

Define

Measure

Analyze

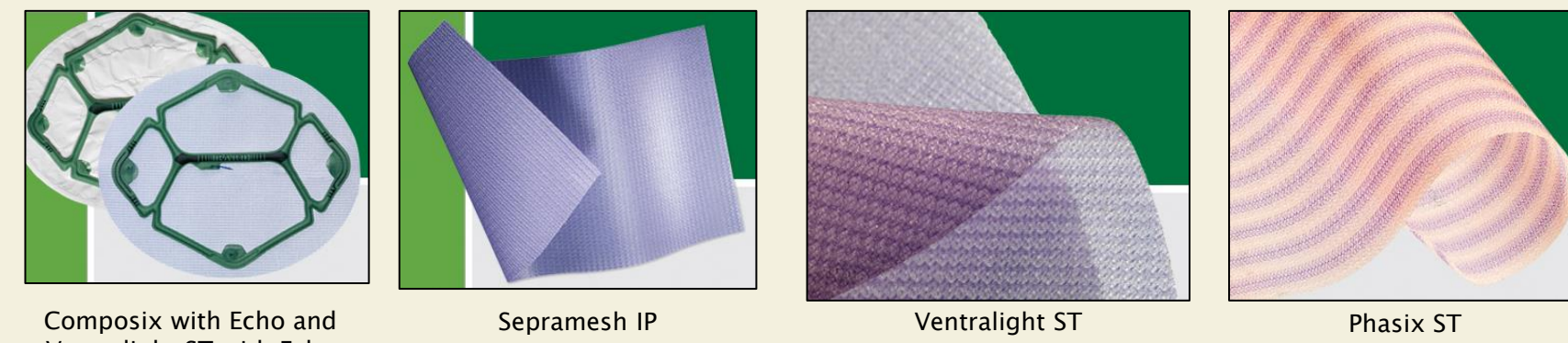
Improve

Control

Background

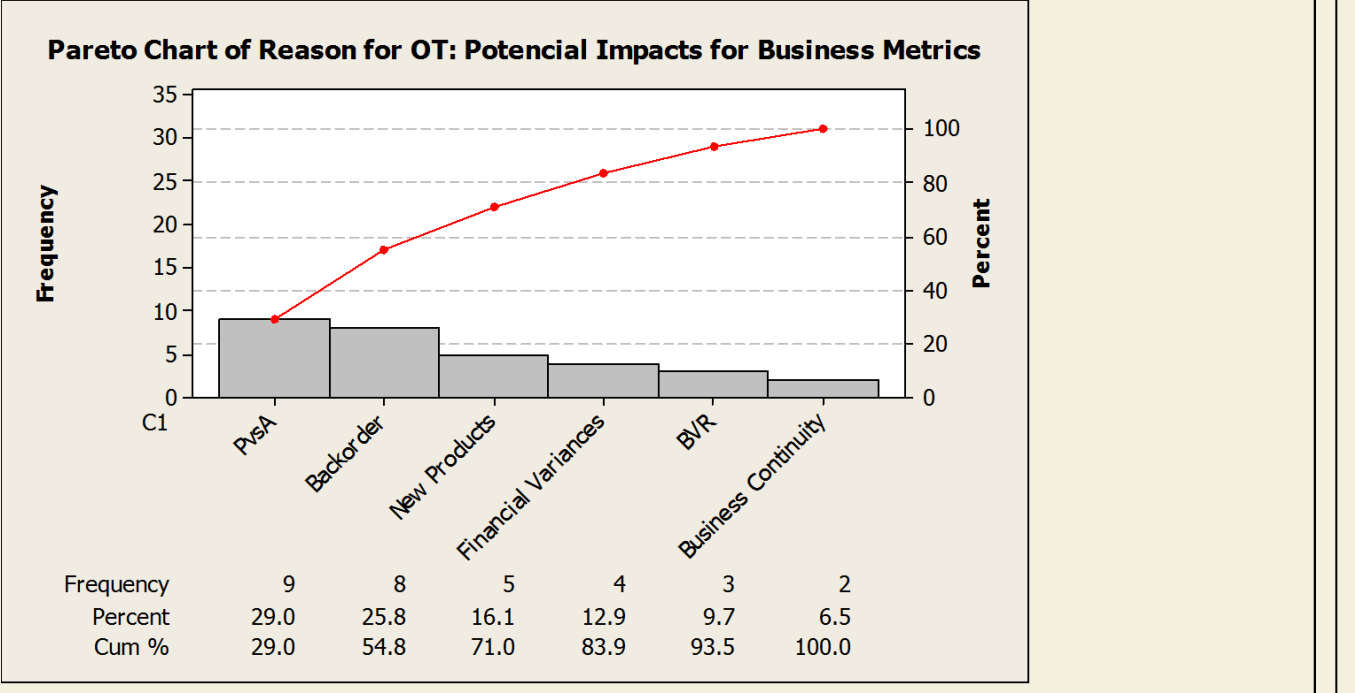
C. R. Bard, Inc. is a leading multinational developer, manufacturer, and marketer of innovative, life-enhancing medical technologies in the product fields of: Vascular, Urology, Oncology and Surgical.

Sepramesh is a types of mesh with a hydrogel safety coating, which resorbs, providing visceral protection during the critical healing period.

