Senior Project

Final Report for

Process Validation of IACV screw

In the partial fulfillment of TECH 4945

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Executive Summary

Process validation is an analysis tool that is always used in engineering for design and quality improvement with how to improve upon processes. This project is to create new IACV Screws with the improvements added into the original design and not just material that was chosen. The original screw was created out of a high heat resistant plastic with a Philips head as part of the original design and that was very commonly prone to stripping out and this will cause the loss of being able to adjust the screw. The new and improved screw is made with 4140 Stainless steel with a 8 mm hex head milled in to prevent the loss of ability to adjust the screw. The goal of this project was to acquire the data needed to know where the improvement is needed to create the perfect process.

The validation of this process was to create thirty machined screws that was repeatable and accurate. The process was check to industry standards and tolerances were taken from design guides as needed. Each part was checked with precision measuring instruments and machined with CNC and manual machines. The data taken from each critical dimension was collected using excel and calculations were done to obtain $C_{P,}$ C_{PK} , and Standard Deviation. Finally the results, revealed that this process is not in control and will need to be revised and revalidated.

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Introduction

The fundamentals of process validation are the analysis of data that is obtained throughout design and manufacturing a product to confirm the process or processes used to design and manufacture said product can product reliable and consistent results all of which are set by regulatory authorities. Depending on what is being is being products the regulations will be set by different groups. "Process Validation refers to knowing a process thoroughly and approaching the same in a structured way. It involves ultra-careful Documentation for every step, including manufacturing, device history, standards of operations (SOPs), and other controlled documents. If the process validation is not conducted, you will eventually be producing a poor-quality product." (Admin) In the automotive world, the group that works with the regulations would be Nation Highway Traffic Safety Administration (NHTSA) who issued the Federal Motor Vehicle Safety Standard (FMVSS). The standards are followed by automotive manufacturers and designers all throughout the United States with other standards for different countries around the globe. In 1989, Nissan first introduced the SR20DET engine in the Nissan Bluebird and later the engine was placed into the Nissan Silvia. The project will be based on an engine part that would help the engine idle at the correct RPM (rotations per minute). This is called an Idle Air Control Valve screw (IACV screw) as shown in Figure 1. The project used a Computer Numerical Controlled Lathe (CNC Lathe) to machine thirty of these screws and each screw will have the critical dimensions all checked and verified that they are in tolerance. "A lathe is a machining tool that is used primarily for shaping metal or wood. It works by rotating the workpiece around a stationary cutting tool. The main use is to remove unwanted parts of the material, leaving behind a nicely shaped workpiece." (Precision) A CNC Lathe is a computer-controlled machine which will cut pre-programmed products. With this project the screw was designed in Siemens NX which is a Computer Aided Design (CAD) Software which will allow us to create a 3D model of the screw and create a working drawing of this for manufacturing. A working drawing will show the engineers and machinists which dimensions are critical and how the finished product will look like. In Figure 2, it will show a finished version of the product. This screw was made from AISI 4140 Stainless Steel which is a heat-treated stainless steel. "AISI 4140 steel is a low allow steel containing chromium, molybdenum, and manganese. It is widely used across numerous industries and is an excellent material choice due to its toughness, high fatigue strength, and abrasion and impact resistance." (Btiernay) After screws are machined, they will all be verified with dial caliper and micrometer to ensure the critical dimensions are within tolerance. The threads on the screw will be checked using the three-wire method and micrometer to ensure they are with in tolerance. "A Dial caliper is a calibrated precision measuring tool that is useful for taking accurate measurements." (Wonkee) "A micrometer is a precision measuring instrument, used to obtain very fine measurements and available in metric and imperial versions. Metric micrometers typically measure in 0.01mm

increments and imperial versions in 0.001 inches." (Chris) "The three-wire measuring process is one of the most precise procedures for determining the pitch diameter of threads." (Proteus)

