

**Monitoring Processes with Parts  
Per Million Defective**

**S.H. Steiner and R.J. MacKay**  
*University of Waterloo*

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# Monitoring Processes with Parts Per Million Defective

**Stefan H. Steiner and R. Jock MacKay**  
Institute for Improvement of Quality and Productivity  
University of Waterloo  
Waterloo, N2L 3G1 Canada

Many processes have defective rates measured in parts per million (PPM). When the process yields such a high level of quality, traditional methods of process monitoring, such as control charts on the number of defectives or the time between defectives, may not be effective. However, it may still be desirable to monitor such processes to look for changes or opportunities for improvement. In this article, we take a critical look at attempts to apply control charts in this situation. As an alternative, we suggest that since defectives are so rare, we should carefully study any that are observed. By comparing the characteristics of the defectives to good units, both in terms of their physical dimensions and properties, and the process records from their production, we may be able to identify the key differences. Using this retrospective study, the goal is to identify a combination of continuous explanatory variates that can be monitored instead of the process output.

Keywords: PPM processes; Control Charts; Case/Control Study; Retrospective Study; logistic regression

## Introduction

Currently, many processes generate defectives at a rate less than 100 parts per million (PPM). We shall refer to such a process as a PPM process. For any process monitoring scheme, quickly detecting a deterioration in the defective rate is desirable. Since a PPM process produces so few defectives, looking at the process output does not provide much information on per unit basis. This information problem is accentuated if we are not employing 100% inspection. Here, we address the question: “Can statistical methods be effectively used to monitor changes in the rate of defectives in a PPM process?”

To answer this question, we should first clearly define the problem. We assume that each part can be judged defective or not defective. This is a discrete environment where all non defective units are considered equivalent. The framework implies that either there is no known underlying continuous measurement or that it is not (cheaply) observable. For example, the environment does preclude the situation where a part is called defective because a continuous measurement is outside of specification. If this were the case, the problem is greatly simplified by monitoring the underlying continuous measurement. We also exclude the possibility of using compressed limits where units are classified using pseudo-specification limits that are narrower than the actual specifications (Geyer et al. 1996). In this way, a PPM process is transformed into one with a much larger "defective" rate and is thus more amenable to standard monitoring methods.

This article is organized in the following manner. In the next section previously suggested control chart based approaches are criticized. We demonstrate the weaknesses of using a p-chart to monitor the defective rate directly or using a Shewhart or sequential chart for the time between defectives.

Next a possible remedy is discussed. The approach is based on using a retrospective analysis to identify continuous variables whose values are related to the defective rate. Monitoring a linear combination of these variables reduces to an application of standard control charts. We explore in more detail how well a control chart based on this combination performs,

compared to the usual charts for detecting changes in the defective rate. An example from the automotive industry is given.

## **Critique of Previously Proposed Approaches**

One approach to monitor the process performance of a PPM process is to use control charts on the process output. Control charting has a long and successful history. The idea is that by quickly determining when the process performance deteriorates, the cause of the deterioration can be identified and eliminated. Standard control charts work well when the process output can be measured on some continuous scale or when the defective rate is not close to the extremes 0 or 1.

To implement any control chart, we must first observe the process in an in-control state for long enough to allow us to estimate the in-control process performance accurately. However, with PPM processes, given the paucity of defectives, a large number of units must be inspected to gather enough information to establish the chart.

### **Control Charts to Monitor the Proportion Defective**

In the environment described here, one recommended monitoring procedure is that based on a p chart (Montgomery, 1991). Subgroups of size  $n$  are taken periodically from the process and the proportion of defectives in each subgroup is recorded. If there is 100% inspection, subgroups are formed by defining adjacent lots of units. To set up a p-chart, the standard rule is to set the control limits at  $p_0 \pm 3\sqrt{p_0(1-p_0)/n}$  where  $p_0$ , the in-control proportion defective is estimated as  $\bar{p}$ , the average defective rate in numerous subgroups from the process during an in-control period.

These control limits, based on a normal approximation, are not totally satisfactory if  $np_0$  is small, as is likely the case in a PPM environment. The limits may be improved either by using an *arcsin* transformation or better yet, by using probability limits derived from the binomial distribution (Ryan, 1989).

