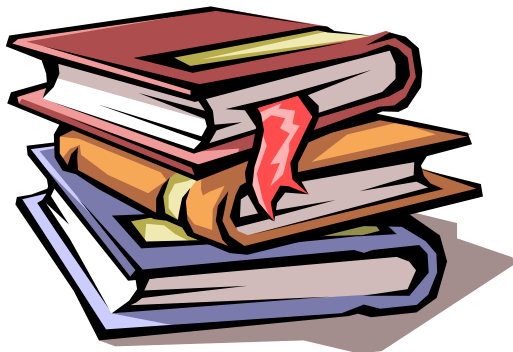


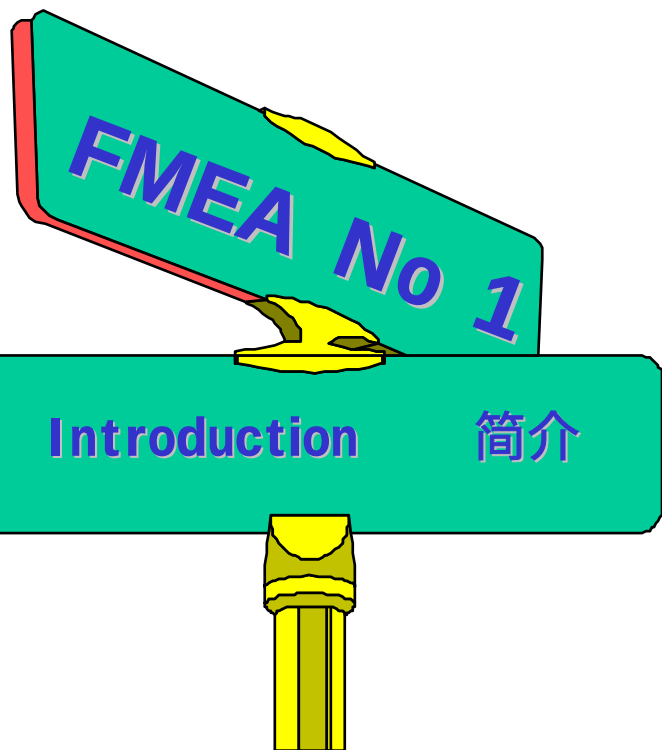
FMEA

失效模式与效应分析



*Presented By: McCain.Koo
CAQ Senior Black Belt Consultant
ASQ Certified Six Sigma Black Belt
China Executive Representative of
Dr.Mikel Harry's Six Sigma Management
Institute*

FMEA 背景篇



为何进行FMEA？

- FMEA的定义，目的，益处，类型
- FMEA的工作模式
- 产生/管理
- 小组法

FMEA Failure Mode (cause) Effect Analysis

F: Failure 失效、失败 → 定义：达不到预期的功能或目的
Fail to reach Scope. Objective. Purpose

谈**Failure**，先谈**定义**

要层别得够细，否则收集的
资料会很混淆。

在规定条件下不能完成其规定的功能，
或参数不能保持在规定的范围内，
或操作者失误，造成产品功能失效，
及因应环境力变化导致功能散失。

FMEA Failure Mode (cause) Effect Analysis

M: Mode 在所有失效中，出现最多的（众数）

例：2, 3, 3, 3, 4, 5, 5, 6, 7

集中点：

1. 数学平均值 = $\bar{X} = \frac{\sum_{n=1}^n X_n}{n} = 4.2 \rightarrow 4$
(Math. Average)

2. 中位数 = 4
(Medium)

3. 众数 = 3
(Mode)

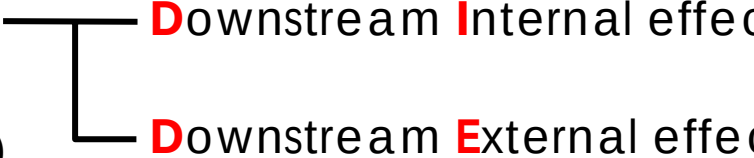
在有限资源的状况下，
从失效最多的状况开始着手，
此即失效模式

FMEA Failure Mode (cause) Effect Analysis

Effect 影响

影响包括三种:

1. **L**ocal effect
(对本身的影响)

2. Next high level effect 
(对同一Level的影响，
也可能对Next high level effect)

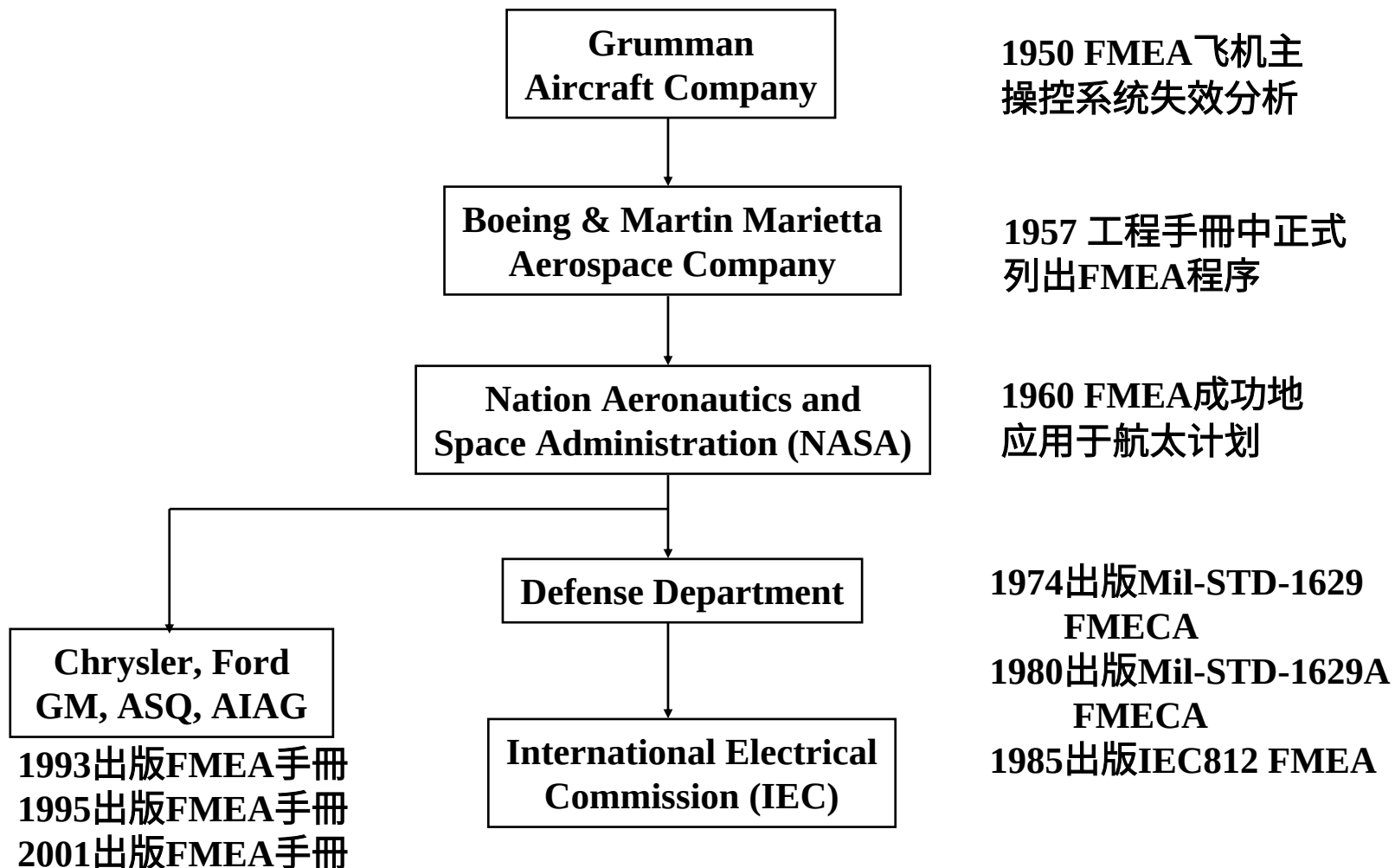
3. **E**nd effect
(对产品使用者的影响)
(对end product的用户影响, 产品跑到用户身上，使用时才发现)

FMEA 之定义

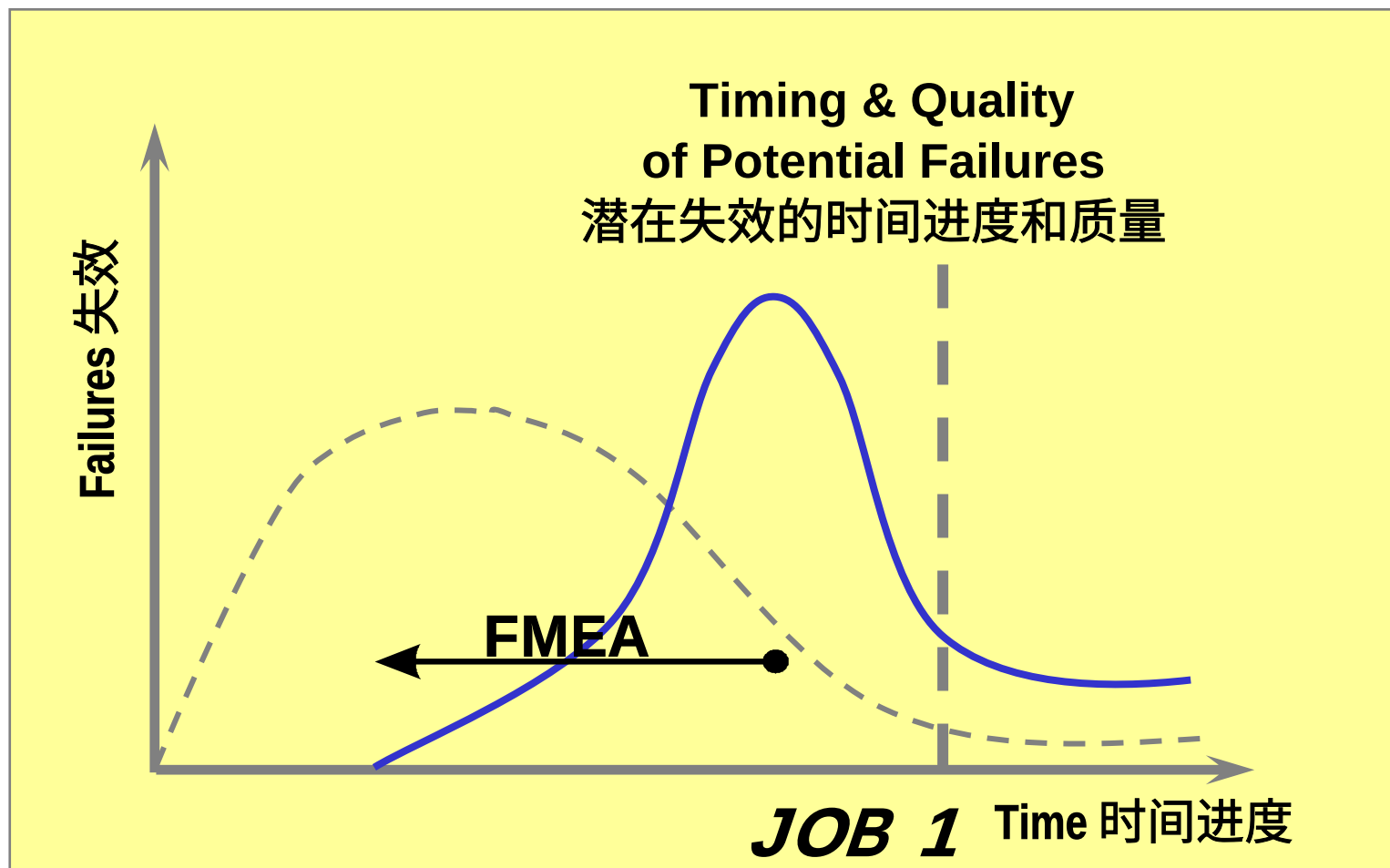
FMEA是一组结构化的活动...，这些活动：

- 识别潜在的失效模式*
- 确定措施，并排列其有限顺序*
- 对过程进行文件化*

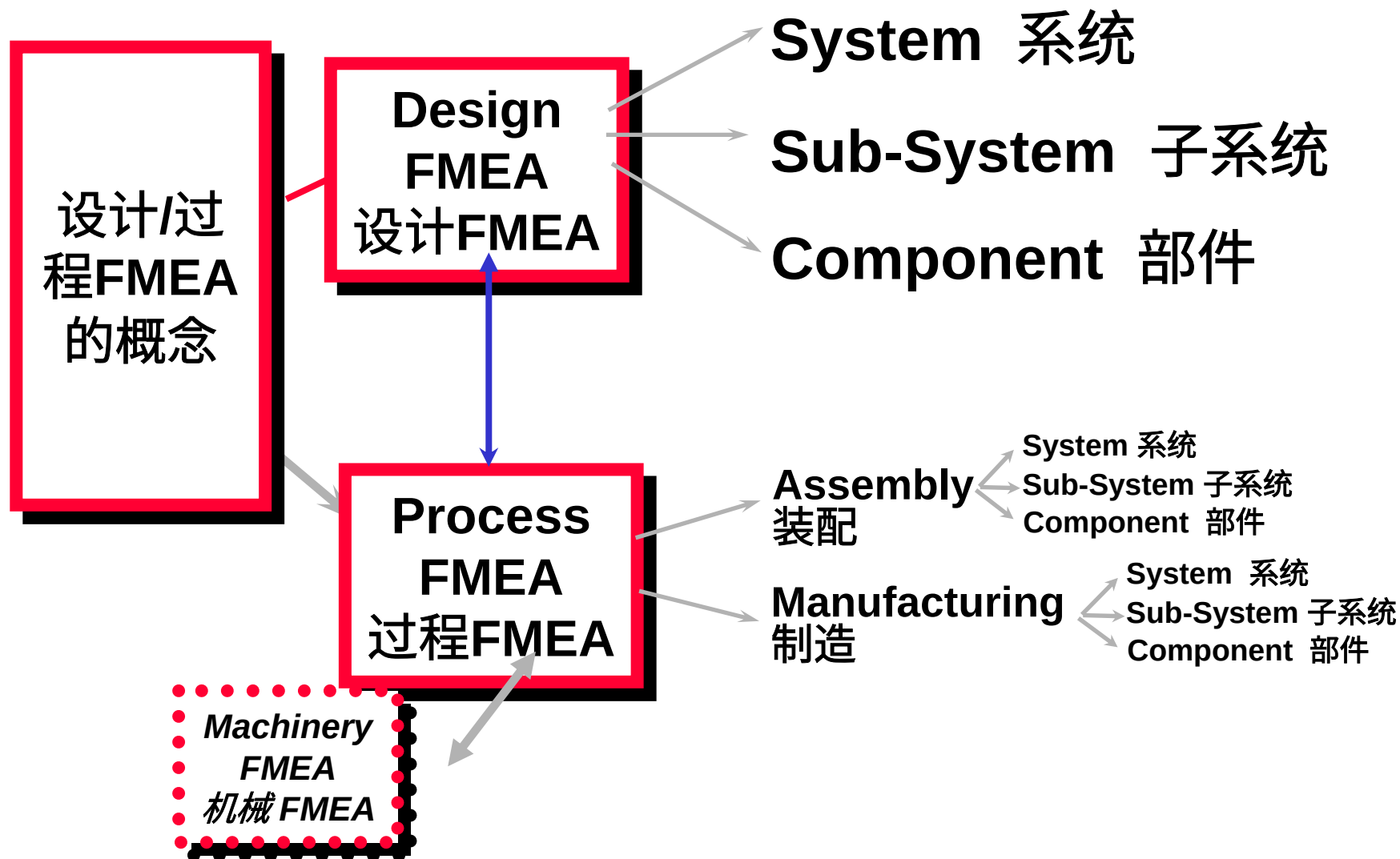
FMEA 之沿革



为何进行FMEA？



FMEA类型？



FMEA之益处

Design 设计

Concept 概念

Process 过程

- 帮助评价要求和可供选择的方法
- 帮助DFM, DFA, DFS和DFR的初始设计
- 帮助进行项目的完整策划, 有效开发和确认。
- 开发一份按优先顺序排列的措施清单
- 帮助识别潜在的特殊特性；
- 评估所有顾客的效果
- 识别潜在的制造和装配原因, 对降低发生率和/或提高探测度进行重点控制
- 开发一份按优先顺序排列的措施清单
- 文件化制造或装配过程的结果
- 识别确定的, 需要特别控制的特殊特性

FMEA之更新

FMEAs are living documents, and are updated when ...

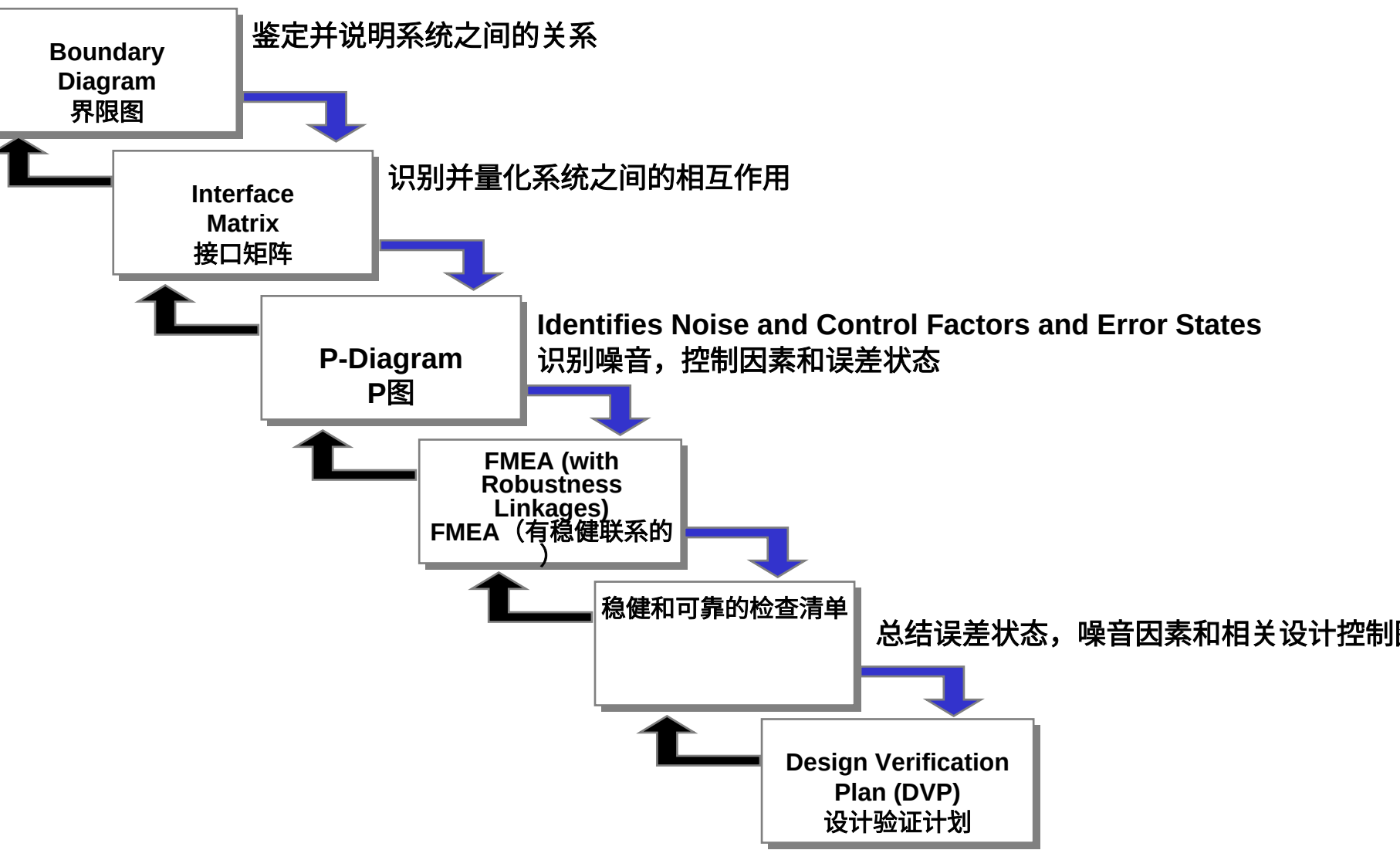
FMEA是动态文件，在以下情况下进行更新...

