Time Cycle Reduction of the Scrap Process in a Medical Device Company

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Abstract — *As part of an assessment performed for continuous improvement it was identified that the Nonconformance (NC) Timeline metric shows 23% over the goal of 30 days closure. From the list of NC Reports (NCR) impacting this metric, 31% were classified with scrap disposition. This project focused in the improvement of the overall SCRAP process. This process include product under an NCR which disposition is SCRAP and for material to be SCRAPPED for any other reason. The main objective of the project was to reduce the cycle time for product to be SCRAPPED. Improvements considered eliminating those non-value added activities that were being performed and that were impacting the timeline of the NC Process and the SCRAP process. This project reduced the NC timeline by 56.75% in average for NCRs with SCRAP disposition. In addition this project brought a labor cost reduction of 74%.*

Key Terms *— Methodology DMAIC, Nonconformance, Timeliness metric*

INTRODUCTION

Companies regulated by the Federal Drug Administration (FDA) and the International Organization for Standardization (ISO) must have systems and controls to assure that they can consistently fulfill quality and regulatory requirements[1][2]. This will assure companies to stay in business by consistently meeting customer's quality expectations by delivering the right product and quantity, at the right time and place, and at the right price. For this reason companies must establish the Quality Management System (QMS) to determine:

- Needs and expectations of customers.
- Establish quality policies and quality objectives.
- Implement process for the continual improvement of the QMS.
- Implement projects to prevent nonconformities and eliminate their cause.s
- Implement methods that can measure effectiveness and efficiency of each process.
- Determine the processes and the resources required to attain the quality objectives.

Management shall review the organizations QMS at defined time intervals to ensure suitability, adequacy and effectiveness. Assessment helps to identify opportunities for improvement and the need for changes to the QMS. In addition, tracking metrics helps to achieve cost savings and companies may have a clear picture of how they are performing over time.

This system is followed at a Medical Device Company regulated by FDA and ISO agencies. During a recent periodic review performed for the QMS of the Company, it was identified an area of opportunity in the Nonconformance system which was impacting the timeliness metric. Timeliness of nonconformance's could be impacted due to a failure in a proper handling of the issue, problems identifying ways to prevent future nonconformance's and to further improve product quality.

RESEARCH OBJECTIVES

This project will focus in areas of opportunities identified that are impacting the metric of Nonconformance (NC) timeline. These opportunities were identified after performing a thoroughness assessment of the NC System considering the following areas (refer to Figure 1):

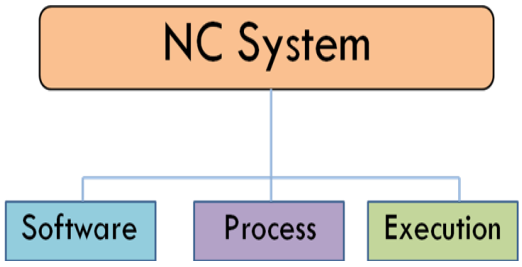


Figure 1
Areas to be assessed from the Nonconformance System

After evaluating Software, Process and Execution of the NC System it was identified areas of opportunities in the three areas. In the Process area of the NC System it was identified that the major areas of opportunities were in those NC reports that involve nonconforming product and that final disposition was SCRAP.

This project will focus in the improvement of the overall SCRAP process. This process include product under an NC Report which disposition is SCRAP and for material to be SCRAP for any other reason.

The main objective of this project is to reduce the cycle time for product that will be SCRAPPED. Improvements will consider eliminating those non-value added activities that are performed currently and that are impacting the timeliness of the NC Process and the SCRAP process. Project will assure that improvements implemented be in compliance with the applicable regulations of the Medical Device Company.

RESEARCH CONTRIBUTIONS

This project will support the timeline metric of the nonconformance process. Implementation of the project will significantly contribute the SCRAP process by:

- A standardize SCRAP process.
- Better utilization of the resources.
- Eliminate redundant activities.
- Better usage of supplier services (Recycling services supplier).
- Reduction in NC timeline metric.
- Paperless process for the non-conforming product with SCRAP disposition.

