QUALITY TOOLS & TECHNIQUES INTEGRATION

4.0 FAILURE MODE & EFFECTS ANALYSIS (F.M.E.A.)

4.1 INTRODUCTION

4.2 DESIGN F.M.E.A.

4.3 PROCESS F.M.E.A.

4.0 FAILURE MODE AND EFFECTS ANALYSIS

4.1. Introduction

This step on the Holistic Quality Assurance Process examines the various ways in which a product or service may fail and what the effect of each mode of failure will be. The technique leads to the identification of the most important possible modes of failure, so that action can be taken to reduce the risks. In this respect FMEA is a pareto type of analysis, homing in on the "vital few" failure modes. FMEA can be applied to Design of Products, Design of Processes or Design of Systems. This guideline will explain the first of these types of FMEA. The F.M.E.A. technique should be done as early as possible in the Program Management Process and can be done at Pre-study stage prior to quotation of the product to the customer. However, this will have to be refined a lot more once the Initial Product Specifications and Process Sequence charts have been detailed. It should be a live document and should be reviewed following Engineering Changes, Quality Concerns and during any continuos improvement activity.

F.M.E.A. begins by assembling a group of multi disciplined people who are familiar with the product, process or system. The group will brainstorm all possible causes of failure using where possible surrogate data. In addition to brainstorming, designers and engineers should be able to advise on likely modes of failure. Each mode is then analysed under three sets of criteria: - seventy occurrence and detection. A score is then given to each of the three based on current knowledge, data and controls. These scores are then combined to give an overall score. Action is then taken to either eliminate or mitigate the highest scores. Good problem solving skills are essential to minimize the high scoring items.

Further explanation of this is found further on and also in the Program Management Guideline.

4.2 DESIGN FAILURE MODE & EFFECTS ANALYSIS

4.2.1 Purpose

To ensure designs are developed right just in time and the effective utilization of resource is achieved prior to final designs being issued.

4.2.2 Output

A matrix which is intended to:

- Focus attention on and evaluate the potential failure modes and causes associated with a product design.
- Identify actions which will eliminate or mitigate the chance of failure.

4.2.3 Benefits

- Significant savings by changing the design at an early stage of the Program Management process.
- Reduction in undesirable, unplanned effects due to last minute changes.

4.2.4 Shortcomings

- Difficult to identify combinations of causes which trigger a failure.

- Ineffective if scoring of severity occurrence and detection is not based on reality.

4.2.5 Introduction to Design F.M.E.A.

Every product / part should be reviewed to identify how it can fail, why it might fail, what is the effect of the failure, where the failure can occur, when the failure may occur and how the design can be modified t avoid failure. Lessons learnt from previous F.M.E.A.'s and customer plant concern, recalls, campaigns, warranty etc. must be used and addressed in the current part DFMEA.

The attached Pro-forma and guideline should be used to construct the DFMEA and can also be found in the Program Management Guideline PMG

POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(DESIGN FMEA)

Customer _____ (1)
- System
- Subsystem
- Component _____ (3)

FMEA Number _____ (2)

Page _____ of _____

Model Year(s) Vehicle(s) _____ (6)

Process Responsibility _____ (4)

Prepared by _____ (5)

Core Team _____ (9)

Key Date _____ (7)

FMEA Date (Orig.) _____ (Rev.) _____ (8)

Item (10) / Function	Potential Failure Mode (11)	Potential Effects(s) of Failure (12)	Sev (13)	Class (14)	Potential Cause(s)/ Mechanism(s) of failure (15)	Occur (16)	Current Design Controls (17)	Detec (18)	RPN (19)	Recommended Action(s) (20)	Responsibility & Target Completion Date (21)	Action Results (23)				
												Actions Taken (22)	Sev	Occ	Det	R.P.N.

