Implementation of a Scrap Monitoring Process in a Manual Manufacturing Line of Medical Devices

Alvin A. Velázquez Osorio
Master of Engineering in Manufacturing Engineering
Rafael Nieves, PharmD
Industrial Engineering Department
Polytechnic University of Puerto Rico

Abstract *— In the context of a manufacturing industry of medical devices, every organization has two primary goals that the organization has to accomplish: 1. Meet the expected performance of every produced product and 2. Produce revenue or income to the company. When an organization improves production quality to levels that guarantee high production efficiency and prevent waste is achieving a prime goal financially. The Cost of Quality is a measure of the costs associated with this achievement. This metric include costs incurred for prevention of non-conformance, appraisals for conformance and failures to meet requirements. One of the purposes to monitor scrap in a production line is for economic reasons. However, it gives the opportunity to evaluate the efficiency of other related control systems and provides valuable data for process improvement opportunities impacting the current process and related suppliers. This project will consist of the implementation of a scarp monitoring process on a manual production line, whose inspection methods are mainly visual inspections, made by several operators. To achieve the implementation a Define – Measure – Analyze – Improve and Control (DMAIC) methodology will be used.*

Key Terms *— Cost of Quality, DMAIC, Manual Manufacturing Line, Scrap Monitoring Process, Scrap Reduction, Waste.*

PROBLEM STATEMENT

One of the main improvements that provide competitiveness to any industry is the implementation of initiatives aimed to reduce and prevent scrap costs. Scrap reduction programs not only carries benefits to improve its source but also could serve as a critical listening system to feed the life cycle of the product.

This project will consist of the implementation of a scarp monitoring process on a manual production line, whose inspection methods are mainly visual inspections, made by several operators.

Research Description

The manufacturing line focused on this project consists of multiple workstations, where individual operators perform the entire process of visual inspection and assembly. All rejected material is supposed to be counted by an associate, however due to their workload and the number of rejections document, this count is not accurate. After the implementation of the improvements, every manufacturing period will collect scrap data, analyze the performance and implement corrective actions to reduce or eliminate the incidents.

Research Objectives

The main objectives to be focused could be resumed in three (3) aspects: 1) Obtain a reduction of cost of quality associated with scrap, 2) Provide a detection control of errors made by the inspector during the inspection process and 3) Monitor the process performance of the manufacturing line that leads the reduction of Cost of Quality (COQ).

Research Contribution

In general, four categories are directly impacted by aspects of quality: prevention controls, appraisal, internal failures and external failures [1]. The sum of the costs incurred in these categories constitutes the total cost of quality. A process aimed to monitor the scrap in manufacturing line have a positive impact on these four aspects.

This project will function as a listening system to multiple stakeholders in the operation area, as for Process, Quality, and Manufacturing Engineers.

Data collected during the gathering phase will be used to determine actual process behavior and as a starting point for initiatives for scrap reduction.

LITERATURE REVIEW

Throughout the industry history, "Quality" has been defined in several instances. Several individuals made significant contributions to quality control and improvement. In summary, a product conforms to Quality in three main dimensions: Customer – when its purpose serve customer needs, Design Specification – when the product meets its design, and the State of Control – when the output of the process established to create a product is consistently meeting "Quality."

In the context of a manufacturing industry of medical devices, every organization has two primary goals that the organization has to accomplish at the end of the day, these are 1) Meet the expected performance of every produced product and 2) Produce revenue or income to the company. To the organization be capable of achieving these two goals, they have to pay attention to their processes (activities) and control methods (checkpoints). The more efficient the processes are conducted, the fewer detection controls should be needed to assure quality. Accounting for quality costs and reporting are part of many quality standards.

When an organization improves production quality to levels that guarantee high production efficiency and prevent waste is achieving a prime goal financially. One of the performance metrics of any organization that links the costs associated with the type of wastes is Cost of Quality (COQ), presented by J.M. Juran in 1951. The Cost of Quality can be segregated into three segments: 1) The cost incurred by investing in the prevention of non-conformances 2) Costs of appraising a product or service for conformance to requirements 3) Costs of failure to meet requirements [2]. The goal of any quality cost system is to reduce quality cost as low as possible.

From the fourteen points of W. Edwards Deming three (3) concepts pin out toward achieving quality through continuous improvement. These are 1) solutions comes when the focus is on improving the process, rather than accusing the people, 2) improvements should have a multidisciplinary approach, and 3) empirical data should be used to make decisions [3].

One of the techniques used to monitor the manufacturing process is the integration of feedback control systems to the process. In the context of production lines, the use of SPC and feedback control system are commonly focused on task related to the manufacturing process, where is the variation to minimize. However, such systems are also applicable for monitoring scrap tendencies.

