RISK REDUCTION

Quality & Industrial Performance

“Going From Reactive to Proactive”

PURPOSE:

- Reduce the risk of initial quality failures
- *Error proofing* past quality failures
- Ensure that Failure Modes have proper controls (prevention/detection) and work properly
- Identify potential risks which could impact to plant

SCOPE:

- Assembly Area
- Manufacturing Operations
- Shipping / Receiving
- All Operations
- Other Support Functions

RESPONSIBILITY:

- Ownership
  - ✓Engineering Manager
  - ✓Operations Manager
- Contingency Plan for All Situations

Benefits

- Supports continual improvement as expected by ISO/TS16949.
- Allows leadership to allocate limited resources to critical areas.
- Provides a basis for effective error-proofing and problem solving.
- Core tool for APQP and PPAP requirements.
- Provides a Lessons Learned archive.
- Promotes cross-functional teamwork.
- Meets customer expectations for “living documents”.

Risk Reduction, what are we searching for?

Item	Requirement	#Criteria	Criteria requirement
RR1	PFMEA's shall be developed and maintained by cross-functional teams for all manufacturing processes and support functions.	RR11	**PFMEA are available for all part numbers and all operations (including labelling, intermediate storage, transport,...) and developed by cross-functional team**
		RR12	**Failure modes of rework are considered in PFMEA, identified in Process Flow with its reintroduction at or prior of removal point.**
		RR13	**All areas/operations that could be affected by contamination and failure modes related to contamination are Identified and considered in PFMEA.**
		RR14	The generic PFMEA must be updated as a normal PFMEA
		RR15	If supplier is design responsible, DFMEA has to be used to develop the PFMEA.

Criteria of Requirement

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Next Requirement

PFMEA Overview

PFMEA definition

- An analytical technique for each process step that identifies:
  - Ways a process may fail to meet requirements.
  - Consequences to the internal / external customer (**Severity**).
  - Frequency the failure will/could happen (**Occurrence**).
  - Effectiveness of current controls (prevention & **Detection**).
  - Ranking of causes and effects (**Risk Priority Number**).
- A structured procedure for identifying and eliminating process related failure modes.

PFMEA Overview
PFMEA definition

Process Step / Function	Requirement	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Potential Cause(s) of Failure	Current Process: Controls Prevention	Occurrence	Current Process: Controls Detection	Detection	RPN	Recommended Action	Responsibility & Target Completion Date	Action Results: Actions Taken / Completion Date	Severity	Occurrence	Detection	RPN
Op 70: Manual application of wax inside door panel	Cover inner door, lower surfaces with wax to specification thickness	Insufficient wax coverage over specified surface	Allows integrity breach of inner door panel Corroded interior lower door panels	7		Manually inserted spray head not inserted far enough	None	8	Variables check for film thickness Visual check for coverage.	5	280	Add positive depth stop to sprayer	Mfg Engineering by 0X 10 15	Stop added, sprayer checked online	7	2	5	70
												Automate spraying	Mfg Engineering by 0X 12 15	Rejected due to complexity of				
			hardware			Spray head clogged - Viscosity too high - Temperature too low - Pressure too low	Test spray start-up after idle and preve maintenan program to clean heads		check ickne ack ige.				Mf by 0X	pressure			5	35

Process name/ number and purpose ?

Consequences on:

Customer Plant, Ultimate Customer, Govt Regulations

What could go wrong?

Why part reject at Op?

What would be unacceptable to customer

How could part not conform to spec.

How Bad is it?

What are the Cause(s) described in terms of something that can be corrected / controlled.

How Often does it happen?

What Controls are in place to:

Prevent / reduce occurrence of causes

Detect failure mode

How good is this method of finding it?

Actions to reduce Severity/ Occurrence/ Detection ratings?

- Design Change
- Process Changes
- Special Controls
- Changes to Standards, procedures

RISK PRIORITY NUMBER (RPN) = S x O x D

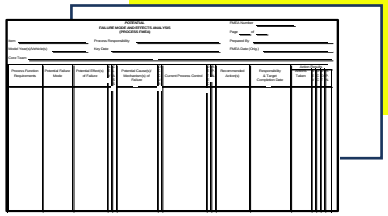
S = Severity O = Occurrence D = Detection

1 = Lowest 1000 = Highest

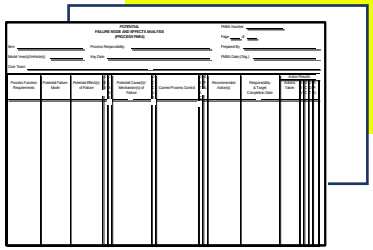
PFMEA Overview

PFMEA concept

Master / Equipment / Similar part PFMEA…

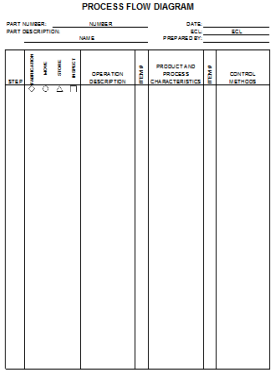


DFMEA



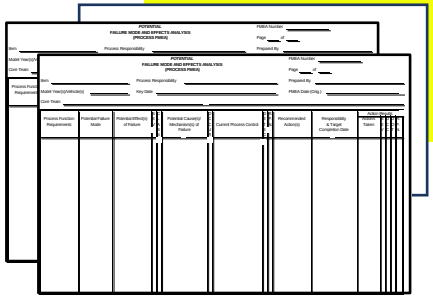
- HIGH RPNs

PROCESS FLOW



- LISTS EACH OPERATION
- KEY CHARACTERISTICS

PFMEA



- POTENTIAL FAILURE MODES
- CURRENT CONTROLS
- ENHANCED CONTROLS FROM RECOMMENDED ACTIONS
- KEY CHARACTERISTICS

PFMEA Overview

- PFMEA's shall be developed and maintained by cross-functional teams.

  During the initial development of the PFMEA, the responsible engineer/team leader is expected to directly and actively involve representatives from affected area which should include but are not limited to:

  - Quality,
  - Assembly (including next assembly),
  - Manufacturing,
  - Design (product, tool),
  - Logistic (material handling),
  - Other supporting departments (Maintenance, Supplier Quality etc.).

  PFMEA team members have to be trained for PFMEA process. Site Leadership should review the need for PFMEA training at least once per year.

PFMEA Overview

- PFMEA's shall take into account all manufacturing operations from individual components to assemblies and include all support processes within plant that can impact the manufacturing and assembly operations:
  - Exist for all product lines / part numbers,
  - Support processes include: receiving, material handling, labelling, shipping, repair, rework, etc.).
- PFMEA's shall:
  - Conform to customer requirement (current AIAG or PSA guidelines),
  - Have accurate Severity/Occurrence/Detection ratings,
  - Be updated on a regular basis (living documents),
  - Be utilized for Continuous Improvement.

PFMEA Overview

- If supplier is design responsible or customer's DFMEA is available, DFMEA is used for development of PFMEA.

- PFMEA assumption is that the product design will meet the design intent. However PFMEA team may identify design opportunities which, if implemented, would eliminate or reduce occurrence of a process failure mode (e.g.: adding a feature to a part eliminates wrong orientation). Such information need to be provided to :
  - responsible design engineer,
  - tooling or fixture design engineer, if applicable.

Auditor hints

Check member of PFMEA team. It has to be cross-functional. Check a team member got PFMEA training.

Evidences that PFMEA prepared for all the P/Ns and all operations even the base was a generic PFMEA (typically missed: labelling, rework, material handling).

Scoring is according to predefined standards: PSA: Q242110_EX_EN / GM: AIAG PFMEA Reference Manual.

