

What is the difference between a DESIGN and PROCESS FMEA?

Making your first design (and product), a reliable design (and quality product).



WORKBOOK

Presented by

Dr Chris Jackson

Reliability engineer



Copyright © 2023 Christopher Jackson

All rights reserved. No part of this publication may be reproduced, distributed or transmitted in any form or by any means, including photocopying or other electronic or mechanical methods without the prior written permission of the author (Christopher Jackson), except as permitted under Section 107 or 108 of the 1976 United States Copyright Act and certain other non-commercial uses permitted by copyright law.

For permission requests, write to Christopher Jackson using the details on the following pages.

Limit of Liability/Disclaimer of Warranty: While the author has used his best efforts in preparing this document, he makes no representations or warranties with respect to the accuracy or completeness of the contents of this document and specifically disclaim any implied warranties of merchantability or fitness for a particular purpose. No warranty may be created or extended by sales representatives or written sales materials. The advice and strategies contained herein may not be suitable for your situation. You should consult with a professional where appropriate. The author shall not be liable for any loss of profit or any other commercial damages, including but not limited to special, incidental, consequential, or other damages.

Who is your teacher? ... Dr Chris Jackson

Dr Jackson holds a Ph.D. and MSc in Reliability Engineering from the University of Maryland's Center of Risk and Reliability. He also holds a BE in Mechanical Engineering, a Masters of Military Science from the Australian National University (ANU) and has substantial experience in the field of leadership, management, risk, reliability and maintainability. He is a Certified Reliability Engineer (CRE) through the American Society of Quality (ASQ) and a Chartered Professional Engineer (CPEng) through Engineers Australia.

Dr Jackson is the cofounder of is4 online learning, was the inaugural director of the University of California, Los Angeles (UCLA's) Center of Reliability and Resilience Engineering and the founder of its Center for the Safety and Reliability of Autonomous Systems (SARAS). He has had an extensive career as a Senior Reliability Engineer in the Australian Defence Force, and is the Director of Acuitas Reliability Pty Ltd.

He has supported many complex and material systems develop their reliability performance and assisted in providing reliability management frameworks that support business outcomes (that is, make more money). He has been a reliability management consultant to many companies across industries ranging from medical devices to small satellites. He has also led initiatives in complementary fields such as systems engineering and performance-based management frameworks (PBMFs). He is the author of two reliability engineering books, co-author of another, and has authored several journal articles and conference papers.



We all get how important it is for the customer or user to *like* whatever it is we are creating for them. But sometimes we are under constant pressure to meet deadlines and budget NOW. It might feel like spending time on reliability is 'wasting time' if the most important thing is meeting my production goals TODAY.

Well ... did you know that you **can save up to 75 per cent of your production costs** and **reduce your production schedule by 50 per cent** by just having what we call a *reliability mindset*? This is because *reliability engineering* is all about eliminating problems. *Problem #1* is something your customer or user discovers. We call that a 'failure.' *Problem #2* is an issue you discover during your final production run. We call this a 'crisis.' *Problem #3* is an issue you discover toward the end of your design schedule. This means a very expensive redesign. *Problem #4* is something you discover at the start of your design. This makes it cheap and easy to solve.

And finally, there is what we call '*problem #5*' – a problem you pre-empt and anticipate before you start designing so that it never happens. In fact, *problem #5* is not even a problem at all.

So far from being an impediment to speed and costs, reliability is THE WAY to smash through your production issues. And the *FMEA* is perhaps the most important tool you can use to achieve all this. To do that you need to understand some of the basic elements of *causality*. This simply means we understand the steps that need to occur for your product, system or service to fail. Understanding these steps can help us get to the cause of failure.

It is the cause that we can do something about.

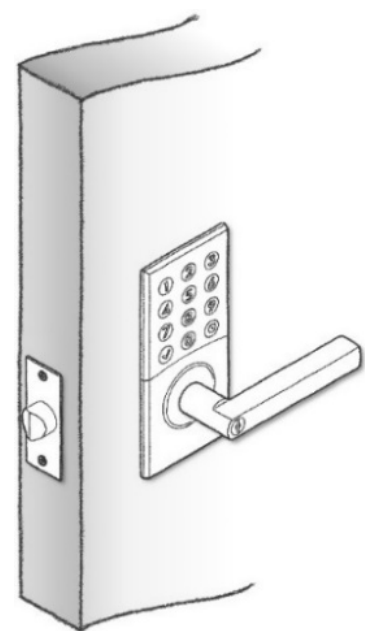
FMEAs are about finding these causes before we start designing, so that all our problems are '*problem #5*.'

What should DESIGN FMEAs do for us?

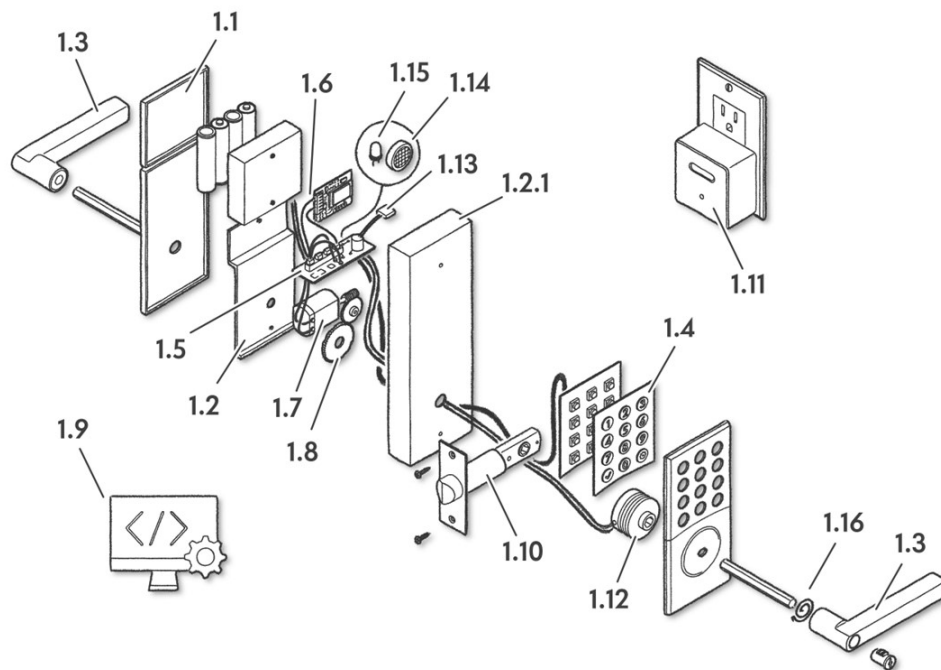
Reliability engineering happens when we incorporate simple and effective design characteristics from the very start. Every problem (no matter how technologically complex your 'thing' is) has a range of solutions. The cheapest and easiest are ALWAYS those that can only be solved using a design characteristic BUILT INTO YOUR FIRST DESIGN.

