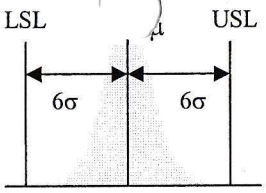
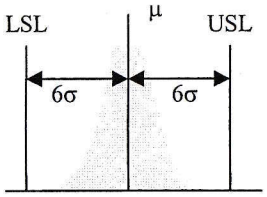


The Tech Group

Lean Sigma Training

FMEA

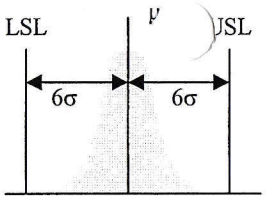
Failure Modes & Effects Analysis



The Tech Group

Objectives

- Understand the Purpose of FMEA's and how they help us to focus on what is important
- Learn the steps to perform an FMEA
- How to screen out process steps or inputs that are not important
- Understand how to perform an FMEA on "product" versus a "process"

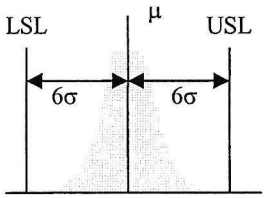


What is a FMEA ?

The Tech Group

A systematic approach for identifying, quantifying and ranking the risk of failure modes and prioritize the efforts to mitigate risk.

- Identify potential failure modes and rate the severity of their effect
- Facilitate process or product improvement
- Improve product safety and reliability
- Identify and eliminate concerns early in the development of a product or process
- Improve the "Bottom Line" - $$$$$
- Improve customer satisfaction 
- Catalyst for the stimulation and interchange of ideas between people
- Document the actions taken to reduce risk

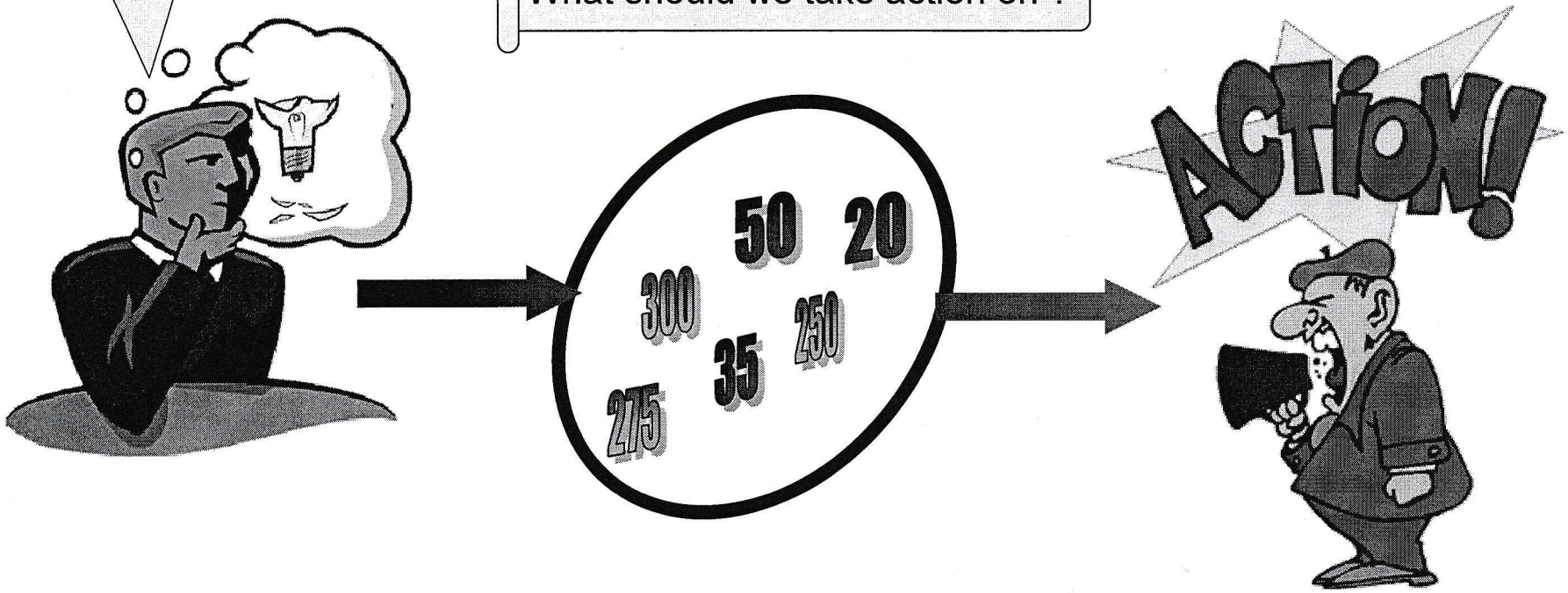


Conceptual FMEA

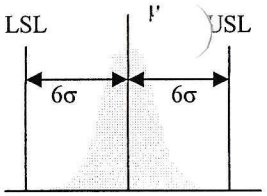
The Tech Group

What can go wrong ?
What will cause it ?

What's the biggest risk?
What should we take action on ?

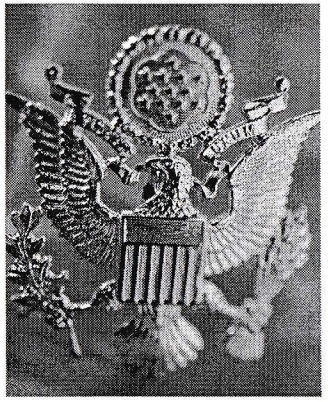


How we focus on the cause of the problem

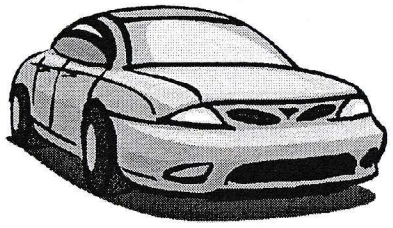


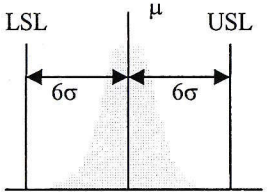
FMEA History

- Developed by the U.S. Military in 1949 (MIL-Std-1629)
  - Reliability evaluation tool
  - Used to classify impact on mission success
  - Used for development of the rocket



- AIAG Revised the military version in 1993
  (Automotive Improvement Action Group)
  - Headed up by the BIG 3 (FORD, GM and Chrysler)
  - Meet ISO / QS 9000 Requirements
  - Large, all inclusive exercises





FMEA Steps

The Tech Group

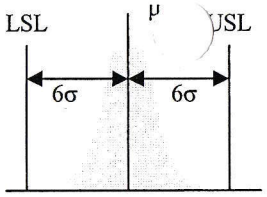
Failure Modes and Effects Analysis (FMEA) Form

The Tech Group
WE PROVIDE INNOVATIVE SOLUTIONS

Product/Cell: _____ Participants: _____ Tech Group Location: _____
Process: _____
Problem: _____ FMEA Revision: _____ Date: _____
Facilitated By: _____ Ext: _____
Date:

Process Step/Input ①	Potential Failure Mode ②	Potential Failure Effects ③	SEV	Potential Causes ④	OCC	Current Controls ⑤	DET	RPN	Actions Recommended ⑦	Plans / Responsibility ⑧	pSEV	pOCC	pDET
												⑨	
						⑥							

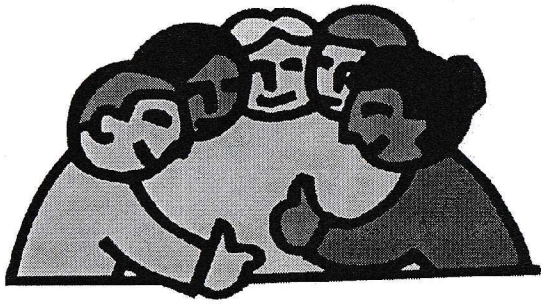
1. List the process step
2. Identify potential failure mode
3. Describe the effects of failures
4. Determine causes
5. Describe controls
6. Rate severity, occurrence, detectability and calculate RPN
7. Recommend actions
8. Define plan and responsibility for action
9. Assess actions



