

# ***Improvement in the Visibility of Nonconforming Product Inventory and Reduction***

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**Abstract** — *One of the major problems reported in a company is the Nonconforming product inventory, reducing the availability to use space for new production lines and storage of conforming product. Company wants to understand why the nonconforming products are exceeding the expected product disposition closure date, why the hold cages are full causing difficulty of locating a particular nonconforming production order in the storage areas. There are key elements of information to understand the actual status of nonconforming inventory. Therefore, the implementation of an optimized NC Monitoring Report system, through the using an ERP System, helps to prioritize Product Dispositions execution, reducing the aging of inventory and improving the allocation of resources to value added activities. After evaluation of current NC Monitoring Report system and proposed new NC Monitoring Report systems, waste removal in the cycle time is reduced from 223 minutes to 31, which represents a reduction of 86%.*

**Key Terms** — *Disposition, Nonconformance, Nonconforming product, Product Inventory.*

## **PROBLEM STATEMENT**

Improvement in the visibility and reduction of inventory of nonconforming products is the purpose of this study. Currently, the regulated industry inspect and verify that the product meets specifications prior to release and deliver the finish product to customers. When a nonconformance occurs, the product is segregated and placed on hold until complete product evaluation and final disposition. Therefore, it is necessary to have visibility of how many products are contained due to nonconformances to properly dispose of the product.

Increasing the visibility of this product could help to assign priorities and establish internal targets to dispose of the product in a pre-defined period to reduce the inventory of nonconforming products. The research uses methodologies and techniques to:

- Discuss the impact of having nonconforming products in the inventory.
- To conclude, how can increase the visibility of the nonconforming units?

Therefore, this research will help the company to understand why nonconforming products are not disposed of quick manner by improving the visibility of product placed on hold.

## **Description**

In a company, the nonconforming product is physically segregated and placed on hold waiting to complete product impact evaluation and dispositions following applicable procedures. As part of this process, it is necessary to monitor this type of inventory to ensure that product disposition is completed in a timely manner. The expectation is to reduce the nonconforming products to eliminate two (2) kinds of Lean Wastes:

- **Defects:** Wastes created due to defective product or service not meeting a specification. In this case, materials or products are manufactured without following applicable manufacturing procedures or requirements. This waste directly impacts the finances of the company since products are categorized as damaged and cannot be sold to another customer.
- **Inventory:** Wastes related to store excess of products or materials not processed. For example, nonconforming material pending for evaluation and final disposition.

## Objectives

The objective of the research is to identify the factors associated with high inventory of nonconforming products, to complete a 50% reduction of NC Monitoring Report system process.

As a result of this research, identifying factors that cause the high inventory of nonconforming products will help to reduce it by improving the NC Monitoring Report process. The use Lean Methodology concepts and techniques will help to understand and evaluate the processes, identify inefficiencies in the NC Monitoring Report process, identify areas of improvement, identify non-value-added activities, reduce bottlenecks in the process, facilitate the decisions making, help to prioritize activities, allows the opportunity to provide to the customers the product that is expecting, with higher quality and lower cost.

The following objectives in the project scope:

- Reduce the inventory of nonconforming products.
- Increase the visibility of nonconforming products placed on hold.
- Standardize the nonconforming product dispositions.
- Understand how to prioritize the dispositions of nonconforming products.

## Contributions

As part of this research, the expectation is to provide the necessary information to enhance the visibility of nonconforming products to other companies and understand the impact of having this kind of inventory in company. In addition, the contribution of documenting this research is to understand how to reduce the inventory associated to nonconforming products by analyzing current processes using many techniques available in the industry. Thus, understanding the impact of the nonconforming product in the supply change will be helpful to remove the waste in many companies.

By implementing the reduction of nonconforming product inventory, the companies will have the following benefits:

- Use the available space to implement value added activities. For example, optimize the manufacturing areas providing the opportunity to use this space to implement additional manufacturing lines.
- More space availability in the storage areas, providing space for the storage conforming product instead of nonconforming product.