Verify content:

- Effects evaluated from both customer and manufacturing point of view.
- Potential cause of failure defined specifically, ambiguous phrases (e.g., operator error or machine malfunction, etc.) should not be used.
- Real preventive actions are listed.

Proactive approach of Risk Reduction, what are we searching for?

Item	Requirement	#Criteria	Criteria requirement
RR2	Proactive approach for reduction of PFMEA highest risk items are implemented.	**RR21**	**Content of PFMEA fields and scoring are defined properly in accordance with customer guideline.** **Neverless if the rules used by supplier is different but defined properly in their own procedure, PSA can accept if all risks are taking account.**
		RR22	**For high severity rankings or high risk items, FMEA team ensures that the risk is addressed through existing design controls or recommended actions.**
		RR23	**Recommended actions are documented into P-FMEA with responsibles and due date.**
		RR24	Pareto highest "RPN" must be implemented to follow the action plans to ensure and control the conformity of process. After each action (highest risk and highest RPN) the reevaluation must be engaged.

Criteria of Requirement

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Prev. Requirement Next Requirement

PFMEA Overview

Content of PFMEA fields are defined properly in accordance with current AIAG or PSA guidelines. Main highlights on different elements:

- **Requirement** are the outputs of each operation/step and relate to the requirements for the product. Provide a description of what should be achieved at each operation/step.
- **Potential Failure Mode** is defined as the manner in which the process could potentially fail to meet the requirement. Basic assumptions:
  - incoming part/material are correct (exception: historical data),
  - basic design of product is correct,
  - failure could occur but may not necessarily occur.
- **Potential Effect** is described in terms of what the customer (it can be internal customer as well) may notice or experience. Following questions raised:
  1. Does the Potential Failure Mode physically prevent downstream processing or cause potential harm to equipment or operator?
  2. What is the potential impact on the End User?
  3. What would happen if an effect was detected prior to reaching the End User?

PFMEA Overview

- **Potential Cause** is defined as an indicator of how the failure could occur and is described in terms of something can be corrected or controlled. Only specific errors or malfunctions should be listed. Ambiguous phrases should not be use like ”operator error”.
- **Current Process Controls** are descriptions of the controls that can either prevent to the extent possible, the cause of failure from occurring or detect the failure mode or cause of failure should it occur.
  - Prevention: eliminate (prevent) the cause of the failure or the failure mode from occurring, or reduce its rate of occurrence,
  - Detection: identify (detect) the cause of failure or the failure mode.
- **Recommended Actions** intent is to reduce rankings in:
  - Severity: only a design or process revision can bring
  - Occurrence: process or design revision may be required. Actions for Preventive Control brings reduction.
  - Detection: preferred method is the use of error proofing.

PFMEA Overview - AIAG scoring guideline

Severity

Effect	Criteria: Severity of Effect on Product (Customer Effect)	Rank	Effect	Criteria: Severity of Effect on Process (Manufacturing/Assembly Effect)
Failure to Meet Safety and/or Regulatory Requirements	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.	10	Failure to Meet Safety and/or Regulatory Requirements	May endanger operator (machine or assembly) without warning.
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.	9		May endanger operator (machine or assembly) with warning.
Loss or Degradation of Primary Function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation).	8	Major Disruption	100% of product may have to be scrapped. Line shutdown or stop ship.
	Degradation of primary function (vehicle operable, but at reduced level of performance).	7	Significant Disruption	A portion of the production run may have to be scrapped. Deviation from primary process including decreased line speed or added manpower.
Loss or Degradation of Secondary Function	Loss of secondary function (vehicle operable, but comfort / convenience functions inoperable).	6	Moderate Disruption	100% of production run may have to be reworked off line and accepted.
	Degradation of secondary function (vehicle operable, but comfort / convenience functions at reduced level of performance).	5		A portion of the production run may have to be reworked off line and accepted.
Annoyance	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by most customers (> 75%).	4	Moderate Disruption	100% of production run may have to be reworked in station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by many customers (50%).	3		A portion of the production run may have to be reworked in-station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by discriminating customers (< 25%).	2	Minor Disruption	Slight inconvenience to process, operation, or operator.
No effect	No discernible effect.	1	No effect	No discernible effect.

PFMEA Overview - AIAG scoring guideline

Occurrence

Likelihood of Failure	Criteria: Occurrence of Cause - PFMEA (Incidents per items/vehicles)	Rank
Very High	≥ 100 per thousand ≥ 1 in 10	10
High	50 per thousand 1 in 20	9
	20 per thousand 1 in 50	8
	10 per thousand 1 in 100	7
Moderate	2 per thousand 1 in 500	6
	.5 per thousand 1 in 2,000	5
	.1 per thousand 1 in 10,000	4
Low	.01 per thousand 1 in 100,000	3
	≤.001 per thousand 1 in 1,000,000	2
Very Low	Failure is eliminated through preventive control.	1

Detection

Opportunity for Detection	Criteria: Likelihood of Detection by Process Control	Rank	Likelihood of Detection
No detection opportunity	No current process control; Cannot detect or is not analyzed.	10	Almost Impossible
Not likely to detect at any stage	Failure Mode and/or Error (Cause) is not easily detected (e.g., random audits).	9	Very Remote
Problem Detection Post Processing	Failure Mode detection post-processing by operator through visual/tactile/audible means.	8	Remote
Problem Detection at Source	Failure Mode detection in-station by operator through visual/tactile/audible means or post-processing through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.).	7	Very Low
Problem Detection Post Processing	Failure Mode detection post-processing by operator through use of variable gauging or in-station by operator through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc).	6	Low
Problem Detection at Source	Failure Mode or Error (Cause) detection in-station by operator through use of variable gauging or by automated controls in-station that will detect discrepant part and notify operator (light, buzzer, etc.). Gauging performed on setup and first-piece check (for set-up causes only).	5	Moderate
Problem Detection Post Processing	Failure Mode detection post-processing by automated controls that will detect discrepant part and lock part to prevent further processing.	4	Moderately High
Problem Detection at Source	Failure Mode detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing.	3	High
Error Detection and/or Problem Prevention	Error (Cause) detection in-station by automated controls that will detect error and prevent discrepant part from being made.	2	Very High
Detection not applicable; Error Prevention	Error (Cause) prevention as a result of fixture design, machine design or part design. Discrepant parts cannot be made because item has been error-proofed by process/product design.	1	Almost Certain

PFMEA Overview - PSA scoring guideline

Severity

End customer criteria	S ratings	Downstream customer criteria
Minimal effect. The customer does not notice it.	1	No effect on the following production operations or in the customer's factory.
Minor effect that the customer may detect, but which only causes a slight problem and no notable deterioration to the overall performances.	2 or 3	Minor effect which the downstream operator or the customer factory may detect but which only causes a slight problem without affecting production flow.
Effect with a preliminary symptom which annoys the customer or puts him ill at ease.	4 or 5	Effect with a preliminary symptom which annoys the downstream operator or the customer factory. Slight disruption to production flow.
Effect without a preliminary symptom (or with preliminary symptom and without solution) which annoys the customer. It antagonises the customer or puts him ill at ease. A deterioration in performances of the sub-assembly are noted. The repair costs are moderate.	6 or 7	Effect without a preliminary symptom which annoys the downstream operator or the customer factory. Moderate disruption to production flow. May cause product rejects or repairs. Moderate process repair costs.
Effect with preliminary symptom which causes major annoyance to the customer and/or high repair costs due to a faulty vehicle or sub-assembly.	8	Effect with a preliminary symptom which causes major annoyance to the downstream operator or the customer factory. Significant disruption to production flow. High product rejects or repairs. High process repair costs.
Effect without preliminary symptom which causes major annoyance to the customer and/or high repair costs due to a faulty vehicle or sub-assembly.	9	Effect without a preliminary symptom which causes major annoyance to the downstream operator or the customer factory. Significant disruption to production flow. High product rejects or repairs. High process repair costs.
Effect involving safety problems or non compliance problems with current regulations.	10	Effect involving safety problems for the downstream operator or in the customer factory. Production process stopped.

