

FMEA

FMEA

Failure Mode and Effects Analysis

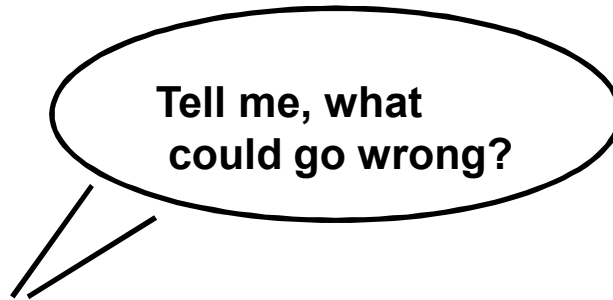
A Risk and Reliability Assessment Tool

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FMEA

Your objectives?

The Challenge

- **Effectively apply and sustain the FMEA Methodology as a Risk and Reliability Assessment tool.**
- **Integral part of your Preventive Action process.**



FMEA Objective

- “ The goal of FMEA is to prevent quality, reliability and safety problems.
- “ Most effective when used early during product design and manufacturing process development.

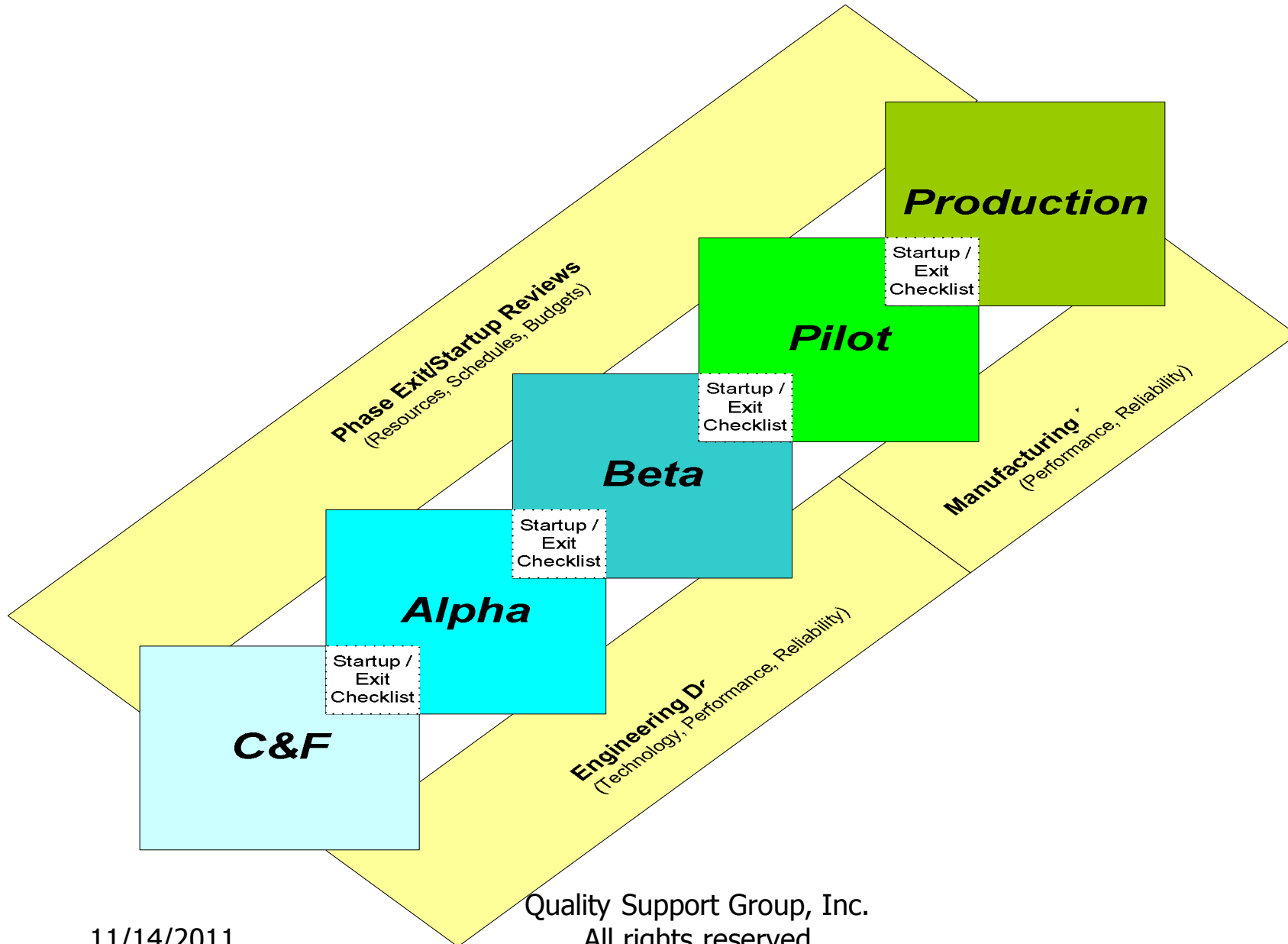
Key Concepts of Risk

- “ The consequences/severity (S) of that failure
 - . how severe it might be to the stakeholders

- “ The probability (O) of occurrence of failure
 - . how often the failure may occur

- “ The ability to prevent the failure from occurring or detect the failure (D) followed by action to prevent any effect on the stakeholders

Product Development Process



Design Concept Requirements

- “ Reliability goal determination
 - . Ensures that reliability will get a proper attention during development
- “ Product usage profile
 - . Must be set in the concept phase as a basis for all modeling and reliability analyses

Product definition and preliminary design

- “ Reliability goal included into the product spec.
 - . Ensures that reliability becomes part of the design engineering
- “ Reliability requirements for key components
 - . Provide supply engineering with guide to select manufacturers of reliable and quality components

Full scale design

- “ Reliability estimate, using any or a combination of reliability assessment methods including failure mode and effects analysis
 - . IEC60300-3-1, Reliability methods
- “ Key components selection for reliability
