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FMEA Free Giveaways

FMEA Field Guide

FMEA Template

FMEA Practice Exam

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FAILURE MODE AND EFFECTS ANALYSIS

Process: _____
Component: _____
Part Number: _____
Description: _____
Prepared By: _____

FMEA Number: _____
Approved On: _____
Approved By: _____
Revision: _____
Pages: _____

Unique Identifier	Process Steps	Potential Failure Mode	Effects of the Failure	SEV	Potential Cause	OCC	Current Controls	DET	RPN	Actions Recommended	Actions Results				
											Action Taken	New Sev.	New Occ.	New Det.	New RPN

Detection

Ranking	Qualitative Term	Quantitative
1	Certain	100% Detection
2	Almost Certain	95% Detection
3	High	75% Detection
4	Moderate	50% Detection
5	Low	25% Detection
6	Undetectable	<10% Detection

Occurrence

Ranking	Qualitative Term	Semi-Quantitative	Quantitative
1	Extremely Unlikely	1	Less than 1 in 1,000,000
2	Remote	2	Between 1 in 1,000,000 & 1 in 100,000
3	Unlikely	3	Between 1 in 100,000 & 1 in 10,000
4	Occasional	4	Between 1 in 10,000 & 1 in 1,000
5	Frequent	5	Between 1 in 1,000 & 1 in 100
6	Often	6	Greater than 1 in 100

Severity

Ranking	Category	Definition
1	None	No relevant effect on reliability or safety
2	Very Minor	No damage, no injuries, only results in a maintenance action (only noticed by discriminating customers)
3	Minor	Low damage, light injuries (affects very little of the system, noticed by average customer)
4	Moderate	Moderate damage, injuries possible (most customers are annoyed, mostly financial damage)
5	Critical	Causes a loss of primary function; Loss of all safety Margins, 1 failure away from a catastrophe, severe damage, severe injuries, max 1 possible death
6	Catastrophic	Product becomes inoperative; the failure may result in complete unsafe operation and possible multiple deaths

Failure Mode and Effects Analysis

An **FMEA** or **Failure Mode Effects Analysis** is a systematic process & tool that requires a thoughtful consideration for all of the potential failure mode associated with a new design or process.

This tool also facilitates the analysis & assessment of the risk associated with all of the identified failure modes & their resulting effect on your customer.

Below is an example of an FMEA, which is basically a table that captures all of the major areas within the analysis, including the failure modes, effects, causes & current controls.

FAILURE MODE AND EFFECTS ANALYSIS

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CQE ACADEMY

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											Action Taken	New Sev.	New Occ.	New D

These tools can be used during the product & process design phase to **improve Reliability/Quality & Safety** of your product.

This improvement is achieved through the **identification, assessment & correction of potential issues** that might introduce risk to your customer in terms of safety or reliability, which is exactly what these risk management tools can do for you.

The FMEA process captures the steps of **Risk Identification**, **Risk Analysis** & **Risk Assessment** all in one. The FMEA also serves the user in **communicating risk** & ultimately result in the **mitigation of risk (Risk Control)** through corrective action.

This is also a good time to mention exactly why this topic is being discussed in the "Design" chapter - *because the cost of identifying and correcting an issue become increasingly more expensive as you move through the design process and into full production.*

This is why it is imperative that you perform these assessments early in the design process so that you can easily address any issues that are uncovered.

Lastly, **to maximize the effectiveness of these tools**, you should ensure that they are executed within a **cross-functional team** that includes members from different departments.

This would include team members from Quality, Reliability, R&D, Engineering, Operations & Marketing to ensure that all perspectives are considered and captured.

The Benefits of Risk Management

The FMEA is a singular tool that works through the entire risk management process which has a ton of benefits for your organization and your customer.

From a **design perspective**, the FMEA provide a method for selecting the safest & most reliable design and or manufacturing process. It can also be used to compare alternate designs against each other to determine which design has higher levels of reliability or safety.

The DFMEA can also be useful in reducing the time required to design a product or process as it helps you to holistically understand the risks associated with your new product or process and avoid any design rework etc.

From a **reliability/quality/safety/improvement perspective**, the FMEA is very useful in identifying components that are critical to Safety/Quality/Reliability. Identifying these critical features can allow you to take advantage of the pareto principle and focus your attention on the critical few during the design process eventually full-scale production to deliver a product with quality/reliability & safety.

