

## **Statistical Process Control**

Up to now the class has covered basic business statistics and regression analysis. We now move to an application of statistics known as Operations Management. It involves (in part) the challenge of designing and operating processes that provide a service package to the total satisfaction of customers. The failure to satisfy customers (be they internal or external) is a process failure. Thus, evaluating process performance is an important element of process analysis.

### **I. Total Quality Management**

**TQM** is a philosophy that stresses three principles for achieving high levels of process performance and quality: Customer Satisfaction, Employee Involvement, and continuous improvement in performance.

#### **1. Customer Satisfaction**

Customers (internal or external) are satisfied when their expectations regarding a service or product have been met or exceeded.

- Conformance to specifications
- Value
- Fitness for use – how well the service or product performs its intended purpose.
- Support
- Psychological Impressions – atmosphere, image, or aesthetics

#### **2. Employee Involvement**

- Cultural Change. Under TQM everyone is expected to contribute to the overall improvement of quality. Thus one of the challenges is to define *customer* for each employee. The external customer(s) are often far removed from particular employees. Thus the notion of internal customers is important here.
- Teams.

### **3. Continuous Improvement**

Continuous improvement involves identifying benchmarks of excellent practice and instilling a sense of employee ownership in the process.

Generally firms will use a “plan-do-check-act” cycle in their problem-solving process

## **II. Statistical Process Control**

One practical type of continuous improvement is the use of statistical process control. This is the application of statistical techniques to determine whether a process is delivering what the customer wants. SPC primarily involves using control charts to detect production of defective services or products or to indicate that the process has changed and that services or products will deviate from their design specifications unless something is done to correct the situation. Examples:

- A decrease in the average number of complaints per day at a hospital,
- A sudden increase in the proportion of bad lab tests,
- An increase in the time to process a lab test, chart, billing claim, etc.

- An increase in the number of medication errors
- An increase in the absenteeism rate in a particular nursing unit.
- An increase in the number of claimants receiving late payment from an insurance company.

Suppose that the manager of the accounts payable department of an insurance company notices that the proportion of claimants receiving late payment has risen from an average of .01 to .03. Is this a cause for alarm or just a random occurrence? Note that if it is random, any resources devoted to “fixing” the problem would be wasted, but if there is truly a problem, then it may be worthwhile to attempt to fix.

### **Variation of Outputs**

Even if the processes are working as intended there will be variation in outcomes, but it is important to minimize the variation because variation is what the customer sees and feels. We can focus on the types of variation:

