In-process Testing Redesign in Packaging Line of Oral Solid Dosage

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Abstract *— Packaging process area request to redesign the in-process testing to reduce waste and increase the efficiency during the in-process testing activities without increase in the defective unit found by Quality during their final sampling inspection neither increase, the complaint reports for the defect evaluated in the Capper Station. To identify the non-value activities and waste/reduction opportunities, a total of two years (April 2017 to April 2019) of in-process tests results of two products are gathered and statistically evaluated. Taking in consideration that testing results and quality historical data (deviation records, batch records) from those in process testing resulted in a low occurrence of quality events, and according to the switching rules described in the ANSI/ASQ Z1.4, the current sampling frequency (one sampling inspection every 30 minutes) can be changed the current normal inspection frequency (every 30 min) to a reduce mode inspection.*

Key Terms *— AQL, In-Process, Packaging, Testing.*

PROBLEM STATEMENT

The problem is to address the voice of the customers from packaging process, which request to reduce waste and increase the efficiency during the in-process testing activities without compromising the product quality.

Background

The current in-process testing requires a series of labor-intensive activities such as sample withdraw, visual inspection, measurement inspection thru the use equipment, documentation using data entry and artifact handling, units handling (discard or returned the tablet to the process as applicable). Following procedure "In-Process Testing of the Packaging Process" all those activities should be executed within a 30 minutes time interval of or less. Since the inspection frequency is every 30 minutes, the activities required to be performed as part of the in-processing testing by the packaging personnel consume or could extend the maximum time allowed by the procedure. Taking in consideration that the activities related to In-Process testing are considered as a non-value-added activity according Lean Manufacturing Philosophy [1], it was recommended to reassess the whole packaging process for identification of non-value activities or redundancy as well as the quality of the process of the packaging. The historical data (deviation records, batch records) from those in process testing resulted in a low occurrence of quality events, demonstrating that the packaging process present a high level of compliance against the quality requirements. In-Process testing are performed for each batch during a packaging process by packaging personnel.

A packaging process is divided in two areas: primary and secondary. Refer to figures 1 and 2 for the equipment in each primary and secondary process area [2], respectively.

The In-Process testing are performed in four stations: Capper, Retorque, Labeler and Bundle. In-process testing in the Capper station is performed in the Primary packaging area [2]. The Retorque, Labeler and Bundle In-process testing are performed in the secondary packaging area. The In-Process testing is performed in each station as follows:

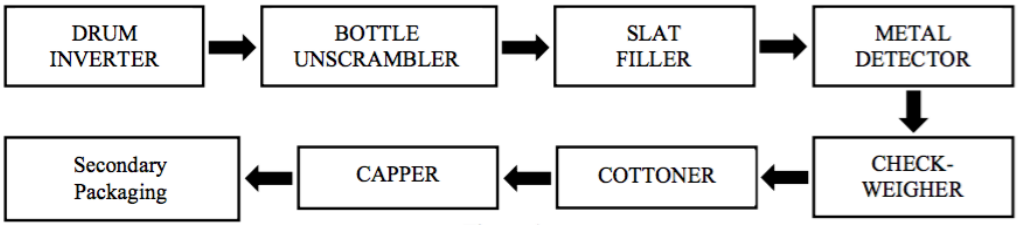

Figure 1

Primary Packaging Process Equipment

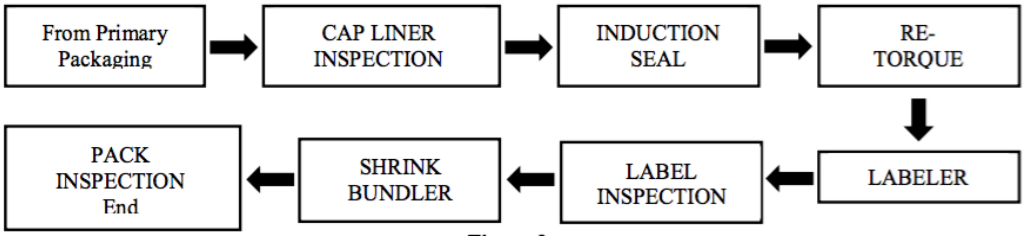

Figure 2

Secondary Packaging Process Equipment

- Capper station:
  - Cap and bottle appearance
  - Removal torque verification
  - Cotton presence verification
  - Tablet count verification
  - Appearance verification
- Retorque station:
  - Retorque verification
  - Cap induction sealing verification
- Labeler station:
  - Presence of correct outsets.
  - Presence of the correct label including product, dose, lot number and expiration date.
  - Evaluation of bottles for presence of global trade item Number (GTIN), serial number and two-dimensional (2D) code (on the label and bottle's bottom).
- Bundler station:
  - Bundle appearance (2 x3) verification.
  - Bundle label presence, presence of global trade item number (gtin), serial number and two-dimensional (2d) barcode in the bundle label.
  - Lot number presence and correctness.