Based on that definition, these CTQ's or CQA's naturally have an element of risk associated with them because, if they are not fully met by your product or process, they will introduce risk to your customer in the form of a hazardous situation, etc.

These CTQ's from your FMEA should then be directly tied into your design validation & process validation activities; which ensure that your design meets your customers' needs & intended use and that your process is capable of routinely producing product that meets specifications.

These CTQ's essentially become the acceptance criteria of those validation activities. So you can see how the risk management process can have a huge impact on your ability to be successful in designing a new product or process.

Your FMEA, and it's identified CTQ's should then **translate into your control plan** during routine manufacturing.

This will ensure that your high-risk product attributes or process steps are being appropriately controlled & monitored to mitigate the risk associated with a failure.

From a **financial perspective** (Cost of Quality), identifying and eliminating failure modes results in the reduction of internal & external failure costs (scrap, rework, complaints, etc) that drive down the Cost of Poor Quality & ultimately make your organization more cost effective.

It is important to note that the FMEA can take a significant investment in time and resources, however if the process is executed properly, it will have a return on investment that will ultimately make it a cost-effective decision.

Lastly, your risk management tools should also be used to assist you in managing changes to your product or process.

If you're making changes to a part of your process, you can go back to your PFMEA to understand exactly which quality attributes can be impacted by that process step. This can help you assess the level & type of testing required to support your proposed change.

The 10 Step FMEA Process

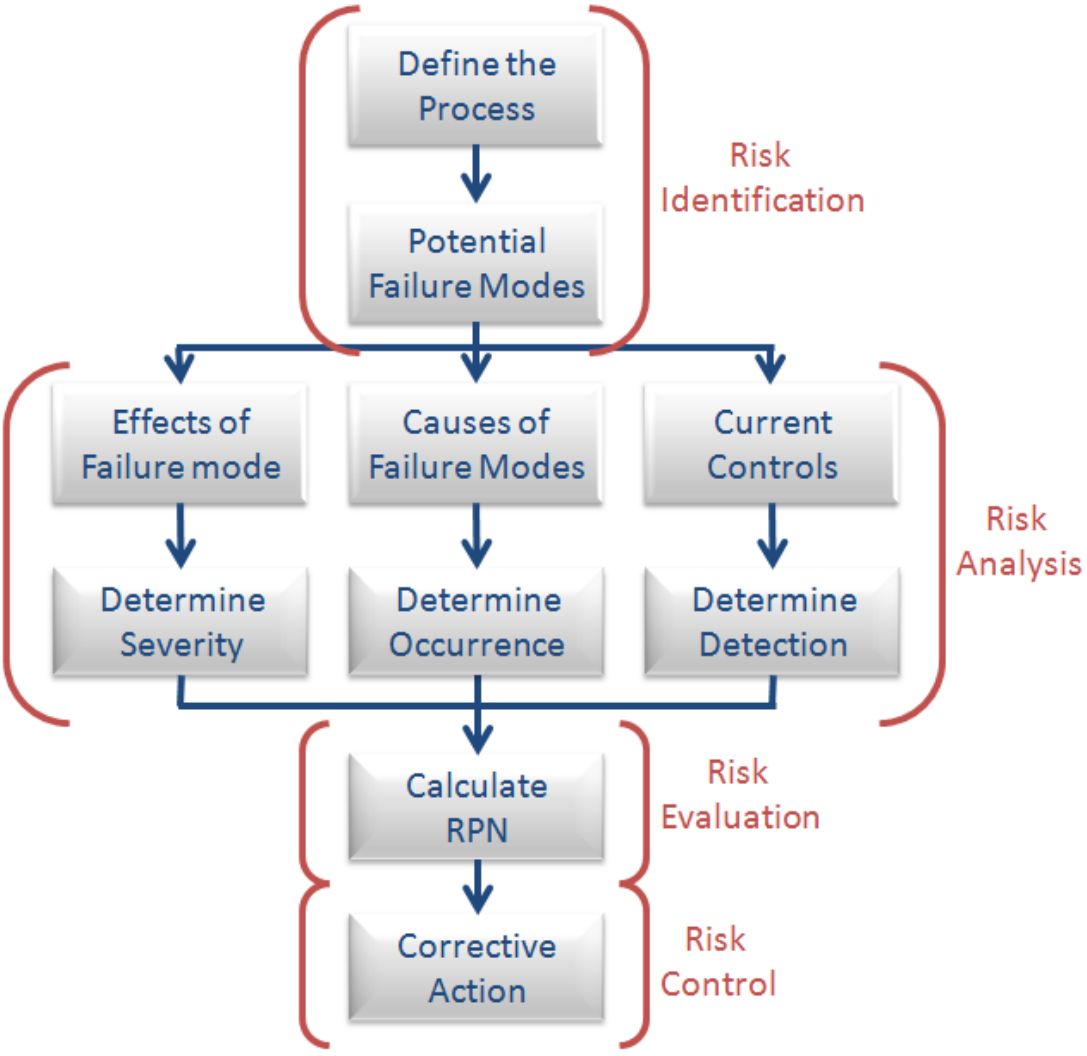
Below is a high-level review of the 10 step FMEA process, where each step is discussed in more detail below.