Occurence

CRITERIA	O ratings	* Risk of the failure occurring (example)
VERY LOW PROBABILITY. Failure non existent on similar processes.	1 or 2	1/200,000 1/100,000
LOW PROBABILITY. Very few failures on similar processes.	3 or 4	1/20,000 1/10,000
MODERATE PROBABILITY. Failures appeared occasionally on similar processes.	5 or 6	1/5,000 1/2,000
HIGH PROBABILITY. Frequent failures on similar processes.	7 or 8	1/1 000 1/500
VERY HIGH PROBABILITY. It is certain that the failure will occur frequently.	9 or 10	1/200 >1/100

PFMEA Overview – PSA scoring guideline

Detection

CRITERIA	D rating	* Risk of allowing a faulty product to pass (example)
Very low probability of failing to detect the cause of a failure or allowing the failure to pass before the product exits the operation in question. Example: automatic and permanent surveillance of process parameters and 100% of product characteristics (foolproofing, etc).	1 or 2	1/200 000 1/100 000
Low probability of failing to detect the cause of a failure or allowing the failure to pass before the product exits the operation in question. Example: the failure is obvious, some failures escape detection (single inspection by the operator).	3 or 4	1/20 000 1/10 000
Moderate probability of failing to detect the cause of a failure or allowing the failure to pass before the product exits the operation in question. Example: difficult manual / visual inspection.	5 or 6	1/5 000 1/2 000
High probability of failing to detect the cause of a failure or allowing the failure to pass before the product exits the operation in question. Example: the inspection is subjective.	7 or 8	1/1 000 1/500
Very high probability of failing to detect the cause of a failure or allowing the failure to pass before the product exits the operation in question. Example: the point is not inspected or cannot be inspected. The failure and its causes cannot be detected.	9 or 10	1/200 >1/100

Auditor hints

Verify content:

- Effects evaluated from both customer and manufacturing point of view.
- Potential cause of failure defined specifically, ambiguous phrases (e.g., operator error or machine malfunction, etc.) should not be used.
- Real preventive actions are listed.

PFMEA risk reduction process

Suppliers are required to have a formal and documented risk reduction process:

- Proactive RPN Reduction Process - Reducing the risk of potential quality failures (e.g.: reverse PFMEA Process),
- Reactive RPN Reduction Process – reducing the risk of past quality issues.

PFMEA proactive risk reduction process

Upon completion of the PFMEA review:

- Establish and maintain a list of the highest Risk Reduction opportunities based on the PFMEA documents.
- An action plan or equivalent shall be utilized by the cross-functional team to track progress in reducing the RPN ratings.

Risk prioritization

Once Severity, Occurrence and Detection have been defined, PFMEA team must decide if further efforts are needed to reduce the risk.

One approach to assist in action prioritization to use Risk Priority Number (RPN):

RPN = Severity(**S**) x Occurrence (**O**) x Detection (**D**)

PSA's RPN threshold for recommended action is **36**.

Risk prioritization

Besides RPN threshold, focus of the team should be oriented towards failure modes with the highest severity rankings. When the severity is 9 or 10, it is imperative that the team ensure that the risk is addressed through existing design controls or recommended actions.

For failure modes with severities of 8 or below the team should consider causes having the highest occurrence or detection rankings. It is the team's responsibility to look at the information, decide upon the approach and determine how to best prioritize their risk reduction efforts.

An example for prioritization decided by PFMEA team **(Example)**

1. High Severity (9 or 10)
2. High S/D combination
3. High S/O combination
4. High O/D combination

Recommended action

Intent of any recommended action is to reduce rankings in Severity, Orrurrence and Detection. Example approach to reduce these:

- to reduce Severity ranking: only a design or process revision can bring about a reduction in the severity ranking,
- to reduce Occurrence ranking: process and design revisions may be required. A reduction in the occurrence ranking can be effected by removing or controlling one or more of the causes of the failure mode through a product or process design revision,
- to reduce Detection ranking: the preferred method is the use of error/mistake proofing. A redesign of the detection methodology may result in a reduction of the detection ranking.

The name of the individual and organization responsible for completing each recommended action including the target completion date should be entered. The process-responsible engineer/team leader is responsible for ensuring that all actions recommended have been implemented or adequately addressed.

Temporary action

If a risk identified but implementation of recommended action for its reduction requires time, than organization should ensure that risk is under control till action implemented and verified.

As example the following quality tools can be applied:

- *Verification Station* has to double check high risk item,
- Working instruction and training are focus to high risk item,
- *Layered Process Audit* to verify preventive controls are done according to *Standardized Work*
- *Layered Process Audit* to verify current controls performed according to inspection instruction, etc.

Recommended action verification

Site Leadership responsibilities:

- shall support RPN reduction activities and provide necessary resources,
- shall monitor and review the RPN reduction activities regularly,
- shall ensure that formal cross-functional teams are utilized in the preparation and on-going review of PFMEA's.

After the recommended action has been completed, rankings (S/O/D) have to be determined and recorded. Actions alone do not guarantee that the problem was solved thus an appropriate analysis or test should be completed as verification.

If further action is considered necessary, analysis has to be repeated.

The focus is always on continuous improvement.

List of the Highest Risk Reduction Opportunities

(Proactive)

(Example)

No.	OP No.	Function & Failure Mode	RPN Value	Who	Recommended Actions	Completion Date	Revised RPN
1	10	INCORRECT BEARING INSTALLED	490	B. SHAD	SENSOR TO DETECT BEARING TYPE	12/1/2008	112
2	20	INCORRECT OR REVERSED SUBASSEMBLY	126	N. ADAMS	INSTALL LASER STATION	12/31/2008	42
3	50	HOLE MISSING	168	S. BROWN	INSTALL POST ON ASSEMBLY FIXTURE	12/23/2008	42
4	60	INCORRECT LABEL	112	V. WAGNER	IMPLEMENT SCANNER	1/30/2009	21

The number of RPN reduction opportunities on the list is dependent on complexity of parts and process, technology, time, resources, customer feedback and other factors.

Auditor hints

Review risk reduction action plan, evaluate that actions are defined against root cause or improve detection, target dates are kept.

Evaluate that Quality Tools implemented are efficient to keep risk under control.

Review some scorings after recommended action implemented.

Where Severity 9 or 10, detection is low (visual inspection alone is not acceptable).

Periodic review of PFMEA, what are we searching for?

Item	Requirement	#Criteria	Criteria requirement
RR3	PFMEA is reviewed periodically as proactive and reactive activities.	RR31	**PFMEA and or Generic PFMEA are reviewed and updated for each quality issue and corrective action that have been implemented within target completion date.**
		RR32	**PFMEA reviews are based on process capability, process/product changes, etc… which cover:** **- all processes (production, logistics, maintenanace...) and their controls are included,** **- detection ratings are accurate,** **- occurrence ratings are analysed using data (SPC, FTQ, ppm, scrap data, Verification Station results etc.).** **- Results of LPA audits.**
		RR33	**A schedule of reverse PFMEA is implemented and regularly updated by the plant management (timing for review with prioritization of operation and its status /planned-done/).**
		RR34	Lessons Learned which are easily retrievable by all who need the information (e.g. Master FMEA, APQP Program check list reviews) are deployed.