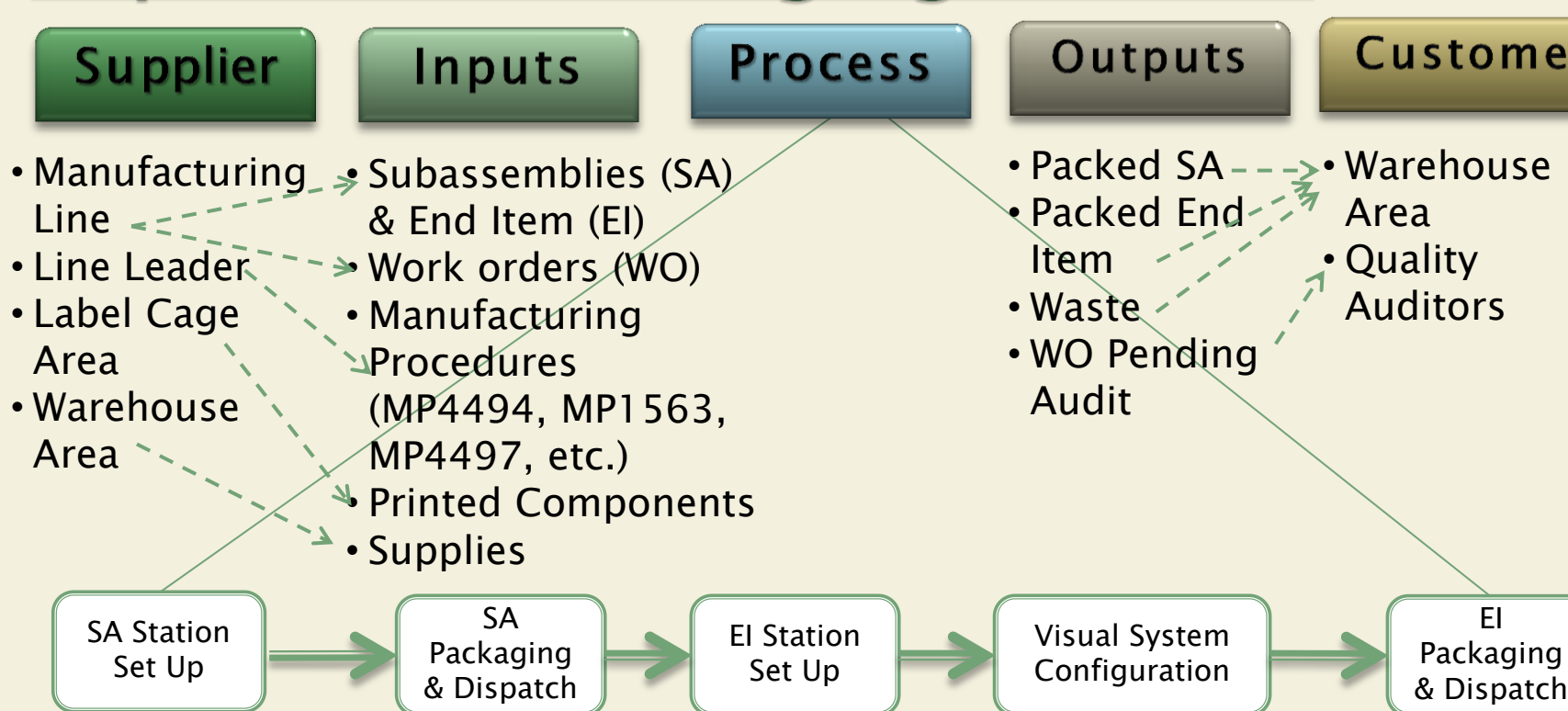


Project Charter

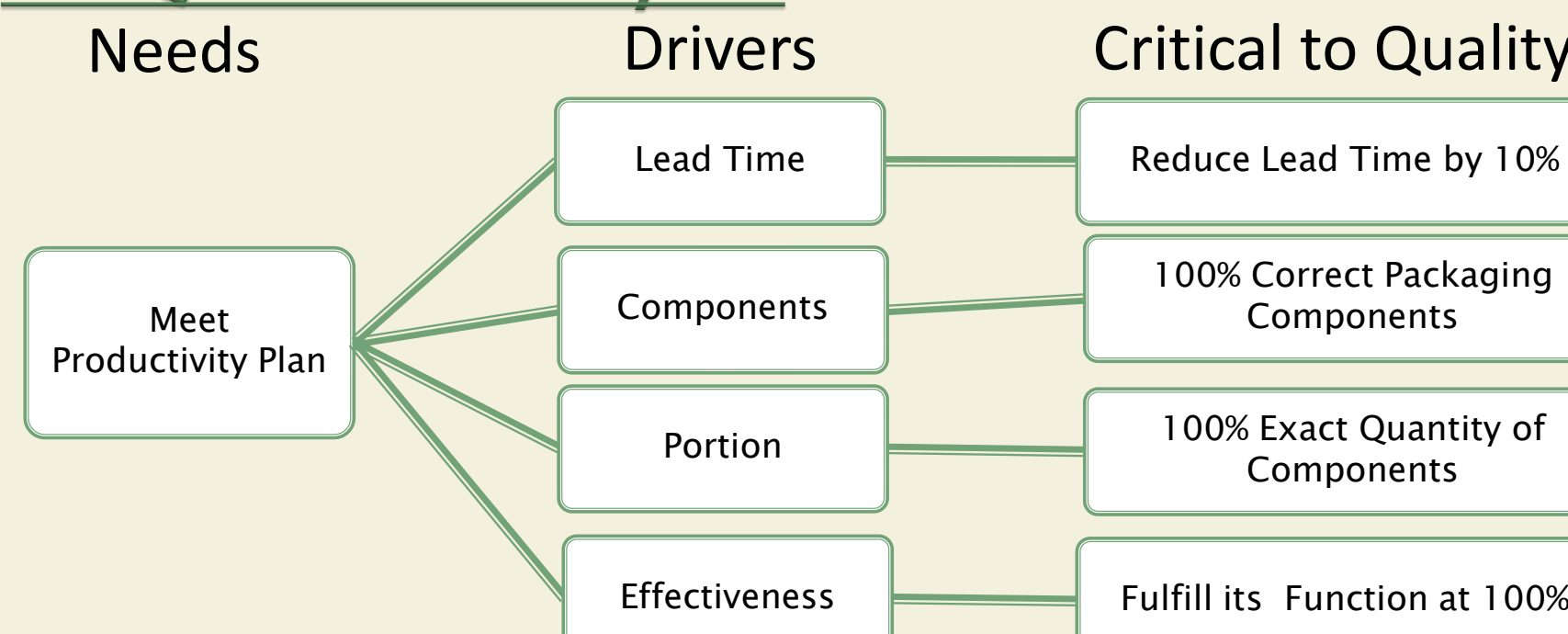
| | | |
|---|--|-----------------------|
| Project Name: Boxing Area: Improvements of the Sepramesh Production | Project Leader: Stephanie Rodriguez / Angelyn Grullon | Date: 11/14/16 |
| Problem Statement: | | |
| Boxing Area pack all the manufacturing products of Bard Puerto Rico, which are handler in different stations. The Sepramesh stations do not meet the productivity plan; the difference between the production plan with the actual production is between 20% and 80% with a variation of 18%. Currently this problem leads to incur in overtime, which represents a 17% of the plant. | | |
| Project Scope: | | |
| Improve workstations designs; add flexibility and capability to pack any product. In addition, increase the productivity of the area. As a result, it is expected an increase in productivity, and improvement in communication and material flow. | | |
| Out of Scope: | | |
| Processes related to Label Cage, Warehouse and Manufacturing Areas. | | |
| Business Case: | | |
| Boxing Area is responsible for all the products final packaging at BPR. Currently, the Sepramesh Products production its handler in four work stations. This area works two (2) shifts from Monday to Saturday and one (1) shift on Sunday. By evaluating the area, it was found that there is not a continuous flow of products being received from the manufacturing area. Products completed at the manufacturing area needs to wait inside the Clean Room area since there is no space available at boxing for material pending final packaging process. This causes another problem since the space currently being used to store the products is one of the main hallways for raw material request and replenish, thus impacting material flow. The higher reason of incurring in overtime is to accomplish the production planned, that's why it was decided to improve the production in the station, instead in incurring in overtime. As it is established in the Pareto Chart: | | |