- New design or process is planned
- 计划了新的设计或过程
- Modification to a component, process or system is planned, including those due to Global 8D
- 计划了部件，过程或系统的更改，包括8D过程的更改
- Component is to be used in new environment, location, or application
- 部件将要用于新的环境，现场，或应用。

FMEA展开时机

1. 依照**FMEA**定义, 它是一种方法, 消除或减少已知或潜在问题, 以强化客户满意至最大极限。因此, 为了要达成此目的, 展开**FMEA**的时机必须愈早愈好! 纵使相关数据/信息仍然未知时。**FMEA**的口号为: (就你所有, 尽全力而为)
2. 经由**品质功能展开(QFD)**已知某些资料时, 就应立刻展开**FMEA**。
3. 当设计**新的系统, 新的设计, 新产品, 新过程, 新服务**时。
4. 当现有系统, 设计, 产品, 过程, 或服务等不管是何种理由, 将要**变更**时。
5. 当既有的系统, 设计, 产品, 过程, 或服务的条件有**新的应用**时。
6. 当既有的系统, 设计, 产品, 过程或服务被**考虑要改善**时。

FMEA展开流程



谁负责FMEA开发

- FMEA总负责人为PDT/PMT Leader或QIT Leader,
因为Leader要对开发案或改善案成败负责;
- 系統組裝工程師及TEAM负责系统组装FMEA,
並將此給PDT/PMT/QIT;
- 设计工程师及TEAM负责設計FMEA,並將此給PDT/PMT/QIT;
- 过程工程师及TEAM負責过程FMEA,並將此給PDT/PMT/QIT;
- 设备工程师及TEAM负责设备FMEA,並將此給PDT/PMT/QIT;
- 各阶段制作FMEA工程师必定是PDT/PMT/QIT成員.

何时处理FMEA文档

- FMEA必须按照全球信息记录保持时间标准对这些文档进行保存
 - DFMEAs：最终使用后+10年
 - PFMEAs：最终使用后+10年

何时才算完成FMEA

- FMEA是动态的文档
- FMEA“完成”是在与已发布/批准的产品或过程相符时
 - CFMEA：当系统设计规范冻结和设计功能确定时
 - DFMEA：当产品设计发布用于生产时
 - PFMEA：当所有的生产都被考虑到，所有的特殊特性都被适当安排，以及控制计划完成时

谁来更新FMEA？

- FMEA由相应的系统、产品或制造/装配工程师进行更新。
- 供应商负责对他们自己的FMEA进行更新。

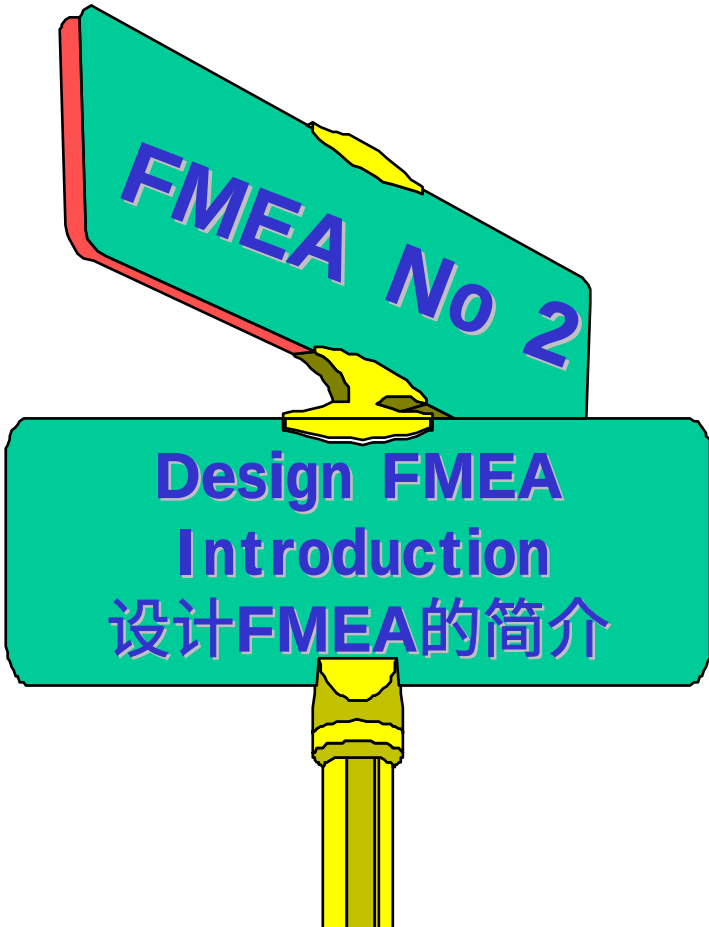
谁是FMEA的客户？

- 所有的FMEAs:
 - 最终用户
 - 售后服务
- CFMEA和DFMEA：
 - 与设计有关的行动
 - 与制造有关的过程
- PFMEA：
 - 下一工序或下游的制造或装配

FMEA何时启动和更新？

- DFMEA
 - 在设计概念前或决定时启动
 - 在产品开发的各个阶段进行更新
 - 基本上，在生产用图纸正式发放用于模具开发前应完成
- PFMEA
 - 在可行性分析前或开始时启动
 - 基本上，在生产用工装制造前完成

设计FMEA篇



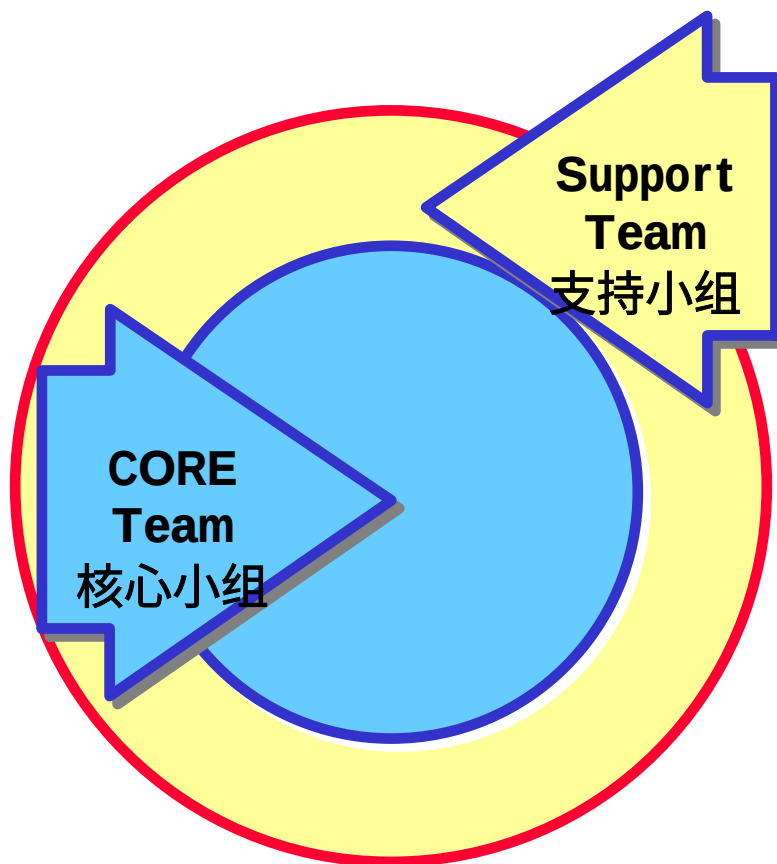
FMEA No 2

**Design FMEA
Introduction**
设计FMEA的简介

- ❖ 成立DFMEA小组
- ❖ 确定范围
- ❖ 功能描述
 - » 头脑风暴
 - » 功能树
- ❖ 实践练习1

设计FEMA小组

设计工程师
制造/过程工程师



代表来自:

- 顾客服务
- 供方
- 全球试验业务
- 公司质量

设计FEMA范围

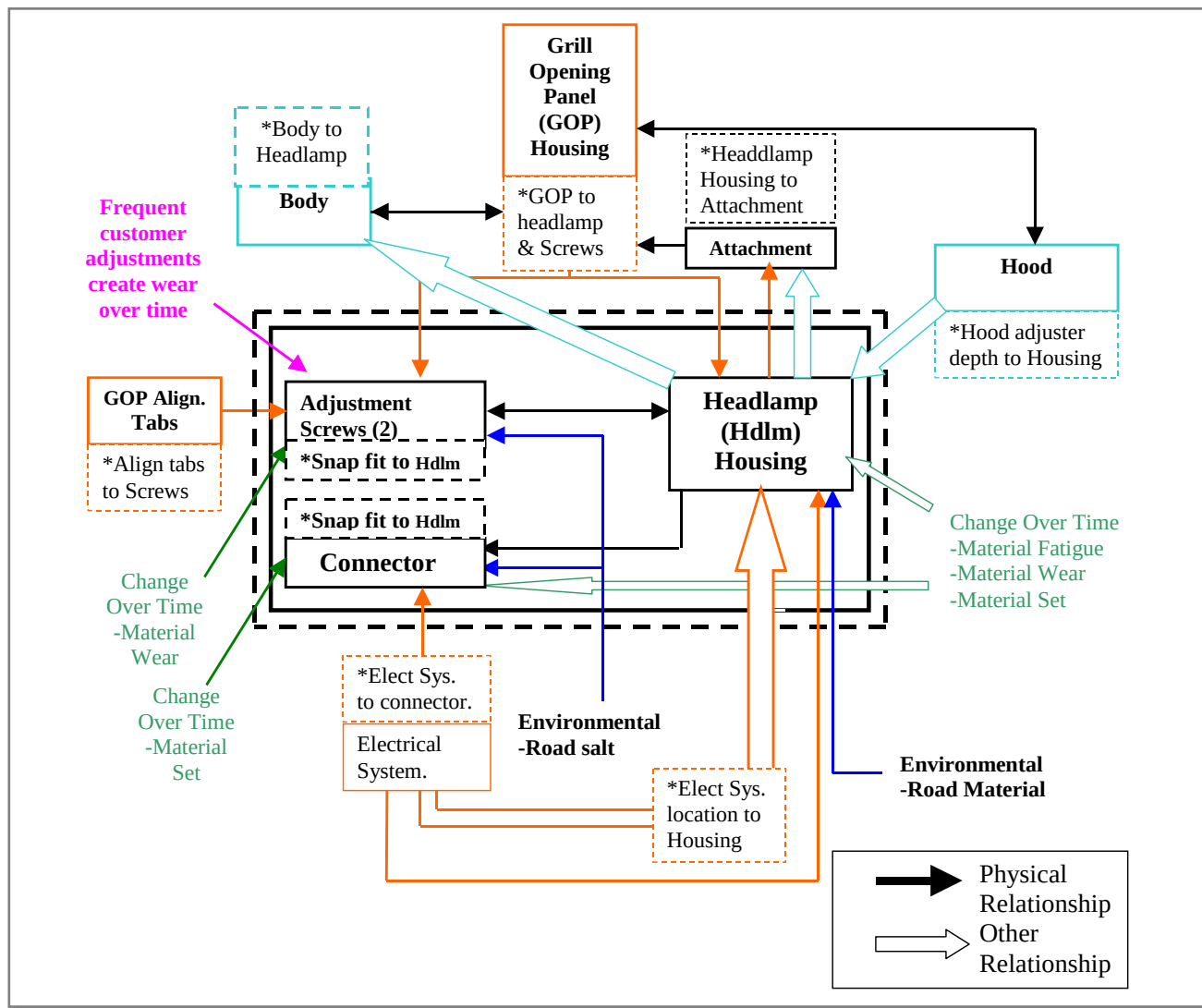
- 分析的界限或程度是否确定包含什么，不包含什么？
- 不正确的范围会：
 - 延长分析
 - 偏离目标分析
 - 错误地识别小组成员

设计FEMA范围

一旦成立了核心小组...

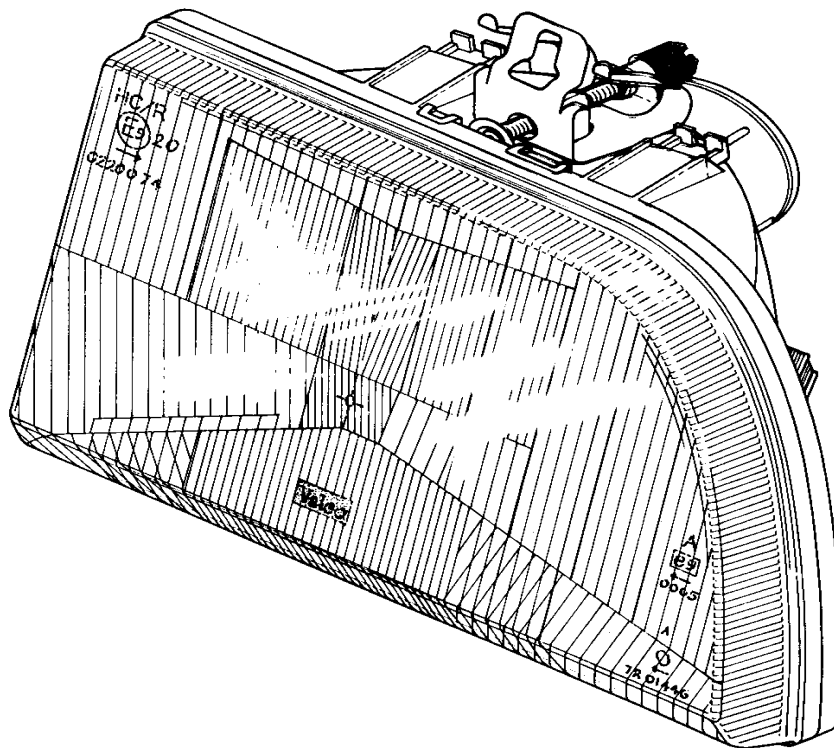
- 创建界限图
- 确定分析界限
- 确定支持小组的成员

创建界限图



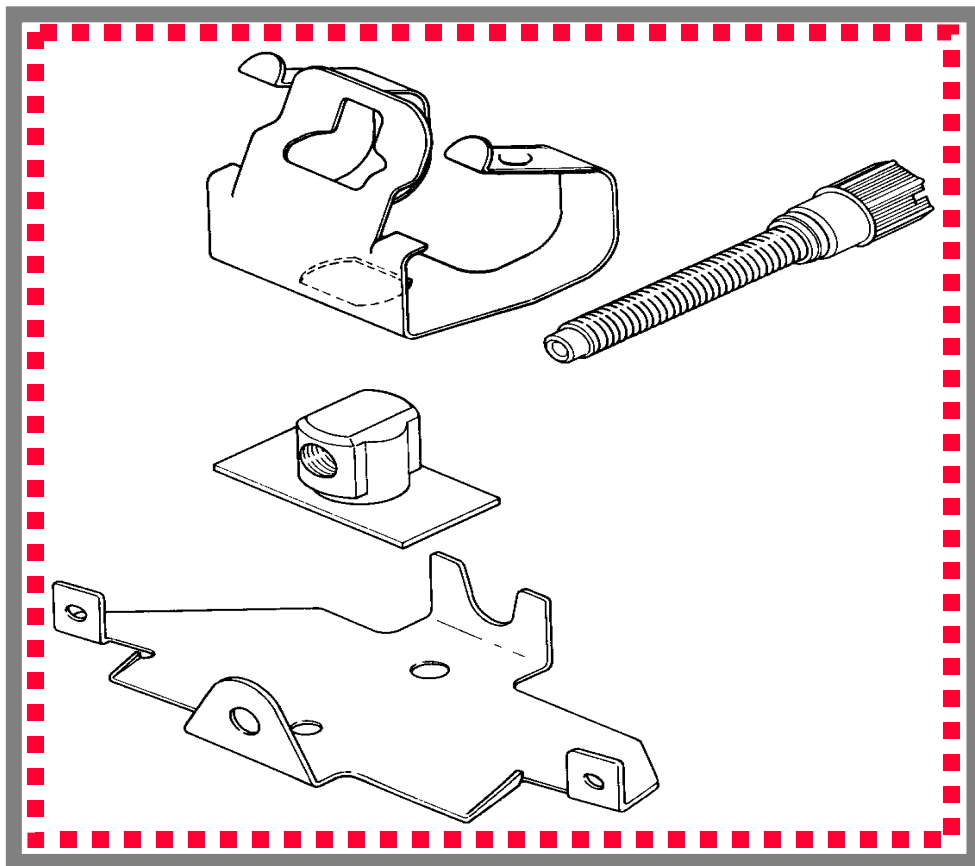
界限图范例

Headlamp Assembly 前灯装配

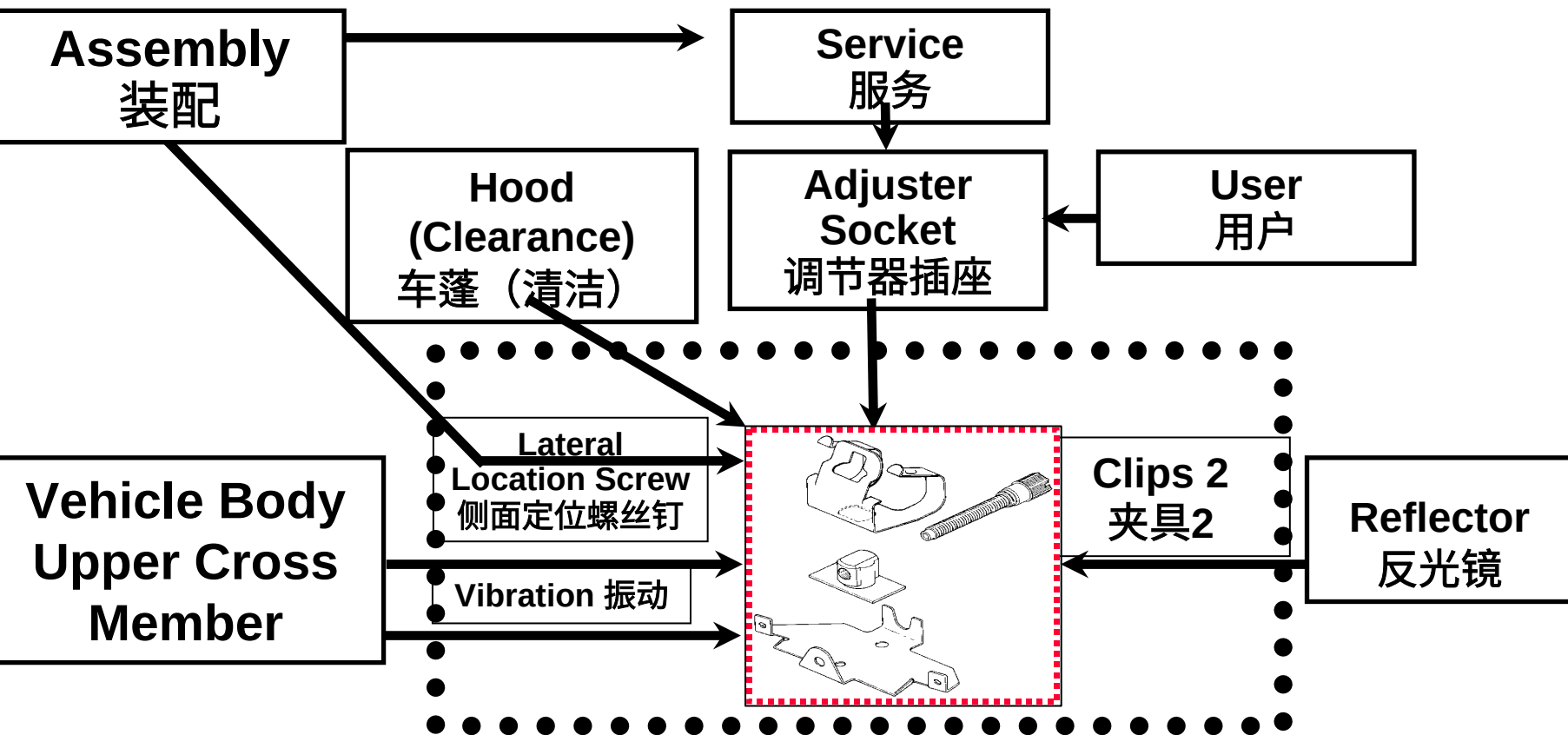


界限图范例

垂直调整片的装配



界限图范例



东菱练习



接口矩阵

- Recommended robustness tool that acts as an input to a Design FMEA
- 接口矩阵是推荐的作为设计FMEA输入的稳健工具
- Identifies and quantifies the strength of system interactions by:
- 接口矩阵可以通过以下方式识别并鉴定系统的相互作用：
 - Showing whether the relationship is necessary or adverse
 - 显示系统间的关系是互利的还是不利的
 - Identifying the type of relationship
 - 确定关系的类型