However, even with probability limits, there are two major difficulties in using and setting up a p chart in the PPM environment. First, to obtain any reasonable power to detect changes in the PPM process, large subgroup sizes are needed. Montgomery (1991) recommended subgroup sizes large enough so that the probability of finding at least one defective in the subgroup is at least 95%. For a small defective rate  $p_0$  this requirement translates approximately to a subgroup size larger than  $3/p_0$ . For example, assuming the process produces 50 PPM defectives when in control, then the  $3/p_0$  rule implies subgroups of at least 60,000 units. A second problem is that to set up the chart, we need to estimate  $p_0$  accurately. Assuming we follow the standard recommendation to initially collect at least 20 subgroups in order to set up the chart, in the above example, we must inspect 1.2 million units (from an in-control process) before we can begin to monitor. Similarly, when the defective rate is 5 PPM, the minimum sample size is 600,000 units and 12 million units are needed just to set up the control chart! In most applications, we suspect that these numbers are so large as to make the procedure inoperable.

### **Control Chart to Monitor the Time Between Defectives**

A clever idea, if there is 100% inspection, to alleviate the discreteness inherent in monitoring the number of defectives is to monitor the time (or number of good units) between defective units. Denote the time between defectives as  $Y$ . In this way, we change the problem from one with discrete measurements to one with a more continuous scale. Note that we also avoid the difficult problem of subgroup definition.

Using the time between defectives as a test statistic, we may employ either a Shewhart type chart, or some sequential procedure, such as an EWMA chart or CUSUM chart (Nelson, 1994). This approach was first suggested by Montgomery (1991), and further explored by Nelson (1994), and McCool and Joyner-Motley (1998). Nelson (1994) suggests an individual chart of  $Y^{.2777}$  to monitor the time between defectives. McCool et al. (1998) consider a number of different possible test statistics and control charts. In particular, they suggest that an

exponentially weighted moving average chart (EWMA) of  $Y^{.2777}$  or  $\log(Y)$  would be appropriate.

Unfortunately, there remain inherent difficulties with this approach in the PPM environment. First, it is expensive to perform the 100% inspection of units required to determine the time between defectives. Second, a good estimate of in-control mean time between defectives is needed to set appropriate control limits. For PPM processes, the time between defectives is long, and thus the amount of time (or number of units) required to gather enough information to allow reasonably precise estimation of the mean time between defectives may be too long to be practical. For example, Nelson (1994) suggests that two dozen values of the time between defectives, while the process is in control, are required to reasonably estimate the mean time between failures. When the process produces 5 PPM defective, the expected number of parts between defectives is 200,000. Thus to get 24 values of  $Y$  requires about 4.8 million units. While these data are being collected the process must remain, for the most part, in a state of control.

Even if we were able to estimate the in-control mean time between defectives accurately the control chart is not very effective. For example, we may consider some typical results from McCool et al. (1998) for the 5 PPM process. They give the average run length (ARL) for a control chart based on the time between defectives. When the defective rate has increased to 500 PPM, the ARL is given as 118.85. However, there are still, on average, 2000 units between failures, therefore on average the chart will pick up a change to 500 PPM defective only after on average 377,000 units have been inspected. Looking for increases in quality is even worse because the average time between defectives increases. If the defective rate is reduced to .5 PPM then the ARL is 2.07 and this corresponds to, on average, over 4 million parts!

This problem is not avoided by using a sequential procedure such as an EWMA chart. The performance of an EWMA chart in detecting small shifts will be somewhat superior to the Shewhart chart, but the initial implementation of the EWMA control chart still requires an initial estimate for the in-control defective rate which is not available without massive production

volume. While monitoring, since such massive sample sizes are needed, special causes may come and have disappeared before the chart signals their presence.

## A Possible Remedy

The major difficulty in monitoring the output of a PPM process, as described above, is the small amount of information per unit inspected that such data provides. One solution to this problem is to find a continuous explanatory variate or combination of explanatory variates that is (strongly) related to the defective rate. In the discrete environment described in the introduction, we assume that the identified explanatory variate is not the underlying continuous measurement that defines defectives and non-defectives, but rather some other product or process characteristic.

In this case, the identified explanatory variate will not be a perfect predictor of whether a unit is defective or not. However, changes in the explanatory variate should be related to the defective rate. We may illustrate this idea with Figure 1.

