

An Overview of Phase I Analysis for Process Improvement and Monitoring

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We provide an overview and perspective on the Phase I collection and analysis of data for use in process improvement and control charting. In Phase I, the focus is on understanding the process variability, assessing the stability of the process, investigating process-improvement ideas, selecting an appropriate in-control model, and providing estimates of the in-control model parameters. In our article, we review and synthesize many of the important developments that pertain to the analysis of process data in Phase I. We give our view of the major issues and developments in Phase I analysis. We identify the current best practices and some opportunities for future research in this area.

Key Words: Assignable Cause; Change Point; Common Cause Variation; Control Chart; Self-Starting Chart; SPC; Statistical Process Control.

1. Introduction

CONTROL CHARTS are used to aid practitioners in the production of quality goods and services.

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There are generally two phases in the application of these methods. In Phase I, the practitioner collects a fixed-size sample of time-ordered data in order to learn about the process. Of course, after collecting some data, one could decide to collect more but, in Phase I, the data are analyzed and studied in the aggregate while maintaining the time order. The goals of a Phase I analysis include quantifying the current process quality performance and better understanding the nature of the variation over time. In Phase I, it is also important to establish process stability by investigating the data for unusual results and removing assignable causes of variation. Then the remaining data are used to estimate the in-control process parameters. Often, one must assess the capability of the process to meet specification limits. Finally, the practitioner selects an appropriate in-control model and estimates the process parameters in order to determine an appropriate Phase II monitoring scheme.

There is an exploratory aspect to Phase I and there can be efforts to improve process performance based on knowledge and insights gained from the data. The purpose of Phase II monitoring is to detect changes from the assumed in-control model.

The Phase I data can serve as a baseline by which to judge the success of future quality-improvement initiatives. In some cases, the process knowledge and resulting process improvement from a Phase I analysis is sufficient and there may be no need for on-going Phase II monitoring except to ensure that the process improvements are sustained. As additional improvements are made to the process, one may consider periodic revisions of the control limits and center line of the charts (see, e.g., Montgomery (2013), p. 243).

The vast majority of research on process monitoring has considered the development and performance of Phase II control-charting methods. Most of the Phase II methods are based on the assumption that the in-control process model is known or that the process parameters have been accurately estimated from an in-control reference sample. Although it is well-known that the use of estimated parameters significantly affects the statistical performance of Phase II control charts (Jensen et al., (2006)), the research regarding methods to actually obtain an in-control reference sample has received less emphasis.

It is frequently advocated that one apply standard Phase II charts retrospectively to Phase I data to identify an in-control reference sample. When using this approach, it is common for the charts to signal quite frequently, making it difficult to distinguish between in- and out-of-control events. Most research on the retrospective use of control charts shows that the control limits of Phase II charts must be widened, often substantially, in order to control the overall false-alarm rate.

Others recommend that self-starting methods be used to avoid the need for a Phase I study, but research on self-starting charts suggests that they do not perform well if the process is initially unstable or if there are deviations from the assumed model. The process knowledge and insights gained from Phase I data and analysis can be too important for one to move quickly into Phase II, even if this is possible in theory. A Phase I analysis should encompass more than simply applying a control chart to data to determine which observations are in control. A Phase I analysis should include visualization of the process data as well as the application of statistical meth-

ods in order to gain richer insights into the process and determine the appropriate model for process improvement and monitoring.

In our paper, we comment on some of the important aspects of Phase I analysis and review some of the recent developments in this area. Due to the large number of papers on this topic, we did not attempt a complete literature review. Chakraborti et al. (2009) provided a detailed literature review on the retrospective use of univariate control charts in Phase I, with important technical details about performance measures and comparisons of various control charts. The scope of our paper is somewhat broader and less technical. We consider not only univariate control charts but also control-chart design issues and other Phase I methods, including graphical methods, self-starting charts, change-point methods, classification methods, robust parameter estimation, and multivariate methods.

We begin in Section 2 with an overview of a number of Phase I issues, including subgrouping, sample size, graphical methods, selecting an in-control model, and performance measures. In Section 3, we discuss approaches to Phase I, including self-starting charts, change-point methods, classification methods, and robust parameter estimation. The remainder of the paper is more technical in nature. In Sections 4–6, we discuss some developments in the retrospective use of Phase I univariate and multivariate control charts. In Section 7, we briefly discuss Phase I analysis of profile data. Section 8 contains our conclusions.

2. Phase I Issues

2.1. Overview

Prior to developing a process-monitoring scheme, one must determine and give operational definitions for the key variables necessary to measure process quality. Once identified, an analysis of the measurement system should be conducted to ensure that it is adequate to produce reliable measurements of the process performance. For more information on assessing the capability and reliability of measurement systems, see, e.g., Montgomery (2013, pp. 379–397) and Steiner and MacKay (2005, pp. 89–104). Steiner and MacKay (2005) recommended using Phase I data in the assessment of the measurement system, especially in the estimation of process variation.

The most common approach to determine the stability of a process is to apply a Shewhart control

chart retrospectively. It is important to note that cumulative sum (CUSUM) and exponentially weighted moving average (EWMA) control charts are used in Phase II because they can more quickly detect process shifts. Speed of detection is not of importance with a fixed historical dataset in Phase I, so our discussion of retrospective control charts centers on Shewhart-type control charts. Plots of cumulative deviations from the historical mean have been recommended, however, for diagnosing process changes. See, for example, Box and Luceño (1997). In addition, change-point methods, discussed in Section 3.3, can be used to detect smaller process shifts to which the Shewhart charts are insensitive.

The statistical performance of control-chart methods for Phase I data is dependent on the distributional characteristics of the process, the nature of the process variation, the sampling frequency, the size of the reference sample, whether subgrouped or individual data are used, and the method used to estimate the unknown process parameters. In fact, it is impossible to disentangle the effects of each on the control-chart performance. For instance, one cannot consider the effect of the sample size on the statistical performance of a control chart without considering whether the data are subgrouped, how the parameters are estimated, and the process distribution.