Definitely the implementation of this project will provide to the company the ability of allocate resources based on value added projects for the company. At the same time the company will continue executing at a level of excellence as they are used to execute, by consistently meeting the plant goals and metrics.

RESEARCH BACKGROUND

Companies must be able to understand how well they perform and how this performance affects their financial to address the return on investment. For this reason if they are not able to measure the performance of their product development processes there is a very low probability to compete with today's best-in-class product makers.

It is impossible to optimize a process, if it is not measure or there is no knowledge in how to measure it. A study performed by AMR Research (AMR Research is a supply chain research team) discovered that 79 percent of the companies surveyed had formal new product development processes, however only 52 percent had actually applied metrics to these processes [3]. Most of these companies may ignore the variety of business benefits that could bring an effective, visible metrics that are consistently and constantly measured.

Some of these benefits are:

- That companies can evaluate their product development capabilities, measure their effectiveness and identify areas of opportunity.
- Allows to prioritize their initiatives and established strategies.
- Enables companies to establish external benchmarks they can use to evaluate their competitiveness and compare their performance against best-in-class companies.
- Helps companies establish predictive measures they can use to anticipate

performance problems and take corrective or preventive actions.

- Allows companies to creates a benchmark for aligning company incentives with performance goals.

It was during a recent periodic review performed for the QMS of the Company, it was identified that the timeline metric in the Nonconformance system was not being met. Timeline of nonconformance's could be impacted due to a failure in a proper handling of the issue, problems identifying ways to prevent future nonconformance's and to further improve product quality. After a thoroughly assessment it was identified that there was an area of opportunity with the NC reports that involve nonconforming product and their final disposition was classified as SCRAP.

Current SCRAP process is totally manual and depends of an employee to coordinate with three different departments until the SCRAP activity is completed and closed in the NC Software system. Employee needs to print a form, complete the heading of the form with the information of the material that will be scrapped, takes the form to the finance department for account number where the cost will be allocated and assigned total cost based in the total quantity of material that will be scrapped. Once this information is completed, form will be approved based on the total cost of the material to be scrapped. The Approval requirements start with a representative of the specific department or manager (Supply chain, finance and operations) up to the general manager approval. Once the form is approved, coordination with contractor for material destruction needs to be performed. SCRAP activity is completed and closed in the NC Software system once the contractor destroys material; provide the certificate of destruction and remove the material from the ERP system. Refer to Figure 2 for flowchart of the current scrap process.

This activity is taking in average 11 days over 30 days available to investigate and implement all actions from a Non-conformance report. In order to address this area of opportunity the methodology DMAIC will be used.

This methodology provides a systematic way to approach a problem. It is used to root out and eliminate the causes of defects, it has five phases (refer to Figure 3).

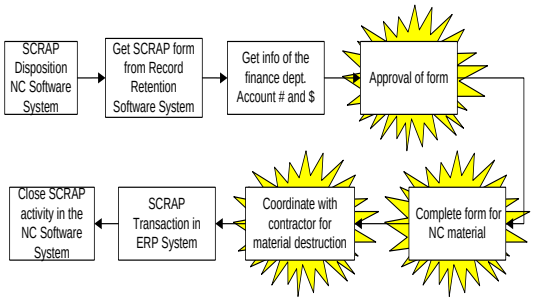


Figure 2
Flow chart of the Current Scrap Process

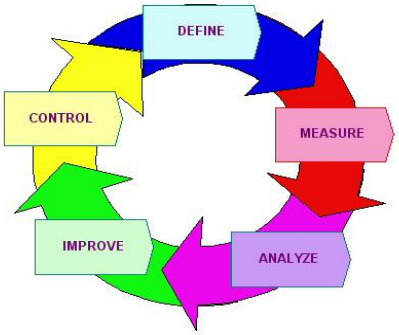


Figure 3
Methodology DMAIC

Each phase is defined as follow:

- ***Define*** the problem, the voice of the customer, and the project goals, specifically.
- ***Measure*** key aspects of the current process and collect relevant data.
- ***Analyze*** the data to investigate and verify cause-and-effect relationships. In this phase it can be determine what the relationships are, and attempt to ensure that all factors have been considered. Seek out for root cause of the defect under investigation.
- ***Improve or optimize*** the current process based upon data analysis using techniques such as design of experiments, poka yoke or mistake proofing, and standard work to create a new, future state process.

