NIPES

Journal of Materials Engineering, Structures and Computation

Journal homepage: www.nipesjournals.org.ng

Development of a Quality Control Chart for Phase II Product Net weight monitoring in a Manufacturing Enterprise

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ARTICLE INFORMATION

Article history:
Received 21 February 2025
Revised 05 March 2025
Accepted 12 March 2025
Available online March 2025

Keywords:
Quality Control charts; statistical process control; phase II; parameter estimation; product net weight; quality monitoring.

https://doi.org/ 10.5281/zenodo.15028195

ABSTRACT

In order to meet regulatory requirements, reduce rework and scrapping of completed goods, and maintain competitiveness in the current global and competitive economy, manufacturers need to come up with a way to monitor important aspects of manufactured goods in real time and make sure they remain within predetermined control limits. Therefore, in light of regulatory regulations regarding the net content of packaged goods, the goal of this study is to create quality control charts that are appropriate for deployment in phase II product net weight monitoring and subject to only common causes of fluctuation. The Minitab 2021 statistical software package was used for data analysis. The X-bar-S chart was used to investigate process stability and variability. Also, probability plots, process capability analysis, and the summary report obtained from the dataset, as well as the β-risk and the Average Run Length (ARL), were useful tools guiding the effective deployment of the X-bar chart for phase II product net weight monitoring. The probability of detecting a shift in the mean of the manufacturing process was found to be 95% with an ARL of one, which informs us that the process mean must be monitored batch by batch to ensure the mean remains within the desired control limits to ensure the product net weight conforms to regulatory standards.

1 Introduction

Statistical techniques are employed in industry to track the stability of industrial processes[1]. The primary purpose of control charts, which was first created by Walter Shewhart as a tool for monitoring and managing manufacturing processes, is to identify changes in the process mean or its standard deviation, which may point to a decline in the standard of industrial processes[2]. In addition to testing parametric changes over time, quality control charts are able to differentiate between two sources of variation: common causes that are inherent to any process and unique causes that arise from factors that are external to the process[2,3].

Control chart functions are considered in two stages: Phase-I is a retrospective review of the process, where the control chart is designed by determining parameters that are not known and to guarantee that the process is in an in-control state and have only common cause variation prior to the final control limits and center line for the control chart are determined. This allows for the quick identification of transitions from an in-control state to an out-of-control state, which can lead to improvements to the process and reduce variability in the observed quality characteristic of a manufactured product. In Phase II, this control chart design is utilized to track the production process and conduct an ongoing evaluation of the process to identify out-of-control conditions[1-4].

To make sure that manufacturing processes create lots that are acceptable based on the net content reported on the package before such items are released into the market in accordance with regulatory rules, phase II product net weight monitoring is essential in the industry[5,6]. A number of studies that assess the performance of control charts assume that process parameters are known[7,8]. In practice, however, the process parameters are frequently unknown and need to be calculated during phase I. To guarantee that the process is in a condition of statistical control, it is crucial to remove all out-of-control observations during phase I. This is required because the performance of the control charts during phase II operations may be impacted by mistakes resulting from parameter estimates when the process is unstable[9-12].Quality control charts are a common tool in manufacturing and belong to the field of industrial statistics [13-15]. However, they are now used in the healthcare sector to track fluctuations in clinical variables like blood pressure, blood glucose levels, and several other health care variables[2], [16-18]. Therefore, the objective of this paper is to design a quality control chart for phase II product net weight monitoring in a manufacturing enterprise.

2 Materials and Methods

For the study, a manufacturing company located in the south-south that produces bar soaps for the general public was chosen. In order to fulfill established regulations for the net weight of packaged products [5, 6, 19, 20], to keep the manufacturing process consistent and well within predetermined control limits, the manufacturer wants to make sure that the bar soaps produced are continuously monitored. This guarantees that the net weight of the product never falls less than the stated net weight of 70 grams. The process of making bar soap is carried out in batches, and it has been discovered that getting the product into molds for final shaping is essential to reaching the product's target net weight. The work of Ezewu et al[19] which identified critical to quality (CTQ) characteristics that guarantee a higher consistency in reaching the specified net weight in the manufacturing of bar soap, is taken into consideration here. There is a 70-gram lower specification limit (LSL) and a 73-gram upper specification limit (USL) for the production process. Samples for the investigation were weighed out using a digital electronic laboratory weighing balance (5000 g × 0.1 g) with ISO-certification.

