DMAIC-Based Optimization of In-Process Monitoring for Scrap Reduction in a Regulated Industry

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Abstract *— Process monitoring and control are critical for quality assurance in the regulated medical device industry, supporting ongoing verification of processes and confirming they remain capable and in control. Many in-process monitoring activities require destructive testing, thereby increasing scrap costs. This project focuses on Line X, where in-process monitoring scrap significantly increased scrap costs, totaling $0.279 per unit over six months. Production volume growth forecasts and new product introductions suggest that the current monitoring strategy will further affect manufacturing efficiency. DMAIC methodology was applied to evaluate and optimize the in-process monitoring strategy. The project objective was to reduce monthly scrap costs associated with monitoring samples in Line X, focusing on destructive tests such as mechanical integrity and leak testing. All modifications were required to maintain product quality and regulatory compliance, and to prevent nonconforming units from reaching the customer. The optimized sampling strategy reduced costs and implemented controls to sustain improvements.*

Keywords *— DMAIC, In-Process Monitoring, Sampling Strategy, Scrap Reduction.*

PROBLEM STATEMENT

Process monitoring and control (commonly known in industry as “in-Process Monitoring”) is an essential element of quality assurance in the regulated medical device manufacturing industry, supporting the ongoing verification of a process to ensure it remains capable and in control [1],[2]. These in-process monitoring activities are intended to detect process variations early and support preventive behavior to avoid non-conforming products from leaving the facility.

Currently, in-process monitoring relies on destructive testing methods. Due to the nature of most of these tests, such as pull tests and leak tests, mechanical integrity and functional performance require testing until failure or breakage occurs. These monitoring tests are designed to be performed in accordance with industry standards that require physical breakage of the unit to confirm compliance. As a result, the units/samples used for in-process monitoring cannot be returned to the production line and must be scrapped after testing. The quantity of in-process monitoring samples is not arbitrary; it is defined by regulatory expectations, risk management, statistical rationale, and historical data [1],[2]. The facility must demonstrate that the sampling plan is scientifically justified and based on the criticality of the characteristic being evaluated and the test's ability to detect process variation [3],[4]. Destructive tests, such as pull and leak tests, and sample-size-based procedures and standards require a minimum sample size to confirm the lot's integrity, resulting in unavoidable scrap.

During the first and second quarters of the year (Q1 and Q2), from May to October, the scrap generated by in-process monitoring at Line X ranked among the top 10 contributors to production-area scrap. The combined scrap cost per unit associated with in-process monitoring samples was $0.279. Driven by incremental volume and new products, the existing in-process monitoring strategy will further increase its negative impact on scrap generation and operational efficiency. The objective of this project is to reduce the total monthly scrap cost due to In-process monitoring samples at Line X from $0.279 to $0.23 by Q4 (April), without impacting the product quality.

Research Description

This research focuses on the identified major offenders affecting production scrap, evaluates, and optimizes various In-process monitoring (i.e., in-process control) methods that require destructive testing. This initiative focuses on minimizing waste from destructive testing while upholding quality and compliance.

Based on DMAIC methodology, this project will define and measure the problem, analyze root causes, identify improvements, and establish controls to sustain gains [5]. This structured approach, combined with stakeholder alignment, ensures a well-coordinated path toward achieving meaningful reductions in scrap at Line X [6].

The scope of the research includes mechanical integrity and leak testing, including burst, pull, and leak tests. It excludes Dye tests and any change that could increase the risk of unacceptable units reaching the client [6].

Research Timeline

This research followed DMAIC methodology with a defined project timeline (Refer to Figure 1). The opportunity was identified at Line X at the end of Q2 (October), and a preliminary project charter draft was created. It was then reviewed and discussed with the stakeholders. After several productive meetings, valuable input was incorporated, leading to the project charter's endorsement [6]. Following this endorsement during the Define phase, a dedicated project team was established in November, and a certified black belt coach was appointed. We continued with the measure phase in parallel with the final stage of the project charter. The Measure phase focused on data collection from Q1-Q2 to establish baselines using validated reporting systems.

The baseline data gathering was followed by the Analyze phase executed between December and January. This phase focused on further data evaluation and the application of 6sigma tools to identify root causes and prioritize them accordingly.

Activities for the Improve phase started in January with the identification of the deliverables. These were divided into 2 categories to have a 2-phase implementation and provide manufacturing with the benefits as soon as possible. The phase 1 actions were implemented in January; the final and more complex solutions were implemented in February. Post-implementation activities began in March as part of the monitoring activities in the Control phase. It included completing procedures and document changes, training, and a follow-up report to confirm that the improvements were sustained over time. A final review was conducted with all stakeholders in April to obtain final endorsement for project closure.

