Quality Sampling Plan Re-Design for Secondary Packaging Operation

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Abstract

A significant decrease in the lot size has been observed year to year and volumes expected to increase by mid2021. Therefore, there was the need to evaluate alternatives to enhance the current Quality Assurance (QA) Inspection Regime to provide flexibility to the Secondary Packaging Operations. As part of the evaluation, sampling plan alternatives for the Cosmetic Defect inspection were evaluated, which can accommodate lot size variations, provide flexibility to meet service needs and avoid or minimize recruitment of further personnel because of expected volume increase. To archive this goal, it was required a reduction of 30% of the current cycle time for the QA audit process.

Using lean manufacturing principles and DMAIC methodology to develop this project, a reduction of a 62% in cycle time during the QA audit process was obtained. The implementation of this project exceeded the objectives of the project, sustaining the existing Quality Standards.

Key Terms — Sampling Plan, DMAIC, Quality Assurance audit, and Statistics.

Introduction

As part of the Secondary packaging process for a Medical Device Manufacturing Company it is required by regulation that a Quality Assurance (QA) audit is performed for each lot prior release as part of the final disposition process. This QA audit currently required an inspection of 13 samples per lot taken strategically (samples must represent the beginning, the middle and the end of the lot) for visual inspection (attribute/cosmetic defects) to assure product compliance. However, this QA audit can impact in the time for the product final disposition due to increase in volume, therefore, the improvement of this QA audit method can enhance the Secondary Packaging Operation.

Objectives

- Determinate the adequate cycle time for the QA audit process.
- Determinate which factors or variables can directly affect the cycle time and identify the opportunities to improve the QA audit methodology.
- Reduction of 30% of the current cycle time.

Methodology

DEFINE PHASE:
The company have seen an increase in the packaging volume but a decrease of the lot sizes, therefore, there is going to be more volume and more lots for final inspection.

MEASURE PHASE:
Process flow development to evaluate the current process. Also, data gathering regarding the current cycle time, for capability analysis and pareto chart to evaluate tendencies.

ANALYZE PHASE:
All data is evaluated to identified potential root cause by using problem solving tools such as cause-and-effect (Fishbone) analysis diagram.

IMPROVE PHASE:
Implementation of the corrective action to address and eliminate the root cause of the problem. Kaizen event to introduce rapid change using the ideas and motivation of the personnel.

Methodology

CONTROL PHASE:
Control the implemented action to correct the problem and assure that it is follow for future process execution. Actions such as standard operation procedure (SOP) change, QA audit release application update with new inspection plan.

Results and Discussion

QA Audit for cosmetic defect inspection as part of the release process in the Secondary Packaging Operation required the following sampling plan for minor defects consist with an Accepting Quality Level (AQL) = 2.81%, samples (n) = 13 / Accept (a) = 1, Reject (r) = 2). This AQL complies with Spec AQL's between 2.5% and 4.0% established in procedure for this type of defect. As part of the Measure phase of the project, the current cycle time was measured for the QA Audit process. Per Table 1, the QA Audit process has a total average time of 8 minutes/lot.

Table 1: Current cycle time for QA audit process

Time Study	Observations (mins)					
Lots	1	2	3	4	5	Average time (mins)
Operator Shift A	8.0	7.9	8.3	7.9	8.0	8.02
Operator Shift B	7.8	8.1	8.0	8.0	8.1	8.0
Operator Shift C	8.0	8.1	8.0	7.9	8.0	8.0
Operator Shift D	8.0	8.0	8.1	7.8	8.0	7.98
Total Average Time (mins)						8.00