- ***Control*** the future state process to ensure that any deviations from target are corrected before they result in defects.

RESEARCH METHODOLOGY

The ultimate goal for this project "Time Cycle Reduction of the Scrap Process in a Medical Device Industry" is to have no SCRAP material as consequence of a non-conformance. While this ideal goal is met there is a reality, every manufacturing process will have material for scrap especially if it is classified as nonconforming. This project will focus in the following methodology:

Define

Aspects that will be define as part of this project:

- Define the actual problem with the SCRAP process for nonconforming material in the Medical Device Company.
- Define the objectives, goals and benefits that project will bring to the company by implementing recommendation.
- Define areas of opportunities.
- Define the requirement of the project.
- Develop an action plan.

Measure

The following data will be collected as part of this project to measure the improvements of the project:

- Measure current timeliness in completing an NCR that has material which final disposition is defined as scrap.
- Measure the new NC timeline after implementing the recommendations.

Analyze

The following data collected will be analyze as part of this project:

- Analyze current timeline and estimate new time with the implementation of project recommendation.
- Develop several alternatives until taking in consideration cost, compliance, and system restrictions.
- Select the best alternative that can help to decrease NC timeline for nonconforming material with SCRAP disposition.

Implement and Improve

Implement and Improve the best alternative selected.

Control

Monitor changes implemented to avoid any deviations from the project objective.

RESULTS AND DISCUSSION

After showing an actual NC Timeline metric of 23% over the 30 days closure goal there was sufficient evidence that the NC Process had an area of opportunity. From the list of NCRs impacting this metric, 31% of them were classified with scrap disposition. When these NCRs were evaluated it was noticed that most of them were near the 30 days or exceeding the 30 days of aging in some cases related to the scrap disposal process and not because time required to perform the assessment for the nonconformance. A value stream map was generated for the SCRAP process for nonconforming material in order to understand the process and identified the areas of opportunities (refer Figure 4).

Prior implementing the recommended changes the cycle time of NC Actions for scrap material was in average in 11 days over the 30 days goal. The intention of this project is to reduce the excess of the cycle time goal by at least 40%. Improving this process will provide the opportunity to expedite the closing of the NCRs and influencing in the reduction of the NC Timeline metric. After evaluating the different alternatives, cycle time for NC Actions for scrap material will be monitored in order to understand how the implementation of the changes impacted the cycle time. At the same time, this reduction will impact favorable the NC

Timeline metric which is monitored and presented in a monthly basis.

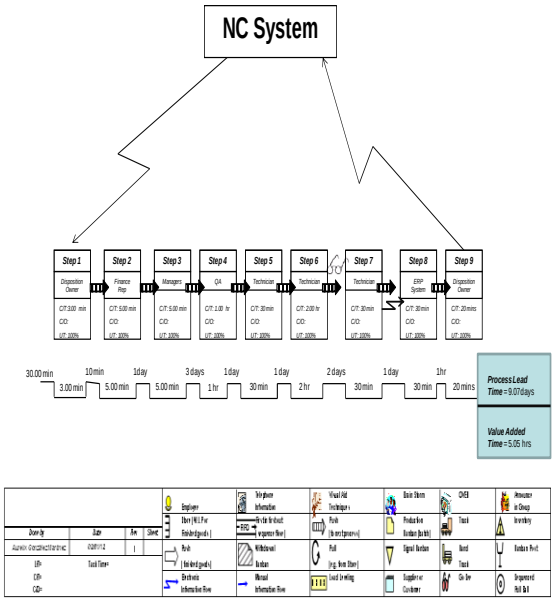


Figure 4
VSM State before Implementation

The first alternative evaluated was to streamline the form used to document the scrap authorization. Figure 5 presents the original form. However, recommended changes on the form, presented the reduction of the approvals required to authorize the scrap of the material. Also the reduction of documentation was focused only in keeping the value added information.

