Innovation in Automated Inspections through Design for Six Sigma

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Abstract — *The use of automated inspections can result in reduced customer risk due to higher defect detection, but their effectiveness can negatively impact business financials. Previous research shows that inspection methods can yield different results, and these 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 DFSS 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.*

Key Terms —*automated inspections, design for six sigma, process design development, quality management.*

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

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

Process Overview

The packaging process studied starts with a paper application into a label, which is later applied to a pre-packaged product. Component and product waste are the process waste components and originate from the inspection points. These inspection points are required to avoid product defects during the process. Figure 1 provides a visual representation of the process.

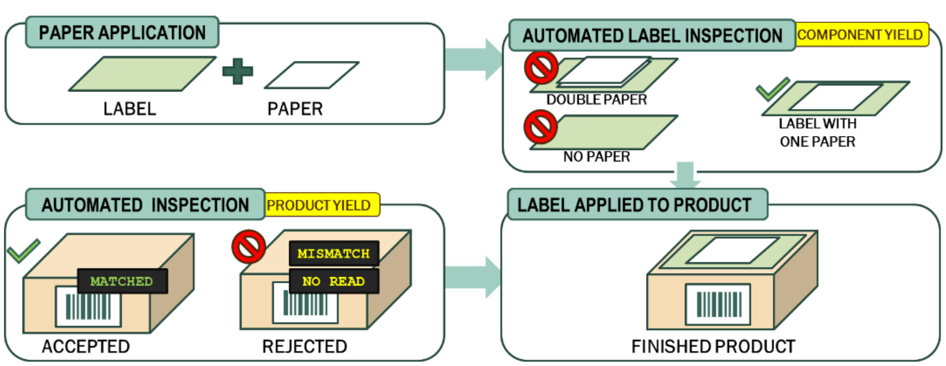

Figure 1
Process Overview Diagram

PROBLEM STATEMENT

To address the current material waste of $199k per year due to rejects from these inspection points, a process re-design was 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, respectively. Based on this problem, the project objective is to devise a detailed design and implementation plan that enables:

- Reduction of material waste from $199K to $53k per year.
- Improvement of component yield from 85% to 95%.
- Improvement of product yield from 99.7% to 99.9%.

METHODOLOGY

The purpose of this study is to develop a process design that reduces component and product waste to drive a reduction of $146k in yearly waste cost. With this purpose in mind, a literature review and methodology were developed, which allowed gaining the most relevant results during process development.

Literature Review

The literature review was performed to answer two key research questions:

- What can be learned from others about the problem?
- What must be considered before selecting an approach to the project's methodology?

First, information pertaining the current control system was reviewed. The current inspection system is composed of three automated inspections. Patch inspection is done with a Keyence LJ-V7000 Series Profilometer per [1] and [2], and an automated 2D 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.

Utilizing the information pertaining the current control system, previous research was reviewed to determine key learnings pertaining automated inspections and their effectiveness. A previous study on automated steel surface inspections [5] was evaluated. This study shows that multiple methods for inspection systems can yield different results across different design criteria. Also, automated inspection systems require "tunning" and user interaction for optimized results. Therefore, it was confirmed that the process can be optimized through alternate inspection methods, which would require a process re-design.

To select the project methodology, to key aspects were reviewed: the philosophy with which the problem be approached, and the methodology that applies concepts within a philosophy that can drive the desired results.

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 DFSS focuses in developing and testing multiple concepts that meet the design criteria and optimizing them based on the results. Reference [7] shows that combining six sigma concepts during the design process can ensure the design meets its intended performance levels. Reference [8] points out that whether to use six sigma or DFSS 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 DFSS was selected.

To approach a problem, a methodology was also selected. Reference [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. Details pertaining what the purpose of each phase was, as well as the tools utilized to meet that purpose, are outlined in Table 1.

RESULTS AND DISCUSSION

Identify Phase

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.