 - . Review of components life test data or mechanical analysis
- “ Failure mode mitigation, reliability growth
 - . Re-assess reliability for resultant changes, plot and monitor reliability growth

OVERVIEW OF THE FMEA PROCESS

- “ Define the scope of the FMEA to be conducted.
- “ Select the FMEA team.
- “ Review Design Intent (DFMEA) or Design Intent & Process Function (PFMEA)
 - . Product - Marketing Plan
 - . Product - Design goals
 - . Process Flowchart
 - . Process function
 - . Historical data
 - . Other information

OVERVIEW OF THE FMEA PROCESS

- “ Identify all failure modes & the corresponding effects.
- “ Rate the relative risk of each failure mode and effect.
 - . Severity

- “ Identify all potential causes.
- “ Rate the relative risk of each cause.
 - . Occurrence

- “ Identify all current design (DFMEA) or process (PFMEA) controls to prevent or detect the failure mode.
- “ Rate the relative risk of all controls.
 - . Detection/Prevention

- “ Prioritize for action.
 - . Calculate the RPN (Risk Priority Number).
 - . Use the Pareto Principle.
- “ Take action and validate action effectiveness.
- “ Calculate the resulting RPN.

FMEA

Item / Design Intent	Potential Failure Mode	Potential Effect(s) of Failure	S e v	C l a s s	Potential Cause(s)/ Mechanism(s) Of Failure	O c c u r	Current Design Controls		D e t e c	R P N	Recommended Actions	Response & Traget Complete Date	Action Results				
							Prevent	Detect					Action Taken	S E V	O C C	D E T	R P N

Design (Product) FMEA

- Led by Design Engineer
- **Does not rely on process controls to overcome potential weaknesses in the design**
- Does take into account the technical/physical limits of the manufacturing process

Process FMEA

É Normally led by a member from Quality, Manufacturing Engineering or Process Engineering team.