接口矩阵范例

	Adjuster	Headlamp Housing	Upper Cross Member	Hood	Adjuster socket			
Adjuster		2 2	2 2	-2 -1	2 2			
Headlamp Housing	2 2		2	1 2	-1 2			
Upper Cross Member	2 2	2		-1 -1				
Hood	-2 -1	-1 -1	-1 -1					
Adjuster socket	2 2	-1 2						

P	E
I	M

P: Physically touching

E: Energy transfer

I: Information exchange

M: Material exchange

Numbers in each corner represent the above interface types, with values denoting the following:

+2 Interaction is necessary for function

+1 Interaction is beneficial, but not absolutely necessary for functionality

0 Interaction does not affect functionality

-1 Interaction causes negative effects but does not prevent functionality

-2 Interaction must be prevented to achieve functionality

接口矩阵范例

	Adjuster	
Adjuster		
Headlamp Housing	2	2
Upper Cross Member	2	2
Hood	-2	-1
Adjuster socket	2	2

P	E
I	M

P: Physically touching

E: Energy transfer

I: Information exchange

M: Material exchange

Numbers in each corner represent the above interface types, with values denoting the following:

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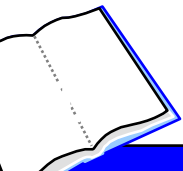
-2 Interaction must be prevented to achieve functionality

东菱练习

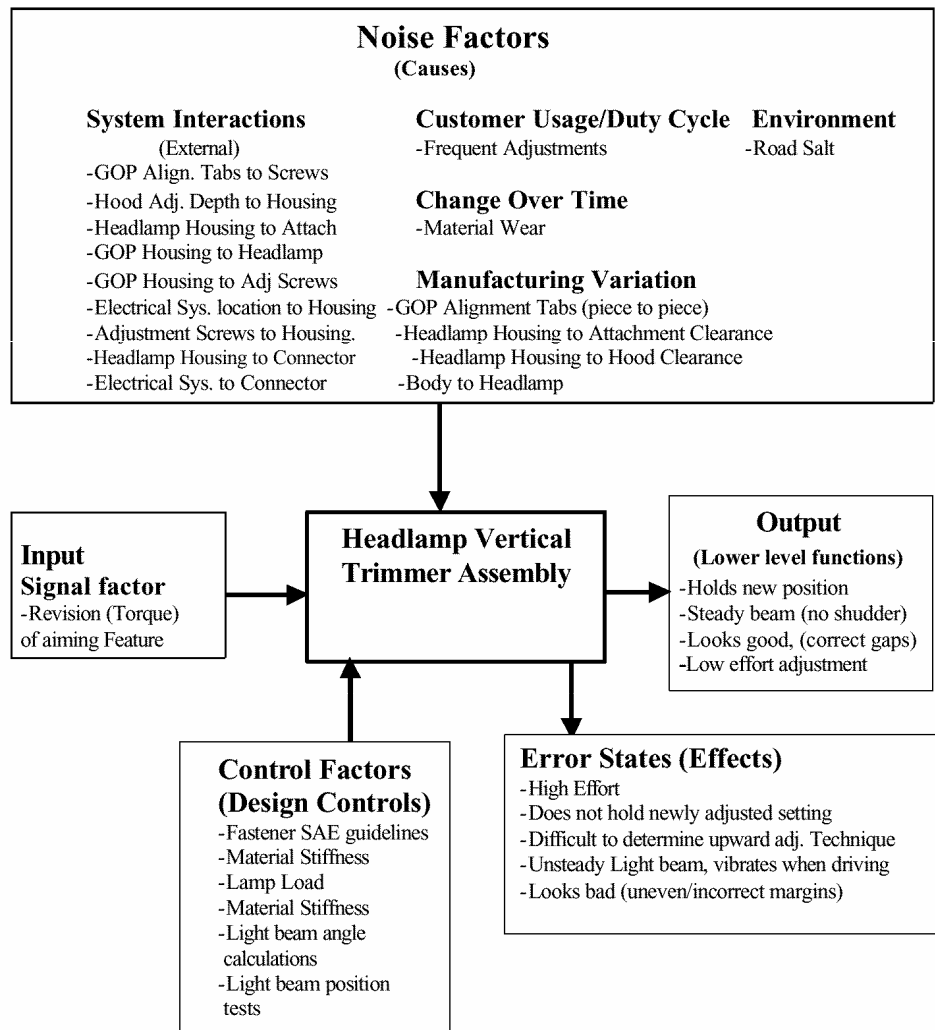


P图

- Recommended structured tool to identify intended inputs and outputs for a function
- P图是推荐的，用于识别某一功能的预期输入和输出的结构化的工具
- Describes noise factors, control factors, ideal function, and error states
- 描述噪音因素，控制因素，理想的功能和误差状态
- Assists in the identification of:
- 有助于识别：
 - Potential Causes for failure 潜在的失效原因
 - Failure Modes 失效模式
 - Potential Effects of failure 潜在的失效后果
 - Current Controls 目前的控制方法
 - Recommended Actions 建议的措施



P图范例



东菱练习



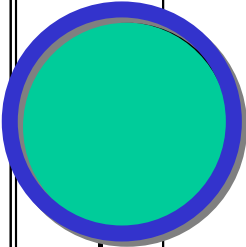
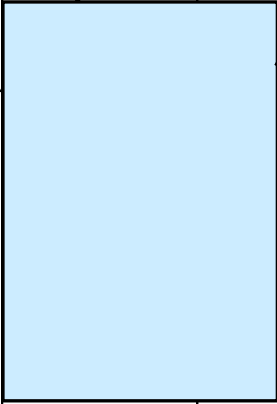
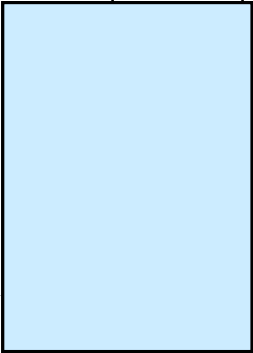
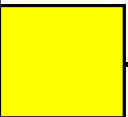
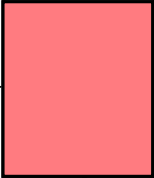
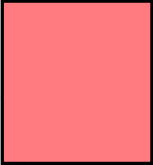
表头信息

- 完成每一区域：
 - 系统、子系统或零件名称和编号
 - 车型 年份/项目
 - 小组成员
 - 设计责任人
 - 关键时间
 - FMEA编号
 - 准备人

功能确定

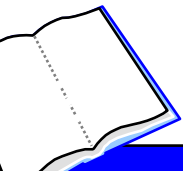
Ford Motor Company

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

Item Function	Potential Failure Mode	Potential Effect(s) of Failure	C l a s s S e v	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r	Current Design Controls – Prevention – Detection	D e t e c t	R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results			
											Actions Taken	S e v	O c c	D e t
														
														
														
														

功能是什么？

- 设计意图或工程要求
- 书面的，可以测量的动名词格式
- 描述所有顾客和系统的所有需要，需求和要求，可以是口头描述的，也可以是非口头描述的



功能描述

Verb 动词

**Indicates action,
occurrence, being**

产生
控制
分配
调整
预防

Noun 名词

**Indicates what the
action relates to**

照明
速度
燃料
座椅调节轮
生锈

零件功能清单

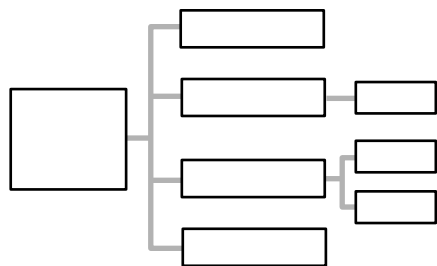
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头脑风暴



Exercise in creative thinking Method to generate ideas
通过创造性思维找到解决办法的练习

功能树

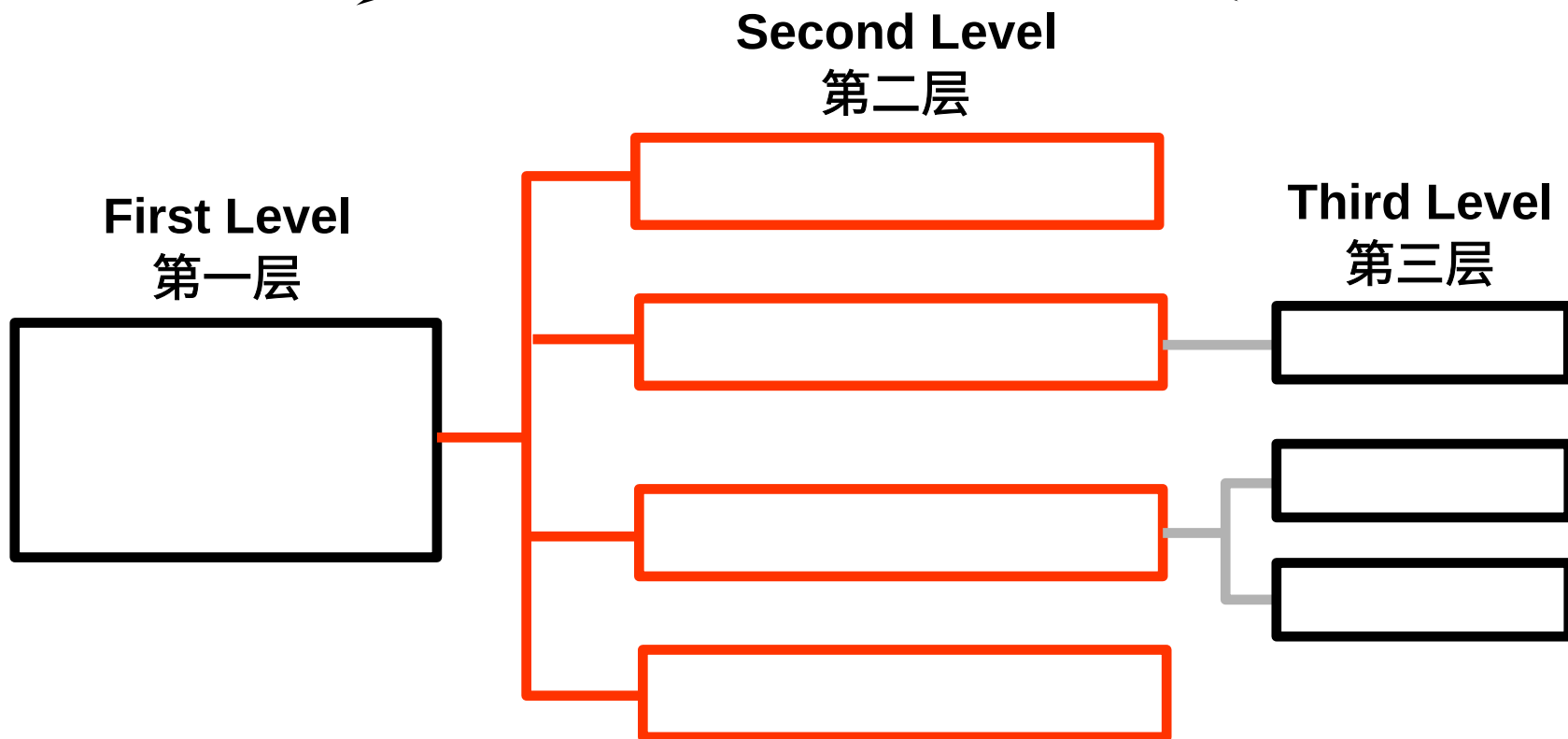


- 提供一种结构化的方法，用于识别产品（或过程）必要的特征
- 有助于确保“spoke”和“unspoke”的要求已经确定
- 提供功能的图示描述，以确保全体小组清楚地理解

建立功能树

WHY ?
为什么 ?

HOW ?
如何做 ?



垂直片调整的功能树

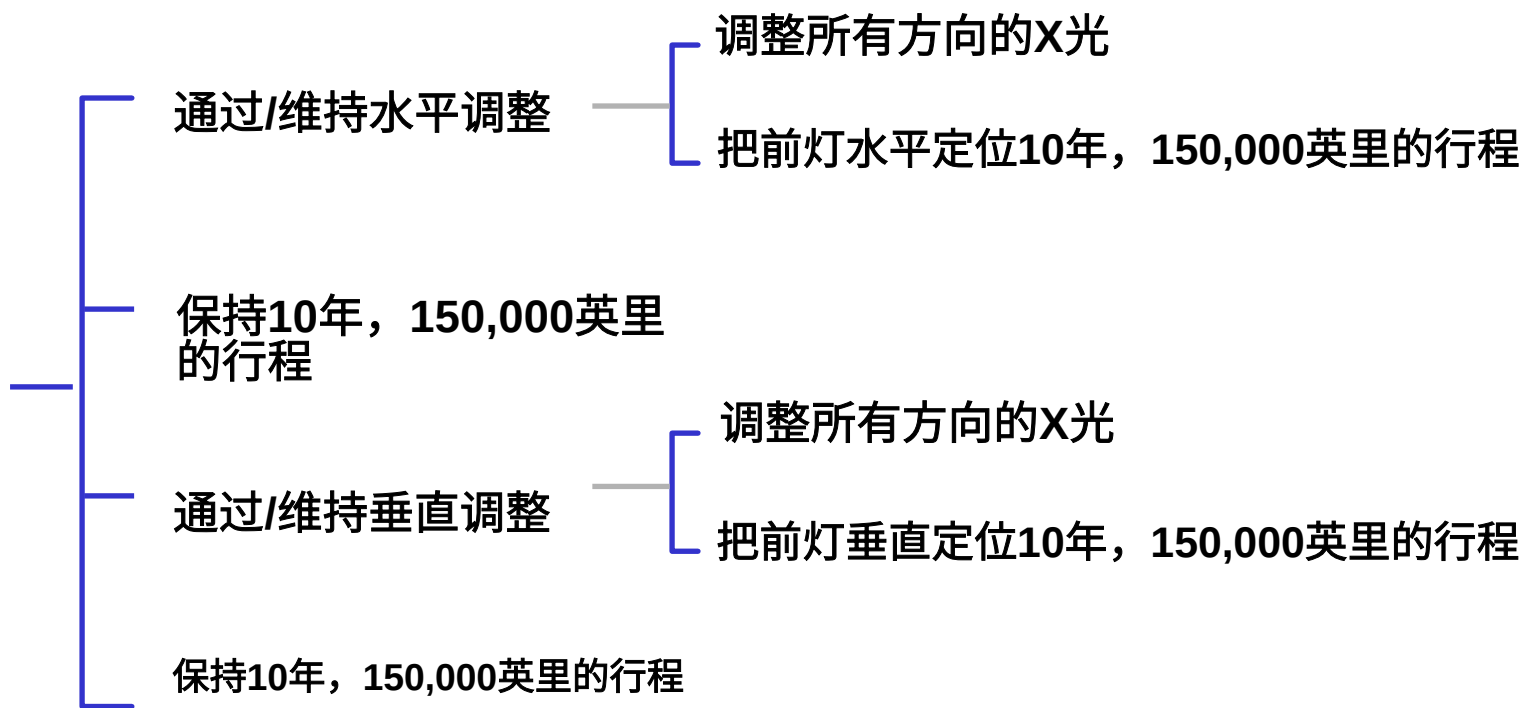
WHY ?

为什么？



HOW ?

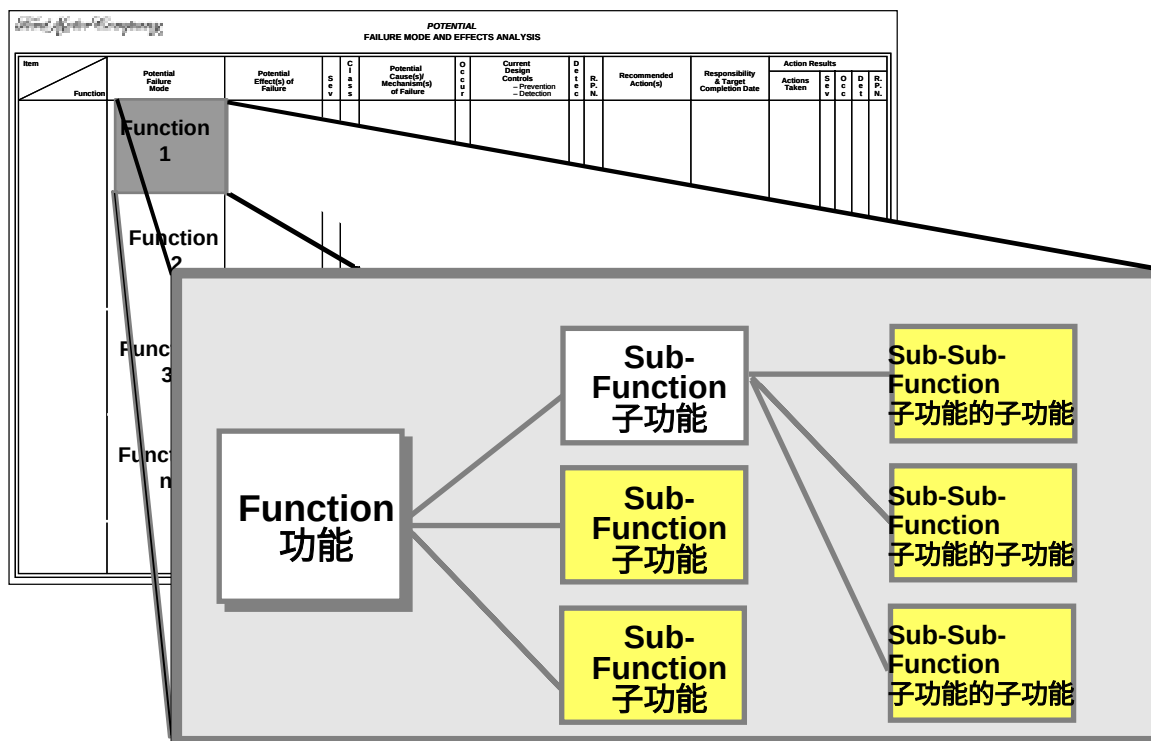
如何做？



建立功能树指南

- 脑力激荡所有功能 (VERB - NOUN)
- 通过提问“如何达到功能？”文件化各自的功能
- 不断从左到右重复，直至到达可执行的层次
- 使用工作表检查可执行的层次是可以测量的
- 从右到左进行，通过提问“为什么包含此功能”检查功能树的结构