In terms of the overall risk management process, Steps 2 - 5 can be considered part of the **Risk Identification** process, while steps 5 - 8 can be considered part of the **Risk Analysis** & **Risk Evaluation** process.

Lastly, steps 9 & 10 are considered to be a big part of the **Risk Control** process and the entire document is meant as a **Risk Communication** & **Risk Review** tool.

1. Define your System or Process to be Analyzed
2. Identify the potential failure modes for each of your product attributes or process steps
3. Determine the potential effect(s) of the failure mode on the system or customer
4. Estimate the severity for each failure mode & effect
5. Determine the potential cause(s) for each failure mode (5 Why's)
6. Estimate the likelihood of occurrence for each failure mode & cause
7. Determine the controls around that failure mode and root cause
8. Estimate your detection level for each failure mode, cause & effect
9. Calculate the Risk Priority Number (RPN) & Risk for each failure mode
10. Take Corrective Action to Reduce/Mitigate or Eliminate Risk

I've summarized this process into a nice little flow diagram:



Step 0 -Establish ground rules for your FMEA

Before any FMEA, it’s important to establish some ground rules for the process.

This step is most easily accomplished with an SOP or Procedure that defines all of the requirements and assumptions associated with your FMEA.

If you don't already have a procedure, you should, at a minimum, define the scales for Severity/Detection & Occurrence (discussed below) that you plan to use.

You'll also want to document any assumptions used in the analysis - for example, if you plan on assuming that all raw material being used within the process is conforming, then you'll want to state this up front.

These ground rules should also capture the acceptance criteria for the final RPN score (Risk Priority Number). It is important to establish this risk criteria prior to beginning the process to avoid any biases that might creep in.

Step 1 - Define Your System or Process

Before beginning the actual FMEA process it's a good exercise to step by and ensure, across the entire team, that everyone agrees to the scope of the analysis.

This is very important for very complex analysis, like an automobile, where you'll have multiple sub-systems that all have their own FMEA.

For a DFMEA, a system block diagram can be used to show the interfaces & relationships between the different aspects of your design, etc. This will allow you to consider all of the functional requirements of that sub-system, and understand all of the interactions of that sub-system with other sub-systems, etc.

For a PFMEA, you can use a flow diagram to define your process and its various manufacturing steps that can contribute to a failure.

Step 2 - Identify Your Potential Failure Modes

Alright - now you're ready to start the FMEA process, which begins by identifying your potential failures modes.

I say potential, because you shouldn't limit yourself to only failures that have occurred, but also consider how your process might foreseeably fail in the future.

For a **DFMEA**, a starting point for failure modes can begin with your functional requirements, where the failures can be the anti-function, or the lack of functionality of the product. You can then brainstorm causes & effects from there.

For a **PFMEA** your failure modes will be related to your various steps in the manufacturing process and how they might fail.

When discussing potential failure modes for each MFG step, consider the 8M's of the Cause & Effect Analysis Tool along with Brainstorming & the 5-Why's Tool to ensure you're capturing all of the potential failure modes associated with each step in your manufacturing process.

I think it's worth repeating these 8M's here because they are all potential sources of a failure mode, with the exception of Materials, which is explained below:

- **Man** - how do the human interactions introduce potential failures; this is especially true for manual processes.
- **Machine** - how can your equipment or machines fail in a way that would result in a failure.
- **Method** - what written procedures do you have in place and how might they result in a failure.
- **Materials*** - this is the one exception to the analysis as generally most PFMEA's & DFMEA's assume that the raw material being used within the process is conforming to specifications.
- **Mother Nature** - how might your production environment contribute to a failure mode.
- **Measurement** - what measurement techniques & equipment are you using & how might that introduce failures.
- **Management** - what are the attitudes & priorities of management that might result in a failure.
- **Maintenance** - what type of maintenance & calibration activities are prescribed for your process and how might that contribute to a failure.