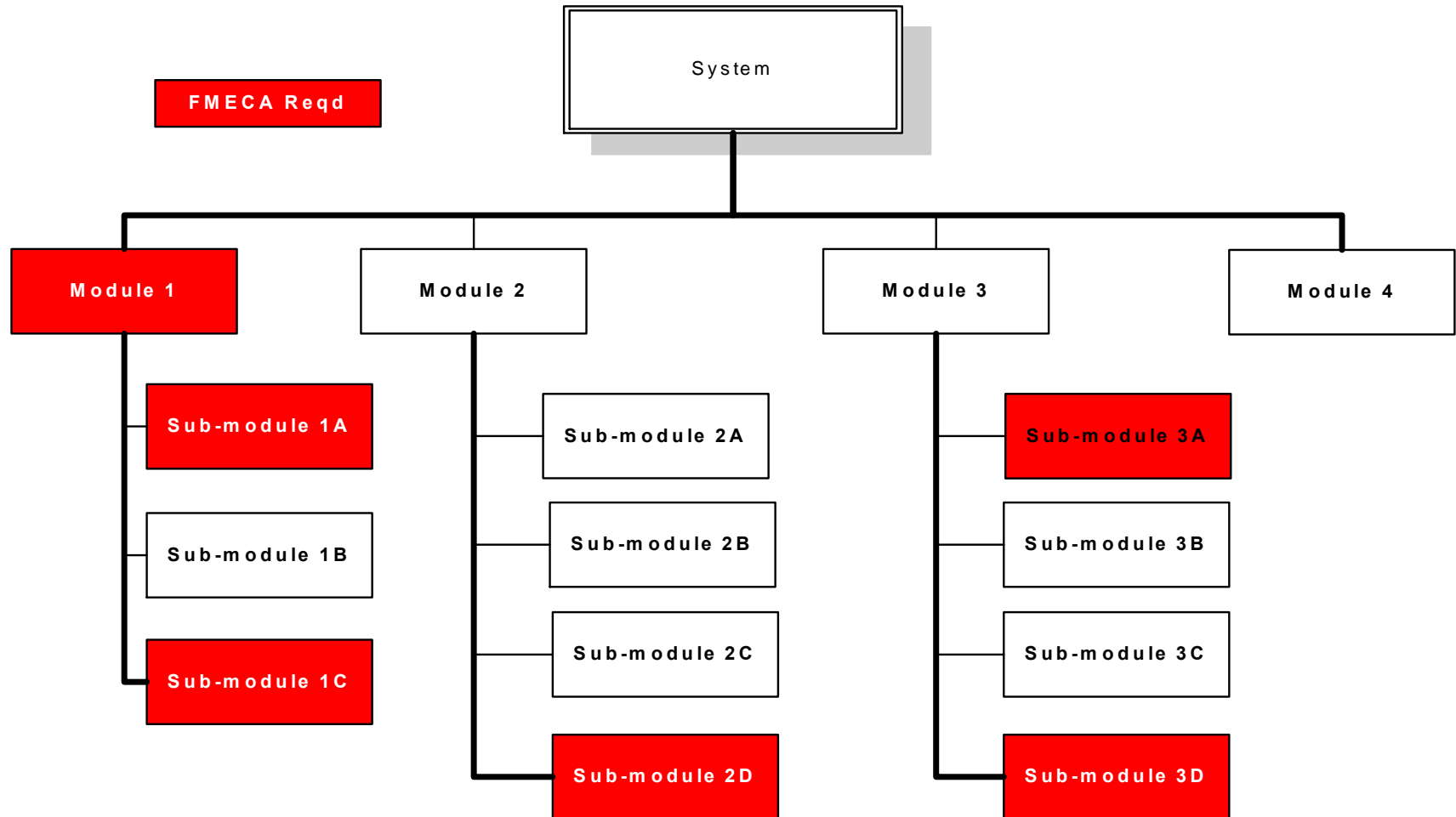
É **The Process FMEA assumes the product as designed will meet the design intent.**

É Process FMEA must meet product design intent and process function.