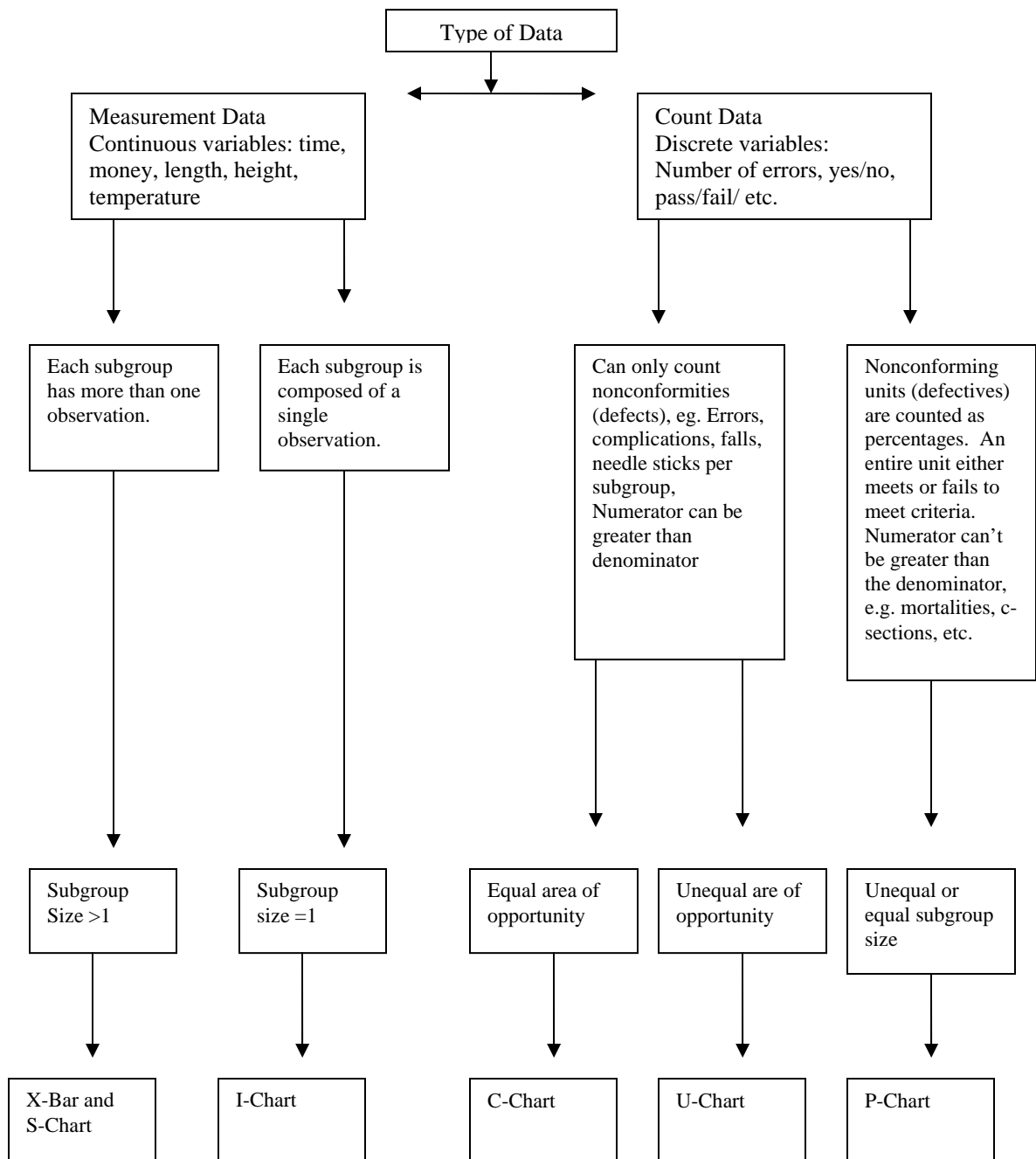
1. Common Causes -- these are purely random, unidentifiable sources of variation that are unavoidable with the current process. Statistically, this is referred to as “noise”
2. Assignable Cause – any variation-causing factors that can be identified and eliminated. An employee that needs training, or a machine that needs repair.

To detect abnormal variations in process output, employees must be able to measure performance variables. One way is to measure variables – that is, service or product

characteristics, such as weight, length, volume, or time that can be measured. Another way is to measure attributes – characteristics that can be quickly counted for acceptable performance. Ex: the number of insurance forms containing errors that cause underpayments or overpayments, the proportion of radios inoperative at the final test, the proportion of airline flights arriving within 15 minutes of scheduled times, etc. The advantage of attribute counts is that less effort and fewer resources are needed than for measuring variables, but the disadvantage is that, even though attribute counts can reveal that process performance has changed, they may not be of much use in indicating by how much.

### **Control Charts**

In order to decide if the variation is out of whack, statistical process control methods use control charts. These are time-ordered diagrams that are used to determine whether observed variations are abnormal.



The chart first splits the decision into two types – those using continuous variables and those using count or discrete data. On the continuous side there are two further classifications. When you have information about the subsamples (say you are looking at the average LOS per week, and you have 100 patients per week to get that average), then we use an X-bar and S-chart (Xbar for average, and S for standard deviation). If, however, we only have information on the average (say we only have the average LOS per week but not the individual observations that generated those averages), then we use an I chart.