This alternative did not considered the complete cycle up to destroying the nonconforming material. For this reason, as a second alternative was considered to eliminate the form and follow a paperless approach, as an alternative to optimize the process. Considering this alternative, it initiated a process of design to include in the NC System all the required documentation elements to scrap a non-conforming material. Three important elements needs to be considered in the design of the scrap process managed paperless through the NC system, and this are:

- Be able to document in a field the account number where scrap value will be charged and the cost. This information will be entered by the finance representative without the requirement of a management level approval.
- Provide evidence that material was verified, reconciled and disposed with a witness without the need of waiting from 2 – 3 days in average to destroy material at supplier site.

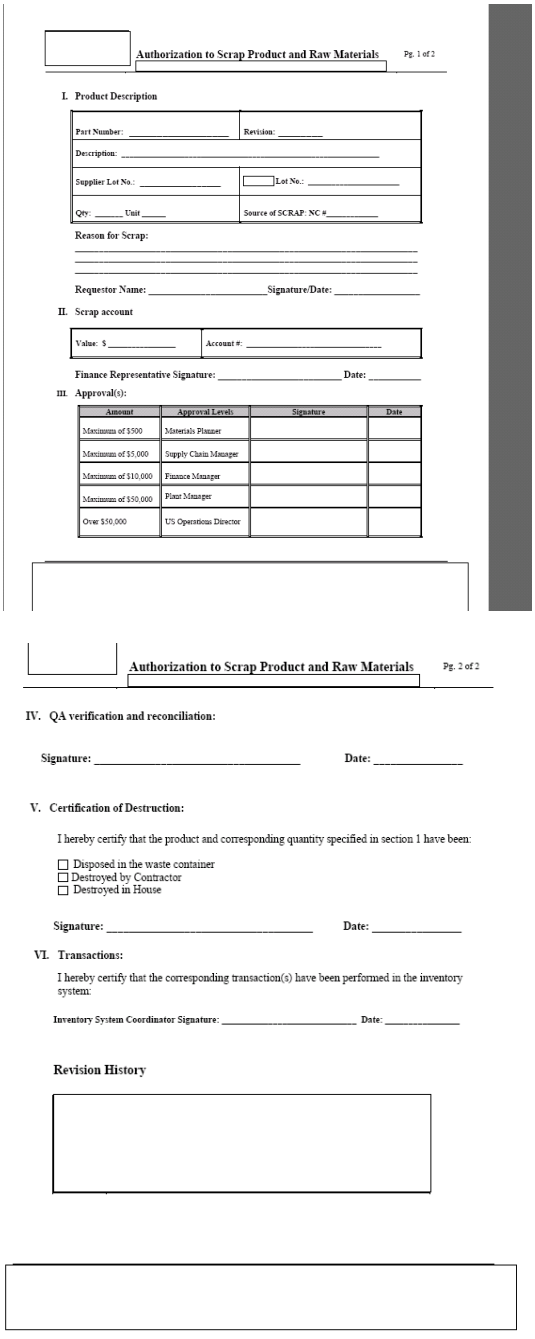
Table 1
Definition of SCRAP Process for Nonconforming Material

Process Step	*Activities performed on Process Step*	*Areas of opportunities*
Step 1	Action owner to scrap material, will print form from the document control system and will document on form the information of material to be scrapped that will be scrapped.	Having the process paperless is an alternative that was evaluated as part of the project in order to help expediting the process and cost reduction. This is considered a redundant activity since information documented on form is also documented at the NC file of the NC System.
Step 2	Request Finance the account number where scrap will be charged and the value of the material followed by the finance representative signature.	N/A
Step 3	Search for the managerial approval depending in the cost of the product to be scrap. Form may require up to five approvals.	Within the approvals required, form requests a second finance representative. Having one finance representative providing the account and cost information is evidence that department is acknowledge of the scrap cost. Two representatives from the Supply Chain department are required (Supply Chain Manager and a Material Planner) also on the form. However, a second approval from the same department is redundant since the intention of their approval is to be aware that the inventory levels will be impacted with the material to be scrapped. At the Plant manager level, the finance department presents in a monthly basis a report which includes material that has been scrapped. Which means that is an area of opportunity to evaluate if this approval is also required in the new design.
Step 4	Action owner must identify an available resource from QA that can perform the Verification and Reconciliation of Material and approve form.	As part of the traceability it is recommended to have a witness for verification and reconciliation of material.

