

Incidences of Incorrect Serial Number Labels

Maria de los A. Rodriguez Rivera
 Master of Engineering Management Program
 Héctor J. Cruzado, PhD, PE
 Civil and Environmental Engineering Department
 Polytechnic University of Puerto Rico

ABSTRACT

Since May thru July 2017, there were reported four – (4) instances of units shipped with incorrect serial numbers. It caused impact to quality metrics at local manufacturing site. Nevertheless, a local project was initiated to pursue a reduction of these shipped defects. DMAIC methodology was applied for this project, and the problem statement was the first step completed for the define phase. Then, the current state of the manufacturing process was evaluated as part of the measure phase. During the analyze phase, key inputs contributing to these defects were confirmed which allowed to start identifying improvements of the process. Finally, improvement process is taking place and controls such as the use of magnifiers, equipment controllers, integrated vision systems and reporting tools solutions were developed and some of them implemented on the corresponding process steps. Further, control phase will be monitoring the improved process to demonstrate the effectiveness of the improvements.

BACKGROUND

A project was initiated to pursue labeling process improvements at a local industry site dedicated to the manufacturer of medical devices. Since May 2017 to July 2017, there were reported four – (4) instances where units were shipped with incorrect serial number labels from the local manufacturing site. Two-(2) out for four-(4) instances were related to serial number labels of the units not matching the sterile tray serial number label; one-(1) instance was related to duplicated serial number labels and one-(1) instance related to serial number in the PTO label that did not match the serial number on the sterile tray label. It resulted in shipped defects which impacted quality performance.

OBJECTIVES

A reduction of 50% of non-conforming product related to this defect of incorrect serial number label is being pursued as part of the goal established in this project. The scope of this project will include local manufacturing site at PR, while other external manufacturing sites were out of the scope.

METHODS

Six Sigma DMAIC methodology was followed to perform project. This methodology provides several phases such as define, measure, analyze, improve and control which permitted a full mapping of the process.

The define phase was the first one completed for the project. Accordingly, a problem statement stated a situation where several units were shipped with incorrect serial numbers from a local manufacturing site. It resulted in shipped defects and therefore, quality performance of the site was affected.

The current state of the process and performance of the line were evaluated as part of the measure phase, and lack of detection controls for some steps of the process were observed. Two operation steps associated to these defects were assessed and Figure 1 presents some related pictures.

First process step is the serial number label generation and it was noticed the following opportunities:

- Serial number entry in manual form/manual traceability
- No verifications of the labels installed in the lead vs. the serial number documented in the manual form

Second process step assessed was the sterile pack operation, as follows:

- Serial number is manually entered system
- No verifications lead label vs. sterile pack label
- Line clearance has opportunities