FMEA

Levels of analysis - Scope of the FMEA

Reliability apportionment-type block diagram. Describe the function and performance specifications for each block



FMEA

Item/ Process Step Function	Potential Failure Mode	Potential Effect(s) of Failure	S e v	C l a s s	Potential Cause(s)/ Mechanism(s) Of Failure	O c c u r	Current Process Controls		D e t e c	R P N	Recommended Actions	Response & Traget Complete Date	Action Results					
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Critical

Process Function & Design Intent (PFMEA)

Design Intent Requirements (5Cs):

- . Critical To Quality**
- . Critical To Application**
- . Critical To Customer**
- . Critical To Process**
- . Critical To Safety/Regulatory Compliance**

FMEA

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	↑																	

Potential Failure Mode

(D) Manner in which a component, subsystem or product could fail to meet design intent

(P) Manner in which the process could fail to meet the process function and design intent

Using this definition a failure does not need to be readily detectable by a customer to still be considered a failure.

Types of Questions to ask

- How can the product or process fail to meet specifications?
- Regardless of the engineering/requirement specs, what would the customer consider objectionable?
- When this operation is being done, what could go wrong? Or, what tends to go wrong?

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Voice of the Customer

Potential Effects

Determine the effects of potential failures.

Effects of the failure mode on the external and internal customer

Severity Ranking

- “ Rating of 1 to 10 with 10 being the most severe impact.
 - . Use a scale.
 - . Use the same scale throughout.
- “ To assign this rating, must assume the failure mode has occurred.
- “ Assign severity rating for every possible effect.
 - . Understand customer effects
 - . Understand internal effects

A Severity 9 or 10 must have preventive action

III. Automotive, SAE FMEA , SAE J-1739: Severity Table

Severity	Criteria	Ranking
None	No discernible effect.	1
Very Minor	Fit and finish/squeak and rattle item does not conform. Defect noticed by discriminating customers (less than 25 %).	2
Minor	Fit and finish/squeak and rattle item does not conform. Defect noticed by 50 % of customers.	3
Very low	Fit and finish/squeak and rattle item does not conform. Defect noticed by most customers (greater than 75 %).	4
Low	Vehicle/item operable but comfort/convenience item(s) operable at a reduced level of performance. Customer somewhat dissatisfied.	5
Moderate	Vehicle/item operable but comfort/convenience item(s) inoperable. Customer dissatisfied.	6
High	Vehicle/item operable but at a reduced level of performance. Customer very dissatisfied.	7
Very High	Vehicle/item inoperable (loss of primary function)	8
Hazardous with warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves non-compliance with government regulation with warning.	9
Hazardous with warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves non-compliance with government regulation without warning.	10

FMEA

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<div data-bbox="751 685 1358 901" style="border: 1px solid black; background-color: #e0f2f7; padding: 10px; display: inline-block;"> Root Cause Analysis Data </div>																														

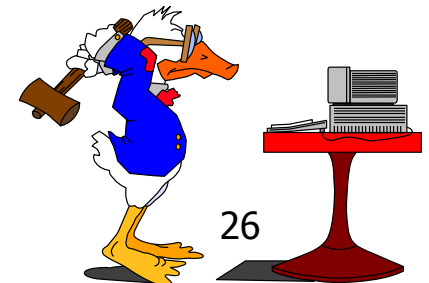
Potential Causes

Determine the potential causes of each of potential failure.
What are the potential causes of the failure mode?

A cause and effect (fishbone) diagram may be helpful here.

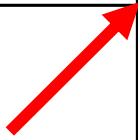
(D) An indication of a design weakness resulting in the failure mode (Material failures, Incorrect Assumptions, Design Errors, Component Selection Errors, etc.)

(P) How the failure could occur during production
(Human Error, Equipment Error, Calibration Issue
Improper mold set-up, Insufficient shot size, mold temperature too high, etc.)