Therefore, to obtain a reduction of 30%, the average cycle time must be approximately 5.6 minutes/per lot.
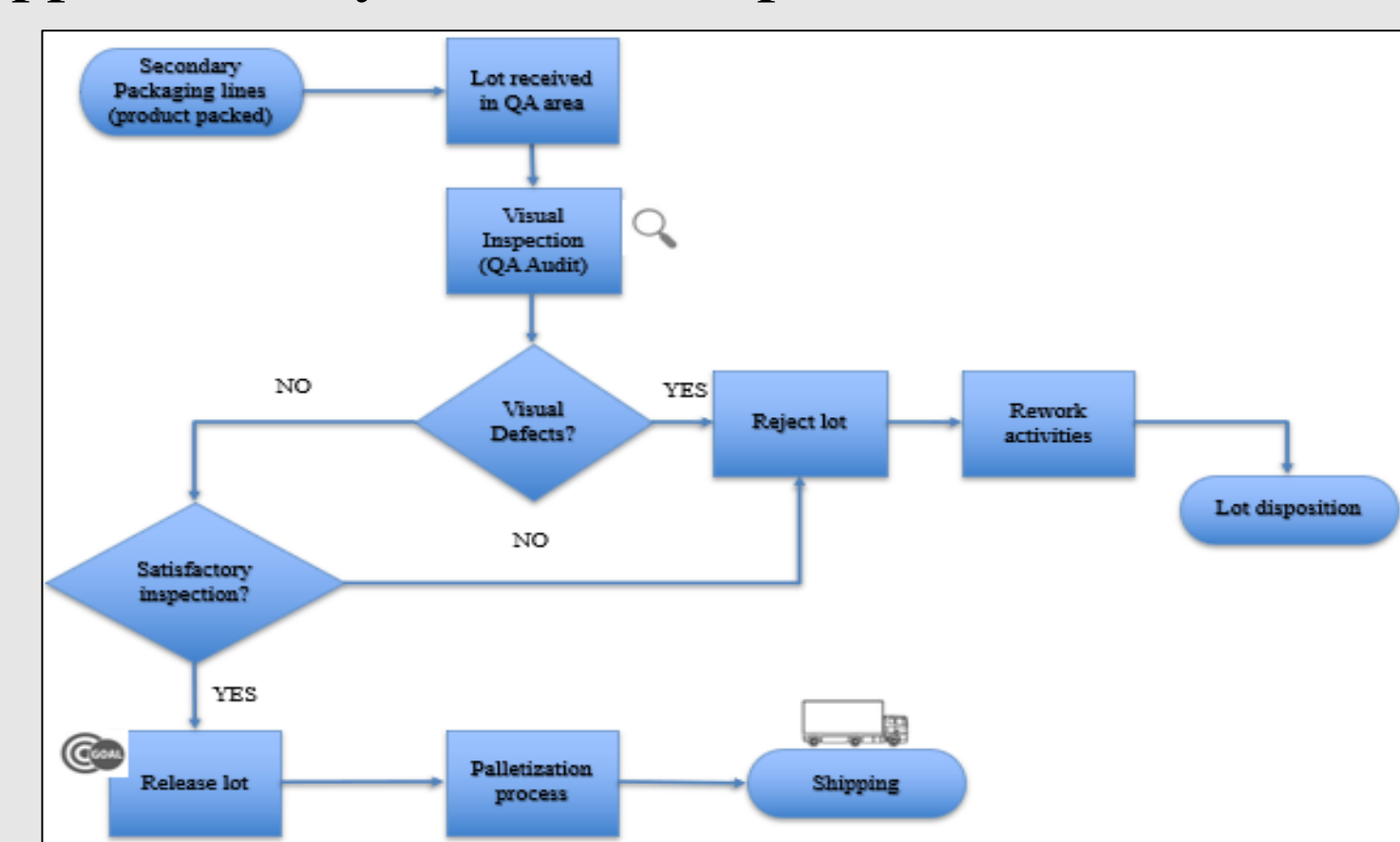

Figure 1: Process Flow Chart for the operations contained in the scope of this project

As part of the evaluation process, a process flow was developed (Figure 1), discussed with the impacted personnel (QC operators) for feedback regarding the QA audit process. The QCs were consisted that when they present more delay during the QA audit process was when packaging lines processed small lot. Therefore, the proposed process improvement was aligned to the sampling plan.