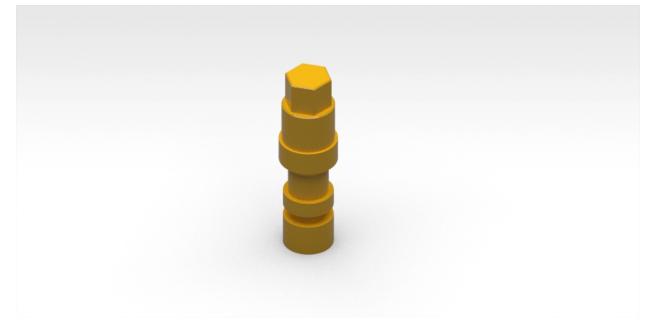


Figure 1- 3D model of IACV screw



Figure 2- Finished IACV screw

Review of Objectives

The primary objective of this project is to create thirty parts and do a process validation on each of the thirty parts that are machined and have all critical dimensions checked and verify that they are within tolerance.

Review of Deliverables

The deliverables for this project were as follows:

- 1. Thirty machined IACV screws
- 2. Verification of critical dimensions of all thirty IACV screws
- 3. Process validation of critical dimensions

Technical Implementation

This screw was designed originally by taking measurements of the original plastic screw which was part of the IACV assembly. After taking the measurements, they were used to create CAD model as shown in Figure 1 above. During the manufacturing of the screws there was a setback; the school where the CNC and manual machines was shut down for summer break. The screws were made to the print shown in Appendix B. Tolerances were determined using design guides from Parker and Fast-Rite. When proofing out the CNC program the chuck of the CNC lathe was not adjusted correctly and was loose when it was clamping on the round stock. This was not noticed until eleven parts had been made and the CNC program was already proofed out. The chuck was readjusted to ensure the round stock would be clamped tightly and it would not move during the machining process. There was no real deviation from the original technical plan. After the screws were all machined, each critical dimension was checked to the print shown in Appendix B using a digital caliper and micrometer.

Evaluation of Plan of Work

The original plan was to have the machining side of the project complete by the end of summer break and do all measuring and data figuring during the school semester. Upon figuring out completing the project during the summer was not possible until Moore Tech was opened back up for the fall semester the machining of the project was able to begin. During proofing out the CNC program the chuck was loose which set back the project in the aspect of wasting material which could have been used to make extra parts in case of scrapping parts during machining process. Once the program was proofed out, a smaller diameter round stock was found and was switched to this smaller size to keep the machining time down. The material hardness was one of the main reasons machining time was high. The choice of this material was chosen due to material availability, characteristics, cost, corrosion resistance, durability, and reliability. 4140 Stainless steel was pick over 6061-T6 aluminum due to the body the screw is going into is cast aluminum and in hopes to prevent galling of the aluminum this was the right choice. This screw would be placed close to the head of the engine which expelled an ampule amount of heat and the stripping of the original adjustment head being a common issue recreating it from plastic was not an option. This created a limitation of options in choosing material. In planning of this project, the use of all carbide tooling was thought to be ideal since the material is stainless steel, and it would be a harder material to machine. During proofing out the program, it was found that a carbide threading tool did not last longer than 5-6 parts. The carbide insert would be broken after 5-6 parts, and the decision was made to switch to High-Speed Steel tooling. A ¼" High-Speed Steel tool blank was used to create a 60° threading tool to replace the carbide tooling. The use of a wire EDM machine in creating the threading tool. The wire EDM was able to cut the 60° threading tool with a 1.5° relief angle as well.

If the project were to be redone the following suggestions would be recommended.

- Ensuring location used to produce parts is accessible.
- Making sure you have everything planned out (time and location management)
- Ensure tooling is up to par if tooling fails have replacements/backup plan.
- Have centralized location for machining, storing tooling, material, and parts.
- Complete as screws as possible in one day to minimize machine changes.

Evaluation Results

In checking the dimensions, the results are taken and used to calculate if these are good and within tolerance. Even if the results are within tolerance it does not mean that it is in the "ideal range limits"; this is where CP and CPK is used to show where the result fall in the "ideal range limits" "CP (Process Capability), which measures the variability of the data and the distance between the process average and the specification limits" (Pannell) and "CPK, short for "Process Capability Index," is a statistical measure used to determine the ability of a process to produce products within specified limits." (Pannell) The general rule of thumb is both C_P and C_{PK} should be as close to the number 1 as possible to be within specification. If the C_P and C_{PK} values are between 0 and 1 the process is within the scope of requirements. USL is calculated with *spec* + *tolerance* and LSL is calculated with *spec* - *tolerance*. C_P is calculated with $\frac{USL-LSL}{6*Std.dev}$. C_{PK} USL is calculated with $\frac{Z USL}{3}$ and C_{PK} LSL is calculated with $\frac{USL-LSL}{6*Std.dev}$. Area of all dimensions from each part. Z USL is calculated with $\frac{USL-LSL}{3}$ and Z LSL is calculated with $\frac{LSL-X-bar}{Std dev}$.