Sepramesh Packaging Process



CTQ Tree Analysis



Data Collection Plan

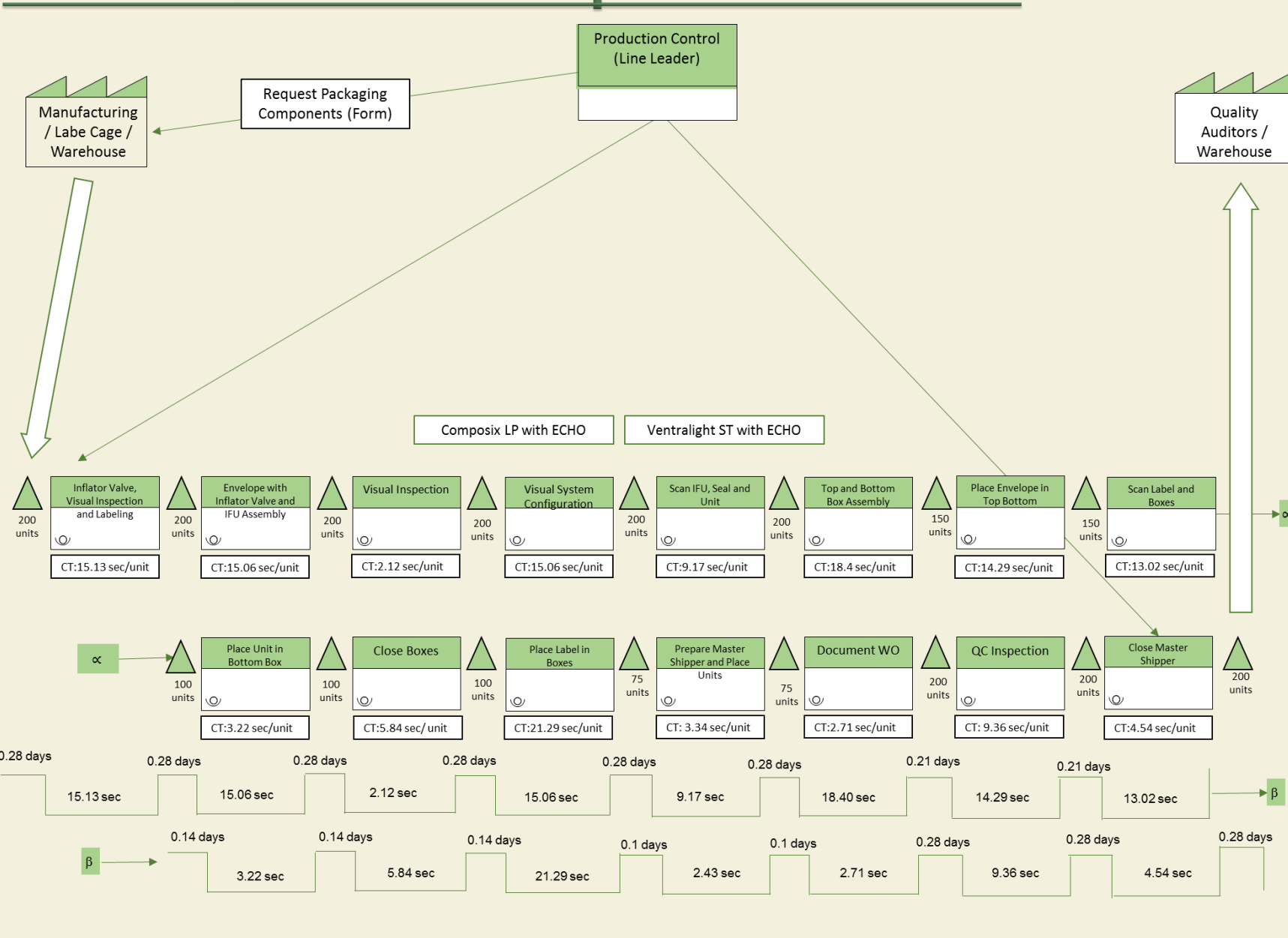
- What questions do we want to answer?
- What part of the process creates waste?
 - How many lots are received?
 - Lead time of packaging process.
 - What is the amount of lots packaged?
 - Which operation is causing delays?
 - The experience of the operator accelerates the process?
 - The quantity of labels varies per product?
 - Is the time of value added process lower than the time of non-value added?
 - How many steps in the process are value added to the process?
 - How many steps in the process are non-value added to the process?
 - Which flow is used in the stations?
 - What is the frequency of the metric PVA that causes overtime?
 - How the metric PVA behave through time?
 - What is the quantity of lots in work in process?
 - How many units are in inventory?

| Data | Operational Definition and Procedure |
|---------------------------------------|--|
| Lead Time to Complete Lots | -Continuous -Time Study |
| -Scrap | -Discrete -Counting the units scrapped |
| -Overtime | -Discrete -Recollecting History Data of Lots Received |
| Hours | -Discrete -Counting the Finished Goods Completed |
| -Incoming Rate | -Discrete -Counting units before and after processes |
| -Finished Goods Completed Rate | -Discrete |
| -Inventory | -Discrete |

IPO (Prioritization Matrix)

| Output Variable | Amount of SA packed | Amount of end items packed | Percent of components wasted | Amount of WIP Pending (unit per day) | Total |
|--|---------------------|----------------------------|------------------------------|--------------------------------------|-------|
| Weight | 5 | 9 | 1 | 9 | |
| Lead time of station set up | 9 | 9 | 1 | 5 | 172 |
| Amount of products scrapped | 5 | 1 | 9 | 1 | 52 |
| Lead time of station set up | 5 | 9 | 5 | 9 | 192 |
| Lead time of visual system configuration | 9 | 9 | 5 | 5 | 176 |
| Amount of products scrapped | 5 | 9 | 9 | 5 | 160 |
| Lead time of packaging & dispatch process | 5 | 9 | 1 | 9 | 188 |
| Product inspection process | 1 | 1 | 1 | 5 | 60 |
| Lead time of packaging & dispatch process | 5 | 9 | 5 | 9 | 192 |
| Amount of subassemblies received from manufacturing line | 9 | 5 | 1 | 1 | 100 |
| Amount of work orders received | 1 | 1 | 1 | 5 | 29 |
| Amount of documentation per process | 1 | 1 | 1 | 1 | 24 |
| Amount of printed components per end item | 1 | 9 | 1 | 1 | 96 |
| Amount of end item received | 1 | 1 | 1 | 5 | 66 |
| Amount of supplies needed to finish a WO | 1 | 1 | 9 | 5 | 68 |

