Desk Reference Guide
For the

FMEA for Beginners: Taking Preventive Action
E-Learning class at www.QualityWBT.com

Content Provider: JP Russell and Elizabeth Bild
Instructional Design By: J.P. Russell
Web Design: Wes Whalen
E-Learning Provider: QualityWBT Center for Education

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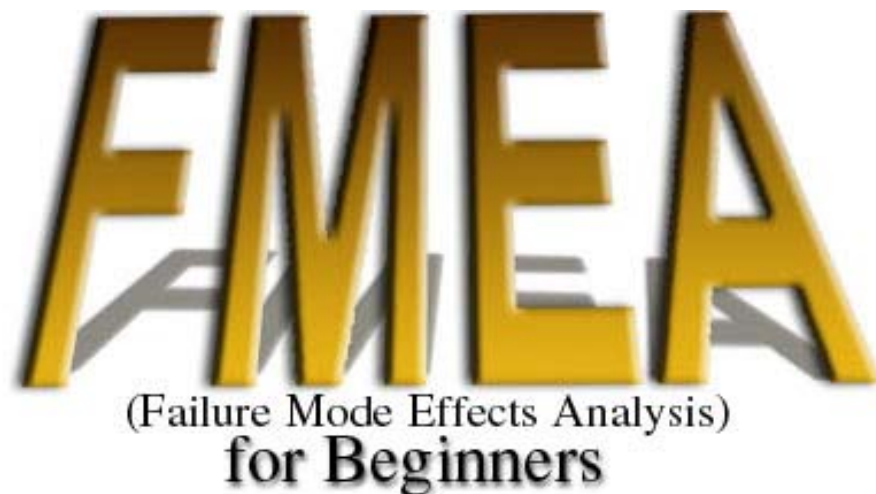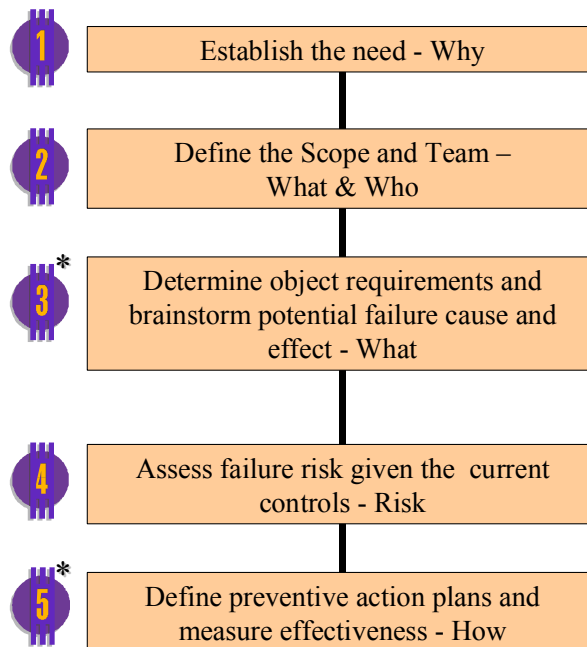
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FMEA for Beginners: Taking Preventive Action

Welcome to the FMEA class. You may be taking this class as a guide for completing a FMEA or this may be your first experience with FMEAs. The acronym FMEA stands for Failure Mode and Effects Analysis. At first, the FMEA technical name may seem somewhat foreboding. It is the popular name for a formal process (system) for identification of potential problems and actions to eliminate their occurrence. FMEA is a proactive activity as opposed to reacting to problems and complaints.

FMEA Process Flow Chart

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1 Establish the need - Why

2 Define the Scope and Team – What & Who

3 * Determine object requirements and brainstorm potential failure cause and effect - What

4 Assess failure risk given the current controls - Risk

5 * Define preventive action plans and measure effectiveness - How

* High risk and important step

The FMEA techniques have been used by industry for many years to identify potential safety and environmental risks. Now FMEA is gaining widespread acceptance because of its inherent benefits.

LESSON 1: Understanding FMEAs
In this lesson, we will review the role, importance and application of potential Failure Mode and Effects Analysis (FMEA). Automotive manufacturers have helped to popularize FMEA by requiring their suppliers to implement and practice the technique. FMEA is a structured and disciplined approach to identify potential failures and their effects, and to identify actions to ameliorate or eliminate potential failures. Regardless of whether your business is manufacturing or service-oriented, FMEAs are a critical tool in effective management. FMEAs can be used as tool to facilitate preventive action and continual improvement. They provide an essential means of discovering and correcting potential process/product weaknesses before they become a problem.

A. FMEA BENEFITS

Since the purpose of a FMEA is to help you find and fix potential failures before they occur, their value should not be underestimated. There may be times you perform a certain task or transaction and say to yourself how easy it was. Or you may work with a product that is easy to use and holds up well. These are not just random events; someone or a team of people put in the time and effort to think through the potential service or product failures and made changes to address the potential failures. If something seems easy, it is probably because people made it that way. When things go smoothly and products work like they are expected to work, customers are more likely to be happy.

