DMAIC-Based Optimization of In-Process Monitoring for Scrap Reduction

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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 significantly increased scrap costs, totaling $0.279 per unit. 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. An optimized sampling strategy was implemented reducing costs, maintain product quality and regulatory compliance, and to prevent nonconforming units from reaching the customer.

Problem Statement

In-process monitoring activities at Line X require destructive testing and generate scrap as part of routine production. Over 6 months, scrap associated with in-process monitoring was identified as a major contributor to overall scrap cost, with an impact of $0.279 per unit. The existing monitoring strategy did not scale with production volume, resulting in increased scrap and reduced manufacturing efficiency as production expanded.

Methodology

The DMAIC methodology was used to evaluate and optimize the existing in-process monitoring strategy at Line X. This methodology is used in Six Sigma projects when an existing process requires improvement to meet performance and quality objectives. The DMAIC methodology consists of five phases: Define, Measure, Analyze, Improve, and Control. Figure 1 presents the project timeline and a brief description of the activities performed in each phase.

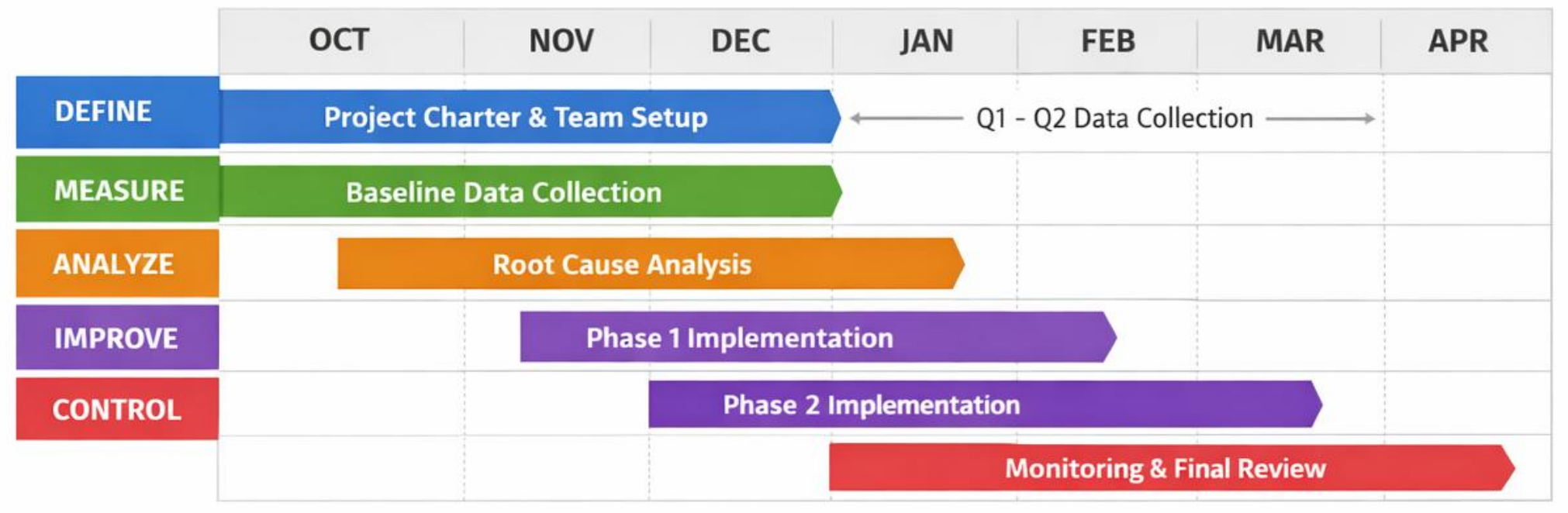


Figure 1: Project Timeline

Results and Discussion

DEFINE PHASE

Tool: Project Charter	Project Name: In-Process Monitoring Optimization
Problem Statement	**Project Y**
At Line X, the scrap generated due to in-process monitoring is part of the top 10 offenders affecting the Production area scrap. During Q1/Q2, the combined scrap cost per unit associated with in-process monitoring samples was $0.279 per unit. **Goal:** Decrease the total monthly scrap cost due to In-process monitoring samples at Line X from $0.279 to $0.23 by Q4.	**Scrap cost per unit due to In-Process monitoring** samples on a monthly basis. **Resources** Team: Yaritza J, Engineer, Supervisor, QC, Finance Stakeholders: Eng Director, MFG Director, Line manager
Scope	**Business Impact and Benefits**
Scope includes: Burst Test, Pull Test, Leak Test, Scope excludes: Dye test Do not harm: Do not increase the risk of unacceptable units reaching the client.	•Define & Measure: November •Analyze: December •Improve: February •Control: April Benefits (Results vs. "pain" of problem statement): •Hard savings: Save approximately $0.05 of the total YTD scrap per unit •Other benefits: Reduction of large setups, increase UPLH.

