

Availability:
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Revision	Description of Change
B to C	Note added to Severity section giving guidance on late deliveries. Minor change made to Classification section to stay current with changes to GS-0004. Minor changes made to Detection table to better clarify control methods.

Changes in relation to previous issue are written with red, alternatively for figures and tables with a red frame around.

Sauer-Danfoss Global Standard

GS 0006

Potential
Failure Mode and Effect Analysis
of Processes
(Process FMEA)

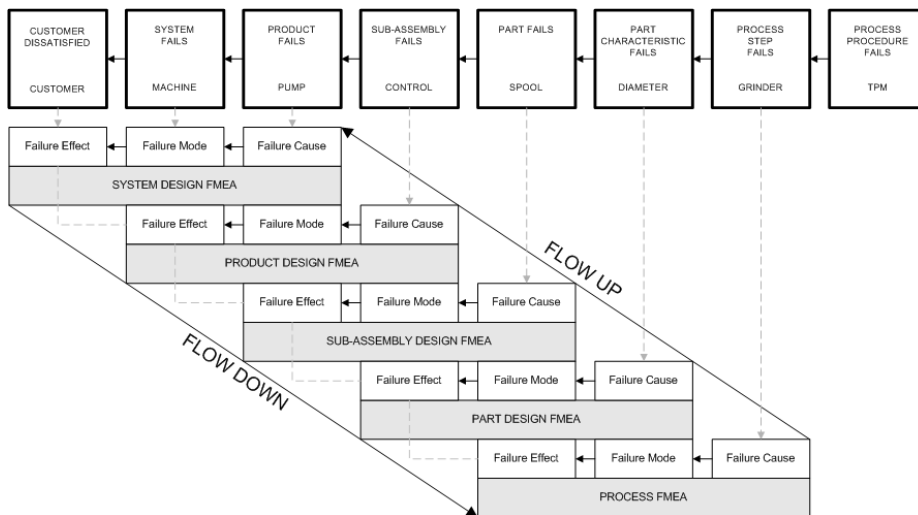
Process FMEA introduction

A Process Potential FMEA is an analytical technique used by a Manufacturing or Assembly-Responsible - Engineer and team as a means to ensure that, to the extent possible, potential failure modes and their associated causes and mechanisms have been considered and addressed. In its most rigorous form, an FMEA is a summary of the team's thoughts (including an analysis of items that could go wrong based on experience) as a process is developed. This systematic approach parallels and formalizes the mental discipline that an engineer normally goes through in any manufacturing planning process.

The Process Potential FMEA:

- Identifies the process functions and requirements
- Identifies potential product and process-related failure modes,
- Assesses the effects of the potential failures on the customer,
- Identifies the potential manufacturing or assembly process causes and identifies process variables on which to focus controls for occurrence reduction or detection of the failure conditions,
- Identifies process variables on which to focus process controls,
- Develops a ranked list of potential failure modes, thus establishing a priority system for preventive/corrective action considerations, and,
- Documents the results of the manufacturing or assembly process.

The figure illustrates the difference and the connection of Process FMEA, Design FMEA and System FMEA.



Customer defined

The definition of "Customer" for a Process FMEA should normally be the "End User." However, the customer can also be a subsequent or downstream manufacturing or assembly operation, a service operation, or government regulations.

Team effort

During the initial development of the Process FMEA, the responsible engineer is expected to directly and actively involve representatives from all affected areas.

These areas should include but are not limited to design, assembly, manufacturing, materials, quality, service, and suppliers, as well as the area responsible for the next assembly.

The Process FMEA should be a catalyst to stimulate the interchange of ideas between the areas affected and thus promote a team approach.

Unless the responsible engineer is experienced with FMEA and team facilitation, it is helpful to have an experienced FMEA facilitator assist the team in its activities.

The Process FMEA is a living document and should be initiated:

- Before or at the feasibility stage,
- Prior to tooling for production, and
- Taking into account all manufacturing operations, from individual components to assemblies.

Early review and analysis of new or revised processes is promoted to anticipate, resolve, or monitor potential process concerns during the manufacturing planning stages of a new model or component program.