With this project, there were five critical dimensions that were decided based on what would be necessary for the screw to be used. These critical dimensions will be discussed below.

CN (Critical Number) 1 is the head of the screw as shown below in *Figure 3*. This was an 8mm hex head machined into the screw, which was needed to fit a socket or nut driver to adjust the screw. According to Fast-rite page 38, the tolerance for an 8mm hex head is 0.22mm which converts to 0.0087 inches. This was a crucial part to fit different brand/manufacturers of an 8mm socket, which is why it is crucial to use industry standards with dimensioning this hex head. All screws were within the limits, but there were more than half below the spec and closer to the LSL which does not mean the screw does not work. The hex head would be slightly loose when a socket or nut driver is being used, but since the amount of torque needed to turn this screw is not very high this would not cause the screw to strip. In addition to measuring all six sides of the hex; the hex head was checked with a combination wrench, sixand twelve-point socket, and a six-point nut driver. The C_P for this is 1.279, which is okay but not good since it is above 1. With the C_P for CN 1 above 1 which it means it is not capable or centered. C_P is calculated with $\frac{USL-LSL}{6*Std.dev}$. The C_{PK} is -0.965 which is not ideal for the C_{PK} ideally it should be 2 or higher.

 C_{PK} USL is calculated with $\frac{Z USL}{3}$ and C_{PK} LSL is calculated with $\frac{Z LSL}{3}$. Figure 4 shows the standard deviation of CN 1, this chart shows where the measurements are with dispersion in relation to the mean or average of the dataset. In Figure 5, this shows where exactly each part falls within the specification and tolerance (USL (Upper spec limit) and LSL (Lower spec limit)). There are sixteen parts out of thirty that are below the specification limit, which is still technically within tolerance, but it is not ideal. In testing with a combination of a combination wrench, six- and twelve-point socket, and a six-point nut driver; the parts that are still functional in its ability to turn the hex head.

