Minimizing Glovebox Glove Breaches, Part IV: Control Charts

M.E. Cournoyer, M.B. Lee, S. Schreiber
Los Alamos National Laboratory
Los Alamos, NM 87545
USA

ABSTRACT

At the Los Alamos National Laboratory (LANL) Plutonium Facility, plutonium isotopes and other actinides are handled in a glovebox environment. The spread of radiological contamination, and excursions of contaminants into the worker's breathing zone, are minimized and/or prevented through the use of glovebox technology. Evaluating the glovebox configuration, the glovebox gloves are the most vulnerable part of this engineering control. Recognizing this vulnerability, the Glovebox Glove Integrity Program was developed to minimize and/or prevent unplanned openings in the glovebox environment, e.g., glove failures and breaches. In addition, LANL implement the "Lean Six Sigma (LSS)" program that incorporates the practices of Lean Manufacturing and Six Sigma technologies and tools to effectively improve administrative and engineering controls and work processes. One tool used in LSS is the use of control charts, which is an effective way to characterize data collected from unplanned openings in the glovebox environment. The benefit management receives from using this tool is two-fold. First, control charts signal the absence or presence of systematic variations that result in process instability, in relation to glovebox glove breaches and failures. Second, these graphical representations of process variation determine whether an improved process is under control. Further, control charts are used to identify statistically significant variations (trends) that can be used in decision making to improve processes. This paper discusses performance indicators assessed by the use control charts, provides examples of control charts, and shows how managers use the results to make decisions. This effort contributes to LANL Continuous Improvement Program by improving the efficiency, cost effectiveness, and formality of glovebox operations.

INTRODUCTION

Programmatic operations at the Los Alamos National Laboratory (LANL) Plutonium Facility (TA-55) involve working with various amounts of plutonium and other nuclear materials. The spread of radiological contamination and excursions of contaminants into the worker's breathing zone is minimized and/or prevented through the use of glovebox technology. Evaluating the glovebox configuration, the glovebox gloves are the most vulnerable part of this engineering control. Thus, the minimization of unplanned openings in the glovebox environment, e.g., glove failures and breaches, is a primary concern in the daily operations. TA-55 proactively investigates processes and procedures that reduce glove malfunctions through the Glovebox Glove Integrity Program (GGIP). This is the fourth paper on this issue [Ref. 1].

LANL has a Continuous Improvement Program in which efficiency, cost effectiveness and formality of operations are constantly being improved and is supported by "Lean Six Sigma" activities using Lean Manufacturing and Six Sigma business practices. [1] Six Sigma, indicates that one has to exceed six standard deviations before finding failure. Six Sigma is a standard of quality striving for 99.9997 percent accuracy (or 3.4 defects per million). This is achieved using a collection of tools to gain a desired outcome. A primary analysis tool of quality improvement in applied science and business is Statistical Process Control (SPC). It helps one to collect, organize and interpret the wide variety of information available to an organization. SPC is used to help measure, understand, and control parameters that affect business processes and/or performance. An account of this approach to radiological processes has been described previously [Ref. 2]. A key component of this methodology is the use of performance indicators. They measure of how well an organization is meeting it objectives and/or achieving its desired outcomes. Performance indicators evaluate the progress of an organization achieving its objectives and goals. To adequately track the performance of an organization, effective performance indicators need to be developed. Effective indicators should have the ability to do the following:

- Measure a process with accuracy
- Provide a comprehensive overview of vital organizational processes
- Measure objectively
- Measure attainable objectives/outcomes
- Measure relevant outputs of processes
- Be verifiable, in which data and conclusions can be checked and replicated by an independent source.