It is only when you are forced to redesign something without 'affecting' other components that fixes become complex and expensive.

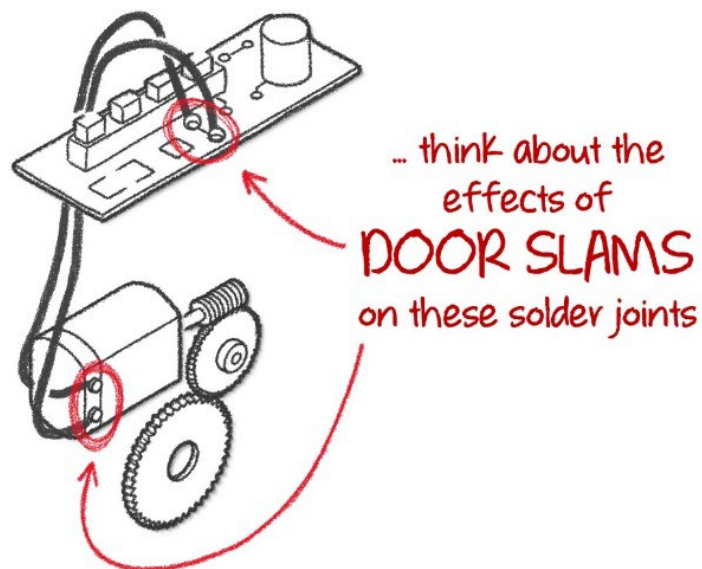
Think about a smart lock, which combines traditional 'mechanical' lock technology with contemporary 'smart' technology.



At the heart of the system is an electric motor controlled by electronic circuitry to transition the lock to or from a locked or unlocked state. Electric motor failure is 'critically bad.'

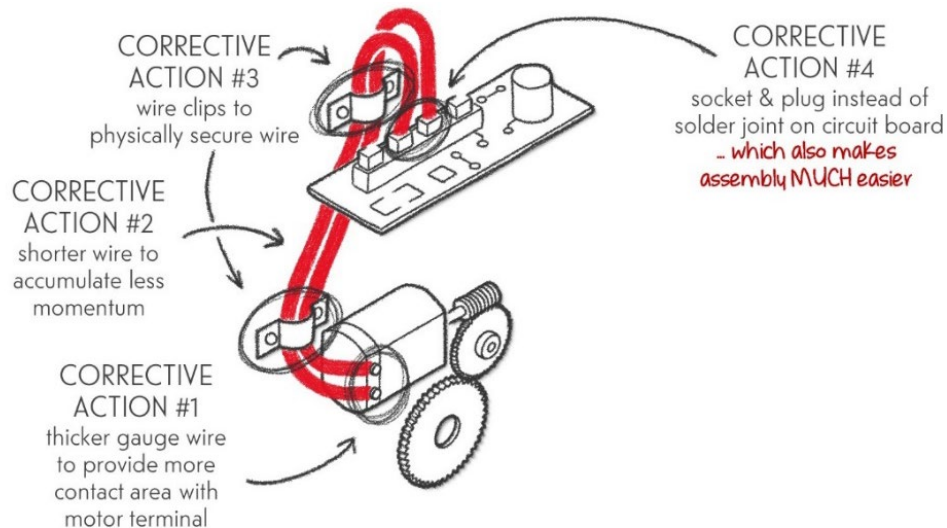


When we design something that is 'novel' or 'cool' we can often overlook the simplest of things. Like electric cables that connect the electric motor to the Printable Circuit Board (PCB). A **BUILD-TEST-FIX** approach means building a prototype that uses soldered cable that is not resilient to shock loads that are generated when a user or customer slams the door shut.



Perhaps qualification testing will uncover this critical design flaw ... as our lock needs to be able to withstand multiple shock forces when the door it is installed on is slammed (which a significant number of our future customers will no doubt do.) Unsecured cables in our smart lock that are only physically restrained with solder is a recipe for failure.

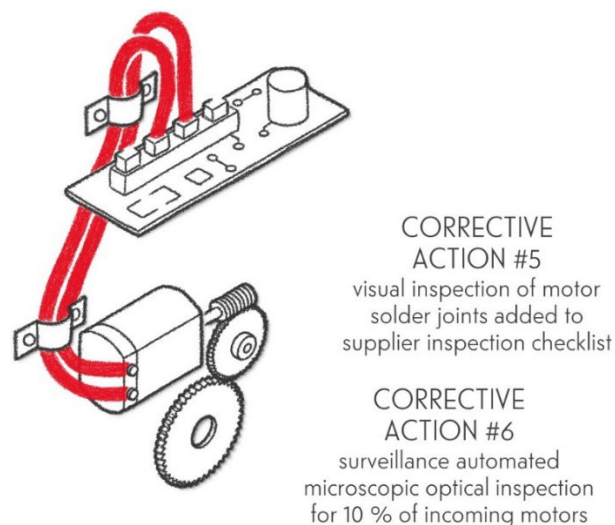
But instead of doing that, the smart lock's design team did 'smart' reliability engineering and perhaps conducted either a **FMEA** or a **FMECA**. The key outputs are a set of **Corrective Actions** that address the design, manufacture, maintenance or anything else that can improve reliability. And look how simple and inexpensive they are.



None of these design changes are complex or expensive *as long as they were thought of at the start*. Which is something that a **BUILD-TEST-FIX** approach can't do. **This is how we make reliability happen.**