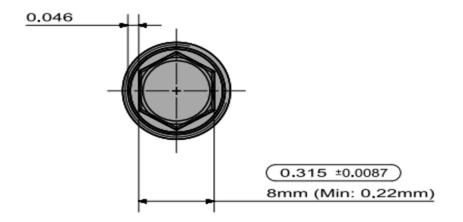


Figure 3 - CN 1 Hex head of IACV Screw

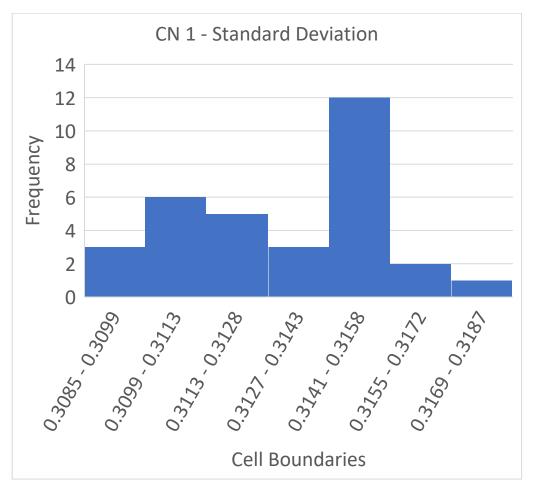


Figure 4 - CN 1 Standard Deviation

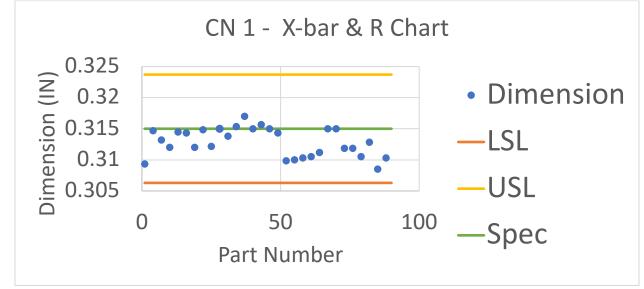


Figure 5 - CN 1 - X-bar & R Chart

CN 2 is the threads of the screw this is a metric M12x1 as shown below in Figure 6. The threads were checked using the 3-wire measuring method to get the more accurate reading. This includes selecting the correct wire diameter for this thread pitch. It requires a wire diameter of 0.023'' or 0.58mm. A steel welding wire was used with this diameter and a measurement of the wire was taken to ensure correct wire dimensions. This welding wire measured 0.02255'' which will work for this application. All the dimensions are within the spec limits, but there are eleven parts right on the line of the LSL which were not to the ideal measurement for the parts should be. The C_P for CN 2 is 1.227 which is okay, but since the actual dimensions are still on the lower bound of the graph this process will need to be improved on. The C_P should be at 1 ideally, with the C_P for CN 2 above 1 which means it is not capable. The C_{PK} for this is -0.325 which is not ideal for the C_{PK} ideally it should be 2 or higher. Which means the C_{PK} is falling short and outside of scope.



Figure 6 - CN 2 M12 x 1 Threads

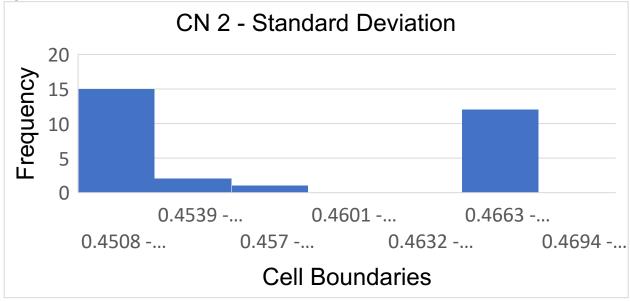


Figure 7 - CN 2 Standard Deviation

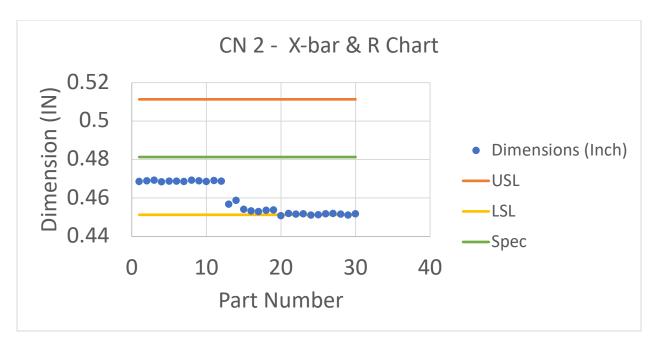


Figure 8 - CN 2 X-bar & R Chart

CN 3 is the groove where an o-ring will be installed as shown in Figure 9. This groove is shown below in Figure 9. This groove was measured with digital calipers. The tolerance of this groove was determined from the use of an o-ring design guide from Parker Hannifin. The guide specifies there is only an allowance in the USL (Upper spec limit) and for LSL (Lower spec limit) will be the dimension the screw is drawn to. Which mean anything that falls below the specification of 0.28" in this case will be out of spec and would be deemed as scrap or not useable. The diameter of this groove is an important because of the surface areas of where an o-ring and the groove meets is crucial for sealing of the screw to this valve itself to allow correct adjustment of air flow. The standard deviation is skewed to the left is not centered and was below the tolerance as shown in Figure 10. Out of the thirty parts there were twenty-three that are out of tolerance as shown in Figure 11. The C_P CN 3 is 0.053 which is far below one. The C_{PK} for this is 0431 which is not ideal for the C_{PK} ideally it should be 2 or higher. Which means the C_{PK} is falling short and outside of scope. This part of the screw is not in tolerance since there are more part that were out of tolerance and consider scrap.



