

# Center Thickness Optimization for Product A

Author: Luis A. Arzola Rodríguez

Advisor: José A. Morales Morales

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## Abstract

Every organization wants to increase its production and reduce the possibility of having scraps. Having to scrap products increases production costs, reduces cost saving, reduces volume output and reduces confidence in the manufacturing process. To release a product in the market, quality approval must be obtained. This approval considers compliance with critical to quality dimensions (CTQ) where no error or deviation must be found. Having a deviation on the CTQ triggers a Non-Conformance Investigation (NCR) that normally is resolved by scrapping the batch and product because there is nothing that can be done to fix it. Using DMAIC methodology, an investigation exercise will be conducted to understand the root cause of why this CTQ fails and how it can be solved and improved. Improving this CTQ will result in the reduction of NCR and make the manufacturing process more reliable, steady by reducing scrapped products and therefore increasing volume output.

Keywords □ CAPA, Center Thickness, DMAIC Method, Tooling Design, SPC.

## Introduction

This project will be about understanding what is the root cause of why the “Center Thickness” dimension fails. The failure of this dimension results on the generation of an NCR that normally results on the scrap of a manufacturing batch. This therefore creates expenditures affecting yield output, volume and manufacturing performance.

## Background

To manufacture product A, a male plastic and female plastic mold is prepared using an injection molding process. This molds are formed by copying a tool design. Molds prepared, the male mold is placed inside the female mold. Between the male and female mold there is a separation gap. In figure 1, it can be appreciated the gap between the male and plastic mold.

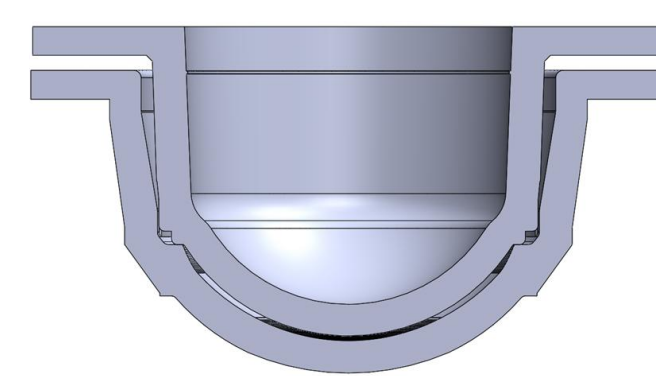


Figure 1. Representation of Male and female plastic mold merged with gap.

That gap is filled by a product A material. After filled, the material along with the molds are cured using an oven to harden the material and make the product copy the plastic properties (provided by the tool design). After cured, a sample of molds are extracted and demolded (male and female mold are removed) to obtain product A. Product A CTQ are measured and verified following a sample criterion. If this criterion is approved, the product passes to the next process. For this first inspection, the gross part of the product that is located on the middle is verified and measured. This dimension is measured using a digital thickness gauge. The dimension obtained must fall between a specified range to comply with Quality Control and the product be able to pass to the next step. This dimension is called “Center Thickness” and if this dimension is found off, the product must be scrapped, adjustment must be made on the process, and the product is not released to the second stage until the first quality control is passed. On figure 2, it can be appreciated a reference of the center thickness.

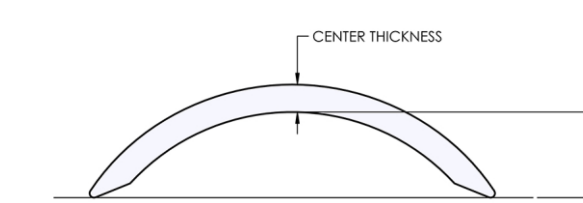


Figure 2. Center Thickness Reference.

If the product cannot be able to approve the first quality control even after adjusting, the product is entirely scrapped, and the product remains closed on the quality system. By staying closed on the quality system, the product cannot be released or passed to the next stage. If the product passes the first quality control, they pass through a second stage process. This second stage starts with the plastic molds passing through a separation process where the male mold is separated from the female mold, and the product stays with the female mold. Then, the product is removed from the female mold and transferred onto an automatic inspection camera to inspect any damage or impurity. After the product is inspected, if approved by the inspection system passes through an extraction and hydration process and then it is packed on a blister that is then sealed and transferred to a sterilization process which is subjected to a second and final quality inspection.