From 2011 the sample size and the in process testing frequency in the four previously mentioned stations had been performed for 10 bottles every 30 minutes for the Capper, Retorque and Labeler stations, and 10 bundles every 30 minutes for Bundler station.

Two products are processed in the Packaging Line: POTTS and STARKS. Those products have different dosages and different quantity of tablets per bottle (count), and one product requires cotton. There is a total of six presentations or stock keeping unit (SKU). Refer to table 1 for the details in product presentations.

Table 1

Product Presentation

Product Name	Dosage	Count (tablets/bottle)	Cotton Required?
STARKS	30 mg	30	Yes
	60 mg		
	90 mg		
POTTS	5 mg	14	No
		60	
	7.5 mg	60	

Although, there are six SKUs, those SKUs share the product materials number. Refer to table 2 for the materials use during Primary Packaging [2] and their respective costs. Therefore, the parameters during the packaging operation for the equipment do not change between changeover of different SKUs.

Table 2
Materials and Costs

Product Name	Dosage	Count (tablets/ bottle)	Product Material No.[1]	Bottle Material No.[1]	Bottle Cost ($/units)[2]	Cap Material No.[1]	Cap Cost ($/units)[2]	Cotton Required?	Cotton Cost ($/unit)[2]
STARKS	30 mg	30	30-1507-30	29100	0.255	32761	0.070	Yes	0.010
	60 mg	30	60-1507-30	29100	0.255	32761	0.070		
	90 mg	30	90-1507-30	29100	0.255	32761	0.070		
POTTS	5 mg	14	05-3180-14	29100	0.255	32761	0.070	No	N/A
	5 mg	60	05-3180-60	29100	0.255	32761	0.070		
	7.5 mg	60	75-3180-60	29100	0.255	32761	0.070		

[1] Material numbers were modified for confidential purpose.
[2] Cost is estimated.

The scope of this project is the evaluation of the in-process testing at the Capper Station for POTTS and STARKS products.

A change of the frequency for the in-process testing will diminish non-value activities and will provide more time to the Packaging personnel to focus in other areas such as process improvement opportunities [1]. In addition, will decrease the scrap, optimizing the product yield. Consequently, the change of the in process testing frequency will bring a reduction in the cost related to the materials and manpower without compromising the product quality.

Define Phase: Voice of the Customer (VOC)

For this project the following requirements were established for the in-process testing:

- **For Operations:** The cost related with the in-process inspection should be reduce by at least 50%.
- **For Customers:** The product should comply with the customer expectation without compromising the quality and packaging functionality.
- **For Quality:** The redesign should not provide an increase in the defective unit found by Quality during their final sampling inspection neither increase, the complaint reports for the defect evaluated in the Capper Station.

METHODOLOGY

A multidisciplinary team was ensembled to gather historical data (from sources as batch record and inspection forms) of two products processed in Packaging Line Capper Station. To identify the non-value activities and waste/reduction opportunities, a total of two years (April 2017 to April 2019) of in-process tests results were gathered and statistically evaluated. The in-process inspection results from 22 POTTS and 82 STARKS batches were analyzed.

The data was tabulated and segregated by quality attribute defects. As well, the complaint historical data for the defect related to quality attribute that are verified in the Capper station were gathered and evaluated. In addition, the cost related to materials and manpower were identified since the in-process testing is considered waste, because it is inspection which does not add value to the product.

Collected Data – Quality Attribute

Table 3 presents the historical performance of POTTS products in terms of quality attributes. It can be noticed that for the whole period covered in the evaluation no defective units (bottles) were observed out of the 2,840 bottles inspected as part of the in-process quality inspection during a packaging process.

Table 4 presents the historical performance of STARKS products in terms of quality attributes. It can be noticed that for the whole period covered in the evaluation no defective units (bottles) were observed out of the 15,560 bottles. In addition, no defects related to torque removal, cap & bottle appearance, cotton presence, and tablets counts were observed out of the 15,560 bottles inspected as part of the in-process quality inspection.

