FMEA (for Business Processes) Reference Guide

FMEA Training for Business Processes

Computer-Based Training Program

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from

Resource Engineering, Inc.

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FMEA Training

Failure Mode and Effects Analysis (FMEA) techniques have been around for over 50 years. In recent years, use of FMEAs has gained popularity as a quality improvement tool. This interest is in large part due to the automotive industry and specifically its IAFT 16949 supplier requirements. Other major industries, including aerospace, medical products and electronics are also using FMEA techniques as part of their improvement and risk assessment strategies.

Unlike many quality improvement tools, FMEAs do not require complicated statistics. FMEA studies can yield significant savings for a company as well as reduce the potential liability of a process or product that does not perform as promised.

FMEAs do take time and resources. Because the foundation of FMEAs is the input of team members, several people are typically involved in these studies. Proper training enables team members to work efficiently and effectively through the FMEA process. The ***FMEA Training*** course is a time- and cost effective alternative to seminars and workshops. The training program walks learners through Process-FMEAs in a step-by-step fashion. Additional training topics include the relationship between FMEAs and quality standards (such as ISO 9000, JCAHO (healthcare), GMP (FDA), HACCP (meat, poultry, and seafood processing), guidelines for customizing FMEA ranking scales, and how FMEAs can be linked to Control Plans.

The ***FMEA Reference Guide*** is a companion guide to the ***FMEA Training*** course. In addition to a recap of the main points in the ***FMEA Training*** course, you will also find copies of worksheet formats used to conduct an FMEA and examples of Custom FMEA Ranking Scales in the Appendices.

Planning Your FMEA Training

The ***FMEA Training for Business Processes*** course consists of two units:

1. FMEA Overview
2. Process-FMEAs

In Unit 1, FMEA Overview, the purpose of FMEAs is explored. The methodology for conducting FMEAs is looked at, the difference between Design-FMEAs and Process-FMEAs is examined and the importance of using a team to conduct FMEAs is discussed.

Unit 2 (Process-FMEAs) is a step-by-step tutorial on how to conduct a PFMEA. The unit starts with a lesson on tips for defining the scope of study for the PFMEA. The 10-steps for a PFMEA are worked through in a step-by-step fashion. Suggestions complete with examples on how to customize the critical ranking scales for Severity, Occurrence and Defection (Control) are included. A lesson showing how a PFMEA is linked to Control Plans follows. The wrap-up lesson is a sample PFMEA.

Unit 1: FMEA Overview

Lesson 1 **What is an FMEA?**	• An overview of what an FMEA is; how the FMEA process works; and why an FMEA is used.
Lesson 2 **The Purpose of an FMEA**	• An explanation of how an FMEA helps identify risks, prioritizes the risks relative to one another, and focuses efforts on an action plan to reduce the risks.
Lesson 3 **FMEAs & Quality Standards**	• Understand how FMEAs and Quality Standards (such as ISO 9000) are linked. • Be aware of guidelines in Quality Standards that refer to the use of FMEAs.
Lesson 4 **Preparation for and FMEA**	• Prepare for conducting an FMEA by: • Developing (or selecting existing) custom ranking scales. • Defining the scope. • Assembling data about the process inputs & outputs. • Identifying detection and prevention control points.
Lesson 5 **The FMEA Process**	• A preview of the 10 steps used to conduct an FMEA.
Lesson 6 **Assembling an FMEA Team**	• Helpful hints on assembling an effective FMEA team.
Challenge	• An assessment of the learner's progress in this unit.

Unit 2: Process-FMEAs

Lesson 1 **Process-FMEA Scope**	• How to clarify the scope for a PFMEA. • Details on how to use the PFMEA Scope Worksheet.
Lesson 2 **10 Steps to Conduct a PFMEA**	• Step-by-step directions on conducting a PFMEA. • Guidance on the use of the FMEA Analysis Worksheet. • Techniques for customizing the Severity, Occurrence, and Detection Ranking Scales for a PFMEA.
Lesson 3 **PFMEAs & Control Plans**	• Using the PFMEA Analysis to develop a proactive Control Plan.
Lesson 4 **Getting More Out of Your PFMEA**	• Tips on the best times and places to conduct a PFMEA. • Tips on how to use the results of an FMEA to trigger continuous improvement.
Lesson 5 **PFMEA Example**	• An example of the application of a PFMEA, working through all 10 steps.
Challenge	• An assessment of the learner's progress in this unit.

Unit 1 Objectives
FMEA Overview

❑ In this unit you will gain a basic understanding of the purpose, format, and application of FMEAs. Upon completion of this unit you will be able to:

- Explain the purpose of conducting an FMEA.
- Describe the link between FMEAs and quality standards.
- Explain the methodology of the FMEA process.
- Assemble an FMEA team.

Unit 1, Lesson 1: Introduction

- ❑ FMEA means Failure Mode and Effects Analysis.
  - Every process (or product) has modes of failure.
  - The effects represent the impact of the failures.
- ❑ An FMEA is a tool to:
  - Identify the relative risks designed into a product or process.
  - Initiate action to reduce those risks with the highest potential impact.
  - Track the results of the action plan in terms of risk reduction.

Unit 1, Lesson 2:
Purpose of an FMEA

- ❑ FMEAs help us focus on and understand the impact of potential process (or product) risks.
- ❑ A systematic methodology is used to rate the risks relative to each other.
  - An RPN, or Risk Priority Number, is calculated for each failure mode and its resulting effect(s).
- ❑ The RPN is a function of three factors: The **Severity** of the effect, the frequency of **Occurrence** of the cause of the failure, and the ability to **Detect** the failure or effect.
  - The RPN = The Severity ranking X the Occurrence ranking X the Detection ranking.
  - The RPN can range from a low of 1 to a high of 1,000.
- ❑ Develop an Action Plan to reduce risks with unacceptably high RPNs.
- ❑ Use FMEAs as the basis for Control Plans. Control Plans are a summary of proactive defect prevention and reactive detection techniques.