Performing FMEAs will promote safety, reliability and control of product costs. This will help the organization achieve customer satisfaction. In today's business environment achieving high levels of customer satisfaction has never been more important.

FMEAs are beneficial throughout the *manufacturing process* and should begin at the design stage, before any significant financial investment is made (i.e. purchase of machinery or raw materials). For *Service Industries*, FMEAs should be performed before the service is available to the end-customer. The earlier potential failures are identified in a project (using FMEAs), the lower the cost of the solution. FMEAs can be performed on new designs and mature products and services during design changes.

An added incentive to conducting ongoing FMEAs is that they are relatively easy to perform and do not require extensive expertise, training, or statistical analysis.

B. HISTORY

In the mid-1960's, the aerospace industry spearheaded the formalized and systematic use of FMEAs. As the safety and quality advantages of FMEAs became apparent, the chemical and automotive industries adopted the technique. In fact, businesses seeking to receive QS-9000 or TS 16949 certification are specifically required to conduct FMEAs. Today, this is no longer a technique used exclusively by engineering or manufacturing departments. With some modifications they are used in a wide range of settings such as: Manufacturing, non-profit, service, and government agencies.

FMEAs can be applied anytime there is an output and a customer or user of the output (product or service). Products can include parts, assemblies, machines, equipment, chemicals, food, devices and so on. Services can include renting, medial treatments, retail sales, insurance or banking services.

C. TYPES

FMEAs fall into two basic categories: PRODUCT / DESIGN and PROCESS

Although both follow similar guidelines and procedures, you will find that their objectives are somewhat different.

Product/Design
The purpose or objective of Product/Design FMEAs is to discover product problems that could lead to safety risks, failures, malfunctions and/or reduce the product's life-span. Ideally, Product FMEAs should be conducted at each stag of design and any changes during production.

Process
The purpose or objective of a Process FMEA is to discover problems with the actual manufacturing of the product or delivery of a service. Both service and manufacturing processes have six components for consideration: People, Materials, Equipment, Methods, Environment, Measures.

Each component should be evaluated separately. Some of you may have experience with using the same six components to determine underlying causes of problems using a Cause and Effect Diagram (see CE Diagram in lesson 3).

LESSON 2: PREPARING FOR THE FMEA
In the last lesson you gained a basic understanding of FMEA objectives, usage, and types. We will now review the steps involved in preparing for an FMEA, including defining its scope and boundaries, as well as assembling an effective team.

A. DEFINITION OF SCOPE
The extent to which a FMEA will be a useful and reliable tool begins with an exact definition of its parameters and focus. The scope defines the object of the investigation and any limitations. Responsibility for scope definition lies with the management of the organization responsible for the project. For example, it could be the director of design or manufacturing, depending on the type of FMEA under consideration (design or process.) The scope definition should be clearly written for all team members to review and any questions should be addressed and documented at this point.

The scope can be any part, component, feature or characteristic of a product or service.
Ensuring that everyone involved understands the assignment from the onset is
- Effective time management (no need to rehash purpose and scope later instrumental to:
- Keeping the team zeroed in on what is important (staying focused)
- Cost control (fewer delays and rework)

Example: Your company, Universal Home Appliances, manufactures several blender models. The scope of your FMEA is limited to evaluating the glass pitcher and lid, which have recently been redesigned. Your team will assess no other components, e.g. the electrical cord, button panel or base.

B. ESTABLISHMENT OF BOUNDARIES
Once you and your team fully understands what it is that needs to be analyzed, the next step is for management to provide the framework within which you will need to operate. This framework consists of four key components:
- Budget - How much can you spend?
- Scope of Responsibility –

Are you merely responsible for conducting the analysis, or also for implementing improvements?
- Resources - What tools are at your disposal? People - Equipment
- Deadline - When is the FMEA due?

Finally, it is helpful for Management to provide a procedure for your team to follow in case the boundaries need to be redefined . For example, if the allocated budget proves insufficient, you will need to know how to go about obtaining additional funds. The FMEA scope, boundaries, and pertinent procedures should be detailed in a FMEA Work Order. The work order may be completed by you or your team leader and shared with all group members

C. ASSEMBLING THE TEAM
Since the purpose of a FMEA is to uncover a wide range of potential product/process weaknesses before they become a problem, it stands to reason that teams are encouraged. By incorporating different areas of expertise, multiple backgrounds, and varying levels of project familiarity, a team effort can yield comprehensive, and in-depth analysis. While having a cross-functional team is advantageous, having too large a team may reduce effectiveness and increase FMEA costs. Teams are typically composed of three to six members.