2.2. Use of Rational Subgrouping

A sampling strategy commonly discussed in the context of statistical process control is rational subgrouping. Rational subgrouping concerns what to measure and how to select samples. Its implementation relies on process knowledge and some common sense. Shewhart (1931, pp. 298–299) discussed the importance of the use of rational subgroups, not only in terms of detecting out-of-control conditions, but also to find the assignable cause of any out-of-control event. Shewhart (1931) stated, “The engineer who is successful in dividing his data initially into rational subgroups based on rational hypotheses is therefore inherently better off in the long run. . . .” The sampling strategy employed in Phase II can be determined from the knowledge gained in Phase I. Certainly, the sampling plan in Phase I does not have to necessarily match that used in Phase II. For example, one might use subgrouped observations with a Shewhart-type control chart in Phase I and use individual observations with a CUSUM chart tuned for fast detection of certain shifts in Phase II.

In general, the subgroups in Phase II should be

selected such that, if there is an assignable cause leading to an out-of-control state, the chance of differences between the subgroups is greater than the chance of differences within the subgroups. This is because it is easier to detect and diagnose changes in the mean than changes in variation.

One simple example of rational subgrouping would be to sample from each 8-hour shift, if it is expected that an assignable cause of variation could affect a single shift. Another example would be to sample from the output of each of several machines, if these machines are performing the same task, instead of sampling from items after the output of the machines has been combined. Each data stream would be monitored separately. The consequences of a poor sampling scheme can lead to ineffective process monitoring. Nelson (1988), Wheeler and Chambers (1992), and Palm (1992) provided very good descriptions of rational subgrouping and emphasized its fundamental importance.

The presence of an “in-control reference sample” is often a fundamental assumption necessary for selecting and designing an appropriate Phase II control chart. Actually defining the in-control state of the process and finding an in-control sample is not simple. In fact, Shewhart (1939, p. 76) wrote, “In the majority of practical instances, the most difficult job of all is to choose the sample that is to be used as the basis for establishing the tolerance range [control limits]. If one chooses such a sample without respect to the assignable causes present, it is practically impossible to establish a tolerance range that is not subject to a huge error”.

Montgomery (2013, p. 201) gave two approaches to sampling. In his first approach, one consecutively samples units that occur essentially at the same time or in very near succession in order to form subgroups. This approach gives snapshots of the process over time and is useful for monitoring to detect process shifts. In the second approach, one randomly selects and measures units produced during a sampling interval and assigns these values to a subgroup. The second approach is useful in making decisions about the entire set of units over a fixed time period, which may be a goal of a Phase I analysis. However, with the latter approach, one loses some of the time ordering of the data, which may make it difficult to detect certain types of process changes.

Practitioners should give careful consideration to their sampling methods, collecting data in a way that

takes advantage of important information about the process. Doganaksoy and Hahn (2012) suggested a five-step process for collecting the “right” data and discussed the practical difficulties that may be encountered, including additional costs and issues of data ownership. Perla et al. (2013) provided guidance for determining useful samples in healthcare process improvement applications. Anderson-Cook and Borror (2013) and Vining (2013) also considered data-collection strategies for quality monitoring and analysis.

It is important to note that most Phase I statistical methods can only be applied with subgrouped observations; however, process-quality characteristics are often observed and recorded as individual observations ($n = 1$). There is little guidance in the literature on the benefits or drawbacks analyzing Phase I data as individuals or in subgroups. To a large extent, the data-collection decision depends on the application of interest.

2.3. The Size of the Phase I Sample

In some applications, it may not be necessary to collect new data for a Phase I analysis because there are historical observational data available. It is often difficult, however, to determine the in-control baseline sample from a large historical data set (see, e.g., Zhang et al. (2010)). Whether gathering data specifically for use in Phase I or using a historical data set, the number of observations available for a Phase I analysis plays an important role in the estimation of the values of the in-control parameters. A major goal of a Phase I analysis is to estimate process variability, which is difficult with small sample sizes and requires much larger samples than estimating a mean. The accurate and precise estimation of the process parameters is critical for achieving specified Phase II chart performance. Jensen et al. (2006) gave a review of the literature on the effect of estimation error on control-chart performance in Phase II. The general conclusion of the considerable amount of work on this topic is that the size of the Phase I sample must often be quite large in order to be confident that the performance of the control chart will come close to the performance under the assumption that the values of the in-control parameters are known. The amount of Phase I data can be prohibitively large in many cases; see, for example, Albers and Kallenberg (2004), Zhang et al. (2013), and Saleh et al. (2014).

Phase I sample-size requirements for Phase II control charts vary quite a bit, depending on the type

of control chart and dimensionality of the data. We recommend that readers review studies on the effect of estimation error on the Phase II performance on their specific control-chart type.

In addition to the necessary size of the sample, it is also important to consider the length of time over which the sample data are gathered. Processes have both long- and short-term characteristics. Phase I samples should be taken over a long enough time period to assess both the short- and long-term process variation in the mean. This is a fundamental data-collection principle of the variation-reduction approach of Steiner and MacKay (2005).

2.4. Graphical Methods and the Multivari Chart

The first step in any data analysis should be plotting the data. One should consider histograms, time-series plots, and scatterplots for multivariate applications. Another very useful plot is the multivari chart introduced by Seder (1950a, 1950b) as a graphical method for studying sources of process variability. In their most common form, multivari charts use pictograms to graphically present multiple sources of variability (e.g., within-piece, piece-to-piece, and time-to-time variability). Shainin (2008) presented a thorough overview of multivari charts and illustrated their use in two case studies.