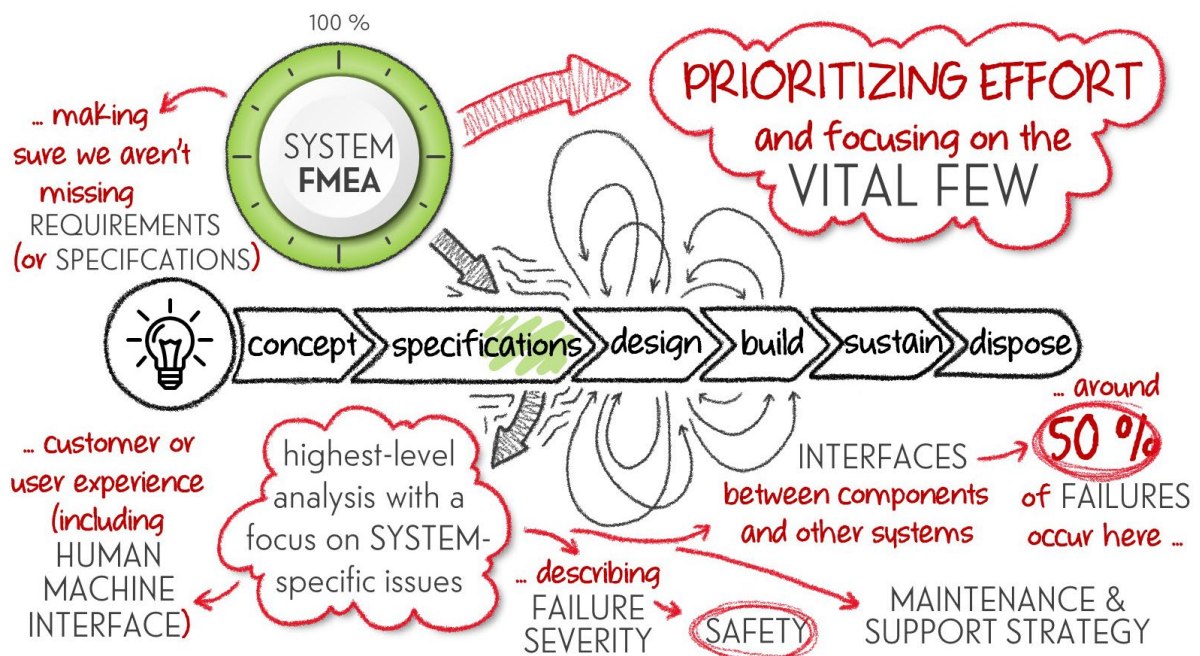
Many organizations struggle with testing. They get to the 'end' of production and have a confidence attack. They then reach for 'standard' tests and other activities that they hope will evaluate the **reliability** of their product. This approach rarely works.

Why? Because the best way to test is to focus on the **VITAL FEW** weak points of your product or system. Many 'randomly' selected tests focus on the strengths of your products. This tests nothing. Because **FMEAs** are all about understanding the weak points of your system, they automatically help you come up with meaningful tests that are fast and effective. Like those for the handheld radio below.

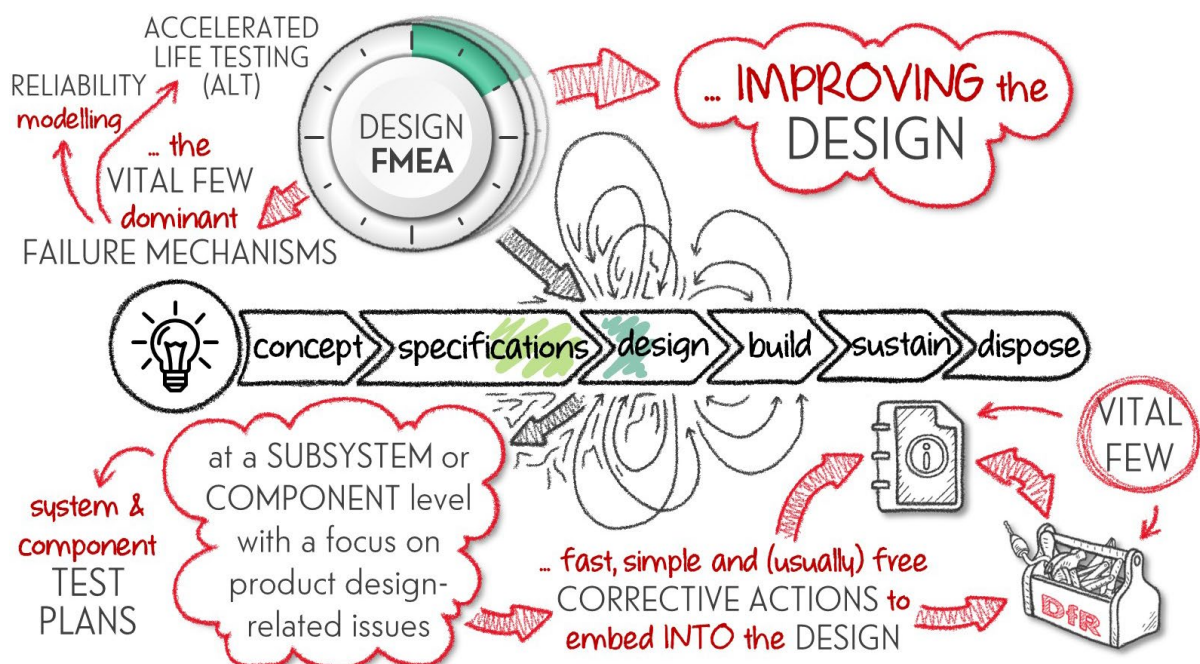


... so how do FMEAs work?

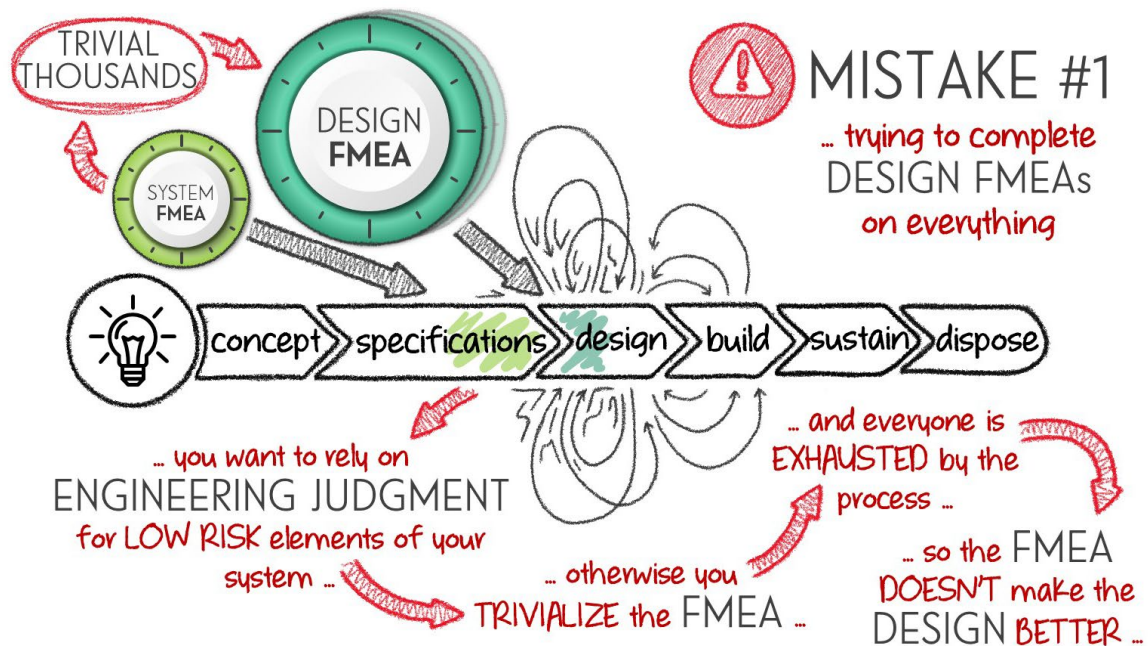
There are different types of **FMEAs** that we need to conduct at different times on our production schedule. The first is the **System FMEA** which focuses on higher-level issues.