DESIGN FMEA

DEVELOPMENT OF A DESIGN FMEA

1.	**CUSTOMER**	Enter the customer to which the part is to be manufactured for.
2.	**FMEA NUMBER**	Enter the FMEA document number, which may be used for tracking.
3.	**SYSTEM, SUBSYSTEM, OR COMPONENT NAME AND NUMBER**	Indicate the appropriate level of analysis and enter the name and number of the system, subsystem or component being analysed.
4.	**DESIGN RESPONSIBILITY**	Enter the customer department/group with design responsibility.
5.	**PREPARED BY**	Enter the name, telephone number, company of the engineer responsible for preparing the FMEA.
6.	**MODEL YEAR(S)/ VEHICLE(S)**	Enter the intended model year(s) and vehicle line(s) that will utilize and/or be affected by the design being analysed (if known).
7.	**KEY DATE**	Enter the initial FMEA due date, which should not exceed the scheduled production design release date.
8.	**FMEA DATE**	Enter the date the original FMEA was compiled, and the latest revision date.
9.	**CORE TEAM**	List the names of the responsible individuals and departments which have the authority to identify and/or perform tasks. (It is recommended that all team members names, departments, telephone numbers, addresses, etc. be included on a distribution list).
10.	**ITEM/FUNCTION**	Enter the name and number of the item being analysed. Use the nomenclature and show the design level as indicated on the engineering drawing. Prior to initial release, experimental numbers should be used. Enter as concisely as possible, the function of the item being analysed to meet the design intent. Include information regarding the environment in which this system operates (e.g., define temperature, pressure, humidity ranges). If the item has more than one function with different potential modes of failure, list all the functions separately.

11. POTENTIAL FAILURE MODE

Potential Failure Mode is defined as the manner in which a component, subsystem, or system could potentially fail to meet the design intent. The potential failure mode may also be the cause of a potential failure mode in a higher level subsystem, or system, or be the effect of one in a lower level component.
List each potential failure mode for the particular item and item function. The assumption is made that the failure could occur, but may not necessarily occur. A recommended starting point is a review of past things-gone-wrong, concerns reports, and group "brainstorming". Potential failure modes that could only occur under certain operating conditions (i.e. hot, cold, dry, dusty, etc.) and under certain usage conditions (i.e. above average mileage, rough terrain, only city driving, etc.) should be considered. Typical failure modes could be, but are not limited to:

Cracked	Sticking
Deformed	Split
Loosened	Door Freeze
Leaking	Fractured

Note: Potential failure modes should be described in "physical" or technical terms, not as a symptom noticeable by the customer.

12. POTENTIAL EFFECT(S) OF FAILURE

Potential Effects of Failure are defined as the effects of the failure mode on the function, as perceived by the customer. Describe the effects of the failure in terms of what the customer might notice or experience, remembering that the customer may be an internal customer as well as the ultimate end user. State clearly if the function could impact safety or noncompliance to regulations. The effects should always be stated in terms of the specific system, subsystem or component being analysed. Remember that a hierarchial relationship exists between the component, subsystem, and system levels. For example, a part could fracture, which may cause the assembly to vibrate, resulting in an intermittent system operation. The intermittent system operation could cause performance to degrade, and ultimately lead to customer dissatisfaction. The intent is to forecast the failure effects to the Team's level of knowledge.

Typical failure effects could be, but are not limited to:

Noise	Rough
Erratic Operation	Inoperative
Poor appearance	Unpleasant Odour
Unstable	Operation Impaired
Intermittent Operation	

13. SEVERITY(S)

Severity is an assessment of the seriousness of the effect (listed in the previous column) of the potential failure mode to the next component, subsystem, system or customer if it occurs. Severity applies to the effect only. A reduction in Severity Ranking index can be affected only through a design change. Severity should be estimated on a "1" to "10" scale.

Suggested Evaluation Criteria:
(The team should agree on an evaluation criteria and ranking system, which is consistent, even if modified for individual product analysis).

