SNAP-ON INCORPORATED
STANDARD ON
FMEA PROCESS FOR
QUALITY PROBLEM SOLVING
(FAILURE MODE &
EFFECT ANALYSIS)

Issued By:	Approval:	Date:

FMEA PROCESS FOR QUALITY PROBLEM SOLVING (FAILURE MODE & EFFECT ANALYSIS)

1.0 SCOPE

The FMEA process adopted by Snap-on is a key component of the Quality Forward System. The initiation of a FMEA activity at an individual business unit will be driven by unfavorable performance data or information or the need to make incremental improvement. The process can be initiated by a business unit manager or by the SEQ Group.

Generally, an on-site FMEA team is a multifunctional team facilitated locally or by an SEQ Group Advanced Quality Engineer. The objective of the team is to identify all of the reasons why quality of a process or product is not in conformance to expectations. The failure or defect in service or product quality shall be fully investigated by the team with conclusions and recommendations made to the business unit manager within 90 days of the team forming date. The business unit manager will have an additional 90 days to gain approvals from senior management and implement the team's solution/recommendations if the results have been sanctioned by the appropriate management level.

2.0 IMPLEMENTATION

The FMEA process adopted follows the following protocol:

- Problem Statement

  A concise and focused description of the quality problem or opportunity for improvement, "what went wrong" or "what needs fixing."

- The Goal Statement

  A description of what is to be accomplished in quantifiable terms "reduce by," "increase by," "eliminate," etc.

The problem statement and goal should consider:

i. What is wrong?

ii. What is the gap between desired quality level and actual level?

iii. Which process/es is involved?

iv. What department or cell is the deficiency occurring in?

v. Is the problem cyclic, can it be attributed to specific events?

vi. What are the appropriate metrics to measure?

vii. What is the impact on operational fitness and profitability?

viii. What is the net filtering to the bottom line if reduced, increased, eliminated?

ix. Are recognized constraints a problem early on? If so, they should be explored and clarified with the appropriate management level.

- Completion of the start-up worksheet. The team should complete the start-up worksheet (Figure 1) as soon as the problem statement and goal are defined.

Figure 1. FMEA Team Start-Up Worksheet

FMEA Number: _____ Date Started: _____

Date Completed: _____

Team Members:

_____ _____ _____

_____ _____ _____

_____ _____ _____

Facilitator: _____

1. Are all affected areas represented?
   YES NO Action _____
2. Are different levels and types of knowledge represented on the team?
   YES NO Action _____
3. Is the customer involved?
   YES NO Action _____
4. Who will take minutes and maintain records? _____

FMEA Team Boundaries of Freedom

5. What aspects of the FMEA is the team responsible for?

FMEA Analysis	Recommendations for Improvement	Implementation of Improvements

6. Have resources been committed? _____
7. Does the project have a deadline? _____
8. Do team members have specific time constraints? _____
9. What is the procedure if the team needs to expand beyond these boundaries?

   _____

10. How should the FMEA be communicated to others? _____
11. What is the problem statement and goal of the FMEA? (Be specific and include a clear definition of the process on product to be studied.)

    _____

    _____

    _____

3.0 Process

- Process FMEAs uncover process problems related to the manufacture of the product. For example, a piece of automated assembly equipment may misfeed parts resulting in products not being assembled correctly. Or, in a chemical manufacturing process, temperature and mixing time could be sources of potential failures resulting in unusable product.

- It is helpful when conducting a process FMEA to think in terms of the five elements of a process: people, materials, equipment, methods and environment. With these five elements in mind, ask, "How can process failure affect the product, processing efficiency or safety?"

All process FMEAs follow these nine steps:

Step 1: Review the process.

Step 2: Brainstorm potential failure modes.

Step 3: List potential effects of each failure mode.

Step 4: Assign a severity rating for each effect.

Step 5: Assign an occurrence rating for each failure mode.

Step 6: Assign a detection rating for each failure mode and/or effect.

Step 7: Calculate the risk priority number for each effect.

Step 8: Prioritize the failure modes for action.

Step 9: Take action to eliminate or reduce the high-risk failure modes.