2.1 Mode of Data Collection/Sample size

To determine the variability in the manufacturing process, and also considering that the bar-soap production is done in batches, ten random samples were collected across twenty-five batches of bar-soaps produced. Studies associated with the capability of a manufacturing process suggests a sample size of N ≥ 100 [21-23]. We therefore consider a sample size of 25 in subgroups of 10, which gives us a total of 250 individual samples as a larger sample size is well known to give more reliable results[21]. Figure 1 shows a sample within a batch weighing 71.5 grams.

Figure 1. Weighing out of samples from a batch

2.2 Investigating Process Stability

The theory of normality and independence are vital and fundamental to the study and performance of an X-bar control chart which is very useful for assessing its suitability for phase II operations[1]. Therefore, to investigate process stability, we test for normality of our dataset after which we deploy the X-bar and S chart also known as the mean and standard deviation chart which are the recommended charts for a subgroup size of 10 samples[24]. The control limits for the X-bar and S chart are computed using the equations given in equation (1) and (2):

The control limits for the X-bar are;

$$\begin{gathered} \mathrm{UCL} = \bar{\bar{x}} + A_3\bar{s} \\ CL = \bar{\bar{x}} \\ LCL = \bar{\bar{x}} + A_3\bar{s} \end{gathered} \tag{1}$$

Control limits for the S chart are obtained using;

$$\begin{gathered} UCL = B_4\bar{s} \\ CL = \bar{s} \\ LCL = B_3\bar{s} \end{gathered} \tag{2}$$

Where, $\bar{\bar{x}}$ represents the average net weight across all samples which also represents the centerline; $\bar{s}$ is the mean sample standard deviation across all samples collected; A3, B3 and B4 are constants obtained from tables on the basis of sample sizes used [1], [24].

2.3 Process Capability Analysis

The potential process capability index Cp and the actual capability index Cpk of a manufacturing process which takes process centering into account are two important indices used to explain a manufacturing process ability to produce products within specified limits[25-28]. Mathematically, the potential process capability index Cp is computed thus;

$$\mathrm{Cp} = \frac{\mathrm{USL}-\mathrm{LSL}}{6\sigma} \tag{3}$$

While the measurement of the actual capability index Cpk is calculated as;

$$\mathrm{Cpk} = \mathrm{Min}\left[\frac{\mathrm{USL}-\mu}{3\sigma}, \frac{\mu-\mathrm{LSL}}{3\sigma}\right] \tag{4}$$

Where LSL and USL are the lower and upper specification limit for the manufacturing process, σ represents the standard deviation of the process and μ the mean.s

2.4 Process Shift Detection and Average Run Length (ARL)

For the chart used in Phase II bar-soap net weight monitoring process, the probability of not detecting when the process net-weight mean of bar-soaps manufactured shifts from the centerline to any of the sigma limit (k), on the x-bar control chart having a three-sigma limit (L), with a sample size of n, is known as the β-risk (β), and can be computed from equation (5)[1];

$$\beta = \Phi\left[\mathrm{L} - \mathrm{k}\sqrt{\mathrm{n}}\right] - \Phi\left[-\mathrm{L} - \mathrm{k}\sqrt{\mathrm{n}}\right] \tag{5}$$

As a result, the Probability of detecting the mean net weight process shift is (1 – β). Where Φ is the standard normal cumulative distribution function[1].
The expected number of samples to be taken across batches before the process shift is detected is known as the average run length (ARL), which we can obtain from equation (6)[1], [24];

$$\mathrm{ARL} = \frac{1}{1-\beta} \tag{6}$$

3 Results and Discussion

The random samples of ten bar-soaps collected across twenty-five batches produced was weighed out on a digital electronic weighing balance and the data is presented in Table 1. The probability plot for the dataset is presented in Figure 2, which shows that the bar-soap net weight of the 250 bar-soaps collected is normally distributed with a P-value of 0.505 (significance level α=0.05), and a mean weight of 71.62 grams.