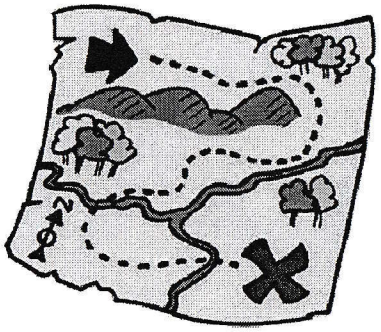
Preparation for a FMEA

The Tech Group

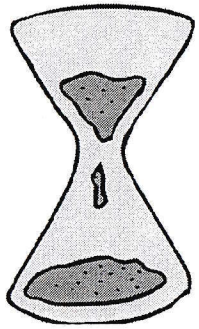
- Compile a team with knowledgeable representation
  - Designer
  - Engineering
  - Process Development or Manufacturing
  - Quality
  - Purchasing

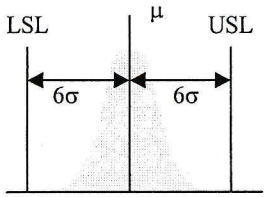


- Complete PMAP
  - Process steps
  - Outputs
  - Inputs



- Schedule meeting (Max. 3 hrs per meeting)

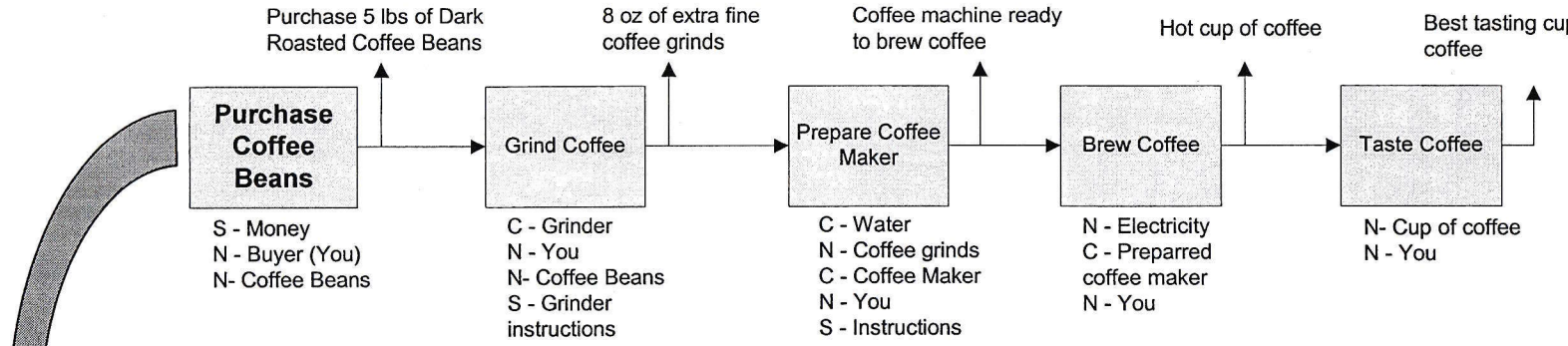




Step 1: List the Process Step

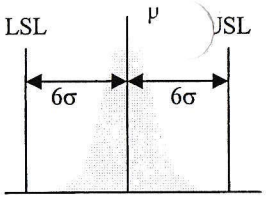
The Tech Group

"Your" process map for making a great cup of coffee.



Process Step/Input	Potential Failure Mode	Potential Failure Effects	S E V	Potential Causes	O C C	Current Controls	D E T
Purchase Coffee Beans							

List the process steps from your PMAP in the FMEA



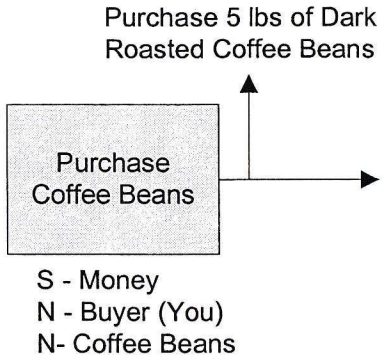
Step 2: Identify Potential Failure Modes

The Tech Group

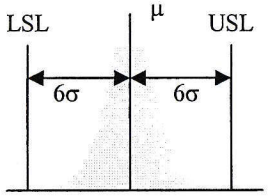
How the process could fail to conform to process requirements as described by the needs, wants, and expectations of the internal and external Customers.

It is typically the converse to what you want to happen (y's) at a process step.

Failure Mode is the Converse to this



Process Step/Input	Potential Failure Mode	Potential Failure Effects	S E V	Potential Causes	O C C	Current Controls	D E T
Purchase Coffee Beans	**Do not purchase 5lbs of Dark Roasted coffee beans**						



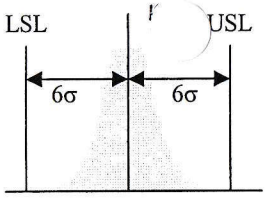
Step 3: Describe the Effects of the Failure

The Tech Group

An adverse consequence that the customer might experience. The customer could be the next operation, subsequent operations, or the end user

Process Step/Input	Potential Failure Mode	Potential Failure Effects	S E V	Potential Causes	O C C	Current Controls	D E T
Purchase Coffee Beans	Do not purchase 5lbs of Dark Roasted coffee beans	**Can not make a cup of coffee**					

There can be multiple effects for each Failure Mode



Step 4: Determine the Cause(s)

The Tech Group

Process Step/Input	Potential Failure Mode	Potential Failure Effects	S E V	Potential Causes	O C C	Current Controls	D E T
Purchase Coffee Beans	Do not purchase 5lbs of Dark Roasted coffee beans	Can not make a cup of coffee		**You left your money at home**			
				Store is out of Dark Roasted coffee beans			
				Dark Roasted coffee beans are not fresh			

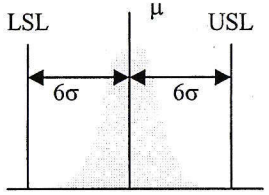
Purchase 5 lbs of Dark Roasted Coffee Beans

Purchase Coffee Beans

S - Money
N - Buyer (You)
N -Coffee Beans

The means by which a particular element of the process results in a Failure Mode

Root causes are inputs (x's) to the process



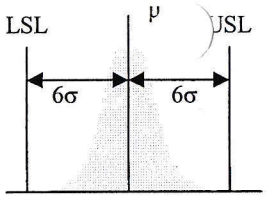
Step 5: Describe the Controls

The Tech Group

Process Step/Input	Potential Failure Mode	Potential Failure Effects	S E V	Potential Causes	O C C	Current Controls	D E T
Purchase Coffee Beans	Do not purchase 5lbs of Dark Roasted coffee beans	Can not make a cup of coffee		You left your money at home		**You check your wallet when leaving for the store**	
				Store is out of Dark Roasted coffee beans		**None**	
				Dark Roasted coffee beans are not fresh		**Store employees test coffee made with beans 1x per day**	

What you are currently doing to:

a) Prevent the cause from occurring
b) Reduce the rate of occurrence for the cause
c) Detect the cause before it results in the failure mode
d) Detect the failure mode before customer experiences the effect



Step 6a: Create Severity, Occurrence and Detection Tables

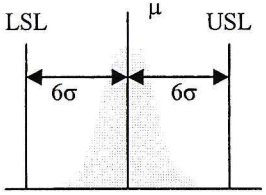
The Tech Group

- ✓ Develop rating tables that are appropriate for your situation
  - 3 to 5 levels
  - The full range of levels should be used
- ✓ Refer back to them often to avoid shift and drift in standards
- ✓ Keep the tables with the FMEA

Ranking	Criteria for Severity
9	Coffee can not be made
7	Bad coffee taste, not drinkable
4	Coffee flavor is weak
1	Too much time

Ranking	Criteria for Occurrence
9	Happens > 50% of the time
7	Happens >25% and < 50%
4	Happens 1% to 25%
1	Happens less than 1%

Ranking	Criteria for Detect ability
9	No controls
5	Person dependent control, detect before customer feels the effect.
1	Proven system, can detect cause and prevent failure mode



Step 6b: Rate Severity, Occurrence and Detection

The Tech Group

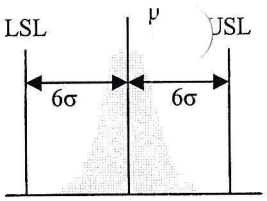
Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET
Purchase Coffee Beans	Do not purchase 5lbs of Dark Roasted coffee beans	Can not make a cup of coffee	9	You left your money at home	1	You check your wallet when leaving for the store	5
			9	Store is out of Dark Roasted coffee beans	4	None	9
			9	Dark Roasted coffee beans are not fresh	1	Store employees test coffee made with beans 1x per day	5

Severity is an assessment of how serious the effect is on the customer

Occurrence is an estimate of the likelihood that a specific cause will occur and result in the failure mode

Detection is an assessment of the ability of the current control to either detect the failure mode, detect the cause, and /or prevent the cause from occurring