One of the purposes to monitor scrap in a production line is for economic reasons. To make intelligent business decisions organizations needs to develop cost estimates, and continuously compare actual operating costs with a business plan. In an activity-based costing (ABC) method, the activity involved in the production of a product or service is that creates cost. The cost of a product or service includes the cost of raw materials and the costs of all activities used to produce the product [4]. Hence, from the perspective of the scrap produced in the manufacturing process, it is advantageous always to monitor its behavior and compare it with its allocated standard to this activity.

Other benefits to monitoring and analyze scrap tendencies are that it gives the opportunity to evaluate the efficiency of other related control systems and provides valuable data for process improvement opportunities impacting the current process and related suppliers.

METHODOLOGY

To achieve the implementation of a scrap monitoring process in a manual production line a Define – Measure – Analyze – Improve and Control (DMAIC) methodology will be used. DMAIC structure is used in Six Sigma projects and multiples kind of organizations, as a way to implement sustainable solutions for process improvements problems. The benefits that bring this methodology

is its gives a systematic approach to problem-solving situations. As every step of the process is dependable to each other, problem definition, data gathering and analysis are essentials throughout the project deployment.

- Define: This stage will be dived in three major components including project definition (scope and goal), top-level of current process definition and team formation. Analysis of existing data will be performed as needed during this phase to help on the definition of the project scope.
- Measure: This stage will include the definition of the actual process, which will include details of decision points and functions. Reliable metrics will be selected to evaluate the process and communicate the status to the stakeholders. Also, based on the data available a process baseline will be established to ascertain how the current process is behaving.
- Analyze: During this stage, data will be analyzed to determine the sources of process variation and identify the process drivers of the current scrap. Data will be analyzed to establish the relationship between codes, defects, and production quantity.
- Improve: During this stage a solution for the scrap monitoring system will be developed, and the identified improvements will be defined. The proposed solution will be verified to ensure that can be achievable prior final deployment and minimize the impact or occurrence of failures.
- Control: Once the solution is implemented, the new process will be monitored to verify the improvements are maintained. The new solution will be periodically evaluated to sustain the improvements.

RESULTS AND DISCUSSION

This section contains the analysis of the problem statement and the results of this research work toward the project objectives, using the DMAIC strategy.

Define Phase

The extend of this project is limited to the manual manufacturing line, assigned to assemble a single product line of five different codes. The main objectives are 1) The implementation of a system to monitor rejections occurred during the manufacture of the final product. 2) Reduce by 20% the reported scrap after project completion.

The project team will consist of the supervisor manufacturing, quality engineer, process engineer and staff from training and assembly area.

The process of final product assembly is performed in two parallel lines of 10 stations each, where two major steps are performed: one print station and ten simultaneous assembly stations. Each station performs two main quality checks (before and after the assembly process). Before to the assembly process, the associated visually inspect the piece for three major non-conformities. After the assembly process, the part is inspected again for a fourth major non-conformity. The associate segregates all non-conforming part into a container; otherwise, if no defects have found, the assembled part is packed.

Upon completion of the manufacturing period, the total quantity of all defective units are documented. However, the current process does not allow for an efficient way to document the characteristic of which was rejected.

Measure Phase

The following diagram (Figure 1) shows the decision points and the interaction of the functional groups involved in the process of manual assembly. Through this diagram it can be seen that the task of counting and documenting rejections made by the 20 stations falls on only one person (the Quality Technician). In addition, the documentation is performed at the end of the shift of manufacturing.

To establish a baseline of the average amount of the scrap percent (%) was collected. Figure 2 shows that over the period of six months of Year 1 the most frequently used category of classifying rejection was “Other”. However, this data did not match the reality observed in the manufacturing process. Based on the

analysis of the current documentation process for scrap, the cause for this discrepancy is assignable to the method used for documentation.