It is not advisable that a company establish a "permanent" FMEA team, but rather that teams be formed on a case-specific basis and be disbanded once the FMEA is completed. In that way, teams are always tailored to meet the specific tasks at hand.

D. TEAM DYNAMICS

Given that FMEAs are essentially fault-finding exercises, there is considerable potential for defensive or otherwise negative behaviors on the part of those most familiar with the product or process under consideration. Adhering to these basic guidelines will minimize friction and generally improve interpersonal communications:

Understand that each team member is uniquely valuable. On the previously referenced blender example, you may have both an engineer's perspective and a stay-at-home mother who has had practical, hands-on experience with many such appliances. Both your input and her input are essential to a successful FMEA.

Appreciate your equality within the team. By definition, a team is not hierarchical. In order to encourage participation, it is essential that every member be made aware that he or she is just as important as the next member. Even the team leader's role is that of a facilitator/coordinator rather than final decision-maker.

Treat each other with respect and consideration.
Listen to each other
Never disparage somebody else's ideas/ input
Encourage those less vocally inclined to participate
Vote on issues where there is no consensus

In anticipation of potential split vote situations, the team as a whole may decide to appoint someone as final arbiter. The selected arbiter should be the individual most familiar with the object of the FMEA, e.g., the product or process expert.

If product/ process experts on the team become very defensive and disrupt the team, they should be replaced. For many, it is difficult to listen to others criticizing their work without defending themselves.
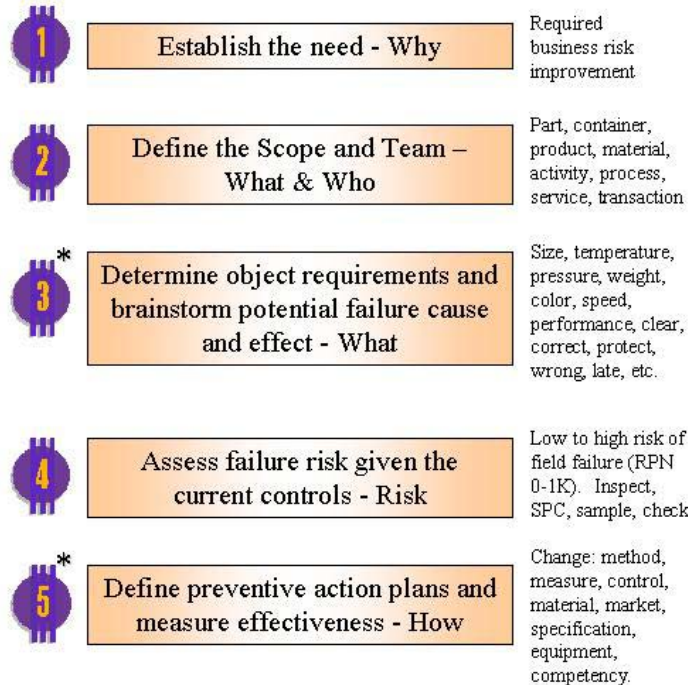
Now that you understand the basic steps involved in preparing to conduct FMEAs, you're ready to actually begin the process. *The next lesson will show you how to both gather and develop preliminary data.*

LESSON 3: Gathering and Developing Preliminary Data
In Lesson 2 we reviewed the steps leading up to a FMEA. Now you will begin the actual analysis by studying all existing product/process information and then generating new data of your own

FMEA Process Flow Chart
Compliments of QualityWBT.com Training Center

1	Establish the need - Why	Required business risk improvement
2	Define the Scope and Team – What & Who	Part, container, product, material, activity, process, service, transaction
3 *	Determine object requirements and brainstorm potential failure cause and effect - What	Size, temperature, pressure, weight, color, speed, performance, clear, correct, protect, wrong, late, etc.
4	Assess failure risk given the current controls - Risk	Low to high risk of field failure (RPN 0-1K). Inspect, SPC, sample, check
5 *	Define preventive action plans and measure effectiveness - How	Change: method, measure, control, material, market, specification, equipment, competency.

* High risk and important step

A. Review All Available Products/Process Information
In the previous lesson we made a blender's glass pitcher and lid the focus of a hypothetical FMEA. To expand on that example, your first task would be to learn everything there is to know about the product or process. Having detailed customer requirements and/or specifications is essential. Potential failure modes (possibilities) may be highly dependent on the environment (i.e. hot or cold) and conditions of product use. Potential failure modes may be different if the blender pitcher is used by one person in a home or by numerous bartenders blending frozen drinks in a semi-dark cabana bar.

Rather than study the actual product, for a process FMEA you must obtain a detailed description of the process steps and activities. The Process Expert should be questioned and any available information on similar processes reviewed. Data from existing or similar processes would include:

• nonconformance report	• equipment failure
• unscheduled outages	• excess shipping charges
• customer complaints	• design changes
• improvement projects	• process capability

For out-sourced materials and services, purchasing should be contacted for monitoring information relevant to the scope of the FMEA. Team members should be assigned the responsibility for collecting

and analyzing data prior to the meeting. For simple products and processes, it may be obvious what all Potential Failures Modes might be.