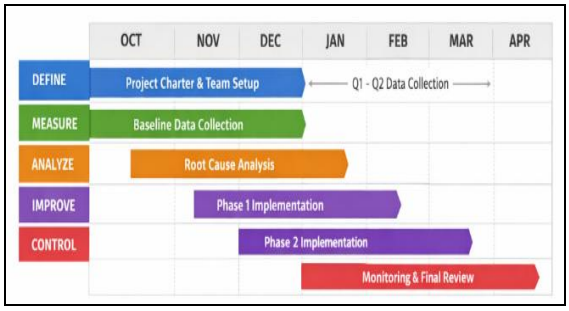


Figure 1
Project Timeline

Research Contributions

This research contributed to improving the manufacturing process by demonstrating how the use of DMAIC and 6sigma tools supports risk-based optimization of in-process monitoring to reduce scrap costs without compromising compliance or product quality. Amongst the key contributions are:

- The application of DMAIC and 6sigma tools for in-process control in a regulated environment
- Being able to quantify the financial impact associated with in-process controls in a specific manufacturing line
- Demonstrate how good practices and alignment on sampling and testing practices will drive scrap cost reduction

- Demonstrate how operational costs can be reduced without negatively impacting quality and compliance
- Demonstrate that by establishing suitable controls, improvements, and performance could be sustained.

Regulatory Requirements And Business Rationale

Regulatory Basis for In-Process Controls. FDA Regulation requires manufacturers to establish and maintain production and process controls to ensure that devices conform to their specifications [1]. These requirements include monitoring and controlling manufacturing processes to maintain process control and ensure product quality [1].

FDA guidance on process validation emphasizes ongoing process monitoring as an essential element for maintaining the process's validated state throughout production [2]. In addition, ISO 13485 requires organizations to monitor and measure manufacturing processes to ensure that products conform consistently and comply with regulatory requirements [3].

In-process controls provide objective evidence that the process parameters identified as critical and the product characteristics continue to meet the requirements established during validation [2], [3]. This monitoring data supports the statistical evaluation of process behavior over time and the identification of sources of variation [6].

Although output and scrap costs should not be the primary factors in determining a sampling strategy for in-process monitoring, they should be considered, as supporting regulatory compliance and operational needs is essential. The sampling requirements must be based on scientific data and risk-based to ensure compliance with the process control. When inefficiencies are identified, optimizations can be achieved by reassessing the sampling strategy, ensuring there is no increase in customer risk, and ensuring validation procedures and regulations are followed. This project enables the continuous improvement of culture to continue meeting compliance while also supporting operational metrics such as scrap reduction and cost per unit.

Expected Benefits

- Hard savings: Save approximately $0.05 of the total Year to date (YTD) scrap per unit
- Reduction of in-process monitoring tests' setup time
- Increase Units per Labor Hour (UPLH) and labor productivity across shifts and lines
- Decrease the total monthly scrap cost due to In-process monitoring samples from $0.279 to $0.23
- Standardize methods and document good practices to become part of the Standard Operating Procedure (SOP)
- Demonstrate that the lines will maintain their performance and benefits long after project completion.
- Improve alignment between sampling strategy and risk
- Maintain compliance requirements by not increasing the risk of unacceptable units reaching the client.

Methodology – DMAIC Approach

DMAIC is a structured, data-driven problem-solving methodology used to improve existing processes that do not meet performance expectations [5]. According to Pyzdek and Keller, DMAIC provides a disciplined framework for identifying performance gaps, determining their root causes, and implementing sustainable improvements through systematic analysis and control [5].

The methodology emphasizes statistical thinking, process understanding, and fact-based decision making to ensure improvements are effective and repeatable [5]. DMAIC is organized into five sequential phases: Define, Measure, Analyze, Improve, and Control.

Define

The Define phase focuses on clearly articulating the problem, establishing project objectives, and defining the scope of the improvement effort [5]. During this phase, stakeholders are aligned, customer requirements are identified, and critical-to-quality characteristics are defined.

Key outputs of the Define phase include a problem statement, a project charter, and a high-level understanding of the process under study. This phase ensures the project is focused on a relevant, measurable problem [5].

Measure

The Measure phase is dedicated to understanding current process performance through data collection and measurement system evaluation [5]. The objective is to establish a reliable baseline that quantifies the problem's magnitude.

Activities in this phase include defining performance metrics, validating data sources, and collecting data that accurately represents the process. The Measure phase provides the factual foundation required for meaningful analysis [5].

Analyze

The Analyze phase aims to identify and validate the root causes of the performance gap observed in the Measure phase [5]. Analytical and statistical tools are used to examine relationships between process inputs and outputs. This phase emphasizes distinguishing between potential causes and verified causes, allowing improvement efforts to focus on the most significant factors affecting performance [5].