As on the first quality inspection, a sample representative of the batch is taken to inspect quality dimensions. For example, Center Thickness is verified again on the second quality inspection since on the extraction and hydration process the product increases its center thickness due to the hydration process. The product increases its dimensions because on the hydration process, the product is humidified and absorbs a specified liquid that dictates the change of dimension. This change in dimension makes the Center Thickness grow a significant amount and that is why is verified again. As part of the second quality inspection, a quality sample is followed. If this quality sampling is approved for the Center Thickness, along with other critical dimensions, the product is released to the market. If not, an NCR is developed resulting in the scrap of the product and entire batch. The NCR opens an investigation that normally results on the scrap of the batch because it indicated the product was out of dimensions and nothing could be done to fix it. For this project, since a significant number of NCRs were been obtained due to Off Center Thickness, a Corrective Action & Preventive Action Activity (CAPA) was opened to investigate what we’re causing the Center Thickness going off.

## Problem

For this project, the focus will be on understanding and improving a CTQ dimension for a manufacturing product. This CTQ is called “Center Thickness” and is a measurement taken during the quality inspection of product A. This CTQ must comply within a tolerance range, if a sample is found out of tolerance an NCR is made and normally as a result the batch tends to be scrapped because the product cannot be saved.

## Methodology

To understand the how the “Center Thickness” can be improved, a methodology must be adopted. A DMAIC (Define, Measure, Analyze, Improve & Control) methodology will be used. This methodology will be applied because it has different tools that help in understanding what part of the process could be affecting the “Center Thickness” and what can be proposed to improve it.

## Results and Discussion

Task	Start	End
Define Stage	Week 1	Week 2
Project Assignment with Objectives & Resources	Week 1	Week 1
Project Charter including Business Case, Goal Statement, Scope & Timeline	Week 2	Week 2
Measure Stage	Week 2	Week 4
Data Collection Exercise	Week 2	Week 4
Statistical Analysis	Week 5	Week 5
Meeting with Product Designer	Week 6	Week 6
Analyze	Week 6	Week 9
Brainstorm Analysis	Week 6	Week 9
Engineering Testing Baseline	Week 7	Week 12
Improve	Week 12	Week 12
Tooling/Recreation Design 1	Week 12	Week 14
Tooling/Recreation Testing 1	Week 15	Week 18
Tooling/Recreation Design 2	Week 19	Week 21
Tooling/Recreation Testing 2	Week 22	Week 25
Tooling/Recreation Design 3	Week 26	Week 28
Tooling/Recreation Testing 3	Week 29	Week 31
Tooling/Validation on Pilot Line	Week 33	Week 34
Control	Week 34	Week 52
Deployment of New Tool Design	Week 35	Week 52
Process Monitoring of New Tool Design	Week 35	Week 52

Figure 3: Gantt chart

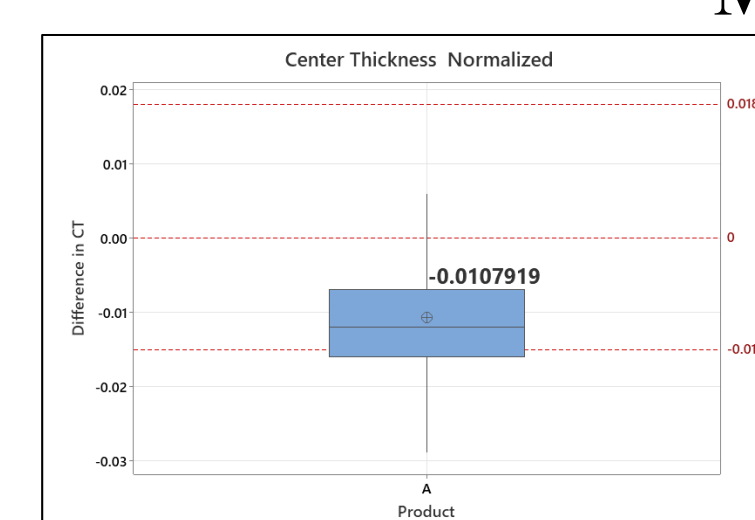


Figure 4. Center Thickness Behavior Normalized.