To establish the problem statement, an analysis of the previous year's data for the medical devices company under study was performed, which showed a total waste of $199,170.92 in the last year. An expected reduction of 73.32% of waste in this process is required, for an expected savings of $146,046.45. The company considers the current process variability (2.55σ) inherent to the process design and is looking for disruptive innovation in the process to achieve the improvement. To achieve the waste reduction, a DFSS approach shall be used to develop a process design capable of improving the process from 85.48% to 95.0% in component yield and from 99.69% to 99.9% in product yield, for a rolled throughput yield change from 85.2% to 94.91%, which shall improve the overall process sigma level from 2.55σ to 3.14σ.

Define Phase

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

Table 1
Project Methodology Overview

Phase	Purpose	Tools Utilized
Identify	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
Define	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
Develop	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)
Optimize	Test and refine design effectiveness and tolerances through experiments.	Benchmarking, Pugh Concept Selection Matrix, Data Collection Plan, Pilot Testing, Final Design Concept
Verify	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

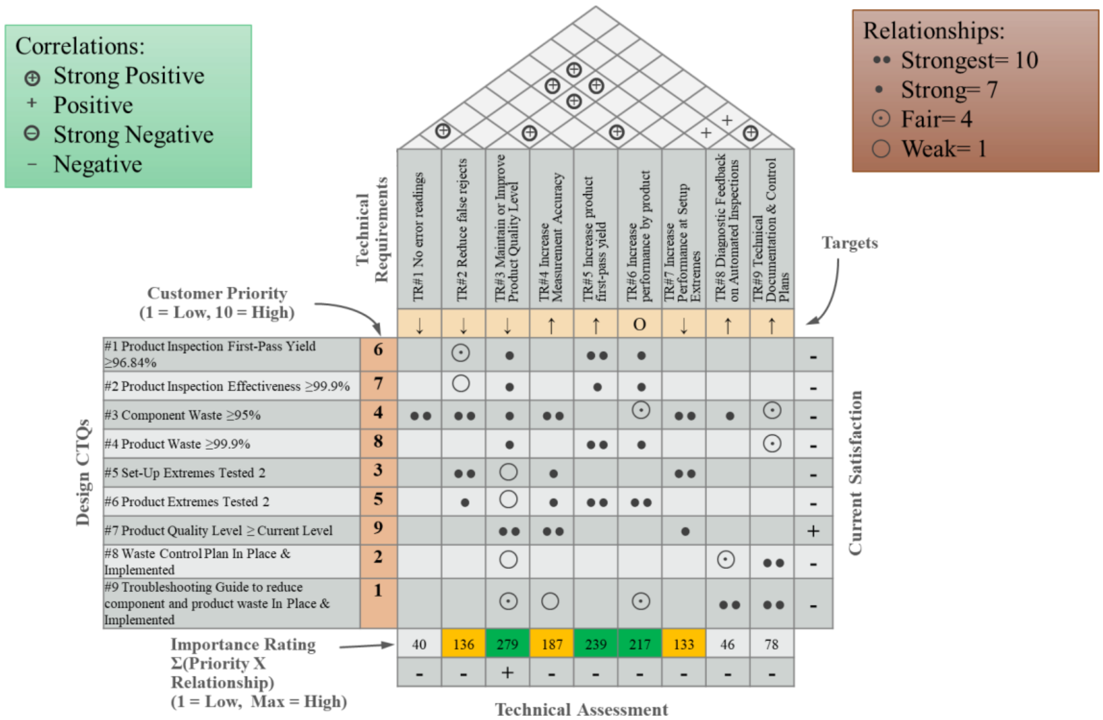

Figure 2

Quality Function Deployment (QFD): House of Quality #1 from CTQs to Functional Requirements

After completing a Supplier, Input, Output and Customers (SIPOC) analysis, it was determined that internal customers in the process would be interviewed to determine what the customer needs for the process are. Based on the voice of the customer (VOC), critical to quality (CTQ) requirements were identified. These were then translated into technical requirements utilizing the house of quality, as shown in Figure 2.

Using the Kano Model, functional requirements were categorized into basic expectations (must implement), performers (optimize to improve design efficacy), and delighters (nice to have) as follows:

- **Basic Expectations (Must Have):** Maintain or improve current product quality level.
- **Performers (Optimize to Improve Design Efficacy):** Increase product first-pass yield, increase performance by product, increase measurement accuracy, increase performance at extremes, reduce false rejects, and implement a waste control plan.
- **Delighters (Nice to Have):** No error readings, diagnostic feedback on automated inspections, and technical documentation.