Improve

The Improve phase involves developing and implementing solutions that address the verified root causes identified during the Analyze phase [5]. Testing and validation activities are often conducted to confirm that proposed improvements achieve the desired results before full implementation. The goal of this phase is to optimize the process and eliminate the causes of poor performance [5].

Control

The Control phase ensures that improvements achieved during the Improve phase are sustained over time [5]. This phase focuses on standardizing successful changes and establishing monitoring mechanisms to detect deviations. Control plans, performance metrics, and ongoing reviews are implemented to maintain the improved level of performance. The Control phase completes the DMAIC cycle by transferring ownership of the improved process to routine operations [5].

RESULTS' DISCUSSION

This chapter explains how the project advanced after each DMAIC phase. It provides detailed information on the data collected, problem-solving tools used, and deliverables for each phase that contributed to the successful implementation of the in-process monitoring sampling optimization strategy.

Define Phase

During the Line X monthly scrap evaluation meeting, it was noted that the samples discarded due to in-process monitoring were among the top ten (10) major offenders affecting production scrap.

A preliminary draft of the Project Charter was created with the problem statement ("pain") identified as the high scrap cost associated with the in-progress monitoring samples. After discussion with stakeholders, project Y was identified as "The scrap cost due to In-process monitoring samples on a monthly basis", and the Project Charter was endorsed. See Figure 2 for the approved project charter. Tools applied during this phase:

- Project Charter – Stakeholders identification. Team member's selection
- Voice of the Customer (VOC)
- Project Scope and Schedule

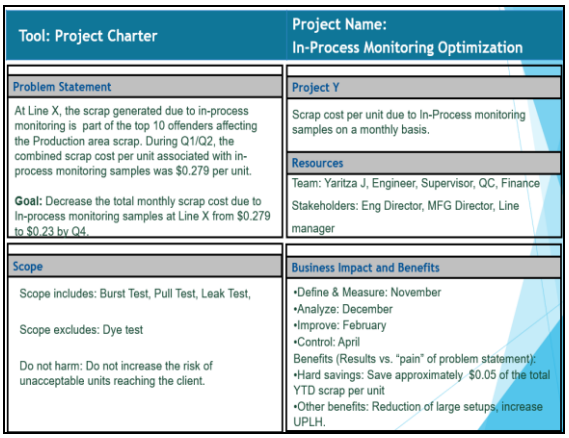


Figure 2
Project Charter

Measure Phase

The main objective of the measure phase is to understand the current state of the process and to collect data, such as quality metrics and costs, to serve as a baseline for the project "Y". Historical scrap and yield data were collected from validated reports to ensure adequate measurement systems were used during the assessment. In addition, during the measure phase, a process map was created, and the project charter was reviewed and validated. Tools applied during this phase included:

- Validated MES reporting systems
- Pareto analysis to evaluate the scrap major
- Process flowchart
- Baseline capability assessment

During the measure phase, the problem statement was confirmed, showing that Encasement and Patch in-process monitoring were identified as the top major offenders for Line X, with a combined scrap cost of $0.25. Furthermore, the combined scrap cost for all in-process monitoring samples was $0.27, totaling approximately 27,000 units over the last two quarters (refer to Figures 3 and 4).

To understand the Y of the project, the scrap cost baseline was determined by gathering data from validated systems for Q1 and Q2 (May to October). The data consisted of the combined scrap cost per week for Line X, including the major offenders, Encasement and Patch in-process monitoring. Refer to Figure 5 for the complete analysis.