Performance indicators can be divided into two major groups, lagging and leading indicators. Lagging indicators tend to reflect the outputs of multiple processes or outcomes. Leading indicators provide information on single or multiple outputs that supply partial contribution to the overall outcome. In addition, this information measured from an output of a process or a larger process results in an outcome measured by a lagging indicator. In other words, a lagging indicator represents an outcome of an overall process consisting of multiple outputs while a leading indicator represents a measure of one or more of the outputs of the overall process. Leading indicators provide information at a rate greater than lagging indicators. Receiving information about the quality of a process using lagging data is ineffective. Leading indicators identify issues more quickly and provide a warning before the process goes completely out-of-control. Conversely, lagging indicators detect processes when they are out-of-control, which usually has high and adverse consequences for the organization that are more difficult to mitigate. The frequency of leading indicators should not be used as a predictor for future outcomes or be used to forecast more serious events; they only measure and monitor the process concurrently. The consequence for each occurrence of a leading indicator should be negligible to low. In contrast, lagging indicators may include outcomes that are either moderate or highly significant. Leading indicators measure inputs, outputs, or outcomes that occur at a level of quality for concern that is below that of the customer or external regulator. Conversely, lagging indictors measure inputs, outputs, or outcomes that are significant to the customer or external regulator. Control charts are tools that can be used for both leading and lagging indicators.

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[1] Named after the number of standard deviations around the mean (6σ),

CONTROL CHARTS

Control chart are used to validate the variation of measurement of processes or performance. They cannot determine what actions should be taken. The causes of variation in a control chart can be classified as random or systematic. Random causes in a process are indicated by small intrinsic variations that are present at all times. Systematic causes in a process are signified by large variations or unswerving patterns that are identifiable and preventable. Processes are considered to be under statistical control (stable) if all the variation is random; and out of statistical control (unstable) if the variation is systematic.

Control charts are divided into two categories depending on the type of data charted, which include variable and attribute control charts. Variable control charts use data that can be measured on a continuous scale such as temperature, weight, volume or length. Attribute control charts use data that are discrete and/or dichotomous for example, good or bad, possessing or not possessing a particular characteristic, acceptable or unacceptable or etc. Variable control charts provide better information about a process than attribute data; and require fewer samples to draw meaningful conclusions. Conversely, attribute control charts provide quick summaries of various processes. Attribute control charts are accepted more by managers because they are easier to understand.

Control charts are constructed by selecting a measurement and plotting values for that measure for a specified time interval (monthly, quarterly, etc.). Control limits are then established; and if data points meets the criteria of a fixed set of rules (trend), then a systematic cause is assumed to be present. Although there are many types of control charts, this document discusses only the *c*-chart that plots attribute data.

The *c*-chart, also known as a count chart, monitors the number of times an output occurs. The control limits for this chart are based on the Poisson distribution (the standard deviation is the square root of the average). The following equations are used to construct the *c*-chart.

1. The average or baseline is calculated using:

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x$$

2. The standard deviation is calculated using:

$$\sigma = \sqrt{x}$$

3. The upper control limits (UCL) and lower control limits (LCL) are calculated using;

$$\text{UCL} = \bar{x} + 3\sqrt{x} \quad \text{and LCL} = \bar{x} - 3\sqrt{x}$$

A trend is defined by the relationship of data points plotted on a control chart and are detected through preset rules. If a trend is detected, the special cause of the trend is determined. Trends in the existing data are determined by the following criteria [Ref. 3]:

- One point outside the control limits (Definitive)
- Two out of three points two standard deviations above/below average (Sigma Zone)
- Four out of five points one standard deviation above/below average (Sigma Zone)
- Seven points in a row all above/below average (Patterns)
- Seven points in a row all increasing/decreasing (Patterns)
- Ten out of eleven points in a row all above/below average (Patterns)

If a trend is detected, then determine the reason(s) for the trend. Depending on the cause and the direction of the trend, the objective becomes to reinforce the positive trend, stabilize performance, or correct the adverse trend. A trend may be positive or negative depending on the direction and requires an analysis of the cause of the trend to make this decision. If a trend does not exist, decide whether to (1) maintain the current performance or (2) strive for improvement. To make this decision, either assess essential benchmark data, perform a risk analysis and/or determine customer/ management expectations.