The FMEA process shall be documented using the FMEA worksheet (Figure 2). This form captures all of the important information and serves as an information tool.

Figure 2. Potential Failure Mode and Effect Analysis

Process/Product: ____________

FMEA Team: ____________

Team Leader: ____________

FMEA Number: ____________

FMEA Date: (Original) ____________

(Revised) ____________

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FMEA Process											Action Results				
Item and Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurrence	Current Controls	Detection	RPN	Recommended Action	Responsibility and Target Completion Date	Action Taken	Severity	Occurrence	Detection	RPN
Total Risk Priority Number									Resulting Risk Priority Number						

All copies of FMEA documents must be filed with the SEQ so that senior management is kept abreast of quality improvement efforts.

Step 1 – Process Review

To ensure that everyone on the FMEA team has the same understanding of the process that is being worked on, the team should review a blueprint (or engineering drawing) of the product if they are conducting a product FMEA, or a detailed flowchart of the operation if they are conducting a process FMEA.

If a blueprint or flowchart is not available, the team will need to create one prior to starting the FMEA process.

With the blueprint or flowchart in hand, the team members should familiarize themselves with the product or process. For a product FMEA, they should physically see the product or a prototype of the product. For a process FMEA, the team should physically walk through the process exactly as the process flows.

It is helpful to have an "expert" on the product or process available to answer any questions the team might have.

Step 2 – Brainstorm Potential Failure Modes

Once everyone on the team has an understanding of the process (or product), team members can begin thinking about potential failure modes that could affect the manufacturing process or the product quality. A brainstorming session will get all of those ideas out on the table. Team members should come to the brainstorming meeting with a list of their ideas. In addition to the ideas members bring to the meeting, others will be generated as a result of the synergy of the group process.

Because of the complexity of some manufactured products and manufacturing processes, it is best to conduct a series of brainstorming sessions, each focused on a different element (for example; people, methods, equipment, materials and the environment) of the product or process. Focusing on the elements one at a time may result in a more thorough list of potential failure modes.

It is not unusual to generate dozens of ideas from the brainstorming process. In fact, that's the objective!

Once the brainstorming is complete, the ideas should be organized by grouping them into like categories. Your team must decide the best categories for grouping, as there are many different ways to form groups with failure modes. You can group them by the type of failure (e.g., electrical, mechanical, user-created), where on the product or process the failure occurred, or the seriousness (at least the team's best guess at this point) of the failure. Grouping the failures will make the FMEA process easier to work through.

Without the grouping step, the team may invest a lot of energy jumping from one aspect of the product to a completely different aspect of the product and then back again. An easy way to work through the grouping process is to put all of the failure modes onto self-stick notes and post them on a wall so they are easy to see and move around as they are being grouped.

The grouping also gives the team a chance to consider whether some failure modes should be combined, because they are the same or very similar to each other. When the failure modes have been grouped and combined, if appropriate, they should be transferred onto the FMEA sheet.

Step 3 – List Potential Effects of Each Failure Mode

With the failure modes listed on the FMEA worksheet form, the FMEA team reviews each failure mode and identifies the potential effects of the failure should it occur. For some of the failure modes, there may be only one effect while there may be several effects for other failure modes.

This step must be thorough, because this information will feed into the assignment of risk ratings for each of the failures. It is helpful to think of this step as an ***if-then*** process: ***If*** the failure occurs, ***then*** what are the consequences.

Step 4, 5 and 6 – Assigning Severity, Occurrence and Detection Ratings

Each of these three ratings are based on a 10-point scale, with 1 being the lowest rating and 10 being the highest.

It is important to establish clear and concise descriptions for the points on each of the scales, so that all team members have the same understanding of the ratings. The scales should be established before the team begins the rating process. The more descriptive the team is when defining the rating scale, the easier it should be to reach consensus during the rating process.

A generic rating system for each of the scales is provided in Tables 1, 2 and 3. This system should be customized by the team for their specific FMEA project.

Even if the rating system is clear and concise, there still may be a disagreement about the rating for a particular item.

Table 1. Severity Rating Scale*

Rating	Description	Definition
10	Dangerously high	Failure could injure the customer or an employee.
9	Extremely high	Failure would create noncompliance with federal regulations
8	Very high	Failure renders the unit inoperable or unfit for use.