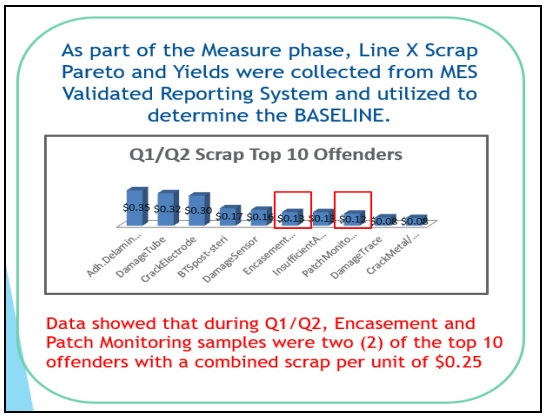


Figure 3
Measure Phase-Data Gathering and Baseline Definition

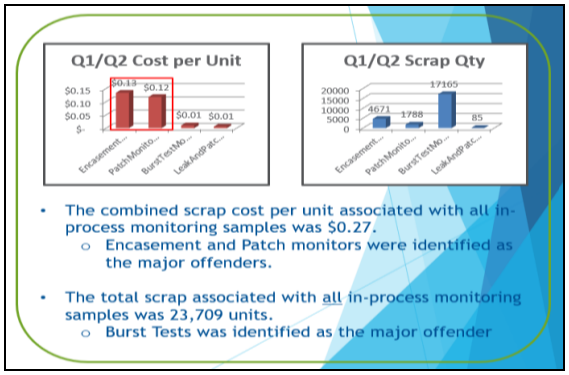


Figure 4
Measure Phase-Data Gathering and Baseline Definition

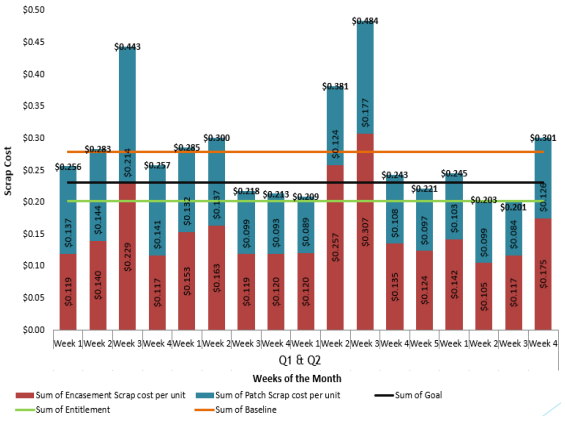


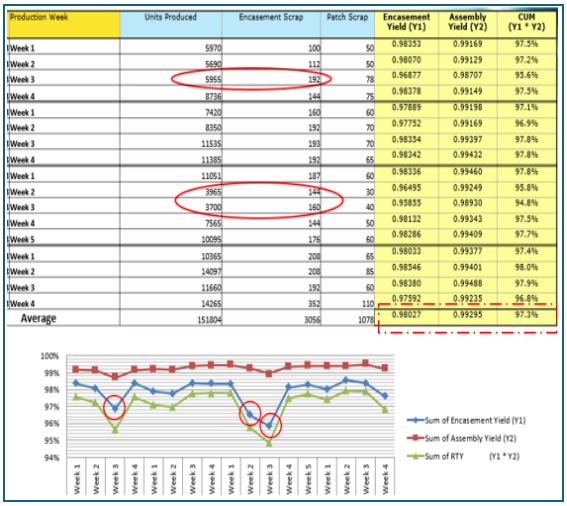
Figure 5
Measure Phase- Baseline

As shown in Figure 5, the data analysis indicates that the lowest scrap cost in the past two quarters was $0.279, which serves as our Entitlement, as it is the lowest achievable scrap cost based on data before any optimization. The

Baseline represents the average Q1 and Q2 performance for scrap cost per unit (project Y) at $0.279. With this information, the project charter goal of $0.230 was deemed achievable and validated by stakeholders.

During the measure phase, the in-process monitoring scrap impact on weekly production and the line's yield was also considered to define the Y initial capability. Figure 6 summarizes the number of units scrapped due to in-process monitoring of major offenders (Encasement and Patch) compared to units produced during the week, showing that the line's yield is visibly affected in the weeks with the highest in-process monitoring scrap (highlighted in red).

Based on the data analysis and VOO interviews, the potential X's ('likely suspects") were identified and evaluated. The current sampling method was evaluated and compared against SOPs across different operators and shifts to identify opportunities. Refer to Figure 7 for the sampling method evaluation results. During the evaluation of these processes, it was observed that operators and supervisors had doubts about the sampling size and monitoring frequency. This gap was addressed immediately, and a "refresher" training session was provided to all shifts in accordance with established procedures.



Production Week	Units Produced	Encasement Scrap	Patch Scrap	Encasement Yield (Y1)	Assembly Yield (Y2)	CUM (Y1 * Y2)
Week 1	5970	100	50	0.98353	0.99169	97.5%
Week 2	5690	112	50	0.98070	0.99129	97.2%
Week 3	5955	192	78	0.96877	0.98707	95.6%
Week 4	8736	144	75	0.98378	0.99149	97.5%
Week 1	7420	160	60	0.97889	0.99198	97.1%
Week 2	8350	192	70	0.97752	0.99169	96.9%
Week 3	11535	193	70	0.98354	0.99397	97.8%
Week 4	11385	192	65	0.98342	0.99432	97.8%
Week 1	11051	187	60	0.98336	0.99460	97.8%
Week 2	3965	144	30	0.96495	0.99249	95.8%
Week 3	3700	160	40	0.95855	0.98930	94.8%
Week 4	7565	144	50	0.98132	0.99343	97.5%
Week 5	10095	176	60	0.98286	0.99409	97.7%
Week 1	10365	208	65	0.98033	0.99377	97.4%
Week 2	14097	208	85	0.98546	0.99401	98.0%
Week 3	11660	192	60	0.98380	0.99488	97.9%
Week 4	14265	352	110	0.97592	0.99235	96.8%
Average	151804	3056	1078	0.98027	0.99295	97.3%