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 noncompliance 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 noncompliance with government regulation with warning.	9
Very High	Vehicle/item inoperable, with loss of primary function.	8
High	Vehicle/item operable, but at reduced level of performance. Customer dissatisfied.	7
Moderate	Vehicle/item operable, but Comfort/Convenience item(s) inoperable. Customer experiences discomfort.	6
Low	Vehicle/item operable, but Comfort/Convenience item(s) operable at reduced level of performance. Customer experiences some dissatisfaction.	5
Very Low	Fit and Finish/Squeak and Rattle item does not conform. Defect noticed by most customers.	4
Minor	Fit and Finish/Squeak an Rattle item does not conform. Defect noticed by average customer.	3
Very Minor	Fit and Finish/Squeak and Rattle item does not conform. Defect noticed by discriminating customer.	2
None	No Effect	1

14. CLASSIFICATION

This column may be used to classify any special product characteristics (e.g., critical, key, major, significant) for components, subsystems, or systems that may require additional process controls.

Any item deemed to require special process controls should be identified on the Design FMEA form with the appropriate character or symbol in the Classification column and should be addressed in the Recommended actions column.

Each item identified above in the Design FMEA should have the special process controls identified in the Process FMEA.

15. POTENTIAL CAUSE(S)/ MECHANISM(S) OF FAILURE

Potential Cause of Failure is defined as an indication of a design weakness, the consequence of which is the failure mode.

List, to the extent possible, every conceivable failure cause and/or failure mechanism for each failure mode. The cause/mechanism should be listed as concisely and completely as possible so that remedial efforts can be aimed at pertinent causes.

Typical failure causes may include, but are not limited to:

Incorrect Material Specified
Inadequate Design Life Assumption
Over-stressing
Insufficient Lubrication Capability
Inadequate Maintenance Instructions
Poor Environment Protection
Incorrect Algorithm

Typical failure mechanisms may include, but are not limited to:

Yield	Creep
Fatigue	Wear
Material Instability	Corrosion

16. OCCURRENCE (O)

Occurrence is the likelihood that specific cause/mechanism (listed in the previous column) will occur. The likelihood of occurrence ranking number has a meaning rather than a value. Removing or controlling one or more of the causes/mechanisms of the failure mode through a design change is the only way a reduction in the occurrence ranking can be effected.

Estimate the likelihood of occurrence of potential failure cause/mechanism on a "1" to "10" scale. In determining this estimate, questions such as the following should be considered:

- What is the service history/field experience with similar components or subsystems ?
- Is component carryover or similar to a previous level component or subsystem ?
- How significant are changes from a previous level component or subsystem ?
- Is component radically different from a previous level component ?
- Is component completely new ?
- Has the component application changed ?
- What are the environmental changes ?
- Has an engineering analysis been used to estimate the expected comparable occurrence rate for the application ?

A consistent occurrence ranking system should be used to ensure continuity. The "Design Life Possible Failure Rates" are based on the number of failures which are anticipated during the design life of the component, subsystem, or system. The occurrence ranking number is related to the rating scale and does not reflect the actual likelihood of occurrence.

Suggested Evaluation Criteria:
(The team should agree on an evaluation criteria system, which is consistent, even if modified for individual product analysis).

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 is unlikely	£ 1 in 1,500,000	1

17. CURRENT DESIGN CONTROLS

List the prevention, design validation/verification (DV), or other activities which will assure the design adequacy for the failure mode and/or cause/mechanism under consideration. Current controls (e.g., road testing, design reviews, fail/safe (pressure relief valve), mathematical studies, rig/lab testing, feasibility reviews, prototype tests, fleet testing) are those that have been or are being used with the same or similar designs.

There are three types of Design Controls/features to consider; those that : (1) Prevent the cause/mechanism or failure mode/effect from occurring, or reduce their rate of occurrence, (2) detect the cause/mechanism and lead to corrective action, and (3) detect the failure mode.

The preferred approach is to first use type (1) controls if possible; second, use the type (2) controls; and third, use the type (3) controls. The initial occurrence rankings will be affected by the type (1) controls provided they are integrated as part of the design intent. The initial detection rankings will be based upon the type (2) or type (3) current controls, provided the prototypes and models being used are representative of design intent.