Figure 2: Project Charter

MEASURE PHASE

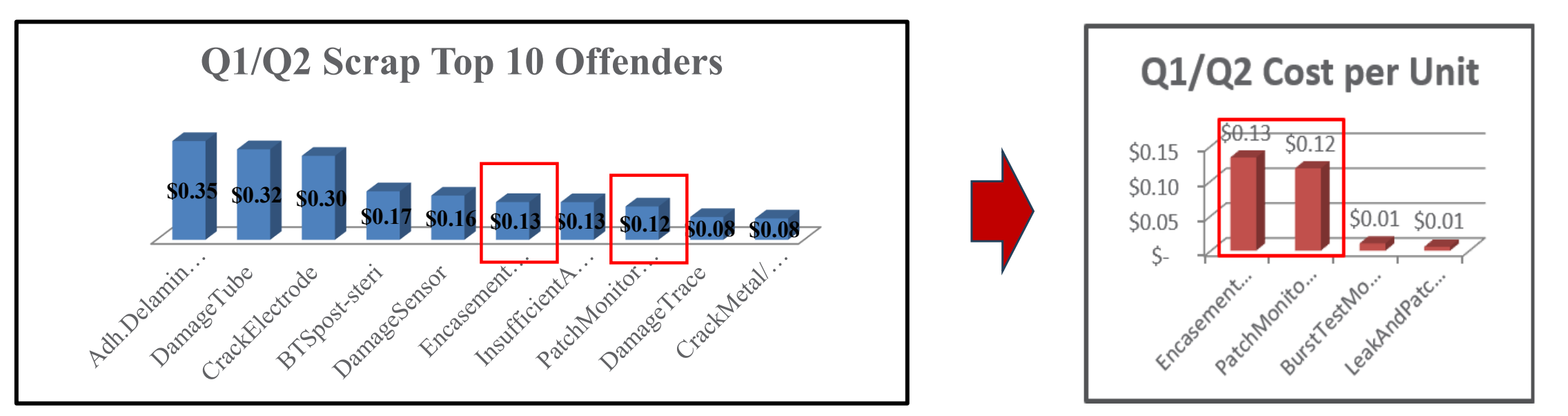


Figure 3: Combined Scrap Cost Per Unit Associated With In-process Monitoring

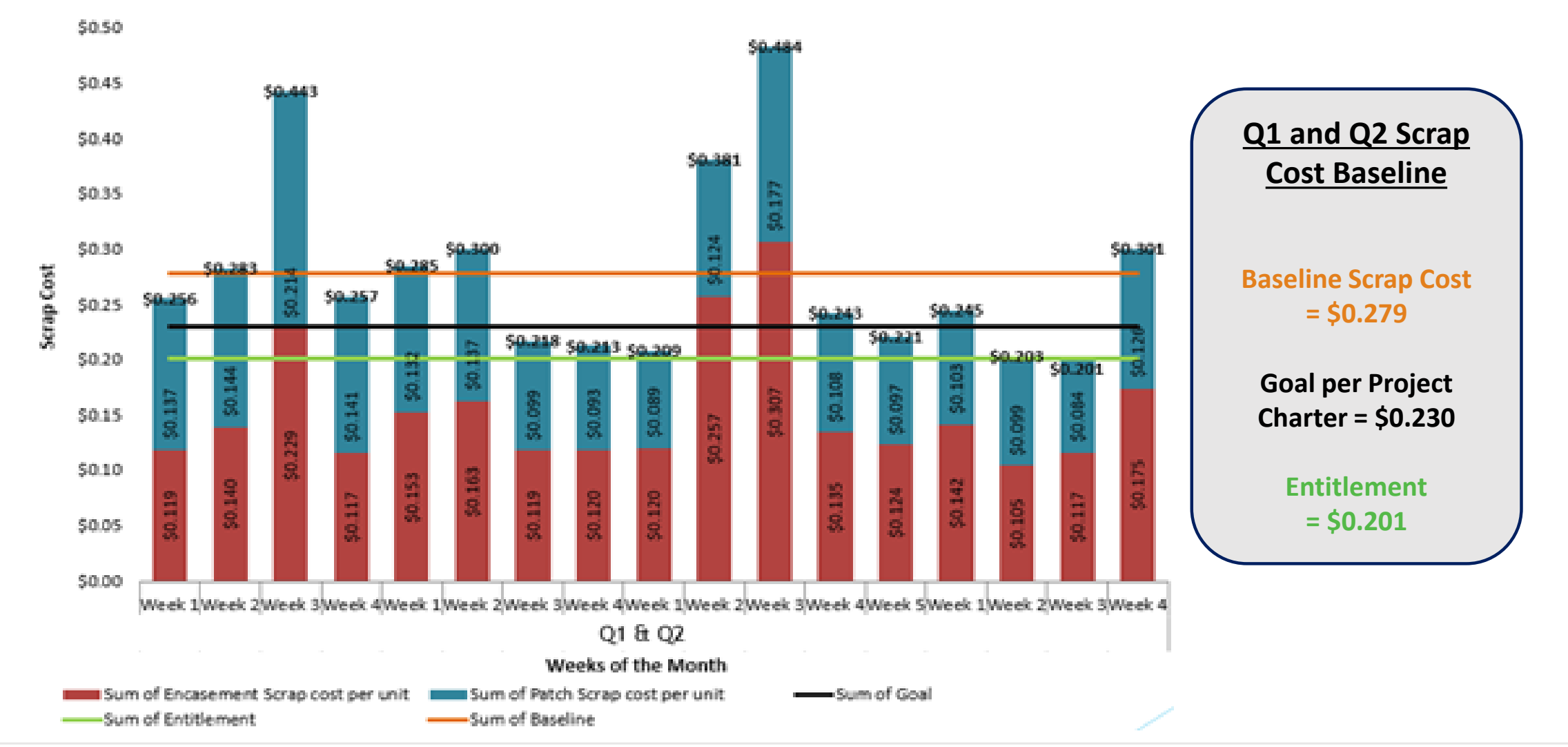


Figure 4: Understanding the "Y" - Q1/Q2 Scrap Cost Per Unit Baseline

Measure phase data analysis findings:

- Major Offender Identified: In-process monitoring scrap
- Yield Impact Confirmed
- Initial Y Capability Established
- Potential X's Identified
- Sampling Standardization Gap Addressed
- Shift Expansion Impact Observed