Finally, in terms of defective bottles, no defective bottles were observed out of the 18,400 bottles inspected for both products (POTTS and STARKS).

Table 5 presents the historical performance of POTTS products in terms of quality attributes. It can be noticed that for the whole period covered in the evaluation no defects related to tablet appearance were observed during the in-process quality inspection out of the 143,720 tablets inspected.

Table 6 presents the historical performance of STARKS products in terms of quality attributes. It can be noticed that for the whole period covered in the evaluation one defects related to tablet appearance was observed during the in-process quality inspection out of the 466,200 tablets inspected.

Table 3
POTTS Product Quality Inspection Attribute Data (Unit = Bottle)

POTTS Products Summarized Data					
Total Quantity of Manufactured Batches	**Quantity of in-process test per lot**	**Total Sample units per lot**	**Total Torque Removal Defective Units**	**Total Cap & Bottle Appearance Defective Units**	**Total Tablet Count Defective Units**
22	284	2840	0	0	0

Table 4
STARKS Product Quality Attribute Data (Unit = Bottle)

STARKS Products Summarized Data						
Total Quantity of Manufactured Batches	**Quantity of in process test per lot**	**Total Sample units per lot**	**Total Torque Removal Defectives units**	**Total Cap & Bottle Appearance Defective units**	**Total Cotton Presence Defective Units**	**Total Tablet Count Defective units**
82	1556	15560	0	0	0	0

Table 5
POTTS Product Quality Attribute Data (Unit = Tablet)

POTTS Products Summarized Data					
Total Quantity of Manufactured Batches	**Quantity of in-process Test**	**Bottles per IP Test**	**Units per bottle**	**Total Sampled Units**	**Total Tablet Appearance Defective units**
22	284	10 bottles/IP test	3 batches -14 units/bottle 19 batches - 60 units/batch	143,720	0

Table 6
STARKS Product Quality Inspection Attribute Data (Unit = Tablets)

STARKS Products Summarized Data					
Total Quantity of Manufactured Batches	**Quantity of in-process Test**	**Bottles per IP test**	**Units per bottle**	**Total Sample Units**	**Total Tablet Appearance Defective units**
82	1554	10 bottles/IP test	30 units/bottle	466,200	1

Collected Data – Costs

The cost related to materials and manpower to perform the in-process check were gathered to evaluate the actual cost to perform the activity and eventually compare with cost after the Implementation of the redesign project (tables 7 and 8). The cost included in tables 7 and 8 do not include the tablet costs, the manufacturing process costs neither the packaging process costs.

Table 7
Cost Related to Perform In-Process Check for the POTTS Product for the Review Period

POTTS Products	
Batch Qty.	**Total Cost Per 22 Lot Prior Implementation ($)[1]**
22	5,913

[1] Cost is estimated.

Table 8
Cost Related to Perform In-Process Check for the STARKS Product for the Review Period

STARKS Products	
Batch Qty	**Total cost per 22 lot prior implementation ($)[1]**
82	32,396

[1] Cost is estimated.

RESULTS

Analyze Phase

There are four categories for defects: Critical, Major A, Major B and Minor. The worst-case scenario was used for this project and the assumptions were established considering all the defects as critical. Refer to tables 9 and 10 for the critical defect category sampling plan. These tables present the current acceptance sampling plan for Critical Defect.

Table 9
Normal Sampling Plan for Critical Defect (Bottles)

Normal Sampling Plan for Bottles			
Defect Category	**Sample Size**	**AQL**	**Acc/Rej**
Critical	80	0.064%	0/1

Table 10
Normal Sampling Plan for Critical Defect (Tablets)

Normal Sampling Plan for Tablets			
Defect Category	**Sample Size**	**AQL**	**Acc/Rej**
Batch size < 500,000 tablets			
Critical	800	0.0064%	0/1
Batch size > 500,000 tablets			
Critical	1250	0.0041%	0/1

OC Curve graphs were generated using the sampling plan scheme plan for Critical Defect of Bottles as well tablets as units of sampling. The OC Curve describes the discriminatory power of an acceptance-sampling plan. The OC curve plots the probabilities of accepting a batch versus the lot percent defective. An Operating Characteristic (OC) Curve was generated for each defect classification using an Acceptance Quality Level (AQL) of 95% and Rejectable Quality Level (RQL) of 10%.