Figure 6
Measure Phase- Initial Y Capability

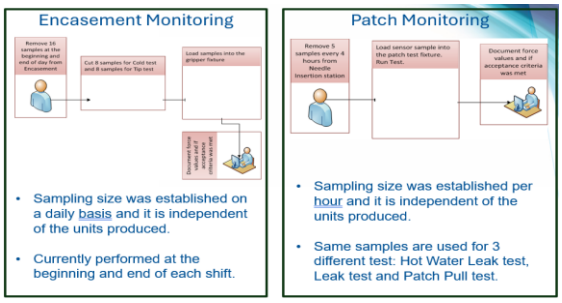
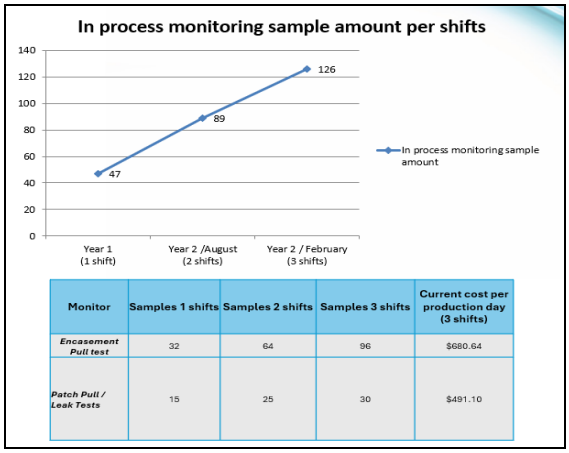


Figure 7
Measure Phase Potential X's - Current Sampling Method

Line X was a new line that started with only one shift. As the volume demand grew, more shifts were added, multiplying the impact of the in-process monitoring scrap. Figure 8 shows the relationship between in-process monitoring samples and the number of shifts. It is not surprising that by the time the third shift starts production, the in-process monitoring scrap has begun to appear on the major offenders' list.



Monitor	Samples 1 shifts	Samples 2 shifts	Samples 3 shifts	Current cost per production day (3 shifts)
Encasement Pull test	32	64	96	$680.64
Patch Pull / Leak Tests	15	25	30	$491.10

Figure 8
Measure Phase Potential X's - Production Shifts

Analyze Phase

The Analyze phase helps us identify, classify, and document the potential root causes of the problem. Another objective of this phase is to determine how the input factors (X's) affect the output (Y) significantly. The relationship between the critical Xs and the Y is key to prioritizing root causes in the analysis. Some of the tools applied during this phase were:

- Cause-and-Effect Diagram to identify which X's are the potential causes

- Cause-and-Effect prioritization matrix to prioritize the potential causes identified during the cause-and-effect analysis.

The cause-and-effect diagram (Fishbone) performed during the analyze phase served as a roadmap to identify, classify, and document potential root causes. Figure 9 presents the complete exercise conducted for the in-process monitoring evaluation. During several sessions, the team defined and classified potential root causes into the following categories: Measurements, Material, Environment, Methods, Machines, and Personnel (Refer to Table 1). Once the potential X's were identified, the team ranked the most relevant root causes in the cause-and-effect prioritization matrix (see the Total and Ranking columns in Table 1).

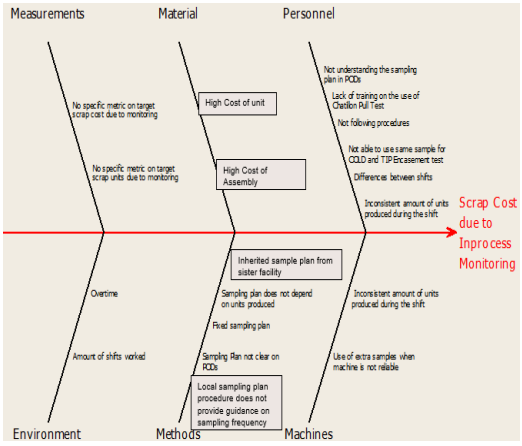


Figure 9

Analyze Phase - Key Xs Affecting Y (Fishbone)

Each potential root cause was assessed based on its impact on the Scrap Cost, Sampling Frequency (Method), and Compliance, and the highest priority was given to the process inputs that have a direct and strong effect on the Y's (output). The items shown in Figure 10 were the ones identified as having a high or moderate impact on the outcome. The Prioritization matrix allowed us to rank the potential X's, narrow the scope of the optimizations, and focus on the primary root causes.