18. DETECTION (D)

Detection is an assessment of the ability of the proposed type (2) current design controls, listed in column 16, to detect a potential cause/mechanism (design weakness), or the ability of the proposed type (3) current design controls to detect the subsequent failure mode, before the component, subsystem, or system is released for production. In order to achieve a lower ranking, generally the planned design control (e.g., preventative, validation, and/or verification activities) has to be improved.

Suggested Evaluation Criteria:
(The team should agree on an evaluation criteria and ranking system, which is consistent, even if modified for individual product analysis).

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

19. RISK PRIORITY NUMBER (RPN)

The Risk Priority Number is the product of the Severity (S), Occurrence (O), and Detection (D) ranking

$$RPN = (S) \times (O) \times (D)$$

The Risk Priority Number, as the product S x O x D, is a measure of design risk. This value should be used to rank order the concerns in the design (e.g., in Pareto fashion). The RPN will be between "1" and "1,000". For higher RPN's the team must undertake efforts to reduce this calculated risk through corrective action(s). In general practice, regardless of the resultant RPN, special attention should be given when severity is high.

20. RECOMMENDED ACTION(S)

When the failure modes have been rank ordered by RPN, corrective action should be first directed at the highest ranked concerns and critical items. The intent of any recommended action is to reduce any one or all of the occurrence, severity, and/or detection rankings. An increase in design validation/verification action will result in a reduction in the detection ranking only. A reduction in the occurrence ranking can be effected only by removing or controlling one or more of the causes/mechanisms of the failure mode through a design revision. Only a design revision can bring about a reduction in the severity ranking. Actions such as the following should be considered, but are not limited to:

- Design of Experiments (particularly when multiple or interactive causes are present).
- Revised Test Plan.
- Revised Design.
- Revised Material Specification.

If no actions are recommended for a specific cause, indicate this by entering a "NONE" in this column.

21. RESPONSIBILITY (FOR THE RECOMMENDED ACTION)

Enter the Organization and individual responsible for the recommended action and the target completion date.

22. ACTION TAKEN

After an action has been implemented, enter a brief description of the actual action and effective date.

23. RESULTING RPN

After the corrective actions have been identified, estimate and record the resulting severity, occurrence, and detection rankings. Calculate and record the resulting RPN. If no actions are taken, leave the "Resulting RPN" and related ranking columns blank.

All Resulting RPN(s) should be reviewed and if further action is considered necessary, repeat steps 19 through 22.

FOLLOW-UP

The design responsible engineer is responsible for assuring that all actions recommended have been implemented or adequately addressed. The FMEA is a living document and should always reflect the latest design level, as well as the latest relevant action, including those occurring after start of production.

The design responsible engineer has several means of assuring that concerns are identified and that recommended actions are implemented. They include, but are not limited to the following:

- Assuring design requirements are achieved.
- Review of engineering drawings and specifications.
- Confirmation of incorporation to assembly/manufacturing documentation.
  Review of Process FMEAs and Control Plans.

4.3 Process Failure Mode and Effects Analysis

4.3.1 Purpose

To ensure manufacturing processes are developed right just in time and the effective utilization of resource is achieved prior to the start of production.

4.3.2 Output

A matrix which is intended to:

- Focus attention on and evaluate the potential failure modes and causes associated with a process design.

4.3.3 Benefits

- Significant savings by changing the process at an early stage of the Program Management process.
- Reduction in undesirable, unplanned effects due to last minute changes.

4.3.4 Shortcomings

- Difficult to identify combinations of causes which trigger a failure.
- Ineffective if scoring of severity occurrence and detection is not based on reality.

4.3.5 Introduction to Process F.M.E.A.

Every product / process should be reviewed to identify how it can fail, why it might fail, what is the effect of the failure, where the failure can occur, when the failure may occur and how the process can be modified t avoid failure. Lessons learnt from previous F.M.E.A.'s and customer plant concern, recalls, campaigns, warranty etc. must be used and addressed in the current process DFMEA.