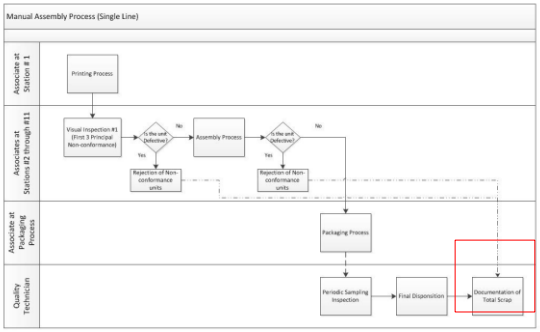

Figure 1
Manual Assembly Process Map

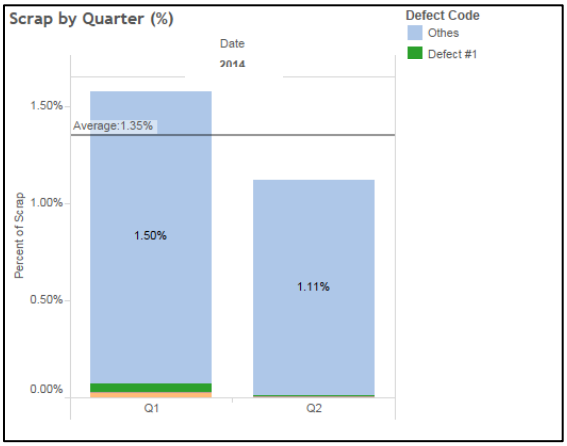

Figure 2
Scrap Percentage (%) by Quarter Year 1 (Q1 & Q2)

To help improve the categorization of all rejections, a manual counter of five categories was established at each assembly station. Four of these groups were assigned to represent major non-conformities or known high incidence; the fifth group was identified as "Other," to include any other minor defects. In contrast to the previous process, the categorization of the defects is now performed by the inspector and documented in the manual token from his station. Upon completion of the shift of production, Quality Technician totals the defects found, using the data available in the manual counter each station. The impact on the process of this change is shown in Figure 3.

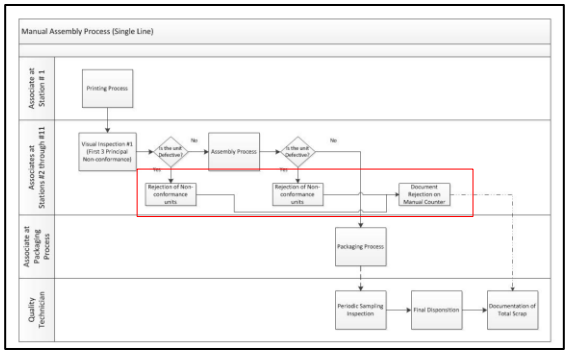

Figure 3
Manual Assembly Process Map - Revised

After this improvement, data collection was held for six months obtaining a better representation of the actual rejections. Figure 4 shows the resulting data from 3rd Quarter and 4th Quarter of Year 1.

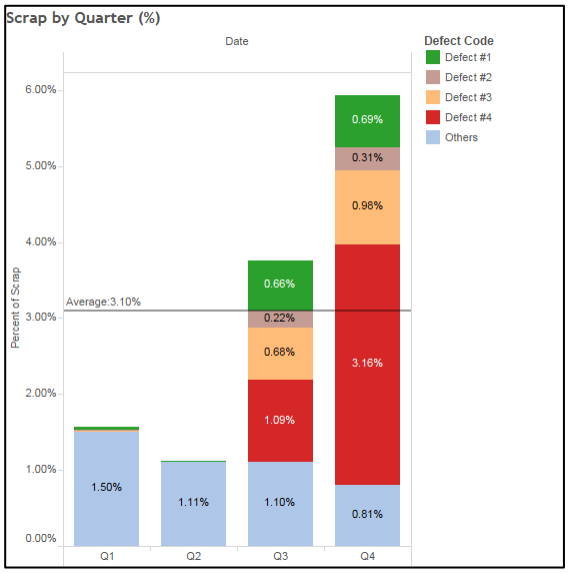

Figure 4
Scrap Percentage (%) by Quarter during Year 1

Analysis Phase

After obtaining a better resolution of the data of rejections, it proceeded to analyze the 3rd quarter and 4th quarter, grouped by code. The primary objective of the analysis was to determine a warning limit of the number of rejections occurred by batch manufactured. As a first step, the data was observed using a boxplot by code (See Figure 5).

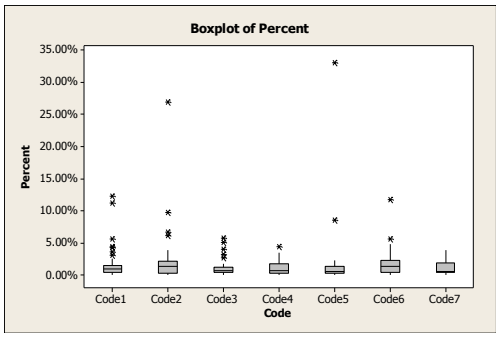

Figure 4
Boxplot of Scrap Percentage by Code

Once the outliers were removed from the data, it was proceeded to visualize the distribution of rejections grouped by code. The remaining data was considered to be representative of the expected process variation. The maximum scrap percent observed in the remaining data was established as the warning limit (See Figure 5).

