# Solutions Process Engineering – Mind Your Tolerance

A process Engineer is responsible for the systems, equipment, and processes involved in the manufacture of products. One of the responsibilities of a Process Engineer is to monitor how accurately items are being produced according to their design specifications, and to report anomalies that could indicate the need for an adjustment in the equipment or process.

During the manufacture of Metered Dose Inhaler canisters, the valves are crimped onto the canister. To ensure integrity of the product, In-Process Checks are conducted on the crimped canisters. Each Canister is measured for Crimp Height (*mm*), Crimp Diameter (*mm*), and Net Fill Wt. (*g*). Results are recorded in the "Sample 1" and "Sample 2" sheets of the CanisterSampleData_Student spreadsheet. Answer the following about your assigned Exercise.

1. Analyze the In-Process Check Data in order to determine if any product has one or more measurements that are not within specifications. Record a "flag", or note, for any canister with a measurement that is outside the tolerance of specified design value:
    - The Crimp Height must be within $0.08\,mm$ of the design spec of $6.96\,mm$.
    - The Crimp Diameter must be within $0.10\,mm$ of the design spec of $17.80\,mm$
    - The Net Fill Weight must be within $0.30\,g$ of the specified $6.50\,g$.

a. Do you notice any trends in the data? Be sure to examine columns as well as rows. Explain below.

In Samples 1 & 2, Fill Weights are increasing for the last several samples. Most are still within tolerance, but this could indicate the need for an adjustment in the equipment. In Sample 3, the mean for the Crimp Height measurements is high, suggesting a possible need to adjust the machine.

b. Does the data cluster around a particular value, or is it spread out?

Answers may vary. Since canisters are expected to be uniform, we would hope the data clusters around the designed value.

c. Briefly explain how you identified the information requested above. Could a graphical representation of the data be helpful? What might that look like? Encourage students to be as specific as possible.

Most students will have visually scanned the data for readings that are outside the range of tolerance, i.e., below 6.96-0.08, or 6.88, or above 6.96+0.08 or 7.04, etc. Some may have generated a graph of the data in the spreadsheet or in a graphing tool such as Desmos to see any data points that may fall outside the interval of tolerance.

d. Compute the mean and standard deviation for each parameter (measurement) in your worksheet.

i. Explain what the mean and standard deviation tell you about the crimp height, crimp diameter, and fill weight of a run of canisters.

The mean gives the typical measure. If the mean is noticeably out of tolerance, equipment may need adjustment. The standard deviation describes the variance in measures of the data set. If this number is large, the equipment is not producing canisters consistently indicating a need for service.

ii. What would you expect the mean to be? Explain.

Crimp Height: $6.96\,mm$ or very close, because this is the design specification.
Crimp diameter: $17.80\,mm$ or very close.
Net Fill Weight: $6.50\,g$ or very close.

iii. What would you hope the standard deviation would be? Explain.

We would like the standard deviation to be very close to 0. If the equipment is operating within close tolerances, there should be very little variance in the readings.

iv. Explain what the mean and standard deviation tell you about each measurement, and how you would use these values to make recommendations.

The mean tells you how closely to tolerance the products are being produced. The Standard Deviation indicates how consistently the equipment is operating. If the Mean is off, but the standard deviation is very close to zero, the machine is running consistently, but its settings need adjustment. If the Mean is on-target, but the standard deviation gets large, the equipment may need

maintenance.

e. What recommendations would you make based on these results?

With the increasing trend in Fill Volume measurements in samples 1 & 2, the machine or the measurement device may be having problems and needs attention. With the CrimpHeights running high in Sample 3, that machine or measuring device may need adjustment.

During the manufacture of Metered Dose Inhaler canisters, the suspension (active medicine along with additives) is recirculated to fill the canisters with the proper drug concentration or mixture. To ensure integrity of the product, In-Process Checks are conducted on the process parameters related to the filling vessel and system. Every 50 canisters the process equipment is checked and the parameters of **Temperature (*°C*), Stir Rate (*rpm*), Recirculation Rate (*L/min*) are recorded.**

Results are recorded in the "Remix Sample 3" sheet of the spreadsheet.

2. Analyze the In-Process Check Data in order to determine if the product is within specifications. Record a "flag", or note, for any canister with a measurement that is outside the tolerance of specified design value.
    - The temperature must be within 2.00°C of 21.00°C
    - The Stir Rate should be within 5 *rpm* of 200 *rpm*
    - The Recirculation Rate must be within 0.10 *L/min* of 2.50 *L/min*

a. Do you notice any trends in the data? Explain below.