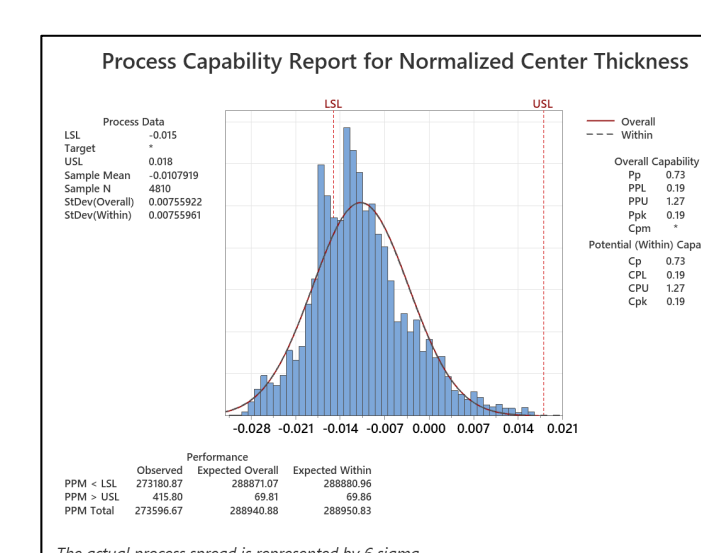


Figure 6. Center Thickness Process Capability.

Table 1: Project Charter.

<b>Project Title:</b>	Center Thickness Optimization for Product A
<b>Problem Statement:</b>	Center Thickness out of tolerance causing NCR generation and product scrap.
<b>Scope:</b>	Optimize Center Thickness behavior for Product A
<b>Risk and Issues</b>	Manufacturing Line availability for testing
<b>Deliverable</b>	Center Thickness Capability Improved
<b>Stakeholders</b>	Operational Excellence Director Operational Excellence Manager Quality Process Improvement Manager

## MEASURE PHASE

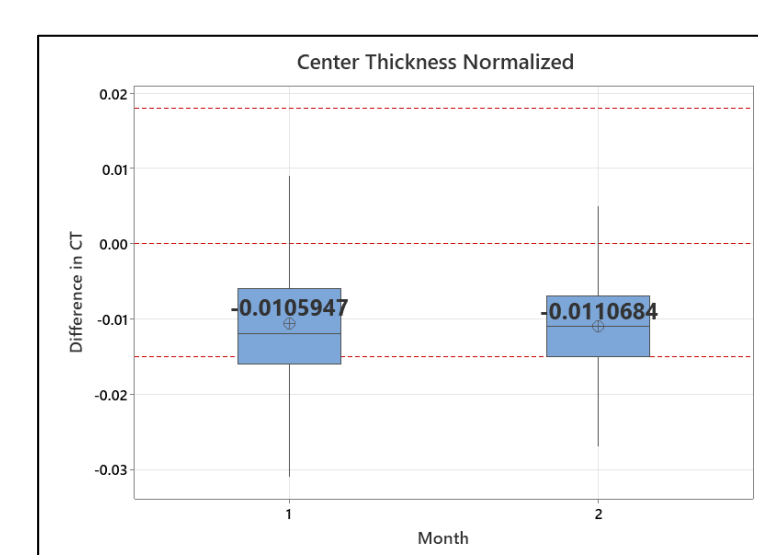


Figure 5. Center Thickness Behavior by Month.

- Data Collection Exercise from two months obtained from Quality System Database.
- Center Thickness Behavior below specification & cpk of 0.19.