## LITERATURE REVIEW

The following key terms were used to evaluate the objectives:

- Specific: The specific infinite/action verbs used in the objectives are identify and reduce. To define the project, it was required to understand the Voice of the Customer (VOC) [1]. The company has the expectation to reduce 50% of NC Monitoring Report system process for inventory associated to nonconforming product. This will be the initial phase of a project to make sure the nonconforming products are eliminated to the nonconforming storage areas. The specific terms used in this objective are the period, the percentage of reduction (50%) and the type of inventory under research (nonconforming product).
- Measurable: To make sure that the objective is measurable, it is necessary to identify how many units are currently placed on hold and located in the quarantine area prior to start the activities needed to reduce the percentage of nonconforming product. This action will help to determine if the objective was reached as established and make a comparison between the initial quantity of nonconforming product and the final quantity of nonconforming product after improvements. Therefore, it is necessary to identify what is the correct source to collect the data to make sure the data is accurate. For the Analysis phase, all data gathered in the measurement phase will be evaluated [1].
- Achievable: To develop the correct strategy to meet the established objective, the company

should know the purpose of the objective and “why” this objective was developed. In this case, the company confirmed that inventory and defects are two (2) wastes to be reduced following Lean Methodology. To do this activity, the company must confirm that they have all the necessary resources to complete the product dispositions in an established period, for example: money and resources.

- **Realistic:** The company must analyze if this objective is realistic based on the resources that they have. If is necessary, they will incur in hire new employees to expedite the product disposition to achieve the objective in the established period.
- **Timely:** It is necessary to establish the correct target taking into consideration that the research includes the identification of factors that cause a high inventory of nonconforming units. The identification of these factors is necessary to reduce this type of inventory, therefore, the strategy should be performed as planned to achieve the objective.
- **Five (5) S:** One of the Just in Time methodology concepts that helps the industries is 5s. This concept also can be used to improve the workplace to reduce waste in the processes. The 5s are Sort (remove unnecessary items), Set in order (place the items in the right place), Shine (inspect and maintain tools/equipment), Standardize (standardized work/tasks) and Sustain (keep the habit) [1].

## **METHODOLOGY**

The research objectives will be achieved by using the following DMAIC Methodology:

- **Define:** In the Define Phase, the personnel involved in nonconforming product dispositions and Nonconforming Product Inventory Metric which includes but not limited to supervisors, quality, planning and stakeholders should be interviewed to understand the expected output. Additional information required to understand the process

is to prepare diagrams and Value Stream Map. Once collect all the information required for the Define Category, the business case is created to define the problem, project goal, project milestone and project deliverable.

- **Measure:** The purpose of the measure is to collect data of the current state of the process to be analyzed. Data will include hold documentation, a list of aging of nonconformance products at hold location, procedures, current Nonconforming Metric methodology, among others.
- **Analyze:** For the Analysis phase, the analysis of data collected, current Value Stream Map, and Spaghetti Diagrams are required to identify non-value-added activities in the nonconforming product dispositions. Therefore, based on the outcome of the analysis performed, a strategy will be defined as part of the implementation phase.
- **Implementation:** For the implementation phase, it is necessary to already understand how can be improved in the process to reduce the aging of Nonconforming product Inventory. Therefore, at this phase the actions to be implemented are clearly defined.
- **Control:** For the Control Phase, the implementation of all actions to improve the NC Monitoring Process Report must be completed. In this stage, the effectiveness of the project is measured against the goals and key success measures previously defined in the Define phase.

As part of the DMAIC Methodology, it can use the SIPOC model to summarize the inputs and outputs of process(es), the acronym represents the first letter of each of the five (5) elements evaluated using this tool: Supplier, Input, Process, Output and Customer.

The first element, Supplier, evaluates the personnel or organization who provides the resources to perform the process under evaluation. The second element is Input, this category evaluates the information, material or service

provided. The third element is Process which evaluated the tasks performed to transform the input to output. The fourth category evaluated the output which evaluated the product or service transformed after the process is executed. The fifth element is the Customer which evaluates the person, process, or organization that receives the output. This tool helps to identify what areas to be improved to optimize their processes, taking into consideration since the supplier delivers the material until the customer receives the service or product. Six Sigma methodology establishes that SIPOC model creates, monitors, and improve systems for process management, manufacturing processes, service processes and design.