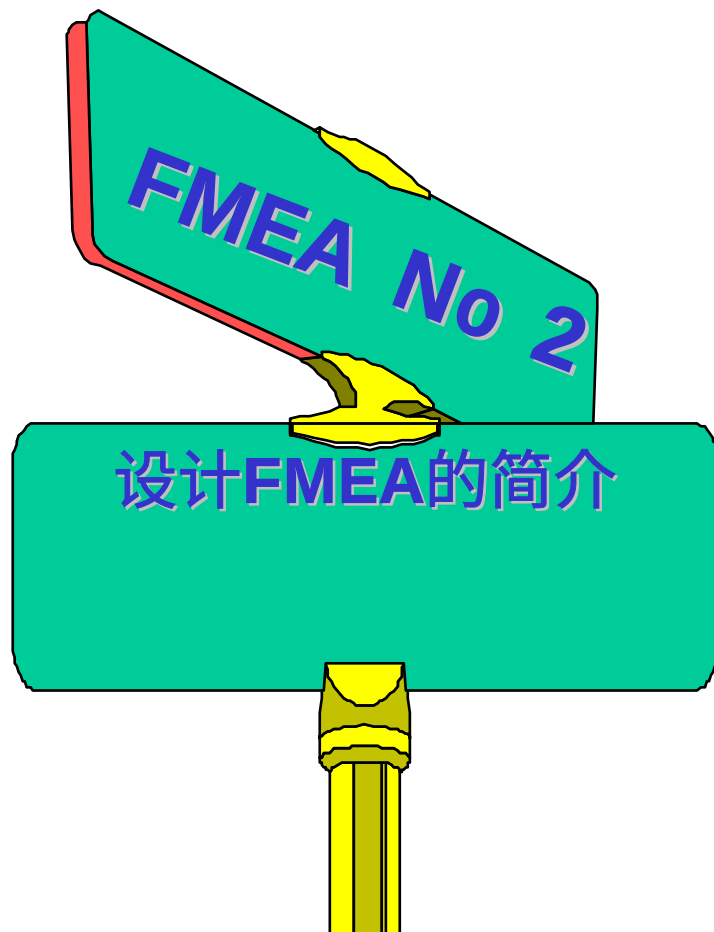
设计FMEA功能展开



东菱练习

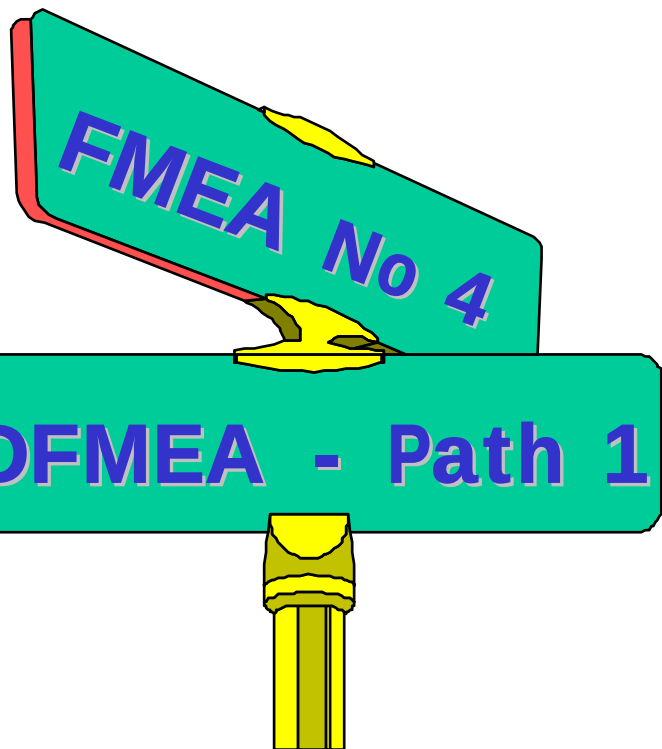


本节总结



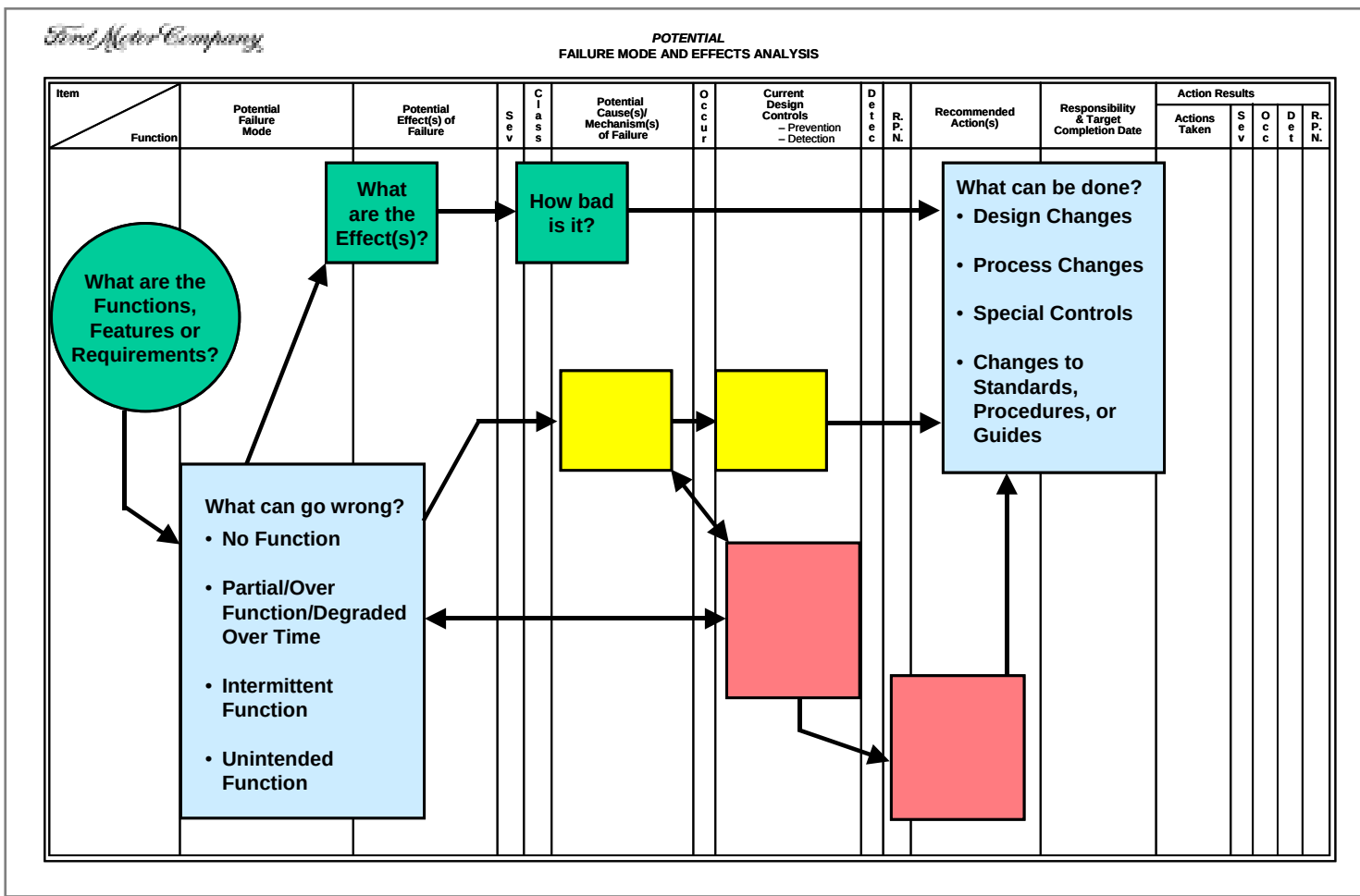
- ❖ 确定DFMEA小组
- ❖ 确定范围，界限图
- ❖ P图，接口矩阵
- ❖ 功能描述
 - » 头脑风暴
 - » 功能树
- ❖ 实践练习

设计FMEA路径和步骤1



- ❖ 失效模式
- ❖ 后果-严重度
- ❖ 潜在特殊特性
- ❖ 建议的措施
- ❖ 实践练习

设计FMEA路径和步骤1



潜在失效模式

Steel Motor Company

POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS

Item 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 Design Controls - Prevention - Detection	D e t e c	R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results					
												Actions Taken	S e v	O c c u r	R. P. N.		

潜在失效模式：

- 没有起作用
- 部分/全部功能降低
- 功能间歇性中断
- 非预期的功能

垂直调整片失效模式

功能：调整所有方向的X光

失效模式的类型

没有起作用

部分/全部的功能降低

功能的间歇性中断

非预期的功能

失效模式的类型

没有调整

朝一个方向调整

有时调整

不知道

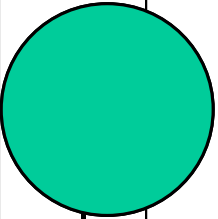
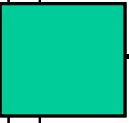
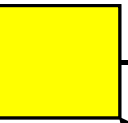
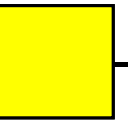
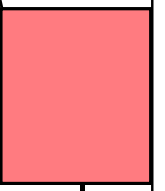
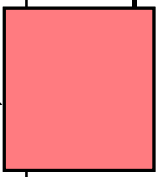
东菱练习



失效模式的后果

Ford Motor Company

POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS

Item Function	Potential Failure Mode	Potential Effect(s) of Failure	C l a s s S e v	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r	Current Design Controls - Prevention - Detection	D e t e c t R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
										Actions Taken	S e v	O c c	D e t	R. P. N.
														
														
														
														

失效模式的后果

Ford Motor Company

POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS

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												Actions Taken	S e v e r e	O c c u r	R. P. N.		

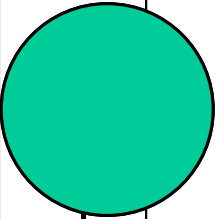
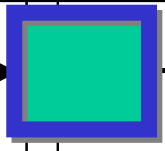
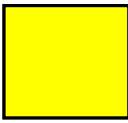
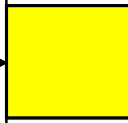
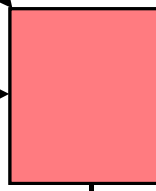
潜在失效模式的后果：

- 零件/分部件
- 更高层的装配
- 系统
- 车辆
- 政府法规
- 顾客（内部的和最终用户）

设计FMEA-严重度

Ford Motor Company

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

Item 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 Design Controls - Prevention - Detection	D e t e c t R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
											Actions Taken	S e v	O c c	D e t	R. P. N.
															
															
															
															

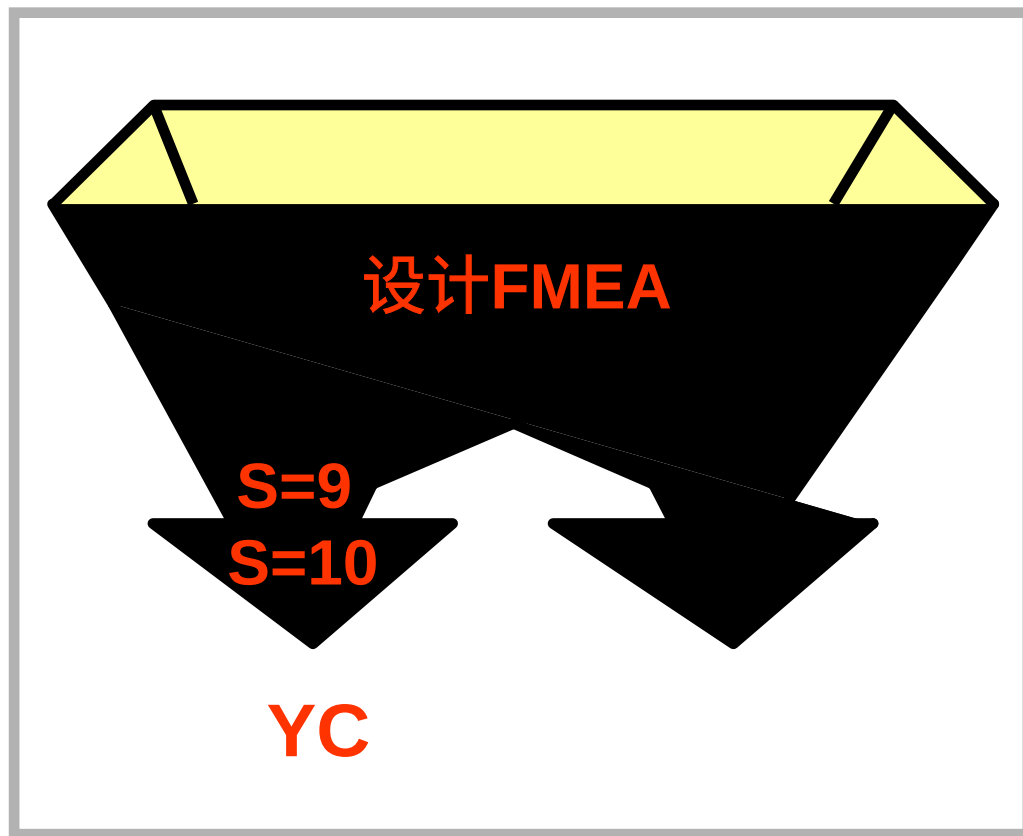
建议的严重度评价准则

Effect 后果	Criteria: Severity of Effect 准则：后果的严重度	Ranking 等级
Hazardous Without Warning 无警告的严重危害	... affects safe vehicle operation and/or government regulation without warning ...影响车辆安全运行和/或政府法规，失效发生时无警告	10
Hazardous With Warning 有警告的严重危害	... affects safe vehicle operation and/or government regulation with warning ...影响车辆的安全运行和/或政府法规，失效发生时有警告	9
Low 低	... operable at reduced level of performance. Customer experience some dissatisfaction ...运行性能下降，顾客有些不满意	5
None 无	No Effect 没有影响	1

设计严重度范例

Item 条款 Function 功能	Potential Failure Mode 潜在失效模式	Potential Effects of Failure 潜在失效后果 Part: May be stripped during adjustment (7) 零件：可能在调整过程中丢失	S E V
Vertical Trimmer/ 垂直调整片 Retains Setting	Does not maintain adjustment 不用继续调整	Next Higher Assembly: Headlamp cannot be adjusted (6) 更高层的装配：前灯不能调整 System: Misaligned lightbeam (8) 系统：光束方向偏离 Vehicle: Impaired night/fog performance (7) 车辆：夜晚/雾天性能下降 Govt Regs: Non-compliance (10) 政府法规：不符合 Customer: Impaired night/ fog (7) 顾客：减少夜晚/雾天行驶	10

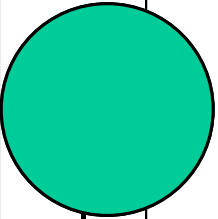
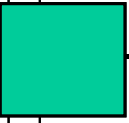
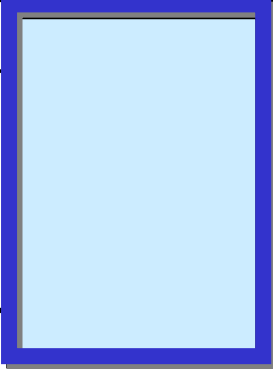
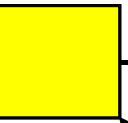
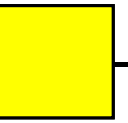
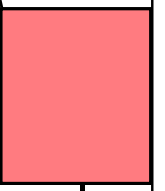
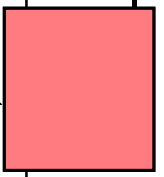
识别潜在的特殊特性



DFMEA-建议的措施

Ford Motor Company

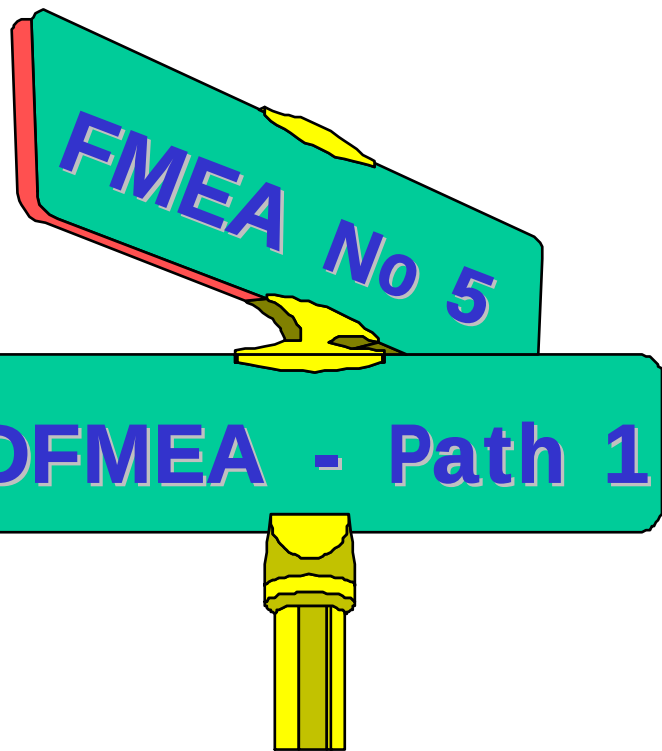
POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

Item 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 Design Controls - Prevention - Detection	D e t e c t R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
											Actions Taken	S e v	O c c	D e t	R. P. N.
															
															
															
															



TIFFANY

本节总结



- ❖ Failure Modes
- ❖ 失效模式
- ❖ Effects -- Severity
- ❖ 后果-严重度
- ❖ Potential Special Characteristics
- ❖ 潜在的特殊特性
- ❖ Recommended Actions
- ❖ 建议的措施
- ❖ Practice Exercises
- ❖ 实践练习

FMEA评审

Ford Motor Company

POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS

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											Actions Taken	S e v	O c c u r	R. P. N.		
Function 1 功能1																
Function 2 功能2																
Function 3 功能3																
Function N 功能N																

Function 功能

Sub-Function 子功能

Sub-Function 子功能

Sub-Function 子功能

Sub-Sub-Function 子功能的子功能

Sub-Sub-Function 子功能的子功能

Sub-Sub-Function 子功能的子功能

FMEA评审

Ford Motor Company

POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS

Item 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 Design Controls - Prevention - Detection	D e t e c t i v i t y	R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results							
												Actions Taken	S e v	O c c u r	R. P. N.				

潜在失效模式：

- 没有起作用
- 部分/全部的重复降低
- 功能的间歇性中断
- 非预期的功能

FMEA评审

Ford Motor Company

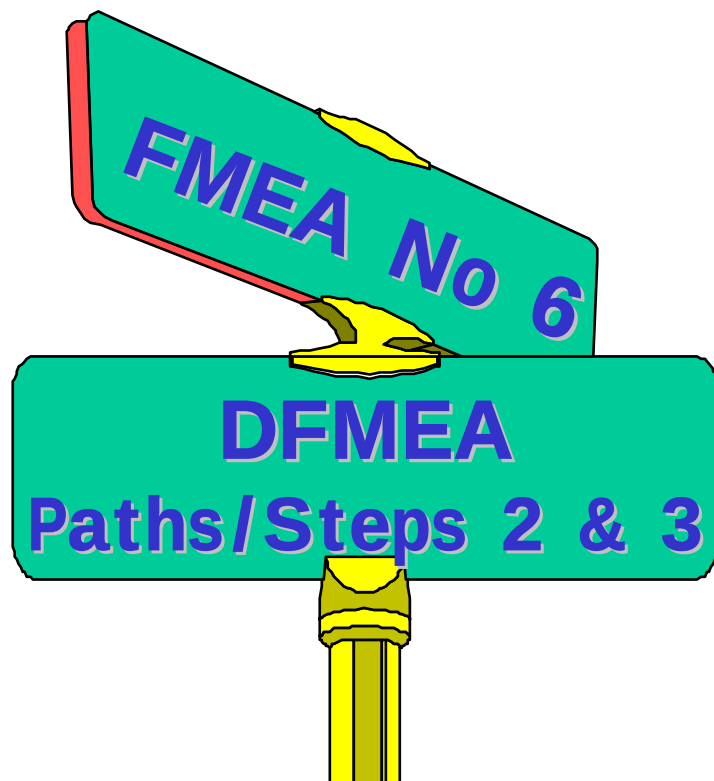
POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS

Item Function	Potential Failure Mode	Potential Effect(s) of Failure	C l a s s e s s	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r	Current Design Controls - Prevention - Detection	D e t e c t R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
										Actions Taken	S e v	O c c u r	D e t e c t R. P. N.	
Function 1	Failure Mode 1													
	Failure Mode n													
Function 2														
Function n														

Potential Effects of Failure Modes:
潜在失效模式的后果：

- Part / Sub-component 零件/分部件
- Next Higher Assembly 更高层的装配
- System 系统
- Vehicle 车辆
- Government Regulations 政府法规
- Customer (Internal and End User)
- 顾客（内部的和最终用户）

设计FMEA路径和步骤2与3



Path/Step 2:

路径/步骤2：

- ❖ **Causes – Occurrence**
- ❖ **原因-发生率**
- ❖ **Special Characteristics**
- ❖ **特殊特性**
- ❖ **Actions 措施**

Path/Step 3:

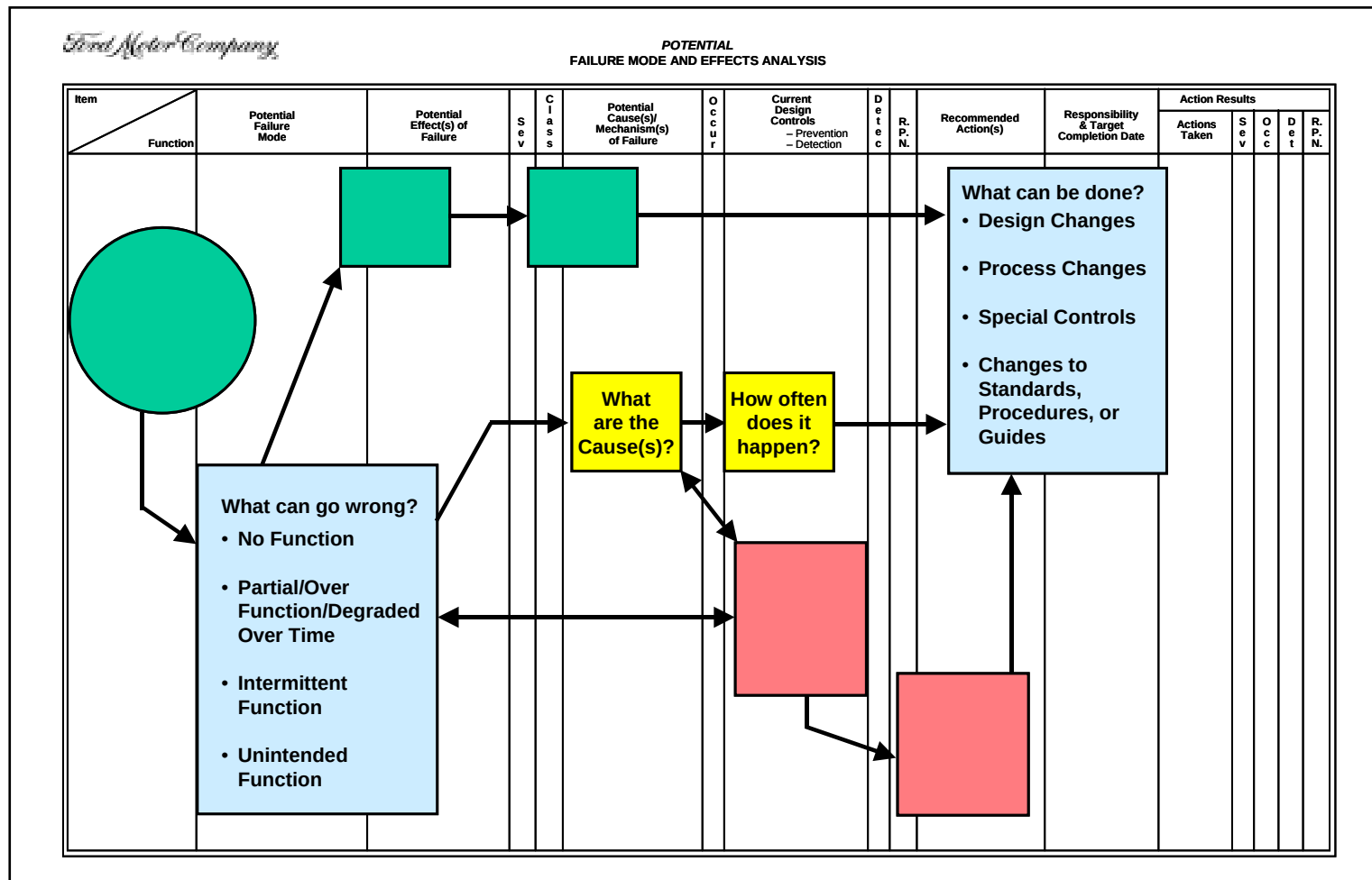
路径/步骤3：

- ❖ **Design Controls**
- ❖ **设计控制**
- ❖ **Assessing Risk**
- ❖ **评估风险**
- ❖ **Actions 措施**

Practice Exercise 3

实践练习 3

设计FMEA路径和步骤2



潜在失效原因

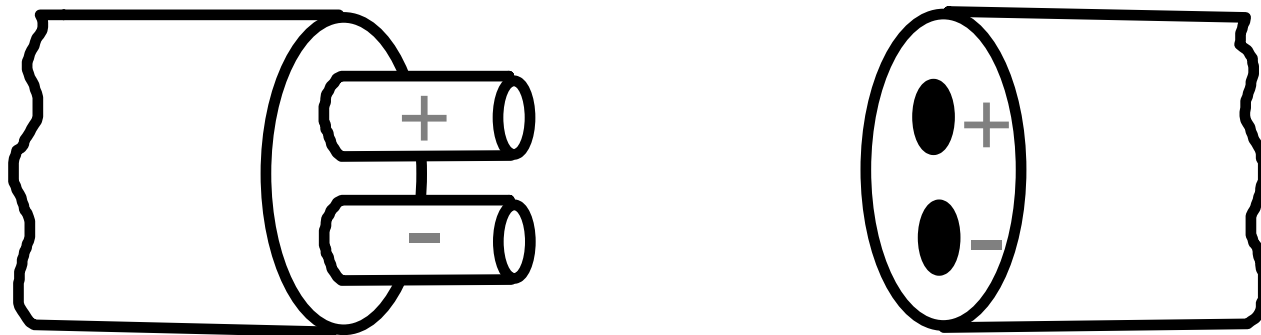
潜在失效原因是由设计缺陷引起的，其结果就是失效模式。

可能导致失效的原因

- 工程规范中已经制造并装配的零件
- 设计中可能包含某种缺陷，这种缺陷可能引起不可接受的变差（错误构造，误差等）

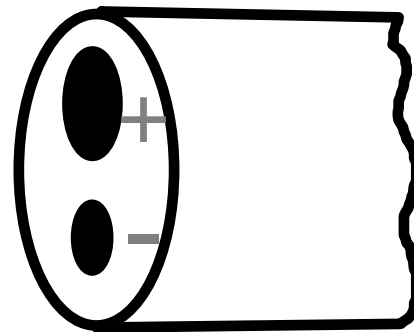
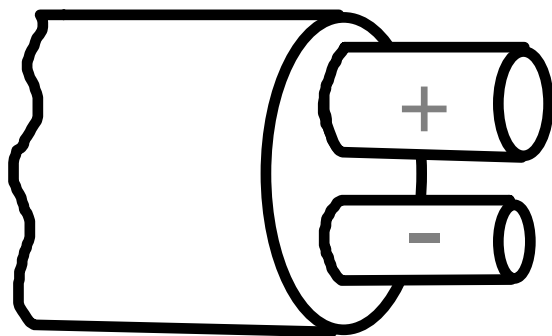
错误的设计

由设计缺陷引起的



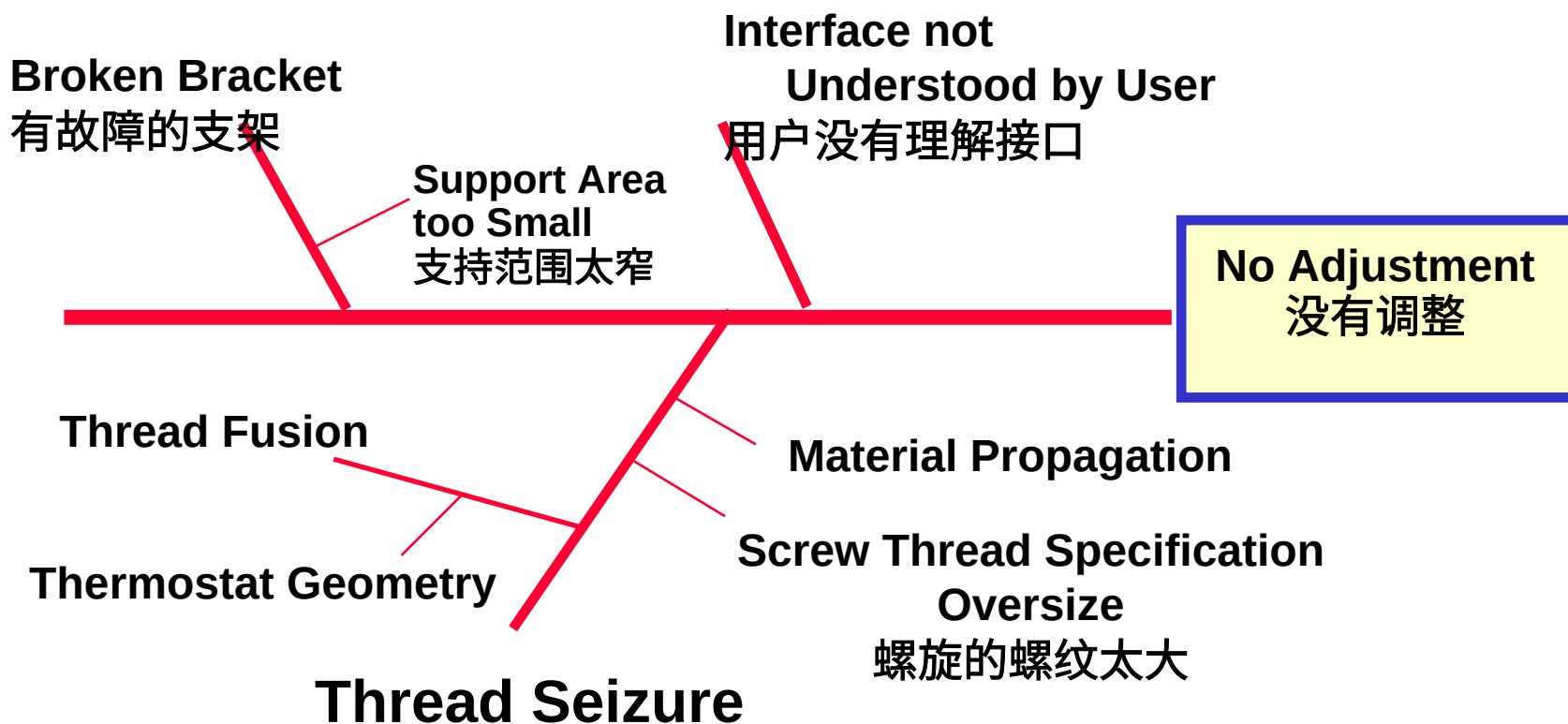
正确的设计

采用防呆法进行设计



失效的原因

使用鱼刺图



失效的原因实例

有故障的支架

**Material
cracked**

**Level 1
第1层**

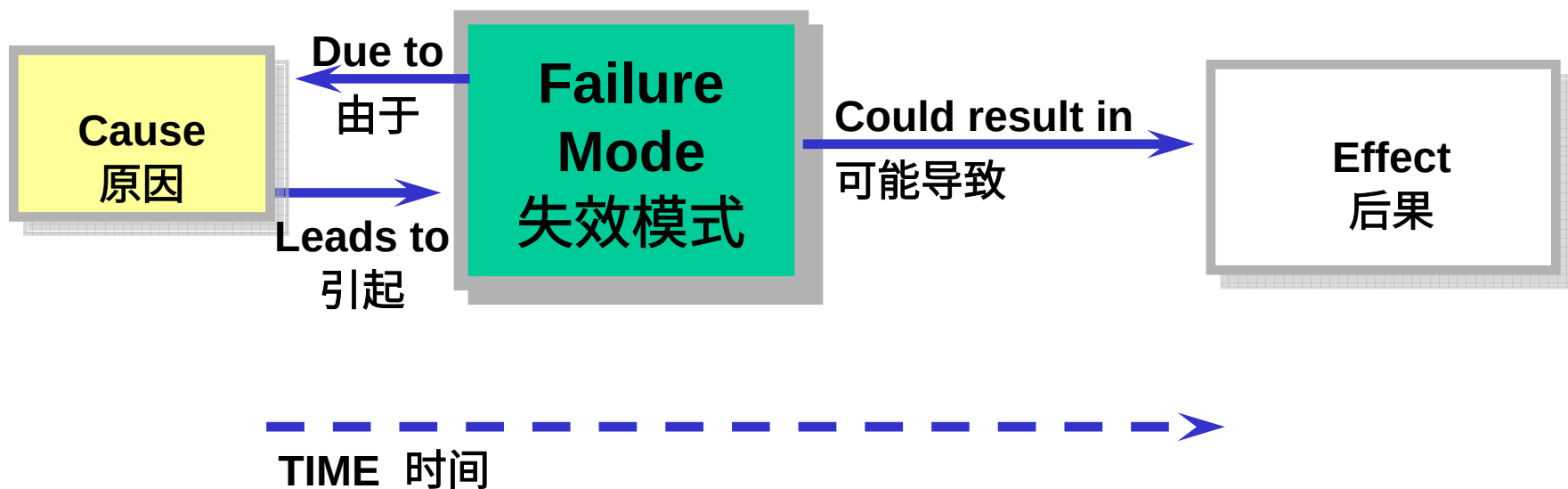
**Part
Bends
零件弯曲**

**Level 2
第2层**

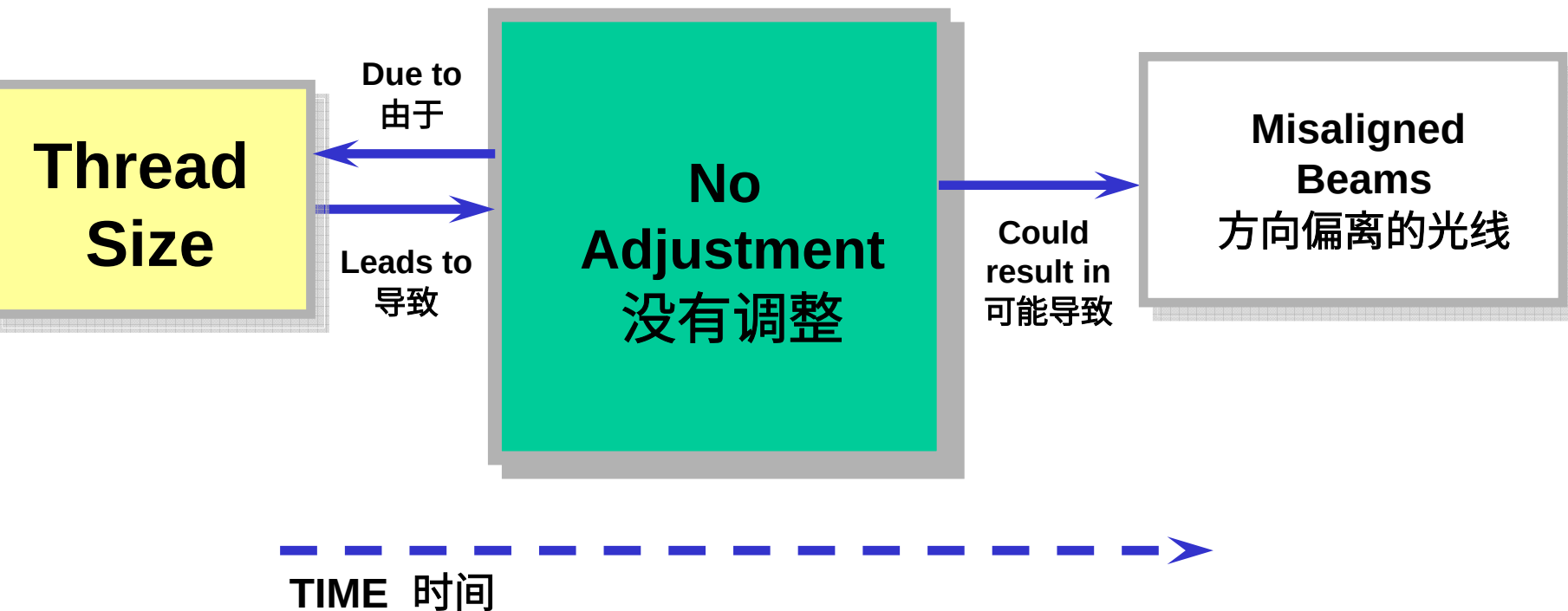
**Support area
too small
支持范围太窄**

**Level 3
第3层**

判断技巧



判断技巧-实例



失效的原因

Ford Motor Company

POTENTIAL
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											Actions Taken	S e v	O c c	D e t	R. P. N.			
Function 1 功能1	Failure Mode 1 失效模式1	→																
	Failure Mode 2 失效模式2																	
	Failure Mode n 失效模式n																	

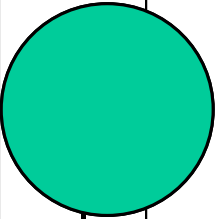
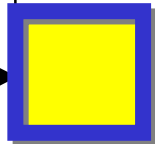
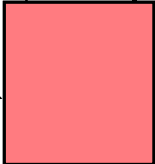
WHY?
为什么?

~~M E P E M~~

设计FMEA--发生率

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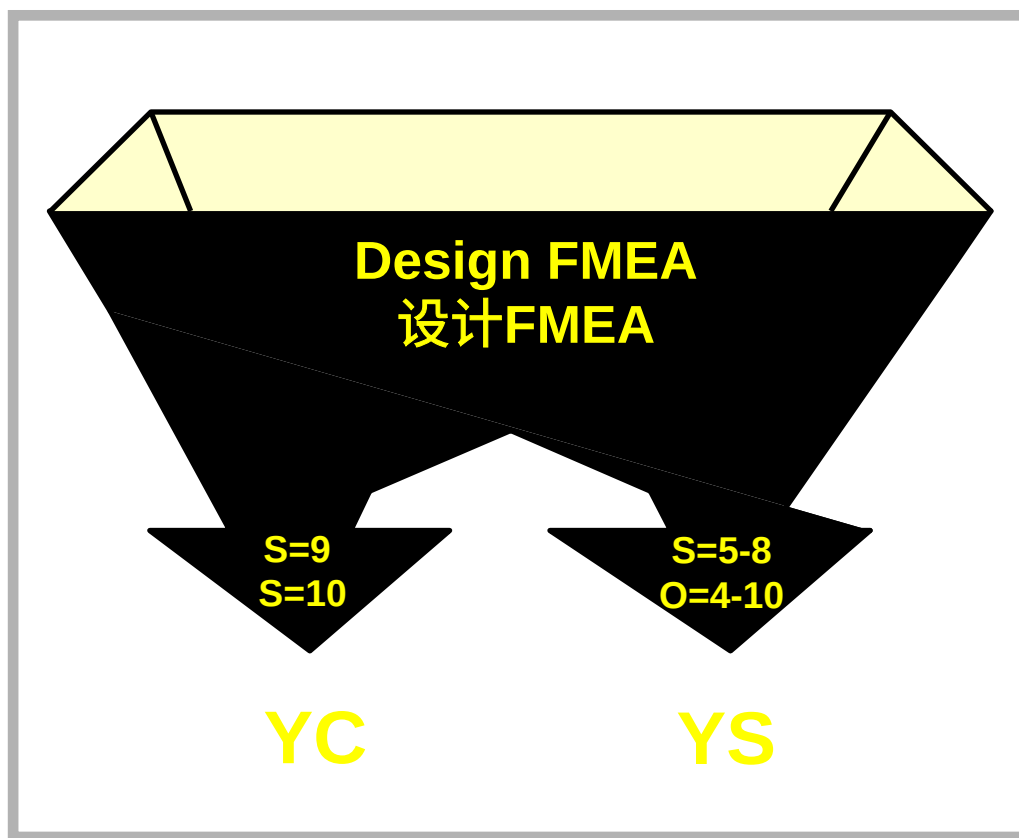
POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

Item Function	Potential Failure Mode	Potential Effect(s) of Failure	C l a s s S e v	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r	Current Design Controls - Prevention - Detection	D e t e c t R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
										Actions Taken	S e v	O c c	D e t	R. P. N.
														