Process Step	*Activities performed on Process Step*	*Areas of opportunities*
Step 5	Coordinate with Maintenance Engineering Technician and supplier for the pickup the material to be scrap and for the certificate of destruction.	If there are dedicated resources from the supplier that disposed of the material at the plant it is a good opportunity which other alternatives does the company have that could help to expedite the destruction process and avoid the delay of waiting for certificate of destruction.
Step 6	Maintenance Engineering Technician will assure that material was picked by the supplier.	If there are dedicated resources from the supplier that disposed of the in process material, probably having them dealing with nonconforming material, will help to allocate the Maintenance Engineering Technician for example in other plant projects. The intention of implementing changes in this aspect will help to expedite the destruction process and avoid the delay of waiting for certificate of destruction.
Step 7	Maintenance Engineering Technician will wait for the Certificate of destruction from the supplier.	Currently there is a robust supplier program at the plant which provides to the Company the confidence that supplier services are in compliance with our requirement. This means that a Certificate of destruction is not the only alternative to confirm that nonconforming scrap material is being managed in compliance per plant requirement. Alternatives were evaluated to help expedite the destruction process and avoid the delay of waiting for certificate of destruction.
Step 9	Once certificate of destruction is received, scanned copy will be attached on the NC System as evidence that material was scrapped by the action owner and action in the NC System may be closed.	An alternative was evaluated to avoid the requirement of uploading to the NC System the evidence that material was scrapped having the necessity of archiving all the documents that requires an authorization to scrap by moving the process to a paperless process.

- Finally provide evidence that scrap transaction or material adjustment was performed at the ERP system.

While this process was in the design phase, possible alternatives were evaluated that could provide us the opportunity to dispose the scrapped material in 2 – 3 days less than the actual time. In process, the scrapped material is disposed in Gaylord containers provided by the Recycling services supplier which are located in different points of the manufacturing area. On a daily basis, Recycling services supplier picked up all the Gaylord containers from the plant that reached their maximum capacity and transported them to his facility. This transportation is documented and stored with the number of the security device that seals carrier truck (which is a unique number) by the Maintenance Engineering Technician.



Authorization to Scrap Product and Raw Materials Pg. 1 of 2

I. Product Description

Part Number: _____ Revision: _____

Description: _____

Supplier Lot No.: _____ Lot No.: _____

Qty: _____ Unit ____ Source of SCRAP: NC #_____

Reason for Scrap:

Requestor Name: _____ Signature/Date: _____

II. Scrap account

Value: $ _____ Account #: _____

Finance Representative Signature: _____ Date: _____

III. Approval(s):

Amount	Approval Level:	Signature	Date
Maximum of $500	Materials Planner		
Maximum of $5,000	Supply Chain Manager		
Maximum of $10,000	Finance Manager		
Maximum of $50,000	Plant Manager		
Over $50,000	US Operations Director		

Authorization to Scrap Product and Raw Materials Pg. 2 of 2

IV. QA verification and reconciliation:

Signature: _____ Date: _____

V. Certification of Destruction:

I hereby certify that the product and corresponding quantity specified in section 1 have been:

☐ Disposed in the waste container
☐ Destroyed by Contractor
☐ Destroyed in House

Signature: _____ Date: _____

VI. Transactions:

I hereby certify that the corresponding transaction(s) have been performed in the inventory system:

Inventory System Coordinator Signature: _____ Date: _____

Revision History

Figure 5
Original Authorization to Scrap Form

This resource will receive the Certificate of destruction making reference to the number of the security device that sealed carrier truck.

After evaluating how the disposal process is managed, it was recognized that to be a robust process. It was recommended to dispose all scrap of nonconforming material in Gaylord containers located in the plant. However, it was noticed that then nonconforming materials traceability can be lost since the containers were not identified. Therefore, the necessity of identifying the Gaylord containers for traceability purposes was established.