In the Analyze phase, to identifying a potential root causes, a cause-and-effect analysis was completed using a Fishbone diagram, refer to Figure 2.
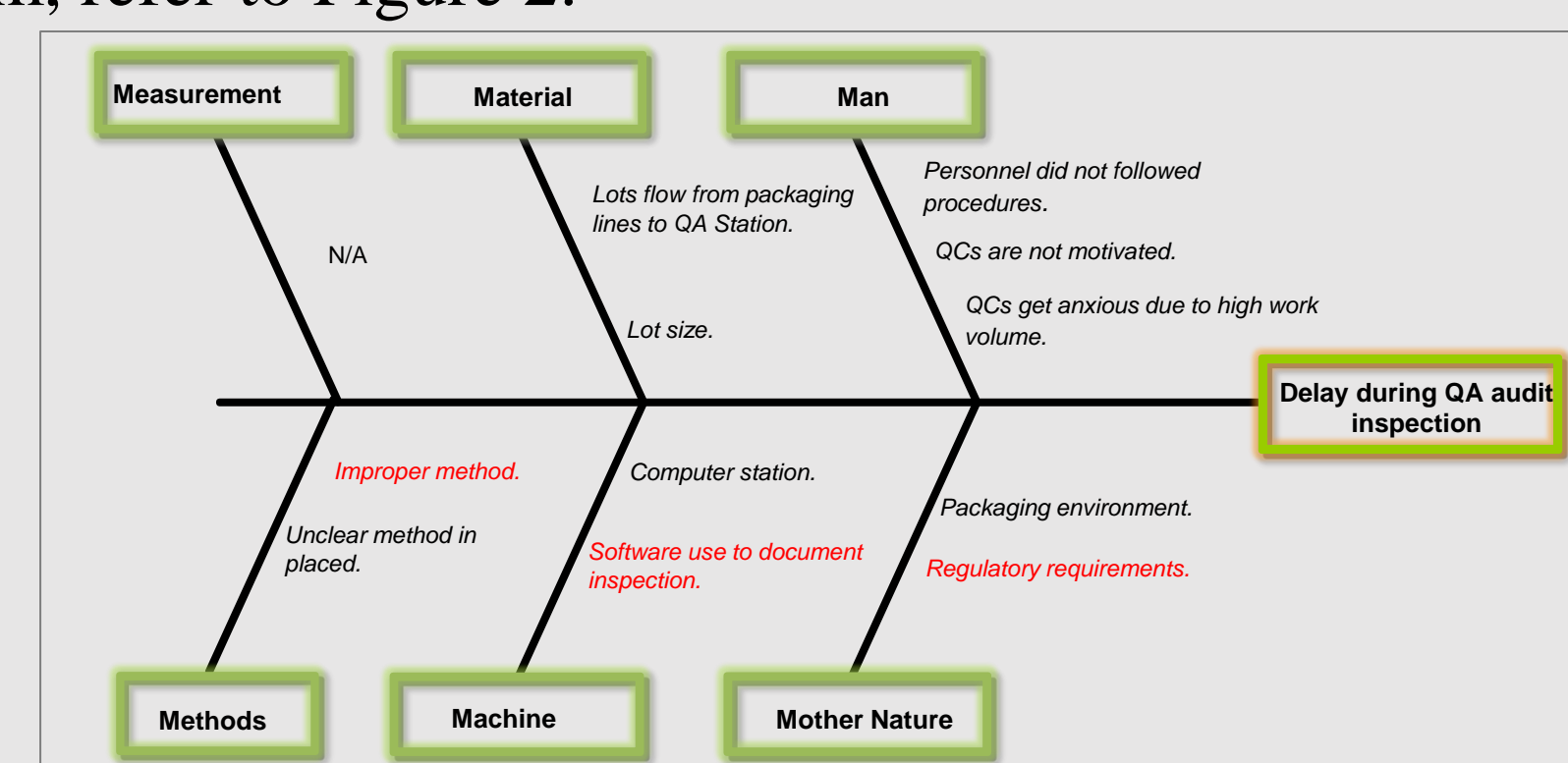

Figure 2: Fishbone diagram for the Cause-and-Effect Analysis

As result 3 out of the 11 potential causes brought during the cause-and-effect analysis, were taken to the next project phase, Improve, due to the high impact proven effect these have on the project.

Results and Discussion

Method:
Improper method – QA audit procedure was evaluated; visual aid segregation and inspection requirements, are detailed in procedure. However, an opportunity was identified in the sampling plan, since no matter the lot size the sample size is the same. For that reason, this alternative can be considered a factor that impact the QA audit process.