The second type of **FMEA** is the **Design FMEA** which focuses on elements of your product or system. This is where the more specialized personnel who are intimately responsible for designing that element focus on improving that design.



But this is where many organizations make a their first **FMEA** mistake. And that is where you conduct **Design FMEAs** on everything. This means the organization didn't use the **System FMEA** to prioritize what the weakest parts of your system are.

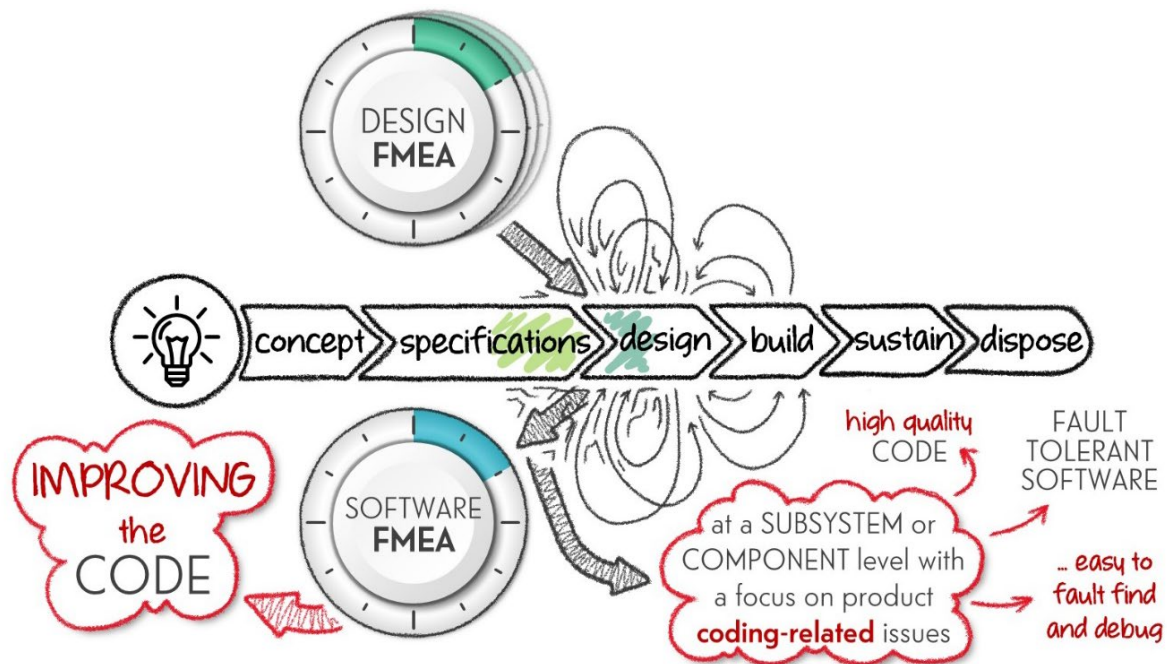


You cannot do **Design FMEAs** on every part of your system! This is what an organization looks like when they try to do it regardless ...

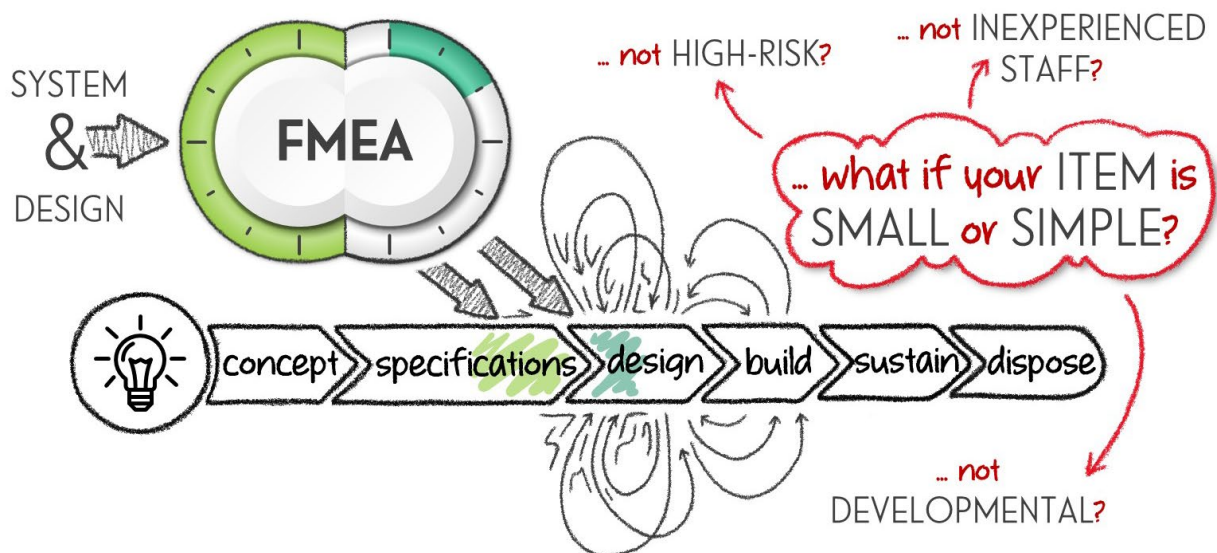


Up until this point we have focused exclusively on looking at our product as nothing more than hardware. This is usually not the case anymore. Even the simplest watch, microphone, fridge and