Figure 9 - CN 3 O-ring groove

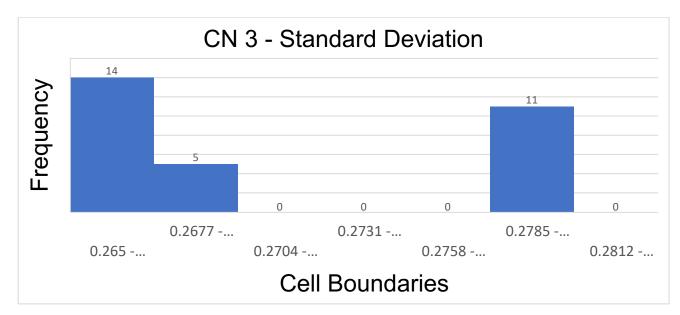


Figure 10 - CN 3 Standard Deviation

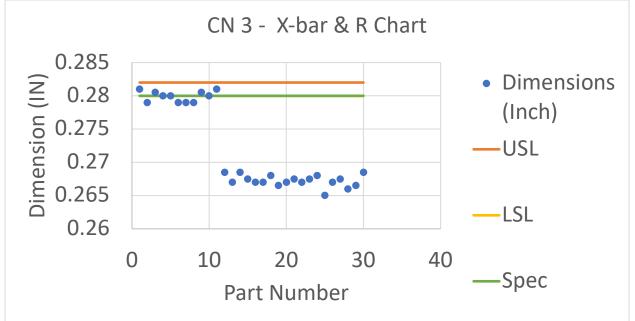


Figure 11 - CN 3 X-bar & R Chart

CN 4 is the "piston" of the screw this is the bottom of the screw as shown in Figure 12, and this is the part that cups the air to the valve to adjust for idling of the engine. There are eleven parts that are in tolerance and there are nineteen parts that are out of tolerance with one that is above tolerance and the rest under as shown in Figure 14. In Figure 14, it shows the Standard Deviation is skewed to the left and not centered. The $C_P CN$ 3 is 0.172 which is far below one. The C_{PK} for this is 0.049 which is not ideal for the C_{PK} ideally it should be 2 or higher. Which means the C_{PK} is falling short and outside of scope. This part of the screw is not in tolerance since there are more part that were out of tolerance and consider scrap.



Figure 12 - CN 4 "Piston" of screw

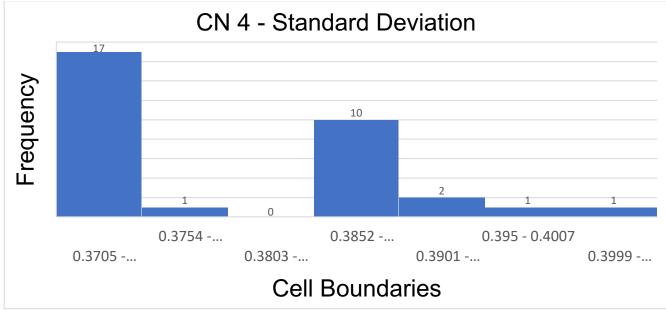


Figure 13 - CN 4 - Standard Deviation

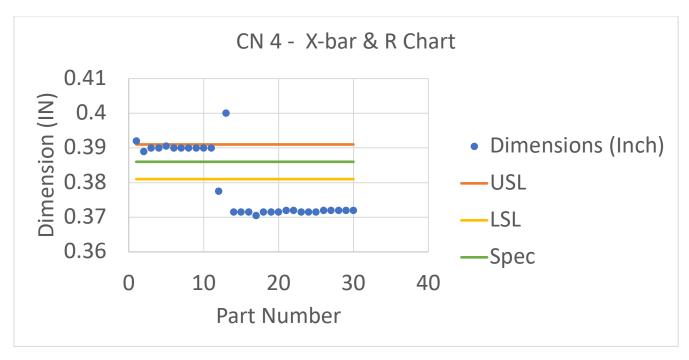


Figure 14 - CN 4 X-bar & R Chart

CN 5 is the overall length of this part. This was a crucial part since if the length is too short this would not work and would be too far down into the valve and it would be not adjustable. The extra length of this part was designed into the length of the hex head and the rest of the screw is not affected by the extra length. During designing of this part this was the intent to allow for more length on the hex head for extra grip of the socket head as shown in Figure 15. In Figure 16, the Standard Deviation is skewed to the even though the parts are within the limits, but the parts were in the lower in the specification. Where the parts fall within the measurement is shown in Figure 17. All thirty parts all fall very close to the Spec and LSL this was controlled from manually parting off the part. The $C_P CN 3$ is 1.577 which is ideal and means this was somewhat in control. The C_{PK} for this is 2.678 which is ideal for the C_{PK} ideally it should be 2 or higher.