Criteria of Requirement

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Reactive risk reduction process

Risk Reduction through *Error proofing* of past quality issues:

- When corrective actions have been implemented, team shall validate the new Occurrence and Detection rankings and resultant RPN.
- Team shall update PFMEA's with all corrective action measures.
- *Error proofing* shall be verified per the *Error Proofing Verification* process.
- Team shall investigate why planning process did not predict failure mode occurred (5 whys for Predict).

Reactive risk reduction process

(Example)

Example of 5 whys approach

Yes		Was the RPN assigned to the failure mode correct?
Why 1		Why was the RPN incorrect? P1 RPN assigned to this failure mode was incorrect (Specify old RPN and correct RPN)
		Common Answers / Reasons
Why 2	A	Severity ranking was too low (Specify old and new Severity ranking)
	B	Occurrence ranking was too low (Specify old and new occurrence
	C	Detection ranking was too low (Specify old and new detection ranking)
	D	Multiplication error in RPN calculation was made
Why 3	A	PFMEA was not updated to customer standards for severity Severity of defect was not understood by APQP team Customer engineering change caused an increase in severity that was missed
	B	PFMEA was not updated to customer standards for occurrence Tier 2 failure rates were wrong / inadequately validated Sudden change in occurrence rate caused ranking to be incorrect Process change caused occurrence rate of defect to increase Occurrence ranking was based on external failures only, not actual Occurrence ranking was determined on a different but similar process Occurrence ranking was determined based on faulty defect data
	C	PFMEA was not updated to customer 3 standards for detection APQP team assumed detection method was more reliable than it really Change occurred that caused detection method to become less effective
	D	RPN calculation formula was incorrect
Why 4 +++		What is the root cause of the failures you have described above? May be more than one remaining Why?

PFMEA Review Process

Cross-functional teams shall review PFMEA's periodically.

- The frequency and/or number of PFMEA reviews shall be determined by supplier leadership based on:
  - customer expectations (customer complaints, 5 whys, launch activities, etc.),
  - process capability (FTQ, SPC, etc.),
  - changes to the process (*Error proofing*, Tier 2 changes, etc.).
- Criteria to prioritize which PFMEA to review include:
  - product from an acquisition, tool move or change in supplier,
  - PFMEA developed without adequate cross-functional involvement,
  - PFMEA for part(s) with history of customer complaints, warranty,
  - Occurrence ratings (FTQ, scrap, etc.) have changed significantly,
  - PFMEA with oldest revision dates.

PFMEA Review Process (Continued)

- PFMEA shall be reviewed and updated based on the following:
  - verification that all operations/processes (paint, heat treat, material handling, labelling, rework/repair, etc.) are included and accurate,
  - all process controls are included,
  - Detection ratings are accurate,
  - Occurrence ratings are analysed using data (SPC, FTQ, Verification Station, scrap rate, Layered Process Audits results, etc.).
  - Verification that the PFMEA meets customer requirements and expectations (AIAG, PPAP, launch etc.).

Reverse PFMEA Process

- **Reverse PFMEA definition**

Reverse PFMEA is an on-station review of all failure modes included in PFMEA conducted by cross-functional team, focused to verify that all failure modes have proper controls (prevention/detection) and they are working properly.

- **Reverse PFMEA purpose**

Reverse PFMEA is intended as a tool to assist in PFMEA reviews and RPN reduction efforts based on actual data from in-station audits of all the failure modes. This review is an attempt to discover or create new Potential Failure Modes not considered during PFMEA development as well as validate Occurrence and Detection ratings based on real data.

Reverse PFMEA Process

Process explanation

- Teams and an audit schedule should be defined. Team should be a cross-functional (similar like PFMEA core team see page 8) with one external auditor as "fresh eyes" for the audit.
- In order to standardize the audit concept, the teams should work together on a Reverse PFMEA. This will assure that the same criteria is used to avoid affecting the result of the audit.
- Confirm the current failures modes have the identified methods and controls in place.

Reverse PFMEA Process

Process explanation

- Experiment with the station in order to try to find new failure modes (example: using similar components that could be mixed, or try to assemble parts inverted to see what happened, etc.)

  NOTE: This verification will be under the supervision of the maintenance engineer to avoid any damage to the station.

- Once they finished the audit all the findings should be documented in an action plan with champion and dates to complete and increase the prevention of defects at the production line.

Reverse PFMEA Process

Reverse-PFMEA Flow Diagram (Example)

According to the calendar start audit in scheduled station by a cross-functional team (e.g.: quality, production, engineering, maintenance, etc) with PFMEA and checklist to review every failure mode described in PFMEA

The failure mode has proper controls (prevention/Detection)?

NO

YES

Are the controls (prevention/detection) working properly?

NO

YES

Develop action plan for all non conformances found during the audit

Verify next failure mode in PFMEA

All Failure Modes in PFMEA verified?

YES

NO

Once all Failure Modes are verified, next step is try to create or find new potential FM's not included in PFMEA

New Potential Failure Modes found?

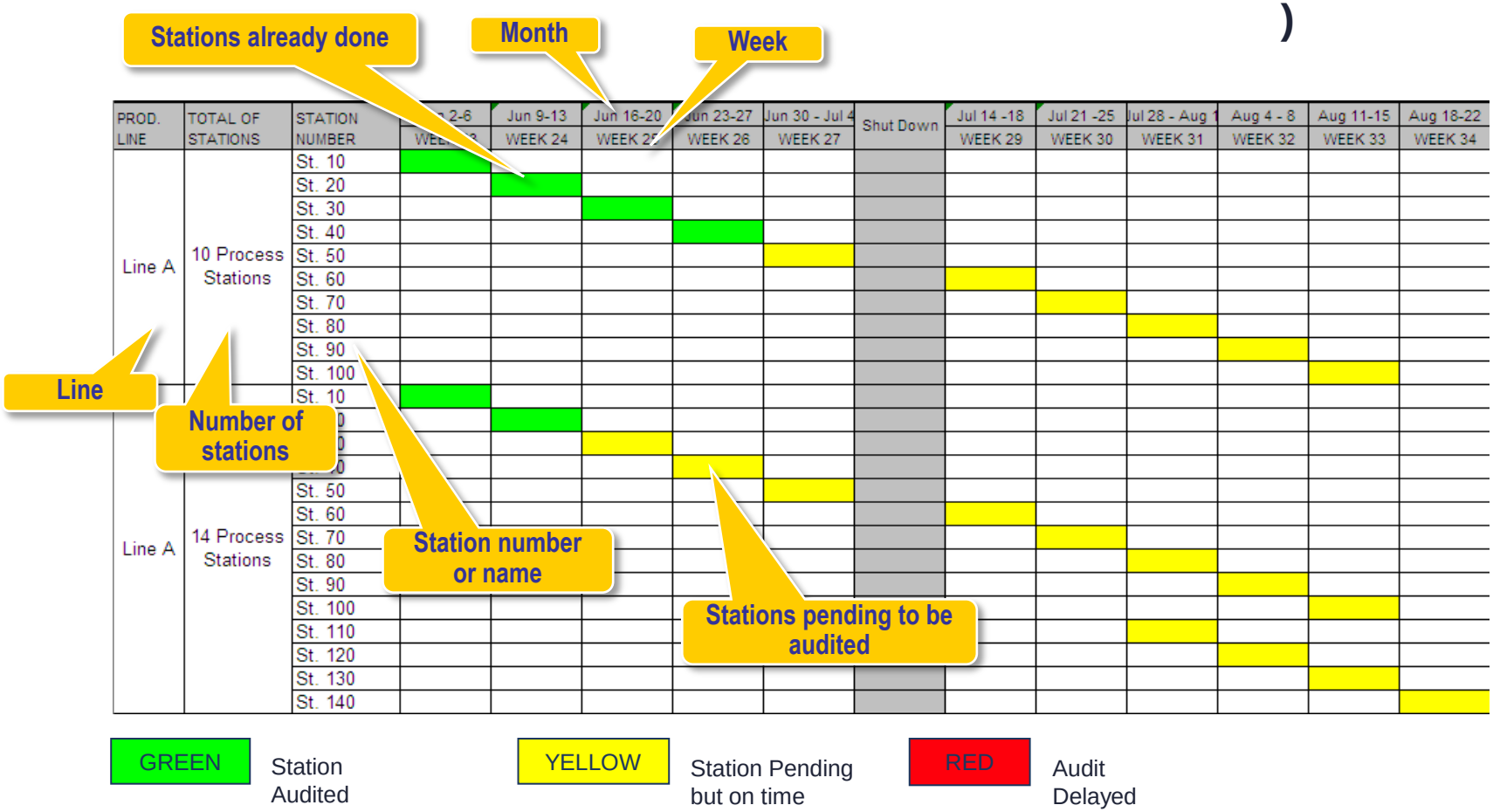
YES

NO

END

Reverse PFMEA Process

Audit Schedule (Example)