The process FMEA assumes the product as designed will meet the design intent.

Potential failure modes that can occur because of a design weakness may be included in a Process FMEA.

Their effect and avoidance is covered by the Design FMEA.

The Process FMEA does not rely on product design changes to overcome weaknesses in the process.

However, it does take into consideration the design characteristics of a product relative to the planned manufacturing or assembly process to assure that, to the extent possible, the resultant product meets customer needs and expectations.

Development of a Process FMEA

The process-responsible engineer has at his or her disposal a number of documents that will be useful in preparing the Process FMEA.

The FMEA begins by developing a list of what the process is expected to do and what it is expected not to do, i.e. the process intent.

The Process FMEA should begin with a flow chart of the general process (example in Appendix A).

This flow chart should identify the product or process characteristics associated with each operation. Identification of some product effects from the corresponding Design FMEA, should be included, if available. A form that may be useful in doing this is included as Appendix B.

Copies of the flow chart used in FMEA preparation should accompany the FMEA.

In order to facilitate documentation of the analysis of potential failures and their consequences, a process FMEA form has been developed and is in Appendix C and D.

The numbers refer to the following text.

- 1. Process FMEA number**
Enter the FMEA document number, which may be used for tracking.
- 2. Name and description**
Enter the name and description of the process being analyzed, including the machine number and description.
- 3. Process Responsibility**
Enter the OEM, department, and group. Also include the supplier name if known.
- 4. Prepared By**
Enter the name, telephone number, and company of the engineer responsible for preparing the FMEA.
- 5. Key Date**
Enter the initial FMEA due date, which should not exceed the scheduled start of production date. **Note:** In the case of a supplier, the initial FMEA due date should not exceed the customer required Production Part Approval Process (PPAP) submission date.
- 6. FMEA Date**
Enter the date the original FMEA was compiled and the latest revision date.
- 7. Core team**
List the names of the responsible individuals and departments that have the authority to identify and / or perform tasks. (It is recommended that each team member's name, department, telephone number, address, etc., be included on a distribution list.)
- 8. Process operational element**
Enter a simple description of the process or operation being analyzed (e.g. turning, drilling, tapping, welding, assembling).
In addition, it is recommended to record the associated process/operation number for the step being analyzed. The team should review applicable performance, material, process, environmental, and safety standards.
- 9. Process purpose**
Indicate as concisely as possible the purpose of the process or operation being analyzed, including information about the design (metrics, measurables) of the system, subsystem, or component. 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 elements.

10. Potential Failure Mode

Potential failure mode is defined as the manner in which the process could potentially fail to meet the process requirements and/or design intent as described in the process function/requirements column.

It is a description of the nonconformance 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 preparing the FMEA, assume that the incoming part(s) / material(s) are correct. Exceptions can be made by the FMEA team where historical data indicate deficiencies in incoming part quality.

List each potential failure mode for the particular operation in terms of a component, subsystem, system, or process characteristic.

Assume that the failure could occur but may not necessarily occur.

The process engineer/team should be able to pose and answer the following questions:

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

Start by comparing similar processes and reviewing customer (end user and subsequent operation) claims relating to similar components.

In addition, knowledge of the design intent is necessary.

Typical failure modes could be but are not limited to:

Bent	Burred	Hole off-location
Cracked	Hole too shallow	Hole missing
Handling damage	Dirty	Hole too deep
Surface too rough	Deformed	Surface too smooth
Open circuited	Short circuited	Mis-labeled

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

11. Failure number

For easy identification and recognition of failure modes, each row should be identified by its own current number.

12. Potential Effect(s) of Failure

Potential effects of failure are defined as the effects of the failure mode on the customer(s). 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 failure mode could impact safety or cause noncompliance to regulations.

The customer(s) in this context could be the next operation, subsequent operations or locations, the dealer, and/or the product/system owner or user.

Each must be considered when assessing the potential effect of a failure.