														
														
														
														

建议的发生率评价准则

Probability of Failure 失效的可能性	Possible Failure Rates 可能失效的比率	Ranking 等级
Very High: Persistent failure 很高：持续的失效	≥ 100 per thousand vehicles/items ≥ 100 件/每千件	10
	50 per thousand vehicles/items 50件/每千件	9
Moderate: Occasional failures 中等：偶尔失效	5 per thousand vehicles/items 5件/每千件	6
	2 per thousand vehicles/items 2件/每千件	5
	1 per thousand vehicles/items 1件/每千件	4
Remote: Failure unlikely 很低：不可能失效	≥ 0.01 per thousand vehicles/items ≥ 0.1 /每千件	1

识别潜在的特殊特性



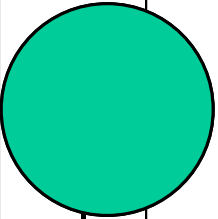
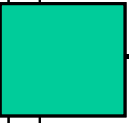
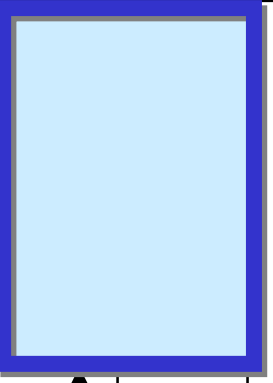
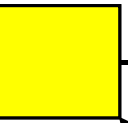
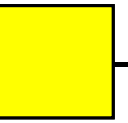
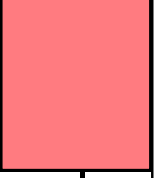
东菱练习



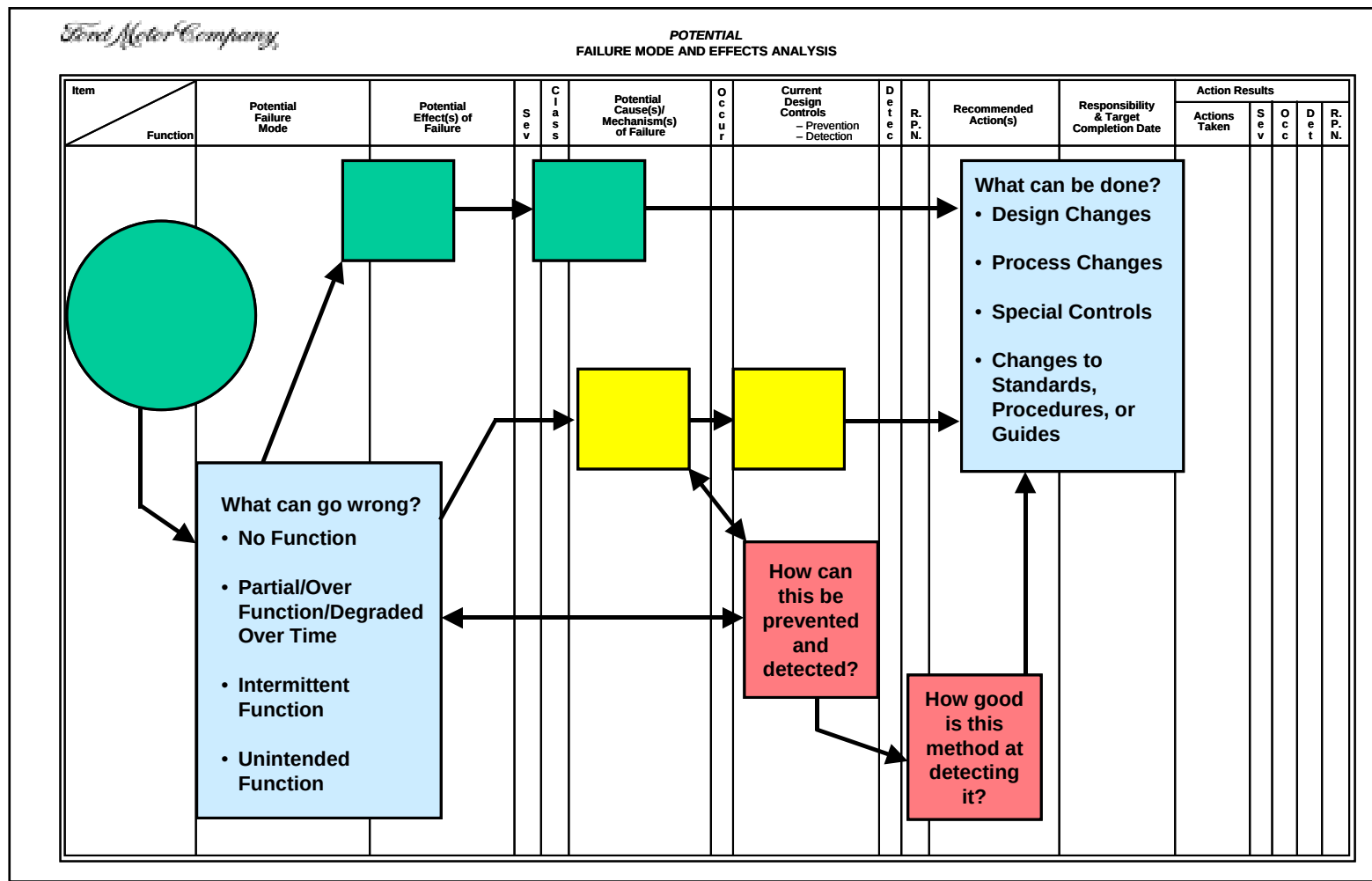
建议的措施

Ford Motor Company

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

Item Function	Potential Failure Mode	Potential Effect(s) of Failure	C l a s s S e v	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r	Current Design Controls - Prevention - Detection	D e t e c t R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
										Actions Taken	S e v	O c c	D e t	R. P. N.
														
														
														

设计FMEA路径和步骤3



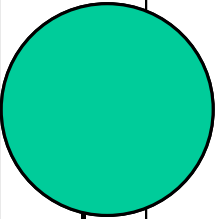
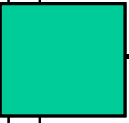
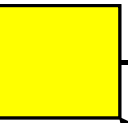
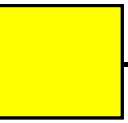
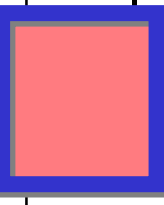
设计FMEA—设计控制

- 类型1 预防：预防失效原因/机理或者失效模式/后果，或减少发生度
- 类型2 探测：在零件生产之前，用分析或物理方法探测失效原因/机理或失效模式

设计FMEA—探测度

Ford Motor Company

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

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										Actions Taken	S e v	O c c	D e t	R. P. N.
														
														
														
														

建议的探测度评价准则

Detection 探测度	Criteria: Likelihood of detection by design control 准则：通过设计控制探测可能性	Ranking 等级
Absolute Uncertainty 确实绝对无法探测	Design control will not and/or cannot detect a potential cause/mechanism ... or there is no design control 设计控制没有和/或不能探测到潜在的原因/机理...或者没有设计控制措施	10
Moderately High 中	Moderately high chance the design control will detect potential cause/ mechanism and ... 设计控制有可能能探测到潜在原因/机理	4
Almost Certain 几乎可以确定	Design control will almost certainly detect a potential cause/mechanism ... 设计控制几乎可以完全确定潜在原因/机理	1

RPN范例

$$\underline{S \times O \times D} = \underline{RPN}$$

$$2 \quad 10 \quad 10 \quad 200$$

$$10 \quad 10 \quad 2 \quad 200$$

$$10 \quad 2 \quad 10 \quad 200$$

RPN范例

$$\underline{S \times O \times D = RPN}$$

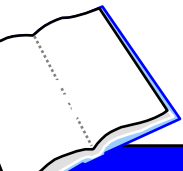
$$10 \quad 2 \quad 2 \quad 40$$

$$3 \quad 10 \quad 2 \quad 60$$

$$2 \quad 5 \quad 10 \quad 100$$

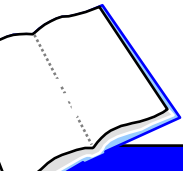
评估风险

- 严重度
- 严重度 $\times$ 发生率
- 严重度 $\times$ 发生率 $\times$ 探测度



建议的措施

- 填写要求的适当措施
- 把每一项措施分配给每一个小组成员，并指定相应的时间
- 如果没有计划的措施，请填写“无”或“此次无”



未来的措施

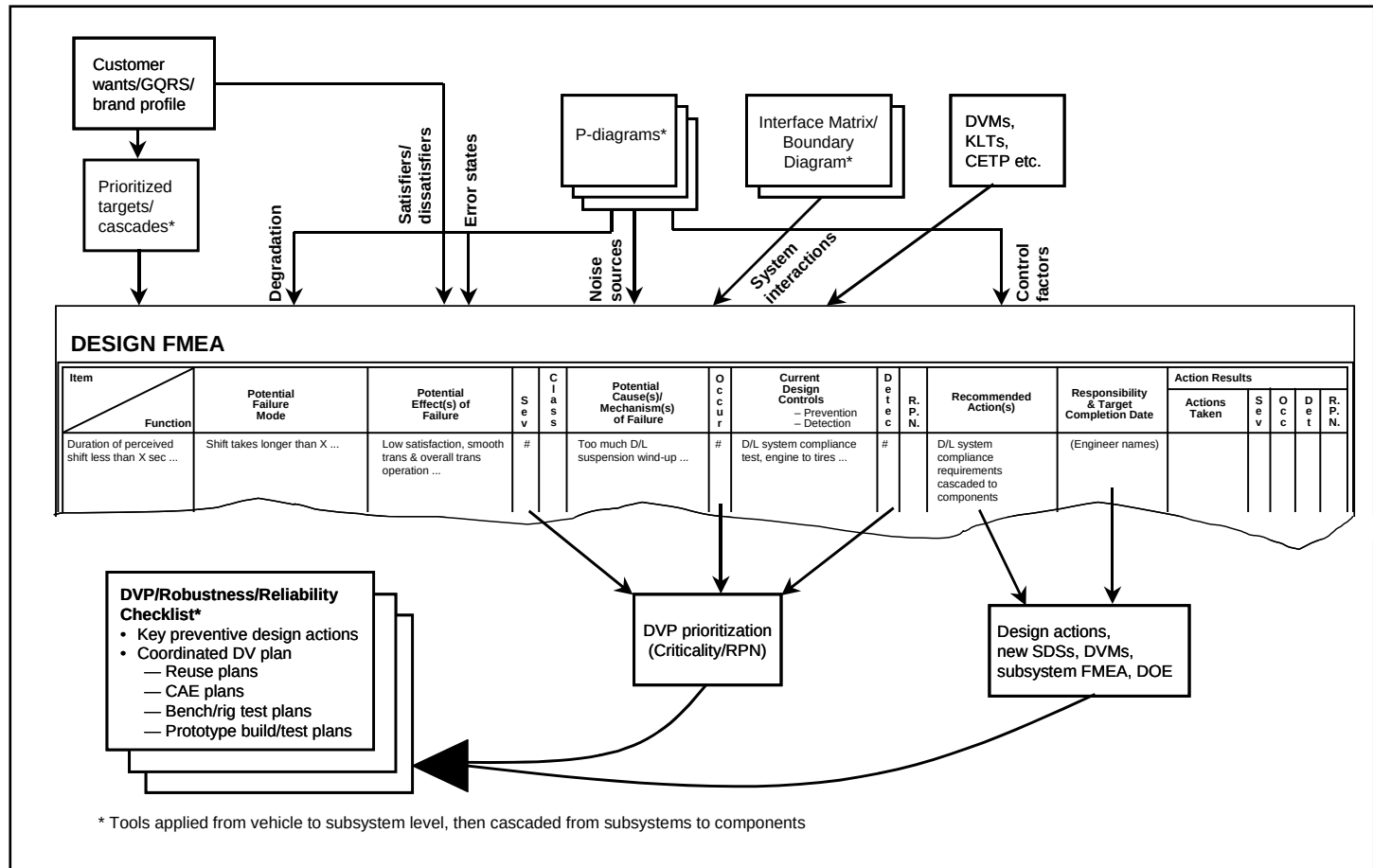
[illegible]





TIFFANY

文件的相互关系



稳健性与可靠性查检表

Reliability and Robustness Checklist (RRCL)

2009 0854

Diving Tower: Diving Board

Living Power: Living Power

Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
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Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
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Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
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Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)										DV Test Controls										DV Test Controls									
Error States		Shortfall Matrix (S-Matrix)										Shortfall Matrix (S-Matrix)																													

本节总结



Path/Step 2:

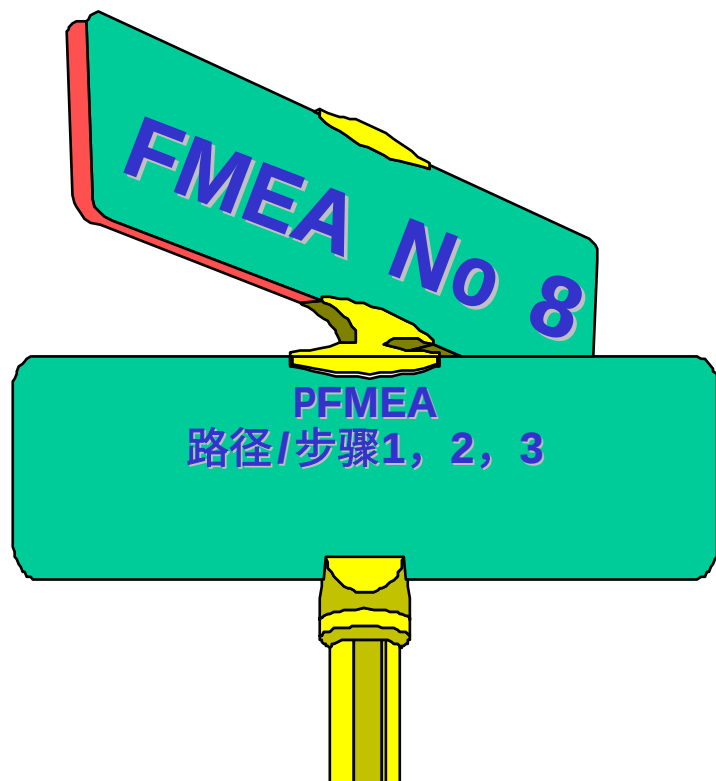
路径/步骤2：

- ❖ Causes – Occurrence
- ❖ 原因-发生率
- ❖ Special Characteristics
- ❖ 特殊特性
- ❖ Actions 措施
- ❖ Path/Step 3:
- ❖ 路径/步骤3：
- ❖ Design Controls
- ❖ 设计控制
- ❖ Assessing Risk
- ❖ 风险评估
- ❖ Actions 措施

Practice Exercise 3

实践练习3

过程FMEA篇



- 路径/步骤1和2
- 实践联系4a
- 路径/步骤3
- 实践联系4b

过程FMEA

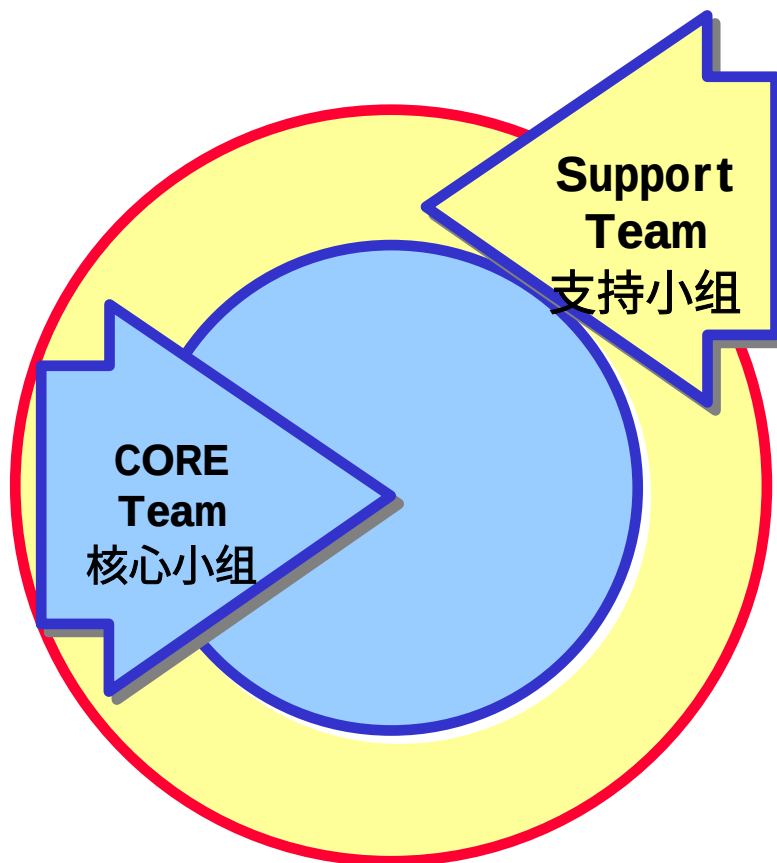
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POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

[illegible]

过程FMEA小组

制造/过程工程师
设计工程师

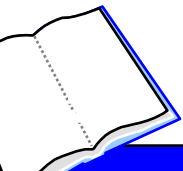


代表来自：

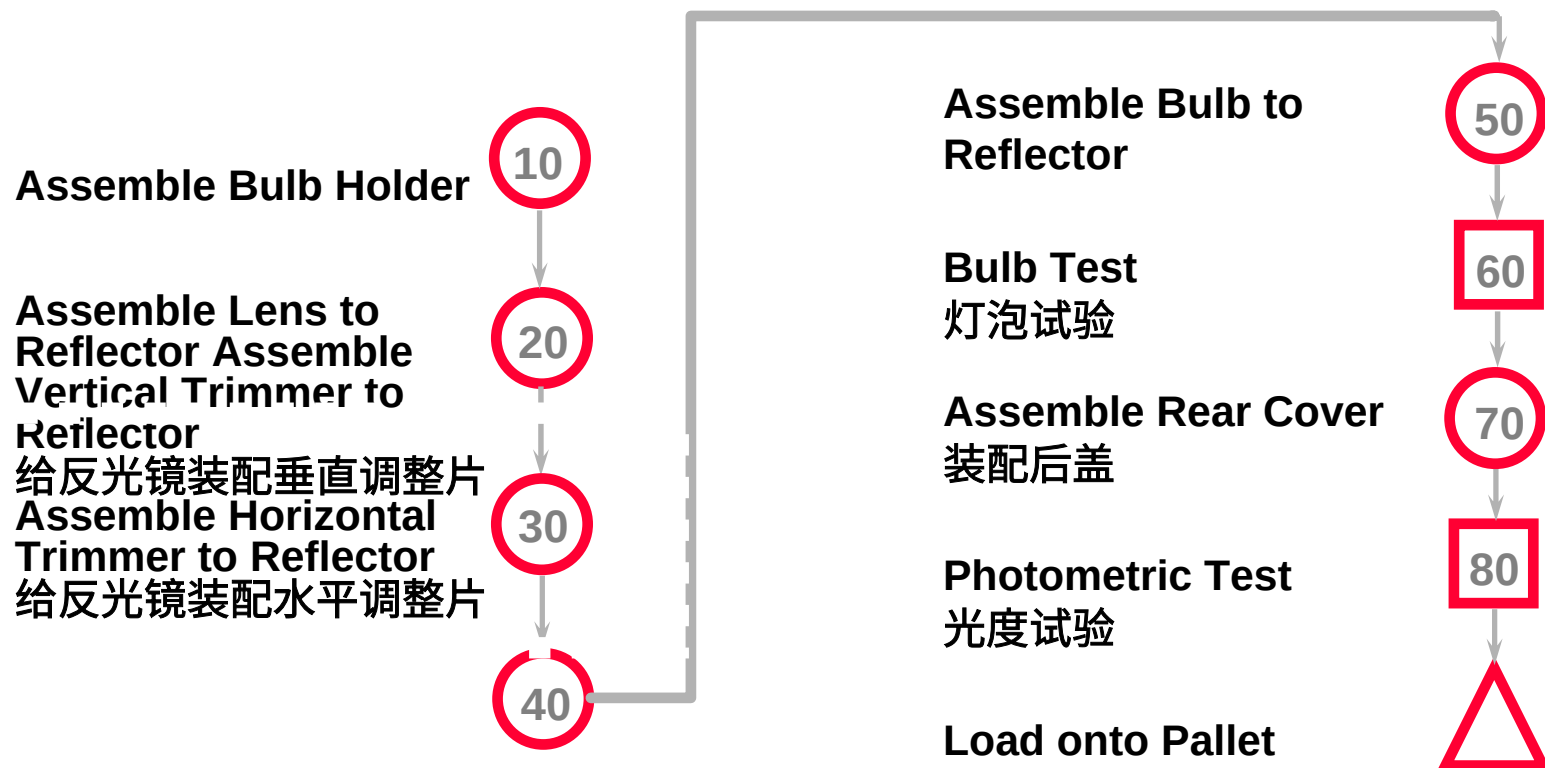
- 专家
- 供方
- 维修技师
- 生产
- 下一个过程的工程师

过程FMEA范围

- 建立宏观的流程图
- 确认分析的界限
- 建立微观的流程图
- 确定支持小组成员



前灯装配—宏观



Inspection
检查



Operation
操作



Storage
存储



Transportation
传递



前灯装配—微观

Op 30-在反光镜上装配垂直调整片

将基座定位和安装（两颗螺钉）于
反射镜。

前端装配、定位预先装配的螺栓和
弹簧
从视觉上检查调整片的装配



特性矩阵

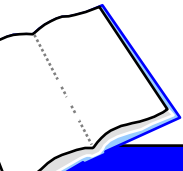
Product Characteristics	Operations		
	30.1	30.2	30.3
• Correct orientation –base plate	A		
• Correct location –base plate	X		
• Two (2) XYZ screws	A		
• Correct torque X +-y	X		
• Correct orientation spring/screw assembly		X	
• Correct location spring/screw assembly		x	
• Positively located spring/screw assembly		X	

Legend

- X** – Characteristic is created or changed
- C** – Characteristic is used for clamping
- L** – Characteristic is used for locating
- T** – Common tool creates more than one characteristic
- M** – Characteristic is automatically monitored
- A** – One finished product characteristic has a strong effect on another

零件的功能清单

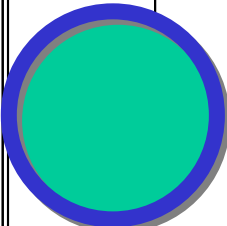
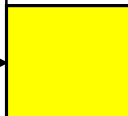
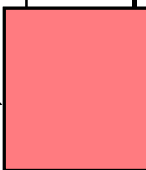
ITEM FUNCTION 零件的功能		
DESCRIPTION 描述		
FUNCTION: 功能： What is the item supposed to do? 哪些是要求的零件？ What is the item not supposed to do? 哪些不是要求的零件？ List all the functions and separate them from the specifications. 列举所有的功能，并与规范保持独立		
List All Functions 列举所有的功能	Specifications 规范	
Function Description: Verb – Noun 功能描述：动-名词	How Much? When? 多少？何时？	



过程目的说明

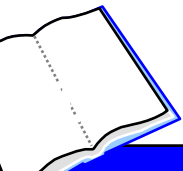
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POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

Item Function	Potential Failure Mode	Potential Effect(s) of Failure	C l a s s S e v	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r	Current Design Controls - Prevention - Detection	D e t e c t R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
										Actions Taken	S e v	O c c	D e t	R. P. N.
														