Remember to write these failure modes as the actual failure mode itself and not the effect on the customer; that will come later.

Step 3 - Determine the Effects for each Failure Mode

Now that you've determined all of the potential failure modes for your product or process, you'll need to determine what the effect of that failure mode will be. This effect is generally thought of as the effect on the end user or customer.

In this situation you'll likely run into a situation where a failure mode can have various effects, depending on the level of severity of the failure.

In this instance it's good to document those multiple effects so that you can properly analyze the severity & likelihood associated with each of those various effects.

Step 4 - Estimate the Severity of each Failure Mode

Ok so at this point in the process, you've identified failure modes, causes & effects, which in opinion is where the bulk of the work lies when it comes to an FMEA.

These first few steps also make up the "risk identification" step of the Risk Management Process.

Now it's time to get into the Risk Analysis portion of the Risk Management Process, which includes the estimation of severity & occurrence (both of the elements of risk), along with detection.

Let's specifically start with Severity, which is a measure of the degree to which the end user is impacted by the failure mode & effect. Severity can also be thought of as a measure of the consequence of the failure mode & effect.

Severity can be assessed semi-quantitatively, using a ranking on a 1 - 10 scale, with 1 being the least severe, and 10 being the most severe.

The 10-scale is not universal however, and you can basically use whatever scale you want.

Severity can also be assesses in qualitative terms using terms like "inconsequential", "very minor", "minor", "marginal", "major", "critical" or "catastrophic" to describe the severity of the failure mode & its effect on the customer.

Below is an example table showing both a semi-quantitative 1 - 6 scale (ranking) with its qualitative terms (Category) for Severity from Wikipedia:

Ranking	Category	Definition
1	None	No relevant effect on reliability or safety
2	Very Minor	No damage, no injuries, only results in a maintenance action (only noticed by discriminating customers)
3	Minor	Low damage, light injuries (affects very little of the system, noticed by average customer)
4	Moderate	Moderate damage, injuries possible (most customers are annoyed, mostly financial damage)
5	Critical	Causes a loss of primary function; Loss of all safety Margins, 1 failure away from a catastrophe, severe damage, severe injuries, max 1 possible death
6	Catastrophic	Product becomes inoperative; the failure may result in complete unsafe operation and possible multiple deaths

Step 5 - Determine the Potential Root Causes for each Failure Mode

The next step in the process is to begin to document the root causes for each of the identified failure modes within your process.

It's important to note here that one failure mode can be caused by various root causes & contributing factors, each having a different effect on the end user.

All of these root causes should be thoroughly documented and can be analyzed later for any commonalities across your process.

These commonalities can clue you in to potential corrective actions to that are able to address these root causes that are common across your process.

Step 6 - Estimate the Occurrence of each Failure Mode & Cause

The next step in the process is to assess the likelihood for occurrence for each failure mode its cause(s).

The Occurrence ranking is generally defined as the ***likelihood*** or ***probability*** that a failure will occur.

This likelihood for occurrence can be draw directly from your process capability studies or failure rate data captured during the development process.

Your Occurrence value should also take into account any other preventative measures that are in place to prevent the failure mode from occurring.

Occurrence should not consider any appraisal methods (testing) that are meant to detect failures after they have occurred, this should be captured in the detection rating.

Occurrence should be a pure reflection of how often the failure mode will occur; and should not include any testing or sorting for that failure mode.

For example, if you knew the DPMO (Defects Per Million Opportunities) or your Process Capability (C_{pk}, P_{pk}) these would be good starting points to estimate the likelihood or probability that a failure mode will occur.

In other situations where you're assessing a potential failure mode, you may have to use your best judgment to estimate the likelihood for failure.

Similar to Severity, the Occurrence can be assessed in qualitative terms, semi-quantitative terms, or quantitative terms.

In qualitative terms, this can mean assessing the likelihood using words like "Never", "Extremely Unlikely", "Remote", "Occasional", "Sometimes", "Often", "Frequent", etc.