GREEN — Station Audited

YELLOW — Station Pending but on time

RED — Audit Delayed

Reverse PFMEA Process

Checklist (Example)

Top half of form

STATION #: Kit or Part Number Description:		Process Description:			
1	Can this component be **INSTALLED IMPROPERLY**?	Yes No			
	How? (ie. upside down, backwards)				
	Is there a method for **DETECTING** components installed improperly?	Yes In Station	Yes Downstream	No Plant Detection	
	Describe detection method and indicate station detection is performed.				
2	If this component is **LEFT OUT**, can it be detected?	Yes In Station	Yes Downstream	No Plant Detection	
	Describe detection method and indicate station detection is performed.				
3	Can a **SIMILAR BUT WRONG** component be installed?	Yes No			
	Is there a method for **DETECTING** the installation of a similar, but wrong component?	Yes In Station	Yes Downstream	No Plant Detection	
	Describe detection method and indicate station detection is performed.				
4	Is there a potential for a part to fall into and become lodged in the assembly? (**BONUS** component?)	Yes No			
	Is there a method for **DETECTING** a part that falls into the assembly?	Yes In Station	Yes Downstream	No Plant Detection	
	Describe detection method and indicate station detection is performed.				
5	Can a **DAMAGED** component be installed?	Yes No			
	Is there a method for **DETECTING** a damaged component?	Yes In Station	Yes Downstream	No Plant Detection	
	Describe detection method and indicate station detection is performed.				

Bottom half of form

ntamination issues been identified for this part? Part storage, dunnage cleanliness, etc.)	Yes In Station	Yes Downstream	No Plant Detection	
detection method for Contamination and indicate station detection is performed.				
n a Repair Station install this component?	Yes No			
RFMEA been completed on the repair station?	Yes No			
Are there installation tools required?	Yes No			
Are they used?	Yes No			
RFMEA Rating (Circle One)	**Green**	**Yellow**	**Red**	
the equipment damage the component.	Yes No			
rk instruction being followed by the operator	Yes No			
ED BY:	Manufacturing Engineer.	Quality Engineer.	Product Engineer.	

efinitions:

GREEN: Process DETECTION method is within the station where the part is being processed. Misbuilds **will not** leave the station without being detected.

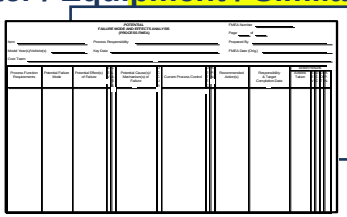
YELLOW: Process has DETECTION method within the Department or Plant. - Misbuilds are able to occur and leave the station undetected. Issue **will be** detected downstream in process prior to shipping (i.e. test stations).

RED: No process DETECTION method. Misbuilds are able to occur and leave the station undetected. Issue **will not be** detected downstream in process prior to shipping.

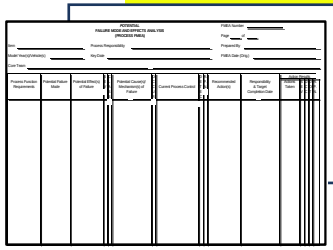
Note: Visual aids, operator instruction sheets and operator visual inspections, are not effective means of detection.

Reverse PFMEA Process

Master / Equipment / Similar part PFMEA

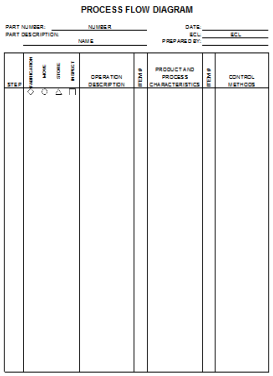


DFMEA



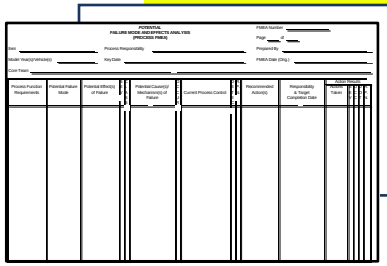
- HIGH RPNs

PROCESS FLOW



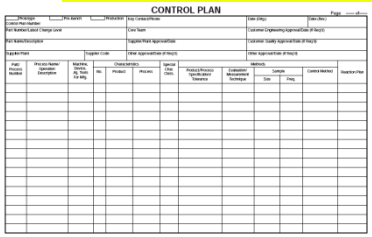
- LISTS EACH OPERATION
- KEY CHARACTERISTICS

PFMEA



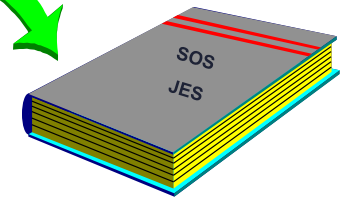
- POTENTIAL FAILURE MODES
- CURRENT CONTROLS
- ENHANCED CONTROLS FROM RECOMMENDED ACTIONS
- KEY CHARACTERISTICS

Control Plan



PER OPERATION:

- INSPECTION FREQUENCY
- GAGE & CHECKING DEVICES
- REACTION PLANS FOR NON-CONFORMING PRODUCT



PER OPERATION:

- INSPECTION FREQUENCY
- GAGE & CHECKING DEVICES
- REACTION PLANS OF NON-CONFORMING PRODUCT

Lessons Learned

Lessons Learned shall be documented. Documentation may include:

- Lessons Learned Form
- APQP Checklist
- Master PFMEA
- Computer Form or Website, etc.

Lessons Learned shall be communicated and kept available to all current and potential users. Communication can be performed by:

- Posting the lessons learned form
- Including on a lessons learned website
- Utilizing a company newspaper or closed circuit TV
- Distribution of pocket cards, etc.

Leadership shall review the Lessons Learned process to assure Implementation.

Auditor hints

Revision date of PFMEA linked to past failures.

Check last customer complaint or quality issues and their update in PFMEA.

Review checklists, agendas or equivalent that assure adequate PFMEA review.

Check some operations/processes (material handling, labeling, rework/repair, etc…) are included and accurate.

Compare top internal scrap data with Occurrence scoring.

Check updates after reverse PFMEA performed.

Chose one station and perform a quick reverse PFMEA to confirm all current controls rated properly and all potential failure mode cover (try to create new ones).

Have the current Occurrence/Detection numbers been revised.

Ask people for examples how they are using Lessons Learned system.

Reverse PFMEA, what are we searching for?