In one example, Shainin (2008) discussed the use of a multivari chart to study the variation in the strength of paper produced for packaging. The sources of variation in strength considered were machine-to-machine variation, variation in the machine direction, and in furnish-to-furnish (batch-to-batch) variation from the raw materials. Figures 1 and 2 show the paper machine and the sampling locations for the measurements of strength in the paper both across the paper and in the machine direction. Figure 3 gives the associated multivari chart for the paper process. As discussed in Shainin (2008), there were some differences across the paper and across the machine, but the largest portion of the variability in strength resulted from differences between furnishes (batches). The furnish-to-furnish variability is indicated by the differences in strength measures between the shaded portion of Figure 3 corresponding to Batch A and the unshaded portion for Batch B. From Figure 3, it also seems that the furnishes differ, not only in terms of mean, but also in terms of variability. If the source of the furnish-to-furnish variation can be removed, then it would be prudent

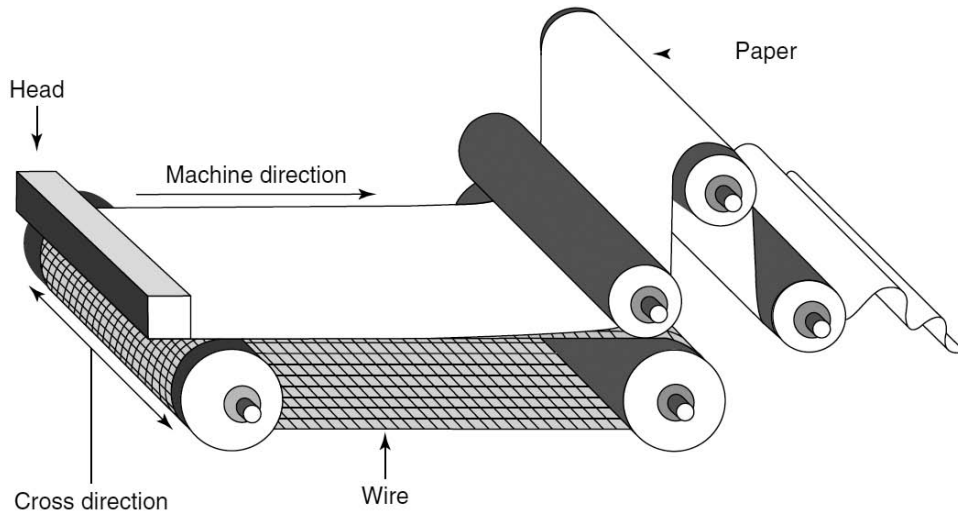


FIGURE 1. Illustration of the Paper Machine Discussed in Shainin (2008). Reprinted with permission, ©2008, John Wiley and Sons.

to collect more data from the refined process in order to determine an appropriate sampling plan and monitoring scheme in Phase II.

Graphical methods like the multivari chart can be used in the early stages of process control to learn more about the process. They can be used to help the practitioner target resources and process improvement efforts toward the largest contributor to the process variability, with the goal of process improvement through variation reduction and bringing the process into an in-control state.

2.5. Selecting an Appropriate In-Control Model

One of the great challenges of Phase I is the need to evaluate process stability without a model of the

process. It is not clear what comes first because one must evaluate process stability, but in order to do so a reasonable model of the process is required. Determining an appropriate model is premature, however, if the process is not stable. Thus, a practitioner is charged with simultaneously determining the model while evaluating process stability. We have no clear roadmap for this difficult problem, but offer some practical points to consider. Wheeler (2011) recommended the use of individuals and moving-range charts without any selection of a model. We support the use of these tools, but do not believe that they are always the best approach.

One should keep in mind that process stability depends to a large extent on the “process view”. A process could be stable with respect to one quality characteristic and a particular sampling plan, but un-

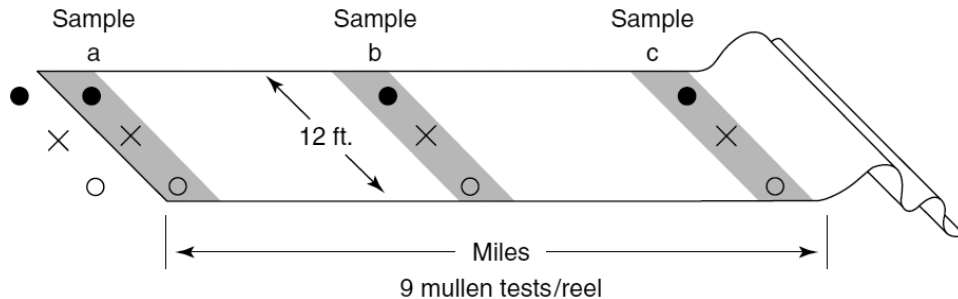


FIGURE 2. Illustration of the Sampling Locations for the Multivari Chart in Shainin (2008). Reprinted with permission, ©2008, John Wiley and Sons.

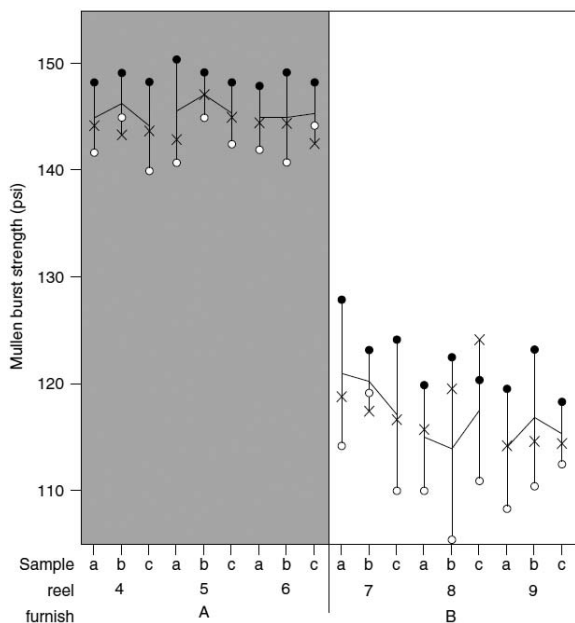


FIGURE 3. Illustration of the Multivari Chart for the Paper Process Discussed in Shainin (2008). Reprinted with permission, ©2008, John Wiley and Sons.

stable with respect to some other choice. This issue can cause some confusion in industrial practice.