Machine:
Software use to document inspection – Software present limitation regarding the QA audit requirements, therefore, this alternative is not a root cause for this issue. However, if the sampling plan is change, the software needs to be update.

Mother Nature:
Regulatory Requirements – As part of the regulation it is required that prior releasing the product to the market the company must assure the product comply with quality standard and the product is safe to be use.

Based on this assessment it was observe that the higher impact was related to the sampling plan. Therefore, it was decided to modify the sampling plan requirements through a QA audit process deviation (effective in February 2021) for data gathering and evaluation of the QA packaging inspection process in the Secondary Packaging Operation.

To identify an adequate sampling plan in which comply with product requirements, statistical analysis was performed evaluating different scenarios, taking in consideration the operational characteristic (OC) curve, the Average Sample Number (ASN) curve and the Average Outgoing Quality (AOQ) curve. This evaluation was performed to evaluate behavior of the different sampling plans versus the current sampling plan. This analysis was performed with two different sampling: Single sampling: n = 5, A = 0, R = 1; AQL = 1.02%, LTPD = 36.9 and Double Sampling: n1 = 8, a1 = 0, r1 = 2; n2 = 8, a2 = 1, r2 = 2 AQL = 2.60%, LTPD = 27.0, AOQL = 6.02.

The following graphs (Figures 3, 4 and 5) represents a comparison of current sampling plan versus proposed sampling plan to evaluate the potential impact.
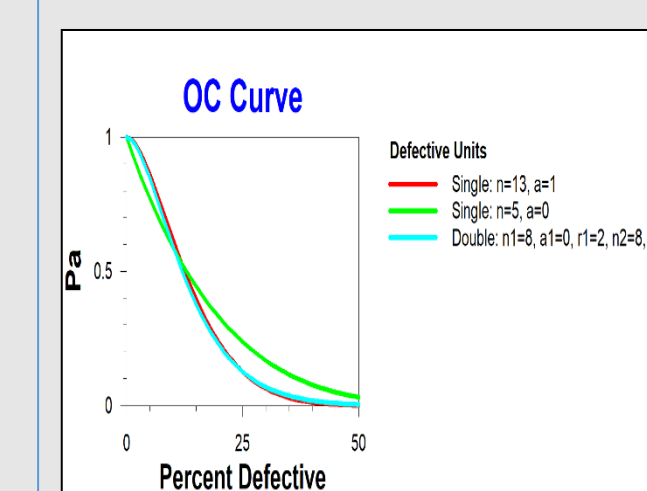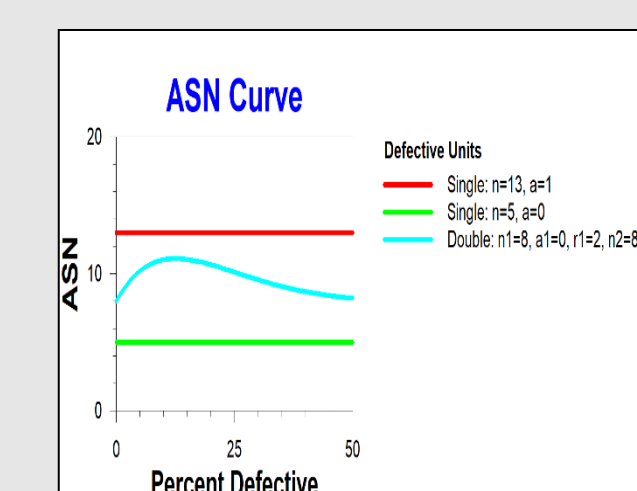