Item	Requirement	#Criteria	Criteria requirement
RR4	Plant Securization Plan is conducted to identify potential risks which could impact to plant (normal processes/activities).	RR41	**Prevention and reaction plans are established and deployed for each identified elementary risk (resources, facilities, tooling, shipping and safety stock...). The risks and the associated plans are periodically reviewed based on the plant, corporate and external lessons learnt.**
		RR42	**There are procedures of backup and recovery of the data (e.g.: EDI, SAP…) and they are regularly tested, when appropriate, plans are audited and simulations are carried out.**
		RR43	**By-pass processes are defined and managed. A procedure is in place to authorize by-passing processes (Production, maintenance, logistics, order and delivery system...)** **During planning phase, potential by-pass processes have to be identified and minimum most critical ones to be considered as part of approved process.**
		RR44	If customer request, a Safety stock warehouse (SSF) is separated from the supplier site.

Criteria of Requirement

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Auditor hints – page 51

Prev. Requirement Next Requirement

General risk identification

It identifies potential risks which could impact to plant normal processes, activities.

It covers risks such as:

- Un-availability of key resources (electricity, pressured air, water etc.),
- Breakdown of key processes
- Breakdown of key tierX suppliers,
- Disasters (fire, flood, earthquake etc.),
- Strikes, etc.

Formalized process of evaluation and control of risks are defined.

The responsibilities of evaluation and management of risks are clearly established, coherent with the typology of the risks such as:

- Maintenance for breakdown of key processes & availability of key resources (electricity…),
- Logistic for breakdown of key tier X suppliers,
- Human Resources for strikes,
- Environmental & Safety for disasters.

General risk identification (Example)

1. Human Ressources
Social Conflict (Strike)
Wages too low
Heavy rate of absenteism
Major safety issue
2. IT
Network breakdown
ERP Breakdown
EDI Breakdown
3. Facilities
Electrical accidents
General loss of power
Transformer breakdown
Other type of accidents
Fluids supply (compressed air, hot water, …)
Fire
Trespasses (theft)
Dangerous industrial neightbourhood
Natural Disasters
Flooding
Storm
Snow

4. Tier X Issues
Tier 2 Disruption
Manufacturing transfer
5. PRODUCTION
Manufacturing Equipment & Tools
Breakdown
Control Equipment
Breakdown
6. LOGISTIC
Production Planning
Customer demand unreachable
Internal log
Handling equipment breakdown
Transport
Downstream flow blocked

General risk evaluation

- Systematic approach is used to evaluate risk (like FMEA approach).
- Multidisciplinary approach is applied (cross-functional team).
- Managed by top management.
- Prevention and reaction plans are defined and delpoyed. When applicable, plan is audited and simulations is carried out.
- The risks and the associated plans are periodically reviewed based on the plant, corporate and external lessons learnt.

General risk evaluation

(Example)

Plant FMEA

		1st Evaluation			Action plan		Updated Evaluation		
Risk	**Impacts**	**S**	**D**	**Criticity**	**Owner**	**Actions**	**S**	**D**	**Criticity**
1. Human Ressources									
Social Conflict (Strike)	Enable to produce or deliver	3	1	**3**	XXXX	Doc Ref.xxxx	2	1	**2**
Wages too low	Loss of critical competencies								
Heavy rate of absenteism	Enable to produce								
Major safety issue	Equipement blocked due to legal investigation								
….	….								

Scoring

Severity

1	2	3
No customer impact	Customer plant minor disruption	Customer plant stop

Detection

1	2	3
Very High	High	Low

Criticity = Severity x Detection

Threshold = 3

Electronic Data Interchange (EDI): Validation, Resource and Backup

- Organization shall have the EDI installed and validated with Customer
- Qualified people must be permanently available to handle with EDI in all shifts
- In case of issues with EDI, a back up solution shall be established and validated by Customer. This back up shall be tested periodically in order to assure it is working properly
  - Example of back up: email, fax, etc.
- Any upgrade of EDI communications must be considered as significant change – refer Managing Change

Bypass Process

Planning Phase

During planning phase, potential Bypass processes shall be identified and, at minimum, most critical ones shall be considered as part of approved process:

- Back up operation
- Temporary rework
- Other

Current Phase

Any time the process is altered outside the approved documented control plan, suppliers shall establish a Bypass Process Control procedure that:

- Defines the minimum requirements for bypassing an existing manufacturing process.
- Defines minimum requirements for verification of the original process when exiting the bypass.

Bypass Process (Continued)

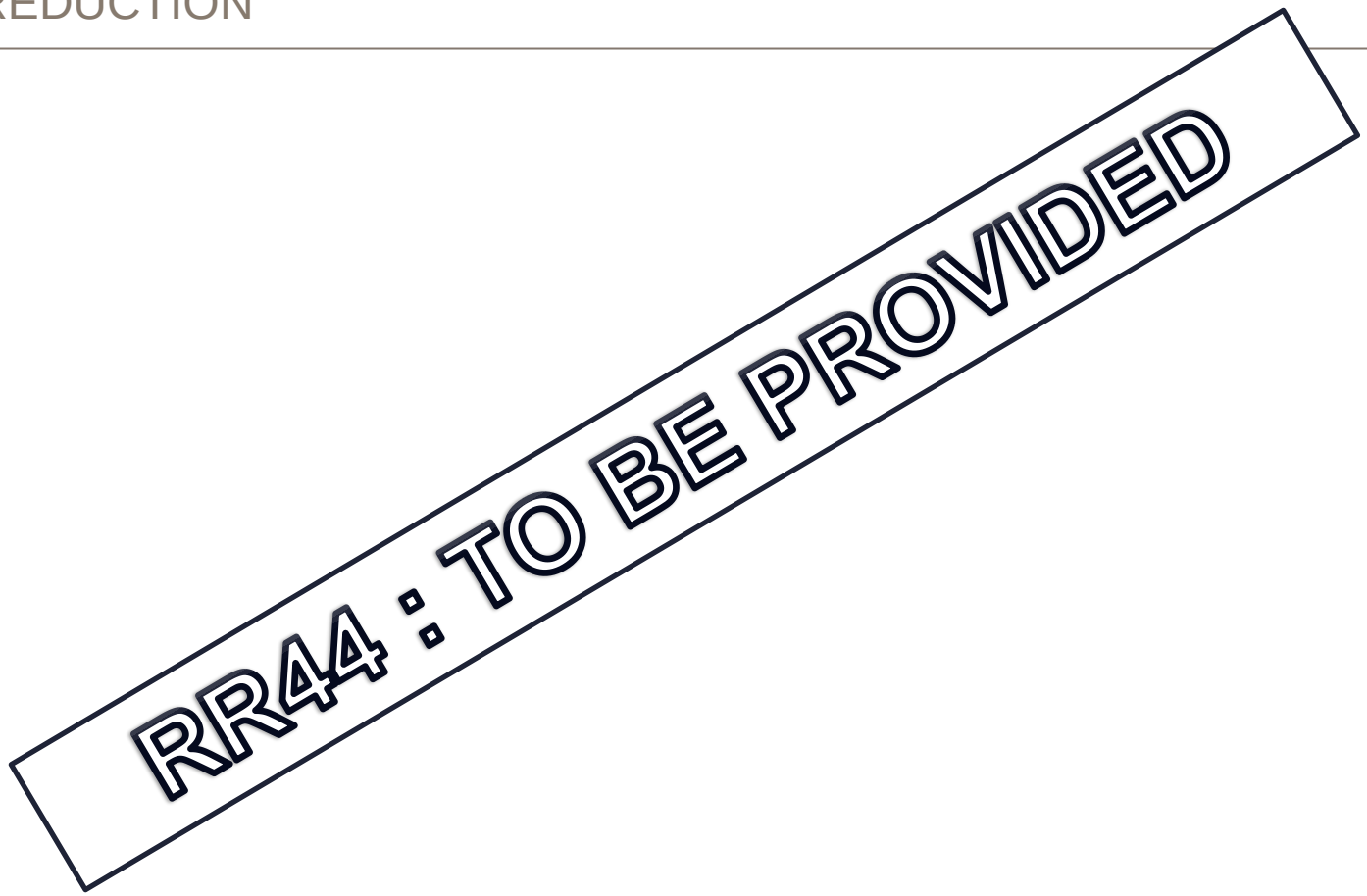
Examples when a Bypass Process may be required:

- Torque gun failures
- Any back up operation outside the normal process flow
- *Error Proofing* or gaging that are turned off
- Any temporary rework to bring part back to specification

The Process Bypass Control procedure should incorporate the following:

- The process methods/controls defined for bypassing an existing manufacturing process are approved by the Operations Manager (process owner), the Engineering Manager and the Quality Manager.
- A list of processes approved for bypass are maintained through the Document Control Process and used in both Planning and Current Phase.
- The PFMEA and Control Plan include the bypass process.
- *Standardized Work* Instructions are established for the bypass process.
- A form of communication is posted at each active bypass point.
- Traceability rules

RISK REDUCTION



Auditor hints

Master securing plan which contains major risks, procedures and owners in case of e.g.: flood, fire etc.