Develop Phase

In the Develop phase, the design concepts were refined and, using Failure Modes and Effects Analysis (FMEA), 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.

The initial step in this phase was to translate the functional requirements into design requirements, using the **Design for X** tool. In this step, the functional requirements were defined for each of the key process elements: the barcode reading product inspection point, the laser profilometer component inspection point, and the camera component inspection point.

As previously mentioned, the key success measure for the process re-design is that the current quality level of the inspections must be maintained or improved. Likewise, most of the key performance requirements that will be optimized are based on the inspection systems’ capability to avoid false rejects.

Company guidelines were used which provide a framework to determine inspection systems effectiveness. These guidelines consider the sampling space of all automated inspection results from the systems being designed. Therefore, it was determined that the measurements of interest were:

- Misses (M) which is the Type-I Error of the inspection system, as expressed in (1) using AB as accepted bad parts, and TB as total bad parts.

$$M = AB/TB \tag{1}$$

- False Rejects (FR) which is the Type-II Error of the inspection system, as expressed in (2) using RG as rejected good parts, and TG as total good parts.

$$FR = RG/TG \tag{2}$$

- System Effectiveness (E), as expressed in (3) using M as Misses and FR as False Rejects.

$$E = M + FR \tag{3}$$

These measures were defined for later use during the optimize phase. Another aspect evaluated was the efficacy of the design through the identification and analysis of its potential failure modes. Industry recommendations [10] on how to perform a failure mode analysis were taken in consideration. As a result, risk evaluation and root cause problem solving were integrated into design to ensure a risk-based design, through the following steps:

- Identification of a cross-functional team, composed of automation engineering, validation engineering, maintenance & reliability, manufacturing operations, quality engineering, and industrial engineering.
- Definition and execution of plan for analysis: map-out & identify process steps, identification of failure modes in each process step and their probability, identification of the effects of failure modes and their severity on meeting design requirements, evaluation of current controls and the probability of detecting the failure mode, calculation of risk priority number, and define of the specific design elements that will address the failure mode and their design approach. Refer to Table 2 for additional details.

Table 2
FMEA Analysis Overview

Variable	Name	What it measures	Rating Criteria
P	Probability	Likelihood of failure mode occurrence	1= Low, 3=Mid, 9=High
S	Severity	Impact on meeting intended design	
R	Risk of Non-Detection	Likelihood of detecting the failure mode	
RPN	Risk Priority Number	Overall risk of failure mode	Average of P, S, and R

- Connection of each failure mode to the overall Process and procedures, or the key process elements, to identify the key design areas that would address the identified failure modes.
- Definition of design complexity and intended design approach for each failure mode, to translate it into design requirements, as shown in Table 3.

Table 3
FMEA Intake into Design Requirements

Design Complexity	Design Approach	Sum of Failure Modes' RPNs	Total RPN %
High	DFSS	21.67	15%
Medium	Benchmarking	80.00	54%
Low	Just-Do-It	37.00	25%
Out of Control Span	None	9.67	7%
Out of Scope	Not Applicable	34.00	N/A

After completion of FMEA Analysis, failure modes were integrated into the design, as shown in Table 4, addressing 96% of the risks efficiently and reducing overall design complexity by:

- Reducing the scope of advanced optimization.
- Using benchmarking as a tool for design optimization.
- Going straight to implementation for simpler design elements.