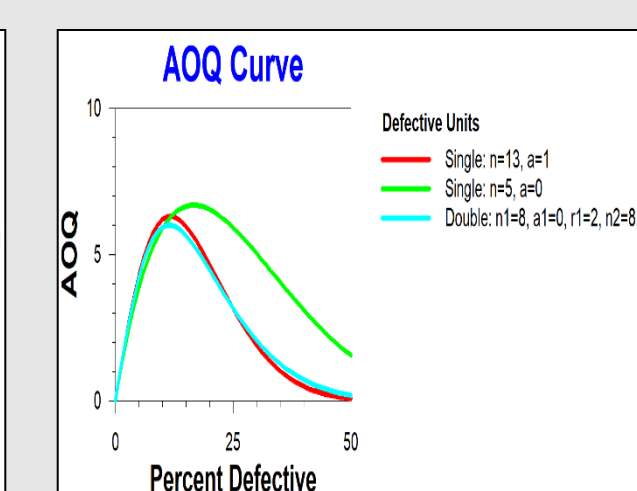**Figure 3: OC Curve**   **Figure 4: ASN Curve**   **Figure 5: AOQ Curve**

Sample Decrease by Individual Lot (single sampling))	Double Sampling /Pooled Sampling
Benefits - Quick and simple implementation (QAI) software and SOP updates. - Efficiency increase (inspect 50% less of samples per lot/same or less resources). **Challenges** - Lot will be rejected irrespective of condition severity. - Defect per million (DPM) results may be higher because of a smaller base of samples.	**Benefits** - Provide a second opportunity to the lot before initiating a Non-conforming report (NCR). - Efficiency increase (~70% less sample inspection) **Challenges** - Software changes are required. Solutions takes longer to implement. - All lots sampled hold until reprocess is completed. - Adds complexity to inspection. (Induces error)

Results and Discussion

After evaluation it was decided to proceed with the new proposed sampling plan (Table 2). This AQL complies with Spec AQL's between 2.5% - 4.0% and 0.25% - 1.0% established in procedure for this type of defect.

Table 2: Proposed Attribute Single Sampling Plan

Classification / Severity	Sampling Plan
Minor / 1 & 2	n = 5, a = 0, r = 1 / AQL = 1.02%, LTPD = 36.9
Major / 3 & 4	n = 5, a = 0, r = 1 / AQL = 1.02%, LTPD = 36.9
Critical / 5	Critical conditions are inspected during QA Audit for the carton(s) content inspection and are not change by this modification.

As result it was observed an increase of the Defects per million (DPMs) during the QA audit process, refer to Figure 6. In addition, Packaging Defects Trend chart corresponding to Feb 2021, was assessed; no adverse trend was identified, it shown to be that the process in under control. Refer to Figure 7.

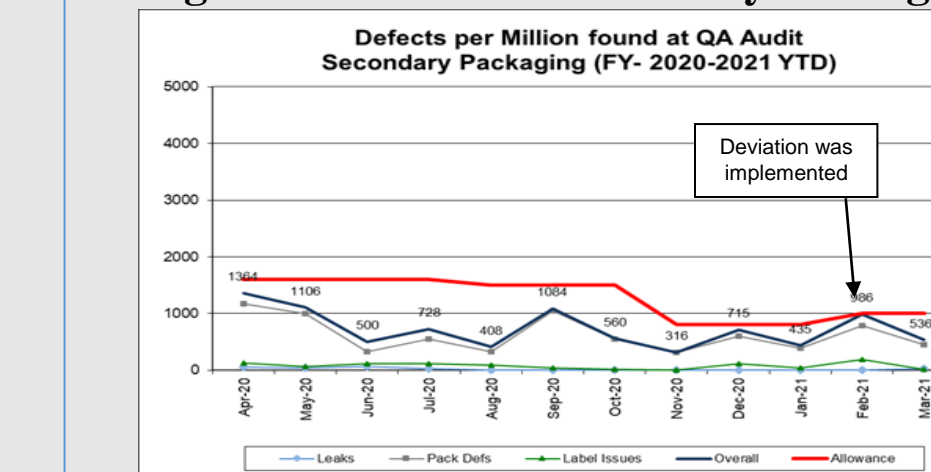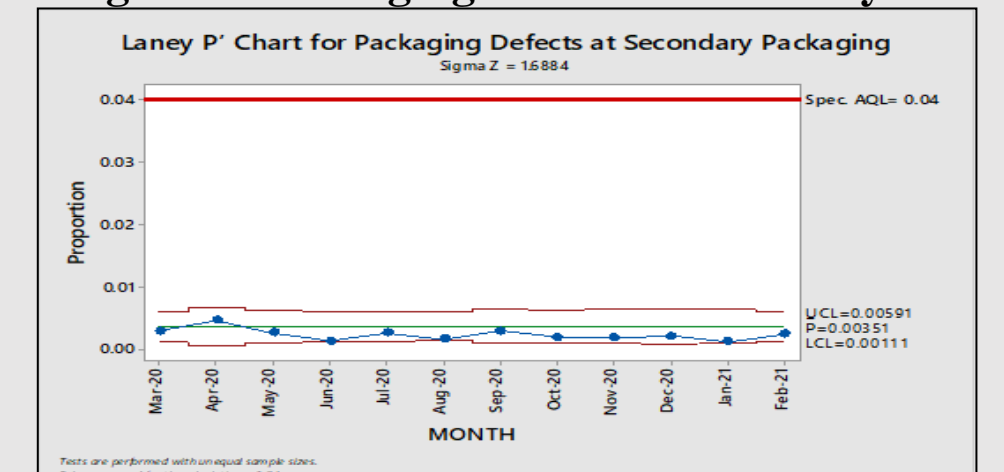**Figure 6: DPMs for Secondary Packaging**   **Figure 7: Packaging Defect Trend Analysis**