Many parametric Phase I statistical methods have statistical performance that is quite sensitive to departures from the model assumptions (see, e.g., Jones-Farmer et al. (2009)). For continuous process variables, the normal distribution is commonly assumed. If planning to use an \bar{X} -chart in the univariate case or a Hotelling's T^2 chart in the multivariate case, retrospectively, it is important to evaluate the distribution of the data. For continuous multivariate process variables, Phase I control charts are not robust to departures from normality (see, e.g., Bell et al. (2014)). Q-Q plots or other methods can be used to ensure that the normality assumption is reasonable; however, out-of-control values can make it appear as if there are departures from normality when none exist. If the normality assumption is not reasonable, transformations of the data or nonparametric methods can be considered.

In addition to considering the form of the distribution for continuous univariate data, one should also check for autocorrelation and overdispersion. In the traditional model of statistical control, the value of any parameter is assumed to be constant over time

and the process observations are assumed to be uncorrelated over time. In many applications, data are collected at such a quick rate that the assumption of independence over time is not reasonable and autocorrelation becomes an issue. For autocorrelated processes, practitioners should consider monitoring the level of the process and residuals from an appropriate time-series model. Overdispersion occurs when large sources of common cause variability occur between subgroups. This could imply that the subgrouping plan is poorly chosen or that the parameter(s) vary over time for some reason. It also may be appropriate to use a multi-stage approach in which the output of the process is monitored only after being adjusted for process-input variables.

2.6. Performance Measures

The Phase II performance metrics, such as average run length (ARL) and average time to signal (ATS), are not relevant for evaluating, comparing, and designing Phase I methods. Most often, Phase I methods are compared on the basis of the overall probability of detecting some specified out-of-control condition such as an outlier or a sustained shift in an underlying parameter. In-control performance is usually characterized by the overall false-alarm probability (FAP), which is defined as any signal from the method used to analyze the historical Phase I dataset when the process is, in fact, stable.

When evaluating Phase I methods, most authors have used alarm probabilities, or the probability of observing at least one alarm when the process is out of control. This method has been used by a number of authors, e.g., Sullivan and Woodall (1996), Vargas (2003), Woodall et al. (2004), Jensen et al. (2007), Alfaro and Ortega (2008), Jobe and Pokojovy (2009), Jones-Farmer et al. (2009), and Graham et al. (2010). In out-of-control situations, it seems more useful to evaluate Phase I methods based on their ability to correctly identify *the right* observations as outliers. The latter approach was recommended by Shiau and Sun (2009) and Chen et al. (2014). In addition, Bell et al. (2014) used the correct detection probability to evaluate the performance of their multivariate-mean-rank chart.

The biggest performance problem that arises when using control charts retrospectively is highly inflated FAP values. Chakraborti et al. (2009) discussed this issue in detail. When there are many false signals, it is difficult to trust the importance of any signal. If the in-control parameters are assumed to be known and

one assumes independent observations, the successive comparisons of the Shewhart-chart statistics to the control limits are independent. In this case, when there is a constant probability of a false alarm for any given chart statistic, p , we have $FAP = 1 - (1 - p)^m$, where m is the number of chart statistics. As an illustration, if the process is normally distributed with known in-control parameters and 3σ control limits are used, the probability of at least one false signal on an \bar{X} chart with $m = 30$ chart statistics is 0.078. With $m = 50$, we have $FAP = 0.126$. Generally, as m increases, the FAP increases. Similarly, when the parameters are unknown, the FAP of retrospective control charts can be substantially inflated over the desired level as the number of samples increases. Some remedies to the problem of increased FAPs are discussed in Section 4.1.

3. Some Phase I Methods

3.1. Checking for Outliers in Phase I

When using retrospective Shewhart control charts in Phase I, it is standard practice to calculate trial control limits and to investigate any values that fall outside the control limits. If a reason can be determined for any points falling outside the limits and the assignable cause is removed from the process, then the points are deleted from the data and the control limits recalculated. This process is repeated iteratively until one is reasonably sure that the data represent what could be expected from an in-control process.

A few practical considerations arise with this approach. First, practitioners sometimes remove the out-of-control data points automatically without any deliberation or investigation. This is an unwise practice in a Phase I analysis, when little may be known about the process. The model on which the control charts is based could be wrong; thus, the points outside of the limits may simply be a reflection of normal process variation. Montgomery (2013, pp. 206–207, 238–239) and Shiau and Sun (2009) also discussed this issue. Regardless of the analysis method, we recommend careful consideration prior to eliminating process observations in a Phase I analysis.

Second, many points falling outside of the control limits may cause concern about considerable instability in the process. However, this could be a reflection of an incorrectly assumed model for the process variable or a poor subgrouping approach. For example, when using an \bar{X} chart in Phase I, it may not

be reasonable to assume a constant in-control mean. There could be an extra component of variation that affects the process mean, as discussed by Woodall and Thomas (1995) and others. Another possible explanation for a large number of points outside \bar{X} or X -chart control limits may be the presence of positive autocorrelation, as demonstrated by Maragah and Woodall (1992). One should remove the source of any such autocorrelation, if possible. If removal is not possible, one should consider the process-control approaches of Box and Luceño (1997), provided there is a control variable. If autocorrelation cannot be removed from the data, then any monitoring in Phase II should take this feature of the data into account.

3.2. Self-Starting Charts

Self-starting control charts are control charts in which successive observations are used to update the parameter estimates and simultaneously check for out-of-control events. The purpose of these charts is to begin Phase II monitoring as quickly as possible with a minimal amount of data. These methods were introduced by Hawkins (1987) to reduce the need for a potentially costly Phase I sample. Self-starting control charts are useful, however, only when data collection is slow and there is insufficient process history available to estimate the in-control process parameters. Such a situation might occur, for instance, in low-volume manufacturing.