For more complex products and processes, data review and analysis may take more time to ensure essential information has been collected. For example, a team is assigned to develop the process FMEA for technical support of a new software release. The team might review results from: previous software releases for volume of phone calls or contacts, frequently asked questions, caller language requirements, time of contacts, length of contacts, unsatisfied callers, training of support personnel, changes made to the technical support system, and equipment operability. In some cases, data may not already be available so part of the team's responsibility will be to collect data in order to do a thorough FMEA.

B. Put it in a Picture – Describe the Object of the FMEA

For Design FMEAs (new or changed product), the FMEA should **start off with a diagram** of the focus of the analysis. For the blender example, it would be a diagram of the blender top with dimensions and specifications (required materials, energy, disposal). Perhaps a simple flow diagram showing the manufacturing step of resin being fed to the extruder and lids coming out onto the conveyer belt. The description of the object or process probably already exists as an engineering drawing and/or specification sheet. Diagrams are especially important for process industries that put liquid, solids and gaseous products in containers.

The description documents for the blender may look something like the image below.
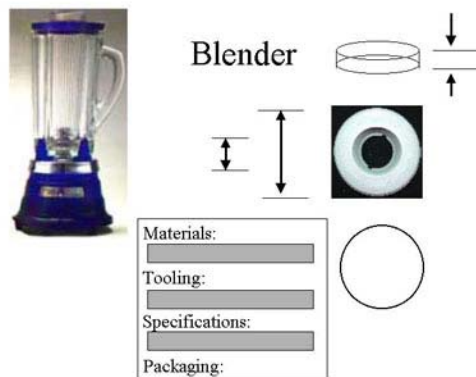
For Process FMEAs (new or changed processes), the FMEA begins with a flow chart. A process transforms inputs into outputs. The flow chart can be sequential steps in outline form or you can use standard flow chart symbols. A flow chart is excellent material for the FMEA kick-off meeting.

C. Develop an FMEA Worksheet

Before brainstorming for Potential Failure Modes, your team needs to prepare a document that will facilitate the process of collecting, organizing, and interpreting data. The FMEA Worksheet incorporates all essential information regarding the FMEA, including:
- A list of the items under analysis
- Potential Failure Modes for each item
- Potential Effects and Causes of each failure mode
- Severity, Occurrence and Detection Ratings
- A Risk Priority Number or RPN
- Recommended Action and assignment of Responsibility
- Action Results and new RPN

Your organization may already have a form that will be similar to one used in class. The FMEA worksheet is a place to keep a record of your analysis and actions taken. In the blender example, a Potential Failure might be warping of the plastic lid due to extreme temperatures (Potential Cause.) A Potential Effect is that the contents of the pitcher could spill out when the blender is running.

The following steps will take place to conduct the FMEA process. The FMEA scope (lid) and team will be defined. The potential failure (warping) cause and effects are brainstormed. The probability of occurrence and risk of undesirable outcomes such as user injury due to hot liquid spilling on the blender user are estimated. Next, the team may make recommendations such that more temperature-resistant polymer be used for the lid and assign responsibility for the action to Jim Cook (Engineering). The last step in the process is for the team to follow-up on the corrective measures, and estimating a new risk level (RPN) to the organization. The new risk level (RPN) should be considerably lower than the original.
If we were to flow chart the FMEA process is would look like the following image:

FMEA Preventive Action Cycle
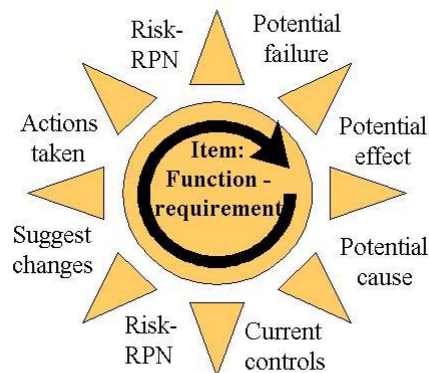
D. Brainstorm on Potential Failure Modes
Once everybody shares an in-depth understanding of the product/process, you are is ready to begin generating a list of potential failures. A brainstorming session is an excellent means of obtaining a wide range of insights in a relatively short period of time, but a few simple guidelines can enhance productivity.

To make sure the output from brainstorming is comprehensive, address each product characteristic or process flow step individually. List the characteristic or requirement in Column 1 on the FMEA form. For our blender example, have a good seal is a product requirement. Next, brainstorm the potential failure modes (what could go wrong) on a piece of paper or use the on-line student notebook. This is a *critical* step in the FMEA process and therefore has high risk. If too few potential failures are listed, the FMEA will not be comprehensive and its utility and value to the organization will be limited. Requirements not specified by your organization or the customer, yet known to you as an expected but not stated requirement (or specific performance), must be included too. When all ideas have been exhausted for requirements and potential failures, your team should review them for relevance.