Table 1

Analyze Phase - Key X's Affecting Y (Prioritization Matrix)

C&E Correlation Rankings:
0 = No Correlation
1 = Process has a small effect on the Y
3 = Process has a moderate effect on the Y
9 = Process input has a direct and strong effect

			Importance to customer				
			4	2	5	(1 Low, 5 High)	
			Output (Y)				
Clasification	#	Potencial Root Cause (X)	Scrap Cost	Sampling Frequency/ Method	Compliance	Total	Rank
Machine	18	Use of extra samples when machine is not reliable	9	9	9	99	1
Personnel	5	Not understanding the sampling plan in PODs	3	3	9	63	2
Personnel	7	Not following procedures	3	3	9	63	3
Methods	13	Local Sampling Plan procedure does not provide guidance on fequency	0	9	9	63	4
Methods	14	Sampling Plan not clear on PODs	3	3	9	63	2
Methods	17	Inherit sampling plan	3	3	9	63	5
Personnel	8	Not able to use same sample for COLD and TIP Encasement test	9	9	1	59	6
Personnel	10	Inconsistent amount of units produced during the shift	9	9	1	59	7
Environment	11	Amount of shifts defined in the area	9	9	1	59	8
Machine	19	Inconsistent amount of units produced during the shift	9	9	1	59	9
Material	3	High cost of units	9	9	0	54	10
Material	4	Hight cost of Assy	9	9	0	54	11
Methods	15	Fixed sampling plan	9	1	3	53	12
Methods	16	Sampling plan does not depend on units produced	9	1	3	53	13
Personnel	9	Differences between shifts	3	1	3	29	15
Personnel	6	Lack of training on the use of Chatillon Pull Test	1	9	3	37	14
Environment	12	Overtime	3	3	1	23	16
Measurements	2	No specific metric on target scrap units due to monitoring	1	0	1	9	17
Measurements	1	No specific metric on target scrap cost due to monitoring	1	0	0	4	18

Improve Phase

During the implementation phase, the team focused on documenting, developing, and implementing solutions to address the confirmed root causes. The implementation strategy was divided into short-, medium-, and long-term phases to allow operations to incorporate changes and benefit from the optimizations as early as possible.

After evaluating the Cause-and-Effect Matrix, all items were regrouped under a Potential X category depending on their classification. The implementation time and feasibility were considered in the solution evaluation. Refer to Table 2 for the action plan defined for each output under the following potential X categories: Equipment used in the test is not reliable, Sampling Method opportunities, SOP Instructions are not clear, Sampling method definition, sampling plan independent of units produced, or production shifts. There were three implementation phases to address each action, as outlined in the implementation timeline.

Table 2

Improve Phase – Group Correlated X's

Rank	Potential X	Action Plan	Implementation (short, med, long)
1	Equipment used in the Test is not reliable	Validate new ATC leak tester to substitute current leak test equipment. ATC is a non-destructive test; units can return to the line.	Medium Requires Equipment Procurement and Validation
2	Sampling Method	Review sampling plan per the site procedure and compare with a sister site sampling plan and process documentation. Modify sampling plan as needed to align both sites.	Short
3	POD Instructions not clear	Modify POD to clarify sampling plans and provide and overview/ process refresh	Short
4	Encasement sampling method	Evaluate the use of only 1 unit to perform the upper and bottom pull tests instead of 1 unit for each test	Long Requires FDA submission
5	Sampling plan independent of units produced	This item is covered as part of item #2 (sampling method)	Short
6	Amount of shifts	Evaluate the sampling plan definitions for samples per shift vs samples per production day. After evaluation of item #2, will cover any modifications needed.	Short

Actions in Phase I involved short-term implementation (more immediate actions), including evaluations of sampling plan methods such as:

- Encasement pull test sampling frequency clarification was performed to align operations with the effective Sample Governance procedure. Completing this action reduced the sample size from 32 per shift to 32 per day, with 16 units tested at the beginning and 16 at the end of the production day.
- Pull test sampling plan was updated per the current governing procedure, enabling a reduction from 15 samples per shift to 12 samples distributed throughout the production day.
- Hot water leak test sample size was revised to align with the current governing procedure, reducing the sample size from 15 per shift to 22 samples per production day. This in-process monitoring will be performed at the beginning and end of the production day.

The total number of samples used (scrapped) for monitoring during the current two shifts decreased from 89 to 54 units. Refer to Table 3 for details on the pull-test and leak-test sample-reduction implementation.

Among the major offenders Pareto presented during the Measure phase (Figures 3 and 4), we recalled that Encasement was the top offender in the In-process monitoring tests. After implementing sampling size reduction and frequency alignment, the scrap cost per unit decreased from $0.135 to $0.077. Refer to Figure 10 for the monthly changes observed after implementing these actions to target this in-process monitoring.