The following additional tools can be included but not limited to:

- **Creating a Value Stream Map (VSM) or Flow Diagrams:** A Value Stream Map (VSM) is a lean management tool used for the identification of all the specific activities occurring along a value stream of nonconforming product, since the product is placed on hold until the product disposition is completed which includes value-added and non-value-added activities [2].
- **Conduct an evaluation using Five (5's):** Five S (5S) is defined as a methodology that can be applied in the workplace to assure that is clean, safe, organized with the purpose of reducing waste. In this research, the wastes under evaluation are defects and inventory. The five principles of 5's are Sort, Set in order, Shine, Standardize, and Sustain. Five 5S is focused on improving the quality, productivity, cost, efficiency, and safety of the area under evaluation.
- **Create a Spaghetti Diagram:** A Spaghetti Diagram is a Lean Process Analysis Tool that visually represents a continuous flow of the process, measuring the travel distance of representatives that has the responsibility to complete nonconforming product dispositions. This tool is considered a quick and easy tool to track distance on the shop floor. The main

purpose of this Process Analysis tool is to maximize the process efficiency and eliminate wastes associated to movement.

- **Evaluating Standard Work:** Standard work is a detailed description of each task to produce a product or complete a service. Evaluate current procedures to assess responsibilities of each representative associated to nonconforming product monitoring and dispositions, defining the equipment and tools required and processing time for each activity.
- **Development of an improved version of Nonconforming Product Inventory Metric:** Lean metrics are measurements that can be used to monitor the behavior of a process or system in a manufacturing or service industry. The lean metrics will help to perform a correct analysis to identify areas for improvement with the purpose of increasing the quality of product or service, reducing wastes, and improving efficiency.

## **RESULTS AND DISCUSSION**

### **Phase: Define**

The main problem of this research is the improvement in the visibility and reduction of inventory of nonconforming products. Therefore, this research pursues the identification of factors associated with high inventory of nonconforming products to complete a reduction in a predetermined period.

Nonconforming products are products that do not meet the product specifications, manufactured without following established procedures, requirements, or regulations. This type of product must be dispositioned using the following methods:

- **Scrap:** This method consists in physically destroying the product and rejecting the units in the applicable documentation following applicable procedures.
- **Release from hold:** This method consists in releasing the product since nonconformance does not impact the product specification,

therefore, no additional actions are required to distribute the product.

- Rework: This method consists in reprocessing the product in a particular operation to complete the specific process steps to meet a product requirement.
- Return to vendor: This method consists in returning raw material to the vendor that does not fulfill a specification.

One of the goals in Medical Device Company is to reduce nonconformances, implementing preventive and corrective actions to reduce and/or eliminate manufacturing events. At the same time, management looks for reducing the aging of nonconforming products by monitoring the Nonconformance (NC) metric.

The VOC was used to receive customer feedback (Product Disposition Owners, Operations, Engineering, and Planning). The input is used to improve processes, enhance our products or service, identify business priorities based on what is value-added for the customers and create a metric. Some of the benefits of knowing the VOC model are understanding the customer’s needs and expectations, which help the company focus on delivering the desired information and clarify what is value-added to the customer.

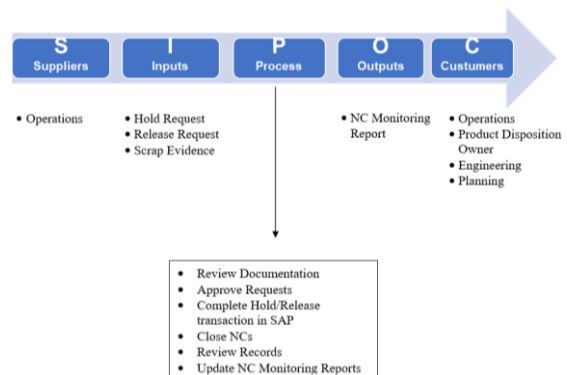
**Table 1**  
**Voice of the Customer**

What are the customers saying?	What Do They Want?	What are the customers saying?
“I don’t know what are the NCs containing more product”	To be informed of what are NCs containing more product.	Product must be dispositioned in a maximum of 15 days of NC aging.
“I don’t know what are the NCs with highest aging”	To be informed of what are NCs high highest aging.	A report must be provided to area owners and product disposition owners to provide visibility of pending product dispositions and aging.
“We have many products contained exceeding the	We need to complete the product	A report must be provided to area owners and product