Univariate self-starting control charts have been considered by Hawkins (1987), Quesenberry (1991), del Castillo et al. (1996), Zou et al. (2007), Li et al. (2010), Zhang et al. (2012), and others. Multivariate self-starting control charts have been studied by Sullivan and Jones (2002), Capizzi and Masarotto (2010), Hawkins and Maboudou-Tchao (2007), Maboudou-Tchao and Hawkins (2011), and others.

Most self-starting control charts are susceptible to estimation error that occurs due to processes that are either out-of-control from the start of monitoring or due to early process shifts. The contamination of the parameter estimates can be quite large in the early stages of monitoring when not much information is available.

Sullivan and Jones (2002) noted the problem of early contamination of the parameter estimates and suggested that the self-starting methods be supplemented with a thorough retrospective analysis once sufficient data had been gathered. Hawkins and Maboudou-Tchao (2007) and Maboudou-Tchao and

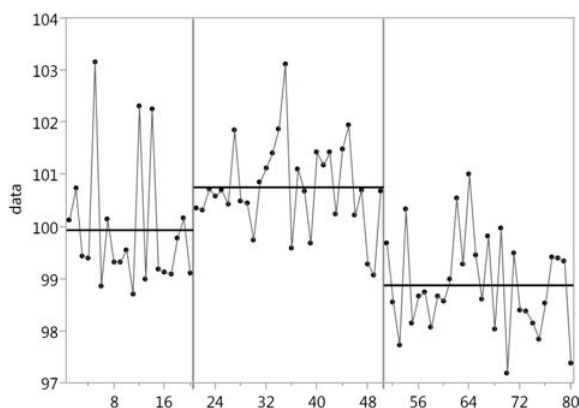


FIGURE 4. An Illustration of Data with Change-Points in the Mean.

Hawkins (2011) addressed the problems with contaminated parameter estimates, suggesting that, in addition to prospectively monitoring with a self-starting chart, one should apply the self-starting methods beginning with the most recent process observation and working backwards to the initial observations.

Self-starting methods are useful tools in processes with slowly accruing data and little process history, but they have not diminished the need for a thorough Phase I analysis. Phase I can provide valuable information about the process, so it should not be bypassed unless absolutely necessary.

3.3. Change-Point Methods

Change-point analysis is a commonly recommended statistical approach for assessing the stability of a process in Phase I. Change-point analysis methods are used to check if any step shifts in the process parameters have occurred, and to estimate the times of these shifts. An illustration is given in Figure 4 for data generated from a normally distributed process with a standard deviation of 1. The mean is 100 for the first 20 observations, shifting to 101 for the next 30 values, and then to a mean of 99.

In a Phase I application, if any change points are detected in the sample, it would be a mistake to combine all of the Phase I data together to estimate the in-control process parameters. If there are shifts in the distribution over time, then some effort should be made to address the root cause of this phenomenon so that process variation can be reduced.

Hinkley (1970) derived a likelihood-ratio test

statistic for testing hypotheses about a change point. In addition, Hinkley (1971) showed the relationship between the CUSUM chart and the likelihood-ratio test. Chen and Gupta (2011) provided a good introduction to change-point methods and discussed many application areas. Several authors have applied the change-point inference framework to statistical process control. A few contributions in the quality-control area include Sullivan and Woodall (2000), Mahmoud and Woodall (2004), Mahmoud et al. (2007), Paynabar et al. (2012), and Pan and Rigdon (2012).

Change-point methods are particularly useful in Phase I analysis when one or more sustained process changes (rather than randomly occurring outliers) are expected. Many opportunities for future research on change-point methods in Phase I still exist. Zhang et al. (2013) and Jones-Farmer et al. (2014) discussed the lack of methods available for conducting a Phase I analysis for attribute processes. Additionally, although some work has been done in developing nonparametric change-point methods (see, e.g., Zhou et al. (2009), Hawkins and Deng (2010), and Zou et al. (2013)), more work is necessary in this important area. For change-point methods to be used by quality-control practitioners, easy-to-use computer software is also needed due to the mathematical and computational complexity of the methods.

3.4. Classification and Cluster-Based Methods

One approach is to frame the Phase I analysis as a classification problem, in an attempt to classify observations into two or more groups (e.g., in-control and out-of-control). Noting that Phase I control charts often fail when multiple shifts occur within a reference sample, Sullivan (2002) introduced a clustering approach to detect multiple shifts in the process mean. Zhang et al. (2010) considered a method for determining a sufficiently long stable run of process observations from a historical data stream. They proposed a robust method for identifying the in-control reference sample using a combination of empirical probability distribution profiles and clustering methods. Jobe and Pokojovy (2009) proposed a computationally intensive clustering algorithm applied to multivariate individual observations in Phase I. They showed that their method was better at detecting randomly occurring outliers and some process shifts than the use of the retrospective Hotelling's T^2 chart.

There are many ways in which a Phase I sample can be contaminated with out-of-control points, including sporadic or randomly occurring outliers, sustained process shifts, sporadic process shifts, nonstationarity, etc. Simple hierarchical clustering methods in which observations are assigned to groups provide the most straightforward results in the case of randomly occurring outliers. Once clusters have been formed, one can look for patterns over time. Some classification methods that preserve the time ordering of the observations have been developed (see, e.g., Liao (2005)). An important opportunity for future research is to expand the study of classification and cluster-based methods for the Phase I situation.

3.5. Robust Estimation of In-Control Parameters

Because it is common to have outliers in Phase I data, the use of robust estimators of in-control parameters along with a carefully designed Phase I method is important. As explained by Mahmoud et al. (2010), we do not recommend the historically popular and continuing practice of using the sample ranges to estimate the standard deviation for the \bar{X} chart. It is much better to use the sample standard deviations because these are much less affected by outliers. Also, see Schoonhoven and Does (2012, 2013) and Schoonhoven et al. (2011) for discussion of robust estimation with univariate Phase I data.