Same effect, Severity rating does not change



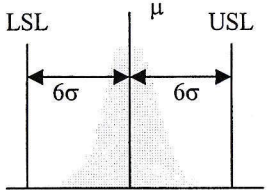
Step 6c: Calculate RPN

The Tech Group

Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN
Purchase Coffee Beans	Do not purchase 5lbs of Dark Roasted coffee beans	Can not make a cup of coffee	9	You left your money at home	1	You check your wallet when leaving for the store	5	45
			9	Store is out of Dark Roasted coffee beans	4	None	9	324
			9	Dark Roasted coffee beans are not fresh	1	Store employees test coffee made with beans 1x per day	5	45

Risk Priority Number (RPN) = Sev x Occ x Det

- This number is then used to place priorities
- However, items with low RPN numbers still require attention if the severity ranking is high



Step 7: Recommend Actions

The Tech Group

Once RPN's are calculated:

- ✓ Identify high RPN items
- ✓ Recommend action

High Severity Rating
Generally requires a design change

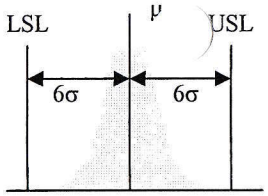
(Difficult to change)

High Occurrence Rating
Activities that lead to a prevention of the failure mode or the cause of the failure mode

High Detection Rating
Improve the design controls to detect the cause and Prevent the failure from occurring
(Easiest to change)

Focus on Defect Prevention

Tip: Re-sort items by RPN Number to position all high RPN's together



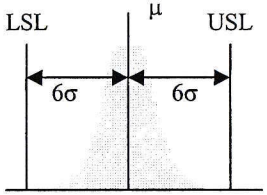
Recommend Actions

The Tech Group

Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN	Actions Recommended	Plans / Responsibility
Do not purchase 5lbs of Dark Roasted coffee beans	Can not make a cup of coffee	9	You left your money at home	1	You check your wallet when leaving for the store	5	45		
		9	Store is out of Dark Roasted coffee beans	4	None	9	324	**Verify by phone, which store has beans prior to leaving to purchase**	
		9	Dark Roasted coffee beans are not fresh	1	Store employees test coffee made with beans 1x per day	5	45		

Institute actions that will lower the Occurrence, Severity and/or Detection ranking for the highest RPN failure modes

Recommend actions for all item based on the natural break In the RPN values or as determined by the team

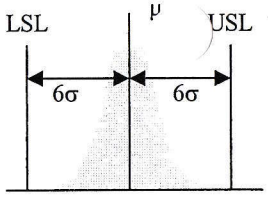


Step 8: Determine the plan and assign responsibility

The Tech Group

Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN	Actions Recommended	Plans / Responsibility
Do not purchase 5lbs of Dark Roasted coffee beans	Can not make a cup of coffee	9	You left your money at home	1	You check your wallet when leaving for the store	5	45		
		9	Store is out of Dark Roasted coffee beans	4	None	9	324	Verify by phone, which store has beans prior to leaving to purchase	**You will implement into your process by June 1, 2003**
		9	Dark Roasted coffee beans are not fresh	1	Store employees test coffee made with beans 1x per day	5	45		

Actions must have dates and who's responsible



Step 9: Assess Actions

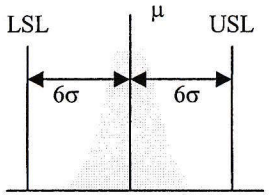
The Tech Group

S E V	Potential Causes	O C C	Current Controls	D E T	R P N	Actions Recommended	Plans / Responsibility	*p S E V*	*p O C C*	*p D E T*	*p R P N*
9	You left your money at home	1	You check your wallet when leaving for the store	5	45						
9	Store is out of Dark Roasted coffee beans	4	None	9	324	Verify by phone, which store has beans prior to leaving to purchase	You will implement into your process by June 1, 2003	9	4	1	36
9	Dark Roasted coffee beans are not fresh	1	Store employees test coffee made with beans 1x per day	5	45						

"*P*" stands for predicted (i.e., how well you expect the change to work)

After the actions are recommended, re-rate and re-calculate the RPN's to see the predicted impact of the actions

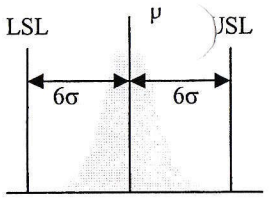
Once the actions are implemented, update the FMEA with the new actuals to see the actual impact of the actions



FMEA Exercise

The Tech Group

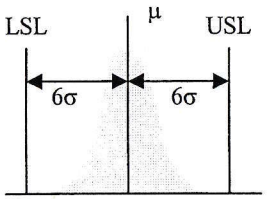
- Using the Process Map developed during the PMAP module, create an FMEA
  - Select 1-2 process step and perform the FMEA
  - Include recommended actions for high RPN items
  - Calculate predicted values
- Be prepared to present your results to the class
- It is helpful to use "Post-it" to avoid rework and rewriting



Exercise Questions ???

The Tech Group

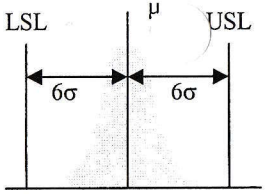
- Did you discover causes that were not listed on the PMAP ?
- Are there any inputs on the process map that are not listed as potential causes on the FMEA?
- Are the converses of each output on the process map listed as failure modes on the FMEA ?



Tool Linkage

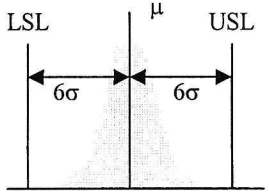
The Tech Group

Process Map	FMEA	TMAP
Process Step	Process Step	
Outputs (Y's)	Failure Modes (problem or Inverse of Y's)	
Inputs (X's)	Potential Cause	
	Actions	Actions



When do you update ?

- Whenever a change is being considered to a product's design or to a product's assembly process
- For 6 Sigma problem solving, the FMEA is complete once the problem is resolved
- For traditional use, FMEA is never complete



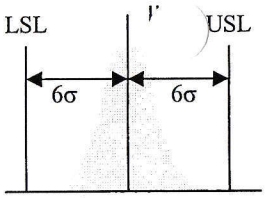
Process FMEA Summary

The Tech Group

FMEA is a systematic method to:

- Recognize, evaluate and prioritize potential failures and effects
- Identify actions which could eliminate or reduce the chance of failures occurring
- Identify the critical inputs that affect the output

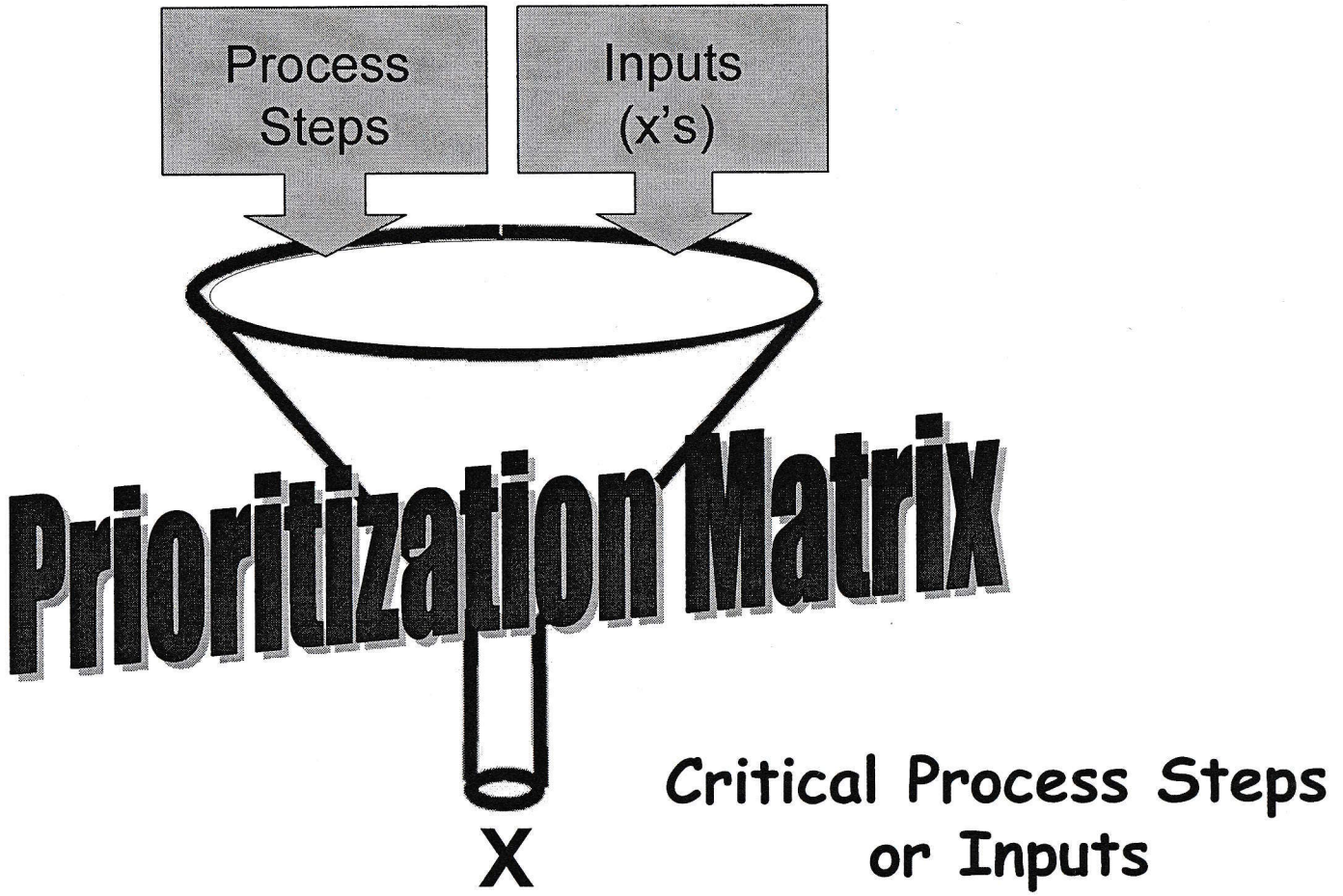
FMEA has links to other tools (PMAP & TMAP)

