)

Processor Product Name:		Prepared by:	Page ___ of ___
Responsible:		FMEA Date (Orig) _____ (Rev) _____	

Process Step / Input	Potential Failure Mode	Potential Failure Effects	SEVERITY	Potential Causes	OCCURRENCE	Current Controls	DETECTION	RPN	Actions Recommended	Resp.	Actions Taken	SEVERITY	OCCURRENCE	DETECTION	RPN
What is the process step and Input under investigation?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements)?		What causes the Key Input to go wrong?		What are the existing controls and procedures (inspection and test) that prevent either the cause or the Failure Mode?			What are the actions for reducing the occurrence of the cause, or improving detection?		What are the completed actions taken with the recalculated RPN?				
								0							0
								0							0
								0							0
								0							0
								0							0

Identify failure modes and their effects

Identify causes of the failure modes and controls

Prioritize

Determine and assess actions

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RATING SCALES

There are a wide variety of scoring "anchors", both quantitative or qualitative

Two types of scales are 1-5 or 1-10

The 1-5 scale makes it easier for the teams to decide on scores

The 1-10 scale may allow for better precision in estimates and a wide variation in scores (most common)

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RATING SCALES

Severity

- 1 = Not Severe, 10 = Very Severe

Occurrence

- 1 = Not Likely, 10 = Very Likely

Detection

- 1 = Easy to Detect, 10 = Not easy to Detect

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FMEA SCORING: SEVERITY

	Severity of Effect	Rating
Extreme	May endanger machine or operator. Hazardous ***without*** warning	10
	May endanger machine or operator. Hazardous ***with*** warning	9
High	Major disruption to production line. Loss of primary function, 100% scrap. Possible jig lock and ***Major*** **loss of Task Time**	8
	Reduced primary function performance. Product requires repair or Major Variance. ***Noticeable*** **loss of Task Time**	7
Moderate	Medium disruption of production. Possible scrap. Noticeable loss of takt time. Loss of secondary function performance. Requires repair or Minor Variance	6
	Minor disruption to production. Product must be repaired. Reduced secondary function performance.	5
	Minor defect, product repaired or "Use-As-Is" disposition.	4
Low	Fit & Finish item. Minor defect, may be reprocessed on-line.	3
	Minor Nonconformance, may be reprocessed on-line.	2
None	No effect	1

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FMEA SCORING: OCCURRENCE

	Likelihood of Occurrence	Failure Rate	Rating
Very High	Failure is almost inevitable	1 in 2	10
		1 in 3	9
High	Process is not in statistical control. Similar processes have experienced problems.	1 in 8	8
		1 in 20	7
Moderate	Process is in statistical control but with isolated failures. Previous processes have experienced occasional failures or out-of-control conditions.	1 in 80	6
		1 in 400	5
		1 in 2000	4
	Process is in statistical control.	1 in 15k	3
Low	Process is in statistical control. Only isolated failures associated with almost identical processes.	1 in 150k	2
Remote	Failure is unlikely. No known failures associated with almost identical processes.	1 in 1.5M	1

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FMEA SCORING: DETECTION

	Likelihood that control will detect failure	Rating
Very Low	No known control(s) available to detect failure mode.	10
Low	Controls have a remote chance of detecting the failure.	9
		8
Moderate	Controls may detect the existence of a failure	7
		6
		5
High	Controls have a good chance of detecting the existence of a failure	4
		3
Very High	The process automatically detects failure. Controls will almost certainly detect the existence of a failure.	2
		1

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DESIGN EXERCISE

Develop an FMEA for your project:

- Identify the ways in which your product/process can fail
- Estimate the risks associated with specific causes
- Prioritizes the actions that should be taken to reduce risk

Complete the FMEA worksheet:

- Electronic version on PolyLearn
- Submit a hardcopy at the beginning of class on Tuesday, 1/25
- One per team

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SOURCES

American Society for Quality (asq.org)

http://www.stat.purdue.edu/~kuczek/stat513/IT/520381_Chap_7.ppt

https://oasis.northgrum.com/general/docs/.../AdvancedPFMEA.ppt

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BONUS SLIDES!

Hey there, how awesome is it that you looked through these slides after class**!**

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WHEN TO CONDUCT AN FMEA

- Early in the process improvement investigation
- When new systems, products, and processes are being designed
- When existing designs or processes are being changed
- When carry-over designs are used in new applications
- After system, product, or process functions are defined, but before specific hardware is selected or released to manufacturing

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HISTORY OF FMEA

- First formalized in the 1960's in the Aerospace industry during the Apollo missions
- In 1974, the Navy developed *MIL-STD-1629* regarding the use of FMEA
- Required by QS-9000 & Advanced Product Quality Planning Process in 1994 for all automotive suppliers
- Driven by liability costs, used to reduce risks related to poor quality

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