In the multivariate normal model case, authors have used different strategies for the estimation of the covariance matrix in Phase I for implementation of Hotelling's T^2 charts. Vargas (2003) recommended using a minimum-volume ellipsoid (MVE) estimate of the covariance matrix for detecting multiple outliers in Phase I. Later, Jensen et al. (2007) compared the MVE estimators with the minimum covariance determinant (MCD), showing that the MVE estimators are best when the percentage of outliers is small and that the MCD estimators are preferred when there is a large percentage of outliers in the Phase I sample. Oyeyemi and Ipinyomi (2010) used an alternative estimator for the covariance matrix for individual's T^2 chart in Phase I that outperformed the MVE and MCD methods in a limited number of cases. Yanez et al. (2010) proposed using a biweight S estimator for location and scatter in a T^2 chart for individual data with simulated limits, showing that it outperforms the T^2 chart based on an MVE estimator for small samples.

4. Univariate Variables Control Charts in Phase I

Because it is often recommended that Shewhart control charts be applied retrospectively to Phase I data, some of the technical issues involved with this approach are discussed in this and the next three subsections. It is commonly assumed that the observations over time are independent and that the in-control values of the parameters are unknown. The goal is to detect any deviation from a stable process with a specified FAP. All proposed methods are based on the assumption that stability corresponds to constant in-control parameter values. The two primary issues with these methods are that the control limits must be widened in order to avoid an excessive number of false alarms and that the performance of the methods does not tend to be robust to departures from the distributional assumptions, usually the assumption of normality. For a more technical description of this topic, we recommend Chakraborti et al. (2009).

4.1. Some Background

Chou and Champ (1995) and Champ and Chou (2003) studied two approaches to dealing with the correlation among the retrospective comparisons of the chart statistics to the control limits for \bar{X} , R -, and S -charts. In one approach, referred to as the "standard limits" approach, the limits are computed in the standard way, but the probability of a signal on each comparison is adjusted using a Bonferroni-like adjustment. This conservative approach results in an actual FAP that is no more than desired, provided the distributional assumptions hold. Another approach, the "individual limits" approach, considers different parameter estimates for each successive comparison of the plotted statistic to the control limits. For a given comparison of a chart statistic to the control limit, the process observations for that statistic are eliminated from the parameter estimates. This approach removes the dependence among the successive comparisons. The study by Champ and Chou (2003) suggested that the "standard limits" based on Bonferroni adjustments performed better than the "individual limits" method. Thus, the methods discussed in this section are based on the "standard limits" approach to computing control limits in Phase I.

4.2. Assessing Stability of the Process Mean

Champ and Jones (2004) recommended control limits for retrospective \bar{X} charts for normally dis-

tributed processes based on the multivariate t -distribution that account for the estimation of the parameters as well as the dependence of the successive comparisons of the chart statistics to the limits. Champ and Jones (2004) also suggested approximate limits for retrospective control charts based on the univariate t -distribution that account for the estimation of the process parameters, but ignored the dependence among the chart statistics. Using simulation, they showed that both approaches resulted in empirical FAP values that were very near the desired FAP.

Newton and Champ (1997) considered the use of analysis of means (ANOM) as a method for constructing control limits for retrospective \bar{X} charts. Nedumaran and Pignatiello (2005) studied the performance of the ANOM-based retrospective \bar{X} limits for normally distributed processes with unknown parameters. Using simulation, they showed that the ANOM-based control limits maintained an FAP that was closer to the desired level and performed slightly better than limits based on a standard normal distribution with a Bonferroni adjustment based on the number of chart statistics. Champ and Jones (2004), however, showed that, when the Bonferroni approach was used to determine the \bar{X} control limits for a sample of m subgroups of size n , the empirical FAP was quite dependent on n . Their simulation study resulted in empirical differences from the desired FAP that ranged from 50% below the desired FAP for subgroups of size $n = 10$ to 36% above the desired FAP for subgroups of size $n = 3$. In the first case, the limits would be too wide, resulting in lower probabilities of detecting out-of-control conditions. In the second case, the limits would be too narrow, resulting in too many false alarms.

Champ and Jones (2004) and Nedumaran and Pignatiello (2005) considered only \bar{X} charts for normally distributed processes. In addition to the effect of estimated parameters on retrospective control-chart performance, the situation is further complicated by the process distribution. Jones-Farmer et al. (2009) studied the in-control performance of using \bar{X} chart limits computed using the methods described in Champ and Jones (2004) under specific departures from normality. In the case of a chart designed with an FAP of 0.10, they showed that, when the process distribution was heavy tailed (t -distribution with three degrees of freedom), the empirical FAP increased dramatically as the number of subgroups, m , increased, reaching close to 50% for some combi-

nations of m and n . Similar, but less dramatic, results were given for the same chart design applied to skewed data, which showed empirical FAP values of around 30% in the case of $m = 50$, $n = 3$.

Jones-Farmer et al. (2009) recommended the use of standardized mean ranks similar to the Kruskal-Wallis procedure (Kruskal and Wallis (1952)) with retrospective control-chart limits. Using simulation, Jones-Farmer et al. (2009) showed that their mean-rank chart maintained the desired FAP under several process distributions and achieved higher signaling probabilities than the retrospective \bar{X} chart in some cases when the process distribution was nonnormal.

Graham et al. (2010) considered a distribution-free Phase I chart for subgrouped data based on the median of the pooled data. Using simulation, they showed that the empirical FAP values were closer to the desired levels than the \bar{X} chart when the process distribution was nonnormal; however, this median-based method requires the subgroup size, n , be much larger than the number of subgroups, m , in order for the FAP values to be near the desired levels. In practice, most process data are gathered as individuals or in small subgroups.