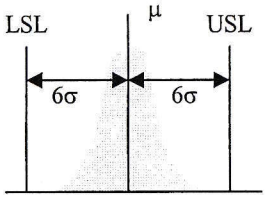


Minimize the Effort

The Tech Group

- FMEA's take time……
- How to get to the critical few variables, in the shortest time



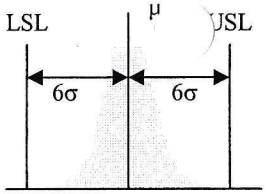


Prioritization Matrix.

The Tech Group

- Why use:
  - Identify *critical* few variables
  - Help focus the improvement initiative
  - Formulate theories about cause & effect
  - Minimize the size of the FMEA

- When to use:
  - There are to many variables or process steps
  - Collecting data about all possible variables would cost too much (Time and $)



Prioritization form

The Tech Group

Cause and Effect Prioritization Matrix

Rating for the effect each input could have on the output	None = 0, no effect or unrelated
	Remote = 1, remote chance of effect
	Slight = 3, may impact but highly unlikely to effect
	Moderate = 5, moderate impact or possible effect
	High/Direct = 9, high impact or direct effect

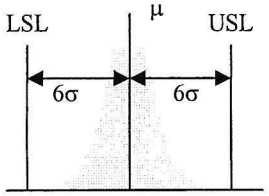
Total Rating = Σ of each Process Input Correlation times its Process Output Weight

	Weight	2							
	Process Outputs	1							Total Rating
Process Steps (Inputs)									
1	3	4							0
2									0
3									0
4									0
5									0

5

Steps:

1. **List outputs**
2. **Assign weight to outputs**
3. **List the inputs**
4. **Evaluate the relationship**
5. **Calculate the correlation ratings**
6. **Assess inputs with high ratings**



Step 1: List Output Variables

The Tech Group

Cause and Effect Prioritization Matrix	
Rating for the effect each input could have on the output	None = 0, no effect or unrelated
	Remote = 1, remote chance of effect
	Slight = 3, may impact but highly unlikely to effect
	Moderate = 5, moderate impact or possible effect
	High/Direct = 9, high impact or direct effect

Total Rating = Σ of each Process Input Correlation times its Process Output Weight

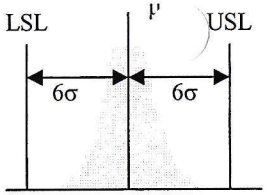
	Weight								
	Process Outputs	Cookie size	Cookie Taste	# of Cookies per Package	Cost				**Total Rating**

"Outputs" can be:

a. *Big Y's* from the process…… or

b. *Output variables* (y's) that require improvement…… or

c. *Customer requirements*, if utilizing the matrix to link process outputs to customer requirements



Step 2: Weight the Outputs

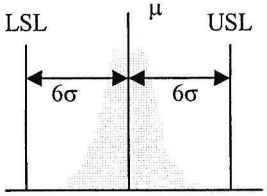
The Tech Group

Cause and Effect Prioritization Matrix	
Rating for the effect each input could have on the output	None = 0, no effect or unrelated
	Remote = 1, remote chance of effect
	Slight = 3, may impact but highly unlikely to effect
	Moderate = 5, moderate impact or possible effect
	High/Direct = 9, high impact or direct effect

Total Rating = Σ of each Process Input Correlation times its Process Output Weight

	Weight	5	8	3	4				
	Process Outputs	Cookie size	Cookie Taste	# of Cookies per Package	Cost				Total Rating

- Team develops the weight, based on customer input
- Higher the importance, the higher the weight value (Recommended range of weights: 1 to 10)



Step 3: List the Inputs

The Tech Group

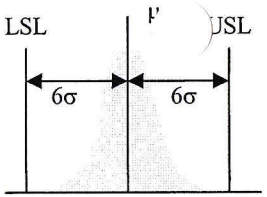
	Weight	5	8	3	4				
	Process Outputs	Cookie size	Cookie Taste	# of Cookies per Package	Cost				Total Rating
Process Steps (Inputs)									
1	Mix cookie dough								0
2	Form cookies								0
3	Bake cookies								0
4	Inspect cookies								0
5	Package cookies								0

"Inputs" can be:

a. *Process steps* from the PMAP…… or

b. *Inputs* (x's)…… or

c. *Process outputs* (little y's from the process), if utilizing the matrix to link process outputs to customer requirements



Step 4: Evaluate the Relationship

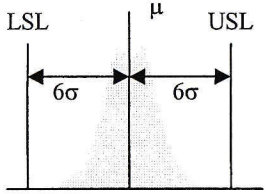
The Tech Group

Cause and Effect Prioritization Matrix

Rating for the effect each input could have on the output	None = 0, no effect or unrelated
	Remote = 1, remote chance of effect
	Slight = 3, may impact but highly unlikely to effect
	Moderate = 5, moderate impact or possible effect
	High/Direct = 9, high impact or direct effect

	Process Outputs	Cookie size	Cookie Taste	# of Cookies per Package	Cost				Total Rating
Process Steps (Inputs)									
1	Mix cookie dough	1	5	0	1				
2	Form cookies	9	1	5	5				
3	Bake cookies	3	9	0	3				
4	Inspect cookies	0	1	0	5				
5	Package cookies	0	1	9	5				

- Rate the effect each input could have on each output
- Use rating scale listed in above form or one developed by the team



Step 5: Calculate Rating

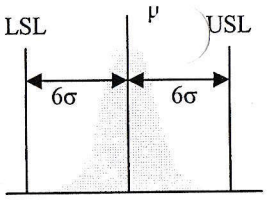
The Tech Group

Total Rating = Σ of each Process Input Correlation times its Process Output Weight

	Weight	5	8	3	4				
	Process Outputs	Cookie size	Cookie Taste	# of Cookies per Package	Cost				**Total Rating**
Process Steps (Inputs)									
1	Mix cookie dough	1	5	0	1				49
2	Form cookies	9	1	5	5				88
3	Bake cookies	3	9	0	3				99
4	Inspect cookies	0	1	0	5				28
5	Package cookies	0	1	9	5				55

- Cross multiply weight and correlation values for each input and sum for each input

Rating (Mix Cookie Dough) = (5 x 1) + (8 x 5) + (3 x 0) + (4 x 1) = 49



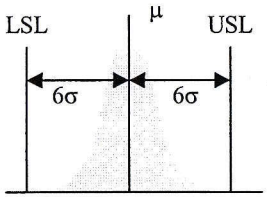
Step 6: Highlight Critical Few

The Tech Group

Total Rating = Σ of each Process Input Correlation times its Process Output Weight									
	Weight	5	8	3	4				
	Process Outputs	Cookie size	Cookie Taste	# of Cookies per Package	Cost				Total Rating
Process Steps (Inputs)									
1	Mix cookie dough	1	5	0	1				49
2	Form cookies	9	1	5	5				88
3	Bake cookies	3	9	0	3				99
4	Inspect cookies	0	1	0	5				28
5	Package cookies	0	1	9	5				55