During the assessment it was confirmed the feasibility of incorporating the authorization process to scrap nonconforming material through the NC System and run the process paperless. In addition, it was defined the strategy to follow up the containers identification to trace the nonconforming material that were destroyed. Having the process designed, project was moved to the implementation phase.

The authorization process to scrap nonconforming material through the NC System was implemented. From the possible seven (7) approvals required on the form, an additional approval required in the NC System from the Operations Department, adds a total of eight (8) required approvals. In the NC System it was reduced to three (3) approvals requiring representatives from Finance, Operations and Supply chain. In addition that now the requirement of approving the disposition was consolidated in the NC system instead of approving through the system and the form.

Five (5) redundant approvals were eliminated from the process followed through the form, eliminating also ten (10) data entries, which eliminates the opportunity of an error in the documentation or by omitting a required documentation which may cause a nonconformance. In addition, this reduction minimizes the delay in the approval process. The approval process through the NC System also provided the flexibility to approve the disposition a manager or a department representative, instead of the requirement of manager approvals as requested in the original form.

The disposition owner will route for approval the scrap disposition in the NC System once it is documented in the NC record the corresponding account number to charge scrap and the value of the material. Once the approval for disposition is granted, lot may be disposed.

In order to expedite the process of disposal of material it was decided to relocate the nonconforming material in the Gaylord container. In order to have traceability and evidence of destruction of the material, labels were created for the containers. Now, each Gaylord container will have a unique identification and Recycling services supplier will provide certificate of destruction making reference to the number of the security device that sealed carrier truck with the list of containers identification that were sent in the transportation. Refer to Figure 6 for label IDs created for the Gaylord container.

Now nonconforming material will be disposed In the container and with this identification scrap actions assigned in the NC System may be closed making reference to this ID, without the need of the availability of the supplier to pick the nonconforming material, destroy it, send the certificate of destruction and finally provide their approval in the scrap authorization form. In average this process of the Recycling services supplier used to take from 2 to 3 days.

In the NC system, the first Action will be assigned to a QA Representative and will be closed after having performed the verification, reconciliation of disposed material, and after witness the material relocation from the HOLD cage to a waste container. A second Action will be assigned to the Area Owner representative and will be closed after relocating the material to the waste container and completion of SCRAP transaction in the ERP System. In this action, before relocating non-conforming material to the waste container QA Representative will perform the verification and reconciliation of material to be disposed and will witness the relocation of the material. Then both

actions will be closed with reference to the waste container number and evidence of SCRAP transaction. Finally this new process implemented is resumed in two actions and three (3) approvals in the NC System. Refer to Figure 7 for flow chart of the new scrap process for nonconforming material.

Figure 6
Gaylord Container identified

Although Authorization to Scrap form is not being used currently for the nonconforming material to be scrapped, it remains activated in the Document Control System for material that needs to be scrapped outside the NC System, for example the experimental material, expired material etc. As part of this project changes to the Authorization to Scrap form were also implemented to provide flexibility to the process of material that needs to be scrapped outside the NC System. Where redundant approvals were eliminated and implemented on form the changes the new process to disposed material.

In order to standardize the changes implemented in the SCRAP process for nonconforming material, these changes were implemented on procedures and the impacted departments that were involved in this process were trained. In addition, NC Timeline metric is monitored in a monthly basis. For this reason it is recommended to continue monitoring the NC Timeline and evaluate other opportunities within the NC process to eliminate non-value added activities.