Value Stream Map: End Items



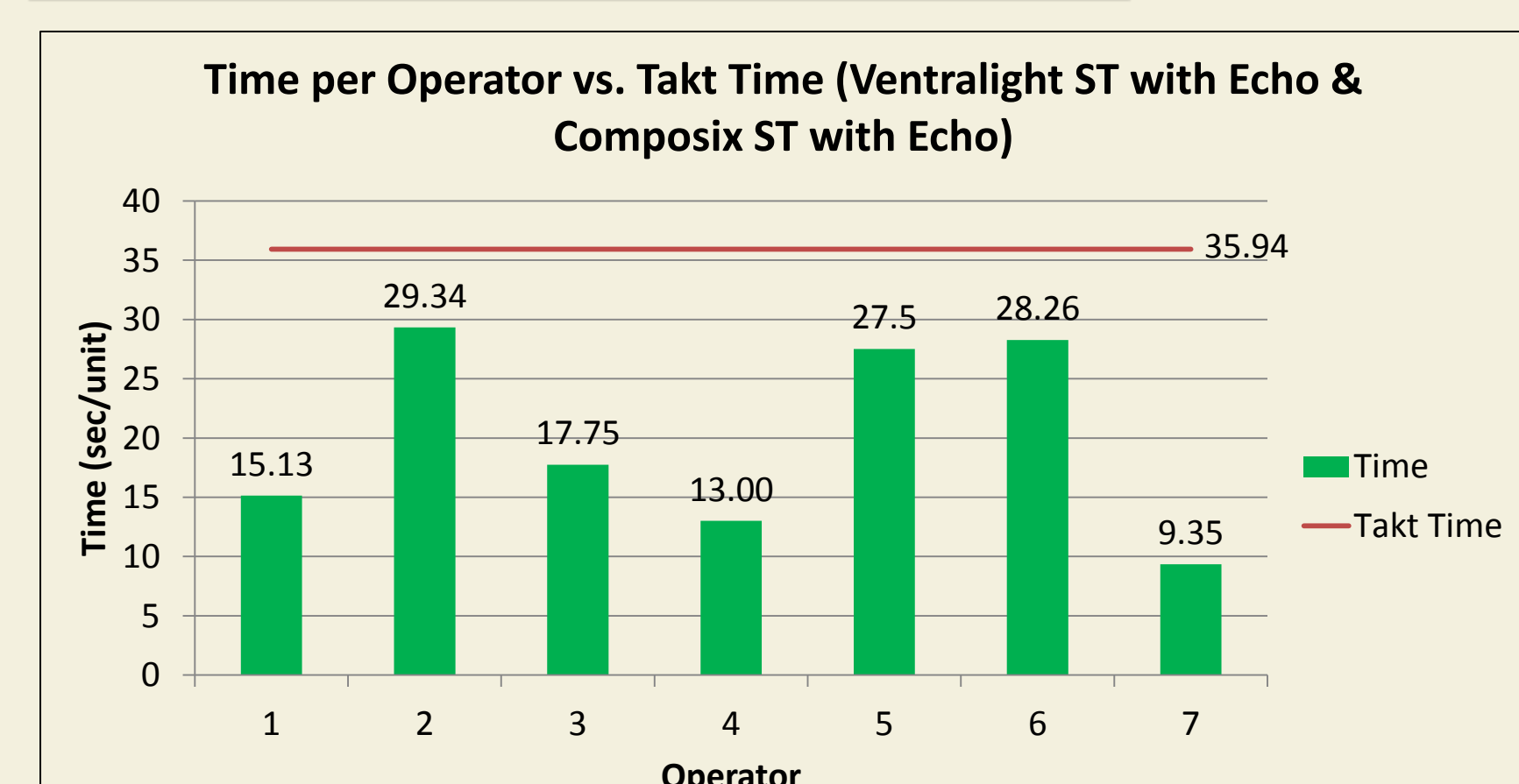
Value Analysis Matrix: End Items

| Process Steps | Process Element | Time (seconds) | VA | NVA |
|---|--|----------------|-------|-----|
| Prepare Master Shipper | Open Master Shipper | 0.13 | | |
| | Close Master Shipper (Bottom Part) | 0.19 | | |
| | Place Master Shipper in Pallet | 0.19 | | |
| Inflator Valve Visual Inspection & Labeling | Inflator Valve Visual Inspection | 7.25 | | |
| | Take Labels from Pallet | 1.96 | | |
| | Place Label in Inflator Valve | 8.82 | | |
| Envelope with Inflator Valve and IFU Assembly | Open Envelope & Put IFU | 8.24 | | |
| | Put Inflator Valve & Close Envelope | 8.24 | | |
| | Visual Inspection | 2.72 | | |
| Visual System Configuration | Visual Inspection | 5.06 | | |
| | Scan Seal | 4.47 | | |
| | Scan IFU | 3.09 | | |
| Scan Seal, IFU & Label | Scan PK Barcode | 1.63 | | |
| | Scan Labels IFU & PK | 1.96 | | |
| | Take Labels from Pallet | 1.33 | | |
| Scan Label and Boxes | Scan Label | 3.03 | | |
| | Scan Top Box | 4.52 | | |
| | Scan Bottom Box | 4.24 | | |
| Top & Bottom Box Assembly | Separate Top & Bottom Boxes | 1.00 | | |
| | Put Pkg Boxes | 0.78 | | |
| | Top Box Assembly | 8.14 | | |
| Paste Envelope in Top Box | Bottom Assembly | 8.47 | | |
| | Peel Adhesive Back Paper from the Envelope | 6.50 | | |
| | Paste Envelope Inside Bottom Box | 7.79 | | |
| Place Unit in Bottom Box | Place Unit in Bottom Box | 3.22 | | |
| | Close Boxes | 8.84 | | |
| | Place Blank Label | 8.13 | | |
| Place Labels in Boxes | Place Printed Label | 13.17 | | |
| | Lot Stamp | 2.71 | | |
| | Place Unit in Master Shipper | 2.43 | | |
| Place Units in Master Shipper | Document WIP | 1.80 | | |
| | QC Inspect Samples | 2.15 | | |
| | Document Verification | 0.12 | | |
| QC Inspection | Sampling | 1.44 | | |
| | Final Document Verification | 1.50 | | |
| | JCL Label Generation (for Master Shipper) | 2.46 | | |
| Close Master Shipper | Put Brown Paper | 2.46 | | |
| | Close Master Shipper | 2.46 | | |
| | Total | 66.44 | 87.55 | |