														
														
														

定义过程目的

- 在此操作中，过程起什么作用？
- 使用动词/名词/可测量的格式填写
- 测量包括所有的终端产品和过程要求



微观流程—过程目标

Purpose 目的

将基座定位和安装（两颗螺钉）于反射镜。

前端装配、定位预先装配的螺栓和弹簧

从视觉上检查调整片的装配

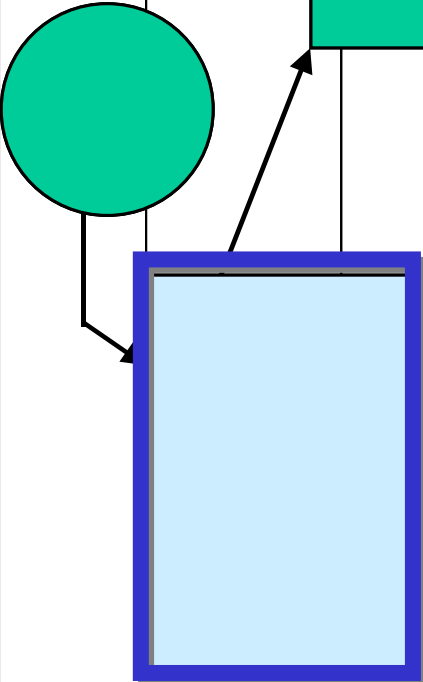
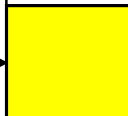


- 基座定位—校正方向
- 确保两个螺钉达到指定的扭力
- 将每个目视辅具前端插入校正位置
- 确保在子装配时螺栓/弹簧的正确定位
- 从视觉上检查（符合零件图纸）：
螺栓，弹簧，位置，安装

确定可能出错的地方

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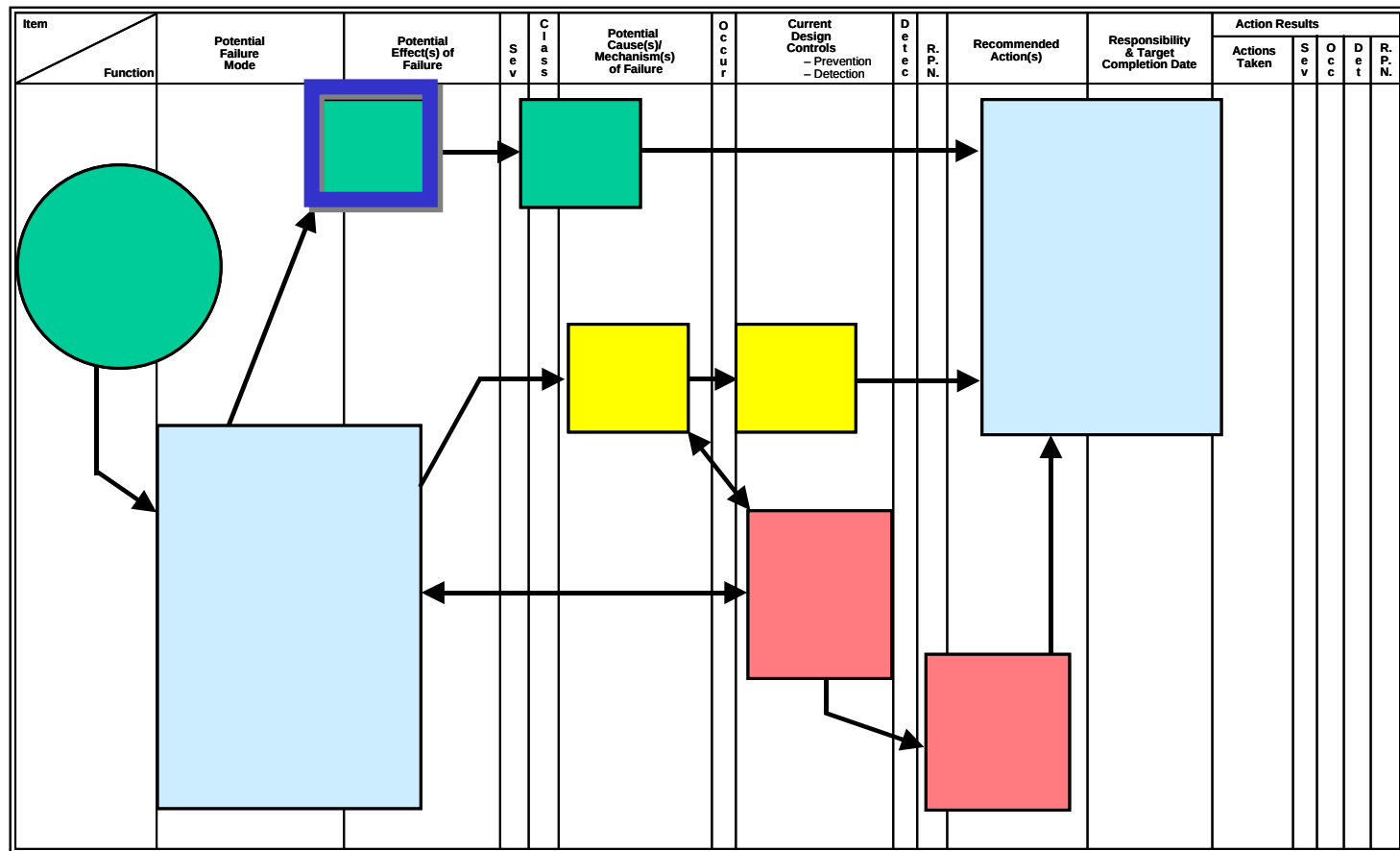
POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

Item Function	Potential Failure Mode	Potential Effect(s) of Failure	C l a s s S e v	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r	Current Design Controls - Prevention - Detection	D e t e c t R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
										Actions Taken	S e v	O c c	D e t	R. P. N.
														

失效模式的后果

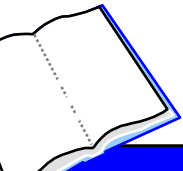
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POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS



失效模式的后果

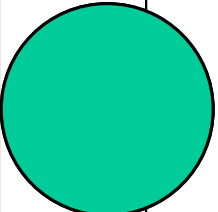
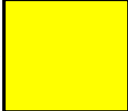
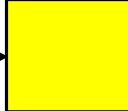
- **Operator safety**
- 操作员安全
- **Next user**
- 下一位用户
- **Downstream users**
- 下游用户
- **Machines/equipment**
- 机器/设备
- **Vehicle operation**
- 车辆行驶
- **Ultimate customer**
- 最终顾客
- **Compliance with government Regulations**
- 符合政府法规规则



过程 FMEA 严重度

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POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

Item Function	Potential Failure Mode	Potential Effect(s) of Failure	C l a s s e v	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r	Current Design Controls - Prevention - Detection	D e t e c t R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
										Actions Taken	S e v	O c c	D e t	R. P. N.
 														

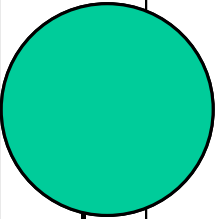
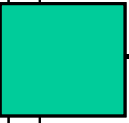
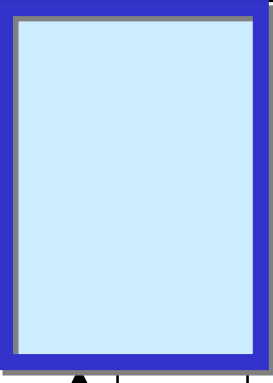
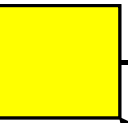
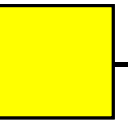
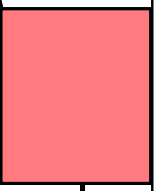
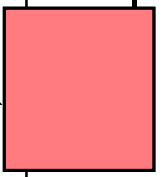
建议的严重度评价准则

Effect 后果	Criteria: Severity of Effect 准则：后果的严重度	Ranking 等级
Hazardous Without Warning 非常严重-无警告	May endanger machine or assembly operator ... noncompliance with government regulation ... without warning 可能危及机器或装配人员的安全...不符合政府法规...无警告	10
Hazardous With Warning 非常严重-有警告	May endanger machine or assembly operator ... noncompliance with government regulation ... with warning 可能危及机器或装配人员的安全...不符合政府法规...有警告	9
Very High 非常高	Major disruption to production line. 100% ... may have to be scrapped ... vehicle/ item inoperable 严重破坏生产线。可能造成生产停滞...车辆/零件不可用	8
None 无	No discernible effect or no effect 没有可识别后果或没有造成后果	1

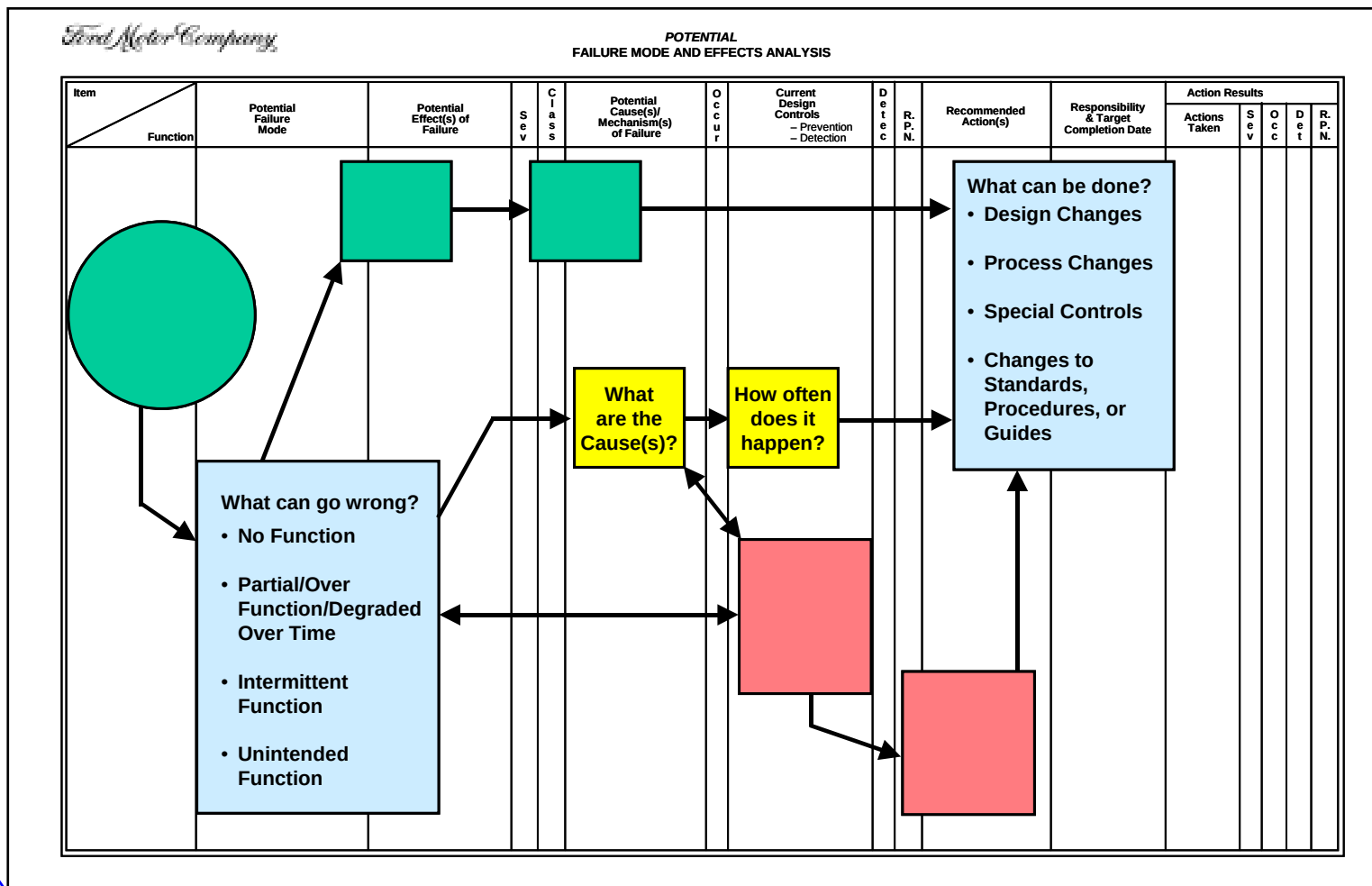
PFEMA 路径/步骤1 措施

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POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS

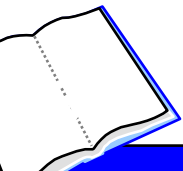
Item Function	Potential Failure Mode	Potential Effect(s) of Failure	S e v	C l a s s	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r	Current Design Controls - Prevention - Detection	D e t e c t R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
											Actions Taken	S e v	O c c	D e t	R. P. N.
															
															
															
															

PFEMA 路径/步骤 2



可能的原因

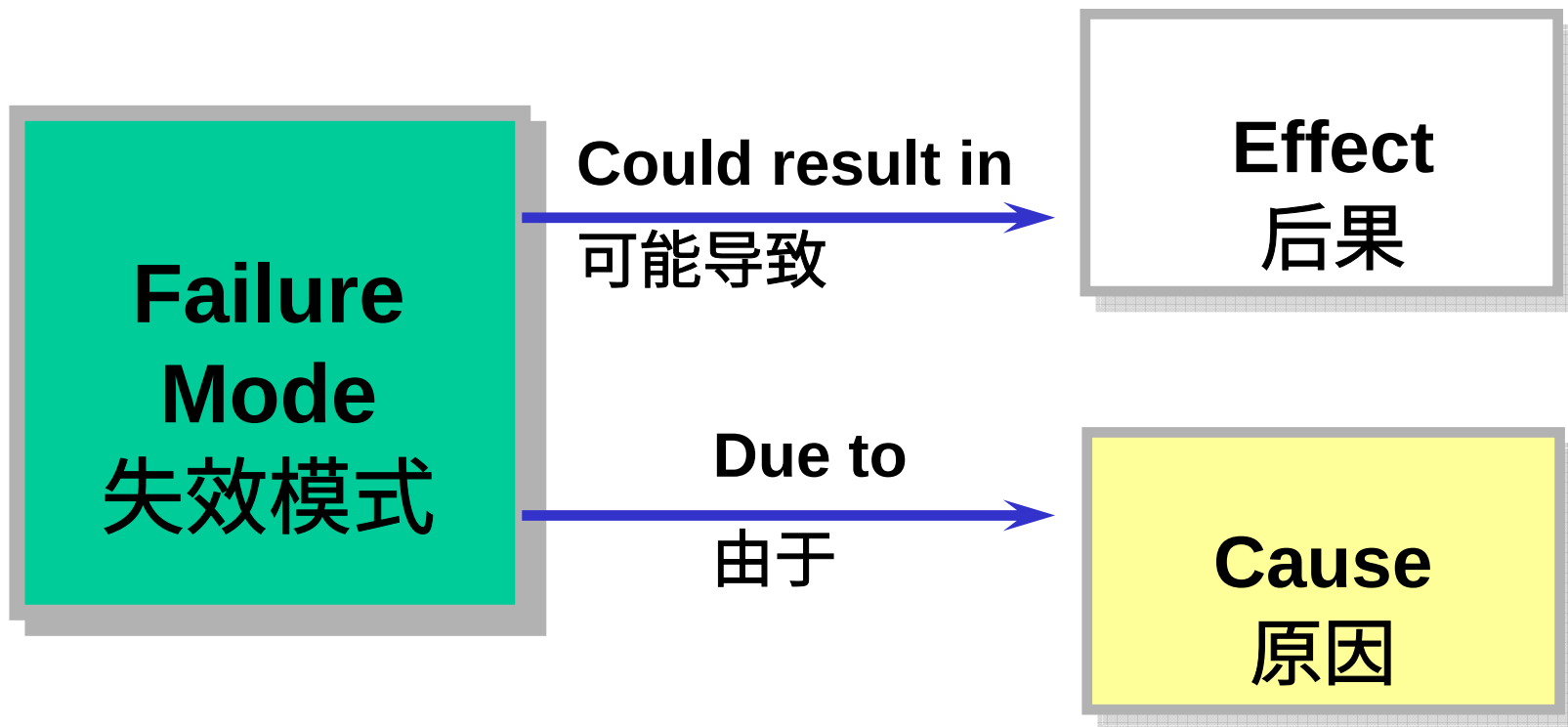
- 假定入厂的零件是正确无误的，是什么原因导致这种情况下的操作失效



过程 FMEA 原因

[illegible]

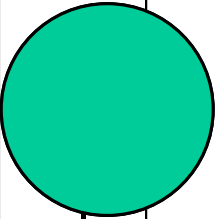
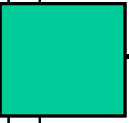
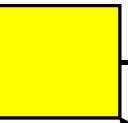
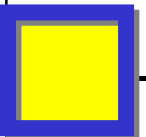
判断技巧



P F M E A 发生率

Ford Motor Company

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

Item Function	Potential Failure Mode	Potential Effect(s) of Failure	C l a s s i f i c a t i o n	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r r e n c e	Current Design Controls - Prevention - Detection	D e t e c t i o n	R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
											Actions Taken	S e v	O c c	D e t	R. P. N.
															