Verify that master security plan covers the relevant major risks.

How risks are evaluate (which criteria, is there a tool like FMEA, etc.).

Who is responsible of the whole process, who is responsible for a precise risk.

An example of risk: fire. Look at the action plan (preventive: extinguisher, training / corrective: site evacuation plan, sprinkler, firemen on site, etc.)

Risk reduction effectiveness, what are we searching for?

Item	Requirement	#Criteria	Criteria requirement
RRE	Targets are defined and followed to ensure effectiveness continuous risk reduction activity.	RRE1	Tracking the number of high risk items (trend chart).
		RRE2	Follow-up of the actions in delays.
		RRE3	Number of new failure modes and root causes covered after complaint (both external and internal)is followed.
		RRE4	A periodic review of Plant Securization Plan is scheduled.

Criteria of Requirement

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3 – page 54
4 – page 55
Auditor hints – page 56

Prev. Requirement
What goes wrong?

RPN reduction summary (Example)

UPDATED

PFMEA RPN REDUCTION SUMMARY - Overall Plant

OPERATION SUMMARY

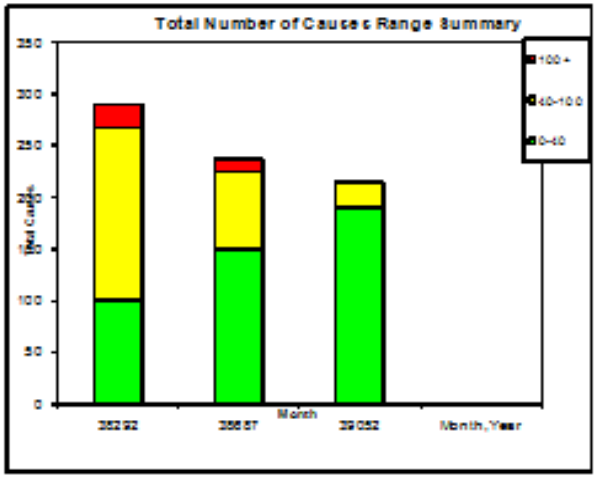
OPERATION NUMBER	COMBINED RPN	TOTAL NUMBER OF CAUSES	# OF CAUSES > 40	HIGHEST INDIVIDUAL RPN
222 WS	0	0	0	0
295 BL	2363	89	11	56
265 QTR	2357	89	7	84
295 DG	1141	37	6	64
5				
6				
7				
8				
9				
10				
TOTAL	5861	215	24	84

MONTHLY COMPARISONS OF OPERATION TOTALS

OPERATION NUMBER	BASELINE	Dec. 2005 RPN	Oct. 2006 RPN	Month Year RPN
222 WS	4078	2440	0	
295 BL	6488	2440	1787	
265 QTR	3355	3355	2357	
295 DG	1235	1235	1141	
5				
6				
7				
8				
9				
10				
TOTAL	15156	9470	5285	0

RPN Reduction Plan - Top Ten

Item	Oper. / STA. #	RPN Value	Function & Failure Mode	Recommended Action(s)	Compl. Date	Responsibility
1	Extrusion	56	Locator pin placement	Error Proofing robot through	31-Jan-06	Kelly Green
2	Assembly	84	Urethane application	Identification mark on all reveals for	1-Mar-07	Taylor Hemming
3	All	64	Missing Bar Code Labels	Implemented Scanning method	31-Jan-07	Adam Ant
4						
5						
6						
7						
8						
9						
10						



Tracking of items

Regular management reviews should follow up open items and where gap is identified resources have to be allocated.

- Delay in completion of recommended action

No.	OP No.	Function & Failure Mode	RPN Value	Who	Recommended Actions	Completion Date
1	10	INCORRECT BEARING INSTALLED	490	B. SHAD	SENSOR TO DETECT BEARING TYPE	01/12/2013
2	20	INCORRECT OR REVERSED SUBASSEMBLY	126	N. ADAMS	INSTALL LASER STATION	31/12/2013
3	50	HOLE MISSING	168	S. BROWN	INSTALL POST ON ASSEMBLY FIXTURE	08/08/2013
4	60	INCORRECT LABEL	112	V. WAGNER	IMPLEMENT SCANNER	30/01/2014

(Example)

- Delay in reverse PFMEA process

TO BE UPD

PROD. LINE	TOTAL OF STATIONS	STATION NUMBER	Jun 2-6 WEEK 23	Jun 9-13 WEEK 24	Jun 16-20 WEEK 25	Jun 23-27 WEEK 26	Jun 30 - Jul 4 WEEK 27
Line A	10 Process Stations	St. 10					
		St. 20					
		St. 30					
		St. 40					
		St. 50					
		St. 60					
		St. 70					
		St. 80					
		St. 90					
		St. 100					
Line A	14 Process Stations	St. 10					
		St. 20					
		St. 30					
		St. 40					
		St. 50					
		St. 60					
		St. 70					
		St. 80					
		St. 90					
		St. 100					

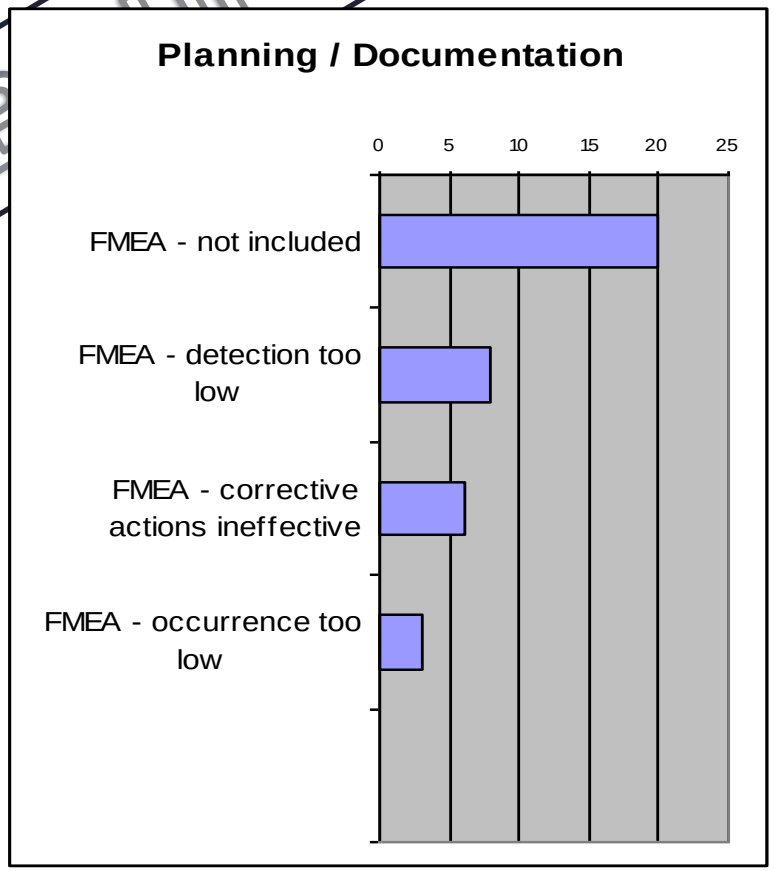
(Example)