**Control Charts for Variables**

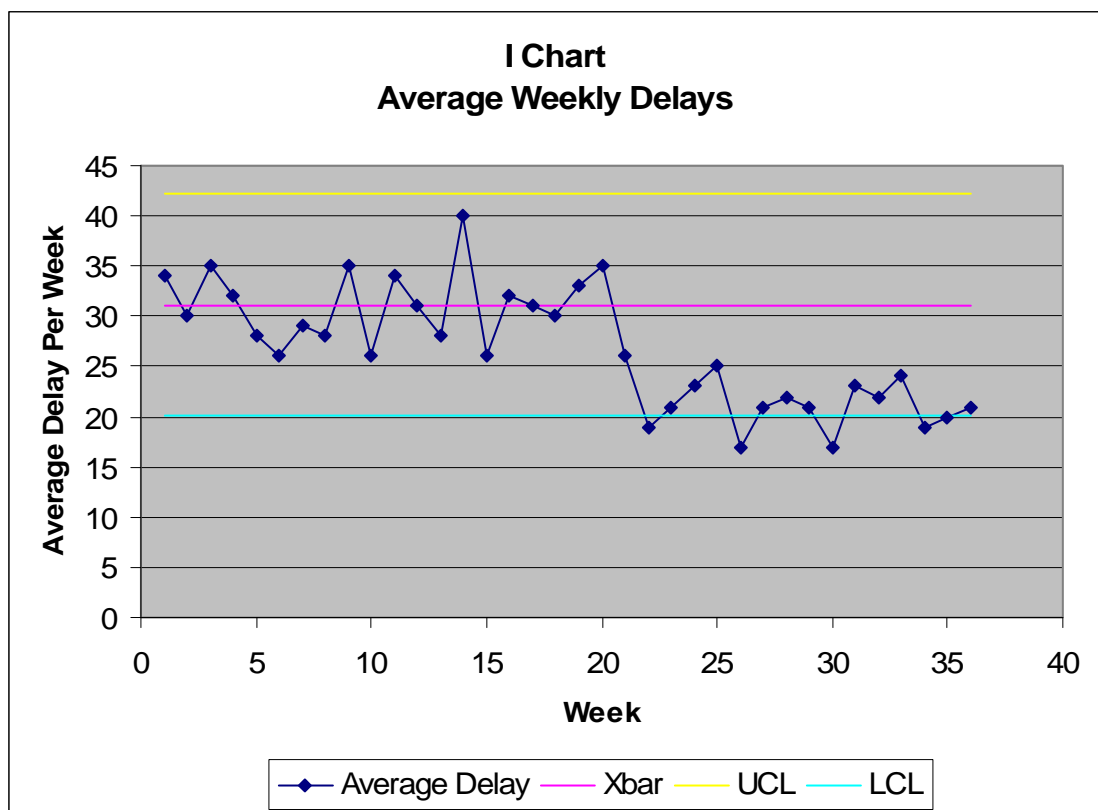
I chart. In the accompanying Excel spreadsheet (SPC Examples.xls) on the worksheet labeled I-chart, is an example of using an Ichart. These data are the Weekly average of delays between an abnormal mammogram and biopsy. Presumably we’d want this number to be as low as possible. What is shown are the average days delay per week over a 36 week period. After week 20 an “intervention” was instituted that was intended to reduce the average delay. We want to know if the intervention helped to reduce the delay. Note that all the information we have is the average delay per week, we do not have the individual data that went into making these averages. Thus we have to construct an I chart.

Basically what all of these charts do is construct a confidence interval that moves through time, then by tracking how each new period’s data falls within that range we can make judgments about how we are doing.

|               |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
|---------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Week          | 1  | 2  | 3  | 4  | 5  | 6  | 7  | 8  | 9  | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| Average Delay | 34 | 30 | 35 | 32 | 28 | 26 | 29 | 28 | 35 | 26 | 34 | 31 | 28 | 40 | 26 | 32 | 31 | 30 | 33 | 35 |

To construct the chart, we first calculate the average of the average weekly delay, this is 31.15. The standard deviation is 3.70. Next we construct the upper and lower control limits. Generally these are constructed to be 3 standard deviations above and below the mean. So  $UCL = \bar{X} + 3S$ , and  $LCL = \bar{X} - 3S$ . You can also do this using “2-sigma” limits as well. Basically it becomes a tradeoff between type I and type II errors. Note that these give slightly different numbers from what the book uses. The book uses a formula based on the range of the data. I prefer using the standard deviation.