Unit 1, Lesson 3:
FMEAs & Quality Standards

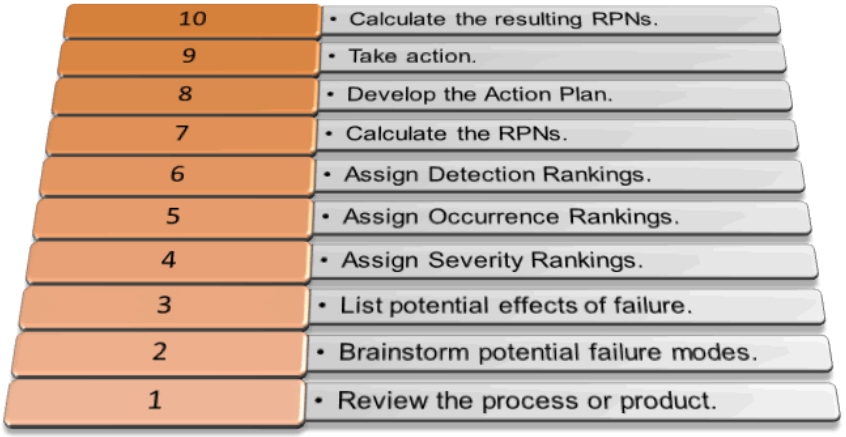
- ❑ FMEAs are widely used as risk assessment and problem prevention vehicles in quality standards.
  - For example, ISO 9000, the generally accepted international standard for defining the requirements and expectations of an overall quality system, recommends the use of FMEAs.
  - Other quality standards such as JCAHO (healthcare), GMP (FDA), HACCP (meat, poultry, and seafood processing), AS-9100 (aerospace industry) and IAFT 16949 (automotive industry) also suggest, or in some cases, mandate the use of FMEAs.
- ❑ The intent of the ISO 9000 Quality System is to ensure the fundamental elements are in place and are consistently used to make processes predictable, properly targeted and reliable.
  - Reliable, predictable processes that are properly targeted lead to customer satisfaction.
  - As Operating Procedures and Work Instructions are updated, use FMEAs to help assess risks to planned changes.

Unit 1, Lesson 4: Preparation for an FMEA

- ❑ Develop FMEA Ranking Scales:
  - FMEAs use scales to rank the severity, occurrence, and detection level for each failure mode and its corresponding effects. The ranking scales should be customized for your organization
  - Create the scales BEFORE starting the FMEA & use the same scales for all FMEAs conducted.
- ❑ Define the scope to be studied:
  - There is more to defining the scope of an FMEA study than selecting the process to be evaluated.
  - What is the process to be studied? Should an FMEA be conducted on the entire process or should only some process steps or components be studied? What about support systems?
  - Identifying the customers of a process is not always as straightforward as it may seem. While the end user must always be considered as the ultimate customer, the next step in a chain of processes is a customer, too.
- ❑ Assemble process data (inputs & outputs):
  - Inputs can include process flowcharts, procedures, and specifications for input materials. A process flowchart (or Value Stream Map if one exists) is a foundation document for conducting FMEAs.
  - Since an FMEA is about identifying and prioritizing risks from potential failures and the effects of those failures, (output) data on process failures is needed. Data on output failure rates such as call center trouble tickets, invoice error logs, customer complaint records and internal rework reports will all be helpful to the FMEA team.
- ❑ Identify process control points:
  - Control points can be either problem detection or problem prevention controls. It's important for the FMEA team to know about the controls built into the process.
  - Controls, especially those intended to prevent problems, may get missed in the study unless the team is aware of their existence. After all, if they are working well, then you probably won't see them.

Unit 1, Lesson 5:
The FMEA Process

- ❑ There are 10 steps to the FMEA process. Both DFMEAs and PFMEAs use the same basic 10 steps.



- ❑ Teams, not individuals, conduct FMEAs.
  - The skills and experience of a balanced team are needed to successfully complete an FMEA.
- ❑ The FMEA process involves the use of several forms including:
  - FMEA Team Start-Up Worksheet
  - FMEA Scope Worksheet
  - FMEA Analysis Worksheet
- ❑ The FMEA process results in the assignment of risk priority numbers (RPNs) to each potential failure. Target failures with the highest RPNs for improvement.
- ❑ A Control Plan is a natural extension of an FMEA, even though it is not considered officially a part of an FMEA.

Unit 1, Lesson 6:
Assembling an FMEA Team

- ❑ FMEAs should always be conducted by teams.
- ❑ The best size for an FMEA team is 4 to 6 people, carefully selected, based on the contribution they can make to the specific FMEA.
- ❑ An FMEA team should represent a cross-section of the company in terms of functional responsibility and level in the organization. Team members typically come from:

• Operation	• Customer Service
• Materials/Purchasing	• Sales & Marketing
• Finance	• Quality
• Tech Service	• Customers
• Suppliers	

- ❑ FMEA team members do not necessarily need to have extensive knowledge of the design or process being targeted. In fact, sometimes it helps to get an outsider's fresh perspective.
- ❑ The FMEA team needs a leader to help set up and facilitate meetings, to ensure the team has the necessary resources, and to make sure the team is progressing toward completion of the FMEA.

Unit 2 Objectives
Process-FMEAs

- In this unit you will learn everything you need to know to conduct Process-FMEAs. Upon completion of this unit you will be able to:
  - Clarify the scope of a PFMEA.
  - Work through the 10 steps of a PFMEA.
  - Develop custom ranking scales for Severity, Occurrence, and Detection.
  - Determine which technology tools to use as aids in your PFMEA action plan.
  - Link the PFMEA to a Control Plan.
  - Learn how to make the PFMEA into a living document.