Process FMEA

For the end user, the effects should always be stated in terms of product or system performance, such as:

Noise	Erratic operation	Effort
Unpleasant odor	Operation impaired	Intermittent operation
Leaks	Rework / Repairs	Scrap
Rough	Excessive	Inoperative
Unstable	Draft	Poor appearance
Product control impaired		Customer dissatisfaction

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

Cannot fasten	Does not fit
Cannot bore/tap	Does not connect
Cannot mount	Does not match
Cannot face	Causes excessive tool wear
Damages equipment	Endangers operator

13. Severity (S)

Severity is the rank associated with the most serious effect for a given failure mode.

Severity is a relative ranking within the scope of the individual FMEA.

A reduction in severity ranking index can be effected through a design change to system, subsystem or component, or a redesign of the process.

If the customer affected by a failure mode is the manufacturing or 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.

See the Severity Evaluation Criteria in the table on next page.

NOTE: For issues of product not delivered to customer on time (either by manufacturer or distributor), choose the ranking that fits the severity of effect (Customer effect). Typically ranked 6 or 7 depending on the level of customer dissatisfaction.

Severity evaluation criteria

Effect	Criteria: severity of Effect This ranking results when a potential failure mode results in a final customer and/or a manufacturing/ assembly plant defect. The final customer should always be considered first. If both occur, use the higher of the two severities. (Customer Effect)	Criteria: severity of Effect This ranking results when a potential failure mode results In a final customer and/or a manufacturing/ assembly plant defect. The final customer should always be considered first. If both occur, use the higher of the two severities. (Manufacturing/Assembly Effect)	Ranking
Hazardous without warning	Very high severity ranking when a potential failure mode affects safe product operation and/or involves non-compliance with government regulation - without warning.	Or may endanger operator (machine or assembly) - without warning.	10
Hazardous with warning	Very high severity ranking when a potential failure mode affects safe product operation and/or involves non-compliance with government regulation - with warning.	Or may endanger operator (machine or assembly) - with warning.	9
Very high	Product/item inoperable (loss of primary function).	Or 100% of product may have to be scrapped, or product/item repaired in repair department with a repair time greater than one hour.	8
High	Product/item operable but at a reduced level of performance. Customer very dissatisfied.	Or product may have to be sorted and a portion (less the 100%) scrapped, or product/item repaired in a repair department with a repair time between a half-hour and an hour.	7
Moderate	Item/item operable but comfort/convenience item(s) inoperable. Customer dissatisfied.	Or a portion (less than 100%) of the product may have to scrapped with no sorting, or product/item repaired in repair department with a repair time less than a half-hour.	6
Low	Product/item operable but comfort/convenience item(s) operable at a reduced level of performance.	Or 100% of product may have to reworked, or product/item repaired offline but does go to repair department.	5
Very low	Fit and Finish. Item does not conform. Defect noticed by most customers. (Greater than 75%).	Or the product may have to be sorted, with no scrap, and a portion (less100%) reworked.	4
Minor	Fit and Finish. Item does not conform. Defect noticed by 50% of customers.	Or a portion (less than 100%) of the product may have to be reworked, with no scrap, on-line but out-of-station.	3
Very Minor	Fit and Finish. Item does not conform. Defect noticed by discriminating customers (less than 25%).	Or a portion (less than 100%) of the product may have to be reworked, with no scrap, on-line but in-station.	2
None	No discernible effect.	Or slight inconvenience to operation or operator, or no effect.	1

Suggested Evaluation Criteria

The team should agree on an evaluation criteria and ranking system that is consistent, even if modified for individual process analysis. (See Severity Table)

Severity should be estimated using this Table as a guideline:

NOTE: It is not recommended to modify criteria for ranking values of 9 and 10.

Failure modes with a rank of severity 1 should not be analyzed further.

14. Classification

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

This column may also be used to highlight high priority failure modes for engineering assessment.

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.

Special product or process characteristic symbols and their usage are directed by **GS-0004, Identification and Documentation of Special Characteristics**, and are not standardized in this document.

15. Potential Cause(s) or Mechanism(s) of Failure

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

List, to the extent possible, every 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 relevant.