Recently, Capizzi and Masaratto (2013) introduced a distribution-free Phase I control chart that can be applied to individual observations. Their method uses a time-ordered segmentation of the individual process observations and is similar to the methods of Sullivan (2002) and Zhang et al. (2010). Capizzi and Masaratto (2013) used a permutation approach for determining the control limits and their methods seem promising for detecting several types of process shifts.

Some control chart limit adjustment approach should be used when applying control charts retrospectively in Phase I. If the assumption of normality is a concern, we recommend a nonparametric method be used. If stability is reasonable based on a nonparametric analysis, the form of the underlying in-control distribution should be assessed to design any Phase II methods. Graphical methods are recommended for determining an appropriate model for the in-control distribution.

4.3. Assessing Stability of Process Variation

The \bar{X} chart for location is generally supplemented with the R , S , or S^2 chart to monitor variability. Similarly, a retrospective location chart should be supplemented with a chart to monitor the

variability of the process. We found relatively little work on the retrospective use of control charts for process variation. Hillier (1969) and Yang and Hillier (1970) considered variance control charts for normally distributed processes with estimated parameters, but did not control for the dependence of the successive comparisons of the chart statistics to the control limits. Champ and Chou (2003) examined the Phase I R and S charts under the independent normal model. Human et al. (2010) used simulation to find empirical control limits that account for both parameter estimation and the dependence of the comparisons in a retrospective analysis. They provided extensive tables of control limit constants for several sample (m) and subgroup sizes (n) for R , S , and S^2 charts based on normally distributed processes.

Jones-Farmer and Champ (2010) used simulation to show that the empirical FAP values for the retrospective R and S charts were inflated over the desired FAP in the case of normal, heavy-tailed, and skewed distributions. For example, in the case of $m = 30$ subgroups of size $n = 5$, the R chart designed for an FAP = 0.1 resulted in an empirical FAP of 0.215 in the case of normal observations and 0.918 in the case of heavy-tailed observations (t -distribution with three degrees of freedom). Jones-Farmer and Champ (2010) compared the performance of several statistics based on the subgroup mean rank of the statistic, $|X_{ij} - M|$, where X_{ij} is the j th process observation from the i th subgroup and M is the median of the observations pooled over all subgroups. They recommended using the square of the pooled ranks charted similarly to the mean-rank chart introduced by Jones-Farmer et al. (2009). This method maintained a near desired FAP value, regardless of the underlying process distribution, and detected increases and decreases in variance with a higher probability than the S^2 chart in the case of nonnormally distributed processes. Jones-Farmer and Champ (2010) recommended using their scale-rank chart in conjunction with the mean-rank chart of Jones-Farmer et al. (2009).

A limitation of the retrospective Shewhart-type control charts in Phase I analysis is that all methods we found require subgrouped observations and performed better for larger subgroup sizes. Further, most of the distribution-free methods we found were all shown to work poorly when the subgroup sizes were small. Jones-Farmer et al. (2009) and Jones and Champ (2010) did not recommend their methods when the subgroup size was smaller than five,

and Graham et al.'s (2010) median-based chart requires large subgroup sizes as well. In many processes, data are often collected as individuals. The applicability of retrospective Shewhart control charts to quantitative variables gathered without subgrouping is an area that needs to be investigated. The effect of the underlying distribution of the quality characteristic will have a strong effect on the Phase I chart performance for individuals data. Because little information is known about the process distribution in Phase I, we recommend researchers develop distribution-free Phase I charts for individuals data, ideally evaluating both location and variation. Little work has been done in this area other than Capizzi and Masarotto (2013).

5. Univariate Attributes Control Charts

We found very few references for the retrospective use of control charts for attributes data. Borrer and Champ (2001) studied the retrospective use of p and np charts, using simulation to show that the FAP is quite high in many cases, especially for a large number of subgroups ($m > 50$). They recommended caution when using these charts for a Phase I analysis.

Jones and Champ (2002) and Dovoedo and Chakraborti (2012) proposed Phase I charts to monitor the times between rare events, basing their method on the exponential distribution. Jones and Champ (2002) considered cases when the in-control process parameters are known and unknown, with approximate control limits provided when the parameters are unknown. Generally, the charts for exponentially distributed data have quite low power in detecting process shifts during Phase I.

There are a number of open issues regarding the Phase I analysis of attributes data. Very large Phase I samples are necessary to estimate parameters precisely enough in order for many Phase II attributes charts to perform similarly to the known-parameters case (Zhang et al. (2013a)). Because very little work has been done in this area, it is important for researchers to study methods based on a large reference sample. Szarka and Woodall (2011) identified some methods that have been proposed to detect change points with sequences of Bernoulli data.

6. Multivariate Control Charts

Most of the multivariate control charts developed for Phase I are variations of Hotelling's T^2 control chart and are based on the assumption of a mul-

tivariate normally distributed process. Tracy et al. (1992) outlined a method to construct Phase I control limits for the retrospective T^2 control chart. Nedumaran and Pignatiello (2000) gave advice for constructing T^2 control-chart limits for retrospective analysis of subgrouped multivariate normal process variables when in-control parameters are unknown.

Very little published research has considered the issue of robust, distribution-free, or nonparametric multivariate control charts for use in Phase I. Bell et al. (2014) evaluated the performance of the retrospective Hotelling's T^2 chart under certain departures from normality and showed that it does not perform well, resulting in an FAP as high as 90% in some cases. Bell et al. (2014) proposed a retrospective mean-rank control chart for elliptically symmetric multivariate data similar to the univariate mean-rank chart of Jones-Farmer et al. (2009). In Bell et al.'s (2014) multivariate mean-rank chart, the ranks are based on the concept of data depth (Tukey (1975)), which measures the depth of a point within a multivariate sample. Liu (1995) introduced the idea of data depth to control charts, developing several Phase II control charts based on simplicial depth. Stoumbos and Jones (2000) evaluated control charts based on simplicial depth, noting that simplicial depth has limitations in distinguishing out-of-control points in a Phase I analysis. Consistent with these findings, Bell et al. (2014) showed that Phase I charts based on simplicial depth do not detect process changes as well as those based on other data-depth methods.

