Improvement of production quality of trays to collect Covid-19 diagnostic samples from airlines passengers

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Abstract. The objective of this research is to study guidelines of defects reduction in producing trays for collecting test tube of Covid-19 diagnostic samples. The goal is to limited defects from thermoforming process at less than 3,000 defect part per million (DPM) with Cpk ≥1.33. Current sigma level is ≥4, reduction methodology has been preceded by following DMAIC of Six Sigma techniques and simulate by general full factorial design for experimenting. The results showed that to reduce DPM in plastics thermoforming process was contributed from controlling level of heat temperature at 230-320°C and forming duration of 2 seconds. Defect is reduced from 0.0153 to 0.0062. Process capability index is improved from ≥ 1.17 to ≥ 1.33 and level of sigma has increased from ≥ 3.5 to ≥ 4.

1. Introduction

This study aims to manage defect reduction in plastics thermoforming production process of trays for collecting test tube of Covid-19 diagnostic samples to enhance production quality and costs reduction. Plastic packaging industry operators in Thailand have been suffered by the Covid-19 pandemic, in terms of plastic cost, labor cost, and operations cease in accordance with Thai national shut down policy. Therefore, manufactures must adapt while also prepare the enterprise to emerge stronger by improving production process to reduce defects. As analyzing basic data collected, it was found that the section of trays for collecting test tube of Covid-19 diagnostic samples production has too high defects for the factory set target. There are 4 types of defects founded, which are (1) incomplete forming (2) unequal material distribution (3) uneven thickness, and (4) leakage. The most popular approach for solving these problems is using Six Sigma principle to minimize production errors, thus reduce production costs. In many leading organizations, Six Sigma approach is deployed to increase capability of business processes. Trust level based on the Six Sigma concepts are shown in table 1 [1]. Comparative study period are from January 10 to April 10, 2020 and from April 11, to July 11, 2020.

Table 1. Six Sigma thresholds with reliability levels based on defects per million

| Sigma level | Reliability level | DPM | Sigma level | Reliability level | DPM |
|-------------|------------------|-----|-------------|------------------|-----|
| 1           | 30.2327          | 697,672 | 4          | 99.3790          | 6,210 |
| 2           | 69.1230          | 308,770 | 5          | 99.9767          | 233  |
| 3           | 69.3189          | 66,810  | 6          | 99.9997          | 3    |

Table 1. Six Sigma thresholds with reliability levels based on defects per million
2. Theoretical and Analysis
Thermoforming is an industrial process in which plastic sheets are heated and then formed into useful product [2]. Plastic forming techniques can be done in three different methods, which are blow or vacuum forming, mechanical forming and combined the two methods. Then, cool down the formed plastic sheet for retaining its shape, and finishing work piece by cutting or circumcision. The remaining plastic waste is collected and recycled back into the process to make new plastic sheets. Finishing products can be painted, printed or glued according to customers’ needs. Common raw materials used are plastic films with thicknesses between 0.1 to 12 millimeters. Plastic sheet is being stretch up to 5 times as much. Thermoforming process has advantage of low machine cost, low mold cost, low temperature and pressure requirement, ability in produce large piece product and fast forming cycles [3]. Defect activities are assessed through; using a check sheet to collect based data from the production process, choosing problems to be solved by the 80:20 rule of Pareto diagram, and finding causes of problem by using cause-effect diagram [4]. Proposed guidelines for problem solving have been done by using PDCA principles. Many activities that can reduce defects, these are including working principles, work procedures improvement, and work development programs such as staff training, manual creating, machine maintenance scheduling, and activities scheduling etc. [5]. Khan, Dalu and Gadekar illustrated ways to improve production processes by controlling key parameters of machine operation condition; forming temperature, screw feeding speed and quality of raw materials [6].