Figure 3 presents the operating characteristic (OC) Curve generated using the sampling plan scheme plan for Critical Defect (units = bottle).

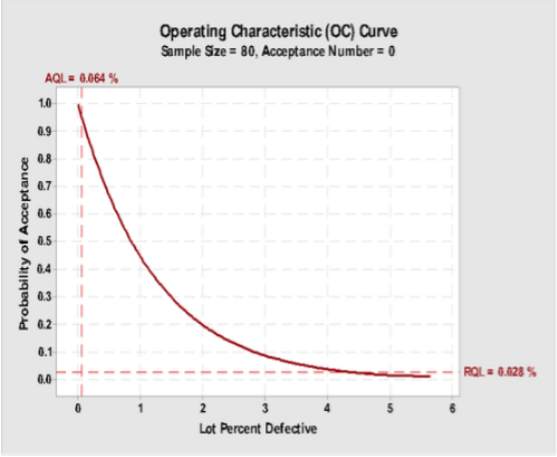

Figure 3
Operating Characteristic (OC) Curve for n = 80, Acceptance = 0 (units = Bottle)

Figures 4 and 5 present the operating characteristic (OC) Curve generated using the sampling plan scheme plan for Critical Defect (units = tablets).

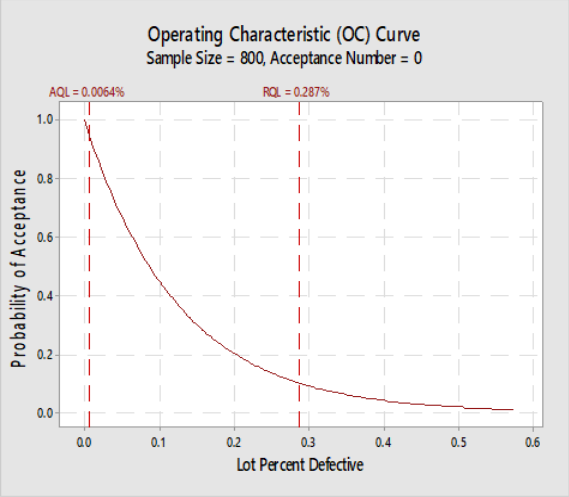

Figure 4
Operating Characteristic (OC) Curve for n = 800, Acceptance = 0 (batch < 500,000 tablets)

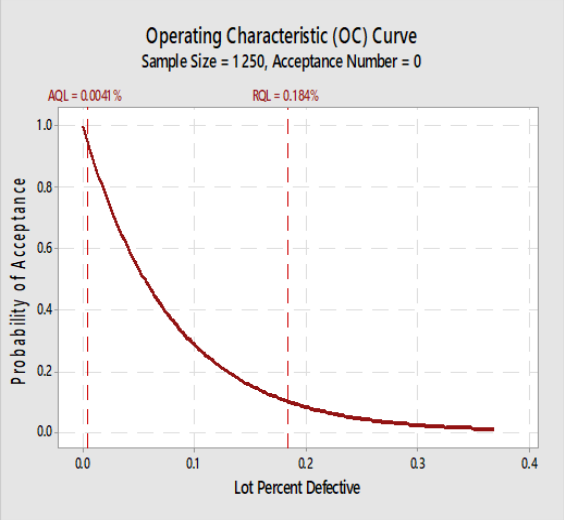

Figure 5
Operating Characteristic (OC) Curve for n = 1250, Acceptance = 0 (batch > 500,000 tablets)

The in-process inspection results from 22 POTTS product batches and 82 STARKS batches were statistically evaluated. The review period covered in this evaluation was from April 2017 to April 2019. The analysis showed the following:

- Summary of Defects Related to Caps and Bottle Appearance, Torque Removal, and Defective Counts for STARKS and POTTS Products (April 2017 to April 2019)
  - No complaints related to primary packaging defects has been received from the 22 POTTS product batches and 82 STARKS batches manufactured from April 2017 to April 2019.
  - A total of 18,400 bottles were sampled as part of the in-process inspection. No defects related to caps and bottle appearance, torque removal, and defective counts were observed out of the 18,400 bottles evaluated during the in-process quality inspection performed during the review period.
  - The upper 95% bound estimated for the percentage on defects related to caps, bottle appearance, torque removal, and bottles with defective counts observed (0.0163%) was significantly lower than 95% acceptable quality level AQL (0.064%) established for critical defects in Visual Inspection procedure.