FMEA

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Occurrence Ranking

- “ How often will each potential cause occur?
 - . Ignore the severity and the possibility that it will or will not be detected.
 - . Rating on a 1 to 10 scale with 10 being the most frequent.
- “ Define root causes of each failure mode
- “ Use data where possible
 - . Cpk information.
 - . Customer complaints.
 - . Root cause analysis.
- “ Occurrence - Need to consider the time frame for evaluation

Automotive, SAE FMEA , SAE J-1739; Occurrence Table

Failure mode occurrence	Rating <i>O</i>	Frequency	Probability
Remote: Failure is unlikely.	1	≤ 0,010 per thousand vehicles/times	≤ 1,00x10 ⁻⁵
Low: Relatively few failures.	2	0,1 per thousand vehicles/items	1,00x10 ⁻⁴
	3	0,5 per thousand vehicles/items	5,00x10 ⁻⁴
Moderate: Occasional failures	4	1 per thousand vehicles/items	1,00x10 ⁻³
	5	2 per thousand vehicles/items	2,00x10 ⁻³
	6	5 per thousand vehicles/items	5,00x10 ⁻³ .
High: Repeated failures.	7	10 per thousand vehicles/items	1,00x10 ⁻²
	8	20 per thousand vehicles/items	2,00x10 ⁻²
Very high: Failure is almost inevitable	9	50 per thousand vehicles/items	5,00x10 ⁻²
	10	≥100 in thousand vehicles/items	≥1,00x10 ⁻¹

FMEA

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Think
Prevention

Current Process Controls

What are the current process controls (PFMEA) to prevent or detect the cause/mechanism of failure leading to the potential failure mode?

Prevention of failure mode or reduction in occurrence. Detection of cause of failure mode leading to Corrective Actions

Detection / Prevention Rating

- “ The assessment of the ability of the % design controls to identify a potential cause or design weakness before the product is released for production to the customer.
 - . Process controls prevent/detect the failure before the product is shipped to the customer

- “ Rate the Detection from 1 to 10 with 10 being no chance of detecting the failure mode or its effect (s).

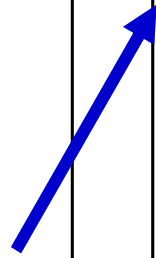
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Think
Prevention

FMEA

Item/ Process Step Function	Potential Failure Mode	Potential Effect(s) of Failure	S e v	C l a s s	Potential Cause(s)/ Mechanism(s) Of Failure	O c c u r	Current Process Controls		D e t e c	R P N	Recommended Actions	Response & Traget Complete Date	Action Results					
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III. Automotive, SAE FMEA , SAE J-1739: Detection

Detection	Criteria: Likelihood of detection by Design Control	Ranking
Almost certain	Design Control will almost certainly detect a potential cause/mechanism and subsequent failure mode	1
Very high	Very high chance the Design Control will detect a potential cause/mechanism and subsequent failure mode	2
High	High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode	3
Moderately high	Moderately high chance the Design Control will detect a potential cause/mechanism and subsequent failure mode	4
Moderate	Moderate chance the Design Control will detect a potential cause/mechanism and subsequent failure mode	5
Low	Low chance the Design Control will detect a potential cause/mechanism and subsequent failure mode	6
Very low	Very low chance the Design Control will detect a potential cause/mechanism and subsequent failure mode	7
Remote	Remote chance the Design Control will detect a potential cause/mechanism and subsequent failure mode	8
Very remote	Very remote chance the Design Control will detect a potential cause/mechanism and subsequent failure mode	9
Absolute uncertainty	Design Control will not and/or can not detect a potential cause/mechanism and subsequent failure mode; or there is no Design Control	10