Unit 2, Lesson 1:
Process-FMEA Scope

- ❑ Defining the scope for a PFMEA can be more difficult than for a DFMEA because a process often has more elements to cover than a design.
- ❑ Your PFMEA team will be most effective when the scope of the FMEA is well-defined.
- ❑ The PFMEA Scope Worksheet provides your team with the necessary information to clarify and fully understand the scope of the study.
- ❑ If the scope of a PFMEA seems too big, your team should consider breaking it up into two or three complementary studies.
- ❑ Once your FMEA team has defined the scope of the PFMEA, use the FMEA Team Start-Up Worksheet. The worksheet will help clarify roles and responsibilities and define boundaries of freedom for the team.

PFMEA Scope Worksheet	
Process:	
Date:	
Scope defined by:	
1	What process components are to be included in the investigation?
2	Who is the customer?
3	What process support systems are to be included in the study?
4	To what extent should input materials be studied?
5	What are the product material requirements & constraints?
6	Should packing, storage & transit be considered part of the study?

Unit 2, Lesson 2:
10 Steps to Conduct a PFMEA

Step 1: **Review the process—Use a process flowchart to identify each process component.**

Step 2: **Brainstorm potential failure modes—Review existing documentation and data for clues.**

Step 3: **List potential effects of failure—There may be more than one for each failure.**

Step 4: **Assign Severity rankings—Based on the severity of the consequences of failure.**

Step 5: **Assign Occurrence rankings—Based on how frequently the cause of the failure is likely to occur.**

Step 6: **Assign Detection rankings—Based on the chances the failure will be detected prior to the customer finding it.**

Step 7: **Calculate the RPN—Severity X Occurrence X Detection.**

Step 8: **Develop the action plan—Define who will do what by when.**

Step 9: **Take action—Implement the improvements identified by your PFMEA team.**

Step 10: **Calculate the resulting RPN—Re-evaluate each of the potential failures once improvements have been made and determine the impact of the improvements.**

Step 1: Review the Process

❑ Review the process components and the intended function or functions of those components.

- Use of a detailed flowchart of the process or a traveler (or router) is a good starting point for reviewing the process.

- ❑ There are several reasons for reviewing the process:
  - First, the review helps assure that all team members are familiar with the process. This is especially important if you have team members who do not work on the process on a daily basis.
  - The second reason for reviewing the process is to identify each of the main components of the process and determine the function or functions of each of those components.
  - Finally, this review step will help assure that you are studying all components of the process with the PFMEA.
- ❑ Using the process flowchart, label each component with a sequential reference number.
  - These reference numbers will be used throughout the FMEA process.
  - The marked-up flowchart will give you a powerful visual to refer to throughout the PFMEA.
- ❑ With the process flowchart in hand, the PFMEA team members should familiarize themselves with the process by physically walking through the process. This is the time to assure everyone on the team understands the basic process flow and the workings of the process components.
- ❑ For each component, list its intended function or functions.
  - The function of the component is the value-adding role that component performs or provides.
  - Many components have more than one function.

Step 2: Brainstorm Potential Failure Modes

- ❑ In Step 2, consider the potential failure modes for each component and its corresponding function.
  - A potential failure mode represents any manner in which the component or process step could fail to perform its intended function or functions.

- ❑ Using the list of components and related functions generated in Step 1, as a team, brainstorm the potential failure modes for each function.
  - Don't take shortcuts here; this is the time to be thorough.
- ❑ Prepare for the brainstorming session.
  - Before you begin the brainstorming session, review documentation for clues about potential failure modes.

Step 3: List Potential Effects of Failure

- ❑ Determine the effects associated with each failure mode. The effect is related directly to the ability of that specific component to perform its intended function.
  - An effect is the impact a failure could make if it occurred.
  - Some failures will have an effect on the customers and others on the environment, the facility, and even the process itself.
- ❑ As with failure modes, use descriptive and detailed terms to define effects.
  - The effect should be stated in terms meaningful to product or system performance.
  - If the effects are defined in general terms, it will be difficult to identify (and reduce) true potential risks.

Step 4: Assign Severity Rankings

- ❑ Assign a severity ranking to each effect that has been identified.
  - The severity ranking is an estimate of how serious an effect would be should it occur.
  - To determine the severity, consider the impact the effect would have on the customer, on downstream operations, or on the employees operating the process.
- ❑ The severity ranking is based on a relative scale ranging from 1 to 10.

- A "10" means the effect has a dangerously high severity leading to a hazard without warning.
- Conversely, a severity ranking of "1" means the severity is extremely low.

❑ The ranking scales (for severity, occurrence, and detection) are mission critical for the success of a PFMEA because they establish the basis for determining risk of one failure mode and effect relative to another.

- The same ranking scales for PFMEAs should be used consistently throughout your organization. This will make it possible to compare the RPNs from different FMEAs to one another.
- See Appendix 8 for the "Generic" PFMEA Severity Evaluation Criteria.

❑ The best way to customize a ranking scale is to start with a standard, generic scale and then modify it to be more meaningful to your organization.

- As you add examples specific to your organization, consider adding several columns with each column focused on a topic.
- One topic could provide descriptions of severity levels for operational failures, another column for customer satisfaction failures, and a third for environmental, health, and safety issues.
- See Appendix 11 for examples of Custom PFMEA Ranking Scales. (Examples of custom scales for severity, occurrence, and detection rankings are included in this Appendix.)

Step 5: Assign Occurrence Rankings

❑ Next, consider the potential cause or failure mechanism for each failure mode; then assign an occurrence ranking to each of those causes or failure mechanisms.

❑ We need to know the potential cause to determine the occurrence ranking because, just like the severity ranking is driven by the effect, the occurrence ranking is a function of the cause. The occurrence ranking is based on the likelihood or frequency that the cause (or mechanism of failure) will occur.