If random causes are associated with the process and the decision is to strive for improvement, the process itself must be changed. When a trend is identified, decide if separate regions with the baseline, UCL, and LCL are warranted, or if the baseline and control limits require recalculation. If a trend is still present after any necessary adjustments, or if no adjustments are needed, then consider it statistically significant.

MEASUREMENT OF GLOVE BREACHES AND FAILURES

Unplanned openings in the glovebox environment can lead to significant costs due to the loss in production, cleanup, and paperwork. There are two main types of unplanned openings in the glovebox environment, glove breaches and glove failures. A glove breach is caused by mechanical damage during operations (e.g., penetration with a sharp object, rotating equipment, pinch points, thermal sources, etc.). The primary means of minimizing glove breaches is through administrative controls and Personal Protective Equipment (PPE). A glove failure is caused by degradation of the mechanical properties over time (e.g. exposure to chemicals and nuclear materials). The primary means of minimizing glove failures is through controlling the service life intervals for the glovebox gloves. The tracking of glove breaches and failures per month are leading indicators that measures effectiveness of processes and programs that could either minimize or prevent outcomes that result in the spread of contamination or internal doses to workers. Another leading indicator of importance is the tracking of near misses per month. A near miss is the determination of a glove that doesn't meet specifications for thickness or chemical resistance but has not caused an opening in the glovebox environment. The increase in near misses could indicate that glove inspections are becoming more effective because degraded gloves are being identified prior to breaching. Glovebox glove breaches, failures, and near misses are tracked through the GGIP database as well as the LANL Radiological Protection Observation database. Glovebox glove changes that are not a result of glove breaches, failures, or near misses are also documented. The result of this analysis will be reported at a later date.

Control charts are constructed using the following approach:

- Plot an x-axis that depicts independent data such as time (months). The x-axis should be linear with constant intervals. **Note:** Plot all data using the same time interval.
- Plot a y-axis that depicts dependent data (glove breaches, failures, or near misses) that corresponds to each time interval. Integer values are used.
- Generate a control chart that consists of a baseline (average); an upper control limit and a lower control limit. Use at least twenty-five (25) data points. Also, it is useful to calculate and plot control limits at $\pm 1\sigma$ and $\pm 2\sigma$ (as long as the value is not below zero) because it facilitates detecting trends.
- Set the control limit to three standard deviations (3σ) around the average so data points will fall inside the limits 99.7% of the time.
- Detect a trend in the existing data by the following criteria [Ref. 3]:

Updating control charts include extending the baseline and control limits horizontally for the *c*-charts. Older data points may be eliminated if the graph becomes too compressed. However, keep at least 25 points on the graph. The time interval for the calculated average and control limits should be documented. Do not recalculated the average for each time interval for any of the control charts, and for *c*-charts do not recalculated the control limits each time interval.

Sometimes unique conditions occur while constructing control charts such as data obscuring a baseline and control limits because of outliers or data falling near or overlapping control limits. Reference 5 provides guidance on how to manage these special conditions as well as others.

RESULTS

Following the approach discussed in the previous section baselines for glove breaches, failure and near misses have been compiled as shown in Table 1.

Table 1. Glove Breaches, Failures, and Near Misses Data

Date	No. of Breaches	No. of Failures	No. of Near Misses
Jan-04	1	0	0
Feb-04	3	1	1
Mar-04	0	0	0
Apr-04	0	0	0
May-04	6	4	0
Jun-04	6	3	2
Jul-04	1	4	0
Aug-04	1	1	0
Sep-04	0	1	1
Oct-04	0	1	1
Nov-04	0	2	0
Dec-04	1	3	0
Jan-05	2	2	2

Feb-05	0	1	1
Mar-05	0	2	0
Apr-05	3	4	0
May-05	1	1	0
Jun-05	1	2	0
Jul-05	0	1	0
Aug-05	1	2	0
Sep-05	1	4	0
Oct-05	2	1	1
Nov-05	1	3	0
Dec-05	1	0	1
Jan-06	2	2	1

The baseline (control limit) averaging 25 months of breaches is one. The UCL is four breaches per month, 2σ is three breaches per month, 1σ is two breaches per month and -1σ is zero breaches per month. Two trends were observed May 2006 and August 2006.