There are a number of important research topics pertaining to retrospective control charts for multivariate processes in Phase I. Although some work has addressed control charts for individual observations, this work is based on the assumption of multivariate normal process distributions. Our experience suggests that the multivariate normal model is rarely adequate in practice; thus, an important area of research is developing robust, nonparametric, or distribution-free Phase I control charts for observations from continuous multivariate processes. Coleman (1997), expressing this view more strongly, stated, "I submit I would never believe the multivariate normal assumption for industrial data, and even if I wanted to, I cannot believe that there are tests for multivariate normality with sufficient power for practical sample sizes that I would even bother to use them; distribution-free multivariate SPC is what we need".

In particular, more consideration needs to be given to the suitability of rank-based methods such as data depth for multivariate Phase I charts. Although some data-depth measures can be difficult and/or time-consuming to compute in higher dimensions, others are much easier to compute. Bell et al. (2014) considered a few data-depth measures, including Mahalanobis' depth, robust Mahalanobis' depth, and simplicial depth. Bell et al. (2014) showed that their Phase I control chart using robust Mahalanobis' depth detected shifts with a higher probability than the same chart using simplicial depth to rank the observations. Interestingly, Mahalanobis' depth requires little more than computing a Mahalanobis' distance measure, while it is quite difficult to compute simplicial depth in two dimensions and no algorithm has been written for computing simplicial depth beyond three dimensions. The results of Bell et al. (2014) suggest that multivariate rank-based control-chart performance depends on the particular data-depth measure chosen; thus, further study is necessary to determine which data-depth measure works best in certain situations.

Additionally, new data collection methods and the ability to combine data from multiple sources provide new opportunities for methodological researchers. Jones-Farmer et al. (2014) illustrated one application area, data quality, where there were correlated attribute variables, and discussed a lack of availability of Phase I methods to establish an in-control baseline sample. There are many research opportunities for developing Phase I (and Phase II) methods for processes that are of high dimension, have hierarchical structures, measured with multiple correlated attributes, or measured with variables of different data types. These and other directions for Phase II research were given by Woodall and Montgomery (2013).

7. Phase I Profile Methods

Profile monitoring is an approach to SPC that is used when the quality of the product or process can be best characterized by a relationship with one or more explanatory variables. Woodall et al. (2004) and Noorossana et al. (2011) provided overviews and literature reviews on profile monitoring. Much of the work on profile data is for Phase I because one must use historical data to determine the form of the profile function. One must also decide if it is reasonable to assume that the underlying profile function remains constant over time when the process is in-

control or if there is some common-cause variation to be expected in the function over time.

In the case of linear profiles, the relationship between the outcome variable and the explanatory variable(s) is often modeled using regression analysis. In Phase II, the regression parameters can be monitored using several univariate charts or a multivariate control chart, e.g., the Hotelling's T^2 chart, with the goal of detecting changes in the regression parameters as quickly as possible.

In order to monitor for changes in the profile parameters, it is important to establish baseline in-control values for the profile parameters. Mahmoud and Woodall (2004) discussed the importance of developing Phase I methods for the simple linear profile and introduced a method based on an F -test for simple linear regression models. Mahmoud et al. (2007) suggested a Phase I method for linear profiles based on change-point methods and showed that the change-point method offered improved detection of sustained step changes in the profile parameters when compared with traditional profile methods.

Ding et al. (2006) and Williams et al. (2007) developed procedures for the Phase I analysis of nonlinear profile data. The method of Ding et al. (2006) consisted of two components: a data-reduction technique to manage the high dimensionality of nonlinear profile data and a data separation method to distinguish in- and out-of-control observations. Chen et al. (2014) proposed a cluster-based method that can be applied to analyze linear and nonlinear profiles in Phase I. They recommended first fitting models to the profiles in an historical data set and then clustering the estimated model parameters to distinguish the in-control from the out-of-control profiles. Estimates of the in-control profile parameters were obtained using a mixed-model approach.

Some Phase I profile methods have been developed for nonparametric and semi-parametric models. See, for example, Abdel-Salam et al. (2013). Overall, there has been a great deal of interest in profile monitoring methods. As other applications and models are considered, there will be a need for additional Phase I methods.

8. Concluding Remarks

We have discussed important issues and developments for Phase I analysis and highlighted several helpful statistical tools. A considerable amount of knowledge about a process can result from the anal-

ysis of Phase I data. Thoughtful decisions on how to collect Phase I data, apply the Phase I methods, and interpret the results will often determine the difference between success and failure of a Phase I analysis. Our focus has been more on industrial applications but establishing baseline performance is also a key issue in public health and other health-related surveillance.

The vast majority of the statistical process-control literature concerns Phase II methods and is often based on the unrealistic assumption that the process model and parameters are known or have been determined very accurately from a Phase I analysis. We believe that Phase I has not received enough attention. In many cases, process improvement results primarily from efforts tied to Phase I with Phase II charts used to ensure that the gains in performance are maintained. We have given our perspective on some of the primary developments in Phase I methods and identified several open problems and opportunities for future research regarding Phase I methodologies.

We emphasize that process monitoring is most effective as a component of a process-improvement system, e.g., Six Sigma or the statistical engineering approach of Steiner and MacKay (2005). Woodall and Montgomery (2013) reviewed how process monitoring can be used within Six Sigma projects. Under the statistical engineering framework of Steiner and MacKay (2005), a variation-reduction approach is tentatively selected after a study of baseline data from the process. The options are to fix an obvious problem, desensitize the process or make it more robust, use feedforward or feedback control, use 100% inspection, or change the process center. The use of observational baseline data is emphasized in their methods, underscoring the importance of a Phase I analysis to process improvement systems.

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