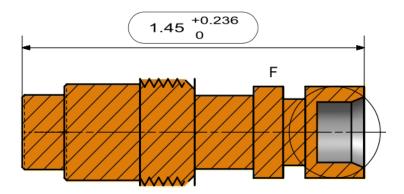


Figure 15 - CN 5 Total length of screw

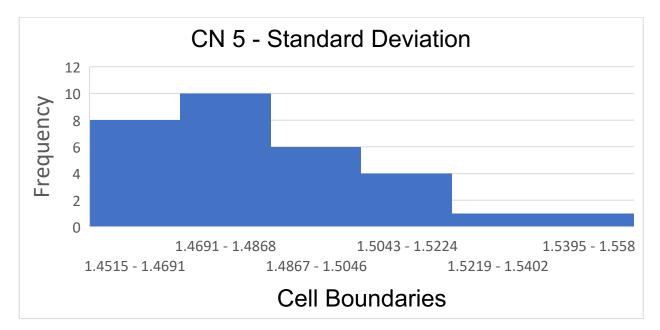


Figure 16 - CN 5 - Standard Deviation

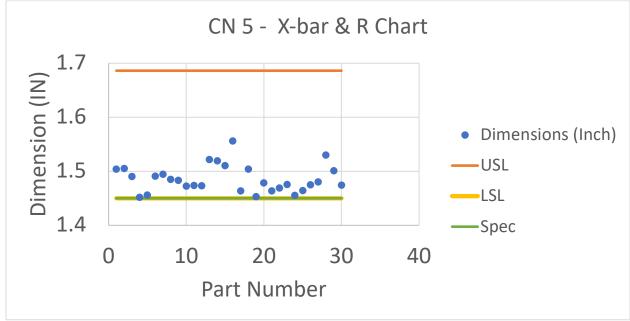


Figure 17 - CN 5 - X-bar & R Chart

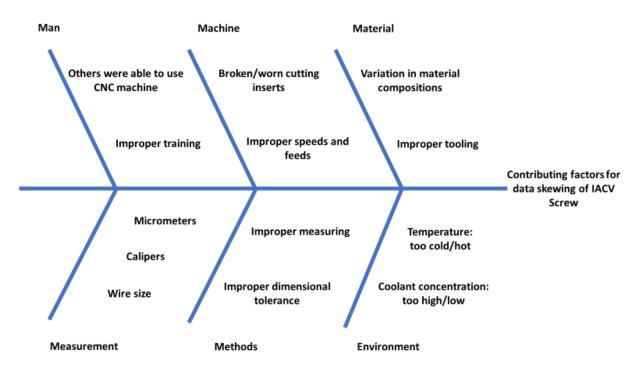


Figure 18 - Fishbone Diagram of Assignable causes

Conclusions

The data retrieved shows the process is not in control with critical dimensions 2-4. The fishbone diagram (shown above in Figure 18) illustrates some assignable causes which could cause errors in the parts. Due to these assignable causes some parts have failed quality check as shown in X-bar & R Chart (as shown in Figure 5, 8 11, 14, and 17) it shows how there are parts that fall below spec (green line). This does not make the part scrap, but it is not ideal. The parts are completed, but the process will need to be improved on before moving forward into a manufacturing setting.

To revalidate this part there will need to be more control set in place and using the Fishbone diagram shown above in Figure 18 as the checklist as to what could be controlled. These assignable causes will be checked off one by one to mitigate each of these possible causes. Tool wear was most likely a big contributor to the dimensions not being in spec. Tool wear is impossible to spot with just eyes alone each part will would need to be checked as the machining is happening and tool wear would need to be adjusted as the parts were being machined. Next, would be a complete revalidation with assignable causes as the limit for each part that would be double checked to prevent scrap parts being produced.

References

"Aisi 4140 Alloy Steel (UNS G41400)." *AZoM.Com*, 18 Dec. 2019, www.azom.com/article.aspx?ArticleID=6769.