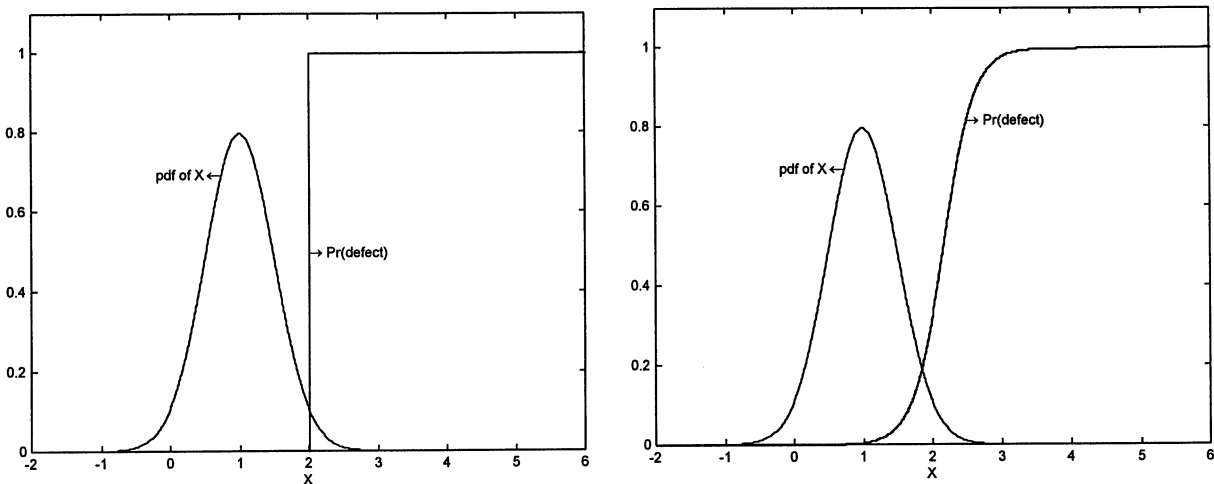


Figure 1: Underlying Continuous Variate versus Explanatory Variate

In the figure, the labeled curve gives the probability that a unit is defective for different levels of the variable  $X$ . In the plot on the left, the  $X$  represents an underlying continuous measurement that defines defectives and non-defectives. We show one-sided specification limits

here for ease of illustration. In the plot on the right, on the other hand, as the explanatory variable  $X$  increases the probability of a defective increases, but it does not suddenly jump to 1. Given the probability function of the variable  $X$  as shown, both examples result in a defective rate of about 2.3%.

If such an explanatory variate  $X$  is found, we can monitor the process using this continuous variate rather than using the defective rate or time between defectives. This approach avoids the discreteness difficulty in the original problem. The problem is how to identify the explanatory variable(s) when there are so few defective units. The key is to focus on the defectives that do occur. The defectives are compared to good units on as many process and product characteristics, denoted  $X_1, \dots, X_k$ , as possible. Variables that best distinguish between defective and good units are candidates for  $X$ . This approach was promoted by Dorian Shainin (see Bhote, 1991) and is the same as the idea underlying case/control studies that are widely used to identify risk factors for rare diseases in human populations (Schlesselman, 1982).

To identify important explanatory variates, we model the relationship between the defective rate  $p$  and the influential explanatory variates using a logistic regression model, i.e.

$$\log\left(\frac{p}{1-p}\right) = g(X) = \beta_0 + \beta_1 X_1 + \dots + \beta_k X_k \quad (1)$$

Note that, in this context, the best model often includes non-linear terms such as  $(X_i - t_i)^2$ , where  $t_i$  is the target value for characteristic  $X_i$ . With quadratic terms, any deviation of  $X_i$  from its target value will increase the defective rate. The parameters in the above model  $\beta_1, \dots, \beta_k$  can be estimated using a sample of defective units and a sample of good units using standard approaches (Hosmer et al. 1989). Based on such data, we can estimate a function  $h(X)$  that differs from  $g(X)$  only in the intercept term. That is, we can estimate

$$\hat{h}(X) = \hat{\alpha}_0 + \hat{\beta}_1 X_1 + \dots + \hat{\beta}_k X_k \quad (2)$$



The intercept term  $\beta_0$  in  $g(X)$  is inestimable without knowledge of the sampling fraction of good and bad units. In fitting this logistic model, the goal is to find explanatory variables whose corresponding model parameters ( $\beta_i$ ) are not zero. When more defectives (and non-defectives) are used in the analysis, significant explanatory variates can be identified more easily.