Doing this and putting it all in a graph gives us the following:



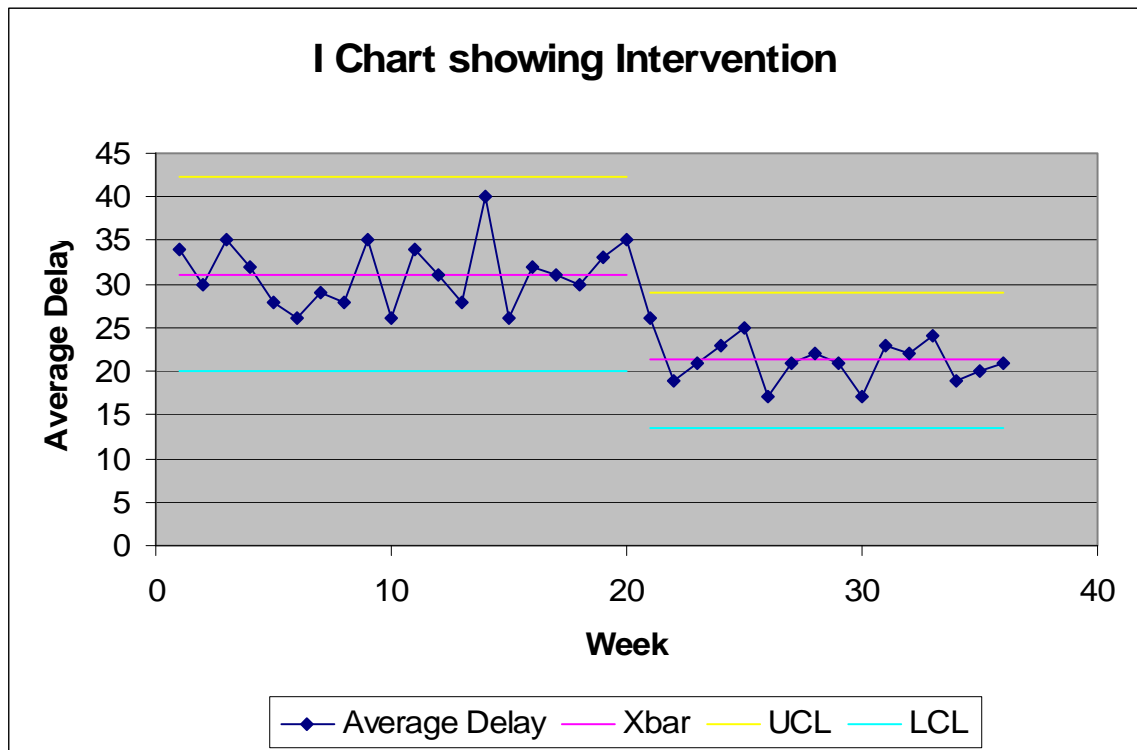
So the Xbar, UCL, and LCL were constructed on the first 20 weeks of data (before the intervention). Plotted are the first 20 weeks, plus the 15 weeks that followed. So what can we say?

### **Detecting Special Causes**

We want to be able to distinguish “information” from “noise” or Special (assignable) causes from common causes. That is when should we pay attention and when should we ignore?

1. **A special cause is indicated when a single point falls outside a control limit.** In weeks 26 and 30, note that we are below the LCL, that is we are more than 3 standard deviations below the mean. It is pretty unlikely for this to be a random event (less than a 1 percent chance), so we would say this is a special cause – something different has happened here.
2. **A special cause is indicated when two out of three successive values are: a) on the same side of the centerline, and b) more than two standard deviations from the centerline.** The 2 sigma LCL is 23.7, so in weeks 21, 22, 23 we have two of three observations below this.
3. **A special cause is indicated when eight or more successive values fall on the same side of the centerline.** So we get this in the above chart weeks 21 to 28 are all below the centerline.
4. **A special cause is indicated by a trend of six or more values in a row steadily increasing or decreasing.** This is not shown in the above graph.

Using the above criteria we can know say something about the intervention. First note that in the first 20 weeks of data there are no special causes – things are pretty stable, but after week 20 we get a different picture, special causes are detected from Tests 1, 2, and 3. So we could conclude that the “world has changed” We could re-do the graph to show this:



These are the same data, but it now shows the new mean, UCL, and LCL after the intervention. So now when we get future data, we compare them to the new numbers, etc. This is the continuous improvement idea.

Recall that this type of chart only had data on the mean per week and so we had to treat each sample as a data point and use the standard deviation (as opposed to the

standard error) to construct the limits. This makes them larger than they would be if we had sample information. This is what the X-bar chart does:

X-Bar and S-Chart When each subgroup has more than one observation then we can use this information to our advantage by accounting for the sample variations. In the worksheet titled “X-Bar and S-Chart” is an example of this. Here we have lab turnaround time from lab to ED using a sample of three tests each day for 23 consecutive weekdays (you don’t have to have the same number of observations per period, but as we’ll see it is easier if you do).