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

- | | |
|---|----------------------------|
| Improper torque - over, under | Part missing or mislocated |
| Improper weld - current, time, pressure | Worn locator |
| Inaccurate gauging | Worn tool |
| Improper heat treat - time, temperature | Chip on locator |
| Inadequate gating / venting | Broken tool |
| Inadequate or no lubrication | Improper machine setup |
| Improper programming | |

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

16. Occurrence (O)

Occurrence is the likelihood that a specific cause/mechanism of failure will occur.

Preventing or controlling the causes/mechanisms of failure through a design or process 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.

A consistent occurrence ranking system should be used to ensure continuity.

The "Likely Failure Rates" are based on the number of failures that are anticipated during the process execution. If statistical data are available from a similar process, these data could with caution be used to determine the occurrence ranking. If internal scrap rates or first pass yield rates are available, these rates can be compared to the DPM column. Do not equate external customer reject rates to the DPM column to estimate the occurrence rating; this will result in an underestimate of the occurrence rating. In all other cases, a subjective assessment can be made by using the word descriptions in the left column of the table, along with any historical data available for similar processes.

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

Occurrence should be estimated using the table as a guideline:

Note: The ranking value of 1 is reserved for "Remote - failure is unlikely".

Occurrence Evaluation Criteria

Probability	Likely Failure Rates	Ranking	PPM
Very High: Persistent Failures	≥100 per thousand pieces	10	≥ 100,000
	50 per thousand pieces	9	50,000
High: Frequent Failures	20 per thousand pieces	8	20,000
	10 per thousand pieces	7	10,000
Moderate: Occasional Failures	5 per thousand pieces	6	5,000
	2 per thousand pieces	5	2,000
	1 per thousand pieces	4	1,000
Low: Relatively Few Failures	0.5 per thousand pieces	3	500
	0.1 per thousand pieces	2	100
Remote: Failure is unlikely	≤ 0.01 per thousand pieces	1	≤ 10

17. Current Process Controls

Current Process Controls are descriptions of the controls that either prevent - to the extent possible - the failure mode or cause/mechanism of failure from occurring, or detect the failure mode or cause/mechanism of failure should it occur.

These controls can be process controls such as error or mistake proofing, statistical process control (SPC) or can be post-process evaluation.

The evaluation may occur at the subject operation or at subsequent operations.

There are two types of Process Controls to consider:

- Prevention: Prevent the cause/mechanism of failure or the failure mode from occurring, or reduce their rate or occurrence.
- Detection: Detect the cause/mechanism of failure or the failure mode, and lead to corrective action(s).

The preferred approach is to first use prevention controls, if possible.

The initial occurrence rankings will be affected by the prevention controls provided they are integrated as part of the process intent.

The initial rankings for detection will be based on process controls that either detect the cause/mechanism of failure, or detect the failure mode.

The process FMEA form in this standard has two columns for the process controls (i.e. separate columns for Prevention Controls and Detection Controls) to assist the team in clearly distinguishing between these two types of process controls (see Appendix C). This allows for a quick visual determination that both types of process controls have been considered. Use of this two column form is the preferred approach.

If a one-column (for process controls) form is used (see Appendix D), then the following prefixes should be used.

For prevention controls, place a 'P' before each prevention control listed.

For detection controls, place a 'D' before each detection control listed.

Once the process controls have been identified, review all prevention controls to determine if any occurrence rankings need to be revised.

18. Detection (D)

Detection is the rank associated with the best detection control listed in the process control column. Detection is a relative ranking, within the scope of the individual FMEA. In order to achieve a lower ranking, generally the planned process control has to be improved.

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.

The team should agree on an evaluation criteria and ranking system that is consistent, even if modified for individual product analysis. (See Detection Table)

Detection should be estimated using the Table as a guideline.

Note: The ranking value of 1 is reserved for "Certain to Detect".