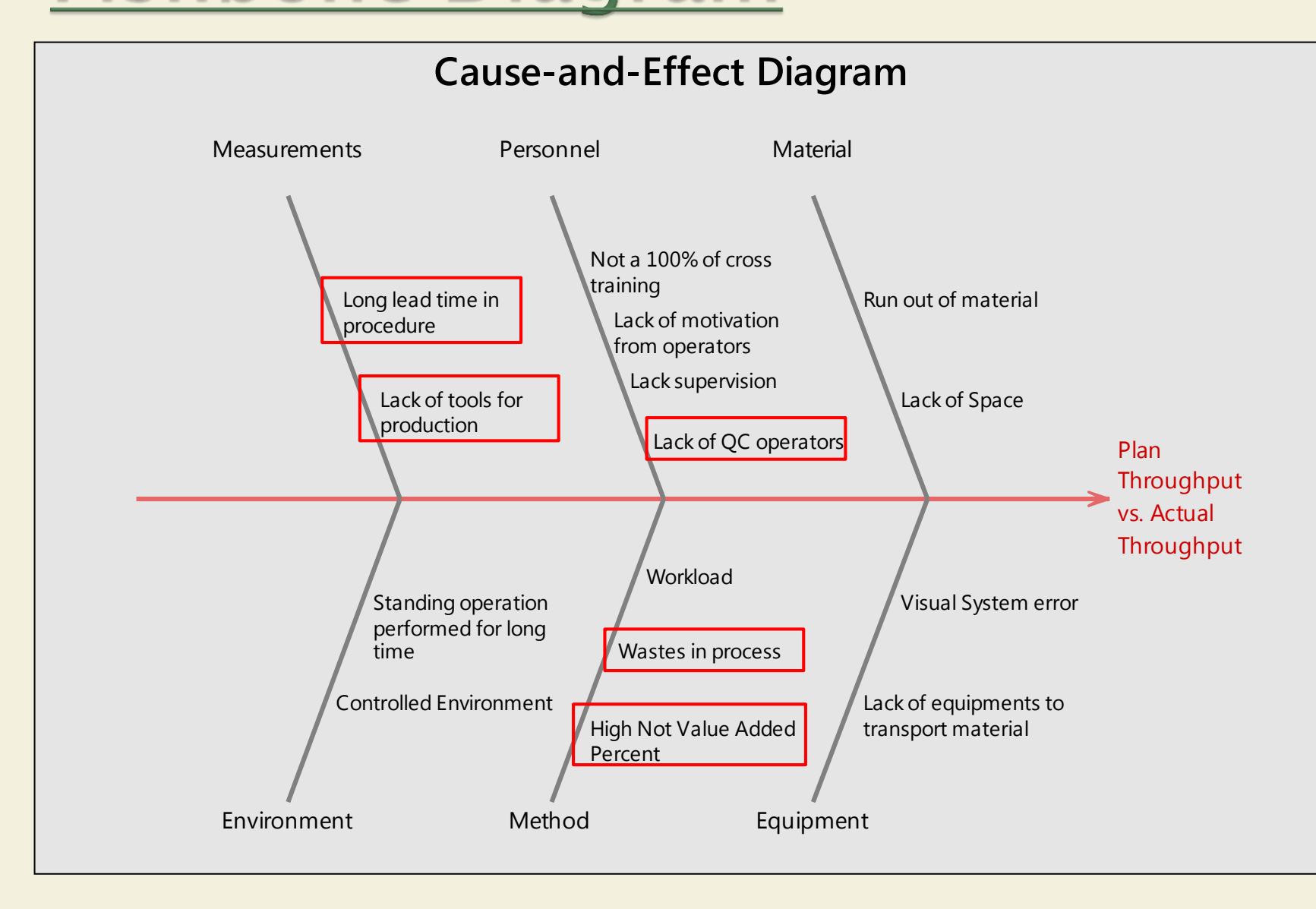
Process Wastes

| Waste(s) | Description | Metric |
|----------------|--|---|
| Inventory | Before scan and close the product we have inventory stock | 10 to 30 units |
| Motion | When the operator stop putting the labels in the packaging of the product to throw waste | 13.95 to 20 sec |
| Transportation | The operator moves to stretch the foam sheet in order to rip the pieces | 5.03 sec |
| Waiting | When the operator has to stop scanning, close and put the label to accommodate the already packaged products that are watered on the worktable | 16.90 sec |
| Overproduction | The operator has to be transported from one place to another to accommodate the boxes | 7.94 sec |
| Overprocessing | The operator has to be transported from one place to another to find the bags to put in the packing box | 8.46 sec |
| People Skills | The operator has to be transported from one place to another to find the tape for close de packing box | 6.38 sec |
| | After performing a count of the product has to transport the product to the packing box | 9.11 to 12.07 sec |
| | The operator had to scan the product several times | 2 to 3 times |
| | The operator has to wait for QC to complete the documents | 30 min |
| | N/A | N/A |
| | N/A | N/A |
| | Comparing one operator to another found that one operator took longer than another because he is in training and the other has more experience | Trainee: 19.14 sec Experienced: 6.74 sec |