At samples 9-12, temperature and recirculation rates were off together. These two variances may be related. All the Stir Rates are within tolerance. no adjustments necessary. This does not happen often in classroom exercises, but it does happen in industry.

b. Can you think of a more efficient way of identifying the canisters that are "out of tolerance" than you described in #1? Explain.

Students will likely suggest there must be a way to have the computer check for them, but may not know how this can happen. Connect the IF commands in spreadsheets with the language they will likely use "If the crimp height is less than 6.88, then it is out of tolerance". Students may not have the tools to construct the spreadsheet commands.

c. Compute the mean and standard deviation for these measurements. What do these results tell you about the mixing process?

The Mean for Temperature is a little higher than the intended value, but the readings are just what we would expect for Stir Rate and Recirculation Rate. The Standard Deviation for temperature is more than half the tolerance. It might work fine, but attention to this reading may be needed to avoid an interruption in production for maintenance. Stir Rate is very consistent at the intended value with very little variance. The standard deviation value for the Recirculation Rate is very close to the tolerance, suggesting that this reading could be out of tolerance fairly often.

Now that you have had some experience with the Process, take a look at the Batch Review sheet of the spreadsheet.

3. How is this sheet different?

The number of samples is considerably larger

4. Will your method for identifying values outside of tolerance from the previous page work well with this new task? Explain.

Visual inspection would probably take a long time, and a graph may not be helpful due to its size - a very long x-interval, with a relatively small y-interval. Hopefully there is a way the software can help.

5. Describe a way that you think the method for identifying readings out of tolerance could be improved over scrolling though the table of numbers. Discuss this suggestion with your partner(s).

Here again, students will likely be attracted to the idea that the spreadsheet should be able to check for them. They may not be familiar with the IF statement in a spreadsheet, but likely could describe the conditions mathematically. Students should describe numbers that are greater than the desired value minus tolerance and are also less than the desired value plus tolerance. This discussion could be valuable in developing the logic behind the IF statement.

Use the fact that a statement like "E5<6.88" is either TRUE or FALSE. If it is TRUE, the spreadsheet will assign it a value of 1; and if it is FALSE, the spreadsheet will assign it a value of 0. The command in H5 could look like
=IF(((E5<6.88)+(E5>7.04)+(F5<17.70)+(F5>17.90)+(G5<6.20)+(G5>6.80))>0, "Out of Range", "")
Each of the six comparison statements is either TRUE or FALSE. If they are all FALSE, all six expressions evaluate to be 0, so their sum is 0. If any reading is outside the tolerance, the expressions will evaluate to 1, and the sum will be greater than 0, and the "Out of Range" flag will be displayed. If they are all FALSE, the sum will be 0, and nothing will be displayed. Having a message appear in that column makes checking for the existence of an error a quick visual observation.
Spreadsheet tools have conditional formatting tools to change the appearance of the cell containing a reading that is out of a range. This method can be useful if there is a need to know *which* reading is out of tolerance.
Add this feature to the spreadsheet. If you downloaded the data as an Excel spreadsheet, upload it into Google Classroom/Canvas.
In the CanisterSampleData_Teacher.xslx file.

6. How do you think you could look for patterns in a data set this large? Did you see any patterns in the data? Speculate on a cause for any patterns that you see.

A graphical display might be helpful in this case. Intervals of increase or decrease or drastic variation will be visually apparent. These would indicate a need for attention to the process.
Look in the results for clusters of "Out of Range" flags. If several consecutive or grouped flags occur, there may have been some problem at that point of the production run.

**Reflection Questions**

For each of the following data patterns, make a conjecture for each situation. Possible answers. Students should be encouraged to use their imaginations

a. Near the end of a production run, the Crimp Diameter was increasing over the final 15 samples. What might cause this? mechanical failure, a component is wearing out or coming loose
b. In the middle of a production run, a "clump" of medication clogged the filling valve to the canisters. How might you be able to recognize this event from a set of sample data? Since the medication is a fine powder, the fill valve may have gotten clogged with lumps. Temperature variation could affect viscosity.
c. The Crimp Height was below the specified tolerance in the first 18 samples, but fell within the tolerance for nearly all the remainder of the samples. What might cause this event? the machine started out misaligned and settled in.
d. Every item in five consecutive production samples has been with specifications on all parameters. Is this likely? What might be a cause? Could be a pleasant surprise with machinery running properly. Measuring tools might be out of adjustment.