What are the customers saying?	What Do They Want?	What are the customers saying?
maximum quantity expected.	disposition in a timely manner.	disposition owners to provide visibility of NCs containing high quantity of products.
“The hold cages are full, and it makes difficult locating a particular production order”	We need to have visibility of how many products will be scrapped, rework or released to prioritize based on complexity.	A report must be provided to area owners and product disposition owners to provide visibility of approved Product Disposition types (Scrap, Rework or Release).

**SIPOC Diagram**

A SIPOC model summarizes the inputs and outputs of the NC Monitoring Report process. The first element, the Supplier, evaluates the person who provides the resources to perform the Process under evaluation. The second element is Input; this category evaluates the information provided. The third element is Process which evaluates the tasks performed to transform the Input (information) into output (NC Monitoring Report). The fourth category evaluated the output, which evaluated the service transformed after the Process was executed. In this case, the information received in the Input is analyzed in the Process phase, and we obtain in the Output the NC Monitoring Report. The fifth element is the Customer, which evaluates the person who receives the Output (NC Monitoring Report).



**Figure 1**  
**SIPOC Diagram for NC Monitoring Report Process**

### **Phase: Measure**

As part of the measure phase, the evaluation of Standard Work, the product hold process and NC Monitoring process was completed, and the following was found:

#### Product Hold Process Flow:

1. Physical Segregation of Nonconforming product in a designated hold cage.
2. The manufacturing area representative will be placed on Hold the Nonconforming product, through ERP system (For example: SAP) transaction code.
3. Product Hold requestor transports Product Hold Documentation from Manufacturing Area to Quality Area for review and approval.
4. Quality Representative review the hold documentation and objective evidence that confirm nonconformance.
5. Quality Representative Approve hold documentation.
6. Quality Representative goes to printer area to scan hold documentation.
7. Quality Representative returns to desk to prepare files and upload documentation to SAP system.
8. Quality Representative sent an email to Requestor, Engineering, Operations, Quality and Planning personnel to notify product hold.
9. Quality Representative delivers product hold documentation in Record Retention Area.

#### Product Hold – Release Process:

1. Product Hold – Release Requestor transport Release Documentation from Manufacturing Area to Quality Area for review and approval.
2. Quality Representative reviews the release request documentation.
3. Quality Representative approves release documentation.
4. Quality Representative complete product release transaction in SAP system.
5. Quality Representative goes to printer area to scan release supporting documentation.

6. Quality Representative returns to desk to prepare file and upload release supporting documentation to SAP system.
7. Quality Representative sent an email to Requestor, Engineering, Operations, Quality and Planning personnel to notify that release has been completed.
8. Quality Representative delivers product release documentation in Record Retention Area.

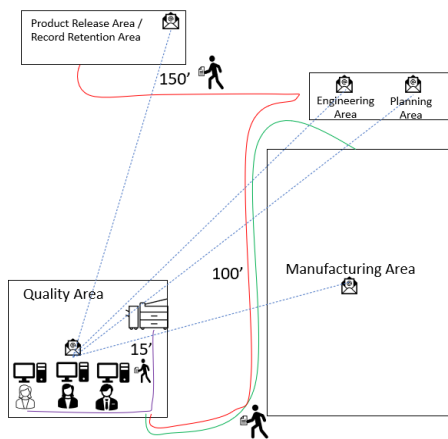
#### NC Monitoring Metric Report Process:

1. Create NC Monitoring Report using the current template and save file with current date of monitoring.
2. Verify status of all Open NCs reported last week are closed.
3. Update NC Monitoring Report to reflect change in status of Closed NCs.
4. Verify each Open NC for partial dispositions. A partial disposition consists in a NC that contains more than 1 Production Order where only some orders were dispositioned, and remaining orders are pending for disposition.
5. Update NC Monitoring Report to reflect partial dispositions in status of Open NCs.
6. Verify if each Open NCs contained product has an approved Product Disposition.
7. Update NC Monitoring report to reflect status of pending Product Dispositions execution.
8. Notify Owner of Approved NC Product Dispositions of pending activities associated to disposition (i.e., complete and deliver a request to close Open NC).
9. Add new NCs opened in the week under evaluation. The NC Monitoring report is conducted on a weekly basis.
10. Include description of each NC, including the following information: NC #, Investigation ID Number, NC Created Date, NC Event Description, Impacted Area, NC Owner, Product Disposition status, Quantity of Impacted Orders, Quantity of Impacted Units, Expected Closure Date (Creation Date + 15 days).

11. Count the total Quantity of Production Orders placed on Hold.
12. Count the total Quantity of units placed on Hold.
13. Identify Top 5 NCs with Nonconforming Product, this consists in identifying the NCs with a higher quantity of nonconforming product.
14. Create a Chart to add the quantity of units contained this week. The chart contains the data of 52 weeks of the year to identify any abnormal trend.
15. Send email to including NC Monitoring Report to Operations, Quality, Engineering and Planning Department.

**Phase: Analyze**  
**Spaghetti Diagram**

The spaghetti diagram showed the extra motion observed in the Product Hold/Release process. This diagram helps to understand the interaction between key areas/departments in the hold and release process. Some of the areas of opportunity are lines in a ‘C’ shape or ‘U’ shape, since require extra movements and must be changed to avoid those shapes to prevent extra movement, based on the requirement and if the facilities' limitations allow these improvements. The NC Monitoring Report under evaluation is generated and sent via email, where no extra movements were identified for this process.



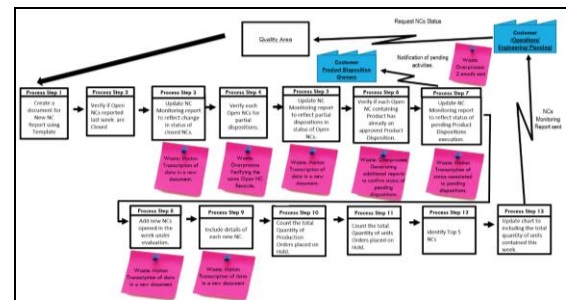
**Figure 2**  
**Spaghetti Diagram for Product Hold/Release Process**

**Value Stream Map (VSM)**

Understanding the process and as part of Kaizen activity, Value Stream Maps are created that show the process flow from the beginning, where the product manufacturing started and finishes in the final step of the process.

To generate a Value Stream, members from multiple departments collaborated and provided information of each process step. Cross functional team members identified as key resources to understand the process are Planning, Operations Department, Quality Department, Engineering and Product Dispositions owners. The current state map for the NC Monitoring Report Process was created by interviewing these key resources to understand the applicable processes and identify the waste. In addition, collect data of the cycle times of each process step.

Value Stream Map was created to show the NC Monitoring Report process flow from the beginning, where the customer requests the NC status until the report is sent to them. This activity helps to identify the non-value-added activities (from the customer’s perspective).



**Figure 3**  
**Current State – Value Stream Map: NC Monitoring Report Process**

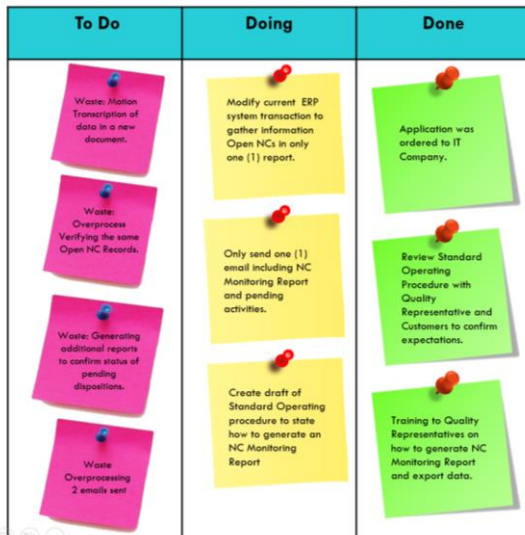
Value Stream Map helps to identify wastes that are occurring within an entire process sequence from start to the end of a process, through the identification of the value-added and non-value-added activities from the customer perspective. Once the non-value-added tasks are identified, projects can be defined to reduce this kind of waste.