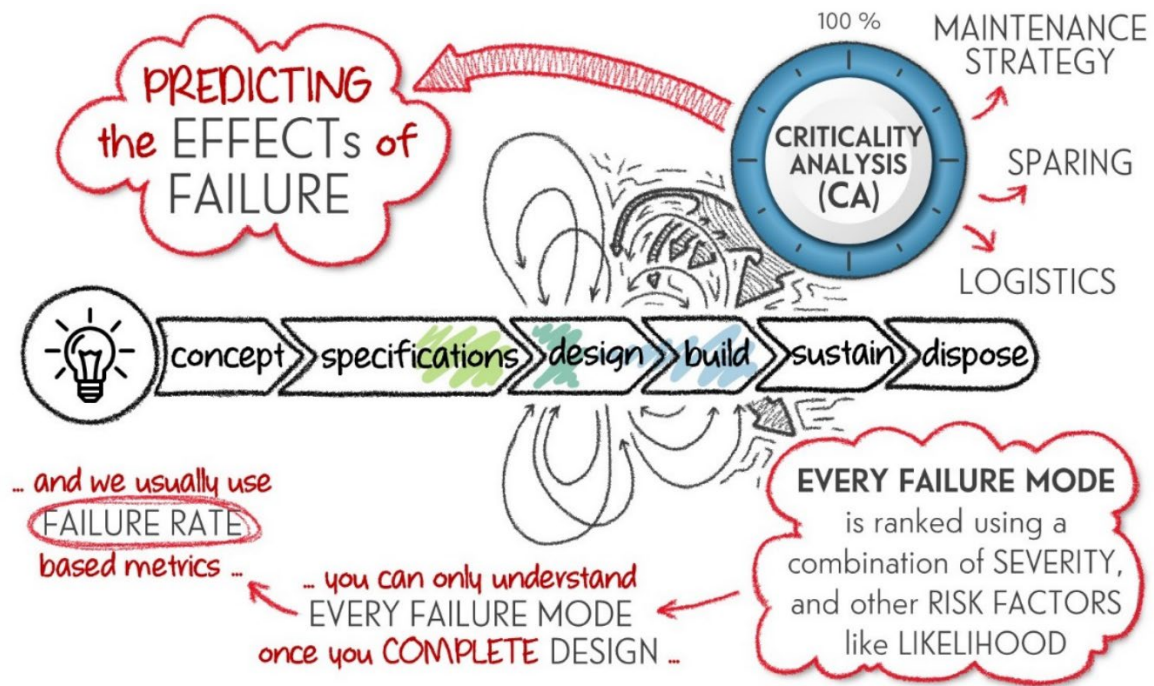
radio involve software. **Software FMEAs** are philosophically identical to **Design FMEAs** ... it is just that their focus is on software elements of the system.



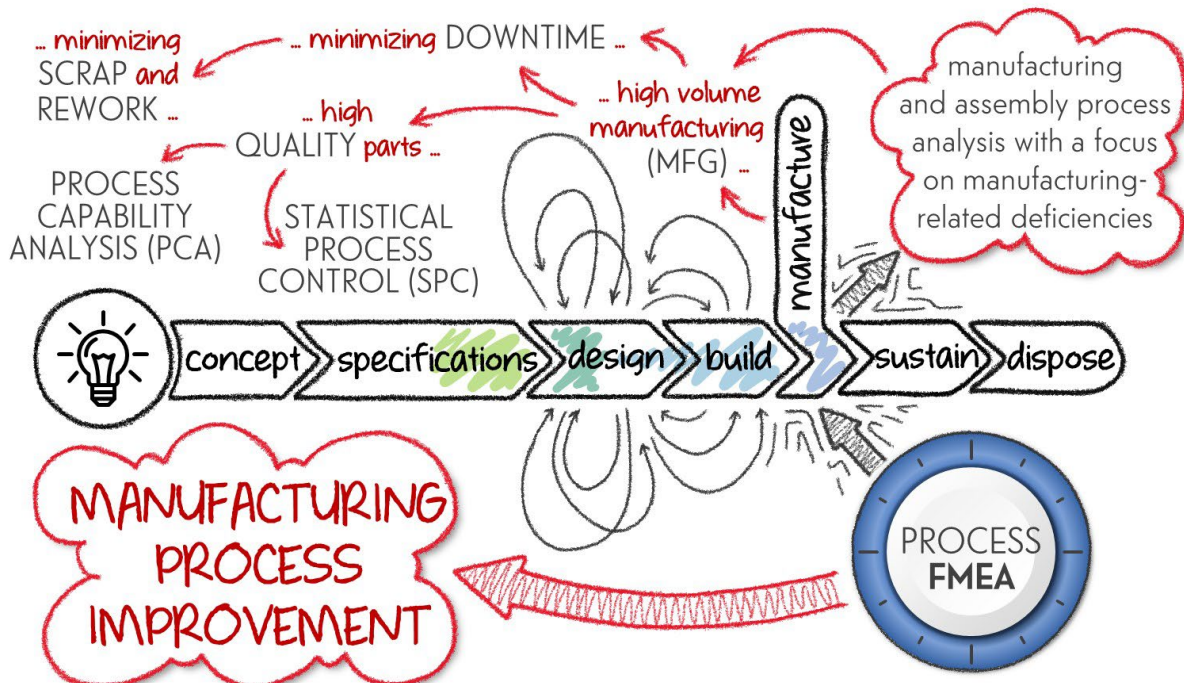
But of course, **FMEAs** need to be tailored. If we go back and focus on hardware only, there is scope to conduct a **System** and **Design FMEA** in one go. We simply call this ... a **FMEA**. You can't do this for every product or system ... especially if they are large, complex or involve severe **failure modes**.



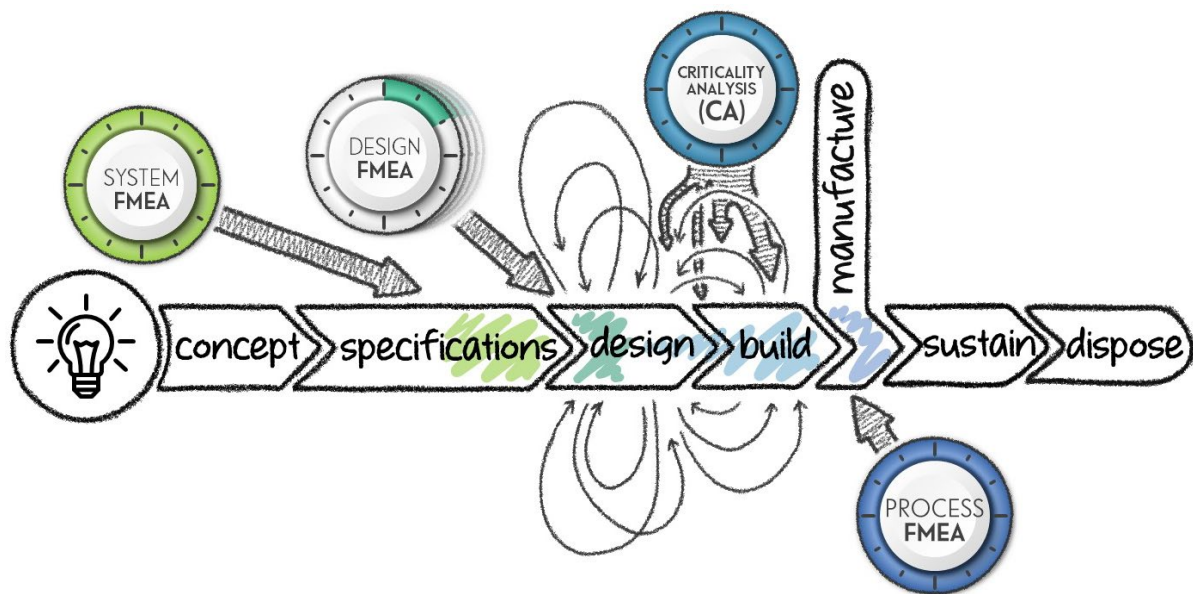
But how does the **Criticality Analysis** we talked about earlier come into play? It must be stressed that there is no broad agreement on what **Criticality Analysis** actually is! In practice, **Criticality Analyses** are less about improving the design and more about trying to understand every possible way your product or system might **fail** ... which is very challenging!