At this point the team may eliminate any entries that appear to be unsubstantiated and group the remainder. If any potential failure modes are not valid, they will be eliminated as a natural part of the following steps. However, if a potential failure mode is overlooked or eliminated too early in the process there could be serious consequences if a potential safety hazard, performance requirement, or environmental risk is not addressed.

Potential failures may be grouped according to:
>**Failure Type** - Is the failure mechanical, electrical or one that could be created by the user?
>**Failure Location** - Where did the failure occur?
>**Seriousness of the Failure** - If the failure occurred, how grave would be the consequences?
>**Process step** – For process FMEAs, potential failures are usually grouped together for each process step and keyed to the process flowchart.

Once grouped, Potential Failures should be transferred to the FMEA Worksheet (column 2, Exhibit E). Refer to columns 1-2 of the FMEA form of the blender example.

E. Potential Effects

Potential Effect (column 3, Exhibit E) is the possible outcome of any given failure and it is essential to assessing the failure's seriousness. In our pitcher lid FMEA example, cracking or chipping around the pitcher's mouth could lead to the potentially life-threatening problem of ingested glass. In this section of the FMEA Worksheet, you should state that at least one Potential Effect of cracked/chipped glass will directly affect consumer safety. You should also note whether the failure would violate any product regulations, such as industry standards for using tempered glass in certain applications.

A final consideration in reviewing Potential Effects, is how the failure could impact the operation of other system components: When all Potential Effects are listed for each Failure Mode, they should also be incorporated in the FMEA Worksheet.

You should also consider potential interactions between product characteristics or process steps too. For example, in a chemical process, the overcharge of an ingredient in one process step may not only result in a problem for that specific step, but if combined with a faulty test result at another stage of the process, it may have additional potential effects. Evaluating a series of "what if" scenarios is an important function of the FMEA process. Most failure investigations show the failure resulted from multiple process/product failures. A function of the FMEA is to anticipate and design for these simultaneous or interactive effects.

Lesson 4: Determining Severity-Occurrence-Detection Ratings
In the last lesson, we collected, generated, and sorted data. We will now review ways to analyze and prioritize that information.

A. Defining the Ratings
Severity, Occurrence and Detection ratings are measures for prioritizing potential failures. One might think of it as a formal guessing process. Guessing about the occurrence of something is not that far fetched and can be pretty accurate. We are using our knowledge and intuition to predict the future. These type of observations are very valuable to an organization. For example you may take a walk in the Park and not know the wind direction in degrees nor the speed in knots, but you do know there was a breeze coming from the South.

A Severity Rating is an assessment of the relative seriousness of a potential effect (Column 4) should the failure occur. It is important to note that any given failure may have several effects and each effect should receive a Severity Rating. In estimating the severity of an effect, you should consider data from past company experiences, as well as drawing from your own expertise and common sense. The Severity Rating for the most serious effect is later used to calculate the RPN for a given failure mode. For our blender lid, the spill effect was rated a #5 (see FMEA form).

Next, the potential cause (column 5) can be entered on to the FMEA form. This statement should be very precise. Add the potential causes or causes. For our bender lid example the potential cause was listed as 'high mold temperature.'

An Occurrence Rating (column 6) focuses on the likelihood a potential cause will occur and the frequency with which it will happen. Once again, any existing data should be reviewed to help determine the Occurrence Rating. For our blender lid example, high mold temperature could occur monthly so it was given an occurrence rating of #7.

If there are current controls, the controls should be categorized as either prevention controls or detection controls. Prevention controls prevent the failure mode from occurring, increase the likelihood of detection, or reduce the rate of occurrence.

The next step is to fill in the measures being used to control the potential cause as either prevention and/or detection (column 7a and 7b). You need to identify the controls (if any) that are currently in place. In situations where there are no controls, the chances of discovering a failure or effect are generally poor and a high detection rating should be assigned. A high detection rating corresponds to a high likelihood the failure would not be detected. Prevention controls are usually the most effective and should result in the lowest detection ratings (see examples on Lesson 4, page 4). For our blender example, we listed high temperature alarm and inspection as preventive controls

Detection controls are used to detect or measure for failures after the fact. The use of only detection controls often leads to higher detection ratings, so the use of prevention controls is the preferred approach. During the preparation of the Design FMEA it is very important to review whether controls are preventive or detection. The design stage is the best time to identify the use of Prevention controls and ensure they become part of the process. For our blender example, we listed testing roundness on every 20th lid as a detection control.