- ❑ If we know the cause, we can better identify how frequently a specific mode of failure will occur. How do you find the root cause?
  - There are many problem-finding and problem-solving methodologies.
  - One of the most effective methods is the 5-Whys technique.
  - Once the cause is known, capture data on the frequency of causes. Sources of data may be scrap and rework reports, customer complaints, and equipment maintenance records.
- ❑ The occurrence ranking scale, like the severity ranking, is on a relative scale from 1 to 10.
  - An occurrence ranking of "10" means the failure mode occurrence is very high, and happens all of the time. Conversely, a "1" means the probability of occurrence is remote.
  - See Appendix 9 for the "Generic" PFMEA Occurrence Evaluation Criteria.
- ❑ Your organization may need an occurrence ranking scale customized for a low-volume, complex assembly process or a mixture of high-volume, simple processes and low-volume, complex processes.
  - Consider customized occurrence ranking scales based on time-based, event-based, or piece-based frequencies.
  - See Appendix 11 for examples of Custom PFMEA Ranking Scales. (Examples of custom scales for severity, occurrence, and detection rankings are included in this Appendix.)

Step 6: Assign Detection Rankings

- ❑ To assign detection rankings, identify the process or product related controls in place for each failure mode and then assign a detection ranking to each control. Detection rankings evaluate the current process controls in place.
  - A control can relate to the failure mode itself, the cause (or mechanism) of failure, or the effects of a failure mode.

- To make evaluating controls even more complex, controls can either prevent a failure mode or cause from occurring or detect a failure mode, cause of failure, or effect of failure after it has occurred.
- Note that prevention controls cannot relate to an effect. If failures are prevented, an effect (of failure) cannot exist!

❑ The Detection ranking scale, like the Severity and Occurrence scales, is on a relative scale from 1 to 10.

- A Detection ranking of "1" means the chance of detecting a failure is certain.
- Conversely, a "10" means there is absolute certainty of non-detection. This basically means that there are no controls in place to prevent or detect.
- See Appendix 10 for the "Generic" PFMEA Detection Evaluation Criteria.

❑ We suggest (at least) three different forms of Custom Detection Ranking options be considered. Custom examples for Mistake-Proofing, Gauging, and Manual Inspection controls can be helpful to PFMEA teams.

- See Appendix 11 for examples of Custom PFMEA Ranking Scales. (Examples of custom scales for severity, occurrence, and detection rankings are included in this Appendix.)

Step 7: Calculate the RPN

❑ The RPN is the Risk Priority Number. The RPN gives us a relative risk ranking. The higher the RPN, the higher the potential risk.

❑ The RPN is calculated by multiplying the three rankings together. Multiply the Severity ranking times the Occurrence ranking times the Detection ranking. Calculate the RPN for each failure mode and effect.

❑ Since each of the three relative ranking scales ranges from 1 to 10, the RPN will always be between 1 and 1000. The higher

the RPN, the higher the relative risk. The RPN gives us an excellent tool to prioritize focused improvement efforts.

Step 8: Develop the Action Plan

- ❑ Taking action means reducing the RPN. The RPN can be reduced by lowering any of the three rankings (severity, occurrence, or detection) individually or in combination with one another.
  - A reduction in the Severity ranking for a PFMEA is often the most difficult. It usually requires a physical modification to the process equipment or layout.
  - Reduction in the Occurrence ranking is accomplished by removing or controlling the potential causes.
    - Mistake-proofing tools are often used to reduce the frequency of occurrence.
  - A reduction in the Detection ranking can be accomplished by improving the process controls in place.
    - Adding process fail-safe shut-downs, alarm signals (sensors or SPC), and validation practices including work instructions, set-up procedures, calibration programs, and preventative maintenance are all detection ranking improvement approaches.
- ❑ What is considered an acceptable RPN? The answer to that question depends on the organization.
  - For example, an organization may decide any RPN above a maximum target of 200 presents an unacceptable risk and must be reduced. If so, then an action plan identifying who will do what by when is needed.
- ❑ There are many tools to aid the PFMEA team in reducing the relative risk of failure modes requiring action. Among the most powerful tools are Mistake-Proofing, Statistical Process Control, and Design of Experiments.
  - Mistake-Proofing (Poka Yoke)
    - Techniques that can make it impossible for a mistake to occur, reducing the Occurrence ranking to 1.

- Especially important when the Severity ranking is 10.

- Statistical Process Control (SPC)
  - A statistical tool that helps define the output of a process to determine the capability of the process against the specification and then to maintain control of the process in the future.

- Design of Experiments (DOE)
  - A family of powerful statistical improvement techniques that can identify the most critical variables in a process and the optimal settings for these variables.

Step 9: Take Action

- ❑ The Action Plan outlines what steps are needed to implement the solution, who will do them, and when they will be completed.
- ❑ A simple solution will only need a Simple Action Plan while a complex solution needs more thorough planning and documentation.
  - Most Action Plans identified during a PFMEA will be of the simple "who, what, & when" category. Responsibilities and target completion dates for specific actions to be taken are identified.
  - Sometimes, the Action Plans can trigger a fairly large-scale project. If that happens, conventional project management tools such as PERT Charts and Gantt Charts will be needed to keep the Action Plan on track.

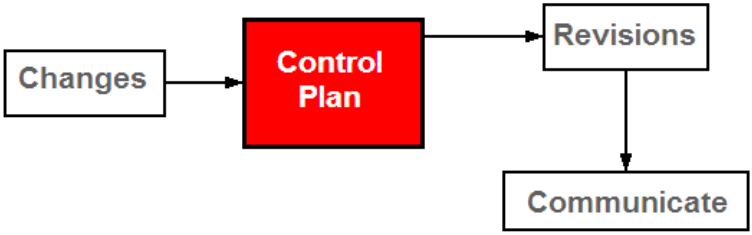
Step 10: Recalculate the Resulting RPN

- ❑ This step in a PFMEA confirms the action plan had the desired results by calculating the resulting RPN.
- ❑ To recalculate the RPN, reassess the severity, occurrence, and detection rankings for the failure modes after the action plan has been completed.