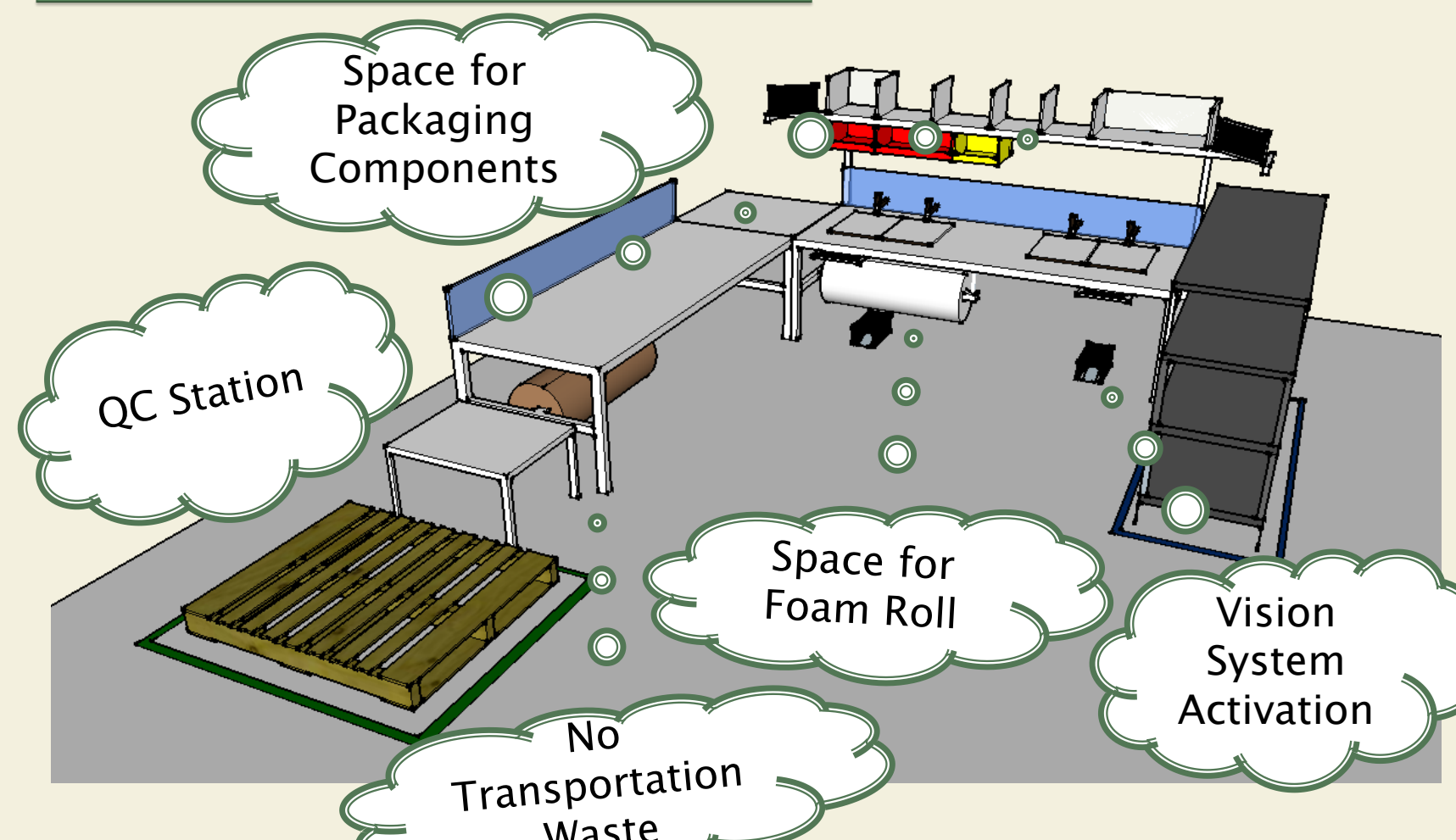
Current Balance: End Items



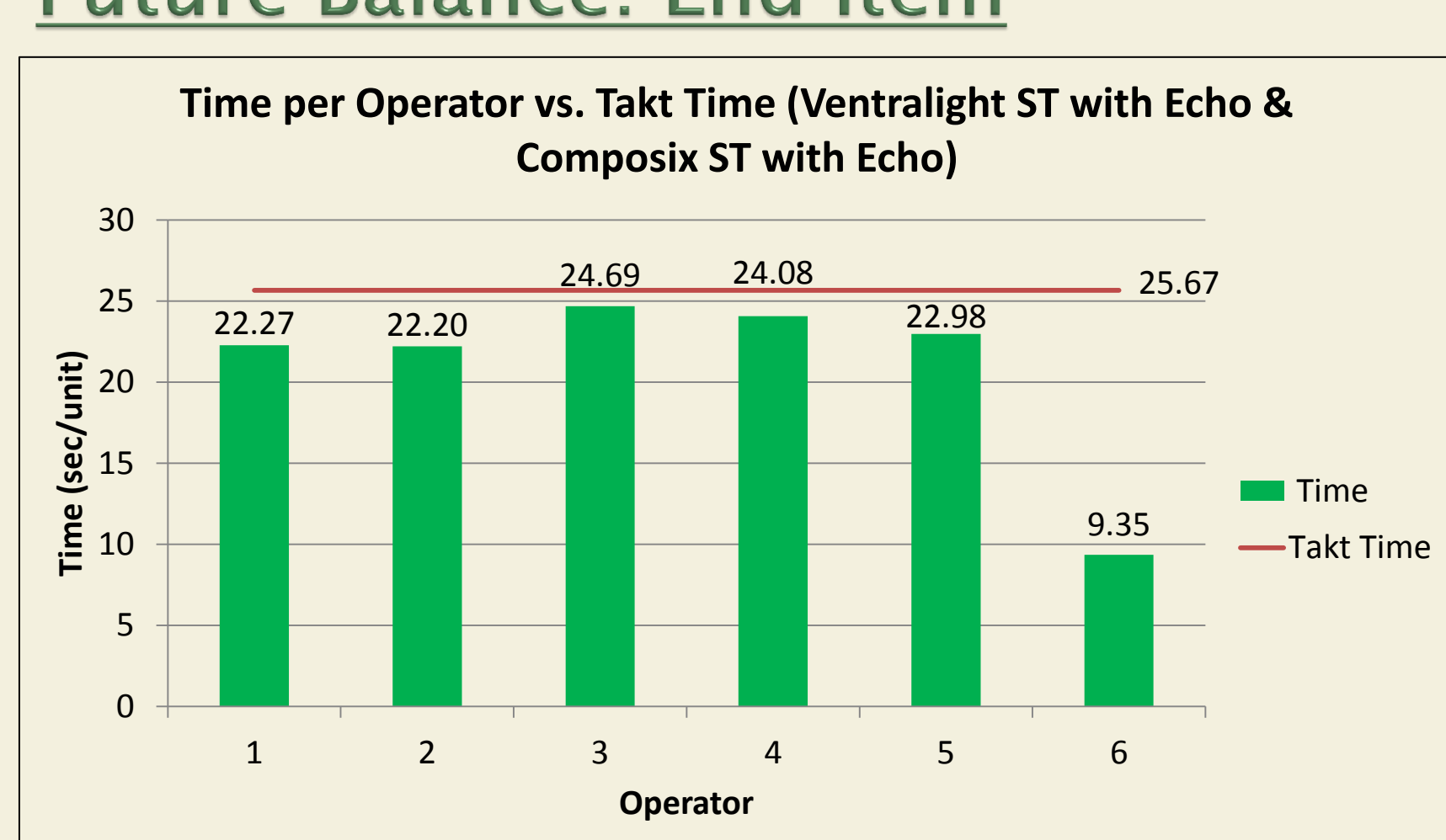
Fishbone Diagram



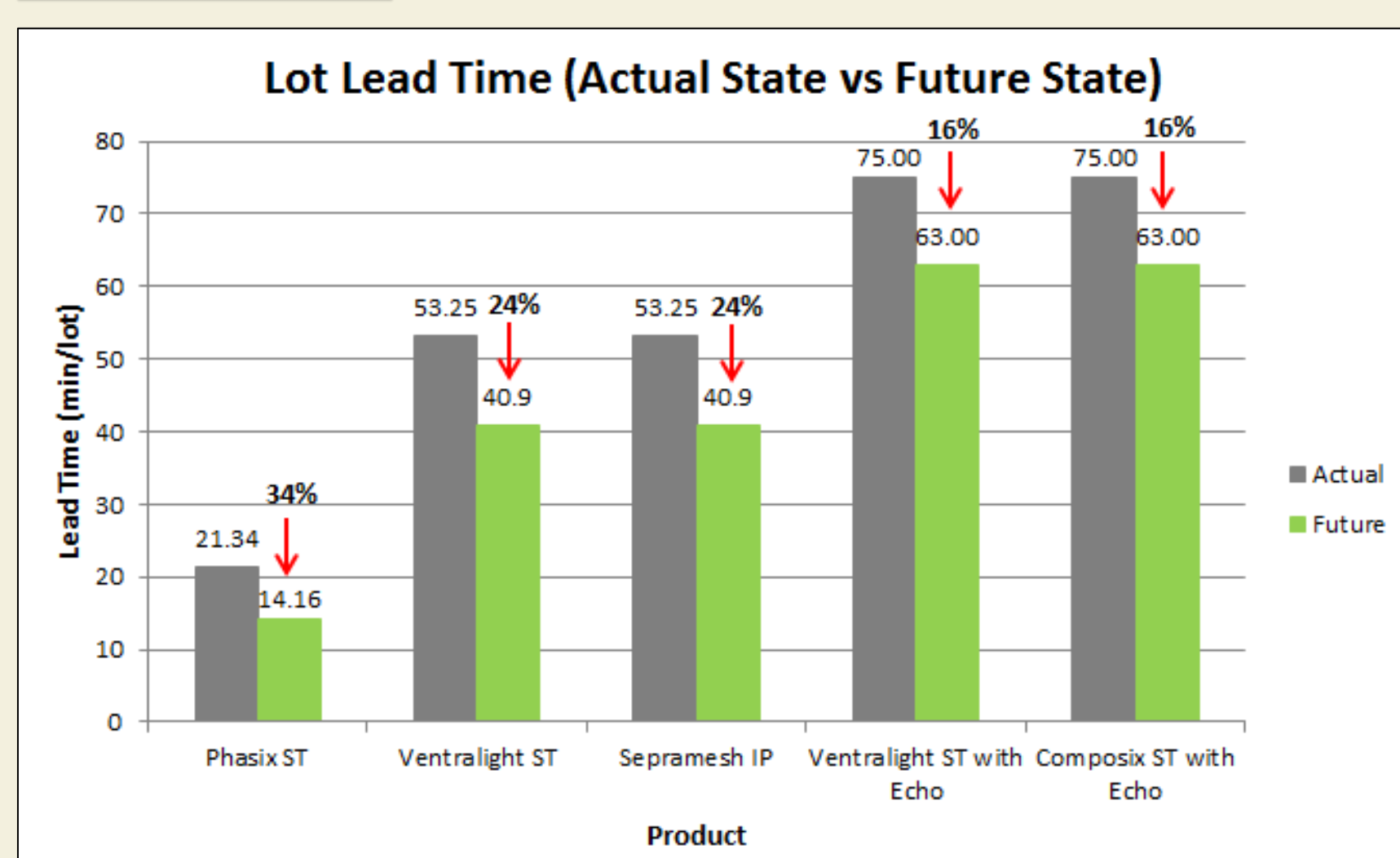
Station Future State



Future Balance: End Item



Future Balance Improvements: End Items



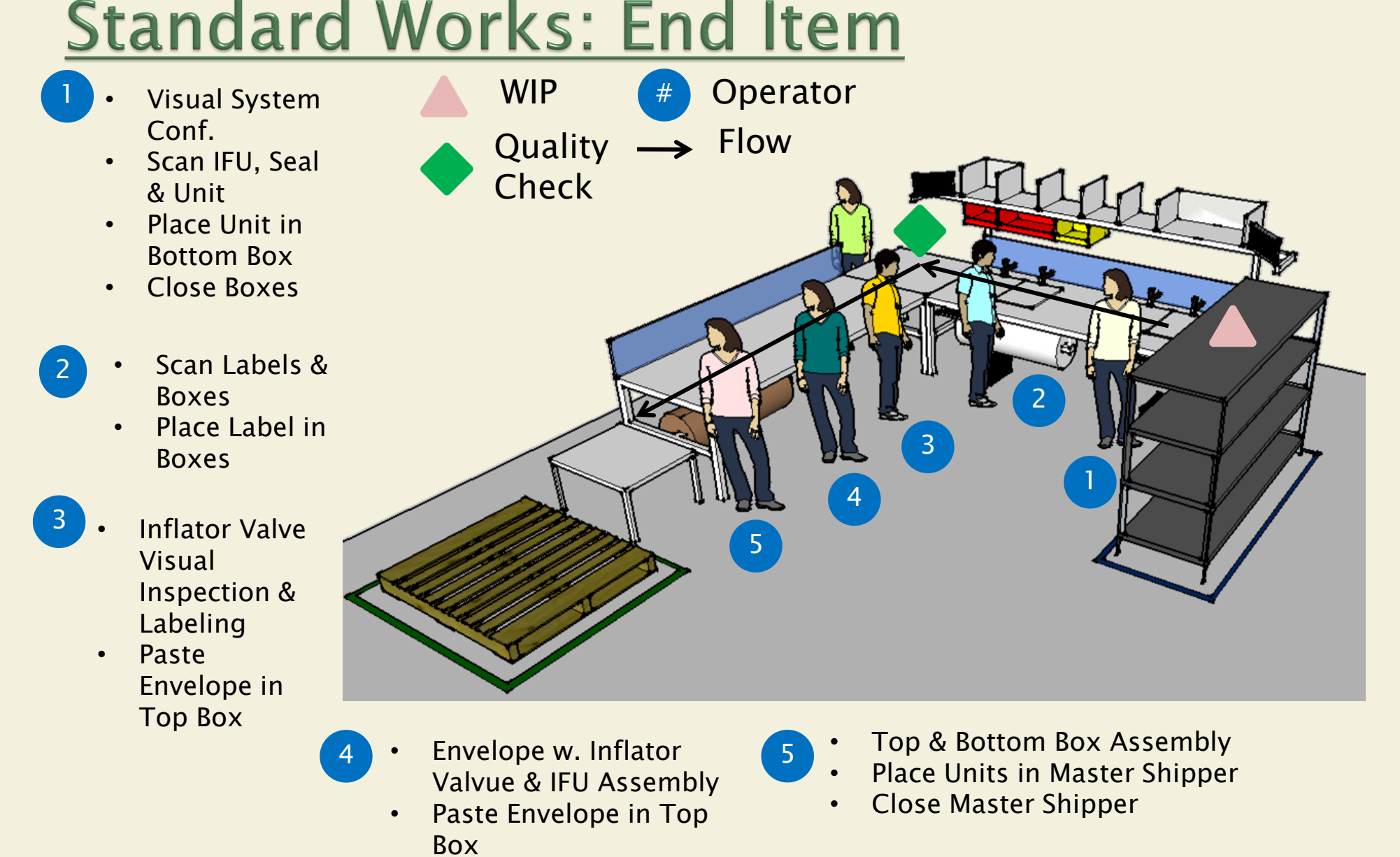
Savings

| Category | Value |
|---------------------------------------|---------------------|
| Overtime Benefit: | |
| Salary per Hour per Operator | \$10.28 |
| Double Salary per Operator | 2 |
| Overtime Salary per Hour per Operator | \$20.56 |
| Operators in Sepramesh Stations | 6 |
| Overtime Salary per Hour | \$123.36 |
| Overtime Hours per Month | 90 |
| Overtime Cost per Month | \$11,102.40 |
| Working Months per Year | 12 |
| Overtime Savings | \$133,228.80 |
| Proposed Balance Line Benefit: | |
| Operator to be Reduced | 1 |
| Salary per Hour | \$10.38 |
| Working Hours per Week | 40 |
| Working Weeks per Year | 48 |
| Operator Savings | \$19,929.60 |