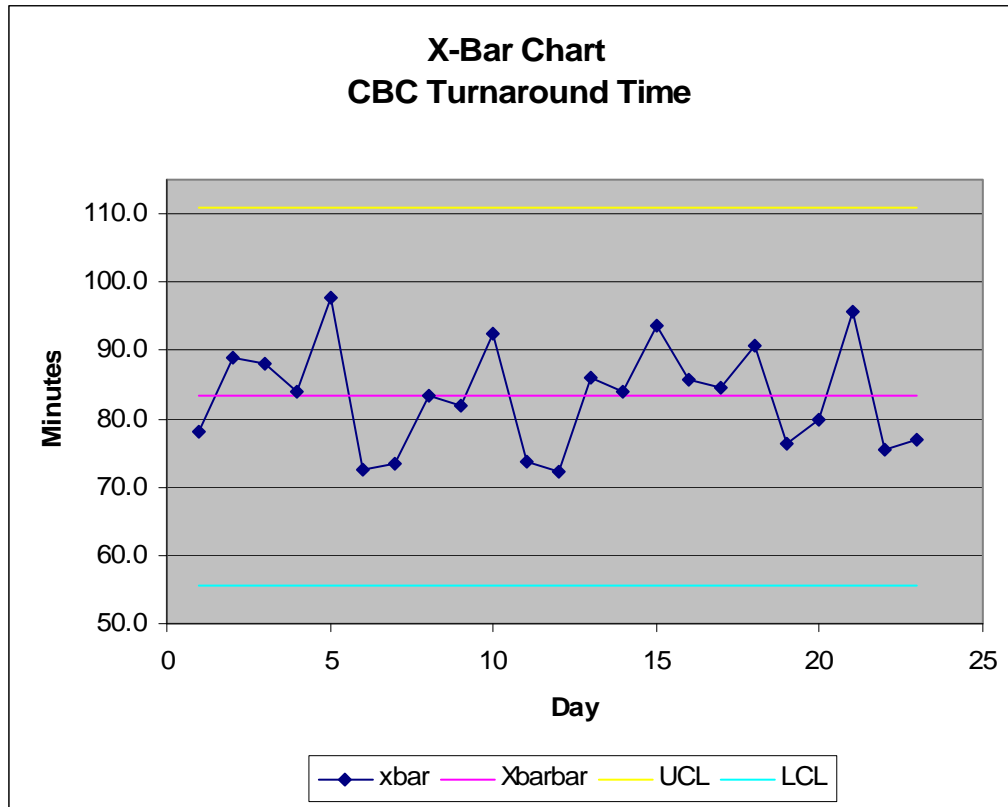
| day    | 1    | 2    | 3    | 4    | 5    | 6    | 7    | 8    | 9    | 10   | 11   | 12   | 13   | 14   | 15   | 16   | 17   | 18   | 19   | 20   | 21   | 22   | 23   |
|--------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| test1  | 86   | 90   | 101  | 76   | 102  | 81   | 75   | 92   | 93   | 109  | 70   | 80   | 85   | 69   | 106  | 89   | 85   | 95   | 72   | 95   | 75   | 60   | 77   |
| test2  | 73   | 82   | 74   | 71   | 76   | 82   | 50   | 65   | 71   | 92   | 84   | 79   | 63   | 71   | 93   | 95   | 101  | 89   | 60   | 84   | 97   | 110  | 55   |
| test3  | 75   | 95   | 89   | 105  | 115  | 55   | 95   | 93   | 82   | 76   | 67   | 58   | 110  | 112  | 82   | 73   | 68   | 88   | 97   | 61   | 115  | 56   | 99   |
| xbar   | 78.0 | 89.0 | 88.0 | 84.0 | 97.7 | 72.7 | 73.3 | 83.3 | 82.0 | 92.3 | 73.7 | 72.3 | 86.0 | 84.0 | 93.7 | 85.7 | 84.7 | 90.7 | 76.3 | 80.0 | 95.7 | 75.3 | 77.0 |
| st dev | 7.0  | 6.6  | 13.5 | 18.4 | 19.9 | 15.3 | 22.5 | 15.9 | 11.0 | 16.5 | 9.1  | 12.4 | 23.5 | 24.3 | 12.0 | 11.4 | 16.5 | 3.8  | 18.9 | 17.3 | 20.0 | 30.1 | 22.0 |