Inputs with largest rating:

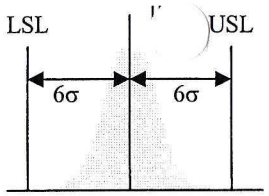
- Most critical, have the biggest impact on the outputs
- To be used in the FMEA



Prioritization Matrix Summary

The Tech Group

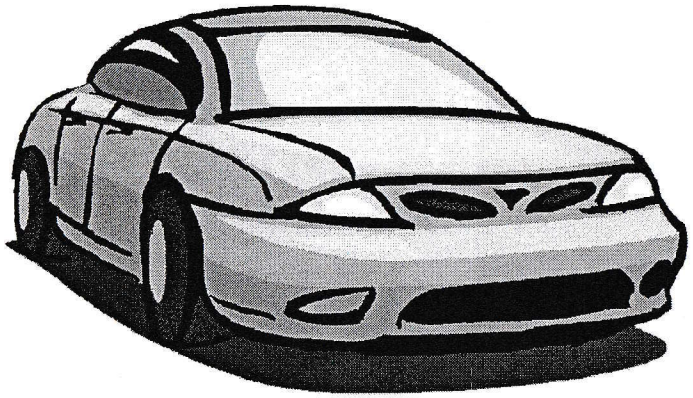
- Identify the critical few
- Provide focus in the correct area(s)
- Establish cause & effect relationship
- Minimize time waste
- Save $$$



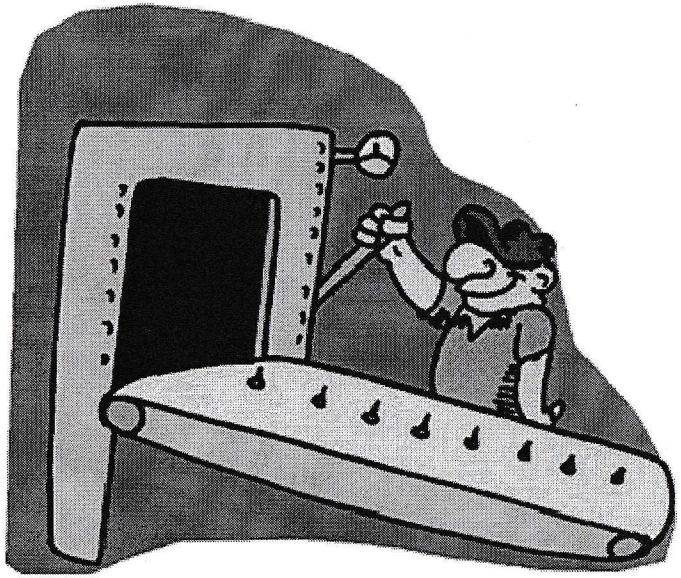
Product vs. Process

The Tech Group

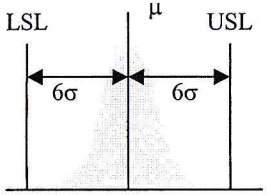
- I'm trying to improve a product……..



Versus



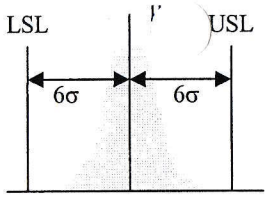
Use a Design FMEA



Design FMEA Benefits

The Tech Group

- Improve product function, reliability and safety
- Reduce cost
- Time reduction
- Design out potential failure modes
- Eliminate concerns early in development



Definitions – Design FMEA

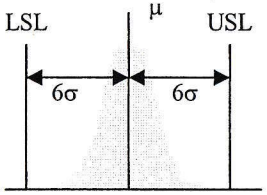
The Tech Group

Detection is an assessment of the ability of the current design control to detect the subsequent failure mode or potential cause of the design weakness before releasing to production.

Item / function is the concise name of the analyzed item with an exact easy-to-understand explanation of the function that is analyzed to meet the design intent.

Potential Failure Mode describes the way a design could fail to perform its intended function.

Potential Cause is the design weakness that causes the potential failure mode.

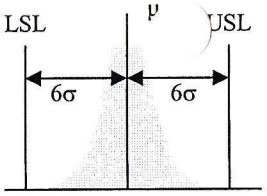


Design FMEA Guidelines

The Tech Group

A design FMEA:

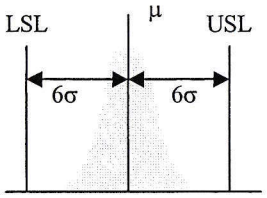
- does not need to include items covered by a process FMEA (failure modes or causes from mfg. or assembly)
- does not rely on process controls to overcome design weaknesses
- will consider technical and physical limits of the mfg. process



Design FMEA Preparation

The Tech Group

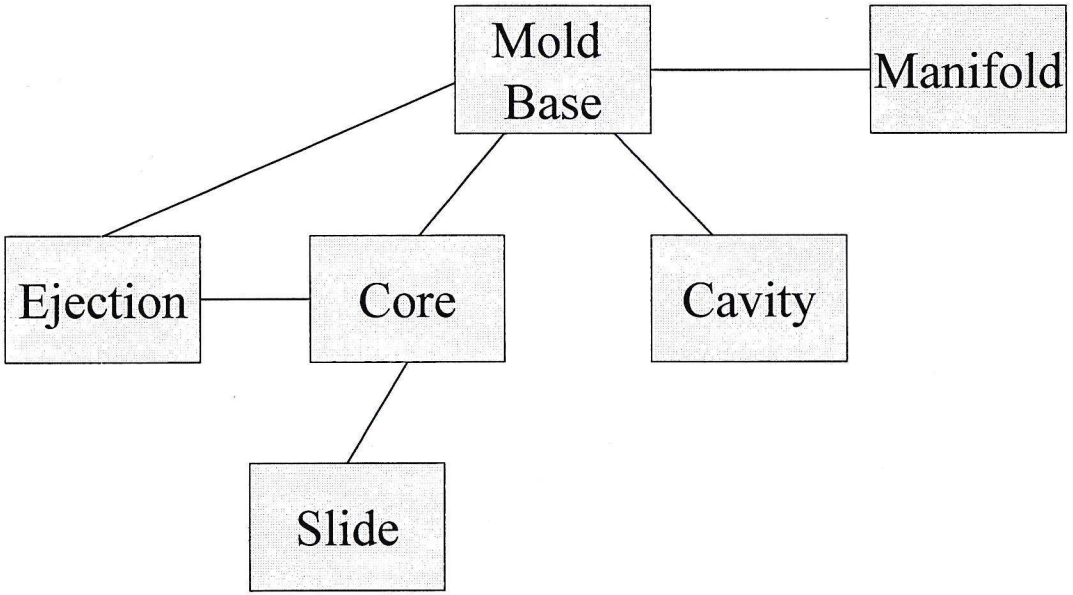
- Compile a team with knowledgeable representation
  - ✓ Design
  - ✓ Engineering
  - ✓ Process Development or Manufacturing
  - ✓ Quality
  - ✓ Customer
- Compile information on "Design Intent"
  i.e, a list of what the design is or is not suppose to do
- Develop a relationship block diagram of the system, sub-system or component
- Schedule meeting (Max. 3 hrs per meeting)



Relationship Diagram Example

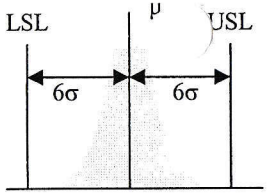
The Tech Group

Relationship diagram for an injection mold design



- The blocks represent the item / function
- The deliverables are the inputs and outputs for each block

Note: Each of these block can be broken down to the sub-system and additional block diagrams can be created



Design FMEA Steps

The Tech Group

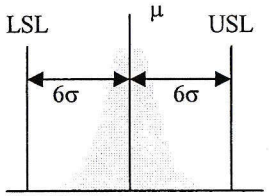
Failure Modes and Effects Analysis (FMEA) Form

Product/Cell: _____
Process: _____
Problem: _____
Prepared By: _____
Date: _____

Severity (SEV): How severe is the effect on the customer? (9 = Mold doesn't function, 1 = Runs semi-automatic parts visibly acceptable)
Probability of Occurrence (OCC): How often does the cause or FM occur? (9 = Always occurs, 1 = Never occurs)
Detectability (DET): How well can you detect the cause or FM using the current controls? (9 = Cannot detech, 1 = Detect and Prevent)
Risk Priority Number (RPN): What is the measure of process risk related to the effects, causes & controls? (RPN = SEV. x OCC. x DET.)