The baseline averaging 25 months of failures is two. The UCL is five failures per month, 2σ is four failures per month, 1σ is three failures per month and -1σ is one failure per month. No trend was observed for failures.

The baseline for near misses averaging 25 months is zero. The UCL is three near misses per month, 2σ is two near misses per month, and 1σ is one near miss per month. Lower control limits were not tracked because zero is lowest number of near misses that is possible. A trend was observed July 2006 for near misses. Control charts for glove breaches, failure and near misses have been plotted for more recent months as shown in Figures 1-3. Circled areas represent trends.

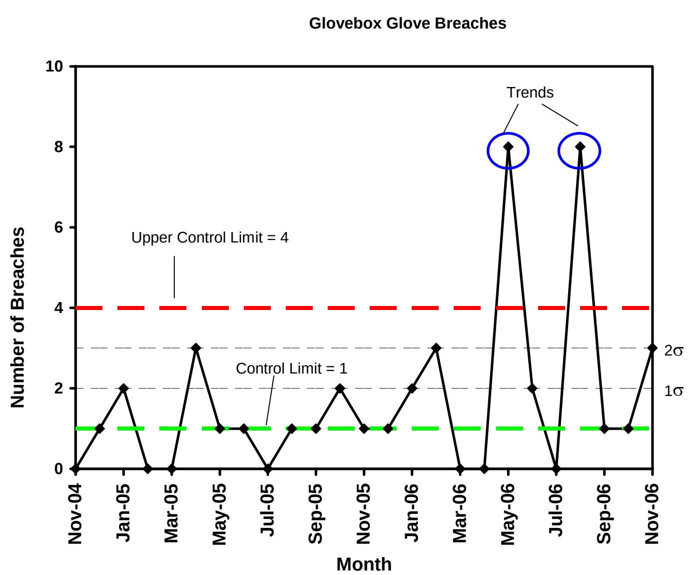

Figure 1. Control chart for monthly glovebox glove breaches

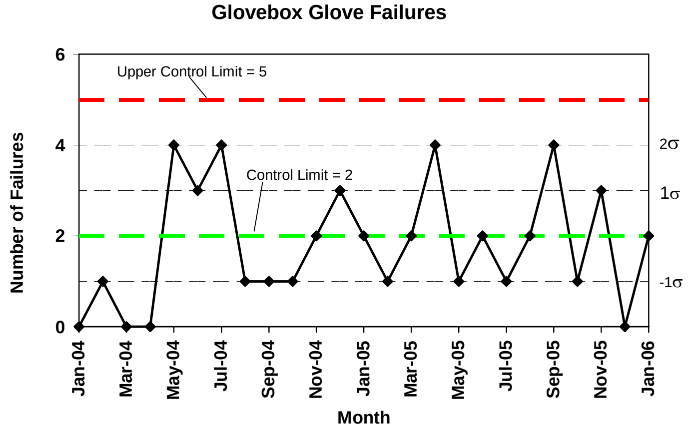

Figure 2. Control chart for monthly glovebox glove failures

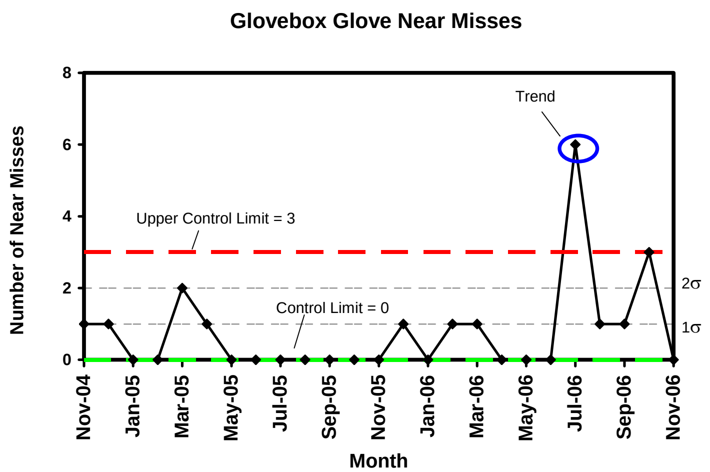

Figure 3. Control chart for monthly near misses.