From a semi-quantitative perspective, this can be a simple 1 - 6 scale, with one being the least frequently occurring failure mode and 6 being the most frequently occurring failure mode.

From a quantitative perspective, you can link your 1-6 scale directly to your known Process Capability or measured DPMO for your process or failure mode.

Ranking	Qualitative Term	Semi-Quantitative	Quantitative
1	Extremely Unlikely	1	Less than 1 in 1,000,000
2	Remote	2	Between 1 in 1,000,000 & 1 in 100,000
3	Unlikely	3	Between 1 in 100,000 & 1 in 10,000
4	Occasional	4	Between 1 in 10,000 & 1 in 1,000
5	Frequent	5	Between 1 in 1,000 & 1 in 100
6	Often	6	Greater than 1 in 100

Step 7 - Determine the Controls for each Failure Mode and Root Cause

Controls are the existing steps in your process that are intended to prevent or detect the specific failure mode, and its root cause from occurring.

Your control plan is a great place to start to identify your existing controls for your product and process.

Your controls can both prevent a failure mode from occurring, but it can also be intended to detect a failure once it has occurred. So some controls will reduce the likelihood of occurrence, and some will improve the detection rating.

Step 8 - Estimate the Detection level for each Failure Mode

Alright, on to the last estimation, the Detection Level.

Your "Detection" is a reflection of the capability of your process to identify the failure mode once it has occurred. This can also be thought of as a reflection of the effectiveness of your process control strategy to identify failures.

Similar to Severity & Occurrence discussed above, your processes Detection capability exists on a scale with 1 being a very strong detection method and 6 being absolutely no detection.

Ranking	Qualitative Term	Quantitative
1	Certain	100% Detection
2	Almost Certain	95% Detection
3	High	75% Detection
4	Moderate	50% Detection
5	Low	25% Detection
6	Undetectable	<10% Detection

This is the 3rd and final rating for each failure mode, which means we're now able to calculate **Risk & RPN** (Risk Priority Number).

Before we get into that thought, let's quickly review the difference between Occurrence & Detection, because that can get a little tricky.

Reviewing the Difference Between Detection & Occurrence

When you're assessing the Detection & Occurrence of a failure mode it's important to have a good understanding of the difference between the two.

You'll also need this understanding when you've taken corrective action as a result of your FMEA, which will force you to decide if you your corrective actions should result in the reduction of the likelihood value or an increase in detection.

So for example, let's say that you've got an existing failure mode with the following 3 scores:

Failure Mode	Severity	Occurrence	Detection	RPN	Risk
XYZ Happens	8	5	5	200	40

Now you've implemented a corrective action and you need to either reduce the occurrence or improve the detection (which would mean a reduction in the detection score) - how do you know which one to pick.

It depends on your corrective action. If the corrective action is increased appraisal (inspection, testing, measurement, etc) that the right answer is to decrease detection.

If the corrective action was the redesign the production tooling to error-proof the process (prevention), then the right answer is to decrease occurrence.

If you were to improve your process capability for a particular manufacturing step by either reducing variation or centering your process, this corrective action would fall in to the occurrence bucket, not detection.

The key to remember here is that preventative measures that prevent the failure mode from ever recurring impact occurrence, and any sort of inspection/testing would be considered an appraisal effort to detect the failure mode after it had occurred.

Step 9 - Calculate RPN & Risk to Identify Opportunities for Improvement

At this point you've laid out your whole process and identified all of the potential failure modes associated with each step on the process, along with their root causes & potential effects on the end user.

You've also analyzed each of those failure modes to determine their frequency of occurrence, the capability of your process to detect that failure once it has occurred, and the severity of that failure on the end user.

Now you must perform the final calculation, but before we get to that, let's spend a second discussing why we perform this final calculation.

You've got limited resources, and you've got a nearly completed FMEA with perhaps hundreds of failure modes. You can't imagine trying to tackle all of these failure modes.

How do you know where to start? This is why we have **RPN & Risk**.

These two concepts give us an ***objective prioritization tool*** to determine the "high risk" failure modes that we should focus on first.

Using these concepts will ensure your time, energy, effort & money is spent effectively in mitigating risks associated with your product or process.

Another perspective here, which we will discuss below, is to go beyond the simple prioritization of failure modes using RPN & Risk and move towards the prioritization of the corrective actions with the **Risk Mitigation Matrix** which is also discussed below.