The attached Pro-forma and guideline should be used to construct the BFMEA and can also be found in the Program Management Guideline PMG

POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(PROCESS FMEA)

Customer _____ (1) FMEA Number _____ (2)

Item _____ (3) Page _____ of _____

Model Year(s) Vehicle(s) _____ (6) Process Responsibility _____ (4) Prepared by _____ (5)

Core Team _____ (9) Key Date _____ (7) FMEA Date (Orig.) _____ (Rev.) _____ (8)

Process Function / Requirements (10)	Potential Failure Mode (11)	Potential Effects(s) of Failure (12)	Sev (13)	Class (14)	Potential Cause(s)/ Mechanism(s) of failure (15)	Occur (16)	Current Process Controls (17)	Detec (18)	R.P.N. (19)	Recommended Action(s) (20)	Responsibility & Target Completion Date (21)	Action Results (23)				
												Action Taken (22)	Sev	Occ	Det	R.P.N.

PROCESS FMEA

DEVELOPMENT OF A PROCESS FMEA

A Process FMEA should begin with a flow chart of the general process. This flow chart should identify the product/process characteristics associated with each operation. Identification of some product effects from the corresponding Design FMEA should be included, if available. Copies of the flow chart used in FMEA preparation should accompany the FMEA.

1.	**CUSTOMER**	Enter the customer to which the part is to be manufactured for.
2.	**FMEA NUMBER**	Enter the FMEA document number, which may be used for tracking.
3.	**ITEM**	Enter the name and number of the system, subsystem or component, for which the process is being analysed.
4.	**PROCESS RESPONSIBILITY**	Enter the department and group with process responsibility. Also include the supplier name if known.
5.	**PREPARED BY**	Enter the name, telephone number and company of the engineer responsible for preparing the FMEA.
6.	**MODEL YEAR(S)/ VEHICLE(S)**	Enter the intended model year(s) and vehicle line(s) that will utilize and/or be affected by the design/process being analysed (if known).
7.	**KEY DATE**	Enter the initial FMEA due date, which should not exceed the scheduled start of production date.
8.	**FMEA DATE**	Enter the date the original FMEA was compiled, and the latest revision date.
9.	**CORE TEAM**	List the names of the responsible individuals and departments which have the authority to identify and/or perform tasks. (It is recommended that all team members names, departments, telephone numbers, addresses, etc. be included on a distribution list).

10. PROCESS FUNCTION/ REQUIREMENTS

Enter a simple description of the process or operation being analysed (e.g., extrusion, mixing, cut to length, finishing, moulding). Indicate as concisely as possible the purpose of the process or operation being analysed. Where the process involves numerous operations (e.g. assembling) with different potential modes of failure, it may be desirable to list the operations as separate processes.

11. POTENTIAL FAILURE MODE

Potential Failure Mode is defined as the manner in which process could potentially fail to meet the process requirements and/or design intent. It is a description of the non-conformance at that specific operation. It can be a cause associated with a potential failure mode in a subsequent (downstream) operation or an effect associated with a potential failure in a previous (upstream) operation. However, in preparation of the FMEA, the assumption should be made that the incoming part(s)/material(s) are correct.

List each potential failure mode for the particular operation in terms of a component, subsystem, system or process characteristic. The assumption is made that the failure could occur, but may mot necessarily occur . The process engineer/team should be able to pose and answer the following questions:-

- "How can the process/part fail to meet specifications ?"
- "Regardless of engineering specifications, what would a customer (end user, subsequent operations, or service) consider objectionable ?"

A comparison of similar processes and a review of customer (end user and subsequent operation) claims relating to similar components is a recommended starting point. In addition a knowledge of the purpose of the design is necessary. Typical failure modes could be but are not limited to:

Uncured	Cracked	Split
Sticking	Deformed	Incorrectly formed
Burred	Dirty	
Handling Damage	Improper Set-up	Tool Worn

12. POTENTIAL EFFECT(S) OF FAILURE

Potential Effects of Failure are defined as the effects of the failure mode on the customer(s). The customer(s) in this context could be the next operation, subsequent operations or locations, the dealer, and/or the vehicle owner. Each must be considered when assessing the potential effect of the failure.

