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## ABSTRACT

The use of automated inspections can result in reduced customer risk due to higher detection of defects, but their effectiveness can negatively impact the business financials. Previous research shows that the inspection method can yield different results, and these inspection system designs can be optimized. For systems design development, methodologies like Design for Six Sigma have been proven adequate to ensure process design meets its intended purpose.

Utilizing a design-for-six sigma approach, the inspection systems for an automated packaging process are re-designed. Through the IDDOV methodology, design elements were identified and confirmed, including a control plan to ensure optimized results are maintained. Design concepts were tested and optimized until defined design requirements were met.

Expected results from re-design reduce material waste at the inspection points by 90%, and improve vision systems effectiveness, reducing both customer and business risk. Therefore, recommendations within this study lay-out the framework for implementation and qualification of improvements in automated inspection.

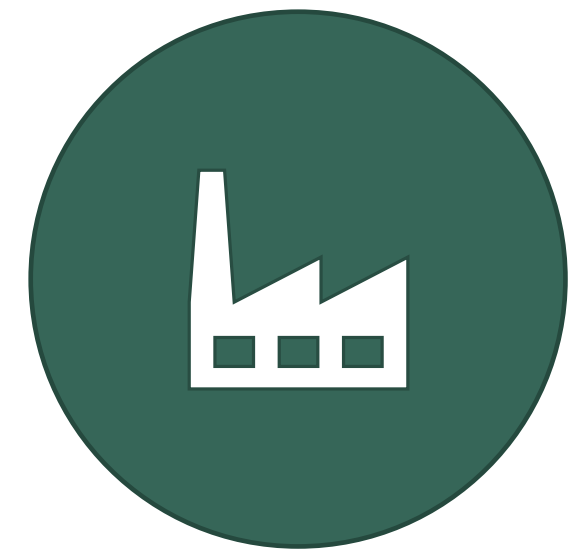
## INTRODUCTION

Application of quality concepts during design is one of the many ways to significantly improve processes. When issues are identified as inherent to the process design, how the process is designed and what it is intended to do are key considerations to ensure process effectiveness. In this project, we evaluate a case of an automated inspection and how its design can be improved to increase its effectiveness.

## BACKGROUND

### The Business Context

This project was developed in a medical devices manufacturing company. The process in question is an automated packaging process, which currently has a process waste opportunity of \$199k per year.