Risk Priority Number (RPN)

The ability to prioritize improvements based on risk or RPN is one of the major benefits of the FMEA because it allows you to analyze all failure modes on a common scale, etc.

RPN or Risk Priority Number is a dimensionless number that is calculated by combining the Severity, Occurrence & Detection rating for each of your identified failure modes & effects.

$$\boldsymbol{Risk\ Priority\ Number = RPN = Severity * Occurrence * Detection}$$

If you were using a 10-scale rating system for Severity, Occurrence & Detection then your maximum RPN would be 1,000, and your minimum RPN would be 1.

Once you've calculated the PRN value for each failure mode within your FMEA, you'll then be able to quickly determine which failure modes have the highest RPN and thus potentially warrant a corrective action to mitigate risk.

Risk

As opposed to PRN, Risk is only a combination of Severity & Occurrence. Risk does not take into consideration the Detection capability associated with your process.

$$Risk = Severity * Occurrence$$

Take for example the below table which is a 6x6 risk table with severity on the Y-axis and occurrence on the X-axis.

This perspective is taken more often in DFMEA's as opposed to PFMEA's because in a DFMEA there's really no such thing as "Detection" and oftentimes the detection of a failure mode is merged into the Occurrence factor.

Below is an example 6x6 risk matrix that could be used to analyze your failure modes.

		Occurrence					
		1	**2**	**3**	**4**	**5**	**6**
Severity	**1**	1	2	3	4	5	6
	2	2	4	6	8	10	12
	3	3	6	9	12	15	18
	4	4	8	12	16	20	24
	5	5	10	15	20	25	30
	6	6	12	18	24	30	36

This risk table can be further grouped into 3 regions:

- Low Risk is any failure mode with a score from 1 to 12.
- Medium Risk is any failure mode with a score from 13 to 24.
- High Risk is any failure mode with a score from 25 to 36.

Step 10 - Corrective Action to Mitigate Risk

The last, and probably the most important step in the whole process is the corrective actions that you take to mitigate risk.

You've now analyzed & assessed the risk associated with each failure mode and determined which risks are the highest and should be mitigated. In fact, you've now characterized the entire risk profile of your process - great job!

But you're not done. You now have to implement corrective actions to reduce risk, where appropriate.

I want to stress that the entire process is worth very little unless you're able to take actionable measures to improve your process/process & reduce risk. Don't get me wrong, it's nice to have a good understanding of your risk profile.

However, the real benefit of performing an FMEA is to identify which failure modes, if they were addressed, would have the biggest impact on your products quality, safety, reliability, etc. So, get to work!

Practice Exam for FMEA (Failure Modes and Effects Analysis)

1. **Identify all of the statements below regarding the FMEA that are true:**
   - Risk Management should be the last activity within the Product & Process Design phase
   - A cross-functional team should be assembled when executing Risk Management Tools
   - The FMEA can identify critical product features that require special attention
   - From a Cost of Quality perspective, Risk Management tools are considered an Appraisal Cost

2. **Identify all of the statements below regarding the FMEA Tool & it's relationship to the design process that are True:**
   - The DFMEA helps to identify product features that have a strong relationship with your products functionality requirements or safety features and thus have an element of risk
   - The PFMEA provides a method for comparing alternate designs to determine which one is the safest & most reliable design
   - The DFMEA reduces the time spent designing a product because it helps you understand risk and avoid any design rework
   - The DFMEA is a static document and does not change after a design is approved and released for manufacturing.

3. **There are 10 steps to the PFMEA process. Which of the following tools would be most appropriate in step 2 when defining the system?**
   - Flow Diagram
   - Brainstorming
   - Fishbone Diagram
   - Affinity Diagram

4. **There are 10 steps to the PFMEA process. Which of the following tools would be most appropriate in step 3 while identifying actual and potential failure modes?**
   - Prioritization Matrices
   - Brainstorming
   - Interrelationship Digraph
   - Matrix Diagram

5. **There are 10 steps to the PFMEA process. Which of the following tools would be most appropriate in step 5 when identifying the causes of a failure mode?**
   - Pareto Chart
   - Tree Diagram
   - Fishbone Diagram
   - Activity Network Diagram

6. **Identify the FMEA term below with the following definition: The degree to which the end user is impacted by the failure mode & effect**
   - Severity
   - Occurrence
   - Detection
   - Failure Mode
   - Effect