Describe the effects of the failure in terms of what the customer(s) might notice or experience. For the End User, the effects should always be stated in terms of product or system performance, such as:

Noise	Rough
Erratic Operation	Excessive Effort Required
Inoperative	Unpleasant Odor
Unstable	Operation Impaired
Draft	Intermittent Operation
Poor Appearance	Vehicle Control Impaired

If the customer is the next operation or subsequent operation(s)/location(s) the effects should be stated in terms of process/operation performance, such as:

Can not fasten	Does not fit
Can not bore/tap	Does not connect
Can not mount	Does not match
Can not face	Damages equipment
Endangers operator	

13. SEVERITY(S)

Severity is an assessment of the seriousness of the effect (listed in the previous column) of the potential failure mode to the customer. Severity applies to the effect only. If the customer affected by a failure mode is the assembly plant or the product user, assessing the severity may lie outside the immediate process engineer's/team's field of experience or knowledge. In these cases, the design FMEA, design engineer, and/or subsequent manufacturing or assembly plant process engineer should be consulted. Severity should be estimated on a "1" to "10" scale.

14. SEVERITY (S) (CONTINUED)

Suggested Evaluation Criteria:
(The team should agree on an evaluation criteria and ranking system, which is consistent, even if modified for individual process analysis).

Effect	Criteria: Severity of Effect	Ranking
Hazardous-without warning	May endanger machine or assembly operator. Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves non-compliance with government regulation. Failure will occur without warning.	10
Hazardous-with warning	May endanger machine or assembly operator. Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation. Failure will occur with warning.	9
Very High	Major disruption to production line. 100% of product may have to be scrapped. Vehicle/item inoperable, loss of primary function. Customer very satisfied.	8
High	Minor disruption to production line. Product may have to be sorted and a portion (less than 100%) scrapped. Vehicle operable, but at a reduced level of performance. Customer dissatisfied.	7
Moderate	Minor disruption to production line. A portion (less than 100%) of the product may have to be scrapped (no sorting). Vehicle/item operable, but some Comfort/Convenience item(s) inoperable. Customers experiences discomfort.	6
Low	Minor disruption to production line. 100% of product may have to be reworked. Vehicle/item operable, but some Comfort/Convenience item(s) operable at reduced level of performance. Customer experiences some dissatisfaction.	5
Very Low	Minor disruption to production line. The product may have to be sorted and a portion (less than 100%) reworked. Fit and Finish/Squeak & Rattle item does not conform. Defect noticed by most customers.	4
Minor	Minor disruption to production line. A portion (less than 100%) of the product may have to be reworked on-line but out-of-station. Fit and Finish/Squeak & Rattle item does not conform. Defect noticed by average customers.	3
Very Minor	Minor disruption to production line. A portion (less than 100%) of the product may have to be reworked on-line but in-station. Fit and Finish/Squeak & Rattle item does not conform. Defect noticed by discriminating customers.	2
None	No Effect	1

14. CLASSIFICATION

This column may be used to classify any special process characteristics (e.g., critical, key, major, significant) for components, subsystems, or systems that may require additional process controls. If a classification is identified in the process FMEA, notify the design responsible engineer since this may affect the engineering documents concerning control item identification.

15. POTENTIAL CAUSE(S)/ MECHANISM(S) OF

Potential Cause of Failure is defined as how the occur, described in terms of something that can be corrected or can be controlled.

List, to the extent possible, every conceivable failure cause assignable to each potential failure mode. If a cause is exclusive to the failure mode, i.e., if correcting the cause has a direct impact on the failure mode, then this portion of the FMEA thought process is completed. Many causes however are not mutually exclusive, and to correct or control the cause, a design of experiments, for example, may be considered to determine which root causes are the major contributors and which can be most easily controlled. The causes should be described so that remedial efforts can be aimed at those causes which are pertinent. Typical failure causes may include, but are not limited to:

Improper preform/postform
Improper cure-temperature, time, pressure
Inaccurate gauging
Improper moulding-temperature time, pressure
Inadequate gating/venting
Inadequate coating
Part missing or mislocated

Only specific errors or malfunctions (e.g., operator fails to install seal) should be listed; ambiguous phrases (e.g., operator error, machine malfunction) should not be used.