## ANALYZE PHASE

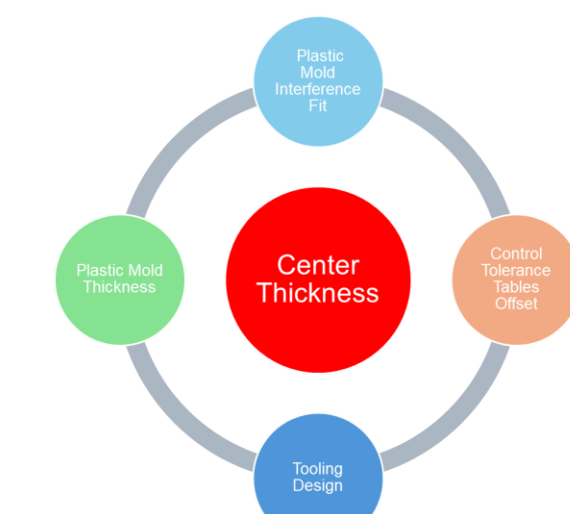


Figure 7: Brainstorming exercise for Center Thickness.

- Brainstorming indicated “Tool Design” cause for Center Thickness off.
- Test confirmed tool design was off by comparing current control measures vs Cross Sectional measurements due to same behavior.

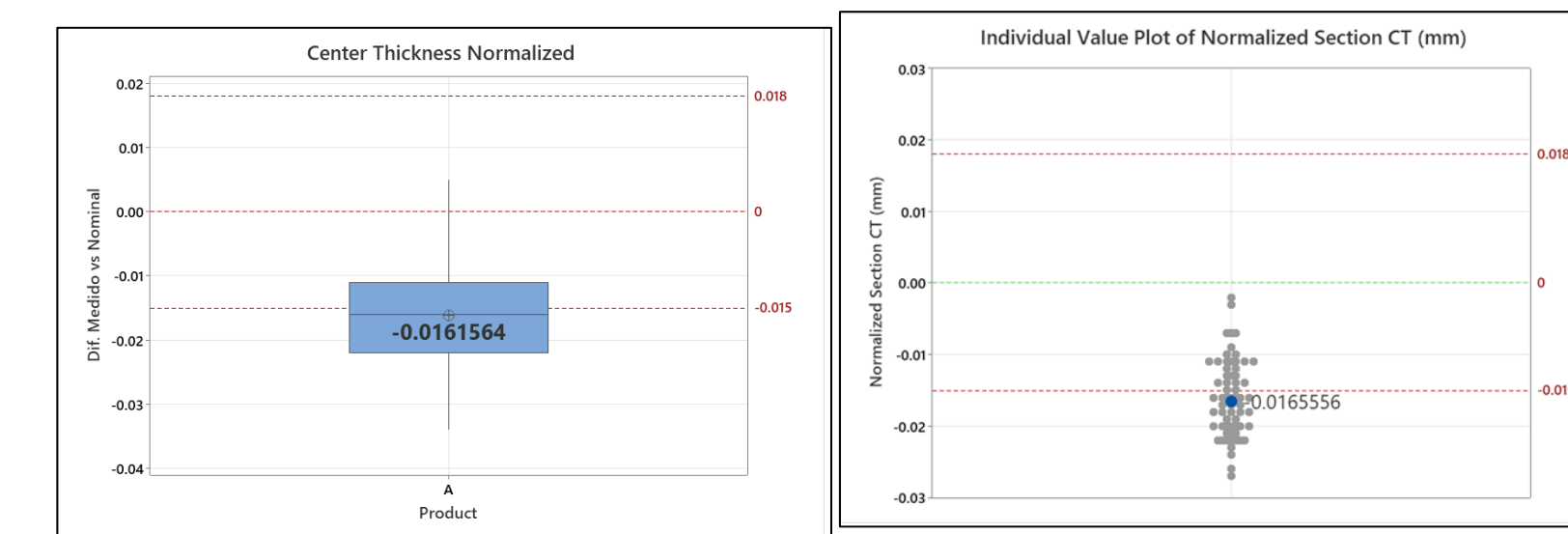


Figure 8. Normalized Center Thickness.