7. **Identify the FMEA term below with the following definition: The likelihood or probability that a failure will occur.**
   - Severity
   - Occurrence
   - Detection
   - Failure Mode
   - Effect

8. **Identify the FMEA term below with the following definition: A reflection of the capability of your process to identify the failure mode once it has occurred**
   - Severity
   - Occurrence
   - Detection
   - Failure Mode
   - Effect

9. **Identify the FMEA term below with the following definition: A fault condition of your product that has an impact on quality/safety or reliability.**
   - Severity
   - Occurrence
   - Detection
   - Failure Mode
   - Effect

10. **Identify all of the quality processes below that can be utilized to assess the occurrence rate within an FMEA**
    - Process Capability
    - Scrap rates (DPM)
    - Process Validation Data
    - Engineering Judgment
    - non-conformance data

11. **At the end of your FMEA you discover that you must implement a corrective action for a particular failure mode because the Risk Priority number is too high.**

    In this instance you decide to redesign your production tooling to prevent the failure mode from occurring. How would you change your FMEA as a result of this corrective action?
    - Reduce the Severity Score
    - Increase the Detection Score
    - Reduce the Detection Score
    - Increase the Occurrence Score
    - Reduce the Occurrence Score

12. **At the end of your FMEA you discover that you must implement a corrective action for a particular failure mode because the Risk Priority number is too high.**

    In this instance you decide to implement a vision camera to sort out rejects which is an improvement over your current visual inspection. How would you change your FMEA as a result of this corrective action?
    - Reduce the Severity Score
    - Increase the Detection Score
    - Reduce the Detection Score
    - Increase the Occurrence Score
    - Reduce the Occurrence Score

13. **Identify all of the statements below regarding the FMEA process that are false:**
    - The PFMEA uses inductive logic and is considered a “Bottoms Up” approach while the DFMEA is a "Top Down" approach.
    - The PFMEA generally only includes single point failures, while the DFMEA generally takes the multi-failure analysis approach.
    - The "effect" in the FMEA is generally thought of as the effect on the end user or customer.
    - Your FMEA can be reviewed for common root causes that can all be mitigated simultaneously

14. **Identify all of the statements below regarding FMEA's & Risk/RPN that are true:**
    - The concept of RPN & Risk gives us an objective prioritization tool to analyze failure modes across a common scale
    - Severity can only be assessed quantitatively
    - RPN or Risk Priority Number is a dimensionless number that is calculated by combining the Severity, Occurrence & Detection
    - An RPN of 100 requires corrective action

15. **You’ve completed your FMEA and below are 4 random failure modes from your analysis, which one deserves the highest priority:**

Failure Mode	Severity	Occurrence	Detection
A	4	8	3
B	2	7	1
C	3	9	2
D	7	5	4

    - A
    - B
    - C
    - D

Solutions for Practice Exam

1. **Identify all of the statements below regarding the FMEA that are true:**
   - Risk Management should be the last activity within the Product & Process Design phase – *false, risk management should start early in the design process*
   - A cross-functional team should be assembled when executing Risk Management Tools. (True)
   - The FMEA can identify critical product features that require special attention. (True)
   - From a Cost of Quality perspective, Risk Management tools are considered an ~~**Appraisal**~~ **Prevention** Cost. (False)

2. **Identify all of the statements below regarding the FMEA Tool & it's relationship to the design process that are True:**
   - The DFMEA helps to identify product features that have a strong relationship with your products functionality requirements or safety features and thus have an element of risk. (True)
   - The ~~**PFMEA**~~ **DFMEA** provides a method for comparing alternate designs to determine which one is the safest & most reliable design. (False)
   - The DFMEA reduces the time spent designing a product because it helps you understand risk and avoid any design rework. (True)
   - The DFMEA is a ~~**static document**~~ **living document** and ~~**does not change**~~ **should be reviewed and updated** after a design is approved and released for manufacturing. (False)

3. **There are 10 steps to the PFMEA process. Which of the following tools would be most appropriate in step 2 when defining the system?**
   - **Flow Diagram**
   - Brainstorming
   - Fishbone Diagram
   - Affinity Diagram

   Creating a **Flow Diagram** of a process can help define the system or process under evaluation.

4. **There are 10 steps to the PFMEA process. Which of the following tools would be most appropriate in step 3 while identifying actual and potential failure modes?**
   - Prioritization Matrices
   - **Brainstorming**
   - Interrelationship Digraph
   - Matrix Diagram

   Brainstorming is a tool that can help uncover the potential failure modes of a new process or system.