Table 3

Sampling Plan Method Modification (Short-Term)

Test	Current cost per production day				Future State (Estimated after Implementation)		
	Samples 1 shifts	1 shift	Sample2 shifts	Sample3 shifts	Implementation Plan	Samples per shift	Cost per shifts
Encase Pull test	32	$226.88	64	96	Clarification of the Sampling plan. The procedure states a total of 32 samples per day.	32 daily (16 at the beginning and 16 at the end of production day) No POD modification required	$161.10
Patch Pull / Leak Test	15	$245.55	25	30	New sampling size 11 per production day. Modify POD. To be perform at the beginning of the production day and at the end.	12 samples to be distributed through the production day.	$360.14
Hot Water Leak Test	15	$245.55	25	30	New sampling size 22 per production day. Modify POD. To be perform at the beginning of the production day and at the end.	22 samples to be distributed through the production day.	$360.14

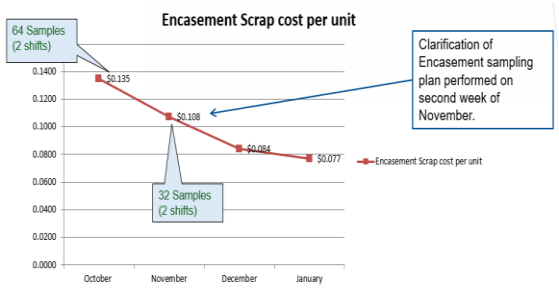


Figure 10

Cost Per Unit After Encasement Sampling Modification

Phase II included actions considered medium-term. This is the case for validating the new leak tester model. The operations team identified this potential X as an opportunity because the current equipment was not functioning as expected, leading to false rejects and delays in the testing process. During the equipment evaluation, a new Leak Test model was selected that will not only eliminate the reliability problem but also eliminate the scrap cost associated with the Hot Water leak test, since it is a non-destructive test. All samples will return to the manufacturing line if they pass the test. Table 4 below summarizes the benefits of the procurement and validation of the new leak tester, showing a daily avoidance of over $500 for two (2) shifts. Even though procurement and validation added costs, the return on investment (ROI) justifies the budget request for the new equipment.

Lastly, Phase III actions were classified as long-term because they required more effort. This

includes modifications to the Encasement Sampling Method.

Table 4
Validation of A New Leak Tester (Medium Term)

Monitor	Samples 1 shifts	Current cost per production day (1 shift)	Samples 2 shifts	Samples 3 shifts	Implementation Plan	Number of samples per shift after implementation	Cost per shifts after implementation
Leak Tests	15	$245.55	25	30	The new Leak Test will test units, which will then return to the line.	22 samples distributed thought the production day	$0

During the evaluation of the Encasement process flow and the observation in the manufacturing area, the team noticed that during the encasement pull test, operators cut the unit in half and used only the top portion for the pull test, discarding the bottom section. Then, to perform the bottom pull test, the unit-cutting process was repeated, this time discarding the top portion and using the bottom for testing. The proposal presented to the quality and operations team was to determine the appropriate method for cutting the unit in half so that both ends of one sample could be used for both tests (bottom and top pull tests).

These process steps were performed in accordance with the current procedure and were part of the product transfer and characterization, which required an FDA submission of the process steps if they were to be changed. This new process was submitted and implemented as part of a separate initiative. Refer to Figure 11 for the proposed process step changes for in-process encasement monitoring.

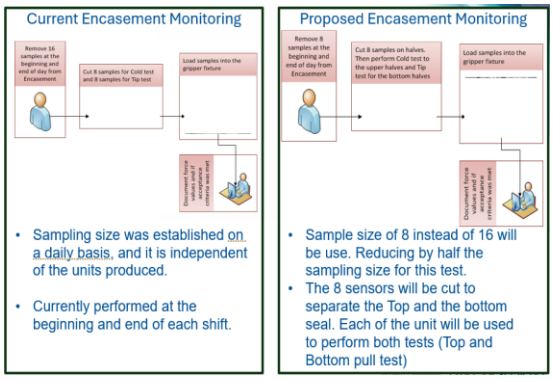


Figure 11
Encasement Sampling Method (Long Term)

After implementing the actions identified during the Improve phase, Line X met and exceeded the project charter goal of reducing the scrap cost per unit associated with In-process monitoring to $0.230. By January monthly closure, the line was reporting an in-process monitoring scrap per unit of $0.162, accumulated across patch and encasement areas, which were the major offenders identified during the define phase (Refer to Figure 12).