But there is one more type of **FMEA** ... the **Process FMEA**. The **Process FMEA** isn't focused on improving the design. It is all about improving any **process** ... including the manufacturing process you use to build your amazing new product or system. Here, the aim is to produce high quality parts that are well within tolerances and **specifications**. There is no point coming up with an amazingly **reliable** design, only to lose all that reliability through low-quality **manufacture**.



So our different FMEAs and Criticality Analyses tend to occur as illustrated below ...



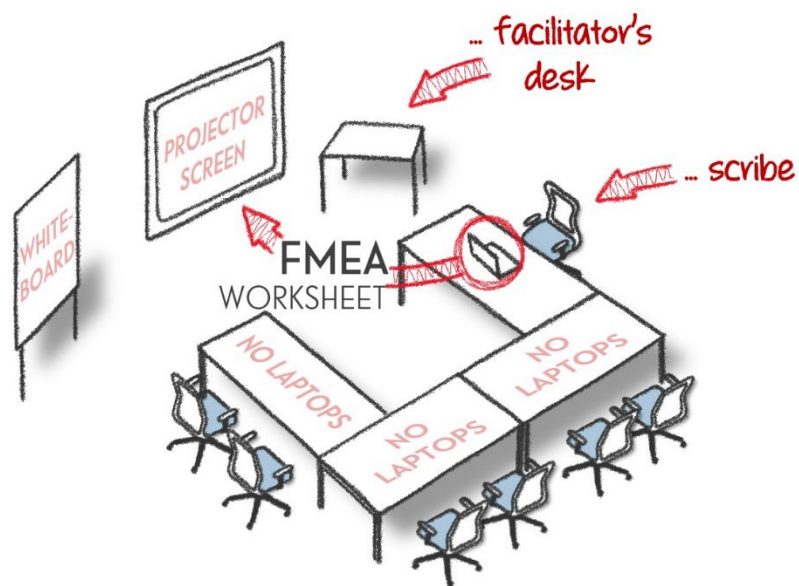
... and the MOST IMPORTANT factor for a FMEA is ...

An amazing FMEA starts with an **amazing FMEA facilitator**. He or she ensures that their **FMEAs are engaging and rewarding**. Of course, they require effort, but participants walk away with a bunch of ideas on how to make their role in creating a product, system or service easier and cheaper.



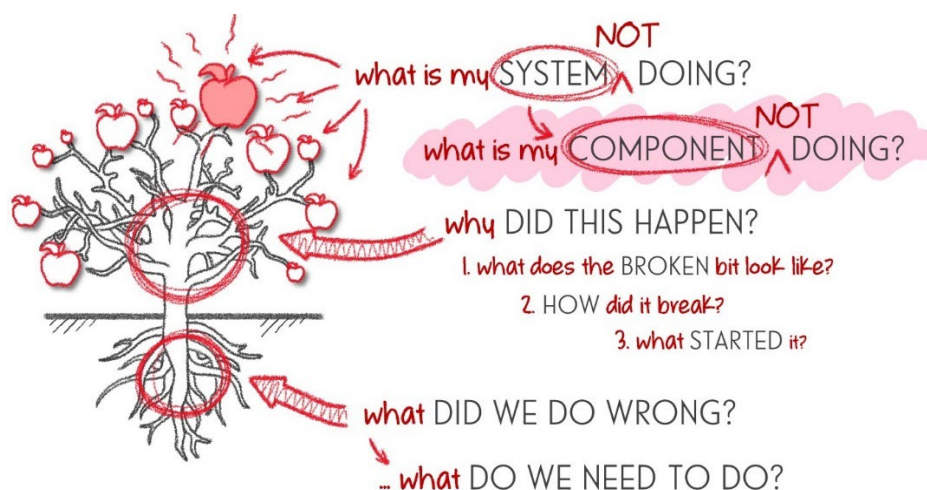
The FMEA itself is a group activity of **4-8 cross-functional expert representatives** that also includes an **amazing scribe**. Different FMEA types have different frameworks, aims and procedures, but they all focus on **really understanding failure**.

As each FMEA is a group activity, we need to get the group dynamic right. This starts with laying out where people sit ...

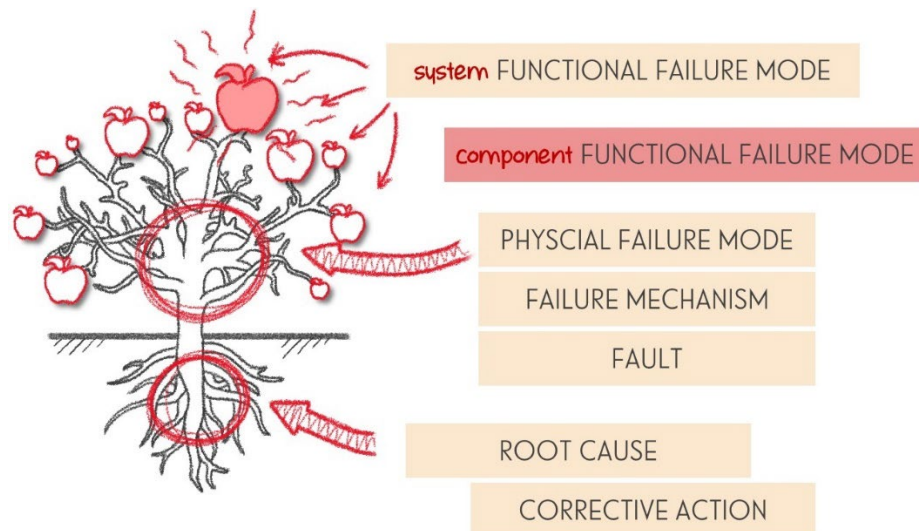


so how do SYSTEM and DESIGN FMEAs?