7	High	Failure causes a high degree of customer dissatisfaction.
6	Moderate	Failure results in a subsystem or partial malfunction of the product.
5	Low	Failure creates enough of a performance loss to cause the customer to complain.
4	Very low	Failure can be overcome with modifications to the customer's process or product, but there is minor performance loss.
3	Minor	Failure would create a minor nuisance to the customer, but the customer can overcome it in the process or product without performance loss.
2	Very minor	Failure may not be readily apparent to the customer, but would have minor effects on the customer's process or product.
1	None	Failure would not be noticeable to the customer and would not affect the customer's process or product.

*Should be modified to fit the specific product or process.

Table 2. Occurrence Rating Scale*

Rating	Description	Potential Failure Rate
10	Very high: Failure is almost inevitable	More than one occurrence per day or a probability of more than three occurrences in 10 events ($C_{pk} < 0.33$).
9		One occurrence every three to four days or a probability of three occurrences in 10 events ($C_{pk} \approx 0.33$).
8	High: Repeated failures	One occurrence per week or a probability of 5 occurrences in 100 events ($C_{pk} \approx 0.67$).
7		One occurrence every month or one occurrence in 100 events ($C_{pk} \approx 0.83$).
6	Moderate: Occasional failures	One occurrence every three months or three occurrences in 1,000 events ($C_{pk} \approx 1.00$).
5		One occurrence every six months to one year or one occurrence in 10,000 events ($C_{pk} \approx 1.17$).
4		One occurrence per year or six occurrences in 100,000 events ($C_{pk} \approx 1.33$).
3	Low: Relatively few failures	One occurrence every one to three years or six occurrences in ten million events ($C_{pk} \approx 1.67$).
2		One occurrence every three to five years or 2 occurrences in one billion events ($C_{pk} \approx 2.00$).
1	Remote: Failure is unlikely	One occurrence in greater than five years or less than two occurrences in one billion events ($C_{pk} \approx 2.00$).

*Should be modified to fit the specific product or process.

Table 3. Detection Rating Scale*

Rating	Description	Definition
10	Absolute uncertainty	The product is not inspected or the defect caused by failure is not detectable.
9	Very remote	Product is sampled, inspected and released based on Acceptable Quality Level (AQL) sampling plans.
8	Remote	Product is accepted based on no defectives in a sample.

7	Very low	Product is 100% manually inspected in the process.
6	Low	Product is 100% manually inspected using go/no-go or other mistake-proofing gauges.
5	Moderate	Some Statistical Process Control (SPC) is used in process and product is final inspected off-line.
4	Moderately high	SPC is used and there is immediate reaction to out-of-control conditions.
3	High	An effective SPC program is in place with process capabilities (C_{pk}) greater than 1.33.
2	Very high	All product is 100% automatically inspected.
1	Almost certain	The defect is obvious or there is 100% automatic inspection with regular calibration and preventive maintenance of the inspection equipment.

*Should be modified to fit the specific product or process.

Step 4– Assign a Severity Rating for Each Effect

The severity rating is an estimation of how serious the effects would be if a given failure did occur. In some cases it is clear, because of past experience, how serious the problem would be. In other cases, it is necessary to estimate the severity based on the knowledge and expertise of the team members.

Because each failure may have several different effects, and each effect can have a different level of severity, it is the effect, not the failure, that is rated. Therefore, each effect should be given its own severity rating, even if there are several effects for a single failure mode.

Step 5– Assign an Occurrence Rating for Each Failure Mode

The best method for determining the occurrence rating is to use actual data from the process. This may be in the form of failure logs or even process capability data. When actual failure data are not available, the team must estimate how often a failure mode may occur. The team can make a better estimate of how likely a failure mode is to occur and at what frequency by knowing the potential cause of failure. Once the potential causes have been identified for all of the failure modes, an occurrence rating can be assigned even without failure data.