16. OCCURRENCE (O)

Occurrence is how frequently the specific failure cause/mechanism is projected to occur (listed in the previous column). The occurrence ranking number has a meaning rather than a value.

Estimate the likelihood of occurrence on a "1" to "10" scale. Only occurrences resulting in the failure mode
should be considered for this ranking; failure detecting measures are not considered here.

The following occurrence ranking system should be used to ensure consistency. The "Possible Failure Rates" are based on the number of failures which are anticipated during the process execution.

If available from a similar process, statistical data should be used to determine the occurrence ranking. In all other cases, a subjective assessment can be made by utilizing the word descriptions in the left column of the table, along
with any historical data available for similar processes.

For a detailed description of capability/performance analysis, refer to publications such as the ASQC/AIAG Fundamental SPC Reference Manual.

16. OCCURRENCE (O) (Continued)

Suggested Evaluation Criteria:
(The team should agree on an evaluation criteria and ranking system. which is consistent. even if
modified for individual process analysis).

Probability of Failure	Possible Failure Rates	Cpk	Ranking
Very High: Failure is almost inevitable	≤ 1 in 2	<0.33	10
	1 in 3	≤0.33	9
High: Generally associated with processes similar to previous processes that have often failed	1 in 8	≤0.51	8
	1 in 20	≤0.67	7
Moderate: Generally associated with processes similar to previous processes which have experienced occasional failures. but not in major proportions	1 in 80	≤0.83	6
	1 in 400	≤1.00	5
	1 in 2.000	≤1.17	4
Low: Isolated failures associated with similar processes	1 in 15.000	≤1.33	3
Very low: Only isolated failures associated with almost identical processes	1 in 150.000	≤1.50	2
Remote: Failure is unlikely. No failures ever associated with almost identical processes	≤ 1 in 1.500,000	≤1.67	1

17. CURRENT DESIGN CONTROLS

Current process Controls are descriptions of the controls that either prevent to the extent possible the failure mode from occurring or detect the failure mode should it occur. These controls can be process controls such as fixture error-proofing or Statistical Process Control (SPC), or can be post-process evaluation. The evaluation may occur at the subject operation or at subsequent operations. There are three types of Process Controls/features to consider; those that:

1. prevent the cause/mechanism or failure mode/effect from occurring, or reduce their rate of occurrence,
2. detect the cause/mechanism and lead to corrective actions, and
3. detect the failure mode.

The preferred approach is to first use type (1) controls if possible; second, use the type (2) controls:

and third, use the type (3) controls. The initial occurrence rankings will be affected by the

17. CURRENT DESIGN CONTROLS (Continued)

type (1) controls provided they are integratedas part of the design intent. The initial detection rankings will be based on the type (2) or type (3) current controls, provided the process being used is representative of process intent.

18. DETECTION (D)

Detection is an assessment of the probability that the proposed type (2) current process controls, listed in column 16, will detect a potential cause/mechanism (process weakness), or the probability that the proposed type (3) process controls will detect the subsequent failure mode, before the part or component leaves the manufacturing operation or assembly location. A "1" to "10" scale is used. Assume the failure has occurred and then assess the capabilities of all "Current Process Controls" to prevent shipment of the part having this failure mode or defect. Do not automatically presume that the detection ranking is low because the occurrence is low (e.g., when Control Charts are used), but do assess the ability of the process controls to detect low frequency failure modes or prevent them from going further in the process.

Random quality checks are unlikely to detect the existence of an isolated defect and should not influence the detection ranking. Sampling done on a statistical basis is a valid detection control.

Suggested Evaluation Criteria:
(The team should agree on an evaluation criteria and ranking system. which is consistent, even if modified for individual process analysis).