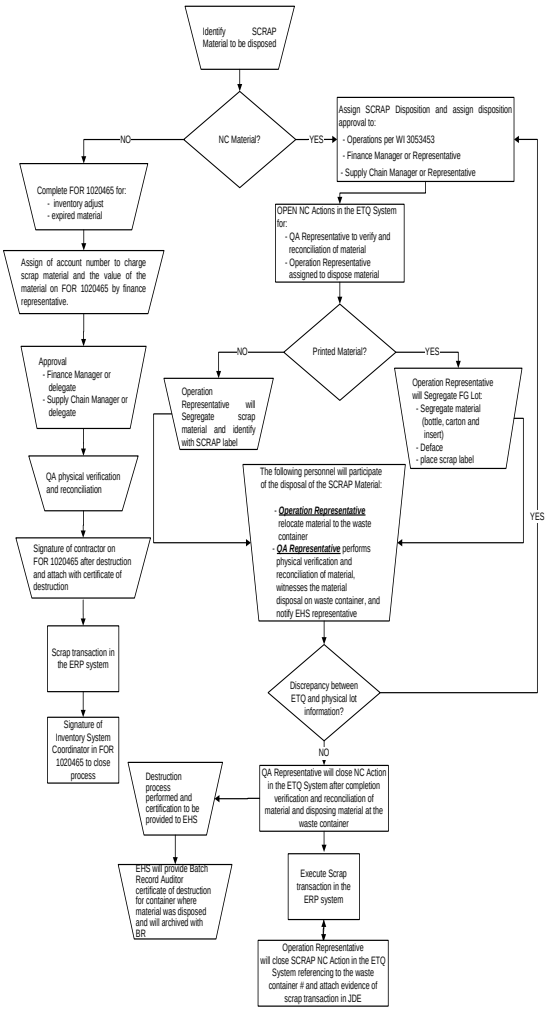
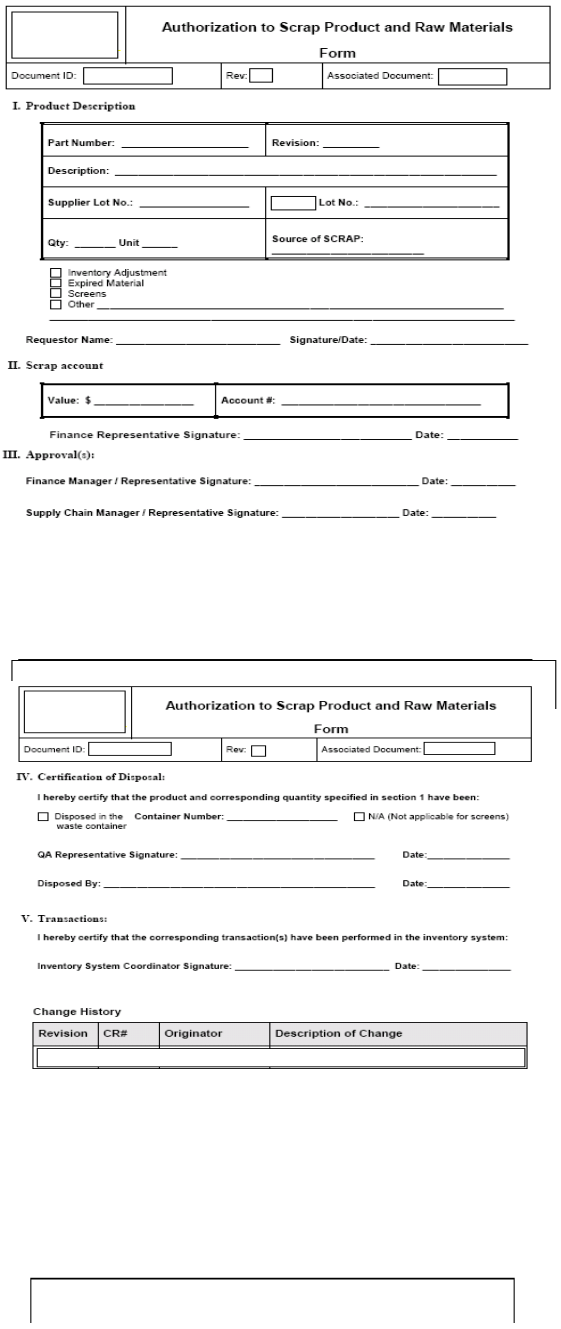


Figure 7
Scrap Disposition Process Flow Chart



Authorization to Scrap Product and Raw Materials Form

Document ID: Rev: Associated Document:

I. Product Description

Part Number: Revision:

Description:

Supplier Lot No.: Lot No.:

Qty: Unit Source of SCRAP:

Inventory Adjustment
Expired Material
Screens
Other

Requestor Name: Signature/Date:

II. Scrap account

Value: $ Account #:

Finance Representative Signature: Date:

III. Approval(s):

Finance Manager / Representative Signature: Date:

Supply Chain Manager / Representative Signature: Date:

Authorization to Scrap Product and Raw Materials Form

Document ID: Rev: Associated Document:

IV. Certification of Disposal:

I hereby certify that the product and corresponding quantity specified in section 1 have been:

Disposed in the waste container Container Number: N/A (Not applicable for screens)

QA Representative Signature: Date:

Disposed By: Date:

V. Transactions:

I hereby certify that the corresponding transaction(s) have been performed in the inventory system:

Inventory System Coordinator Signature: Date:

Change History

Revision	CR#	Originator	Description of Change

Figure 8
Authorization Scrap Form with Changes Implemented

CONCLUSION

As part of this project it was possible with the changes implemented under the SCRAP process for nonconforming material to reduce NC timeline excess days by 56.75% for NCRs with SCRAP disposition. Some of the activities developed through this project were to:

- ❖ Standardize Scrap Process by eliminating inconsistency in the process followed by a SCRAP nonconforming material.
- ❖ Standardize Scrap Process by eliminating inconsistency in the disposal of material by standardizing the process through SOP procedure.
- ❖ Handle all non-conforming material using the NC system.
- ❖ Identify non-value added steps in the SCRAP process and update impacted procedures.

In addition this project brought a labor cost reduction of 74%. The NC Process for SCRAP Material prior implementation had a cost of $136.62 per report. This cost considers all the resources required to complete these tasks. After the implementation of this project, complete the process of scrap for a nonconforming material has a cost of $35.15.

In order to confirm if the improvements in the process were significant, an hypothesis test using a two sample T-Test was performed with data collected prior the implementation and after the implementation. It is intended to demonstrate throughout this analysis if it exist a significant difference between both population data. Having a difference between both data, will mean that changes implemented had significant impact in the process, which in this case the impact that project have after the implementation is the reduction in the NC SCRAP process cycle time.

The hypothesis was defined as follows: A Confidence Intervals = 95%

- ✓ $\alpha = 0.05$
- ✓ $\sigma 1 \neq \sigma 2$
- ✓ H_0: $\mu_1 = \mu_2$
- ✓ H_a: $\mu_1 \neq \mu_2$
- ✓ If ***p-value*** $\geq \alpha$ Accept H_0

Two-Sample T-Test and CI: Prior Implementation, After Implementation

```
Two-sample T for Prior Implementation
vs After Implementation
                          N  Mean  StDev
SE Mean
Prior Implementation  101  11.4   13.6
1.4
After Implementation  187  4.93   4.90
0.36

Difference = mu (Prior Implementation)
- mu (After Implementation)
Estimate for difference:  6.52
95% CI for difference:  (3.75, 9.29)
T-Test of difference = 0 (vs not =):
T-Value = 4.66  P-Value = 0.000  DF =
114
```

This means that by using the p-value, we may established that we have enough evidence to state that mean values have a significant difference. This information confirms statistically that changes implemented through the NC SCRAP process met the time cycle reduction of the Scrap Process as intended the project. Refer to Figure 9 for a better view of the difference in both populations.

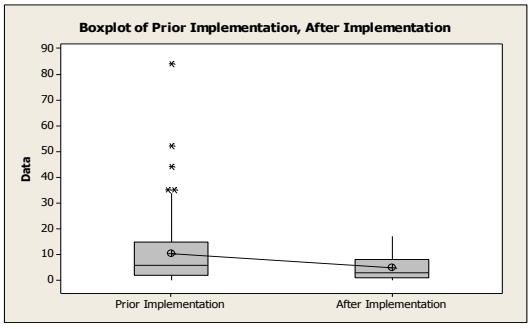


Figure 9
BOXPLOT FOR the cycle time of the NC SCRAP Process

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