A Detection Rating (column 8) assesses the likelihood a failure or the effect of a failure will not be discovered during development or production (prior to service or product release.) To this end, you need to review the controls (if any) that are currently in place. In situations where there are no controls, the chances of discovering a failure or effect are generally poor and a high detection rating would therefore be assigned. A high detection rating corresponds to a high likelihood the failure would not be detected.

B. Risk Priority Numbers

A Risk Priority Number (RPN) is a valuable means of quantifying risk for each failure mode based on the product of its Severity, Occurrence, and Detection Ratings.

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

The RPN (column 9) will always be between 1 and 1000 and represents the baseline RPN for the specific potential failure and cause.

Customers and the company can set targets or specifications for RPN's. A customer may require the RPN for critical product features to be less than 70, for example. Or a company may set a guideline that any item with an RPN over 200 must be addressed with a preventive action plan. You should know your organization's RPN targets and action levels.

The Total RPN for the FMEA is the sum of all the RPN's. The baseline total RPN can be compared to future total RPNs to assess the effectiveness of subsequent preventive actions.

Lesson 5: Preventing Problems
The previous lessons have provided you with an understanding of the purpose and procedures involved in conducting an effective FMEA. This learning culminates with the FMEA's ultimate goal, eliminating the potential problem(s).

A. Recommended Action
Once potential failures have been identified and prioritized, it is essential that your team provide a realistic and clearly defined solution for each problem (column 10, recommended actions). Team consensus should not be problematic in situations where a given potential failure has only one obvious and practical preventive action. If there appear to be several different opinions or should there be questions regarding action feasibility, it is advisable that the team:
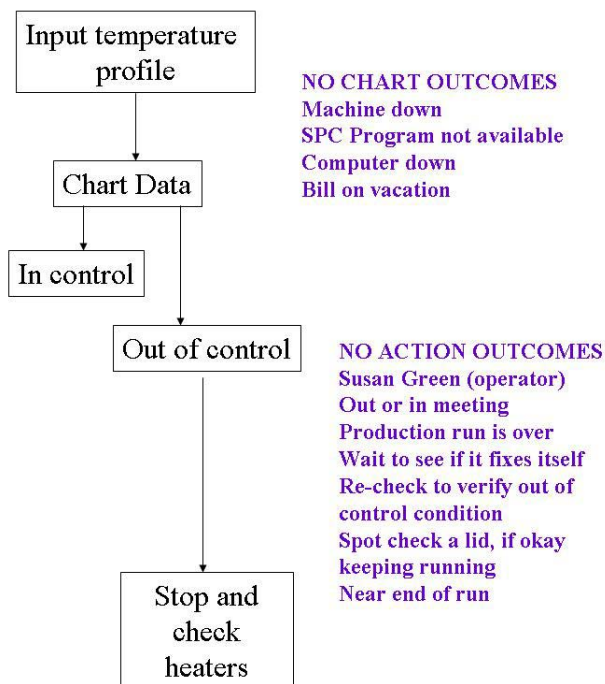
> Depending on the scope of the FMEA, the team may not have the authority to implement or "pick" the final solution. The scope may be limited to recommending potential solutions. There may be constraints on potential solutions, such as cost, customer acceptance, technical limitations, or patent restrictions that would require far more investigation. Your organization's preventive/ corrective action methods should be employed to address the cause of the failure.

B. Expect the Unexpected: Mistake Proofing
If the team has the authority to take action, the team should mistake proof (also called error proofing) or seek the solution to render a potential problem invulnerable to failure. Mistake proofing should be the standard, particularly in situations where a failure could have either serious consequences or a high likelihood of occurrence. In the case of an iron used to press clothes, a good example of mistake proofing is an automatic turn-off feature. This feature counteracts the potential problem of the iron being left on accidentally - *a potential problem that is both likely to occur and could have severe consequences such as consumer injury and/or fire*. Mistake proofing (error proofing) is about expecting the unexpected**.**

In many cases, mistake proofing is utilized when safety or regulatory issues must be addressed. Mistake proofing can ensure 100% compliance and reduce risk to the organization and individuals. For example, presses are designed so that two hands are needed to operate the press to eliminate injuries. Mistake proofing for a product is evaluating the possible methods it may be used to identify probable failures (unexpected outcomes). The automotive industry focuses on using mistake proofing to prevent nonconforming product, but it can also result in improved productivity and efficiency.

Mistake Proof SPC Steps

Input temperature profile

↓

Chart Data

↓

In control

↓

Out of control

↓

Stop and check heaters

NO CHART OUTCOMES
Machine down
SPC Program not available
Computer down
Bill on vacation

NO ACTION OUTCOMES
Susan Green (operator)
Out or in meeting
Production run is over
Wait to see if it fixes itself
Re-check to verify out of control condition
Spot check a lid, if okay keeping running
Near end of run

Mistake proofing is a companion of FMEA. On the FMEA form we included a potential wrong lid problem due to picker error. A mistake proofing technique may be to color code boxes for certain blender models or bar code all parts and require computerized matching before release. Mistake proofing is very useful for services. Mistake proofing should be part of the final validation step for all processes and services to ensure productivity objectives will be achieved.