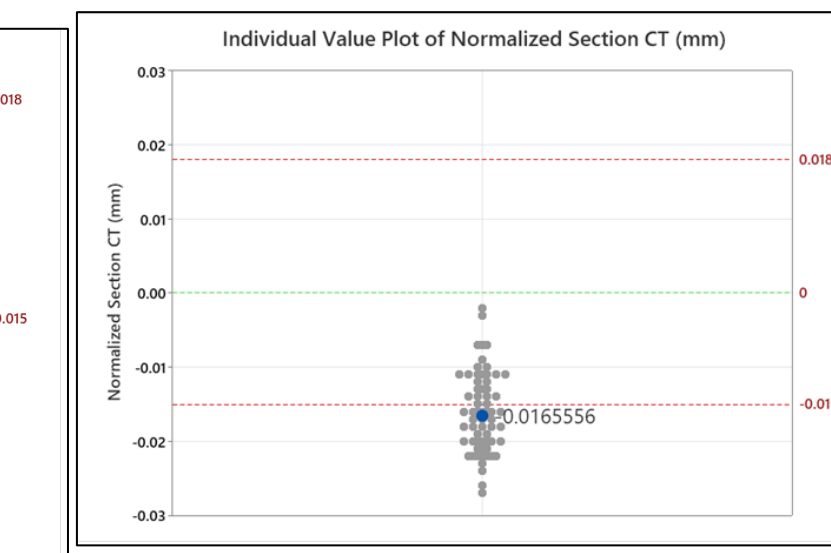


Figure 9. Normalized Cross Sectional Center Thickness.

## IMPROVE PHASE

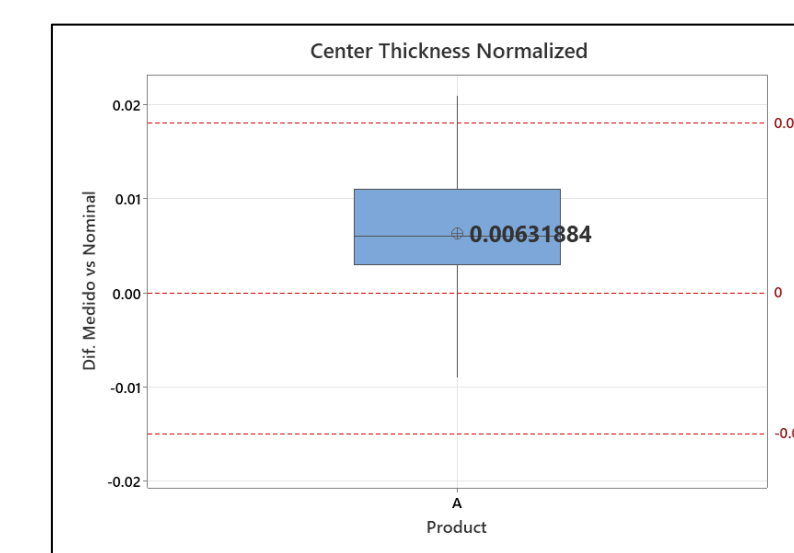


Figure 10. Center Thickness Normalized for Third Iteration.

- Tool redesign to centralize and improve “Center Thickness”. Three iterations required to improve dimension.
- Comparing current control measures vs Cross Sectional measurements due to same behavior.