Based on the current Value Stream Map, the non-value-added tasks were identified; therefore,

the improvements in the NC Monitoring Report process were focused on these process steps to reduce these wastes, overprocess and, motion. The wastes identified are the following:

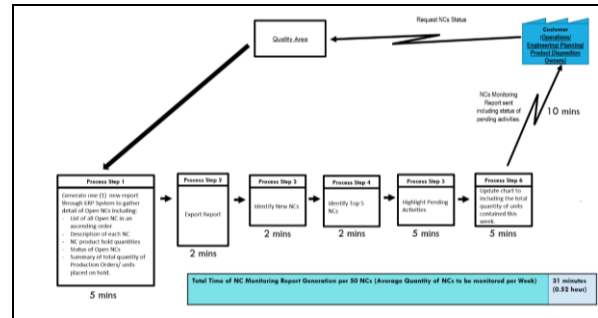
- Generating more than one (1) ERP System report to gather information associated to Nonconformance Records (NCs) and impacted product status.
- Verifying more than one (1) report to generate NC Monitoring Report.
- Transcription of information from different ERP System reports to NC Monitoring Report.
- Sending two (2) emails with a different audience, one (1) email to Product Disposition Owners and 1 email to Operations/Engineering/Planning Departments instead to send one (1) email.

Wastes to be eliminated are listed with the actions taken to eliminate each one, which includes the development of a new report, standard operating procedures, and proper training for the personnel in charge of the NC Monitoring Reports to embrace the continuous improvements and support the initiatives implemented. Therefore, the personnel will have the opportunity to execute according to new changes implemented due to the program and sustain the implementation.



**Figure 4**  
Wastes Identified in Current VSM and Improvements

A Future State – Value Stream Map was generated after the removal of wastes previously identified in the current state. This action helps us to understand how many process steps were eliminated and the impact of each process lapse time.



**Figure 5**  
Future State – Value Stream Map: NC Monitoring Report Process

After waste removal, there was a reduction from 223 minutes to 31 in the NC Monitoring Process, which represents a reduction of 86%.

### Five (5) S Evaluation

The workstation/area of Quality representative and activities required to complete Hold/Release Requests, Scrap Documentation Evidence, SAP Transactions, NC Metrics and supporting documentation was evaluated against Five s (5's) concept. Below are the key elements identified for the improvement of NC Monitoring Metrics and supporting documentation are the following:

#### Standardize

For Product Disposition:

- Implementing a standard process to ensure consistency in the requirements to complete product dispositions and close a Nonconformance Record. The standardization concepts reduce the potential time wasted looking for additional information not required to close NC records. In addition, this helps to reduce the risk of inadequate product disposition execution, including requests documentation or product disposition transactions.



For NC Monitoring Reports:

- Implementing a standard process to identify key elements to conduct the NC Monitoring report. For example, NC #, NC Disposition Owner, Event Area, Area Owner, Process Engineer/SME of associated area, Quantity of Impacted Product, NC Aging (Days since NC was created), Expected Closure Date, among others. This will help to standardize the NC Monitoring reports, reducing the misinterpretation of information and improving communication between departments.
- Define a frequency to share NC Monitoring Report among different departments. This action will help to clarify the expectations among different departments by implementing an expected frequency in a Standard Operating Procedure.
- Identify a standard mechanism that will be used to create, update, maintain and store the NC Monitoring Metric in the established frequency. This monitoring should be completed through contacting the NC Owner to understand what activities are pending to complete NC closure within the Expected Closure Date.
- Identify the Quality representatives responsible for monitoring NC records per manufacturing area. This requirement will help to identify focal employees to contact in case the disposition owner needs support, or any department needs a particular NC information.
- Identifying SME's (Subject Matter Experts) (i.e., Process Engineering) in the documentation of product disposition rationales per area and product type. This action will help to prevent any incorrect rationale reducing feedback in the reviewing process.