Six Sigma Principle is a concept focused on continuous quality improvement by reducing as much as possible defects and wastes in production process for producing acceptable work pieces [7]. Define, measure, analyze, improve, and control (DMAIC) is a data-driven quality strategy used for process improvement. If inputs are controlled properly, product defects would be reduced. Complicate process improvement prefer to used full factorial experimental design, for handling many factors at once to reduce time and cost [2]. Several researches have been applied Six Sigma approaches in manufacturing industries i.e., “Reducing defect in the manufacturing process of plastics factory by applying Six Sigma methodology” [8], “Revolutionize work processes with Six Sigma techniques”[2], and “Modeling and real-time control of sheet reheat phase in thermoforming” [9], their study conclusion are shown in table 2.

| Process | Activity | Tool |
|---------|----------|------|
| Define phase | Define problem by Develop problem statement, goals, process mapping, and their requirements. | Check sheet, Pareto diagram and graph |
| Measure phase | Create a plan to collect data according to current process. | Measure system, Checklists |
| Analyze phase | Analyze the process, identify cause of problems. | Cause-effect diagram, brainstorming technique |
| Improve Phase | Verify solutions and select the best solutions. Set up a plan. Manage and monitor Implementation. | PDCA testing cycling and Hypothesis test |
| Control Phase | Establish mechanisms for controlling situations. | Response plan and check sheet |

3. Methodology.
The study of defects reduction in the forming process of producing trays for collecting test tube of Covid-19 diagnostic samples consists of 5 steps, as shown in figure 1.
Figure 1. The design flow with DMAIC model.

Step 1 Define the problem and objectives. Study the quality control report of defects for three months, between January 10, - April 10, 2020. Create a bar chart to prioritize defects from the highest to least amount. Next, classify the defects generated and calculate its percentage and cumulative percentage. Then, create a Pareto diagram to select the problems affecting production quality the most. Use Pareto rules (80/20) to help prioritize and choose important problems to improve [10].

Step 2 Measurement. Analyze measurement systems and capabilities of the factory's production process, which consists of 5 tasks, i.e.,
1. Prepare plastic sheet for thermo-forming by using information from production planning documents.
2. Mold assembling, cooling water system set up, other support systems set up, and adjusts machine parameters according to product specifications.
3. Forming trays consists of 3 main steps: heating the plastic sheet, use vacuum and compressed air systems for forming, and cooling down the work piece.
4. Inspect the work piece in 3 aspects which are external characteristics, leakage, and thickness.
5. Packing and send to warehouse. Process capability measurement is a proof of processability in its current state indices by sigma level. Analysis beginning with calculating the maximum defects ratio, and then calculate the sigma level and compare with the Process Capability Analysis (Cpk) as shown in Table 3.

Table 3. Mathematical Comparison of Sigma Capability

| Sigma level | 1.5 | 3.0 | 3.5 | 4.0 | 4.5 | 5.0 | 6.0 |
|-------------|-----|-----|-----|-----|-----|-----|-----|
| Cpk         | 0.50 | 1.00 | 1.17 | 1.33 | 1.50 | 1.67 | 2.00 |
| Definition  | Need immediate improvement | Hard to control, should get improve | Good |

Step 3 Analysis the process. Analyze the nature and cause of defects by steps as follow, (1) Analyze root cause by using cause-effect diagram, brainstorming of quality inspector group with 5M1E analysis, raw materials, machines, methods, man, mold and environment. (2) Analyze trends, defects and impacts on products or production processes. Assess the risk with other defects and then prioritize the defects found.

Step 4 Improve. Verify solutions and select the best solutions by
1. generate full design of factorial experiments to specify more than 2 factors at more than 2 different levels
2. do Hypothesis testing to prove work piece leakage and conformed thickness with 95 percent significance level. Then implement and monitor solution activities properly.

Step 5 Control. This phase is to ensure that the previous gains were achieved. The steps of control phase are: (1) Establish key metrics to avoid existing of same problems. (2) Develop the control
strategy. (3) Celebrate and communicate success. (4) Implement the control plan. (5) Measure and communicate improvement [11].

4. Results

**Step 1. Define phase.** From data collected on normal production indicated that the quality of product decreased and too many defects from production existed.

**Step 2. Measurement phase.** 4 quality control staff inspect quality of work pieces by visual inspection at regular lights and with bright lights.