5. **There are 10 steps to the PFMEA process. Which of the following tools would be most appropriate in step 5 when identifying the causes of a failure mode?**
   - Pareto Chart
   - Tree Diagram
   - **Fishbone Diagram**
   - Activity Network Diagram

   Creating a **fishbone diagram** is a tool that can help determine the cause-and-effect relationships between failure modes and their root causes.

6. **Identify the FMEA term below with the following definition: The degree to which the end user is impacted by the failure mode & effect**
   - **Severity**
   - Occurrence
   - Detection
   - Failure Mode
   - Effect

7. **Identify the FMEA term below with the following definition: The likelihood or probability that a failure will occur.**
   - Severity
   - **Occurrence**
   - Detection
   - Failure Mode
   - Effect

8. **Identify the FMEA term below with the following definition: A reflection of the capability of your process to identify the failure mode once it has occurred**
   - Severity
   - Occurrence
   - **Detection**
   - Failure Mode
   - Effect

9. **Identify the FMEA term below with the following definition: A fault condition of your product that has an impact on quality/safety or reliability.**
   - Severity
   - Occurrence
   - Detection
   - **Failure Mode**
   - Effect

10. **Identify all of the quality processes below that can be utilized to assess the occurrence rate within an FMEA**
    - Process Capability
    - Scrap rates (DPM)
    - Process Validation Data
    - Engineering Judgment
    - non-conformance data

    All of these sources of information can be used to assess the occurrence rate of a failure mode in an FMEA.

11. **At the end of your FMEA you discover that you must implement a corrective action for a particular failure mode because the Risk Priority number is too high.**

    In this instance you decide to redesign your production tooling to prevent the failure mode from occurring. How would you change your FMEA as a result of this corrective action?
    - Reduce the Severity Score
    - Increase the Detection Score
    - Reduce the Detection Score
    - Increase the Occurrence Score
    - **Reduce the Occurrence Score**

    Redesigning tooling to prevent the failure mode would **reduce the occurrence score** of the failure mode.

12. **At the end of your FMEA you discover that you must implement a corrective action for a particular failure mode because the Risk Priority number is too high.**

    In this instance you decide to implement a vision camera to sort out rejects which is an improvement over your current visual inspection. How would you change your FMEA as a result of this corrective action?
    - Reduce the Severity Score
    - Increase the Detection Score
    - **Reduce the Detection Score**
    - Increase the Occurrence Score
    - Reduce the Occurrence Score

    Implementing an automated inspection process (vision camera) would improve detectability of a failure mode and thus result in a **reduction of the detection score**. Remember, when detection improves, the score goes down.

13. **Identify all of the statements below regarding the FMEA process that are false:**
    - The PFMEA **AND DFMEA** uses inductive logic and is considered a "Bottoms Up" approach ~~**while the DFMEA is a "Top Down" approach.**~~ (False)
    - The PFMEA **AND DFMEA** generally only includes single point failures, ~~**while the DFMEA generally takes the multi-failure analysis approach.**~~ (False)
    - The "effect" in the FMEA is generally thought of as the effect on the end user or customer. (True)
    - Your FMEA can be reviewed for common root causes that can all be mitigated simultaneously. (True)

14. **Identify all of the statements below regarding FMEA's & Risk/RPN that are true:**
    - The concept of RPN & Risk gives us an objective prioritization tool to analyze failure modes across a common scale. (True)
    - Severity can only be assessed quantitatively – *false, severity can be assessed Quantitatively, Semi-Quantitatively or Qualitatively*
    - RPN or Risk Priority Number is a dimensionless number that is calculated by combining the Severity, Occurrence & Detection. (True)
    - An RPN of 100 requires corrective action – *false, the RPN must be compared against the RPN limit to determine if it requires corrective action*.

15. **You've completed your FMEA and below are 4 random failure modes from your analysis, which one deserves the highest priority:**

Failure Mode	Severity	Occurrence	Detection	RPN
A	4	8	3	96
B	2	7	1	14
C	3	9	2	54
D	7	5	4	140

    - A
    - B
    - C
    - **D**

    Failure Mode D has the highest RPN (140) and thus should be the highest priority of these four failure modes. The RPN is calculated as Severity * Occurrence * Detection.

$$RPN_D = S * O * D = 7 * 5 * 4 = 140$$