Unit 2, Lesson 3:
Linking PFMEAs & Control Plans

- Control Plans assure a system is in place to control the risks of the same failure modes as identified in the PFMEA. While Control Plans can be developed independently of PFMEAs, it is time and cost-effective to link Control Plans directly to PFMEAs.
- The primary intent of Control Plans is to create a structured approach for control of process and product characteristics while focusing the organization on characteristics important to the customer.
  - A Control Plan does assure well thought-out reaction plans are in place in case an out-of-control condition occurs and provides a central vehicle for documentation and communication of control methods.
  - Special attention is typically given to potential failures with high RPNs and those characteristics that are critical to the customer.
- A Control Plan deals with the same information explored in a FMEA plus more. The major additions to the FMEA needed to develop a Control Plan are:
  - Identification of the control factors.
  - The specifications and tolerances.
  - The measurement system.
  - Sample size.
  - Sample frequency.
  - The control method.
  - The reaction plan.

- ❑ Don’t let Control Plans become static.
  - Just like work instructions, make Control Plans a living document.
  - As changes in product or process characteristics, specifications, measurements systems, sampling, control methods, or the reaction plan are identified, update the control plan.
  - Use the revision as a communication tool to spread the word of the changes to the supply chain.
  - By making the FMEA a living document, you can be sure that potentials for failure are continually being eliminated or reduced.



Unit 2, Lesson 4:
Getting More out of PFMEAs

- ❑ PFMEAs should be conducted:
  - On all new processes.
    - PFMEAs should be conducted throughout the process design cycle beginning in the preliminary design stage.
    - Revise the PFMEA in the pilot process stage, revise again in the final design stage, and finalize the PFMEA in the as-built stage.
  - Whenever a change is to be made to a process.
  - On existing processes.
    - Use the Pareto Principle to decide which processes to work on first.
- ❑ Make your FMEA a living document by adding to it and updating it whenever new information about the design or process develops.
- ❑ FMEAs should be updated when:
  - Product or process improvements are made.
  - New failure modes are identified.
  - New data regarding effects are obtained.
  - Root causes are determined.
- ❑ Link FMEAs to Control Plans.

Unit 2, Lesson 5: Sample PFMEA

- ❑ This lesson takes you through a sample PFMEA; here is the checklist the team used to plan and complete their PFMEA:
  - Complete the PFMEA Scope Worksheet.
  - Complete the Team Start-Up Worksheet.
  - Walk through the process and review the work instructions or job traveler. Flowchart the major steps of the process and then add process substeps to the major steps.
  - Brainstorm ways that the process can fail in terms of quality, safety, and productivity.
  - Determine the effects of the failure modes and assign a Severity ranking to each effect.
  - Identify potential causes of the failure modes and assign an Occurrence ranking to each cause.
  - List prevention and/or detection controls and assign a Detection ranking for each control.
  - Calculate the RPN for each failure mode and effect.
  - Determine which failure modes must be targeted for reduction and develop an action plan to address each item targeted.
  - Execute the Action Plan.
  - Assess the results of the Action Plan by reassigning Severity, Occurrence, and Detection rankings reflecting the improvements made. Recalculate the RPNs.
  - Determine the overall impact of the PFMEA.

List of Appendices

The following 15 Appendices will be useful to FMEA teams and practitioners planning and conducting FMEAs.

1. **FMEA Team Start-Up Worksheet**
2. **Process-FMEA Scope Worksheet**
3. **Generic PFMEA Severity Evaluation Criteria**
4. **Generic PFMEA Occurrence Evaluation Criteria**
5. **Generic PFMEA Detection Evaluation Criteria**
6. **Examples of Custom PFMEA Ranking Scales (5 pages)**
7. **FMEA Analysis Worksheet (2 pages)**
8. **Alternative PFMEA Worksheet**
9. **Glossary of Terms**

Appendix 1
FMEA Team Start-Up Worksheet

FMEA Number: _____ Date Started: _____

Team Members: _____ _____ _____

_____ _____ _____

_____ _____ _____

Date Completed: _____

Leader: _____

Who will take minutes and maintain records? _____

1. What is the scope of the FMEA? Include a clear definition of the process (PFMEA) or product (DFMEA) to be studied. (Attach the Scope Worksheet.)

2. Are all affected areas represented? (circle one)

YES NO Action: _____

3. Are different levels and types of knowledge represented on the team? (circle one)

YES NO Action: _____

4. Are customer or suppliers involved? (circle one)

YES NO Action: _____

Boundaries of Freedom

5. What aspect of the FMEA is the team responsible for? (circle one))

FMEA Analysis	Recommendations for Improvement	Implementation of Improvements

6. What is the budget for the FMEA? _____

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? _____

Appendix 2
Process FMEA Scope Worksheet

PFMEA Scope Worksheet	
Process:	
Date:	
Scope defined by:	
1	What process components are to be included in the investigation?
2	Who is the customer?
3	What process support systems are to be included in the study?
4	To what extent should input materials be studied?
5	What are the product material requirements & constraints?
6	Should packing, storage & transit be considered part of the study?

Appendix 3
(Generic) PFMEA Severity Evaluation Criteria

Effect	Criteria: Severity of Effect on Product (Customer Effect)	Rank
Failure to Meet Safety and/or Regulatory Requirements	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulations without warning.	10
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulations with warning.	9
Loss or Degradation of Primary Function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation).	8
	Degradation of primary function (vehicle operable, but at reduced level of performance).	7
Loss or Degradation of Secondary Function	Loss of secondary function (vehicle inoperable but comfort / convenience functions inoperable).	6
	Degradation of secondary function (vehicle inoperable but comfort / convenience functions at a reduced level of performance).	5
Annoyance	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by most customers (>75%).	4
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by many customers (50%).	3
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by discriminating customers (<25%).	2
No effect	No discernible effect.	1

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Appendix 3 (Continued)
(Generic) PFMEA Severity Evaluation Criteria

Rank	Effect	Criteria: Severity of Effect on Process (Manufacturing/Assembly Effect)
10	Failure to Meet Safety and/or Regulatory Requirements	May endanger operator (machine or assembly) without warning.
9		May endanger operator (machine or assembly) with warning.
8	Major Disruption	100% of product may have to be scrapped. Line shutdown or stop ship.
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.
6	Moderate Disruption	100% of production run may have to be reworked off line and accepted.
5		A portion of the production run may have to be reworked off line and accepted.
4	Moderate Disruption	100% of production run may have to be reworked in-station before it is processed.
3		A portion of the production run may have to be reworked in-station before it is processed.
2	Minor Disruption	Slight inconvenience to process, operation, or operator.
1	No effect	No discernible effect.