#### THE BUSINESS

The company focuses on the manufacturing of medical devices



#### THE PROCESS

Its approach uses automated packaging processes

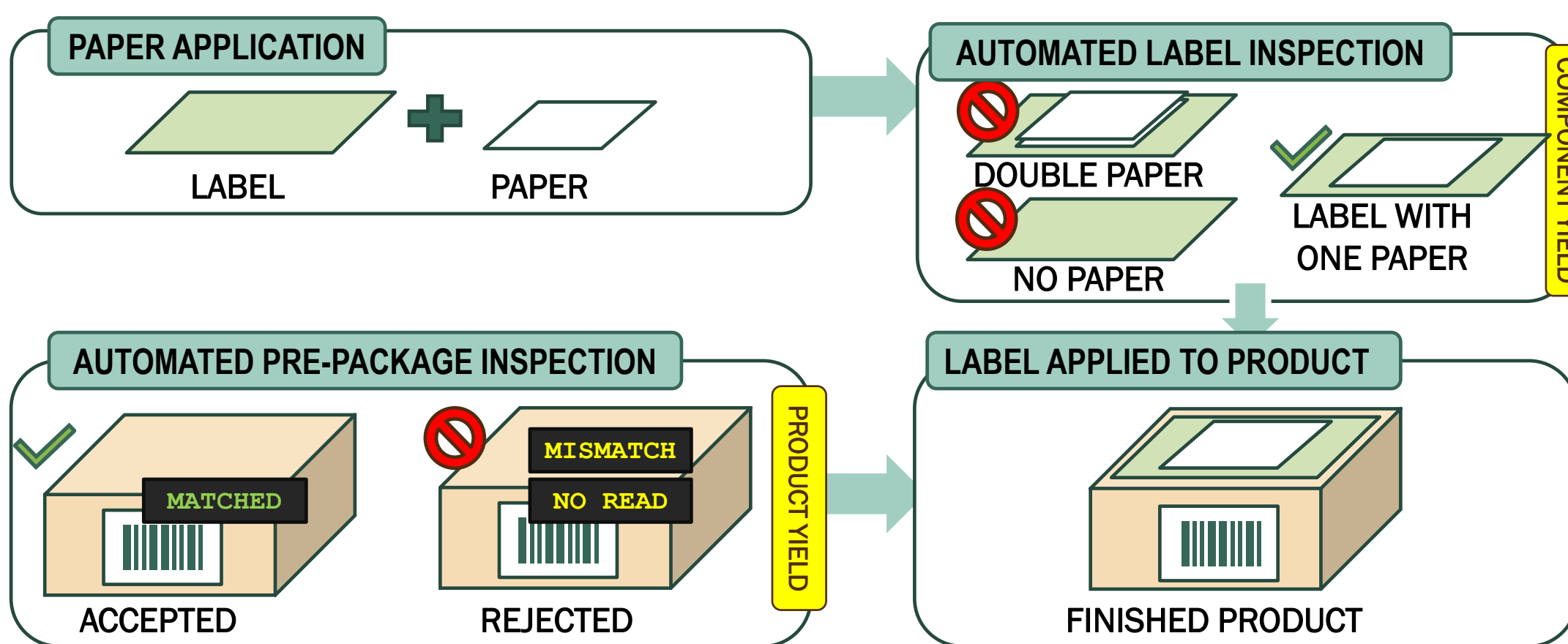


#### THE OPPORTUNITY

A cost of \$199K in yearly waste originates from a single packaging process

### Process Overview

The process is composed of paper application into a label, which is later applied to a pre-packaged product. Component Waste and Product Waste originate from the inspection points. These inspection points are required to avoid product defects during the process.



## PROBLEM

To address the current material waste of \$199k per year due to rejects from these inspection points, a process re-design shall be developed. Expected results from the process re-design should reduce material waste to \$53k or less per year by improving component yield from 85% to 95% or more, and product yield from 99.7% to 99.9% or more.

#### OBJECTIVE



Devise detailed design and implementation plan

#### TO ENABLE....



Reduce material waste from \$199K to \$53k



Improve Component Yield from 85% to 95%



Improve Product Yield from 99.7% to 99.9%

## METHODOLOGY

### Literature Review



#### What do we know of the current control system?

- The current inspection system is composed of three automated inspections.
- Paper inspection is done with a Keyence LJ-V7000 Series Profilometer per [1] and [2], and also using an automated image inspection with a Cognex Insight 7000 Series Camera [3].
- Product inspection is done with a Cognex Dataman 260 Series [4] for a 2D Barcode (Datamatrix) Reading.

#### What have others learned on similar problems?

- A previous study on automated steel surface inspections [5] was evaluated.
- Study shows that multiple methods for inspection systems can yield different results across different design criteria.
- Automated inspection systems require "tuning" and user interaction for optimized results.
- So, it was confirmed that the process can be optimized.



#### With what philosophy can the problem be approached?

- Quality-centered philosophies were evaluated.
- Two of the most well-known philosophies for quality improvement are Six Sigma and Design For Six Sigma (DFSS).
- Based on [6], Six Sigma focuses in identifying key process inputs or variables and optimizing them, while Design for six sigma focuses in developing and testing multiple concepts that meet the design criteria and optimizing them based on the results.
- Study in [7] shows that combining six sigma concepts during the design process can ensure the design meets its intended performance levels.
- Study in [8] point out that whether to use six sigma or design for six sigma should be centered on whether the intent is to develop a new process and/or method or improve the current process.
- Therefore, based on literature reviewed, it was considered that problem requires developing a new solution and Design For Six Sigma was selected.



#### With what methodology can the problem be approached?

- Study in [9] explains the two different methodologies for design for six sigma: DMADV (Six Sigma Approach) and IDDOV (Taguchi's Approach).
- As concluded in [9], Taguchi's approach is the most efficient and effective way to optimize design requirements.
- Therefore, to define the problem, translate into design requirements and optimize process performance, the IDDOV methodology as explained in [9] was utilized.



## PROJECT METHODOLOGY AND TOOLS UTILIZED

The Design For Six Sigma philosophy with IDDOV methodology was selected. The methodology ensures the project is clearly defined while also ensuring the customer requirements are defined, translated into design requirements, and optimized. Design requirements will be iteratively refined and optimized, evaluating different design elements and optimizing based on ability to meet design requirements. Once an optimum design is developed, methodology ensures a plan is put in place to measure and control its results will be put in place to ensure customer requirements are met as well as intended project objectives.