| Total Benefit | \$153,158.40 |

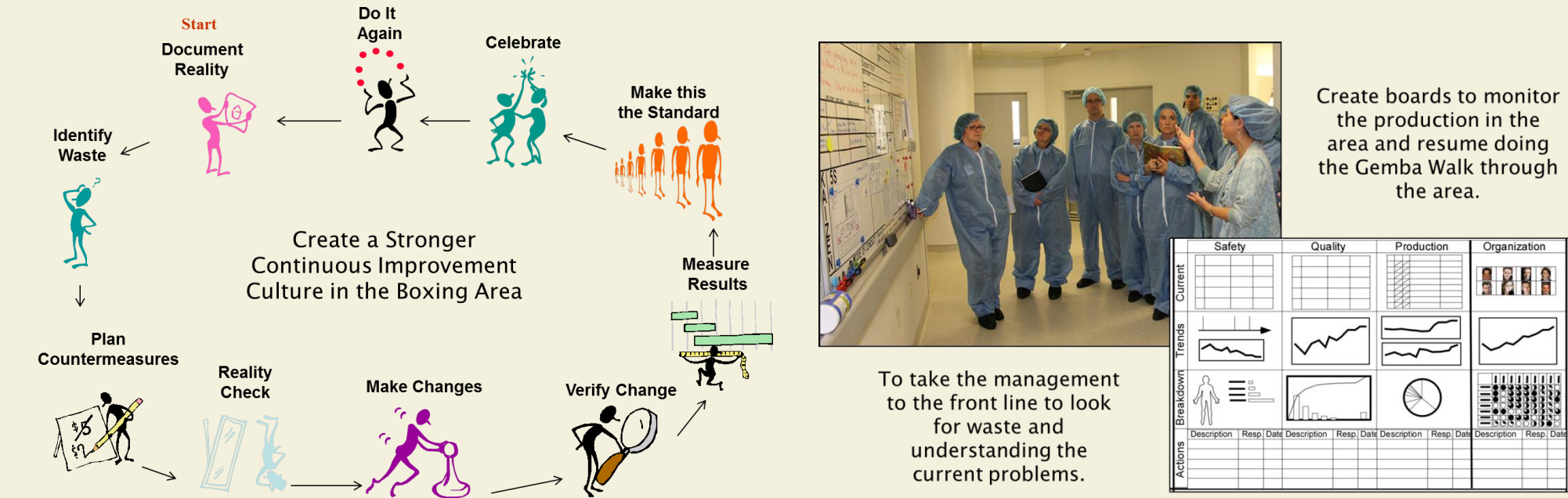
Manufacturing Procedure Changes

- 9.4.3 Take one (1) pouch and inspect for the following:
Note: Refer to WIM0106 procedure.
 9.4.3.1 The pouch seal.
 9.4.3.2 If creases and/or voids are found in seal area, clearly "X" out the packaging material, place it in the reject bin, and notify QC or Supervisor. Product cannot be sealed into a new pouch.
 9.4.3.3 Seal width must be a minimum of 3/16" continuous.
 9.4.3.4 If an unsealed pouch is found, notify QC or Supervisor to initiate the nonconformance procedure per SOP820.90.1.
- Visual Inspection Elimination**
- 9.4 Set up End of Line Visual Inspection System. Refer to WIM0117 for set up of the End of Line Visual Inspection System and the verification of component identification for labeling, barcode and seal verification, as applicable.
 9.4.1 Inspect through the vision inspection system the lot sealed pouches.
 9.4.2 In a separate inspection system report configure and inspect the sealing of the molecular weight and lot testing release samples.
 9.4.3 These units will be packed in a separate box, identify this box as a test sample.

MP4494 - End of Line Visual Inspection System for Phasix Sub-Assemblies Elimination



Kaizen Methodology



Conclusion

In this project, the production of the Sepramesh stations were improved by performing a re-layout and a re-balance in the process. With these changes, an operator was reduced from the packaging process and the area do not incurs in overtime. The implementation projects a saving of \$153,158.40. With this project we had the opportunity to put into practice all the knowledge acquired in class and to use the DMAIC methodology.

Acknowledgments

The team wants to thanks the team of Business Excellence and the operators of the Sepramesh stations for giving us all their support during the project and to make it a successful one.