Appendix 4
(Generic) PFMEA Occurrence Evaluation Criteria

Likelihood of Failure	Criteria: Occurrence of Cause – PFMEA (Incidents per item/vehicle)	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**
	0.5 per thousand 1 in 2,000	**5**
	0.1 per thousand 1 in 10,000	**4**
Low	0.01 per thousand 1 in 100,000	**3**
	≤0.001 per thousand 1 in 1,000,000	**2**
Very Low	Failure is eliminated through preventive control.	**1**

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Appendix 5
Generic PFMEA Detection Evaluation Criteria

Oppt'y 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 the 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

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Examples of Custom PFMEA Scales

Severity: PFMEA Operational Examples

Ranking	Example
10	Critical process equipment damaged and unusable or destroyed.
9	Loss of customer due to late delivery.
8	Entire lot of top-level assembly product scrapped.
7	Full assembly line (or bottleneck operation) down more than 1 week.
6	Rework full lot of top-level assemblies.
5	Scrap full lot of sub-level assemblies.
4	Technical (engineering) resources required to get line operational.
3	Rework sub-level assemblies off-line.
2	Equipment down for more than 1 hour.
1	Engineering disposition.

Severity: PFMEA Customer Satisfaction Examples

Ranking	Example
10	In-service failure that threatens safety.
9	Extensive product recall.
8	Unscheduled engine removal.
7	Premature (unscheduled) component replacement.
6	Oil leak but system still operational.
5	Air-conditioning system not operating properly.
4	Interior panel rattles.
3	Variation in seat colors.
2	Door plugs missing.
1	Scratch on interior of housing.

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Severity: PFMEA EH&S Examples

Ranking	Example
10	Loss of life; serious injury.
9	Large hazardous material spill or release.
8	OSHA Recordable injury.
7	Personnel exposure above PEL.
6	Moderate hazardous material spill or release.
5	Fail internal ISO 14001 audit.
4	Injury requiring first aid.
3	Spill of non-hazardous material.
2	Minor (non-hazardous) coolant spill.
1	Poor housekeeping.

Occurrence: PFMEA Time-Based Examples

Ranking	Example
10	≥1 per occurrence per shift
9	≥1 per occurrence per day
8	≥1 per 2-3 days
7	≥1 per week
6	≥1 per 2 weeks
5	≥1 per month
4	≥1 per quarter
3	≥1 per half-year
2	≥1 per year
1	<1 per 1 year

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Occurrence: PFMEA Piece-Based Examples

Ranking	Example
10	Cpk < 0.33
9	Cpk ≈ 0.33
8	Cpk ≈ 0.67
7	Cpk ≈ 0.83
6	Cpk ≈ 1.00
5	Cpk ≈ 1.17
4	Cpk ≈ 1.33
3	Cpk ≈ 1.67
2	Cpk ≈ 2.00
1	Cpk > 2.00

Occurrence: PFMEA Event-Based Occurrence Examples (or Examples for Complex Assemblies)

Ranking	Example
10	≥1:2 events (or complex assemblies)
9	≥1:10
8	≥1:25
7	≥1:50
6	≥1:100
5	≥1:500
4	≥1:1,000
3	≥1:5,000
2	≥1:10,000
1	<1:10,000

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Detection (Control): PFMEA Mistake-Proofing Examples

Ranking	Example
10	
9	Does not apply.
8	
7	Sensory alert prevention solution; color-coding of drums of raw material.
6	Warning detection solution; audible alarm sounds if over-torque condition is detected with pump.
5	Warning prevention solution; alarm flashes if rate of pump motor torque rise is excessive.
4	Shutdown detection solution; pump shuts down if over-torque condition is detected.
3	Shutdown prevention solution; cycle counter with automated shutdown at MTTF (mean time to failure).
2	Forced control detection solution; automated in-line inspection fixture.
1	Forced control prevention solution; use of asymmetrical features to allow placement of fixture one and only one way.

Detection (Control): PFMEA Gauging Examples

Ranking	Example
10	
9	Does not apply.
8	Periodic NDT.
7	Periodic in-line variable gauging.
6	Periodic in-line GO/NOGO gauging.
5	In-line GO/NOGO gauge on all parts exiting process.
4	Automated inspection on first piece.
3	Dimensions of input materials confirmed with in-process accept/reject gauging.
2	100% automated inspection of 100% of product.
1	Does not apply.

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Detection (Control): PFMEA Manual Detection Examples

Ranking	Example
10	No monitoring, measurement, or sampling.
9	AQL sampling plan used for Final Inspection.
8	100% visual inspection.
7	100% visual inspection with visual standards.
6	100% manually inspected using GO/NOGO gauges.
5	SPC used in-process with Cpk 1.33 or higher.
4	SPC used in-process with Cpk 1.67 or higher.
3	
2	**Does not apply.**
1	

Appendix 7
FMEA Analysis Worksheet

Process/Product: _____
FMEA Team: _____
Team Leader: _____

FMEA Process

Component & Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurrence	Current Prevention Controls	Current Detection Controls	Detection	RPN	Recomm'd Action	Respon. & Target Completion Date