Table 4. Amount of defects in the molding process during Jan10-Mar10, 2020

| Month | No. of produce | Problem | No. of defects (Pcs.) | No. of defects per million (Pcs.) | % of defects |
|-------|----------------|---------|-----------------------|----------------------------------|-------------|
| Jan   | 271,132        | Incomplete forming | 573                  | 1,526                            | 2.96        |
|       |                | Unequal material distribution | 250                  |                                  |             |
|       |                | Uneven thickness | 5,671                 |                                  |             |
|       |                | Leakage      | 8,020                 | 9,580                            |             |
| Feb.  | 442,374        | Incomplete forming | 986                  | 1,389                            | 1.40        |
|       |                | Unequal material distribution | 468                  |                                  |             |
|       |                | Uneven thickness | 3,364                 |                                  |             |
|       |                | Leakage      | 6,207                 | 14,031                           |             |
| Mar.  | 401,203        | Incomplete forming | 1,050                | 1,360                            | 1.73        |
|       |                | Unequal material distribution | 753                  |                                  |             |
|       |                | Uneven thickness | 3,762                 |                                  |             |
|       |                | Leakage      | 6,925                 | 17,261                           |             |
| Average| 371,570        | Incomplete forming | 870                  | 1,425                            | 2.03        |
|       |                | Unequal material distribution | 490                  |                                  |             |
|       |                | Uneven thickness | 4,265                 |                                  |             |
|       |                | Leakage      | 5,717                 | 20,291                           |             |

Table 4 showed type and number of defects from production between 10 Jan-10 April 2020, most of defects were uneven thickness and leakage; followed by incomplete forming and unequal distribution work pieces. At this stage, calculation of sigma level of the passed production, there were 5,717 individual defects per month or 20,291 DMP per month, which was too high, at sigma level 3.5 or the process capability analysis index (Cpk) 1.17. Next, determine which parts of the process have the greatest opportunity for improvement with Six Sigma techniques. For this project, defects per month were set of not exceeding 3,000 DMP.

**Step 3. Analysis phase.** Analyze the data collected, determined causes of problems and proposed solutions. Root causes of uneven thickness and leaky work defects in forming process come from 6 reasons, which are
1) inexperience staff,
2) under specification plastic,
3) under specification mold,
4) improper machine maintenance,
5) improper parameters setting; wide temperature range, improper time for vacuuming and air pressure for effective forming, and
6) unstable air humidity. Causes analysis from quality control staff found that heating temperature is too high and the molding time is too long, results shown as table 5.

Table 5. Results from root cause analysis 5M1E

| Factor     | Problem causes                                | Characteristic                           |
|------------|-----------------------------------------------|------------------------------------------|
| Man        | Lack of expertise                             | Wrong machine adjustment                 |
| Material   | Incorrect feeding plastic into the screw.     | Leaky and uneven thick work              |
| Mold       | Mould size is not as specified                | Unequal material distribution            |
| Machine    | Lack of maintenance                           | Machinery break down/ work not properly. |
| Method     | Too long heating time or intensity             | A lot of defects occurrence              |
|            | and too long vacuum timing.                   |                                          |
| Environment| Unstable temperature and humidity             | Incomplete forming, poor detail          |

**Step 4. Improvement phase.** This phase consist of statistical experimental design test, Hypothesis testing to confirm results, general full factorial experiments is used in order to find the most suitable machine
setting factors [12]. It was found that forming time affects uneven thickness and leakage defects. The shorter forming period produce lower defect. Appropriate temperature produces less of uneven thickness and leakage [13].

**Step 5. Control phase.** Six Sigma approach has potential in achieving goals [14, 15], at this phase implement solutions and tracking success can be done by control strategy. This study proposed the improvement of trays production as here: establish machine operation standard, forming temperature at 240-320 °C and forming time at 2 seconds [16]. Then distribute this document to the operators to use in adjusting the machine correctly.

### 5. Conclusion and recommendations

Quality production improvement of trays for collecting test tube of Covid-19 diagnostic samples by reducing defects in the plastic forming process, which applied the Six Sigma approach reviled that, the problems can be eliminated by reducing heating time and adjusting vacuum or pressure timing. Factors reducing defects of uneven thickness and leakage are heating at 230-320°C and 2 seconds forming time. These two factors allow the factory to reduce defects from 0.0153 to 0.0062 and increase Cpk value in the production process from ≥1.17 to ≥1.33 as showed in table 6.

#### Table 6. Process improvement comparison

| Key Metrics                      | Before improvement | After improvement |
|----------------------------------|--------------------|-------------------|
| Avg. work piece produced per month (Pcs.) | 371,570            | 542,835           |
| No of defects per months (Pcs.)   | 5,717              | 1,016             |
| Percentage                       | 0.0153             | 0.0062            |
| Cpk.                             | ≥1.17              | ≥1.33             |
| Sigma level                      | ≥3.5               | ≥4                |

Techniques used in this research for solving defects problems can be apply with other processes with similar problems.

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