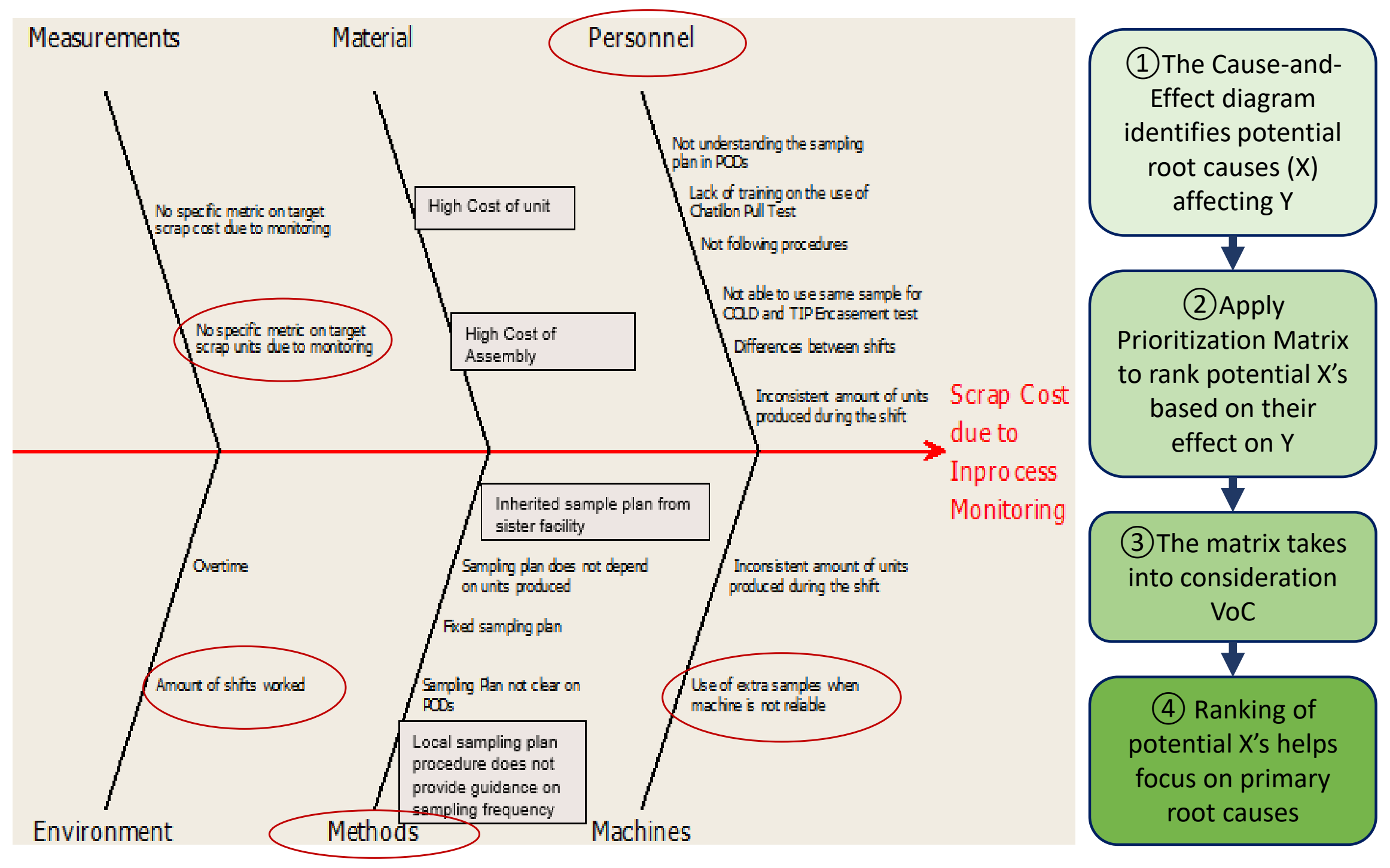
Table 1: Measure Phase- Initial Y Capability

Production Week	Units Produced	Encasement Scrap	Patch Scrap	Encasement Yield (Y1)	Assembly Yield (Y2)	RTY (Y1 * Y2)
Week 1	5970	100	50	98%	99%	97.5%
Week 2	5690	112	50	98%	99%	97.2%
Week 3	5955	192	78	97%	99%	95.6%
Week 4	8736	144	75	98%	99%	97.5%
Week 1	7420	160	60	98%	99%	97.1%
Week 2	8350	192	70	98%	99%	96.9%
Week 3	11535	193	70	98%	99%	97.8%
Week 4	11385	192	65	98%	99%	97.8%
Week 1	11051	187	60	98%	99%	97.8%
Week 2	3965	144	30	96%	99%	95.8%
Week 3	3700	160	40	96%	99%	94.8%
Week 4	7565	144	50	98%	99%	97.5%
Week 5	10095	176	60	98%	99%	97.7%
Week 1	10365	208	65	98%	99%	97.4%
Week 2	14097	208	85	99%	99%	98.0%
Week 3	11660	192	60	98%	99%	97.9%
Week 4	14265	352	110	98%	99%	96.8%
Average	151804	3056	1078	**98%**	**99%**	**97.3%**

High individual station yields (98–99%) "hide" scrap losses; when rolled across stations, RTY drops to 97%

Results and Discussion (cont.)