### **Sort**

Sort means organize and archive original NC documentation per NC Record Number to facilitate the identification of documents.

- In the NC Monitoring metric, organize the NC records by area, NC Owner. This will help to improve the visibility of what is the area with the highest impacted product on hold and monitor records effectively. Some of the waste that can be reduced is Motion, reducing additional movements to looking for NCs associated to a particular area or owner. In addition, there is a reduction in time of generating a NC Monitoring report and the customers will received this report in less time, reducing the waiting time.

### **Set in Order**

- Archive and organize NC documentation per NC Record Number in a sequential order (ascending order), improving the number's identification process.  
When documents are archived in a drawer, by identifying numbers from the front to the bottom of the drawer in an ascending order, this will optimize the productivity of the personnel during the NC documentation identification process and motivate the personnel to work better, since the numbers can be identified easily. Some of the waste that can be reduced is Motion, reducing additional movements to looking for a particular document in different workstations or cabinets instead of looking in a designated area.
- In NC Monitoring Metric, organize of NC Record Number in a sequential order (ascending order), improving the number's identification process.  
The NC Record Number is created in an ascending order, therefore, organizing the NC list in this order will help us to identify what are the NCs with the highest aging improving the visibility of what NCs have the priority of completion in terms of aging.

### **Shine**

In the NC Monitoring Metric table, if NCs are organized in a sequential order number, and each column includes a key element to monitor the status

of the records, this table must be visible and cleaned. A white background in the table and numbers with black color create a contrast which improves and facilitates the identification process. Shine concept improves the area to facilitate the organization process and if there is any situation can be identified easily to identify actions to correct the problem immediately. Some of the waste that can be reduced is Motion (reducing additional movements to looking for a NC number in case that dirt on the table). In addition, personnel feel more comfortable in a clean area.

### **Sustain**

- Maintain organization and archive the NC documentation since documentation is completed Record Retention area by implementing a Standard Operating Procedure. This action will require training the designated Quality Representative resources to correctly execute the NC Monitoring Metric. This action will help to archive records in a standardized manner, helping the identification of documentation for NC monitoring purposes reducing additional in the process Motion.
- Maintain organization of the NC Monitoring Metric by implementing a Standard Operating Procedure. This action will require training the designated Quality Representative resources to correctly execute the NC Monitoring Metric.
- Sustain concept is achieved keeping the implemented procedures and discipline which helps the disorganization in workplaces. Some of the waste that can be reduced is Motion and Overproduction (keeping the current processes will guarantee to prevent any additional motions and overproduction due to disorganization, and incorrect practices).

### **CONCLUSIONS**

The problem "Improvement in the Visibility of Nonconforming Product Inventory and Reduction" has been solved through the development of a new NC Monitoring Report and through the using an

ERP System, taking into consideration key elements to prioritize the Product Disposition Execution: NC description, Material Information, Quantity of Impacted order, and units, affected area, NC aging, among other relevant information.

The contribution of this research includes implementing an NC Monitoring Report that is generated in 86% less time than the original process and will improve the visibility of the non-conforming product in the storage areas, directly impacting Finish Goods' capacity inventory. This report will help the company to prioritize the execution of Product Dispositions with the highest quantity of time, improving the response time of the directly impacted departments, which includes the Planning Department and Operation Department and avoiding the impact of storage capacity, reducing the inventory.

Integrating a standard NC monitoring Report generated automatically from the ERP system, currently used to manage the material inventory and day-to-day business activities, reduces the risk of NC data collection and analysis. Therefore, the research scope is limited to a company that uses an ERP System capable of creating reports with the same capabilities, excluding companies that have only manual documentation.

For future research, optimize the rework process executions associated with non-conforming Products. Product disposition execution related to the reworking process could vary the process steps and completion time based on their complexity. Identifying and standardizing a rework execution process could help the manufacturing area's response time and NC aging reduction.

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