Mistake proofing for a process/ service is evaluating the sequence and interaction of performance steps to identify probable failures (unexpected outcomes). A probable failure is when the process does not proceed in the intended (planned) sequence.

For our blender lid example, requiring SPC may not be enough. It is very possible that SPC could be utilized but not address the potential failure. Review the flow chart to see the possible outcomes that need to be mistake proofed to ensure the solution is effective?

C. Assign Responsibility for and Follow Up on Recommended Action

In lesson 2, we discussed the need to establish boundaries for an FMEA. This process included a definition of the team's breadth of responsibility as issued by Management. A team may be responsible for anywhere from one to all of the following:

- Conduct the analysis
- Make recommendations for improvement (Column 10)
- Assign and Implement the improvements.(Column 11 and 12)

Regardless of whether the team or another party will implement the improvements, it is important to keep in mind any time constraints and/or deadlines to which the work is subject. The Work Order Form should provide this information (remember lesson 2.)

As the deadline draws near, the team should ensure that satisfactory progress is being made. Once again, the Work Order Form provides guidelines for seeking extensions if additional time is required. The FMEA is a "living" document that must be kept up-to-date. As the product or process change, customer requirements change, or knowledge of the product or process changes, the FMEA should be reviewed to insure it is still valid. The original team may be responsible or management may re-convene another team. Responsibility for maintaining the FMEA should be clearly defined in the FMEA Work Order.

D. Re-evaluate Risk

The final step in conducting an FMEA - after the analysis is conducted and improvements are made - is to evaluate the effectiveness of the preventive action and to evaluate the effects of the change on any other part of the process or product. The entire FMEA should be reviewed to ensure that the change(s) does not have negative effects on any other part of the process or product. For example, a change in the

machine controls could cause more nonconformances due to multiple machine starts and stops. Or if a different resin material was used that made the blender lid more resistant to warping, the change could also cause the lid to discolor in the dishwasher or be more susceptible to manufacturing defects. Evaluating the effectiveness of the preventive action involves determining new ratings for severity, occurrence and detection and calculating a resulting RPN (column Final). As you recall, the RPN is the product of the three ratings (RPN = Severity x Occurrence x Detection.

If the product has been significantly improved, the new RPN should meet or exceed the customer guideline or company guideline for acceptable RPN. The team may set a target for a reduction in the RPN, such as the RPN should be at least 50% lower than the original.

Consider the following guidelines when seeking to lower the RPN number:

- The severity rating usually doesn't change much.
- The occurrence rating may be reduced to one if mistake proofing safeguards are implemented.
- Detection controls may be easy to improve and will result in a lower detection rating

For our example refer to the FMEA form (Exhibit E) to view the new RPN.

Keep in mind that improvement is critical when a potential failure has a high severity rating, even if the likelihood of the failure actually occurring is fairly slim. Conversely, a problem with even a low severity rating but a high chance of occurrence should also receive a much lower, new RPN

Conclusion:
Use of FMEAs and Mistake Proofing are valuable preventive action tools. The use of the tools reduces risk to organization by anticipating potential problems rather than waiting on a potential crisis. No only is risk reduced, but FMEAs and Mistake Proofing can differentiate your organization from your competition and give you an edge in the market place.

Exhibit A
SEVERITY RATING SCALE

Rating	Description	Definition
10	Dangerously high	Failure could mean physical injury to the user or an employee
9	Extremely high	Failure would result in violation of federal regulations
8	Very high	Failure makes the product/process inoperable or unserviceable
7	High	Failure would result in significant customer dissatisfaction
6	Moderate	Failure would cause partial breakdown in the product/process
5	Low	Failure's impact on product/process performance would be sufficient to generate complaints
4	Very Low	Failure would result in minor performance loss
3	Minor	Failure is a small nuisance but does not result in performance loss
2	Very Minor	Failure may have such minor consequences thus is unlikely to be apparent
1	None	Failure would not be noticed or affect the product/process

Exhibit B
OCCURRENCE RATING SCALE

Rating	Description	Potential Failure Rate
10	- Exceedingly High - Failure practically inevitable and very frequent	Failures happening more than once/day or a probability of more than three occurrences in ten events
9	- Very High -	Failures happening every three to four days or a probability of three occurrences in ten events
8	- High - Frequent failures	Failures happening once/week or a probability of five occurrences in 100 events
7	- Relatively High -	Failures occurring once/month or one occurrence in 100 events
6	- Moderate - Infrequent failures	Failures occurring once every three months or three occurrences in 1,000 events
5	- Relatively low -	Failures happening once every six months to one year or one occurrence in 10,000 events
4	- Low -	Failures happening once/year or six occurrences in 100,000 events
3	- Very low - Few failures	Failures happening once every one to three years or six occurrences in ten million events
2	- Relatively Remote -	Failures happening once every three to five years or two occurrences in one billion events
1	- Remote -	Failures occurring once in more than five years or less than two occurrences in one billion events.