ANALYZE PHASE



①The Cause-and-Effect diagram identifies potential root causes (X) affecting Y

②Apply Prioritization Matrix to rank potential X's based on their effect on Y

③The matrix takes into consideration VoC

④ Ranking of potential X's helps focus on primary root causes

Figure 5: Identifying and Evaluating Key X's Affecting Y

IMPROVE PHASE

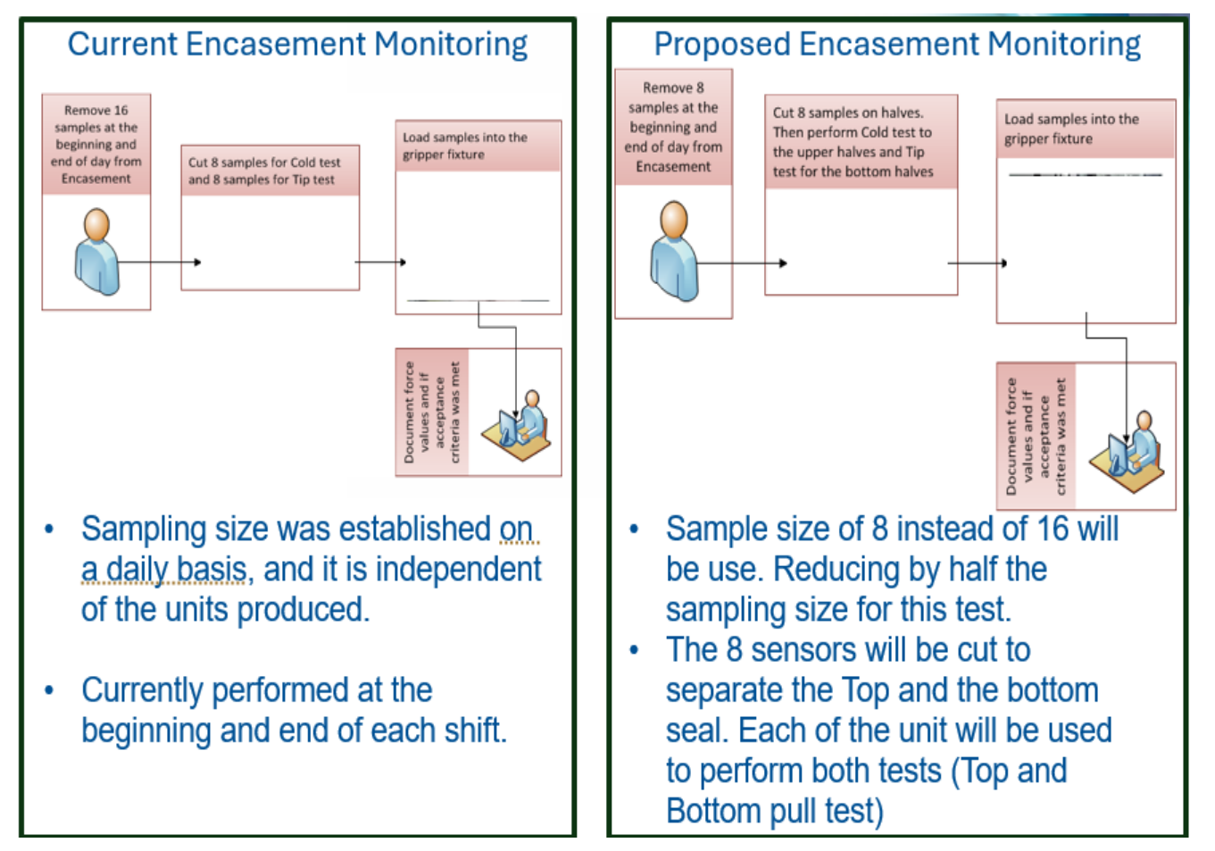
The implementation strategy was divided into short-, medium-, and long-term phases to allow operations to incorporate changes and benefit from the optimizations as early as possible.

Table 2: Short-Term Implementation-Sampling Plan Standardizations and Optimization

Test	Current cost per production day				Future State (Estimated after Implementation)		
	Samples 1 shift	1 shift	Sample2 shifts	Sample3 shifts	Implementation Plan	Sample Qty	Cost per shifts
Encase Pull test	**32**	$226.88	64	96	Clarification of the Sampling plan. Per procedure: 32 samples per day.	**32 daily** (16 at start and 16 at the end of production day)	$161.10
Patch Pull / Leak Test	**15**	$245.55	25	30	New sampling size calculated: 11 per production day. Divided between start and end of production day	**12 samples** through the production day	$360.14
Hot Water Leak Test	**15**	$245.55	25	30	New sampling size calculated: 22 per production day. Divided between start and end of production day	**22 samples** through the production day	$360.14

Table 3: Medium-Term Implementation - New Leak Tester Validation

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



- Sampling size was established on a daily basis, and it is independent of the units produced.
- Currently performed at the beginning and end of each shift.