Conclusions

The Quality Sampling Plan Re-Design for the Secondary Packaging Operation was successfully completed with excellent results. The improvement in the total inspection cycle time was achieved from 8 minutes per lot down to 3 minutes per lot, which represents an improvement of 62%. This exceeds the project objective of improving the time by a 30%. In addition, there was an increase of 40.5% of the amount of lots release per month (Figure 8). Which means that there is no need to increase the personnel, since this new process can manage the increment in volume and sustain the existing Quality Standards.
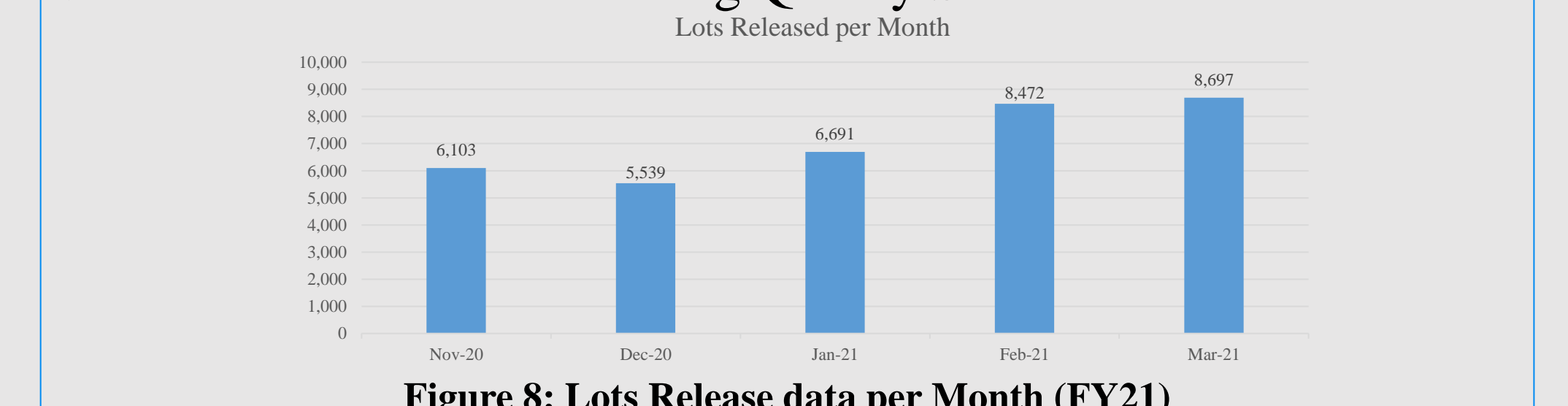

Figure 8: Lots Release data per Month (FY21)

Based on this assessment, modifying to the proposed sampling plan does not present adverse effect in the secondary packaging process and does not affect safety or performance of the product. Impacted procedures were revised under the Document Change Order procedure.

References

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