Budden, A.S. CGTK, 2011, www.cgtk.co.uk/metalwork/calculators/screwmeasurement.

- Cardenas, Javier. *Process Validation: Fundamentals for Success*, 11 Oct. 2018, www.pda.org/docs/default-source/website-documentlibrary/chapters/presentations/southern-california/2018-validation-day/process-validationfundamentals-for-success.pdf?sfvrsn=89a5968e 4.%20%E2%80%8B.
- Fast-rite. *Fast-Rite*, www.fast-rite.com/wp-content/uploads/Fast-Rite_TechnicalSpecsForFasteners_20181210.pdf. Accessed 3 Nov. 2023.
- Pannell, Reagan. "Capability Analysis CP and CPK Explained: Six Sigma." *LeanScape*, LeanScape, 10 Oct. 2022, leanscape.io/what-is-capability-analysis-introduction-to-cp-andcpk/#:~:text=Unlike%20CP%20(Process%20Capability)%2C,is%20from%20the%20speci fication%20limits.
- Parker O-Ring Handbook Parker Hannifin Corporation, Parker, 2021, www.parker.com/content/dam/Parker-com/Literature/O-Ring-Division-Literature/ORD-5700.pdf.

Appendix A – Detailed Testing Results

CN 1 Data	
Min	0.30850
Max	0.31700
Range:	0.00850
n:	30.00000
mean	0.31286
mode	0.31500
Std dev.	0.00227
Sturgis' Rule	
i:	0.00144
h:	6.00000
Tolerance:	0.009
Spec	0.315
USL	0.324
LSL	0.306
Ср	1.279850081
Std. dev	30.26023805
C ⁴	0.9914
Z USL	4.78350
Z LSL	-2.89560
CpK USL	1.594500325
CpK LSL	-0.965199838
X-bar	0.312861111

CN 2 Data	
Min	0.45085
Max	0.46930

Range:	0.01845
n:	30.00000
mean	0.45924
mode	0.45185
Std dev.	0.00815
Sturgis' Rule	
i:	0.00312
h:	6.00000
Tolerance:	0.030
Spec	0.4813
USL	0.511
LSL	0.451
Ср	1.227291073
Std. dev	30.26023805
C ⁴	0.9914
Z USL	6.38969
Z LSL	-0.97406
CpK USL	2.129895475
CpK LSL	-0.324686672
Xbar	0.459236667

CN 3 Data	
Min	0.26500
Max	0.28100
Range:	0.01600
n:	30.00000
mean	0.27188

1	
mode	0.26700
Std dev.	0.00627
Sturgis' Rule	
i:	0.00271
h:	6.00000
Tolerance:	0.002
Spec	0.280
USL	0.282
LSL	0.280
Ср	0.053180296
Std. dev	30.26023805
C ⁴	0.9914
Z USL	1.61402
Z LSL	1.29494
CpK USL	0.538007333
CpK LSL	0.43164674
Xbar	0.271883333

CN 4 Data	
Min	0.37050
Max	0.40000
Range:	0.02950
n:	30.00000
mean	0.37957
mode	0.37150
Std dev.	0.00969
Sturgis' Rule	
i:	0.00499

h:	6.00000
Tolerance:	0.005
Spec	0.386
USL	0.391
LSL	0.381
Ср	0.171955064
Std. dev	30.26023805
C ⁴	0.9914
Z USL	1.17961
Z LSL	0.14788
CpK USL	0.393203913
CpK LSL	0.049293785
Xbar	0.379566667

CN 5 Data		
Min	1.45150	
Max	1.55600	
Range:	0.10450	
n:	30.00000	
mean	1.48565	
mode	1.50400	
Std dev.	0.02496	
Sturgis' Rule		
i:	0.01769	
h:	6.00000	
Tolerance:	0.236	
Spec	1.450	
USL	1.686	

LSL	1.450
Ср	1.577235173
Std. dev	30.26023805
C ⁴	0.9914
Z USL	8.03521
Z LSL	-1.42821
CpK USL	2.678401987
CpK LSL	-0.476068359
Xbar	1.48565

Appendix B – Detailed Drawings (as needed)