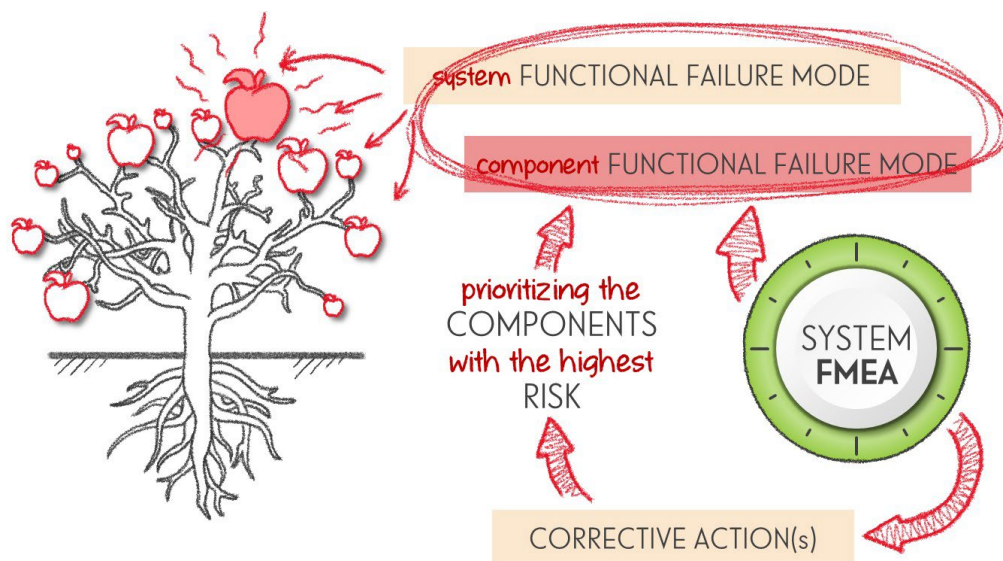
Amazing **FMEAs** and **FMECAs** rely on us prioritizing our efforts. Some systems are simple enough to complete a 'whole' **FMEA** or **FMECA** in one activity. Many systems are too complex. This means we need to be able to break the system into subsystems or modules, and only focus our **FMEA** and **FMECA** efforts on these VITAL FEW. To do this, we need to add one more 'question' to our tree of failure ... *what is my COMPONENT (NOT) DOING?*



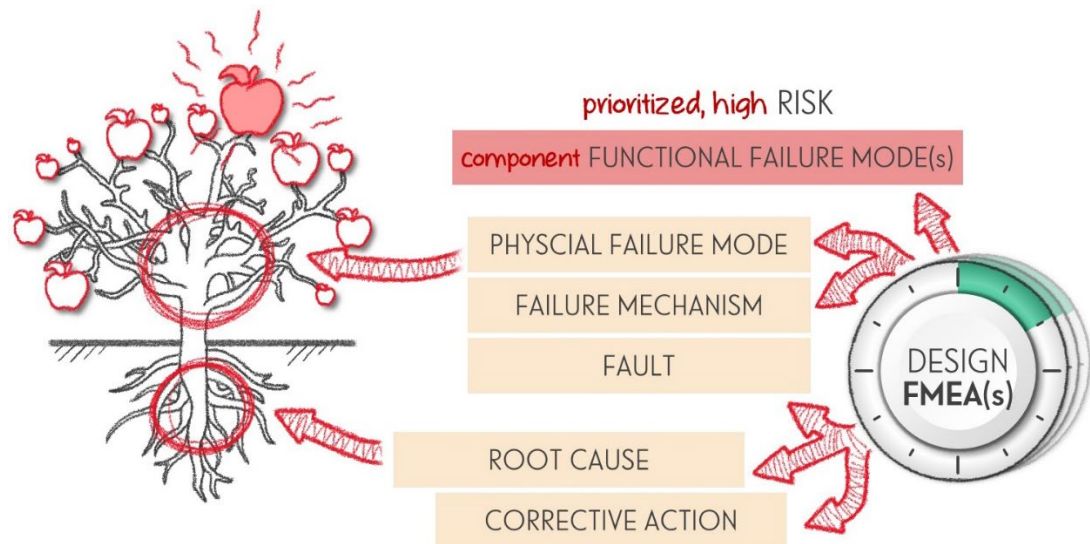
This introduces two new variations of a definition – **system functional failure mode** and **component functional failure mode**. They are both still **functional failure modes** ... just apply to different parts of our system.



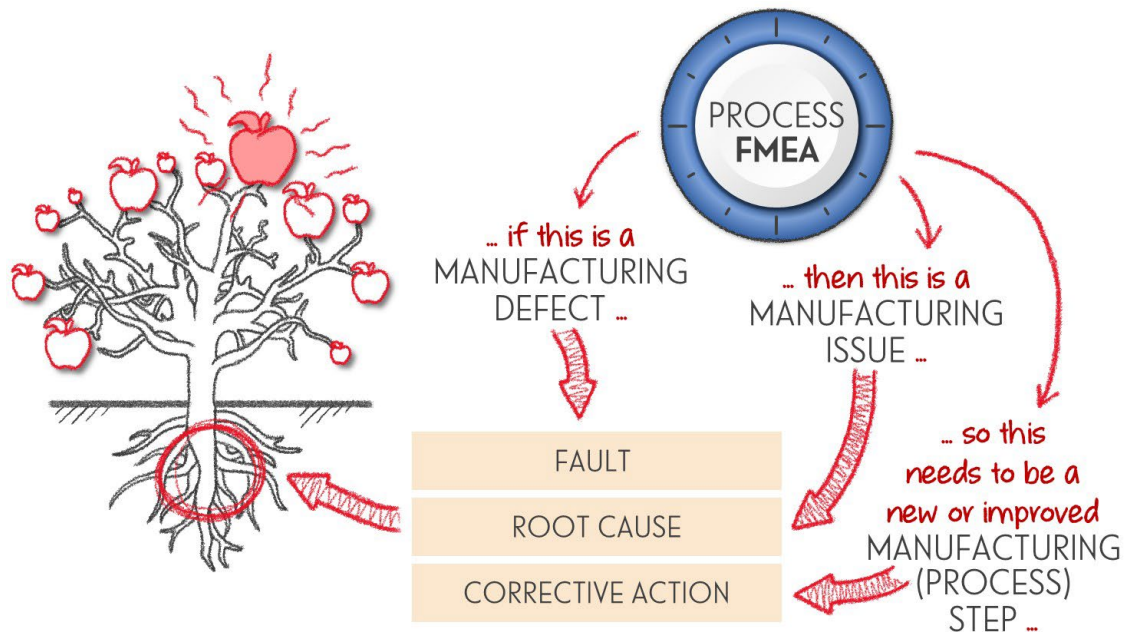
The reason we want to do this is because we want to conduct a higher-level **system FMEA** or **FMECA** that looks at how the system as a whole interacts with the environment and user, what the **specifications** say it needs to do and so on. It only needs to go 'as far down' as working out the VITAL FEW **component functional failure modes**, which will then be used by component-specific **design FMEAs** and **FMECAs**.