- Sample size of 8 instead of 16 will be use. Reducing by half the sampling size for this test.
- The 8 sensors will be cut to separate the Top and the bottom seal. Each of the unit will be used to perform both tests (Top and Bottom pull test)

- **Current:** Required to cut separate units for top and bottom testing
- **Proposal:** Change the sample-cutting method to **use both ends of a single unit** for top and bottom pull tests
- Sample and test prep-time reduction

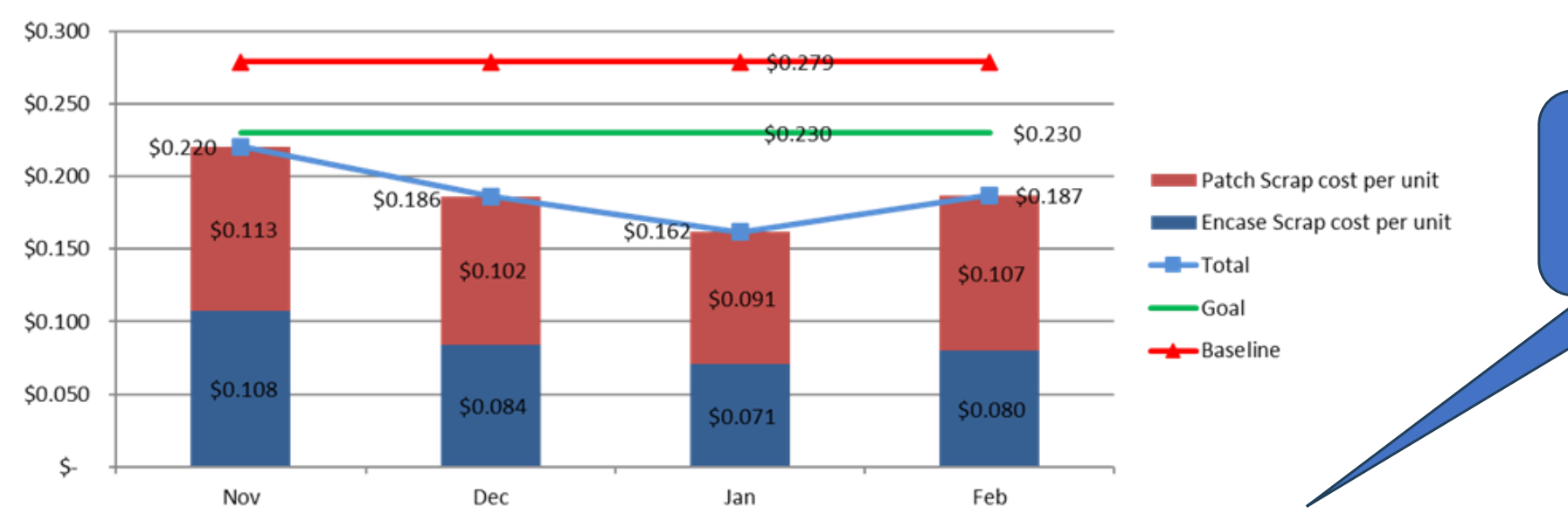
Figure 6: Long-Term Implementation: Sampling Method Modification

Table 4: Improve Phase - Initial vs Final Capacity

Initial Capacity	Units Produced per month	Encase Scrap per month	Patch Scrap per month	Monthly Encase Yield (Y1)	Monthly Assembly Yield (Y2)	Monthly RTY (Y1 * Y2)
Jul	26351	548	253	97.96%	99.05%	97.0%
Aug	38690	737	265	98.13%	99.32%	97.5%
Sep	36376	811	240	97.82%	99.34%	97.2%
Oct	50387	960	320	98.13%	99.37%	97.5%
Average				**98.01%**	**99.27%**	**97.30%**

Final Capacity	Units Produced per month	Encase Scrap per month	Patch Scrap per month	Monthly Encase Yield (Y1)	Monthly Assembly Yield (Y2)	Monthly RTY (Y1 * Y2)
Nov	67497	1024	465	98.51%	99.32%	97.8%
Dec	65909	784	410	98.82%	99.38%	98.2%
Jan	59652	648	360	98.93%	99.40%	98.3%
Feb	66646	752	435	98.88%	99.35%	98.2%
Average				**98.78%**	**99.36%**	**98.16%**

CONTROL PHASE



4 months of data confirmed that the scrap cost goal was achieved

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**						

A control plan was created to ensure the sustainability and consistency of the improvements.

Figure 7: Scrap Cost Per Unit After Optimizations

Conclusions

By applying the DMAIC, this project achieved a significant and sustainable reduction for in-process monitoring scrap at Line X. Key actions included standardizing sampling practices, optimizing sample usage, and evaluating automated testing options while maintaining compliance. Procedural changes were formalized through a control plan and focus meetings, ensuring the sustainability of results. In addition to measurable cost reductions, the project improved operational efficiency, reduced large setups, and increased units per labor hour without increasing product risk.

Acknowledgements

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References

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