This form is shown over two pages to enhance readability. ➔

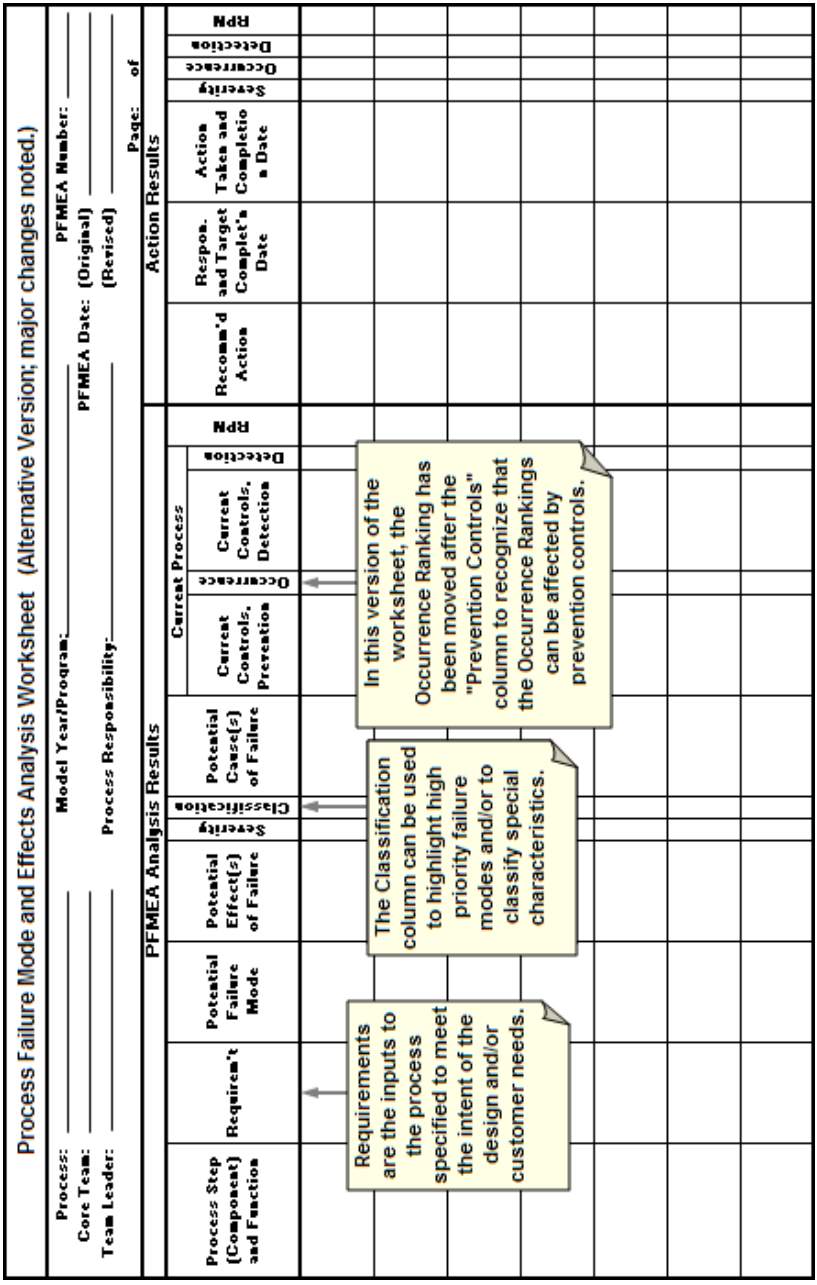
Appendix 7 (continued)
Control Plan Attachment

FMEA Number: _____
FMEA Date: **(Original)** _____
(Revised) _____
Page _____ of _____

Action Results					Control Plan						
Action Taken	Severity	Occurrence	Detection	RPN	Control Factor	Spec or Tolerance	Measure Technique	Sample Size	Sample Freq	Control Method	Reaction Plan

← This form is shown over two pages to enhance readability.

Appendix 8
Alternative PFMEA Worksheet



Appendix 9
Glossary of Terms

AIAG	Automotive Industry Action Group, an organization with a mission to improve the global productivity of its members and the North American automotive industry.
Boundaries of Freedom	A conceptual management tool used to define and communicate predetermined levels of authority for the use of time, funds, and resources.
Bell-Shaped Curve	A pattern of variation known as the normal curve.
Bimodal Distribution	A pattern of variation which has two or more peaks, or modes.
Capable	If the process is stable, normally distributed, and the process spread (six standard deviations) is less than the customer's specification range (T.T.) with room to spare (industries today typically require 25%), the process is capable. Capable only means the process can fit within the specification. However, it may not fall within the specification. Ideally we want a process to be both capable and centered.
Capable and Centered	A process that is capable of meeting the specification and is operating in the approximate center of the specification; it has a Cp approximately equal to the Cpk and the Cpk is equal to or greater than 1.33.
Control Chart	A chart used to maintain statistical control of a process.
Control Plan	Written documentation of the systems to be used to control processes and/or product components.
C_{pk}	The C_{pk} is the best measure of process capability because it not only tells you if the process is capable, but also whether it is centered. C_{pk} = minimum of $\{C_{pu}, C_{pl}\}$. The C_{pu} measures the capability of the top half of the process and the C_{pl} measures the capability of the lower half of the process. The C_{pk} is like a bowling score - the higher the better. In order for a process to be considered capable, the C_{pk} should be at least 1.33.
Design of Experiments (DOE)	A family of statistically based techniques and methods used to conduct organized experimentation. DOE techniques require relatively little time and money compared to conventional experimental techniques. Yet, they can yield comprehensive information about the individual variables being studied as well as interactions between the variables.