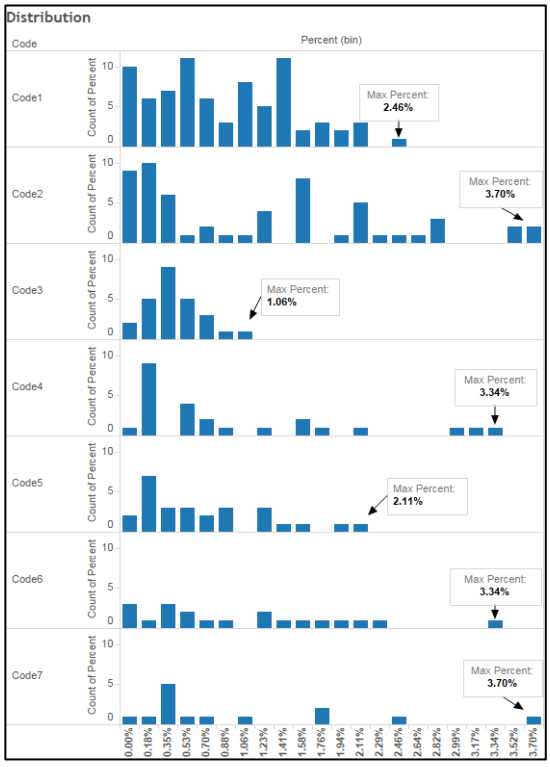

Figure 5
Distribution of Rejections Grouped by Code

However, for the purpose of simplifying future calculations was decided to round these results; these were summarized in Table 1.

Table 1
Resulting Warning Limits for Scrap Percentage (%)

Product	Warning Limit
Code 1	2.5%
Code 2	3.5%
Code 3	1.0%
Code 4	3.0%
Code 5	2.0%
Code 6	3.0%
Code 7	3.5%

Improvement Phase

Once the warning limits were defined for each of the codes, the previously established procedure was revised. This time, it was incorporated into the process of the Quality Technician, a verification of the number of rejections occurred after each production period. The total number of rejections is compared against the warning limit. If the warning limit is exceeded, the Quality Technician conduct an augmented sampling to the batch. Also, the scrap data of each production period is evaluated by the manufacturing supervisor or delegate, before the start of the next production period. This periodic verification aims to achieve a reduction in the number of rejections by implementing corrective actions as needed. Figure 6 present the revised process flow map.

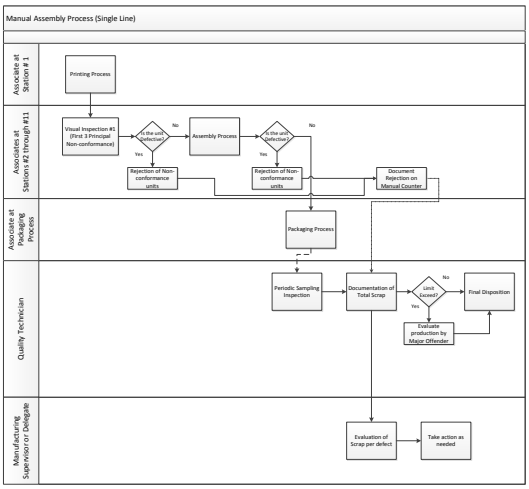

Figure 6
Revised Process Flow Map - Improvement Phase

To mitigate documentation errors and expedite the evaluation process, new forms were created

specific to each code each form was designed with the following characteristics:

1. Fields ordered, in the same way, the Quality Technician gather the information – in this way jumping across sections is avoided when the form is filled. All the known information was prefilled to reduce entries made by the associate.
2. Work instructions were incorporated in sections serving as decision points aimed to avoid omission of critical tasks.

Control Phase

After the implementation, the performance of the new process was monitored in two dimensions: systematically and the amount reduced of scrap. Figure 7 shows the percent of rejections occurred during Q1 to Q4 of Year 2. From the analysis, it can be seen that there is a steady reduction of scrap in the quarter Q1, Q2, and Q4.