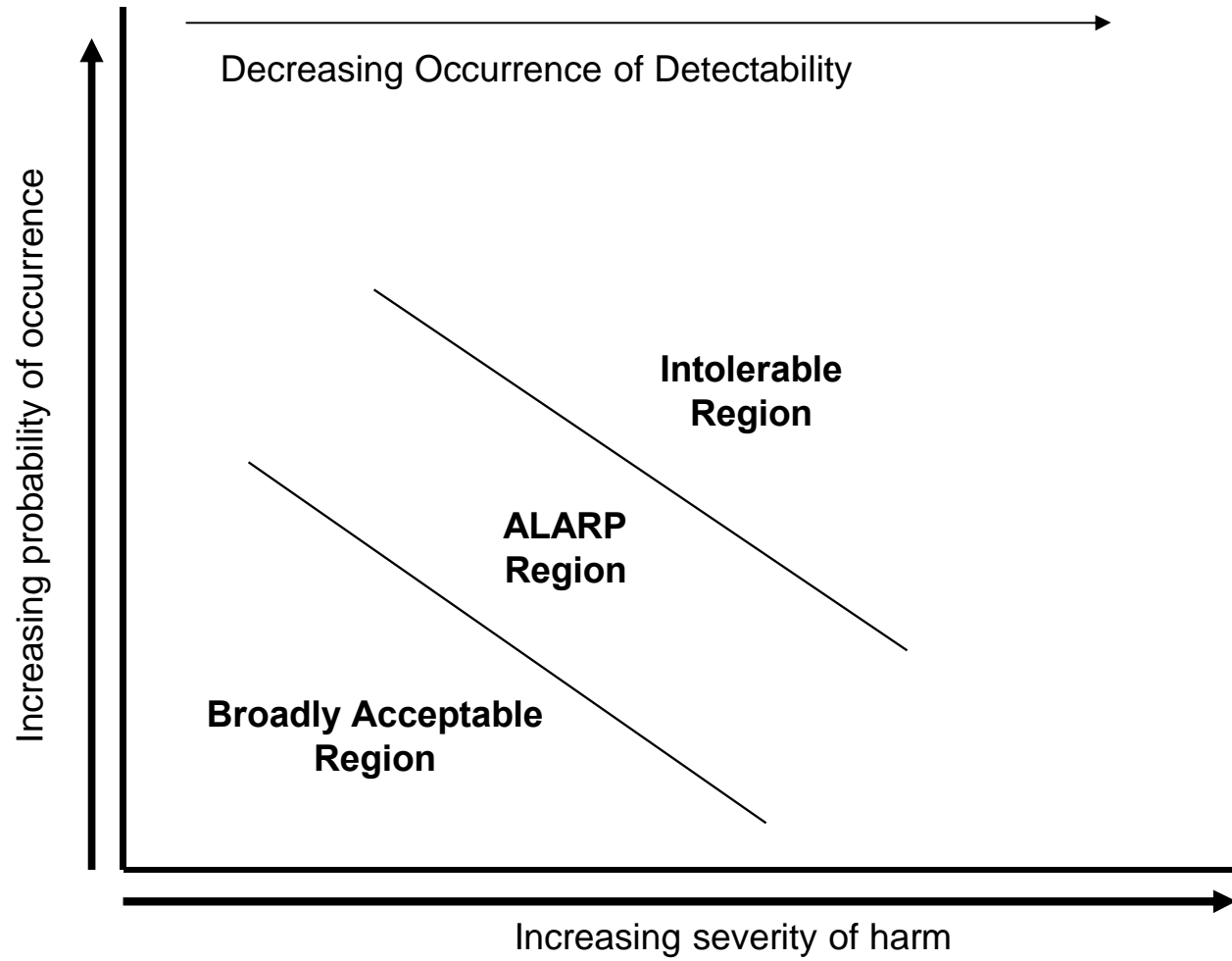
6. Risk Assessment

- **Severity**
The impacts) of failure
- **Occurrence**
The likelihood of a failure occurrence from an identified cause under current controls
- **Detection**
How detectable is the failure at any point?