Figure 6 presents the upper 95% bound estimated for the proportion of defects related to caps and bottle appearance, torque removal, and defective counts.

Test and CI for One Proportion

Method

p: event proportion
Exact method is used for this analysis.

Descriptive Statistics

N	Event	Sample p	95% Upper Bound for p
18400	0	0.000000	0.000163

Test

Null hypothesis	H_0: p = 0.5
Alternative hypothesis	H_1: p < 0.5

Figure 6
95% Bound Estimated – Caps and Bottle Appearance, Torque Removal, and Defective Counts

- Summary of Defects Related to Cotton Presence in Bottles for STARKS Products (April 2017 To April 2019).
  - No complaints related to cotton presence has been received from 82 STARKS

batches manufactured from April 2017 to April 2019.

- No defective units related to cotton presence were observed out of the 15,560 bottles inspected as part of the in-process quality inspection.
- The upper 95% bound estimated for the percentage on defects related to cotton presence observed (0.0193%) was significantly lower than 95% acceptable quality level AQL (0.064%) established for critical defects in Visual Inspection procedure.

Figure 7 presents the upper 95% bound estimated for the proportion of defects related to cotton presence.

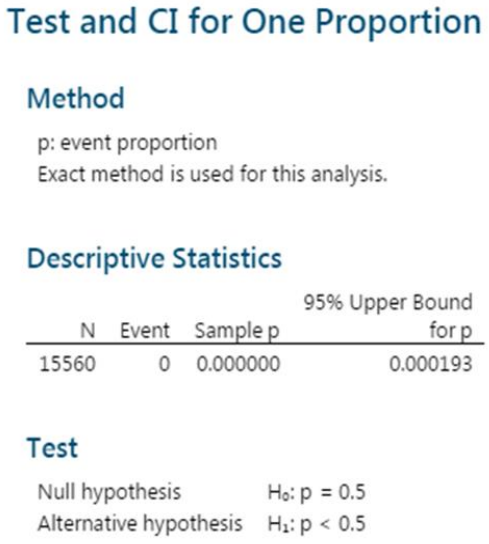

Figure 7
95% Bound Estimated – Cotton Presence

- Summary of Defects Related to Tablet Appearance for POTTS Products (April 2017 To April 2019).
  - No complaints related to tablets appearance defects has been received from 82 STARKS batches manufactured from April 2017 to April 2019.
  - For defects related to cotton presence, no defective units were observed out of the 143,720 bottles inspected as part of the in-process quality inspection.
  - The upper 95% bound estimated for the percentage on defects related to cotton presence observed (0.0021%) was significantly lower than 95% acceptable quality level AQL (0.0064% / 0.0041%) established for critical defects in Visual Inspection procedure.

Figure 8 presents the upper 95% bound estimated for the proportion of defects related to tablet appearance.

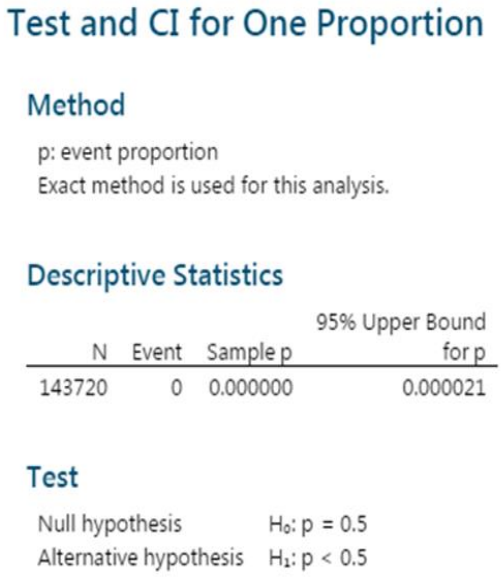

Figure 8
95% Bound Estimated – Tablet Appearance (POTTS Product)

- Summary of Defects Related to Tablet Appearance for STARKS Product (April 2017 To April 2019).
  - No complaints related to tablets appearance defects has been received from 82 STARKS batches manufactured from April 2017 to April 2019.
  - For defects related to tablet appearance, one defective unit was observed out of the 466,200 bottles inspected as part of the in-process quality inspection.
  - The upper 95% bound estimated for the percentage on defects related to cotton presence observed (0.0010%) was significantly lower than 95% acceptable

quality level AQL (0.0064% / 0.0041%) established for critical defects in Visual Inspection procedure.