Detection	Criteria: Likelihood the Existence of a Defect will be Detected by Process Controls Before Next or Subsequent Process, or Before Part or Component Leaves the Manufacturing or Assembly Location	Ranking
Almost Impossible	No known control(s) available to detect failure mode.	10
Very Remote	Very remote likelihood current control(s) will detect failure mode.	9
Remote	Remote likelihood current control(s) will detect failure mode.	8
Very Low	Very low likelihood current control(s) will detect failure mode.	7
Low	Low likelihood current control(s) will detect failure mode.	6
Moderate	Moderate likelihood current control(s) will detect failure mode.	5
Moderately High	Moderately high likelihood current control(s) will detect failure mode.	4
High	High likelihood current control(s) will detect failure mode.	3
Very High	Very high likelihood current control(s) will detect failure mode.	2
Almost Certain	Design Control(s) almost certain to detect failure mode. Reliable detection controls are known with similar processes.	1

19. RISK PRIORITY NUMBER (RPN)

The Risk Priority Number is the product of the Severity (S), Occurrence (O), and Detection (D) rankings.
RPN = (S) x (O) x (D)

This value should rank order the concerns in the process (e.g., in Pareto fashion). The RPN will be between "1" and "1,000". For higher RPN's the team must undertake efforts to reduce this calculated risk through corrective action(s). In general practice, regardless of the resultant RPN, special attention should be given when severity is high.

20. RECOMMENDED ACTION(S)

When the failure modes have been rank ordered by RPN, corrective action should be first directed at the highest ranked concerns and critical items. If for example, the causes are not fully understood, a recommended action might be determined by a statistical designed experiment (DOE). The intent of any recommended action is to reduce the severity, occurrence, and/or detection rankings. If no actions are recommended for a specific cause, then indicate this by

entering a "NONE" in this column.

In all cases where the effect of an identified potential failure mode could be a hazard to manufacturing/assembly personnel, corrective actions should be taken to prevent the failure mode by eliminating or controlling the cause(s), or appropriate operator protection should be specified.

The need for taking specific, positive corrective actions with quantifiable benefits, recommending actions to other activities and following-up all recommendations cannot be overemphasized. A thoroughly thought out well developed Process FMEA will be of limited value without positive and effective corrective actions. It is the responsibility of all affected activities to implement effective follow-up programs to address all recommendations.

Actions such as the following should be considered:

- To reduce the probability of occurrence, process and/or design revisions are required. An action-oriented study of the process using statistical methods could be implemented with an ongoing feedback of information to the appropriate operations for continuous improvement and defect prevention.
- Only a design and/or process revision can bring about a reduction in the severity ranking.
- To increase the probability of detection, process and/or design revisions are required. Generally, improving detection controls is costly and ineffective for quality improvements. Increasing quality controls inspection frequency is not positive corrective action and should only be utilized as a temporary measure, permanent corrective

action is required. In some cases, a design change to a specific part may be required to assist in the detection. Changes to the current control system may be implemented to increase this probability. Emphasis must, however, be placed on preventing defects (i.e., reducing the occurrence) rather than detecting them. An example would be the use of Statistical Process Control and process improvement rather than random quality checks or associated inspection.

21. RESPONSIBILITY (FOR THE RECOMMENDED ACTION)

Enter the Organization and individual responsible for the recommended action, and the target completion date.

22. ACTIONS TAKEN

After an action has been implemented, enter a brief description of the action and effective date.

23. RESULTING RPN

After corrective actions have been identified, estimate and record the resulting occurrence, severity, and detection rankings. Calculate and record the resulting RPN. If no actions are taken, leave the "Resulting RPN" and related ranking columns blank.

All Resulting RPN(s) should be reviewed and if further action is considered necessary, repeat steps 19 through 22.

FOLLOW-UP

The process responsible engineer is responsible for assuring that all actions recommended have been implemented or adequately addressed. The FMEA is a living document and should always reflect the latest design level, as well as the latest relevant actions, including those occurring after start of production with a closed loop into the Concern Management System.