Tracking of new failure modes or RPN misjudgement

TO BE UPDATED

Predict

(Example)

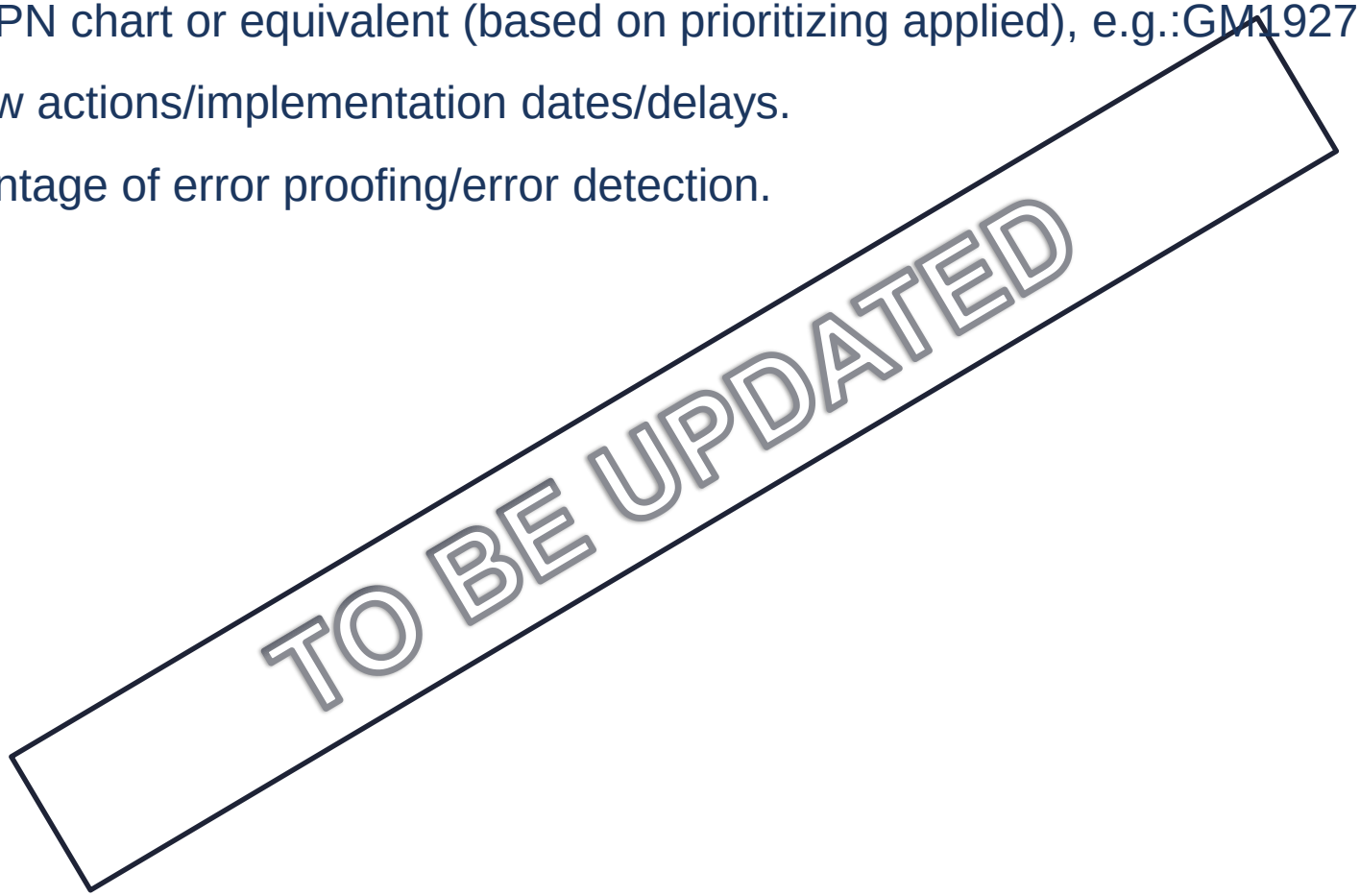


Auditor hints

Top RPN chart or equivalent (based on prioritizing applied), e.g.:GM1927-21.

Review actions/implementation dates/delays.

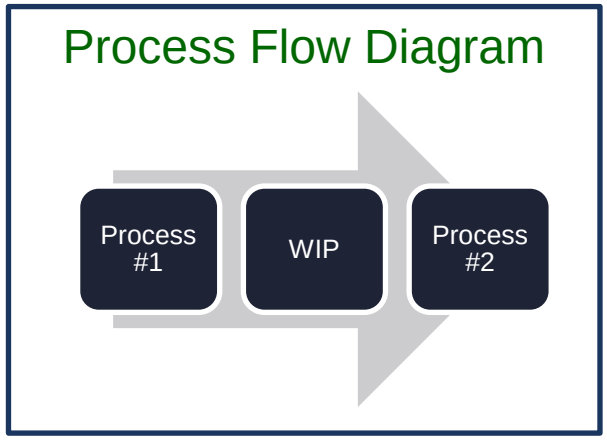
Percentage of error proofing/error detection.



What goes wrong ?

- PFMEA is a „one man show”.
- Scoring is not according to customer guidelines.
- Scoring is not consistent.
- Primary detection method relies heavily on visual inspection.
- Failure modes are missing, not revised at work station.
- Internal/external PPM are not used for Occurrence.
- Scoring driven by low RPN or set by action limit.
- New scoring is not revised after recommended action implementation.
- High risk item identified but not controlled by SQ tools.
- Management is not involved & does not allocate resources for regular reviews.
- PFMEAs not used for continuous improvement - only updated when problems occur.

Process Flow Diagram and PFMEA: storage condition



- Storage areas shall be identified in the Process Flow diagram
- Potential failure modes related to handling (damages, mixture, etc.) and storage (rust, contamination, etc.) shall be captured in the PFMEA

PFMEA

Material Storage and Handling – Potential Failure Modes

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (PROCESS FMEA)

15xxxxx | MODEL YEAR / CARLINE: | REVD DATE: | FMEA DATE: | FMEA CONDUCTED BY: | B.P Level: 001, 7-NOV-02

PROCESS NAME/ NUMBER	PROCESS FUNCTION	POTENTIAL FAILURE MODE	POTENTIAL EFFECT(S) OF FAILURE	SEV	CLASS	POTENTIAL CAUSE(S)/ MECHANISM(S) OF FAILURE	OCC	CURRENT CONTROLS: PREVENTION	CURRENT CONTROLS: DETECTION	DET	RPN	RECOMMENDED ACTION(S)	RESPONSIBILITY & TARGET COMPLETION DATE	ACTION RESULTS: ACTIONS TAKEN	SEV	OCC	DET	RPN
10	Install pilot bearing	Incorrect part installed	Misbuild: part does not function.	7		Manual: incorrect part selected	7	No prevention	No detection	10	490	Sensor to detect bearing type	Shad, B.	3/1/02	7	7	4	146
20	Correct sub-assy	Incorrect or reversed sub-assembly	unable to install	7		Machine Vision ID Incorrect	3	No prevention	In-line Audits	6	126	New Laser Station.	NA		7	3	2	42