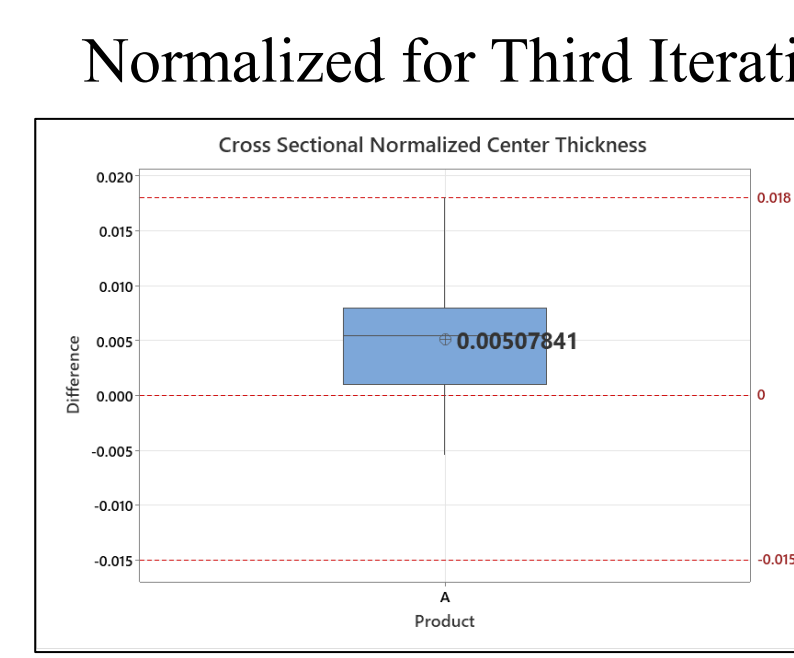


Figure 11. Cross Sectional Center Thickness Normalized for Third Iteration.

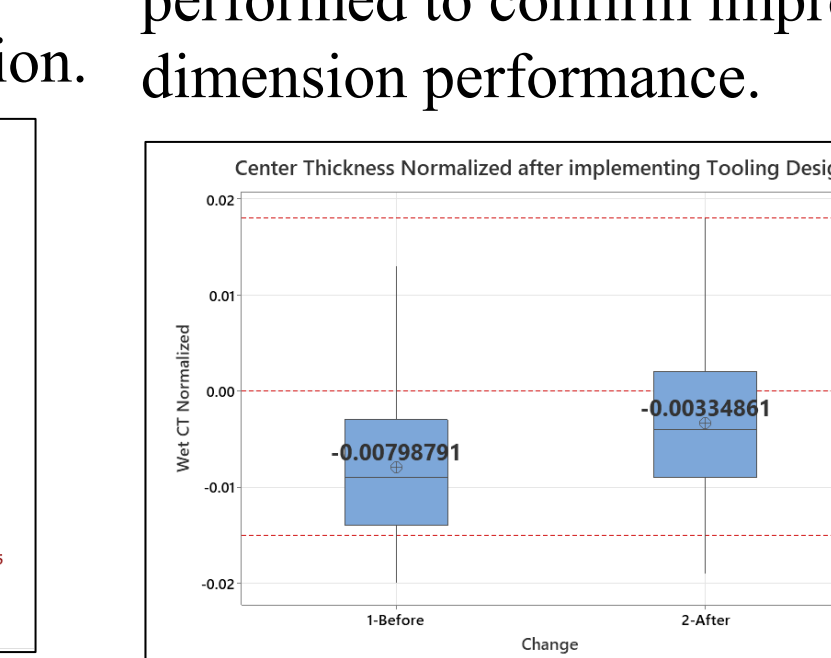


Figure 12. Center Thickness Normalized Behavior after New Tooling Design.