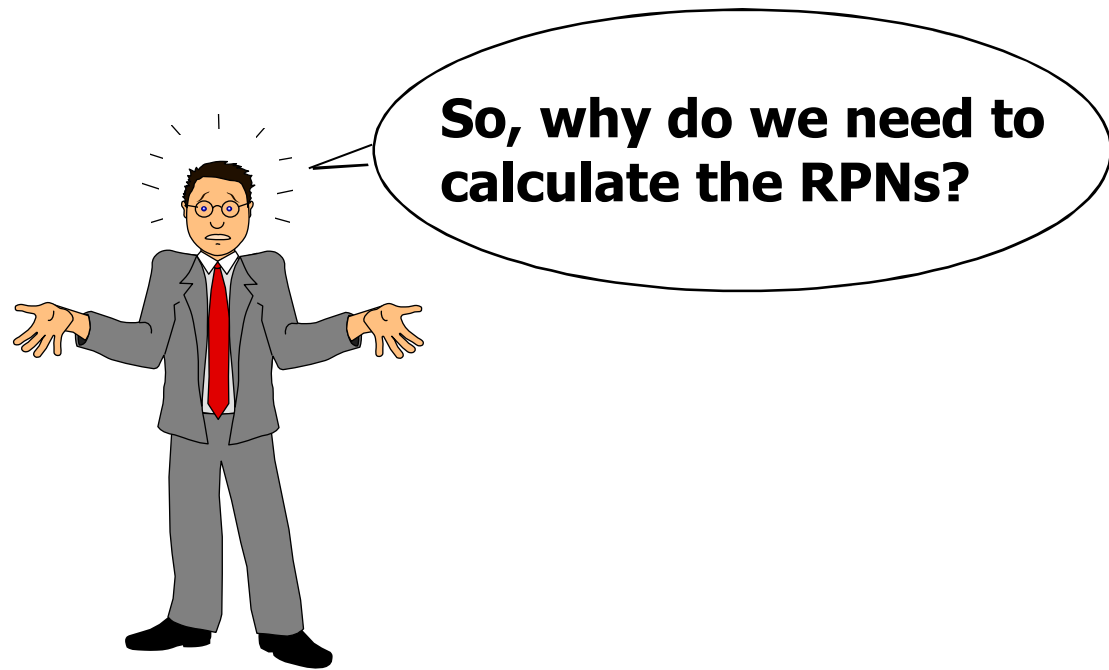
Potential Risk (RPN) = Severity x Occurrence x Detection

Risk Evaluation

Risk Acceptability Decisions



EMEA Safety	Sever-ity	Occur-rence	Detect-ability	Risk Priority Number RPN= S*O*D	Health of Design/ Mfg Process
HIGH RISK 4-10 UNACCEP-TABLE	10	10	10	1000	UNACCEPTABLE Redesign Required
	9	9	9	500	
	8	8	8	400	
	7	7	7	300	
	6	6	6	200	MARGINAL Action Required
	5	5	5	199	
	4	4	4	150	
LOW RISK 1-3	4	4	4	100	GOOD
	3	3	3	99	
	2	2	2	25	
1	1	1	1		



By giving every Failure Mode a RPN rating, we can now prioritize which failure modes to address now and which failure modes we address later.

REDUCING THE POTENTIAL RISK:

First line of defense -

Eliminate causes of failure so that it does not OCCUR - Implement prevention techniques

Second line of defense -

Reduce probability of OCCURRENCE

Third line of defense -

Improve DETECTION of the failure

FMEA Pitfalls – A review

- ◆ No Cross-functionality on the Team
- ◆ Poor Leadership of the Team
- ◆ No Scope Definition
- ◆ No Data Available / Not Used
- ◆ No Customer Involvement / Voice of the Customer
- ◆ Meeting Management problems
- ◆ S,O,D criteria decisions (too long!)
- ◆ No supplier involvement
- ◆ Team Members not committed
- ◆ No Management Commitment & Support

In Conclusion

- ◆ FMEA does take time and effort
- ◆ It does reduce the risk to your customer
- ◆ It does reduce the risk to you
- ◆ It does save time to product launch
- ◆ It does help with Continuous Improvement

Wrap-up

Questions?

Thank you!