10 steps to creating a FMEA

1. **List the key process steps in the first column**. These may come from the highest ranked items of your **C&E matrix**.
2. **List the potential failure mode for each process step**. In other words, figure out how this process step or input could go wrong.
3. **List the effects of this failure mode**. If the failure mode occurs what does this mean to us and our customer… in short what is the effect?
4. **Rate how severe this effect is** with 1 being not severe at all and 10 being extremely severe. Ensure the team understands and agrees to the scale before you start. Also, make this ranking system "your own" and don't bother trying to copy it out of a book.
5. **Identify the causes of the failure mode/effect** and rank it as you did the effects in the occurence column. This time, as the name implies, we are scoring how likely this cause will occur. So, 1 means it is highly unlikely to ever occur and 10 means we expect it to happen all the time.
6. **Identify the controls in place to detect the issue** and rank its effectiveness in the detection column. Here a score of 1 would mean we have excellent controls and 10 would mean we have no controls or extremely weak controls. If a SOP is noted here (a weak control in my opinion) you should note the SOP number.
7. **Multiply the severity, occurrence, and detection numbers**and store this value in the RPN (risk priority number) column. This is the key number that will be used to identify where the team should focus first. If, for example, we had a severity of 10 (very severe), occurrence of 10 (happens all the time), and detection of 10 (cannot detect it) our RPN is 1000. This means all hands on deck… we have a serious issue!
8. **Sort by RPN number and identify most critical issues**. The team must decide where to focus first.
9. **Assign specific actions with responsible persons**. Also, be sure to include the date for when this action is expected to be complete.
10. **Once actions have been completed, re-score the occurrence and detection**. In most cases we will not change the severity score unless the customer decides this is not an important issue.