Figure 9 presents the upper 95% bound estimated for the proportion of defects related to tablet appearance.

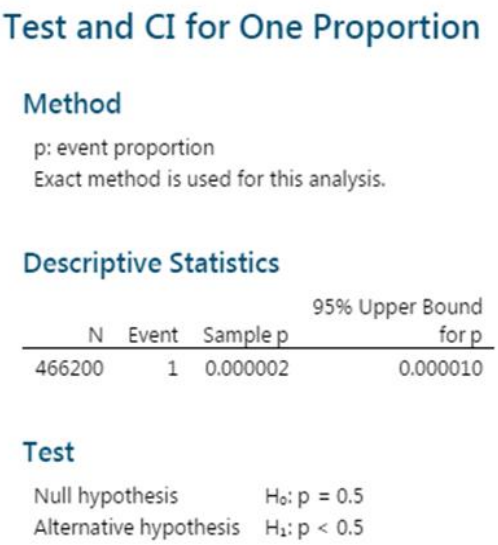

Figure 9
95% Bound Estimated – Tablet Appearance (STARKS Product)

Table 11
Comparison of Actual Vs After Project Implementation Cost for the POTTS Product

POTTS Products	
Total cost per lot prior implementation ($)[1]	**Total cost per lot after implementation ($)[1]**
5,913	**916**

[1] Cost is estimated.

Table 12
Comparison of Actual Vs After Project Implementation Cost for the STARKS Product

STARKS Products	
Total cost per lot prior implementation ($)[1]	**Total cost per lot after implementation ($)[1]**
32,396	**3,331**

[1] Cost is estimated.

In addition, to the evaluation above, a Cost Analysis was performed related to the cost of materials and manpower required to perform the in-process check. Refer to tables 11 and 12 for the comparison of the actual cost and the cost after the project implementation. The cost included in the tables below do not include the tablet costs, the manufacturing process costs neither the packaging process costs.

CONCLUSION AND RECOMMENDATION

The in-process inspection results collected from all POTTS and STARKS lots manufactured since April 2017 to April 2019 demonstrated (in terms of attribute defects) that the Primary Packaging Process [2] is capable of produce lots that will be consistently in compliance with the sampling plan acceptance criteria established for the monitoring of attribute defects in at least 95% of the time. According to the switching rules [1] described in the ANSI/ASQ Z1.4 [3], the current sampling frequency (one sampling inspection every 30 minutes) can be changed to a reduce mode inspection. This is feasible because comply with the minimum switching rule of 10 consecutively preceding lots in compliance with the in-process sampling acceptance criteria [1]. In addition, the inspection of the torque removal in-process monitoring can be changed from an attribute go/no-go inspection to a variable process control system (control charts).

Improvement Phase

The in-process sampling frequency can be changed from every 30 minutes to the first and end stage of each batch. This apply to all the attribute defects covered herein (caps and bottle appearance, torque removal, defective counts, tablets appearance, and cotton presence). This change will not compromise the detection level of the in-process inspection because the compliance capability demonstrated by the packaging process is higher than 95% against all the attribute defects evaluated herein.

The implementation of the propose sampling scheme represents a cost saving of approximately 90% from the current costs for STARKS and a cost saving of 85% for POTTS products.

Control Phase

Perform an Effectiveness Evaluation for the changes implemented in the primary packaging

process area [2] through the evaluation of the QA Sampling Inspection results. It established for a pre-determined period, where changes to any of the possible problem causes (machine, material, measurement, method, manpower & environment) should be controlled until completed the pre-determinate period.

Recommendation

Extend this evaluation to the Secondary Packaging Process area and evaluate the implementation of statistical process Control Charts for the removal torque inspection as preventive action tool.

REFERENCES

[1] J. A. Defeo and J. Juran, "Inspection, Test and Measurent" in *Juran's Quality Handbook: The Complete Guide to Performance Excellence*, 7th ed., McGraw-Hill Education, 2010, ch. 24, sec. 24.16.2.

[2] F. Lamb, "Process System and Automated Machinery" in *Industrial Automation: Hands-on*, 7th ed., McGraw-Hill Education, 2013, ch. 5, sec. 5.3.

[3] J. A. Defeo and J. Juran, "Inspection, Test and Measurent" in *Juran's Quality Handbook: The Complete Guide to Performance Excellence*, 7th ed., McGraw-Hill Education, 2010, ch. 24, sec. 24.16.