Phase	Phase's Purpose	Tools Used
<b>I Identify</b>	Clearly define the problem to be addressed, project scope and the project plan.	Company Background Problem Statement Process Overview Historical Data Review Business & Customer Impact Analysis Project Objectives In-Scope / Out-of-Scope Literature Review Project Plan Project Charter
<b>D Define</b>	Identify the customer and their requirements. Translate customer input into functional design requirements.	SIPOC Analysis Voice of the Customer CTQ Tree Quality Function Deployment Kano Analysis
<b>D Develop</b>	Establish and select design concepts to address how the functional requirements will be met.	Design For X Probability Model Failure Modes & Effects Analysis Risk-Based Integrated Design Plan Design Requirements (Scorecard)
<b>O Optimize</b>	Test and refine design effectiveness and tolerances through experiments.	Benchmarking Pugh Concept Selection Matrix Data Collection Plan Pilot Testing Final Design Concept
<b>V Verify</b>	Ensure that customer requirements are met, benefits are realized, and controls are in place to ensure benefits are sustainable.	Implementation Plan Control Plan Summary of Project Results, Final Design Scorecard Project Benefits Projection

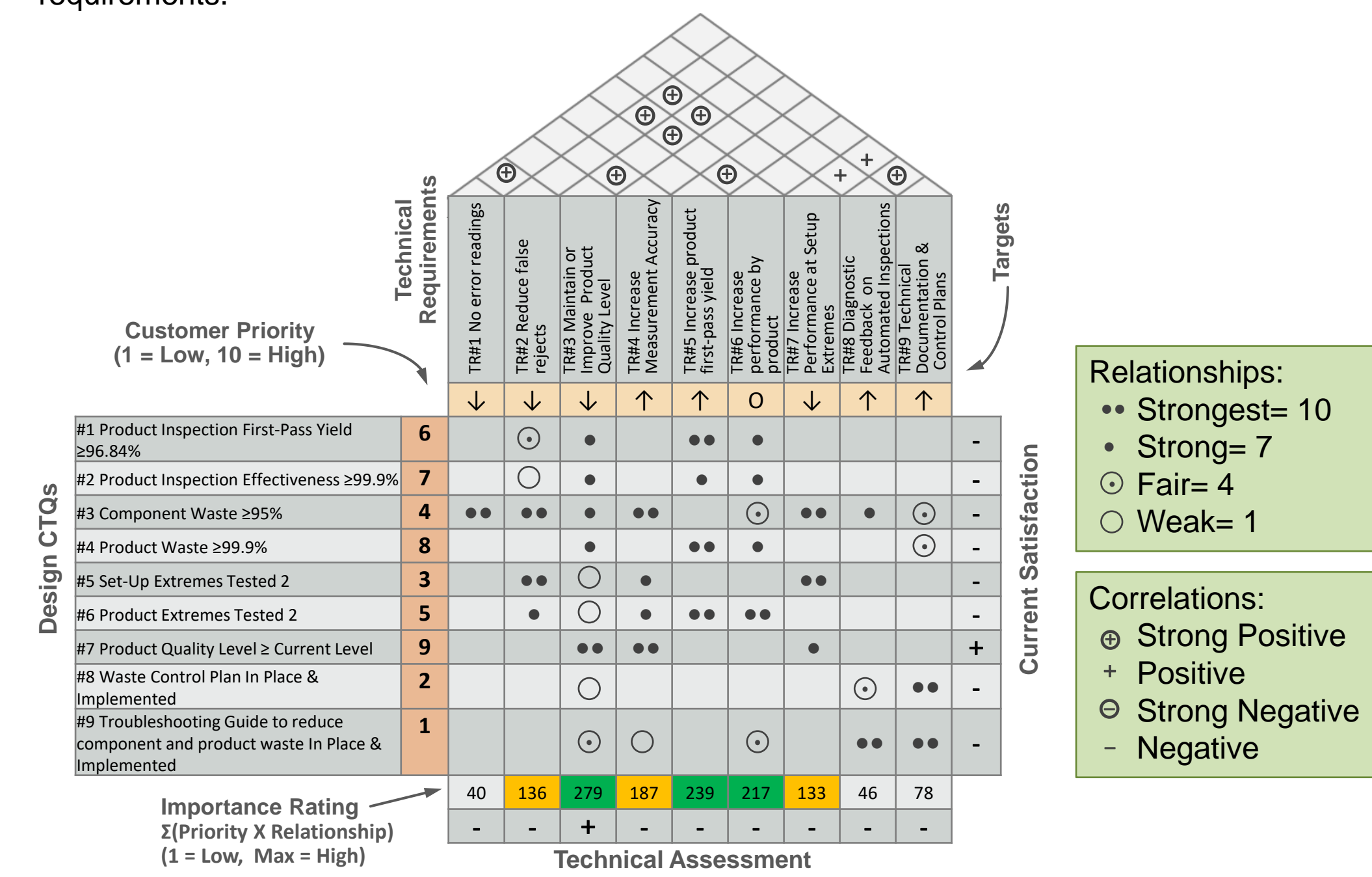
## RESULTS AND DISCUSSION

### IDENTIFY

In the identify phase, the problem statement and all background information was clarified. As a result, the project team was put together, the project objectives defined, and the project chartered. This process ensured that project team and stakeholders were aligned and had a clear definition of the problem under investigation.