Exhibit C

<u>DETECTION RATING SCALE</u>

Rating	Description	Definition
10	Complete Uncertainty	Product is either not inspected or the effects of failure are not detectable
9	Very Uncertain	Product quality control is based on Acceptable Quality Level (AQL) sampling plans
8	Uncertain	Product is accepted if the sample shows no defectives
7	Very low	Product undergoes 100% manual inspection
6	Low	Product undergoes 100% manual inspection using go/no-go or other mistake-proofing gauges
5	Moderate	Product is final inspected off-line and some Statistical Process Control (SPC) is used
4	Relatively High	Product undergoes SPC and there is swift reaction to undesirable conditions
3	High	Product is subject to an SPC program with process capabilities greater than 1.33
2	Very High	All product is 100% automatically inspected.
1	Almost Uncertain	There is 100% automatic inspection with excellent maintenance of the inspection equipment or the defect is obvious.

Exhibit D

Exhibit D: FMEAs Ideas Table

Column 1		Column 2		Column 3	
Requirement/ Function/ Characteristic/ Performance		Potential Failure (Physical or Technical terms)		Potential Effects	
Access	Latch	Abraded	Late	Claim	No Odor
Accurate	Legal	Bent	Leak	Communication	Noise
Activity	Level	Binding	Loose	Complaint	Noisy
Anchor	Load	Blockages	Lost	Damaged	Odor
Capable	Luster	Broken	Mildewed	Danger	Poor appearance
Capacity	On-time	Burred	Miss-marked	Doesn't work	Poor Feel
Clarity	Placement	By-passed	Missing	Early failure	Premature failure
Clear	Polish	Closed	Mold	Environmental	Re-do
Color	Pressure	Communication	No markings	Erratic	Return
Communication	Protection	Corrode	Not enough	High	Rework
Contact	Purity	Cracked	Open	Illegal	Risk
Correct	Rate	Damaged	Oxidized	In-operative	Rough
Cover	Refraction	Decayed	Rot	Increase costs	Safety risk
Credentials	Regulator	Deformed	Rub off	Increase risk	Silent
Damage free	Report	Dented	Rusty	Injury	Small
Dimension	RPMs	Early	Short-circuited	Large	Strong
Dissolves	Size	Eligible	Skipped	Late	Unreliable
Distributed	Strength	Eroded	Slip	Low	Unsafe
Ease of use	Support	Evaporate	Spoiled	Misfire	Unstable
Egress	Surface	Fall	Sticky	Noncompliant	Weak
Error free	Temperature	Fatigue	Too big		
Even application	Tint	Fractured	Too much		
Finish	Transport	Frayed	Too small		
Force	Volume	Freeze	Uneven coverage		
Hardness	Weight	Fret	Waiting		
Honest	Yield	Ground	Warped		
HP		Holding	Wear and tear		
In-control		Holes	Weathered		
Informed		Improper Set-up	Wilting		
		Inaccurate	Worn		
			Wrong placement		
			Wrong size		

Exhibit E
FMEA WORKSHEET

Process/Product:	Blender Lid									*FMEA Number:*	**Y0219MFG**					
FMEA Team:	Lucy Brown, Rob Lowman, Mario Gonzalez, Jane Silver									*Date Opened:*	Feb 19, 20XX					
Team Leader:	John Wright									*Date Closed:*						

1	2	3	4	5	6a	7	6b	8	9	10	11	12	Final			
Item/ requirement function characteristic	Potential Failure (fail to meet design/ process intent)	Potential Effects	Severity	Potential Cause	Current Controls Prevention	Occur.	Current Controls Detection	Detect.	RPN	Recommended Action	Party in charge / date due	Action Taken	Severity	Occur.	Detect.	New RPN
Blender lid -seal	Lid warps	Leaks and spills while operating	5	High mold temperature	-high temp alarm -calibration check every setup	7	Visual inspection	2	70							
							Test roundness on every 20th lid	9	315							
		Lid will not fit	8	High mold temperature	-high temp alarm -calibration check every setup	7	Visual inspection Test roundness on every 20th lid	2	108*	Monitor machine temp profile using SPC	Green 4/1/xy	Online SPC	8	5	2	80
- lid fits blender model	Wrong blender lid	Lid not useable	8	Picker selects wrong lid	- training	4	Final visual check at packing	8	256	Use bar code to pick lid	Green 9/1/xy	Bar code system implemented	8	1	8	64

* The SOD for this example would be 872