Design FMEAs that are conducted on the VITAL FEW components or system elements identified in the **System FMEA** then take the identified **component functional failure modes**, brainstorm more, and develop **root cause statements** for each. This allows **Corrective Actions** to be identified that involve design improvement, testing, material selection, manufacturing specifications and lots of other good ideas that can make the system or product better.



And if the **Design FMEAs** identify **manufacturing specifications** that will improve reliability or quality, they can then be subjected to **Process FMEAs** when it comes time to manufacture.



what is a PROCESS?

There are many ideas of what a **process** is (or is not). The more formal definition of a **process** is ...

... a set of interrelated work activities that transform inputs into outputs.

We are surrounded by **processes**. We are part of **processes**. We use things that are the results of **processes**. Smart technology increasingly means that **processes** are running night and day to help us 'do better' both personally and professionally.

Processes generate 'something.' And that 'something' can be valuable, useful, enjoyable or otherwise worthwhile. But not all **processes** are the same.

Some **processes** are inefficient. Some involve lots of waste and require constant 'reworking' of things already done. Some **processes** don't interact well with human beings (customers and operators).

But perhaps the most important thing we need to remember about **processes** is that ...

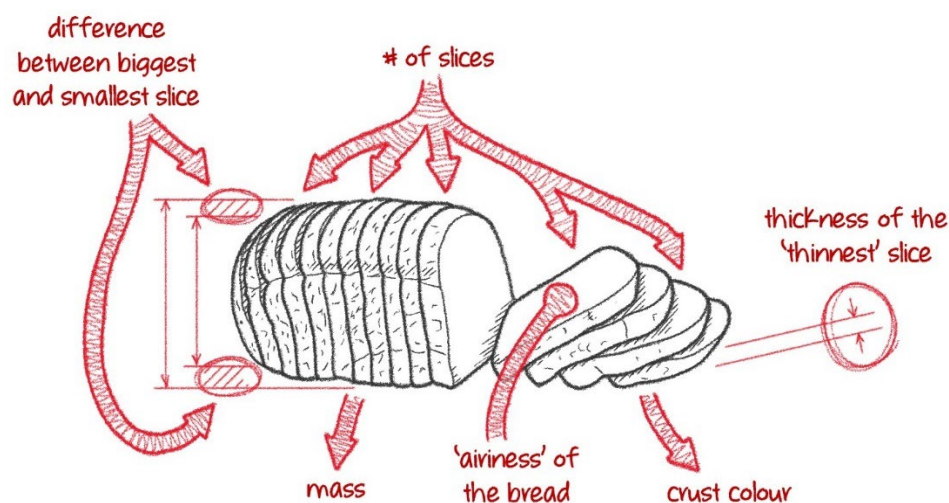
... PROCESSES change, evolve, age and deteriorate.

So what can we do to protect ourselves from **processes** that stop doing what we want them to do? This is a very light introduction into how we can '**control**' **processes** so that they stay well within the bounds of what we call 'acceptable.' And the driving principle behind this is PROACTIVITY. That means we leverage activities like **System, Design and Process Failure Mode and Effects Analyses (FMEAs)** to help us identify the likely VITAL FEW issues that are going to negatively affect our process ... along with **corrective actions** to make sure they never happen. But once our **process** is up and running, the fact that it WILL change, evolve, age and deteriorate means we need to continually fight to retain **control**.

And it is much easier to '**stay in control**' than to '**get back in control.**' Whether your **process** starts producing defective products, takes too long, reaches the wrong customer or anything else that represents something 'bad,' there is usually something that could have been done earlier (at very little cost) to make sure we never got here.

The commercial production of sliced bread is an example **process** to study and learn from. Bread is something that most of us enjoy eating daily. And even if you don't ... you can surely relate to similar foods that are produced in similar ways.

As is the case for most things in life, the **quality** of slice bread can be measured in many ways. A small selection of 'sliced bread characteristics' are illustrated below.

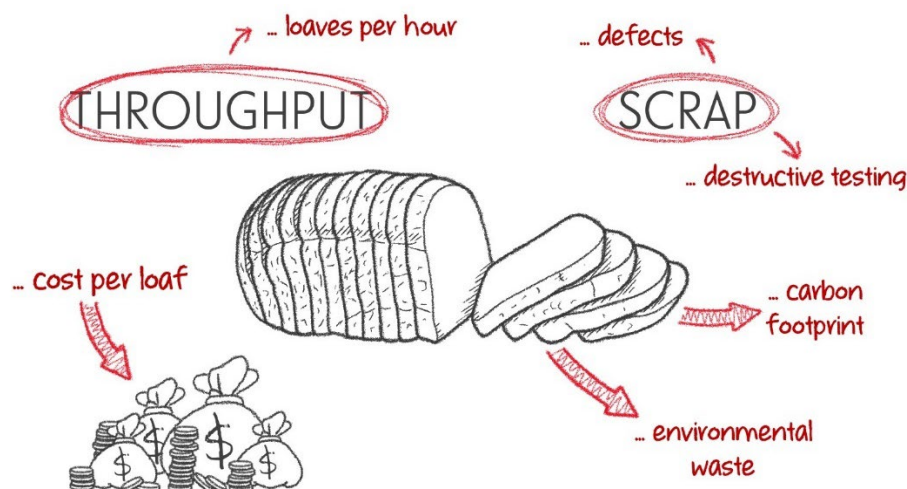


Different characteristics mean different things to different customers. For example, a parent who mainly uses bread to make sandwiches for their children to eat at school might value the consistent

size and shape of each slice. They might value bread that has minimal variation between the geometry of the largest and smallest slices in each loaf. Minimal variation makes it much easier to make sandwiches (which usually require two pieces of bread either side of a filling).

And of course ... other customers may value other characteristics of bread more so than geometry. So it is always important to know who your customer or user is, what it is that motivates them, what it is that they value, and (finally) what characteristics of your **process outputs** they consider 'high quality.'

And while the customer or user is perhaps the most important perspective when it comes to **quality**, we want to make sure our **process** has certain characteristics as well. And some of those considerations for commercial bread making include ...



It often seems difficult to measure what can be subjective things in an objective way. For example ...



This might sound like an 'abstract' or 'impractically subjective' metric. But that doesn't mean that we can't attempt to test the 'chewability' of our bread in an objective way.