METHODS

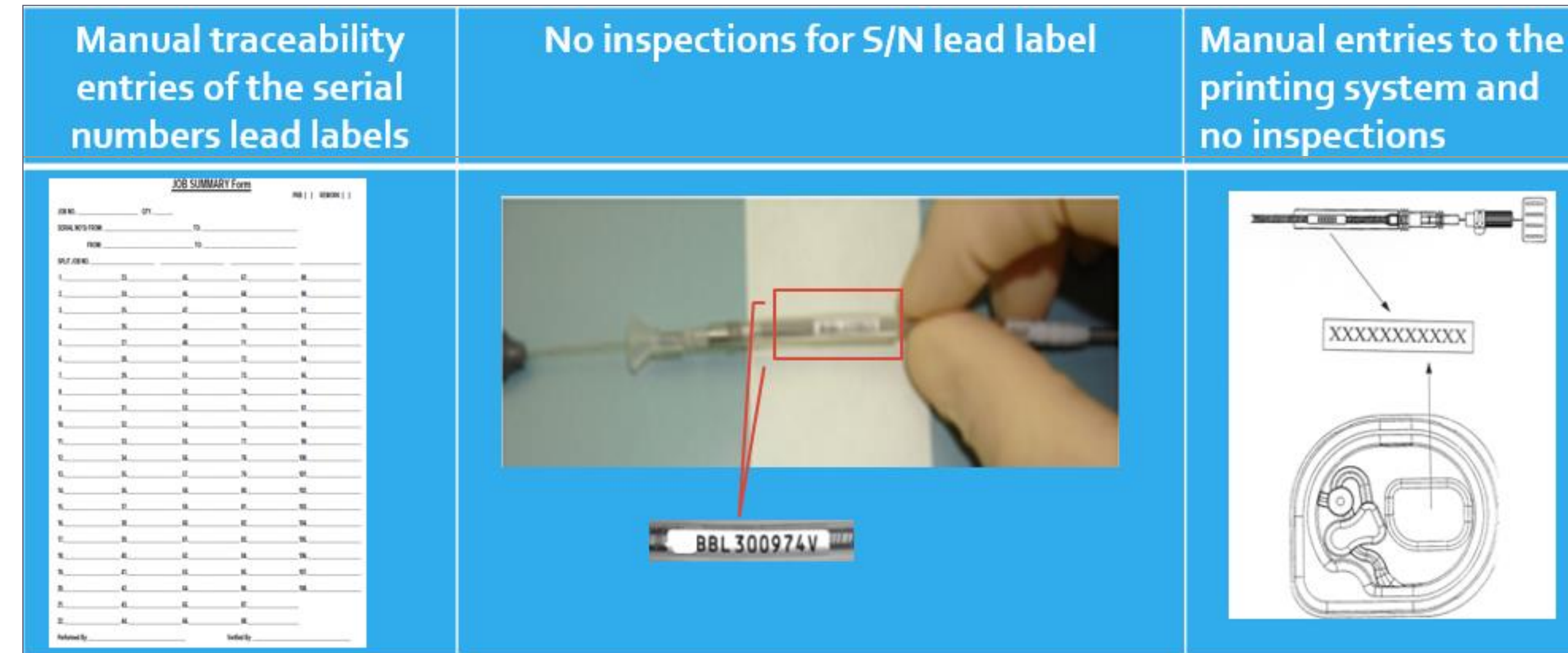


Figure 1

Pictures Showing Examples of Lack of Processes Controls

After evaluating the current performance of the line, it was also noticed an increased trending of these label defects as presented in Figure 2.



Figure 2

Incorrect Serial Number Labels Defect Rate

Cause and Effect Diagram methodology (Fish Bone Tool) was used to identify likely suspected factors (X's). There were three inputs associated to man factor and three inputs associated to method factor. Key inputs affecting the process were identified and confirmed as part of the analyze phase. Table 1 presents a summary of key inputs with their corresponding evidences.

Table 1

Key Inputs Affecting the Process

Input	Evidence	Key Input
Incorrect Serial Number entry in Traceability Documentation	The operator documents the serial numbers in a job summary form.	Yes
Duplicity of serial numbers processed	Two different systems at the label generation step process and sterile pack process that do not share the serial number information.	Yes
No specific controls for verifying that lead serial numbers match the sterile pack label serial number	Labels verification just to assure that serial number labels are legible	Yes
Serial number is manually entered for generation step and sterile pack step.	After serial numbers are entered there are no verification to assure correct entries	Yes
Physical Leads Swapped at Rework Operation	Traceability errors, no controls	Yes
Informal Process Flow for Rework	Traceability errors, no controls	Yes

RESULTS

Solutions and controls were identified to address the key inputs that were confirmed as part of the root cause analysis.

Serial number generation step improvement controls were implemented. An equipment controller (EC) that provides a user interface to automate the assignment of serial numbers to job during the labeling operation of lead manufacturing was implemented. Operator input errors can be detected because the input of data is directly performed to system which serial number is searching into a database to assure that serial number entered belongs to the sequence assigned to the lot being processed and to detect any duplication issue of serial number. In addition, a serial number report is being generated directly from the system to verify that serial numbers entered in the system match the installed serial number labels on the lead. This inspection is performed by using a magnifier which was also added as a tool for the process improvement. Moreover, manual form used to manually document serial numbers was removed. Figure 3 presents pictures of improvements elements at serial number label generation step.

In addition, sterile pack process was improved. MES integrated vision system EC that includes the sterile Pack vision application and equipment controller fixture that will interface with sterile pack vision application is being installed. This system will aid operators to print automatically sterile pack product identification labels once the camera as part of the vision system has read the serial number installed in the lead. Accordingly, operator input errors were eliminated because the input is automatically performed by a reading device which is a camera. EC will control the lot workflow, including the vision application execution, validation and verification of the scanning labels. Accordingly, EC won't allow to work on more than one lot at the same time, which added controls for the line clearance process. Therefore, this EC handles a vision application of optical character recognition that will now facilitate the operator task of printing correct labels and to complete the required traceability aspects in our Manufacturing Execution System. Figure 4 shows pictures of improvements at sterile pack process step.



Figure 3
Improvements at Serial Number Label at Generation Step



Figure 4
Pictures of Improvements at Serial Number Label at Generation Step

CONCLUSIONS

This project pursued at least a reduction of defects related to incorrect serial numbers labels installed in the devices and placed in the sterile pack as well as part of the process operations at local manufacturing site.

DMAIC methodology was followed and in this way problem statement was properly defined while process performance was assessed and opportunities were defined.

Then, systematic solutions were identified and at this point all were implemented. Accordingly, system installed at the first step of the process will allow to detect input errors at the moment of the execution and just correct labels with the corresponding serial numbers to the lot being processed could be installed at the lead. While at the second step of the process the operator input errors were eliminated because the input is automatically performed by a reading device which is a camera and no labels with errors will be printed.

So far, there is just pending one action to be implemented out of six ones, however, these improvements show effectiveness since it has not been reported new labeling issues related to incorrect serial numbers at this moment.