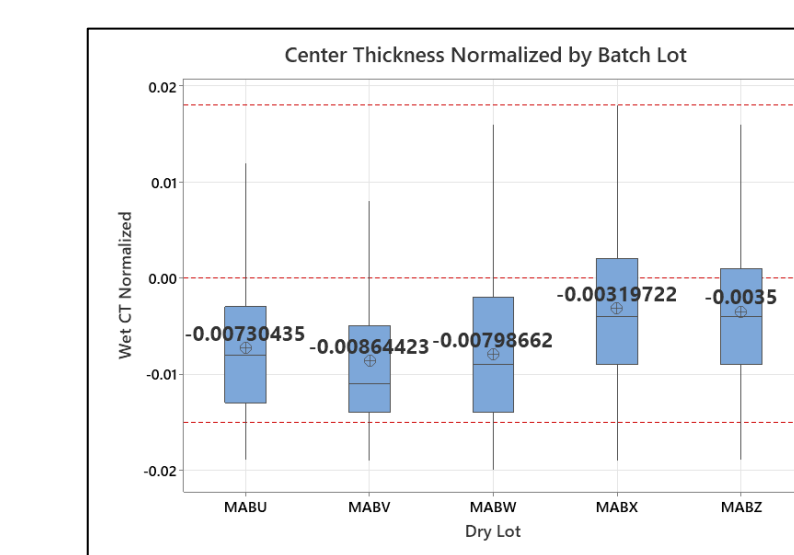


Figure 13. Center Thickness Normalized Behavior by batch lot after new tooling design.

## CONTROL PHASE

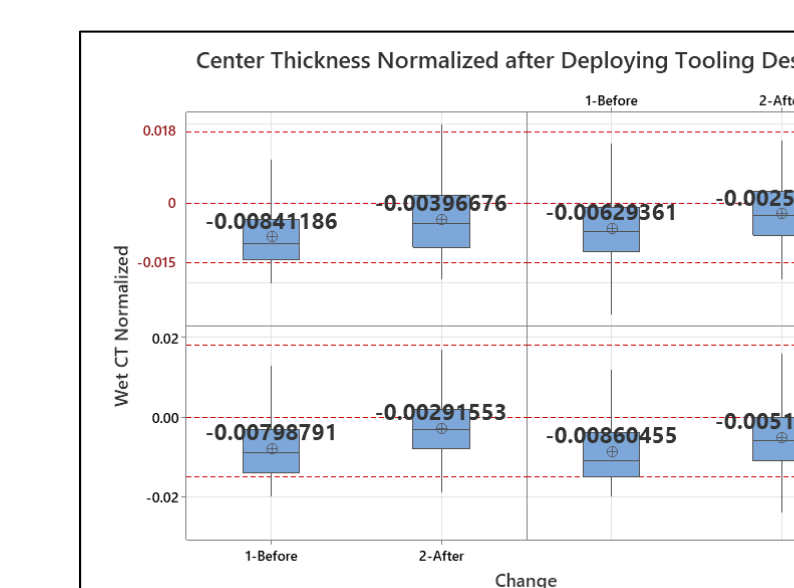


Figure 15. Center Thickness Normalized Behavior after New Tooling Design on deployed lines.

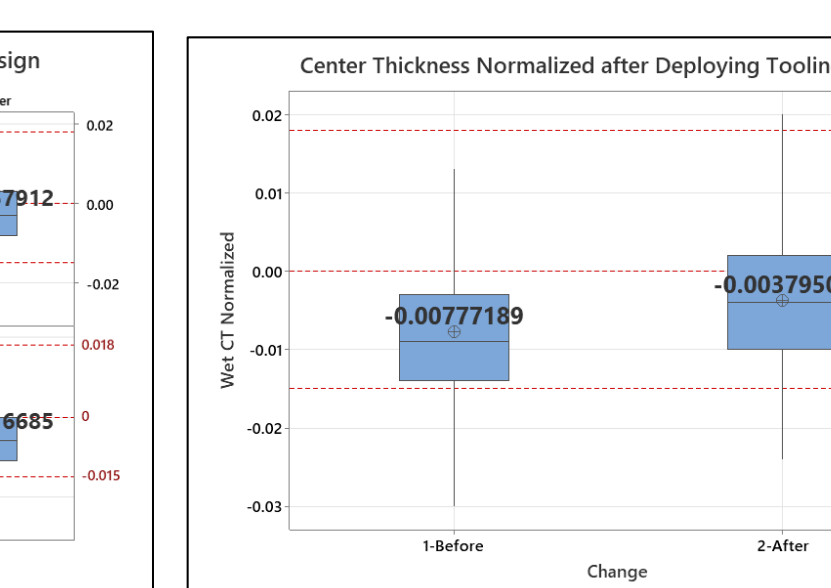


Figure 14. Center Thickness Normalized Behavior after New Tooling Design.