Table 1: Net-Weight of Bar-Soaps Collected across twenty-five Batches

Sample Number	Sub-Group Net-Weights

1	71.7	72.3	71.1	71.7	71.4	71.7	71.8	72.2	71.8	71.1
2	71.2	71.2	71.1	71.9	71.7	72.0	71.3	71.5	71.7	71.8
3	71.4	71.6	71.7	72.2	72.1	72.7	71.8	71.9	72.1	71.4
4	71.8	72.0	71.8	71.4	71.7	71.7	71.6	71.7	71.9	71.4
5	71.6	70.9	72.0	71.4	70.7	71.3	71.4	71.7	72.1	71.7
6	71.7	71.4	71.6	71.5	72.3	72.3	71.1	71.6	71.0	72.3
7	71.3	71.3	72.0	71.6	71.8	71.8	71.3	71.6	71.1	72.0
8	72.0	71.7	71.3	71.3	71.5	71.3	71.5	72.0	71.1	71.8
9	71.9	71.3	71.1	72.1	72.0	71.3	72.1	71.4	71.8	71.2
10	71.5	71.5	70.2	71.7	71.5	71.9	71.8	72.3	71.8	71.6
11	71.8	71.4	71.8	71.9	71.4	71.2	70.8	70.5	71.0	71.9
12	72.2	72.0	71.4	71.8	71.5	71.6	71.2	71.4	71.7	71.8
13	71.5	71.5	71.6	71.8	71.5	71.3	71.2	71.5	71.8	70.6
14	71.7	71.7	72.3	71.5	71.6	71.9	71.5	72.0	71.1	72.2
15	71.6	71.3	71.9	71.9	71.8	71.3	71.9	71.9	71.5	71.6
16	71.2	71.8	71.9	71.9	71.4	72.2	72.0	70.9	71.2	71.6
17	71.5	71.5	71.6	71.8	71.6	71.5	71.7	72.0	71.5	71.6
18	71.6	71.3	71.4	71.6	71.5	71.8	71.5	71.8	72.2	71.7
19	71.9	71.1	71.5	71.5	71.0	72.0	72.1	72.0	71.7	71.7
20	71.4	71.9	71.7	71.6	71.7	71.8	72.4	71.5	71.1	71.8
21	71.5	71.5	71.5	71.2	72.1	71.7	71.1	71.5	71.5	71.3
22	72.1	72.0	71.6	71.6	72.0	71.0	71.9	72.0	71.5	71.5
23	71.1	71.8	71.7	71.5	72.1	71.5	72.0	71.6	71.9	71.7
24	71.5	72.1	71.4	71.4	72.1	71.8	71.8	71.5	71.0	72.1
25	71.1	71.4	72.2	71.7	71.5	71.7	71.7	72.0	71.3	71.4

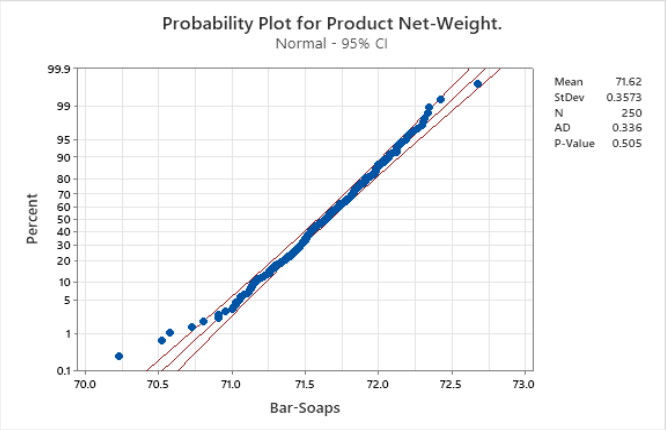

Figure 2. Probability Plot for Product Net weight.

Constructing a 95% confidence interval over the dataset as shown in the summary report presented in Figure 3, reveals that the net weight of 95% of the bar-soaps collected have a mean weight between 71.5 and 71.6 which are well within the specification limit of the manufacturing process.

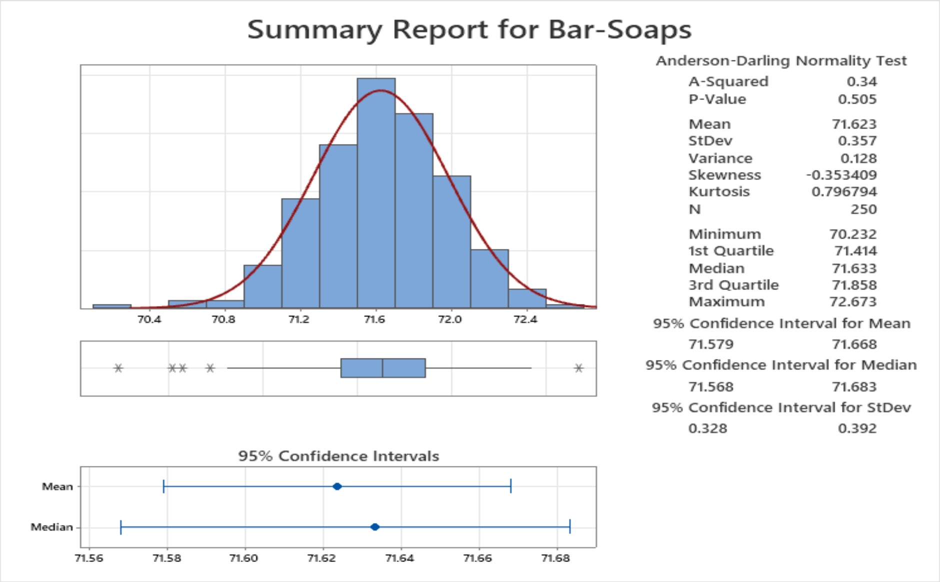

Figure 3. Summary Report for bar-soap production process.