## Control Charts Based on Explanatory Variates

Using the identified important explanatory variates  $X_1, \dots, X_k$ , we propose to monitor the process using the linear combination  $l$

$$l = \hat{\beta}_1 X_1 + \dots + \hat{\beta}_k X_k$$

By monitoring  $l$ , we will be able to quickly detect any changes in the defective rate related to the identified explanatory variates. If  $l$  changes, then we expect that the defective rate to also change.

To monitor PPM processes using explanatory variates, as proposed here, there are a number of steps we must follow. First, using the sample that contains both defective and good units, we must identify important explanatory variates that have an influence on the defective rate, and estimate the model parameters in (1). Then we can follow standard procedures to establish a control chart based on  $l$ . For example to establish an average and range chart, we would collect a number of subgroups of values for  $l$  to set up the charts. The subgroups should be collected from the in-control process and thus typically will have no defective units.

There are two major disadvantages to the proposed approach. First, as with the output charts, a reasonable number of defective units must be obtained in order to identify the important explanatory variates and the corresponding  $\beta$ 's. The assumption is that each of these samples is representative of the two types. However, the defectives do not have to be produced during an in-control period and hence may be easier to find than when a chart based on the process output is being established. However, typically a large number of units will need to be inspected. Second,

a control chart based on  $l$  will detect *only* changes in the proportion defective that occur simultaneously with changes in the identified explanatory variates. Changes to  $p$  that are either not caused by changes in  $l$  or that do not also result in changes to  $l$  will not be detected. As such this proposed solution is not ideal. However, in situations where it is possible to identify important explanatory variates, it is superior to previously suggested approaches. Furthermore it can be used in combination with a traditional output chart that will react to changes in the defective rate due to changes in other explanatory variates than those being monitored in  $l$ .

## Comparison of Approaches

In this section, we consider some design issues and compare the proposed method to a standard  $p$  chart. We suppose that  $l$  has been identified with no estimation error in the coefficients and that, in control, the behavior of  $l$  can be described by a normal distribution with mean 0 and known standard deviation  $\sigma$ . As will be seen below there is no loss of generality in specifying the mean to be 0.

Using these assumptions, for any given  $\beta_0$  and  $\sigma$ , we can calculate the proportion of defectives in the process through the equation

$$\begin{aligned} \log p(\beta_0, \sigma) &= \log \int_{-\infty}^{\infty} \frac{e^{\beta_0+l}}{1 + e^{\beta_0+l}} \frac{1}{\sqrt{2\pi}\sigma} \exp\left(-\frac{l^2}{2\sigma^2}\right) dl \\ &= \beta_0 + \frac{\sigma^2}{2} + \log \int_{-\infty}^{\infty} \frac{1}{1 + e^{\beta_0+\sigma^2+\sigma t}} \frac{1}{\sqrt{2\pi}} \exp\left(-\frac{t^2}{2}\right) dt \end{aligned}$$

The integral in the second expression is easily evaluated numerically. For fixed  $\sigma$ , there is a one to one correspondence between  $\beta_0$  and  $p$ , the process proportion of defectives. For example, if  $\sigma = 1$  and  $p = 50$  ppm, we find that  $\beta_0 = -10.41$ . The right hand side of Figure 2 gives contours of constant  $\log_{10} p(\beta_0, \sigma)$  as  $\beta_0$  and  $\sigma$  vary.