Process FMEA

Detection Evaluation Criteria

Detection	Criteria	A	B	C	Suggested Range of Detection Methods	Ranking
Almost Impossible	Absolute certainty of non-detection.			X	No current process control. Cannot detect or is not checked.	10
Very Remote	Controls will probably not detect.			X	Control is achieved with indirect or random checks only.	9
Remote	Controls have poor chance of detection.			X	Control is achieved with visual inspection.	8
Very Low	Controls have poor chance of detection.			X	Control is achieved with double visual inspection for attributes; or first- and last-piece dimensional verification; or sample-based verification to blue print limits (for example, 1 of 10 pieces checked to print limits).	7
Low	Controls may detect.		X		Control is achieved with statistical methods, such as statistical process control (SPC – including X-bar and R charts), target area control (TAC), or pre-control (PC). Or sample-based verification to reduced limits (for example, all samples to fall within 50% of tolerance, 75% of tolerance, etc.)	6
Moderate	Controls may detect.		X		Control is achieved with statistical methods, such as SPC, TAC, or PC. The control plan also calls for 100% inspection of product back to last in-control sample when out-of-control sample is experienced.	5
Moderately High	Controls have a good chance to detect.		X		Control is achieved with statistical methods, such as SPC, TAC, or PC. The control plan also calls for 100% inspection of product back to last in-control sample when out-of-control sample is experienced. Frequency of sampling ensures that multiple verifications of process control are performed prior to product shipments	4
High	Controls have a good chance to detect.		X		Control is based on variable gauging after parts have left the station, or GO/NO GO gauging performed on 100% of the parts after parts have left the station.	3
Very high	Controls almost certain to detect.	X	X		All parts must be manually loaded into test fixture or gauge with automatic stop feature. Cannot accept discrepant part.	2
Very High	Controls certain to detect.	X	X		All parts are either: a) manually loaded into test fixture or gauge with automatic stop feature and a subsequent operation which verifies passing of all tests prior to pack; or b) automatically checked (variable or go/no-go gauging) with automatic stop feature. Cannot pass discrepant part.	1

Inspection types: A: Error-proofed
 B: Gauging
 C: Manual Inspection

19. Risk Priority Number (RPN)

The risk priority number is the product of the severity (S), occurrence (O), and detection (D) rankings.

$$(S) \times (O) \times (D) = \text{RPN}$$

Within the scope of the individual FMEA, this value (between 1 and 1000) can be used to rank order the concerns in the process.

20. Recommended Action(s)

Engineering assessment for preventive/corrective action should be first directed at high severity, high RPN, and other items designated by the team. A general rule is that an RPN value greater than 100 implies an unacceptable risk and requires action (see next section).

An alternate, but acceptable, approach to this is to use the PFMEA as a continuous improvement tool and address the highest RPN values with actions to reduce risk.

The intent of any recommended action is to reduce rankings in the following order:

Severity, Occurrence, and Detection.

In general practice, when the severity is 9 or 10, special attention must be given to ensure that the risk is addressed through existing design actions/controls or process preventive/corrective action(s), regardless of the RPN.

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

After special attention has been given to severity rankings of 9 or 10, the team then addresses other failure modes, with the intent of reducing severity, then occurrence, and then detection.

Actions such as, but not limited to, 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.
- The preferred method to accomplish a reduction in the detection ranking is the use of error or mistake proofing methods. Generally, improving detection controls is costly and ineffective for quality improvements.

Increasing the frequency of quality controls inspection is not an effective preventive/corrective action and should only be used as a temporary measure since permanent preventive or 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.

Process FMEA

If engineering assessment leads to no recommended actions for a specific failure mode/cause/control combination, indicate this by entering "None" in this column.

After the recommended action has been identified, make a preliminary evaluation of the changes to severity, occurrence and detection and the resulting RPN value.

The purpose is to get an immediate impression of whether the suggested recommended action is adequate, or if further actions have to be implemented.

21. Responsibility for the Recommended Action(s)

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

22. Action(s) Taken

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

23. Action Results

After the preventive or corrective action has 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 related ranking columns blank.

All revised ratings should be reviewed and if further action is considered necessary, repeat the analysis. The focus should always be on continuous improvement.

Follow-Up Actions

The process-responsible engineer is responsible for ensuring 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 the start of production.