The process capability analysis of the manufacturing process is presented in Figure 4, which gives us a potential capability within of Cp 1.43 and a Cpk value of 1.34 which are both satisfactory [26, 28, 29]. The manufacturing process also has a Parts Per Million (PPM) expected overall of 48.33. To investigate the stability and process variability of the batch production process, we deployed the X-bar-S chart shown in Figure 5. In the chart, all points fall within three standard deviations from the mean hence the batch production process is stable as only common causes of variation are present. Hence, the X-bar chart is suitable for Phase II product monitoring.

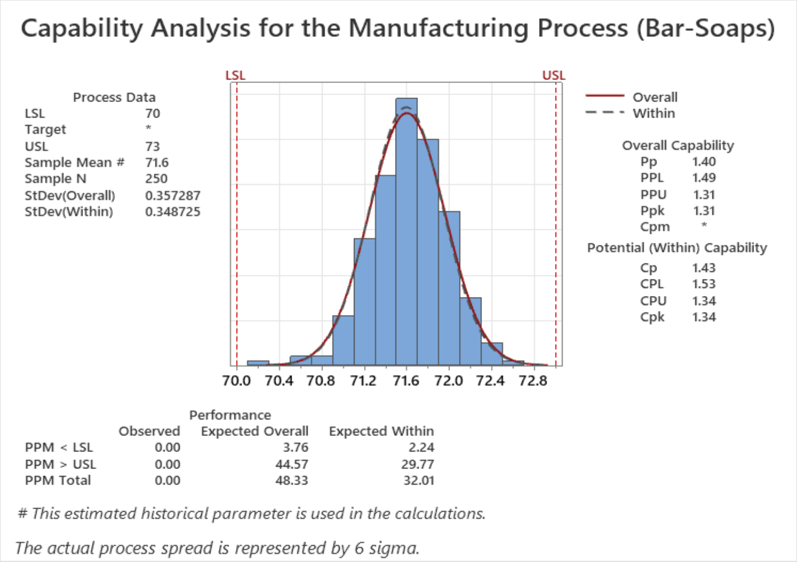

Figure 4. Process Capability Analysis for the production process.

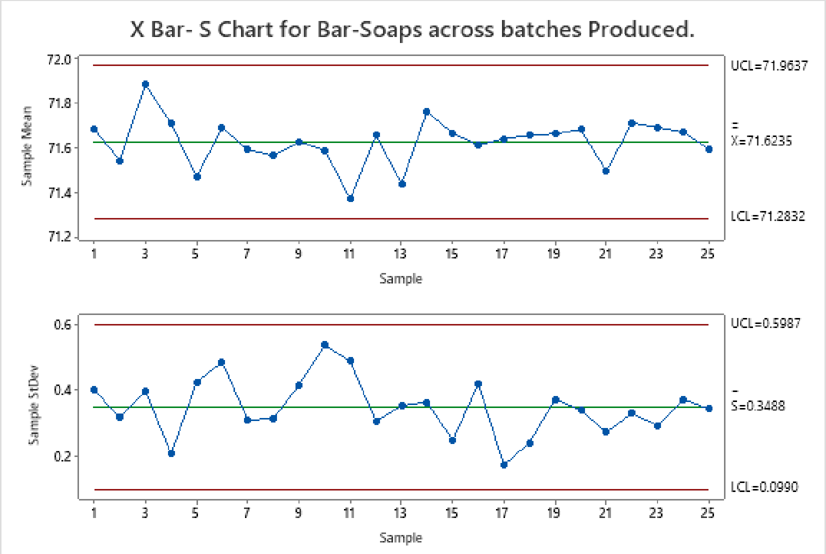

Figure 5. X-bar-S chart for the batch production process.

The X bar chart shown in Figure 6, with a lower control limit (LCL) of 71.28 g and an upper control limit (UCL) of 71.96g will be used for the monitoring of the mean net weight of the bar-soap batch production process.