Table 4
Final Design Requirements after Design for X and FMEA Analysis

Design Req.	Description	Metric	Design Target	Optimization Method	Design CTQs	TR#s	Importance Rating (based on HOQ)
HS-1	Equipment software shall not result in false rejects	Probability of a false reject	<5%	Iterative Testing	1,3	TR#1, TR#2	176
HS-2	Equipment shall effectively read 2D Code of all incoming packages.	Read Rate	≥99.9%	Benchmarking	1,2,4	TR#2, TR#5	375
HS-3	Equipment shall be optimized by products types & alignment	Product Types & Set-Up Extremes Tested	2	Segregated Testing	3,4,5,6	TR#6, TR#7	350
EH-1	Equipment shall effectively identify product without paper or with double paper.	Inspection Effectiveness	≥95%	Iterative Testing	3,7	TR#3, TR#4	466
EH-2	Equipment shall provide indications if patch is misaligned.	Functionality	In-Place	Just-Do-It	3,5,9	TR#9	78
EH-3	Equipment shall provide indications if vision system needs adjustments.	Functionality	In-Place	Just-Do-It	3,5,9	TR#9	78
EH-4	Equipment shall provide troubleshooting instructions for any failed verifications	Functionality	In-Place	Just-Do-It	3,5,9	TR#9	78
SP-1	Procedures to align equipment shall be available	Status of Changes	In-Place	Just-Do-It	3,4,5,9	TR#9	78

Optimize Phase

In the optimize phase, the specifics of the design elements were refined using 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.

The first step taken was to utilize benchmark to determine how can the product inspection be improved, based on the results of other systems. Benchmarks were selected based on systems on-site, material supplier, and the industry. These systems and their key elements were:

- **The process under study:** Barcode scanner technology for reading of laser-etched and ink-jet printed barcodes which currently yield a 68% first pass yield and a 99.69% overall yield across 2 machines.
- **On-Site Benchmark #1:** Barcode scanner technology for reading of ink-jet printed barcodes which currently yield a 90% first pass yield and a 99% overall yield across 10 machines.
- **On-Site Benchmark #2:** Camera technology for reading of ink-jet printed barcodes which currently yield a 99% first pass yield and a 100% overall yield across 10 machines.
- **Material Supplier Benchmark:** Camera technology for reading of ink-jet printed barcodes which currently yield a 95% first pass yield and a 100% overall yield across 7 machines.
- **Industry Benchmark on [11]:** Camera technology for reading of multiple label types which currently yield a 99.5% first pass yield and a 100% overall yield across 2 machines.

Based on the benchmarks, it was identified that although similar inspection systems have better results in on-site equipment if limited to only inkjet printer barcodes, performance of the inspection system is expected to increase if Cameras are used instead of barcode scanners.

Using the data from the benchmarks performed, options were evaluated, and the optimal design was selected utilizing the Pugh Concept Selection Matrix, assigning a rating (-- for Worst, - for Bad, S for Same, + for Good, ++ for Best) for each criterion identified as key to design success. As shown in Table 5, implementation of a camera inspection obtains the best results based on total score, considering the different criteria used. Although option requires a one-time investment of approximately $10k, it is expected to yield an improvement of $140k per year as it is expected to result in a 100% total product yield based on benchmark data.

Table 5
Pugh Concept Selection Matrix

Criteria	Barcode Scanning As-Is	Optimized Barcode Scanning	Camera Inspection
First-Pass Yield	S	+	++
Total Yield	S	+	++
Cost	S	S	- -
Effort	S	- -	-
History of Success	-	+	++
Savings (Cost)	- -	+	++
Total +	0	4	8
Total -	3	2	3
Total Score	-3	2	5

Afterwards, a data collection plan was developed to determine how data pertaining design effectiveness and results was to be gathered. In summary, the data collection plan identified that:

- **Data had already been gathered** pertaining actual values for financial metrics and target improvement: current values for barcode reading metrics, process controls & financial results; and all targets for individual metrics.
- **Additional data had to be gathered** for actual values of financial & process results of the project based on actual process data: current values for metrics of profilometer laser & label camera through development study; actual values for metrics of profilometer laser & label camera through development study; actual values for MES yield lower control limits though VOC with system administrator.

Additional details pertaining data collection plan are presented in Table 6, which connects how the data ties up to design CTQs defined, as well as what the current, the target, and the actual values are and based on what source.

For the laser profilometer component inspection, a pilot test was performed to determine system effectiveness, and inspection method change would improve the results. One of two product types and all setup extremes were tested., which demonstrated that:

- Current inspection method depends on equipment set-up and does not meet the design criteria outlined in the data collection.
- A new inspection method that was available did not over-perform current software, so it was not considered as an option.
- Applying dynamic limits based on the first 10 samples processed increases system effectiveness to meet design criteria regardless of set-up. This was the only pilot test that met all criteria in the data collection plan, resulting in an expected component yield of 95%.