The process-responsible engineer has several means of ensuring that concerns are identified and that recommended actions are implemented.

They include, but are not limited to the following:

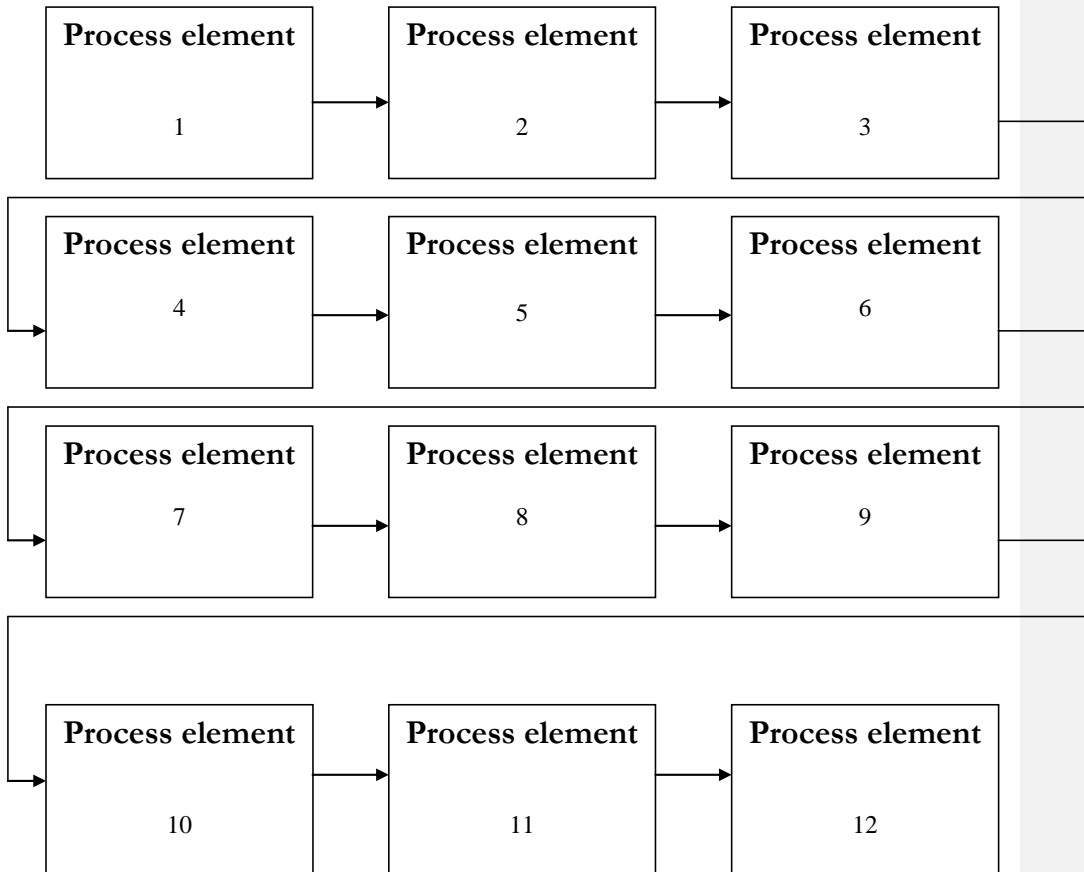
- Ensuring that process/product requirements are achieved,
- Reviewing engineering drawings, process/product specifications, and process flow,
- Confirming the incorporation of changes in assembly/ manufacturing documentation and,
- Reviewing Control Plans and operation instructions.