DISCUSSION

A process is considered "out of control" when data points meets the trending criteria that shows an adverse effect the process. The most commonly used control chart interpretation scheme consists of different tests or indicators that can be loosely grouped into the **definitive**, **patterns**, and **sigma zones** [Ref. 4]. A **definitive** result occurs when one or more points fall outside the control limit as shown in Figures 1 and 3. This is the case when outliers are present, and is the first test for an out-of-control process. **Patterns** occur when a consecutive string of data show a pattern. **Sigma zone** occurs when a certain number of data points can be located in specific control chart zones. The zone category of indicators focuses on the location of the data points rather than on the existence of a pattern. A certain number of points falling within one of the zones or beyond serve as a notice that special cause variation exist and that process adjustments maybe necessary. When the outcome of a process does not meet the criteria that define trends, that process is said to be in a state of statistical control. Variation in the process is measured historically over time and control limits are calculated based on the measurements. Therefore, current process variation can be compared with historical variation, and if the difference is large enough action can be taken. Thus, control charts serve an important function to detect significant change and the control limits act as alarm values. Interpretation of the data in the result section is discussed next.

In May and June of 2004, six breaches per month were documented. The baseline was not recalculated because the average and standard deviation did not change when 30 or 40 months were used. The tracking of breaches from September 2004 to September 2006 yielded two trends, as shown in Figure 1. For the months of May and August, there was twice the number of breaches (8) than the UCL (4). These are more examples of **definitive** results. The first trend was considered adverse. "Lessons Learned" from investigating these incidents indicated that sharps (objects that can potential penetrate surfaces) played a primary role in the formations of several of these breaches. Glovebox workers were not aware that items such as pencils, ball point pens, screwdrivers, etc. can constitute a sharp hazard. As a result, management issued a Notice on the awareness of sharps in gloveboxes [Ref. 5]. The controls stated in the Notice were incorporated into work control documents that identified sharps as a hazard in a glovebox. The second trend was also considered adverse. Sharps in the glovebox environment were, once again, considered the root cause of more than half the breaches. Further study showed that the current controls were not being followed, which initiated additional training for glovebox work [Ref. 6]. This implementation requirement was in effect until the Radiological Protection Observations reflected a rate of glovebox breaches due to sharps decrease to two per month or less for a duration of three months or more. During the same time period, no trends were observed for glove failures. The control chart is stable, but improvement is desired. Management may decide to take action to improve the system. One trend was observed for near misses. Six near misses were reported in June 2006, this was twice the UCL of three near misses. This is another example of a **definitive** result and represents a positive trend that requires no action from management.

As discussed above, management can use reliable statistical practices to determine whether a process must be adjusted. Management can also analyzed chart results to determine whether the adjusted process is functioning within acceptable variation limits and is in statistical control. In addition, control charts help management establish whether a process continues to meet improved standards by using a systematic analysis that identifies special cause variation and designates a process as being in or out of statistical control. In summary, control charts provide a means of presenting data into a visual format that is easy to interpret as well as identifying and conveying something useful about a process.

SUMMARY

In this paper, control charts are used to track and trend effective performance indicators in relation to unplanned glovebox glove breaches and failures. Control charts are useful visual aids that detect statistically significant changes in processes   Management uses this tool in decision making to improve the glovebox environment, process and work practices regarding unplanned glovebox infractions. As a result, excursions of contaminants into the operator’s breathing zone and excess exposure to radiological sources associated with unplanned breaches and failures in the glovebox have been minimized. In conclusion, investigations of control failures and near misses contribute to an organization’s scientific and technological excellence by providing information that can be used to improve operational safety.

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