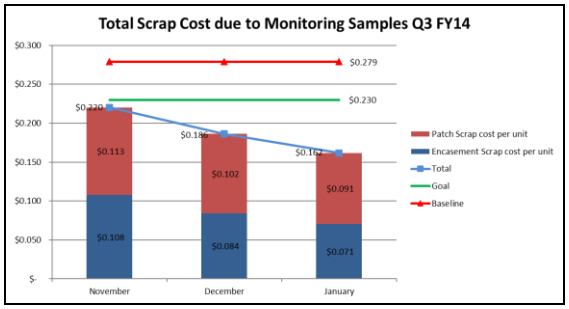


Figure 12
Improve Phase

Control Phase

The control phase ensures mechanisms are in place to sustain the improvements. This helps to prevent problem recurrence and maintain the benefits over time. The tools applied were the Process Control Plan and the Control Chart.

During the control phase, documents and procedures were updated, and training was provided to the operations team to ensure execution aligned with the operating procedure. Training records were updated, and trainers in each assembly area were certified in the new processes.

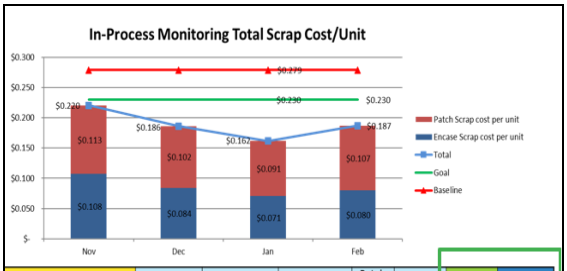
A control plan was created to ensure improvement, sustainability, and consistency. The plan includes standardizing and monitoring procedures at daily Tier Meetings and at the monthly Scrap Forum. Refer to Table 5 for the Control plan created as part of the control phase deliverables.

Data compiled over 4 months after implementation began confirms that the goal of a scrap cost of $0.23 for In-process monitoring was achieved. Figure 13 shows that the current average scrap cost is $0.199.

Table 5

Control Phase – Process Control Plan

Process Name:	In Process Monitors		Origination Date:	XXXX		CP Audit Frequency:	
Process Owner:	XXX		Last Updated:	XXXXXX		Next Audit Date:	
				Control Methods			
Y	X	Specification	Capability /Date	Documentation	Monitoring	Prevention	Reaction Plan
Scrap cost due to In-Process monitoring samples monthly.	Sampling method evaluation	Encasement Pull Test sample size - of 32 samples per day	Initial Capability Q1: Encasement Yield: 98.01% Assembly Yield: 99.27% CUM Yield: 97.3%	Sampling plan documented procedure XXX POD states that 32 samples will be removed for Pull Test.	Tier 2 Scrap Review/ CIP Scrap Forum	PODs are special processes and require certification.	Abnormal condition is identified, a red card will be opened at Tier 2 meeting. Re-training and awareness to involved personnel
	Amount of shifts	Patch pull test will continue to be perform every 4 hours (5 samples). Encasement 32 samples will be distributed throughout the 3 shifts	Final Capability Q3: Encasement Yield: 98.78% Assembly Yield: 99.36% CUM Yield: 98.16%	POD states that 32 samples will be removed for Pull Test per production day.	Tier 2 Scrap Review/ CIP Scrap Forum	PODs are special processes and require certification.	Re-training and awareness to involved personnel



Production Month	Encase Scrap	Encase Scrap cost per unit	Patch scrap	Patch Scrap cost per unit	Baseline	Current Total	Goal
Oct	960	$ 0.135	320	$ 0.104	$ 0.279	$ 0.239	$ 0.230
Nov	1024	$ 0.108	465	$ 0.113	$ 0.279	$ 0.220	$ 0.230
Dec	784	$ 0.084	410	$ 0.102	$ 0.279	$ 0.186	$ 0.230
Jan	648	$ 0.071	360	$ 0.091	$ 0.279	$ 0.162	$ 0.230
Feb	752	$ 0.080	435	$ 0.107	$ 0.279	$ 0.187	$ 0.230
Average	$ 0.199						

Figure 13

Control Phase – Average Scrap Cost after implementations

Key Actions

- Aligned sampling and testing practices with sister sites
- Maintained compliance with sampling standards, proactively assessing any additional risks
- Explored automated testing options to reduce reliance on manual methods
- Optimized sample use by testing both top and bottom halves from a single unit

Sustaining Results

Procedural changes were formalized, with a control plan and daily Tier Meeting monitoring to ensure ongoing consistency and sustainable cost reduction [6]. The results demonstrated that applying the DMAIC methodology enabled a significant and sustainable reduction in in-process monitoring scrap. By identifying and addressing sampling and shift-related drivers, the project achieved cost reduction without increasing product risk. In addition to financial benefits, the project improved operational efficiency, reduced large setups, and contributed to increased units per labor hour as a secondary benefit.

Conclusion

Through the implementation of DMAIC tools and by identifying a combination of process improvements and innovative solutions, this project achieved a significant and sustainable reduction in in-process monitoring scrap at Line X.

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