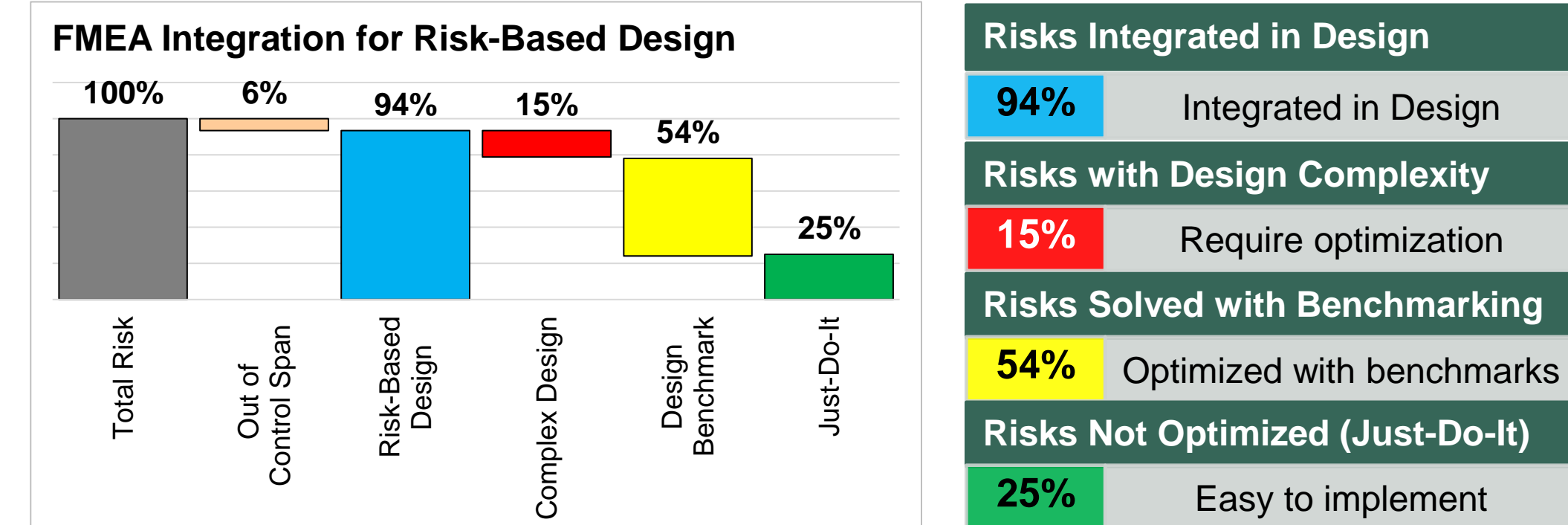
### DEFINE

In the define phase, based on the process data and voice of the customer, CTQ requirements were developed. Furthermore, these requirements were then reviewed through the use of Quality Function Deployment and Kano Analysis to translate into prioritize technical design requirements.



### DEVELOP

In the develop phase, the design concepts were refined and through the use of Failure Modes and Effects Analysis, specific design elements to address design risks were developed. Utilizing the risk assessments, design requirements were defined, tied up to CTQs and technical requirements. Also, utilizing risk ratings, requirements were assigned a priority score



### OPTIMIZE

In the optimize phase, the specifics of the design elements were refined through the use of benchmarking, Pugh concept selection matrix, data collection planning, pilot testing, and final design concept generation. Benchmarking and the Pugh Concept Selection Matrix, allowed to significantly reduce the complexity of optimizing design elements, while the data collection planning and pilot testing ensured that complex elements were optimized for best results.

Criteria	Maintain Current Product Inspection	Optimize Current Inspection to Achieve Best Results Known	Replace Scanner with a Camera Inspection	SELECTION & BENCHMARK
First-Pass Yield	S	+	++	Laser Baseline Pilot: 61% Lowest Effectiveness
Total Yield	S	+	++	Laser New Software: 87% Lowest Effectiveness
Cost	S	S	++	Laser Dynamic Limits: 95% Lowest Effectiveness
Effort	S	-	-	Camera Product Inspection: 100% Effectiveness
History of Success	-	+	++	
Savings (Cost)	-	+	++	
Total +	0	4	8	
Total -	3	2	3	
Total Score	-3	2	5	

### VERIFY

In the verify phase, implementation & qualification plan was outlined as well as the control plan to sustain the expected results of the design requirements. Component yield is expected to meet its intended target once implemented while product yield and financials are expected to exceed their intended target once implemented.