Detection Ranking	A ranking scale ranging from 1 to 10. The easier it is to detect the cause of a failure or the subsequent failure, the better. A high ranking (e.g. 10) means the probability of detection is low. A low ranking (e.g. 1) means the probability of detection is certain.
DFA	The acronym for Design for Assembly. The purpose of DFA techniques is to design a product in a way that makes assembly easier for manufacturing. One example of a DFA technique would be redesigning a part that requires 10 screws in the assembly process so it could snap together instead thereby eliminating the need for any screws.
DFM	The acronym for Design for Manufacturability. The purpose of DFM techniques is to design a product in a way that makes it easier to manufacture. One example of a DFM technique is designing all products to use the same type of fastener rather than specifying a different type of fastener for each product.
DFMEA	The acronym for a Design-FMEA. A DFMEA is used to identify and evaluate the relative risks associated with a product design.
DOE	The acronym for design of experiments. (See Design of Experiments.)
Effect	The potential impact of a failure should the failure occur.
EVOP	The acronym for a type of DOE (see Design of Experiments) called "Evolutionary Operations." The EVOP experimental method targets an experimental region of variables within the current range of operating conditions of a process. Using this method, improvements in output and quality can be achieved without interrupting the process.
Failure Mode	How a product design or process component could fail and have a resulting impact on the product or process performance.
Flowchart	A graphical representation of a process sequence using standard symbols.
FMEA	The acronym for Failure Mode and Effects Analysis. An FMEA is a systematic, structured approach to identify and evaluate, on a relative scale, risks associated with a process or product.
Fractional Factorial	A derivative of the full factorial DOE (see Design of Experiments) in which higher order interactions are assumed unimportant. This reduces the total number of experimental runs to a "fraction" of the number which would be required for a full factorial.
Frequency	The number of times a value or event occurs.

Full Factorial	A type of DOE (see Design of Experiments) in which every possible combination of factors and levels are studied so that the main factor effects and all interactions can be studied.
GR&R Study	The acronym for Gage Repeatability and Reproducibility studies. A GR&R is a study of the variation in the measurement system.
In-Specification	A process or data point from a process that falls within the specification limits.
LCL	The lower control limit of a control chart.
LSL	The lower limit of a specification.
Mean	The arithmetic average for a group of values. Also known as the $\bar{X}$ (x-bar).
Mistake-Proofing	A technique that makes a process or product so robust that it cannot fail. Also known as poka yoke or error-proofing
Mixture Experiment	A special type of DOE (see Design of Experiments) used when studying the effect of varying proportions of components of a mixture. Mixture experiment techniques assure that the sum of the components always adds up to 100% and that each component is accounted for in the experimental design.
Nominal	The value the customer ideally wants for a product parameter.
Normal Distribution	A pattern of variation of a stable process (one with no special causes) in which the distribution resembles a bell-shaped curve.
Occurrence Ranking	A ranking scale, from 1 to 10, used to evaluate how frequently a failure due to a specific cause will occur. A high ranking (e.g. 10) means the failure due to the given cause results occurs very often. A low ranking (e.g. 1) means the failure due to the given cause rarely or never occurs.
Out-of-Specification	A process or data point from a process that falls outside of the specification.
Out-of-Control	A process that is not stable due to special causes of variation.
Pareto Principle	The Pareto Principle is often called the 80/20 rule. It means that approximately 20% of categories account for approximately 80% of the total impact.
PFMEA	The acronym for a Process-FMEA. A PFMEA is used to identify and evaluate the relative risks associated with a process.

Pilot Process	A pilot process is a small-scale operation used to develop new products or to test out process modifications before moving it up to production operations.
Poka Yoke	A technique that makes a process or product so robust that it cannot fail. Also known as mistake-proofing.
PPM	Parts per million.
Process Capability	A measure used to determine if a process output is capable of meeting its specification.
Prototype	A prototype is an early version of a new product. Often the prototype is not a working model or may even be a mock-up.
R	Range. A measure of the dispersion or variation in data.
Range	Also known as R. The highest value in a data set minus the lowest value in the same group. Describes the dispersion in our data.
Reaction Plan	The Reaction Plan is part of the Control Plan. It spells out how the organization will react if a failure mode occurs.
Risk	Risk refers to a potential hazard or quality deficiency associated with a product or process.
RPN	The acronym for Risk Priority Number. The RPN is a product of multiplying the Severity ranking x the Occurrence ranking x the Detection ranking. The RPN will always be a number from 1 to 1000, where 1000 is the maximum risk.
s	The standard deviation of a sample of data.
Sample	A representative subset of data randomly taken from a population of data.
Screening Experiment	A screening experiment is a type of DOE (see Design of Experiments). It is a severe fractional factorial that allows many factors to be studied with relatively few experimental runs.
Severity Ranking	A ranking scale, from 1 to 10, used to evaluate the relative severity of the consequence of a failure. A high ranking (i.e. 10) means the consequence or impact is grave. A low ranking (i.e. 1) indicates that the impact is minimal or unnoticeable.

Six Sigma Quality	Theoretically, a process with a Cpk of 2.0 and 2 ppb defects. However, when used to describe "Six-Sigma" as used by many companies today for "Six-Sigma Quality," it refers to 3.4 ppm quality and not 2 ppb. The reason for this difference is that the Six-Sigma community accounts for long-term process drift that some statisticians have estimated to be approximately 1.5s. Thus a distribution that has ± 6s within the specification and then drifts 1.5s actually has its mean at 4.5s from one of the specification limits at times. Looking only at that tail of the normal curve as being outside the specification gives us the 3.4 ppm (½ of 6.8 ppm in a 4 .5s) quality level.
Skewed Distribution	A pattern of variation which is non-normal; it appears "pushed over" to one side.
SPC	The acronym for Statistical Process Control.
Special Cause of Variation	A cause of variation which is unpredictable and makes the process unstable.
Stable Process	A process that is in-control with only common causes of variation present.
Standard Deviation	A calculation on a set of data that indicates how much variation there is in the data.
Subgroup	A small grouping of samples. For control charts, subgroup sizes usually range from 2 to 5 depending on the variation in the process.
UCL	The upper control limit on a control chart.
USL	The upper limit of a specification.
Variable Data	Data that are measured on a continuous scale.
Variation	The difference between similar items or things.
X	An individual data point or observation.
X-bar	The arithmetic average for a group of values. Also known as the mean.
X-axis	The horizontal axis on a graph.
Y-axis	The vertical axis on a graph.