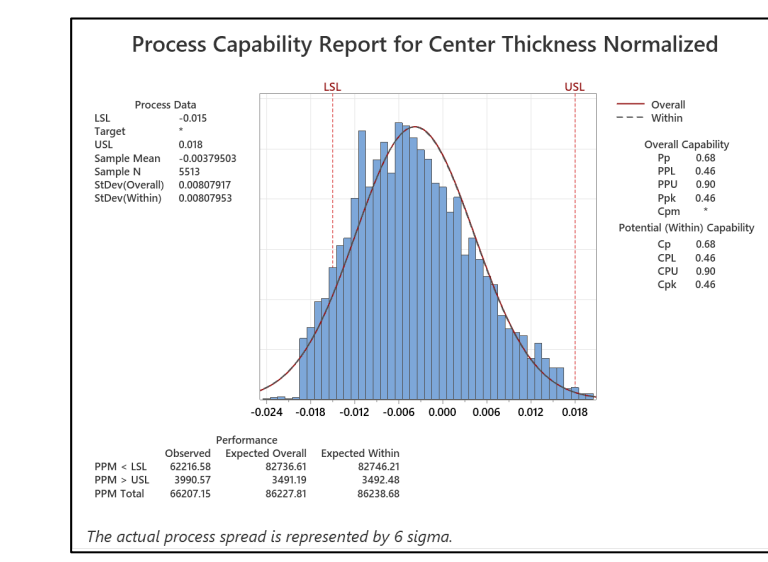


Figure 15. Process Capability for Center Thickness Normalized Behavior after New Tooling Design.

- Cpk of 0.46 obtained representing a 242% improvement.
- Implemented lines represented a statistical change with a p-value of 0.00.

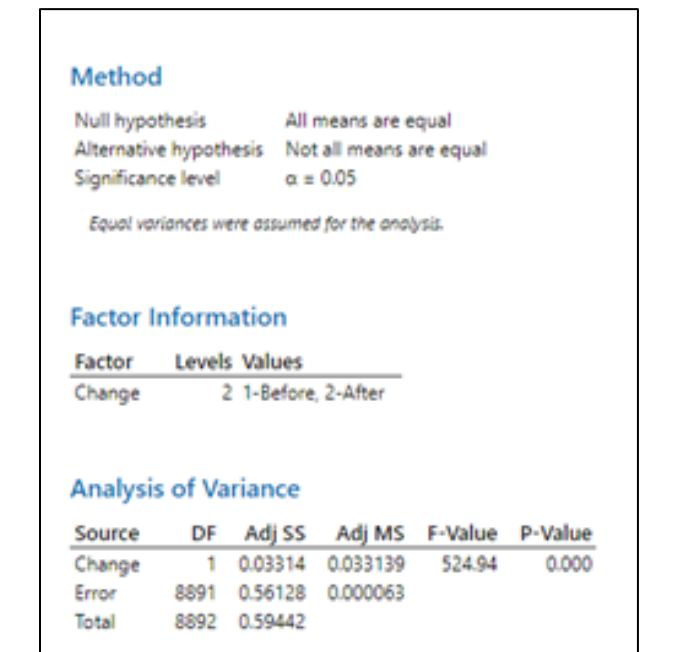


Figure 16. ANOVA for Tool Design Deployment.

- Center Thickness was improved and centralized.
- New tool design implemented on MFG lines.

## Conclusions

For this project, a DMAIC methodology was applied to understand what could cause incorrect Center Thickness. Using brainstorming and data collection analysis, it was confirmed that the tooling design was off. This required redesigning, taking over three iterations resulting in a new and improved tool design. The new tool was validated and is currently being deployed on the manufacturing lines.

Benefits of this project resulted in the improvement of the center thickness capability, centralization and reduction of NCRs regarding incorrect Center Thickness along with the support of CAPA (Corrective Action & Preventive Action) activities.

## Future Work

Next steps regarding this project will be to continue monitoring the Center Thickness behavior to confirm that is sustainable and does not need any new verification.

## Acknowledgements

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