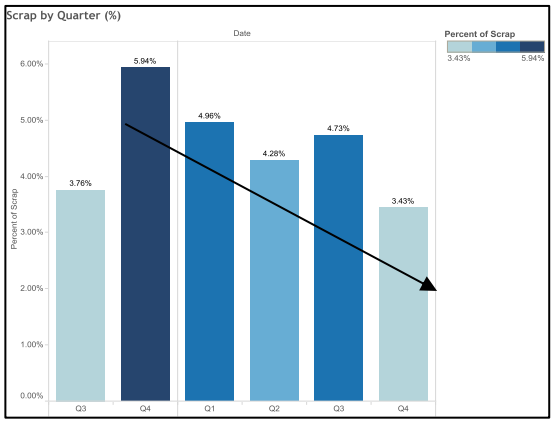

Figure 7
Percent of Rejections from Q1 Year 1 to Q4 Year 2

To calculate the reductions occurred during the implementation of the new process, the following measurements were made:

- Actual Change – measure the increment or reduction of scrap from the previous quarter to current quarter.
- % Change – measure the change in percent of scrap from the last quarter to current quarter.
- Actual $\text{Change}_{\text{Overall}}$ – measure the net increment or reduction of scrap from Q4 Year 1 to Q4 Year 2.
- % $\text{Change}_{\text{Overall}}$ – measure the net increment or reduction of scrap from Q4 Year 1 to Q4 Year 2.

As shown in Table 2, the overall reduction of scrap was reduced from 5.94% to 3.42%. This outcome represents a reduction of 42.3%, surpassing the project goal (scrap reduction = 20%).

Table 2
Summary of Scrap Percent (%) Changes through Quarters

Year	Period	Actual Change	% Change
Y1	End Q4	+2.15%	+57.9%
Y2	End Q1	-0.98%	-16.5%
Y2	End Q2	-0.68%	-13.7%
Y2	End Q3	+0.45%	+10.5%
Y2	End Q4	-1.30%	-27.5%
-	Overall	-2.51%	-42.3%

From the procedural aspect, the implementation of the monitoring system was a success because it allowed greater visibility of defects occurring during the manufacturing of the product. Throughout the period of implementation, the inspectors were regularly oriented of what was considered or not considered defects. This approach helped to reduce false rejections during visual inspections. On the other hand, the new process contributed to identifying problems associated with machines.

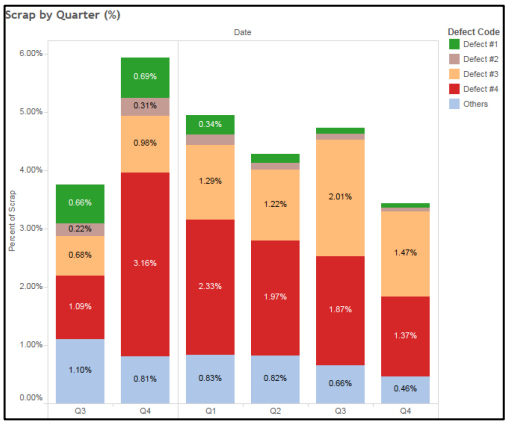

Figure 8
Scrap Percentage (%) by Defect per Quarter

As an example of this, during the beginning of the 3rd quarter, was observed high volume of rejection at the print station (Defect #3). The availability of data and the process implemented helped to act promptly and monitor the effectiveness

of corrective and preventive actions, achieving a significant reduction by the end of the fourth quarter (see Figure 8).

CONCLUSION

The implementation of a process focused on monitoring the impact of rejections was proven that adds value to the company immediately. It is during the visualization and analysis of the data collected where improvement projects arise. During the initial part of data acquisition, it was observed that even if there was a process to collect data, it was not effective. The analysis of historical data shows that it was not representative of the known occurrences. While the collection of data manually could pose significant challenges, the proposed solution was focused on simplifying tasks and reducing input in forms of documentation. After the implementation of the process, all the objectives proposed in the definition of the project were achieved. Some of the essential elements that were the key to success of the project were:

- The inclusion of key associates from the line as part of the team members – this approach helped to understand better the current process and as a consequence be able to define better solutions.
- Have planned the data gathering process – through this part the team defined in advance different ways to see the data to be gathered. With this information, it was created a specific way to storage the data in the system to make compatible with a data visualization software. The use of this software helped to speed up the iteration with the data.

Having established that the achievements of the project, the proposed model has been used as a basis for monitoring the implementation of scrap both in other areas of the company, as also externally.

REFERENCES

[1] D. L. Bottorff, "COQ Systems: The Right Stuff They," in *Quality Progress*, pp. 33-35.

[2] F. M. Gryna, "Quality and Costs," in *Juran Quality's Handbook*, 1999, sec. 8.

[3] H. R. Neave, "Deming '88*. Part 2 and 3: The 14 Points revisited," in *Total Quality Management, 1990,* pp. 169-308.

[4] K. B. Zandin, "Cost Accounting Activity-Based Costing," in *Maynard's Industrial Engineering Handbook,* 5th ed. New York: McGraw-Hill Professional, 2001, sec. 25.