Process (Step/Inpu) Design (Item/Function)	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN	Actions Recommended	Plans / Responsibility	pSEV	pOCC	pDET	pRPN
①	②	③		④		⑤			⑦	⑧			⑨	
						⑥								

1. List the item / function
2. Identify potential failure mode
3. Describe the effects of failures
4. Determine causes
5. Describe design controls
6. Rate severity, occurrence, detectability and calculate RPN
7. Recommend actions
8. Define plan and responsibility for action
9. Assess actions

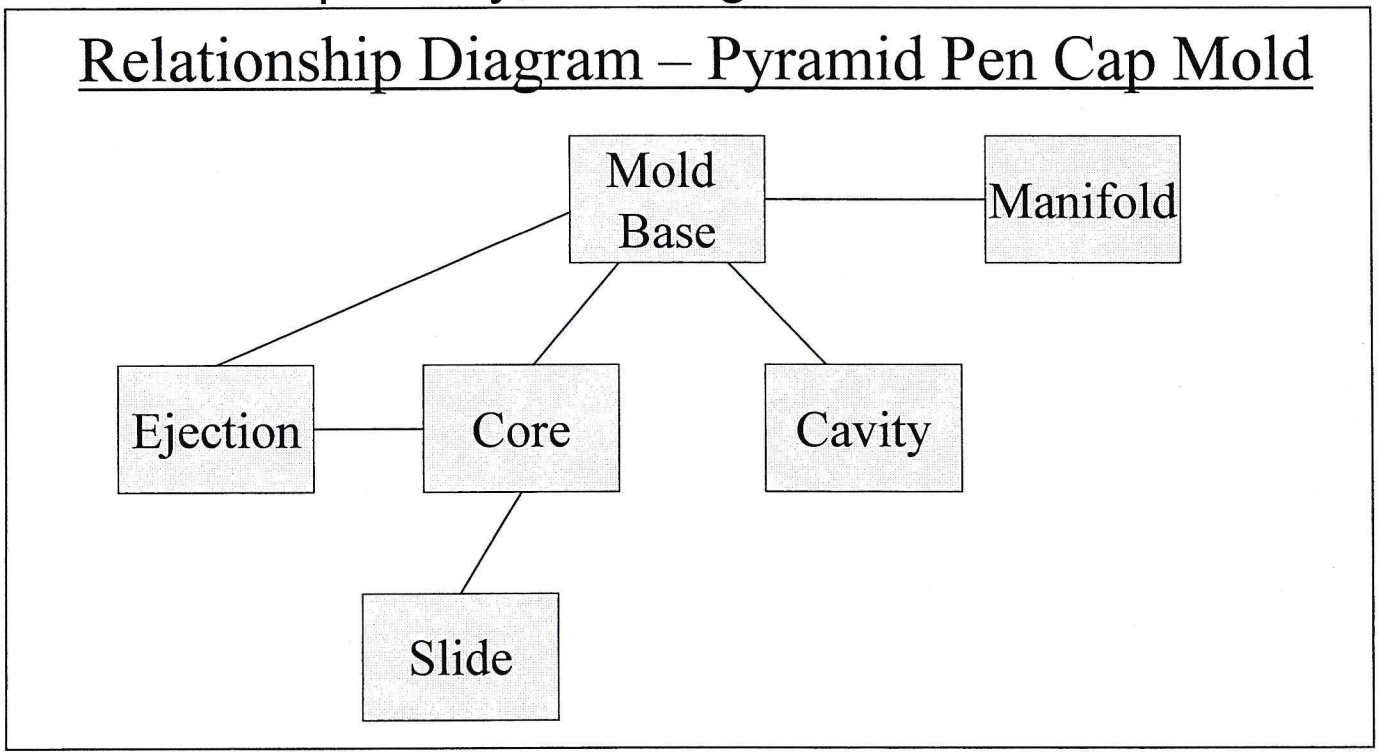


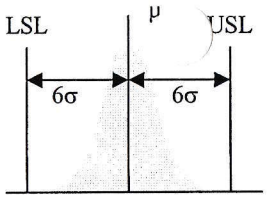
Step 1: Describe the Item / Function

The Tech Group

List the name (number) of the item analyzed with an exact easy-to-understand explanation of the function(s) of the item

- Use your relationship diagram to provide the starting point for the items / functions
- List each function separately, allowing for different failure modes for each





Failure Modes and

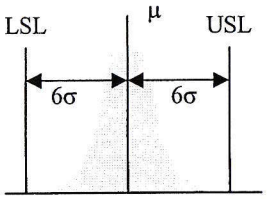
The Tech Group

Product/Cell: Never-Break Pen Company- Pen Cap
Process: Design of the Pyramid Pen Cap Mold
Problem: Functional Mold
Prepared By: John, Doe, Sally Johnson, Jimmy Johnson
Date: Jan. 7, 2001

This is for the "System"

Process (Step/Input) Design (Item/Function)	Potential Failure Mode	Potential Failure Effects	S E V
Pyramid Pen Cap: Mold NB12003 - Produce cap that is CTF capable - Run in a 80 ton demag - Cycle time less than 12 sec - Run auotmatic			

This can be broken out to the sub-system items listed in the block diagram



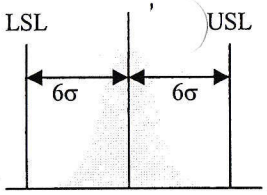
The Tech Group

Failure Modes and

Product/Cell: Never-Break Pen Company - Pen Cap
Process: Design of the Pyramid Pen Cap mold
Problem: Functional Mold
Prepared By: John, Doe, Sally Johnson, Jimmy Johnson
Date: Jan. 7, 2001

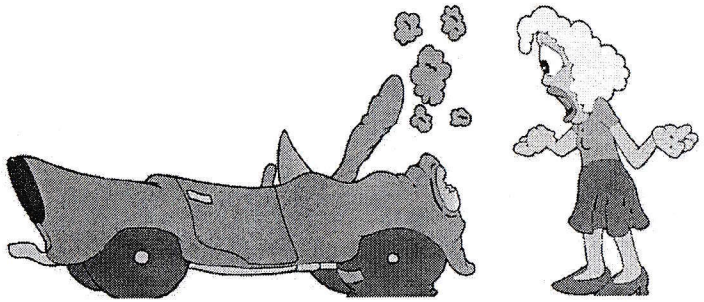
This is for the "Sub-System"

Process (Step/Input) ~~Design~~ (Item/Function)	Potential Failure Mode	Potential Failure Effects	S E V
Pyramid Pen Cap: Base - Housing for all mold components - Run in a 80 ton demag			
Pyramid Pen Cap: Cavity - Form "A" side part geometry - Part to release from steel			
Pyramid Pen Cap: Core - Form "B" side part geometry - Part to release with 1 ejection stroke			



Step 2: Identify Potential Failure Modes

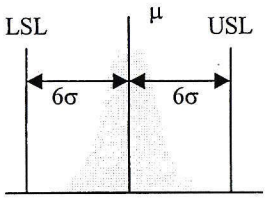
The Tech Group



The way a design could fail to perform its intended function

Process (Step/Input) Design (Item/Function)	Potential Failure Mode	Potential Failure Effects	S E V	Potential Causes
Pyramid Pen Cap: Cavity - Form "A" side part geometry - Part to release from steel	Part sticks in cavity			

Failure modes are converses to what you want to happen



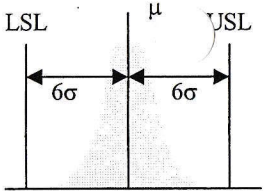
Step 3: Describe the Effects of the Failure

The Tech Group

The effect of the failure mode on the function that the customer will see

Process (Step/Input) Design (Item/Function)	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC
Pyramid Pen Cap: Cavity - Form "A" side part geometry - Part to release from steel	Part sticks in cavity	Mold does not run auto			
		Parts distorted			

There can be multiple effects for a failure mode



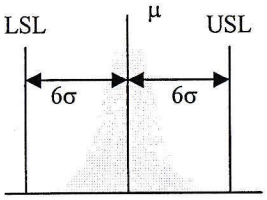
Step 4: Determine the causes

The Tech Group

A design weakness that causes the potential failure mode

Process (Step/Input) Design (Item/Function)	Potential Failure Mode	Potential Failure Effects	S E V	Potential Causes	O C C	Current Controls	D E T	R P N
Pyramid Pen Cap: Cavity - Form "A" side part geometry - Part to release from steel	Part sticks in cavity	Mold does not run auto		Insufficient draft				
				Insufficient or un-equal cooling				
				Incorrect cavity surface finish				