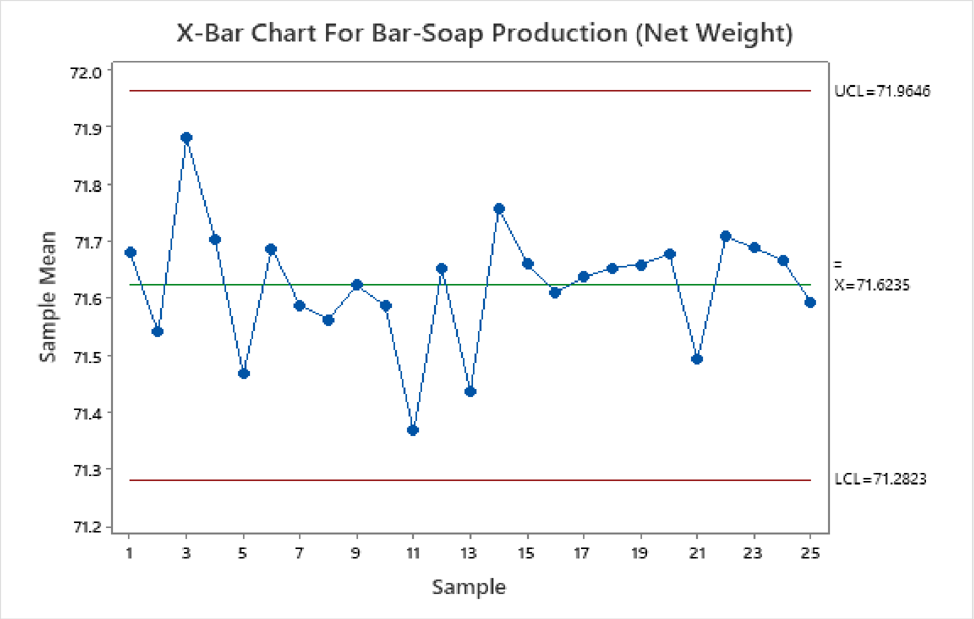

Figure 6. X-Bar chart for Phase II product net weight monitoring

In the monitoring of the batch production process in phase II, the probability that a process mean shift will not be detected is referred to as the β-risk which we can obtain from equation (5);

$$\beta = \Phi\left[L - k\sqrt{n}\right] - \Phi\left[-L - k\sqrt{n}\right]$$

Since we are interested in keeping a close eye on the production process as the control limits are tight, we require a detection of 1.5 sigma from the mean (k = 1.5) on the three-sigma limit chart (L = 3) operating on a sample size of (n = 10);

$$\beta = \Phi\left[3 - 1.5\sqrt{10}\,\right] - \Phi\left[-3 - 1.5\sqrt{10}\,\right]$$

Consulting the cumulative standard normal distribution table, β-risk is thus;

$$\beta = 0.0446$$

Therefore, the probability of detecting the mean shift is (1- β) = 0.9554 (95%)

Applying equation (6), we obtain the $ARL = \frac{1}{1-\beta} = \frac{1}{1-0.0446} = 1.05 \ \approx 1$

With an average run length of one, tells us that the expected number of samples to be taken before a process shift is detected is just one. This informs us that the batch production process must be closely monitored from batch to batch to ensure the process remains stable and within the desired control limits.

As it has been well observed from the process capability analysis, the batch production process though stable, is operating below the six-sigma limit as the Cp and Cpk values are well below 2.0 [24, 28, 29]. Therefore, the control limits of 71.9 (UCL) and 71.2 (LCL) is used to monitor random samples of ten per batch to ensure the process remains stable and out-of-control-action-plans (OCAPS) may be initiated whenever the mean steps outside these limits by looking into the CTQ [19],of the manufacturing process to identify assignable causes to the process shift before it gets outside the specification limits. This will help to improve quality and productivity as decisions taken are data driven which underlies the importance of control charts in the effective management of manufacturing processes.

4 Conclusion

Manufacturers of products for public consumption in view of regulatory laws regarding the net weight of packaged products must begin to realize that they owe their customers a duty of care to ensure that the products released into the market meet the required standard. This can be achieved by monitoring manufacturing processes real time to ensure the desired quality characteristic remains stable. This also helps the manufacturer to avoid losses that may result from reworking or scrapping already finished products. This paper helped in the estimation of the production process parameters to deploy in phase II operations for the monitoring of the net weight for manufactured bar soaps. The X-bar chart for real-time process monitoring was generated using the Minitab 2021 statistical software package in view of the β-risk as well as the ARL for effective management of the manufacturing process. A 95% chance of detecting a process shift of 1.5 standard deviations operating on an ARL of one underlies the importance of a batch-by-batch monitoring of the production process to maximize process yield and to meet regulatory standards.

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