IMPLEMENTATION PLAN	CONTROL PLAN	DESIGN SCORECARD RESULTS	PROJECT RESULTS
100% Complete: Design & Planning	Dynamic Limits	70% of Design Requirements Met	Component Yield from 85.4% to 95%
71% Complete: Quality & Implement	Alignment Procedures	30% of Design Requirements Planned	Product Yield from 99.69% to 100%
	Troubleshooting Guides		Yearly Savings of \$178K from a target of \$146K.
	Process Qualification		
	MES Yield Limits		

## CONCLUSIONS

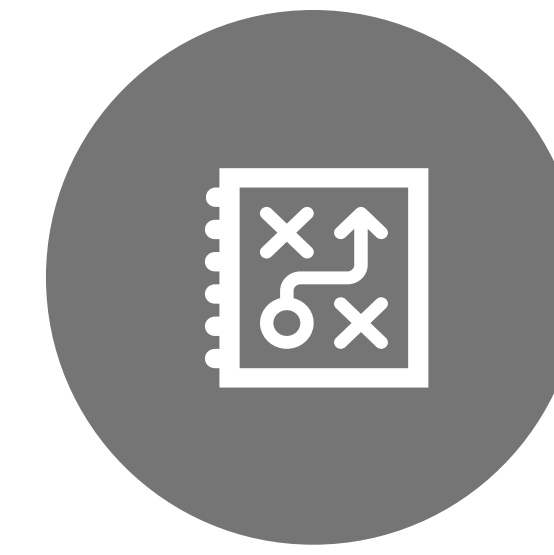
### KEY BENEFITS

Completion of the project resulted in key benefits such as higher defect detection in re-designed system, a defined qualification and control plan to implement and sustain changes, as well as a product waste cost reduction due to increased inspection effectiveness.



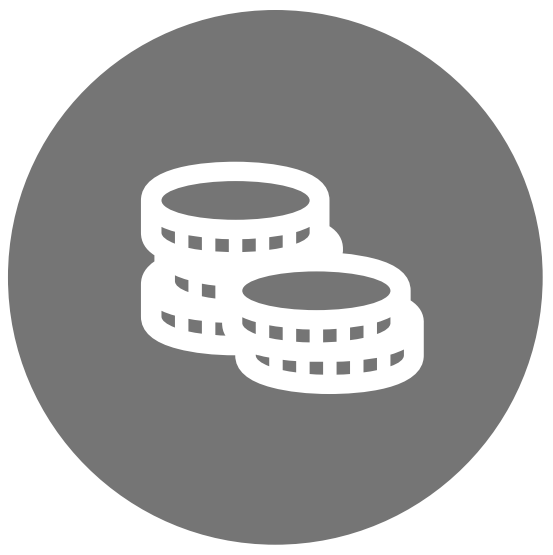
#### HIGHER DEFECT DETECTION

Recommendations improve non-conforming product detection by the inspections



#### QUALIFICATION & CONTROL PLAN

Data collection plan & pilot set the framework for qualification of changes as well as their control plan



#### PRODUCT WASTE COST REDUCTION

Recommendations are expected to yield financial benefits over the project target

## RESULTS ON PROJECT OBJECTIVES

OBJECTIVE	TO ENABLE....
<b>EXCEEDED:</b> Reduce material waste from \$199K to \$53k	<b>EXCEEDED:</b> Improve Component Yield from 85% to 95%
<b>EXCEEDED:</b> Improve Product Yield from 99.7% to 99.9%	

## FUTURE WORK

Design project was able to implement 100% of the design & planning activities defined. Furthermore, implementation & qualification process was 71% complete at the time the project was finalized. It is recommended that the same framework utilized to develop and test recommendations is utilized during qualification process to ensure final results are aligned to the estimates developed. From a process perspective, several aspects of the process were left out-of-scope, which would be recommended areas of further research if further improvement is desired. In addition, the utilization of design for six sigma demonstrated the current process did not meet with the quality requirements for the process. Therefore, it is recommended that other equipment and processes in the business also forego a similar process to improve automated inspections effectiveness. Similar frameworks can also be applied in other processes, companies, or industries.

## ACKNOWLEDGEMENTS

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