- A concise and descriptive list that is as complete as possible
- Root causes of failures, not symptoms



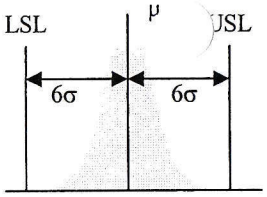
Step 5: Describe the controls

The Tech Group

Activities that prevent the failure mode CAUSE from occurring

Process (Step/Input) Design (Item/Function)	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN
Pyramid Pen Cap Cavity - Form "A" side part geometry - Part to release from steel	Part sticks in cavity	Mold does not run auto		Insufficient draft		Interrogate part model for draft		
				Insufficient or un-equal cooling		Mold flow analysis		
				Incorrect cavity surface finish		None		

Examples of design controls:
design verification test, design reviews, CAE, tolerance analysis



Step 6: Rate Severity, Occurrence and Detectability

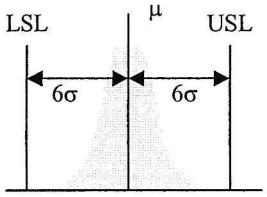
The Tech Group

Occurrence is an estimate of the likelihood that a specific cause will occur and result in the failure mode

Process (Step/Inpu) Design (Item/Function)	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN
Pyramid Pen Cap: **Cavity** - Form "A" side part geometry - Part to release from steel	Part sticks in cavity	Mold does not run auto	9	Insufficient draft	9	Interrogate part model for draft	3	243
			9	Insufficient or un-equal cooling	3	Mold flow analysis	3	81
			9	Incorrect cavity surface finish	5	None	9	405

Severity is an assessment of how serious the effect of the potential failure mode is on the next component, sub-system or system, if it should occur

Detection is an assessment of the ability of the current design control to detect the subsequent failure mode or potential cause of the design weakness before releasing to production



Severity, Occurrence & Detection Tables

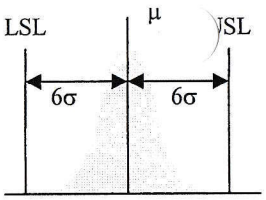
The Tech Group

Effect	Criteria: Severity of effect	Rank
Very High	Never runs on cycle, does not produce parts	9
High	Runs on cycle < 50% of the time	7
Med	Runs on cycle (automatic), parts visually unacceptable (incomplete, large flash, etc)	5
Low	Runs on cycle (automatic), 50% of product is visually acceptable	3
None	Runs on cycle (automatic) and parts are visually acceptable	1

Probability of Failure	Failure Rate (Occurrence)	Rank
Very High	Always occurs, 96-100% of the time	9
High	Occurs often, 50-90% of the time	7
Medium	Occasionally occurs, 10-50% of the time	5
Low	Seldom occurs, 1 -10% of the time	3
None	Never occurs, < 1% of the time	1

Detection	Criteria: Likelihood of Detection By Design Control	Rank
None	Cannot detect a potential cause and subsequent failure mode. No control	9
Very low	Low chance that the design control will detect a potential cause	7
Moderate	Moderate chance to detect a cause but can not prevent the failure mode	5
High	Can detect a cause but difficult to prevent the failure mode	3
Almost certain	Can detect a cause and prevent the failure mode	1

Develop rating tables that are appropriate for your situation

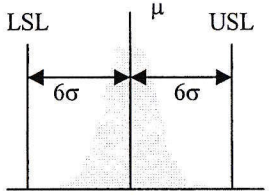


Step 6 Cont.: Calculate RPN

The Tech Group

Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN
Mold does not run auto	9	Insufficient draft	9	Interrogate part model for draft	3	243
	9	Insufficient or un-equal cooling	3	Mold flow analysis	3	81
	9	Incorrect cavity surface finish	5	None	9	405

Risk Priority Number (RPN) = Sev x Occ x Det



Step 7: Recommend Actions

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Once RPN's are calculated:

- ✓ Identify high RPN items
- ✓ Recommend action

Objective of Actions:

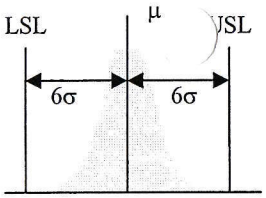
- ✓ Reduce high severity
- ✓ Reduce high occurrence
- ✓ Reduce high detection

High Severity Rating:
Requires a revision in the design

High Occurrence Rating:
Activities that lead to a prevention of the failure mode or the cause of the failure mode

High Detection Rating:
Improve the design controls to detect the cause and prevent the failure from occurring

Tip: Re-sort items by RPN Number to position all high RPN's together

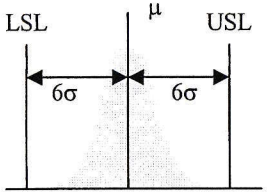


Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN	Actions Recommended
Mold does not run auto	9	Insufficient draft	9	Interrogate part model for draft	3	243	Change design to add appropriate draft to feature "A"
	9	Insufficient or un-equal cooling	3	Mold flow analysis	3	81	None
	9	Incorrect cavity surface finish	5	None	9	405	Add surface finish evaluation to design review process

Institute actions that will lower the occurrence, severity and/or Detection ranking for the highest RPN failure modes

Focus on defect prevention

Recommend actions for all item based on the natural break In the RPN values or as determined by the team



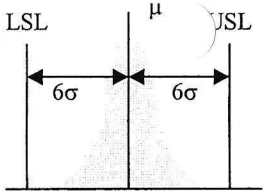
Step 8: Determine the plan and assign responsibility

The Tech Group

Actions must have dates and who's responsible

Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN	Actions Recommended	Plans / Responsibility
Mold does not run auto	9	Insufficient draft	9	Interrogate part model for draft	3	243	Change design to add appropriate draft to feature "A"	Kelly Customer to add draft to part geometry by 1/15/2001
	9	Insufficient or un-equal cooling	3	Mold flow analysis	3	81	None	
	9	Incorrect cavity surface finish	5	None	9	405	Add surface finish evaluation to design review process	Debbie Smith to add surface finish evaluation to design review process by 1/13/2001

Specify actions for high RPN items



Step 9: Assess Actions

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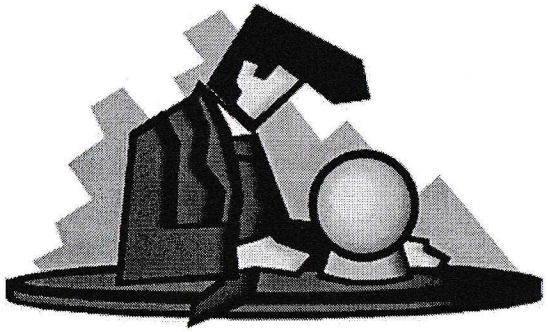
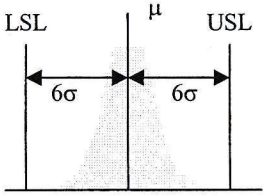


"*P*" stands for predicted (i.e., how well you expect the change to work)

SEV	Potential Causes	OCC	Current Controls	DET	RPN	Actions Recommended	Plans / Responsibility	*p*SEV	*p*OCC	*p*DET	*p*RPN
9	Insufficient draft	9	Interrogate part model for draft	3	243	Change design to add appropriate draft to feature "A"	Kelly Customer to add draft to part geometry by 1/15/2001	9	3	3	81
9	Insufficient or un-equal cooling	3	Mold flow analysis	3	81	None		9	3	3	81
9	Incorrect cavity surface finish	5	None	9	405	Add surface finish evaluation to design review process	Debbie Smith to add surface finish evaluation to design review process by 1/13/2001	9	5	3	135

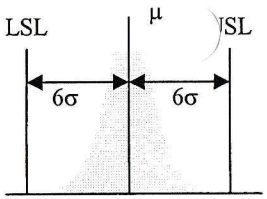
After the actions are recommended, re-rate and re-calculate the RPN's



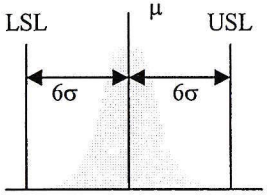
Design FMEA Summary

The Tech Group

- Used for improving a product (design)
- Enables designing out potential failure modes
- Use Relationship diagrams and design intent information in place or PMAP's
- Do not rely on process controls for design issues
- Document the design / process
- Steps are the same as a Process FMEA



Appendix



DFMEA Form Example

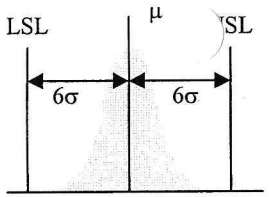
The Tech Group

Failure Modes and Effects Analysis (FMEA) Form

Product/Cell: _____
Problem: _____
Facilited by: _____
Team: _____
Date: _____

Severity (SEV): How serious is the effect of the failure mode on the next component, sub-system or system if it should occur
Probability of Occurrence (OCC): What is the likelihood that a specific cause will occur and result in the failure mode
Detectability (DET): What is the ability of the design control to detect the failure mode or cause of the design weakness before releasing to production
Risk Priority Number (RPN): What is the measure of design risk related to the effects, causes & controls? (RPN = SEV. x OCC. x DET.)