															
															
															

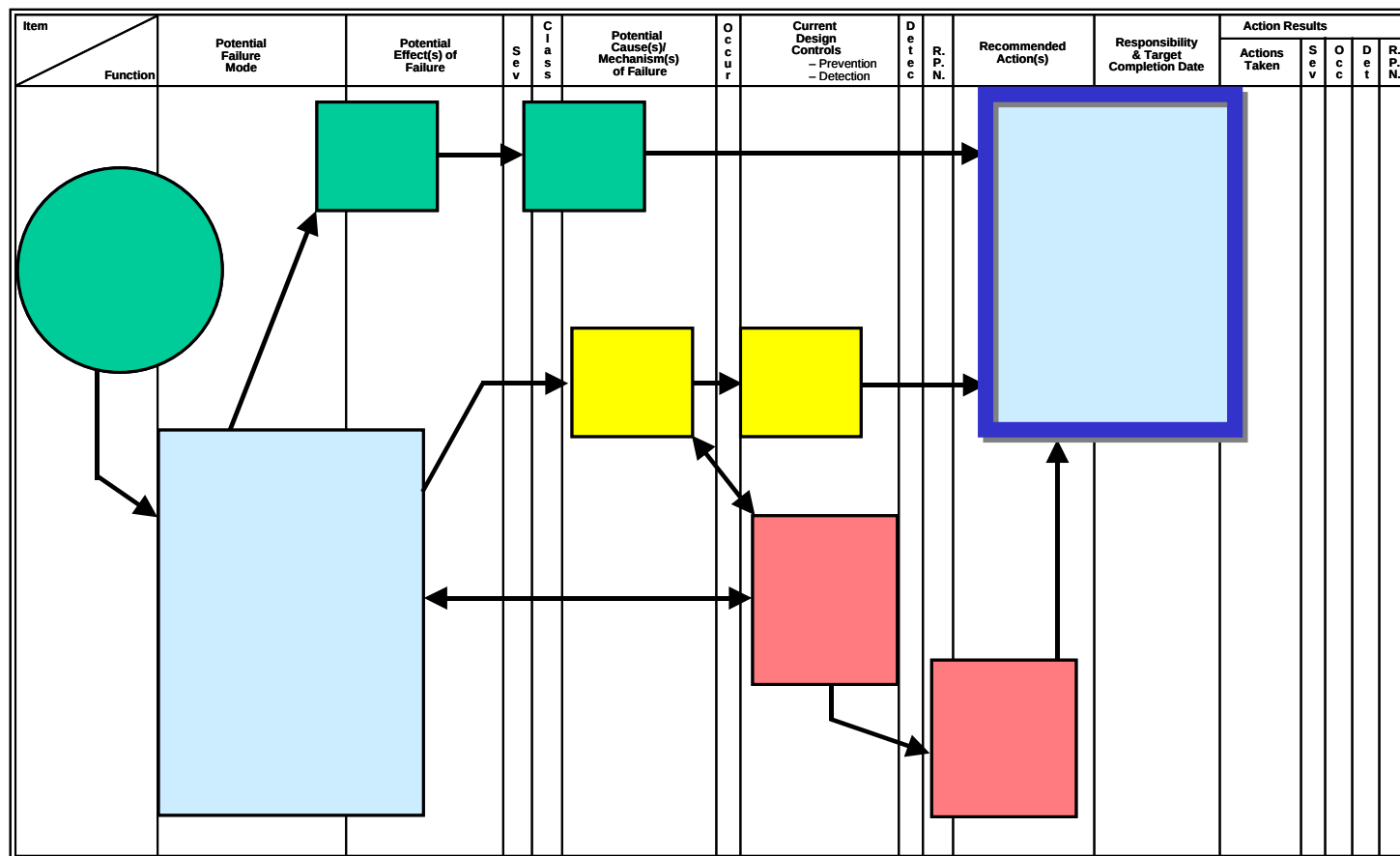
建议的频度评价准则

Probability of Failure 失效的可能性	Likely Failure Rates 可能的失效率	Ranking 等级
Very High: Persistent failures 非常高：持续发生的失效	➤100 per thousand pieces ➤100件/每千件	10
	50 per thousand pieces 50件/每千件	9
Low: Relatively few failures 低：相对较少的失效	0.5 per thousand pieces 0.5件/每千件	3
Remote: Failure is unlikely 极低：不可能失效	≤0.01 per thousand pieces ≤0.01件/每千件	1

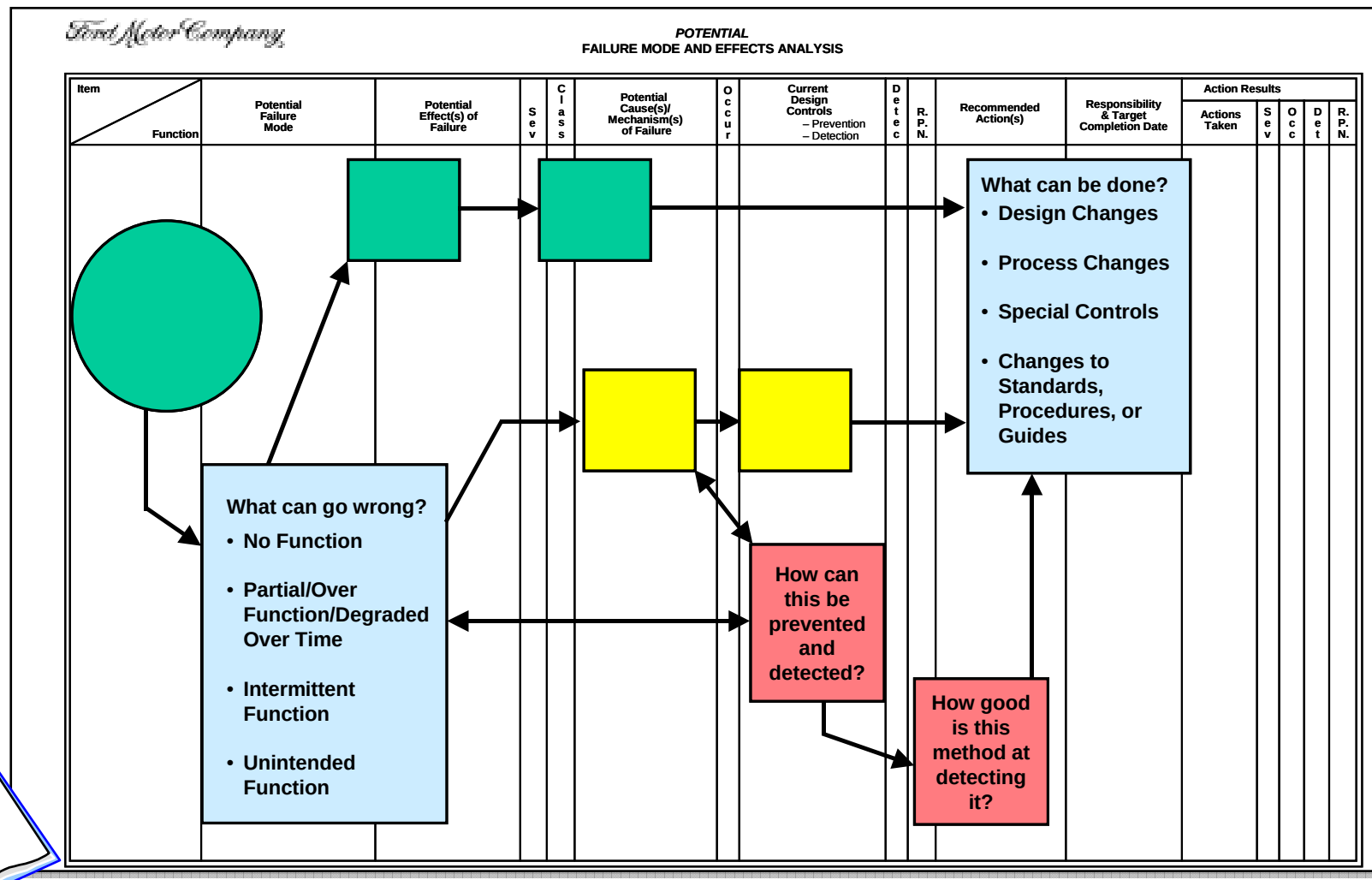
建议的措施

Ford Motor Company

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

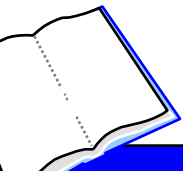


PFEMA 路径/步骤3



过程控制

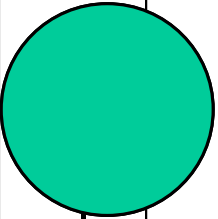
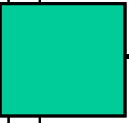
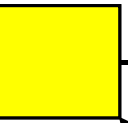
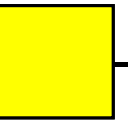
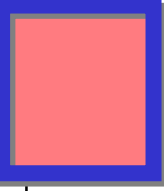
- 类型1 预防：防止失效原因/机理，或者失效模式/后果的出现，或减少其发生频度。
- 类型2 探测：探测原因/机理，实施纠正措施。



PFMEA探测度

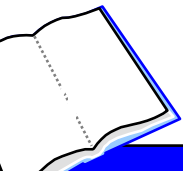
Ford Motor Company

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

Item Function	Potential Failure Mode	Potential Effect(s) of Failure	C l a s s S e v	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r	Current Design Controls - Prevention - Detection	D e t e c t R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
										Actions Taken	S e v	O c c	D e t	R. P. N.
														
														
														
														

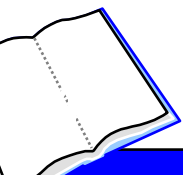
建议的探测度评价准则

Detection探测度	Criteria 准则	Ranking 等级
Almost Impossible 几乎不可能探测到	Absolute certainty of non-detection 绝对探测不到	10
Moderately High 中等高	Controls have a good chance to detect 有可能能够探测到	4
Very High 非常高	Controls certain to detect 可以探测到	1



风险评估

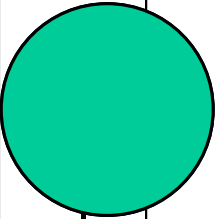
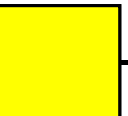
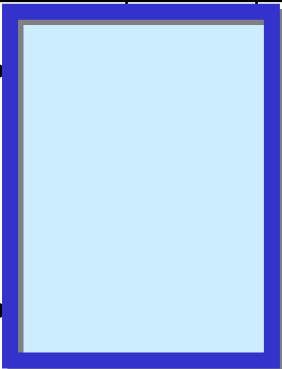
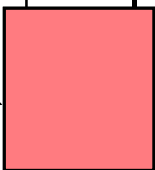
- 严重度
- 严重度 $\times$ 频度 (SO=危险程度)
- 严重度 $\times$ 频度 $\times$ 探测度



建议的措施

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POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS

Item Function	Potential Failure Mode	Potential Effect(s) of Failure	C l a s s S e v	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r	Current Design Controls - Prevention - Detection	D e t e c t R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
										Actions Taken	S e v	O c c	D e t	R. P. N.
 														
														

未来的措施

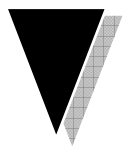
[illegible]

特殊特性

特殊特性涉及影响以下方面的产品和/或过程特性：

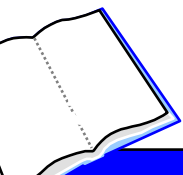
- 车辆或过程安全
- 符合政府法规
- 顾客满意

特殊特性



：指影响政府法规的符合性或安全车辆/产品功能的要求，并且当S=9或10时需要特别控制。

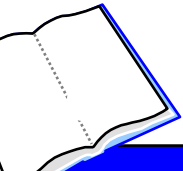
SC重要性：产品和/或试验要求，控制计划，（S=5至8，O > 3）时需要特别控制



特殊性

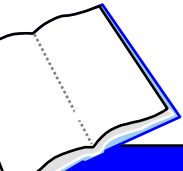
OS 操作人员的安全：与那些可能不会影响产品，但会影响安全或过程操作中政府法规的符合性的过程参数有关。

HI 严重影响：当产品或过程特性超出公差规范时，就会严重影响过程本身的操作或后续的操作（不要求特别控制）



特别控制

- 由制造指导的控制
- 目的是在运送之前，探测并接受与特殊特性相关的缺陷
- 控制计划的文档





FMEA的整合 实践练习

FMEA导入

- 高度推荐层层深入的导入方法.
- FMEA就像洋葱的表面层一样.
 - 越往里剥就越容易接近问题的真因;
 - 越接近问题真因就越具体;
 - 总之, 需要深入层层进行FMEA分析;



FMEA在产品开发中的地位

生命
周期
计划

阶段 0

阶段 1

阶段 2

阶段 3

阶段 4

概念形成和发展

设计可行性研究

设计功能确认

PPAP, CP确认

项目结案
措施检讨

商业层

商业计划制定

商业计划制定

完成项目计划

商业计划确认

商业计划确认

初期服务成本

分配资源

生产和制造决策

系统, 子系统和零部件鉴定

部件附属信息

设计
制作报告

经济定单量

设计风险评估(DFMEA)

产品有效性确认

强制性要求确认

生产报告

设计层

搜寻现有知识

系统, 子系统, 部件规格制定

过程风险评估(PFMEA)

PPAP / IPPAP

措施检讨

定义要求

样式输入

厂内培训

外观和性能要求确定

生产过程定义

过程控制计划

操作指南

过程层

初期制造评估

卡通箱, 原料搬运要求

培训计划
过程审核计划

生产系统确认

QFD
阶段性展开

阶段 I QFD

产品规格

Phase I QFD Injector System		HOWs (Title)			
		Customer Importance	Injector Delivery	Fuel Pressure	Timing
Direction of Improvement					
Power / Unit / Fuel Ratio			⊗	⊗	
Does not make noise				△	○
Injector Gm					

阶段性展开

阶段 II QFD

系统/子系统/部件规格制定

客户原始需求

产品规格

Phase II Injector QFD		Required Spec	Importance	HOWs (Title)					
				BALL	PLUNGER & BARREL	RING	WASHER	PLUNGER	NOZZLE & GP
How	Rated & Idle Delivery		10	△	⊗			⊗	
	Del variation shot to shot		10						
	Delivery Variation injector to inj -		10		○			○	
	Rated & Idle Timing		10	△					
	Timing variation shot to shot		10						
	Timing variation post e-time		10						

DFMEA 失效模式

系统 DFMEA

子系统 DFMEA

部件 DFMEA

输入

- 图纸
- 边界图
- 保证文件
- P图
- 操作手册
- 接口矩阵

完整特性矩阵图

来自DFMEA的潜在
关键或显著特性

依特性重要度排列

生产流程全貌

Special Characteristics Fix	Severity	Process Steps																															Customer Assessment		
		Primary Drive Manufacturing																Process Steps																	
		Receive Material	Serial handling	Shipping	Damage	Component	Vehicle Assembly	Op 100 Step 1 PRE-LOAD DOWEL PINS TO FIXTURE	Op 100 Step 2 PRE-LOAD JACK SHAFT SEAL TO FIXTURE	Op 100 Step 3 PRE-LOAD PRIMARY HOUSING BUSHING TO FIXTURE	Op 110 Pre-load bearing to fixture #2	Op 120 Pre-load main shaft oil seal to mandrel	Op 200 Housing to fixture #1	Op 210 Operate press	Op 220 Retaining ring to top groove	Op 230 Reload fixture #1	Op 300 Housing to fixture #2	Op 310 Operate press	Op 320 Retaining ring to top groove	Op 330 Mandrel to main shaft bore 1	Op 340 Operate press	Op 350 Re-load fixture #2 and mandrel	Op 400 Housing to table	Op 410 Reserved	Op 420 Chain adj sub assy to housing	Op 430 Lubricate bushing & seal	Op 445 Move or stage for final assy	Op 500 O-ring to shifter tube	Op 510 Shifter tube to housing	Op 510 Clamp to shifter tube	Op 520 Assemble shifter lever	Op 520 Wave washer to shifter lever		Op 530 Shifter lever to shifter tube	Op 535 Que for final assy line
Direction of Improvement																																			
Potential Critical and Significant	1.090 TO 1.110 " FACE OF PRIMARY HOUSING BUSHING TO FACE OF JACK SHAFT SEAL	5							G					F																					
	DOWEL PINS 0.260 TO 0.270 " TO FACE	3						H						F																					
	JACK SHAFT SEAL AGAINST SHOULDER	9							H					F																					
	BEARING FLUSH TO SNAP RING FACE	3													G				F	G															
	SEAL COMPRESSION HEIGHT	9								G			H	H	F				H	H															
	PRIMARY GASKET SEAL SURFACE FINISH	9		F	F	Y									H	H			H	H					H			G	G						
	SEALERATION DAMAGE	5																								F									
Weighted Importance		0	81	81	72	0	9	41	0	0	27	54	261	3	0	54	81	3	0	0	27	0	45	9	9	0	0	0	0	0	0	0	0		
Relative Importance																																			

依风险高低程度
处理高风险过程

高度/中度相关是PFMEA的潜在失效模式分析时的重点

系统 DFMEA
子系统 DFMEA
部件 DFMEA

阶段 III QFD

生产运作

阶段 IV QFD

过程参数
和变量

特性
分类

SC's & CC's
Causes from
DFMEA's

High Priority Process
Operations

Phase III Characteristics Matrix

	Required Spec	Importance	Process Steps (How's)
Plunger Surface Finish		10	Receive
Plunger Roundness		10	Wash
Straightness		10	Centerless Grind
Diameter		10	Centerless Brush
Grinder Burn		10	Wash
Cleanliness		10	Relinquish

Phase IV QFD

	Required Spec	Severity	Process Parameters & Variables
7.286 ± 1.3 um		10	Grind Wheel Dressing Frequency
- no grinder burn		10	Wheel Balance
- 0.000 roundness		10	Grinding Wheel Dressing Feed Rate
- 0.000 straightness		10	Dressing Wheel Speed
- surface to be free		10	Revolutions/Minute
- hardness spec: 102HRC		10	Wheel Feed Height
- 100% 1 Class		10	Coolant Characteristics and Concentration
		10	Expanding wheel speed
		10	Coolant Flow Rate
		10	Coolant Nozzle Condition
		10	Grind

SC's & CC's

Process Related
SC's & CC's
From all DFMEA's

Failure
Modes on
PFMEA

Causes on
PFMEA

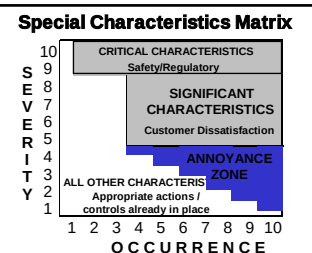
关键控制特性

过程 FMEA

控制计划

Inputs

- Failure Data
- Process Flow
- Process Capability
- Line Layout
- MFMEA



潜在关键特性研究

要求文件

- 强制性
 - 尺寸要求
 - 外观要求
- 要求规格文件
图纸
保修记录

稳健性工具

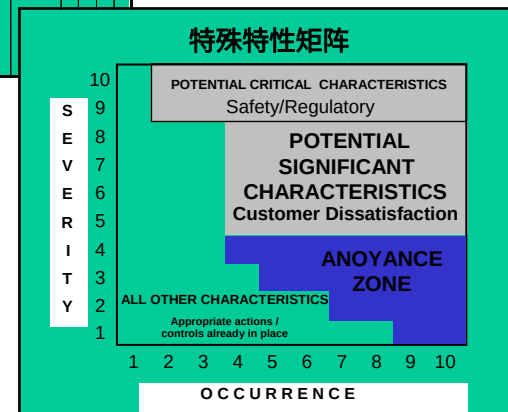
边界图

DOE 接口矩阵

	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 (Prevent/Detect)	D e t e c	R P N	Recommended Actions	Response & Target Complete Date	Action Taken	ACTION RESULTS S E V O C C D E T
DFMEA												

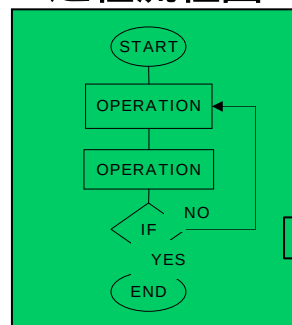
DFMEA

将产品技术要求 展开成具体产品要求



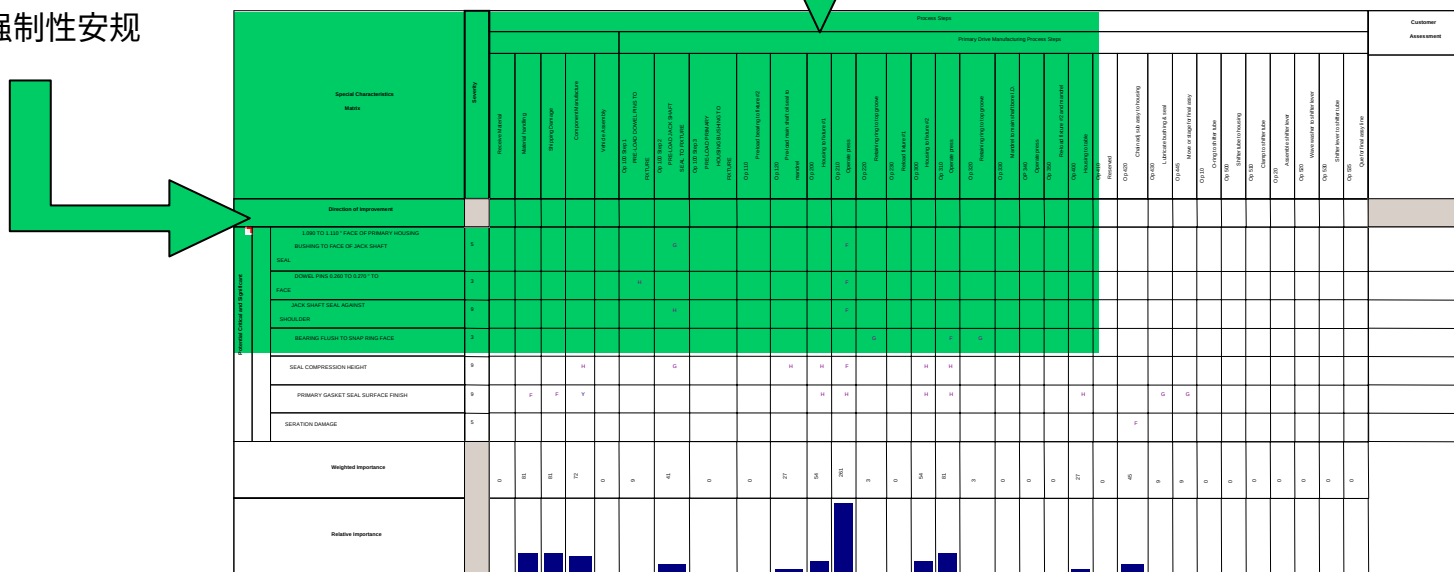
特性矩阵开发

过程流程图



特殊特性来源

- 设计FMEA (潜在关键与显著特性)
- 图纸
- 规定/强制性安规



特性分类矩阵

特殊特性矩阵