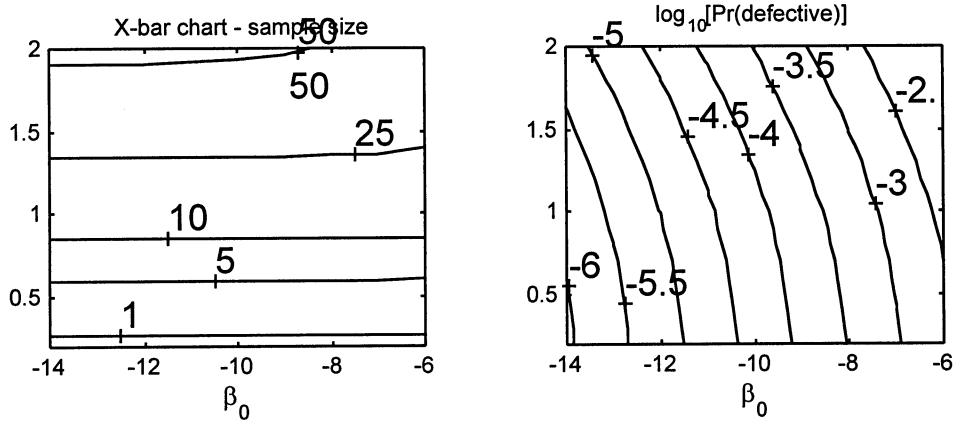


Figure 2:  $\bar{X}$  Sample Sizes and  $p_0$  as a function of  $\beta_0$  and  $\sigma$

Note that as  $\sigma$  gets relatively small, the contours are vertical and evenly spaced which indicates that  $p(\beta_0, \sigma)$  depends only on  $\beta_0$  in this case.

We use this relationship to construct X-bar charts for  $l$  with desirable properties and to compare these charts to the corresponding p-chart. For example, suppose the in-control defective rate is 50 ppm and we want a chart with one sided false alarm rate equal to  $5/1000$  and with power equal to 0.5 to detect a shift to 100 ppm. Again, we suppose that  $l$  has known mean 0 and standard deviation 1. As seen above, the corresponding  $\beta_0 = -10.41$ . If the defective rate increases to 100 ppm, we get a value of  $\beta_0 = -9.71$  which corresponds to a shift in the mean of  $l$  from 0 to 0.70. We can now use the false alarm rate and power requirement to calculate the required subgroup size for an X-bar chart in the standard way. In this case, the subgroup size is 14.

The left hand chart in Figure 2 gives the corresponding sample size more generally, assuming the false alarm rate and power are fixed as above. In each case we hope to detect a doubling in the odds of a defective. Note that for the very small defective rates considered here, this is effectively a doubling of the defective rate. To use the figure, for a fixed  $\sigma$  and in-control defective rate, determine  $\beta_0$  from the right hand chart and then read off the sample size from the

left hand chart. Note the flatness of the contours for small  $\beta_0$  and  $\sigma$ . If the in-control defective rate is small, the subgroup size needed is nearly independent of  $p_0$ .

To compare the above procedure to a p-chart on the process output, we can use a Poisson approximation (assuming  $p_0$  is small) to determine the corresponding subgroup size. If the in-control defective rate is  $p_0$ , then the upper control limit  $c$  and sample size  $n$  satisfy the equations

$$\begin{aligned} P(X_0 > c) &= 0.005 & X &\sim \text{Poisson}(np_0) \\ P(X_0 > c) &= 0.500 & X &\sim \text{Poisson}(2np_0) \end{aligned}$$

We can solve these equations numerically for  $c$  and  $np_0$ . Here we get  $np_0 \approx 10$  so that  $n \approx 10 / p_0$ . In the example with  $p_0 = 50 \text{ ppm}$ , the p-chart requires a subgroup of size about 200,000. As expected, the chart based on a continuous measurement requires much smaller subgroup size.

It is interesting that in the case of a single explanatory variate, a control chart based on explanatory variates is unaffected, in terms of power, by estimation errors in the model parameters. This is because monitoring any linear combination of  $X$  will give the same properties as monitoring  $X$  itself. Thus, assuming the mean and standard deviation of  $X$  can be accurately estimated, when the parameters in (1) are poorly estimated the control chart will not necessarily obtain the power we anticipated, but there will be no loss of power due to the estimation error. However, if there is more than one explanatory variate the resulting control charts are affected by errors in estimation. Fortunately though, even with many explanatory variates we can always set the in-control false alarm rate of the control chart to any desired level, since we can assume that the mean and standard deviation of the linear combination of explanatory variates are accurately estimated.

## Example

Exhaust valve seats are force fitted by insertion into the head of an engine. If the valve seat is not installed correctly, it can lead to a catastrophic engine failure. The quality of the fit is

judged by visual inspection using feeler gauges. Given the high volume (four seats per head, two heads per engine, 1500 engines per day), 100% inspection is very costly and likely to be ineffective, especially since the expected defective rate is low, less than 50 PPM.