Step 6 – Assign a Detection Rating for Each Failure Mode and/or Effect

The detection rating looks at how likely we are to detect a failure or the effect of a failure. We start this step by identifying current controls that may detect a failure or effect of a failure. If there are no current controls, the likelihood of detection will be low, and the item would receive a high rating, such as a 9 or 10. The current controls should be listed first for all of the failure modes, or the effects of the failures and then the detection ratings assigned.

Step 7 – Calculate the Risk Priority Number for Each Failure Mode

The risk priority number (RPN) is simply calculated by multiplying the severity rating times the occurrence rating times the detection rating for all of the items.

Risk Priority Number =
Severity x Occurrence x Detection

The total risk priority number should be calculated by adding all of the risk priority numbers. This number alone is meaningless, because each FMEA has a different number of failure modes and effects. However, it will serve as a gauge to compare the revised total RPN against the original RPN once the recommended actions have been instituted.

Step 8 – Prioritize the Failure Modes for Action

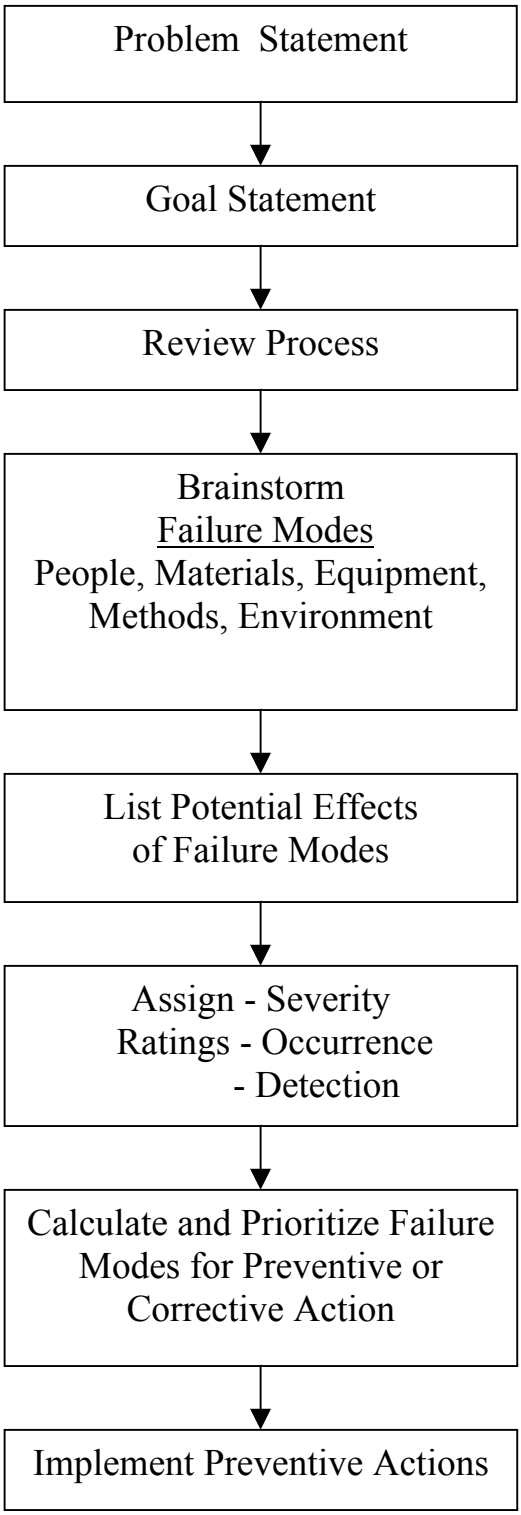
The failure modes can now be prioritized by ranking them in order from the highest risk priority number to the smallest. A Pareto diagram is helpful to visualize the differences between the various ratings.

The team must now decide which items to work on. Usually it helps to set a cut-off RPN, where any failure modes with an RPN above that point are attended to. Those below the cut-off are left alone for the time being.

Step 9 – Take Action to Eliminate or Reduce the High-Risk Failure Modes

Using an organized problem-solving process, identify actions to eliminate or reduce the high-risk failure modes and make recommendations to the appropriate management level.

APPENDIX I
FMEA PROCESS PROBLEM SOLVING



REVISION LOG

Date	Revision Statement
9/13/01	Initial issue.