Process (Step/Input) Design (Item/Function)	Potential Failure Mode The way a design could fail to perform its intended function - Converse of function	Potential Failure Effects The effect of the failure mode on the fuction that the customer will see	SEV	Potential Causes A design weakness that causes the potential failure mode	OCC	Current Controls Activities that prevent the failure mode from occuring	DET	RPN	Actions Recommended	Plans / Responsibility Who is responsible and when will action be compled	*pSEV*	*pOCC*	*pDET*	*pRPN*



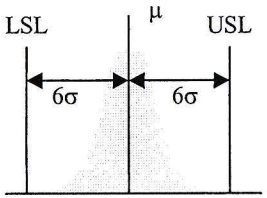
Prioritization Matrix Example

The Tech Group

Rating for the effect each input could have on the output	None = 0, no effect or unrelated
	Remote = 1, remote chance of effect
	Slight = 3, may impact but highly unlikely to effect
	Moderate = 5, moderate impact or possible effect
	High/Direct = 9, high impact or direct effect

Total Rating = Σ of each Process Input Correlation times its Process Output Weight

	Weight	8	10	5	5	8	6		
	Process Outputs (Big Y's)	Mold Build Time (Scheduled)	Developmental Time	Dimensional Requirements	Attribute Requirements	Mold Performance (Cycle, Yield, etc)	Cost - Development		**Total Rating**
	Process Steps								
1	**PM Assigns PE & QE**	1	3	3	3	3	3		110
2	**Update PE / QE on project**	9	9	3	3	1	5		230
3	**Mold requirements meeting with mold builder**	9	1	5	9	3	1		182
4	**Project kick-off meeting**	3	1	5	5	9	5		186
5	**Design mold**	9	0	9	9	9	1		240
6	**Design review(s)**	9	0	5	5	5	3		180
7	**Build mold**	9	0	9	9	1	0		170
8	**Measure & Document CTF dim. In mold steel**	3	3	9	0	0	3		117
9	**Schedule initial mold sample**	0	5	0	0	0	0		50



DESIGN FMEA Example

The Tech Group

Failure Modes and Effects Analysis (FMEA) Form

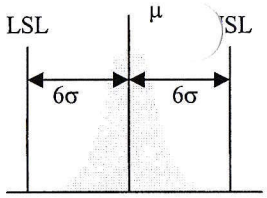
Product/Cell: Bi-Falcon 2+2 Lid Mold
Process: Mold Build
Problem: Problems related to Rev 1 Build of Mold
Prepared By: Derek Marsh
Date: 6/2/2003

Severity (SEV): How severe is the effect on the customer? (See below for scale)
Probability of Occurrence (OCC): How often does the cause or FM occur? (See below for scale)
Detectability (DET): How well can you detect the cause or FM using the current controls? (See below for scale)
Risk Priority Number (RPN): What is the measure of process risk related to the effects, causes & controls? (RPN = SEV. x OCC. x DE

Process Step/Input Which process step is being addressed? (Must appear on PMAP)	Potential Failure Mode What can go wrong with the process step output? - little y's gone bad - converse of outputs in PMAP	Potential Failure Effects What is the impact of the failure mode to the internal and/or external customer? (team determination or customer input)	SEV	Potential Causes What input went bad and how (root cause of input going bad)?	OCC	Current Controls What controls exist that prevent or detect either the cause or the FM prior to leaving the process step?	DET	RPN	Actions Recommended What are the actions for reducing the SEV. of the effect, the OCC. of the cause or improving DET.?	Plans / Responsibility What is the target completion date and who is responsible?
Cavity - Forms half of the parts geometery	Part Doesn't Match the Model	Non-functioning part	5	Tool Design Error	9	No Control	9	405	Create molding from core/cavity and compare to model	Scott (PTC) 6/27/03
	Part Doesn't Match the Model	Non-functioning part	5	Mold Manufacturing Error	9	No Control	9	405	Part comparison to electrode	John (PTC) during electrode manufacture
	Part Doesn't Match the Model	Non-functioning part	5	Mold Manufacturing Error	9	No Control	9	405	Annotate mold print to highlight potential problem	Scott (PTC) produce during creation of prints
Core - Forms half of the parts geometery and removes parts from the mold	Part deformation	Cosmetically unacceptable	5	Lack of Draft	9	Draft Analysis	7	315	Add Draft	HP added to the model 5/22/03
	Part deformation	Cosmetically unacceptable	5	Thin Wall Condition	9	Part Interrogation	7	315	Placement of ejector pins/blades	Design review 12 June 03
	Out of Spec feature (18.66)	Part Assembly Issues	1	Drawing Error	9	No Control	9	81	Recommend steel dimensions based on comparison of steel certs to tool drawing	Derek (C/EC) 6 June 03

Key

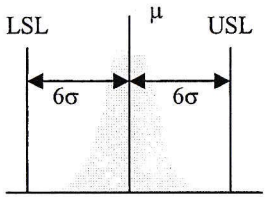
Severity	Occurrence	Detection
9 - Doesn't run automatic, no parts, parts unusable	9 - > 50%	9 - Cannot detect
7 - Runs automatic 50% of time or less	7- 20-50%	7 - System to detect but not always preventable
5- Runs automatic, parts are bad	5 - 5 -20%	5 - Systems in place, can usually prevent
3 - Runs automatic, 1/2 parts good (e.g. intermitten gates)	3 - 2 - 5%	3 - Systems in place, prevent before build complete
1 - Runs automatic, R-status	1 - < 2% of the time	1 - Can detect and prevent



Reference

Reference:

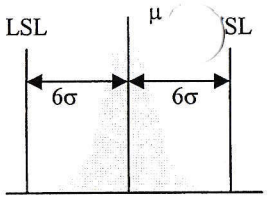
Potential Failure Mode & Effects Analysis (FMEA)
By Chrysler, For, General Motors
AIAG # 248-358-3570



Design FMEA Severity Table by AIAG

The Tech Group

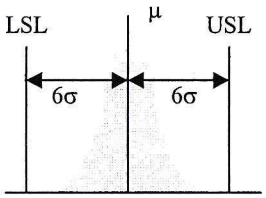
Effect	Criteria: Severity of effect	Ranking
Hazardous – without warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves non-compliance with government regulation without warning.	10
Hazardous – with warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and / or involves non-compliance with government regulations with warning	9
Very high	Vehicle / item inoperable, with loss of primary function	8
High	Vehicle / item operable, but at a reduced level of performance. Customer dissatisfied.	7
Moderate	Vehicle / item operable, but comfort / convenience items inoperable. Customer experience discomfort.	6
Low	Vehicle / item operable, but comfort / convince items operable at a reduced level of performance. Customer experiences some dissatisfaction.	5
Very low	Fit and finish / squeak and rattle items does not conform. Defect noticed by most customers.	4
Minor	Fit and finish / squeak and rattle items does not conform. Defect noticed by average customers.	3
Very Minor	Fit and finish / squeak and rattle items does not conform. Defect noticed by discriminating customers.	2
Low	No effect	1



Design FMEA Occurrence Table by AIAG

The Tech Group

Probability of Failure	Possible Failure Rates	Ranking
Very high: Failure is almost inevitable	> 1 in 2	10
	1 in 3	9
High: Repeated failures	1 in 8	8
	1 in 20	7
Moderate: Occasional failures	1 in 80	6
	1 in 400	5
	1 in 2,000	4
Low: Relatively few failures	1 in 15,000	3
	1 in 150,000	2
Remote: Failure in unlikely	< 1 in 1,500,000	1



Design FMEA Detection Table by AIAG

The Tech Group

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