A sample of 25 defective seat insertions was collected over time. Pareto analysis showed that there was no evidence that the poorly fitted seat depended on location in the head. Since no head had more than one defective seat, the remaining three seats on the head were used as controls.

Eleven measurable, potentially important explanatory variates were identified. These are  $X_1 - X_5$ , measurements of force, work and distance taken during the automated insertion process,  $X_6 - X_9$ , dimensional and physical characteristics of the valve seat and  $X_{10}$  and  $X_{11}$ , dimensional characteristics of the pocket in the head into which the seat is inserted.

The explanatory variates  $X_6 - X_{11}$  were measured on seats after insertion and there was suspicion that their value may have been distorted by the insertion process. Nevertheless these variates were included in the analysis. If any of these variates were identified as being important after  $X_1 - X_5$  were included in the model, then those variates would be included in the monitoring procedure. However, in that case, they would be measured before the insertion process and monitored separately from  $l$ .

A logistic regression model was fit to the 100 observations. Three explanatory variates,  $X_2$ ,  $X_4$  and  $X_9$  were identified as important. Since  $X_2$  and  $X_4$  were measured on every insertion, an automated CUSUM chart based on the estimated linear combination of  $X_2$  and  $X_4$  was constructed using the software available in the insertion process. The characteristic of the valve seat  $X_9$  was monitored separately using an average and range chart based on subgroups of 5 parts collected with a regular frequency. Implementation is not yet complete and 100% inspection has been retained.

## Summary

The monitoring of a process that produces defectives measured in parts per million (PPM) is often desirable. The use of control charts to monitor the defective rate of such processes based on process outputs, such as the number of defectives or the time between defectives is shown to be infeasible. The sample sizes required to set up the charts are much too large in most practical situations. As an alternative, we suggest focussing on the few defectives that are produced. In particular, we suggest a case/control type comparison of defectives and non-defectives based on as many of their other attributes as possible. If we can find some other variable or combination of variables that is associated with defectives (or non defectives) we may be able to determine a continuous variate to monitor.

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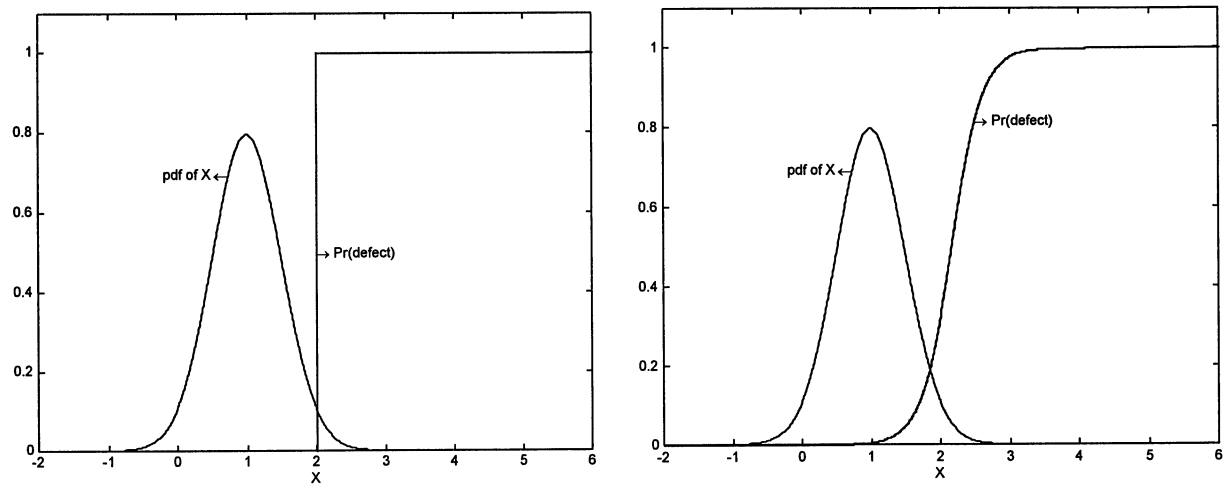


Figure 1: Underlying Continuous Variate versus Explanatory Variate