In addition, a pilot test for camera use during product inspection was performed. It was found that in agreement to benchmarks, use of a camera for product inspection yields a 100% first pass yield, as shown in Table 6.

Table 6
Pilot Testing of Camera for Product Inspection

Inspection Type	Reads	No Reads	First-Pass Yield
Laser-Etched	100	0	100%
Ink-Jet Printed	100	0	100%
Overall	200	0	100%

Table 6

Data Collection Plan

Type	Relation	KPI Impacted	Metric	Current		Target		Actuals	
				Source	Value	Source	Value	Source	Value
Barcode Reading	CTQs 1-4	Product Yield	First-Pass Yield	Benchmark	68%	Benchmark	≥ 95%	Pilot Testing	Need Data
			Total Yield		99.96%		100%		
	CTQs 5-6		Worst-Case Total Yield	Historical Data	53.42%		100%		
	CTQs 7-9		Total Yield Post-Corrections		53.42%		100%		
Profilometer Laser & Label Camera	CTQs 1-4	Component Yield	Probability of False Rejects	Pilot Testing	Need Data	Company Procedures	<5%	Pilot Testing	Need Data
			Probability of a Miss				≤ 0.7%		
			System Effectiveness				≥ 95%		
	CTQs 5-6		Worst Case Probability of False Rejects				< 5%		
			Worst Case Probability of a Miss				≤ 0.7%		
			Worst Case System Effectiveness				≥ 95%		
	CTQs 7-9		Probability of False Rejects Post-Corrections				< 5%		
			Probability of a Miss Post-Corrections				≤ 0.7%		
			System Effectiveness Post-Corrections				≥ 95%		
Process Controls	CTQs 7-9	Component Yield	MES Yield Lower Control Limit	VOC with Administrator	66.34%	Project Defined	90%	VOC with MES Admin	Need Data
		Product Yield			None		98.50 %		
Financial Results	Project Objective	Total Waste	Component Yield	Historical Data	85.48%	Project Defined	95.00 %	Financial & Process Estimates	Need Data
			Yearly Component Waste		$59k		≤ 20k		
			Product Yield		99.69%		99.90 %		
			Yearly Product Waste		$140k		≤ $45k		
			Rolled Throughput Yield		85.22%		94.91 %		
			Sigma Level		2.55		3.14		
			Yearly Savings		$0		≥ $146k		

Based on pilot testing and benchmarking, the final design concept was recommended:

- **Setup:** Develop alignment instructions and include indication in inspection systems if equipment is misaligned.
- **Product Inspection:** Replace Dataman with Camera Inspection.
- **Laser Profilometer:** In product type tested in pilot, utilize current software, and define detection limits based on first 10 pieces after set-up.
- **Camera Inspection:** Verify for paper alignment, provide indication if equipment is misaligned, and provide troubleshooting instructions for any failed inspections.
- **Electronic Batch Documentation:** Include yield limits for component and product yield and develop procedural reaction plan if yield is out of limits.

These design elements are expected to yield the best process design results. Furthermore, as only one product type was tested, it is recommended that the same study is performed for Product B to optimize results obtained.

Verify Phase

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

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: Qualify & 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		

Figure 3
Verify Phase Summary

its intended target once implemented while product yield and financials are expected to exceed their intended target once implemented. A summary of these findings is included in Figure 3, including the expected project results.

CONCLUSIONS

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.

The original project objective of devising a detailed design and implementation plan was met, and the plan developed. This plan exceeded the enabling objective of deduction of material waste from $199K to $53k per year, as expected material waste is $20k after implementation. In addition, it met its enabling objective of improvement of component yield from 85% to 95%. Lastly, the plan exceeded its enabling objective of improvement of product yield from 99.7% to 99.9%, as expected product yield with changes is 100%. As a result, it is considered that project was effective in utilizing design for six sigma to optimize automated inspections effectiveness for the process under study.

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 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.

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