CHANGE HISTORY:

Date	Old/New Rev.	Description of Change
2007-02-07	A / B	<p>I. Occurrence section and table modified: A. Text added to clarify addition of DPM column to table B. DPM column added to occurrence table C. Text describing occurrence as relative measure removed.</p> <p>II. Detection table modified A. Range of detection methods modified to better match criteria B. Additional detection methods added to clarify ratings for actual practice.</p> <p>III. Text added to 'Recommended Action' section to indicate action should be taken if RPN > 100 or on highest RPN values.</p> <p>IV. An optional form was added to assist with PFMEA creation.</p>
2009-10-05	B / C	<p>Note added to Severity section giving guidance on late deliveries.</p> <p>Minor change made to Classification section to stay current with changes to GS-0004F.</p> <p>Minor changes made to Detection table to better clarify control methods.</p>

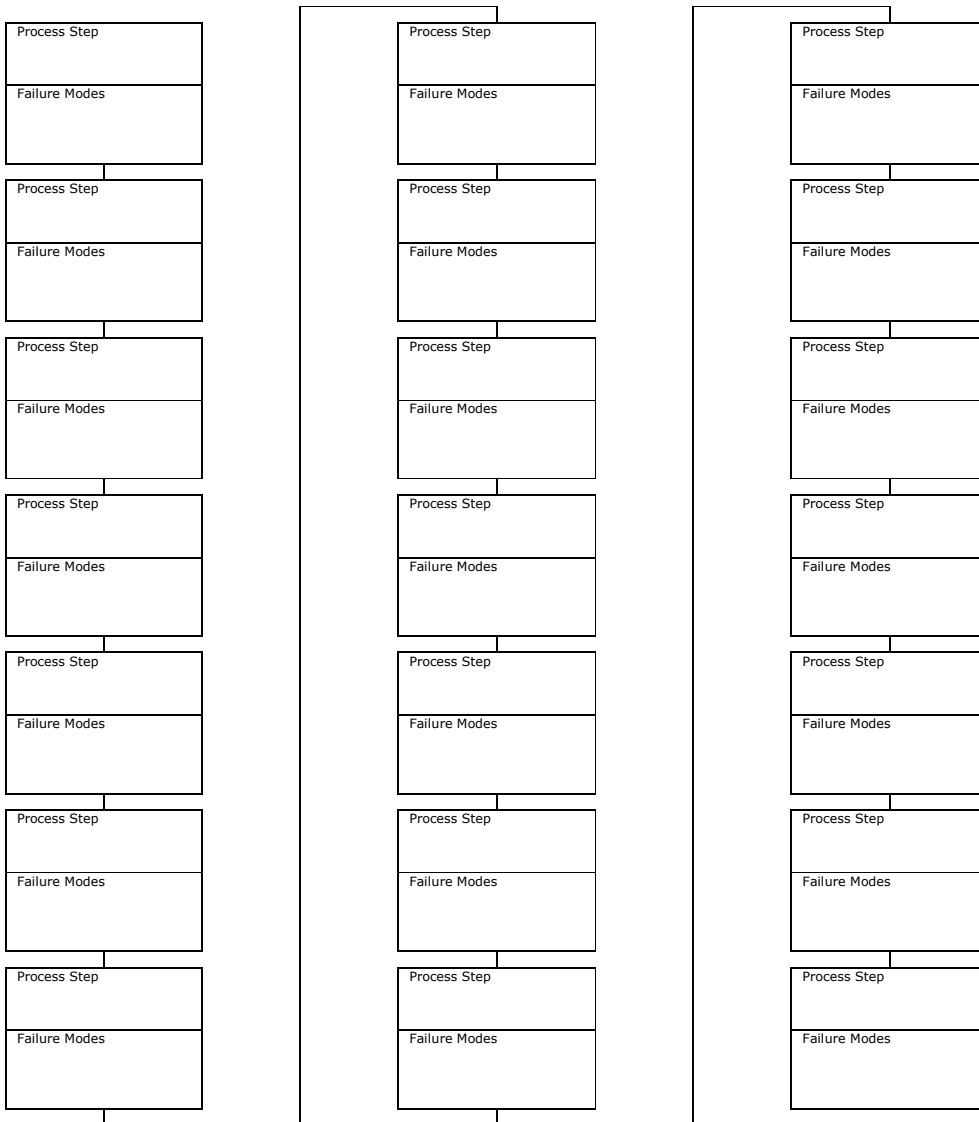
Appendix A

Process Flow Chart



Appendix B

Process Flow Chart with Failure Modes



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