So xbar is the average for each day, sdev is the standard deviation for each day. If we take the average of the average (Xbarbar) we get 83.28, and if we take the standard deviation of all the sample means (Sbar) we get 15.99. Now we can construct the UCL and LCL as:

$$UCL = Xbarbar + 3*Sbar/sqrt(n)$$

$$LCL = Xbarbar - 3*Sbar/sqrt(n)$$

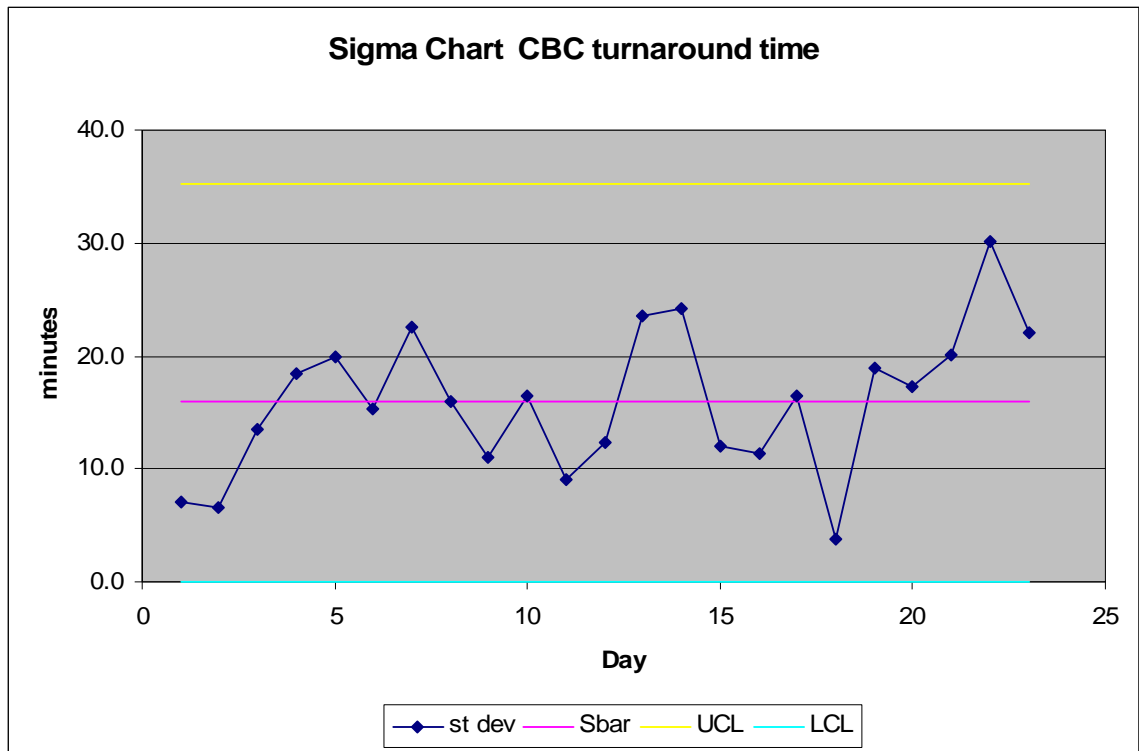
Where n is the size of the sample from each day – so if the sample sizes are the same for each period the UCL and LCL will be the same across the chart, but if the sample sizes vary, then the UCL and LCL will also vary. Doing this and graphing gives us the Xbar chart:



Note that things here look pretty stable: there are no observations outside the 3-sigma limits. The two sigma limits are 101.7 and 64.8 and no observations are outside of them either. There are not eight successive values above or below the centerline, and there is not a trend of six or more.

Note that we also can (and should) look at what is happening to the variance over time. This is the s-bar chart. Basically we do the same thing with the standard deviation as we did with the mean. We know the standard deviation for each period, and we can construct the average of the standard deviations and look at how day to day observations bounce around the standard deviation. First we construct the average of the standard deviations and then the standard deviation of the standard deviations. Then use 3 times this standard deviation to construct the

UCL and LCL. Note that if the LCL is calculated to be negative, we set it equal to zero since negative values do not make sense.

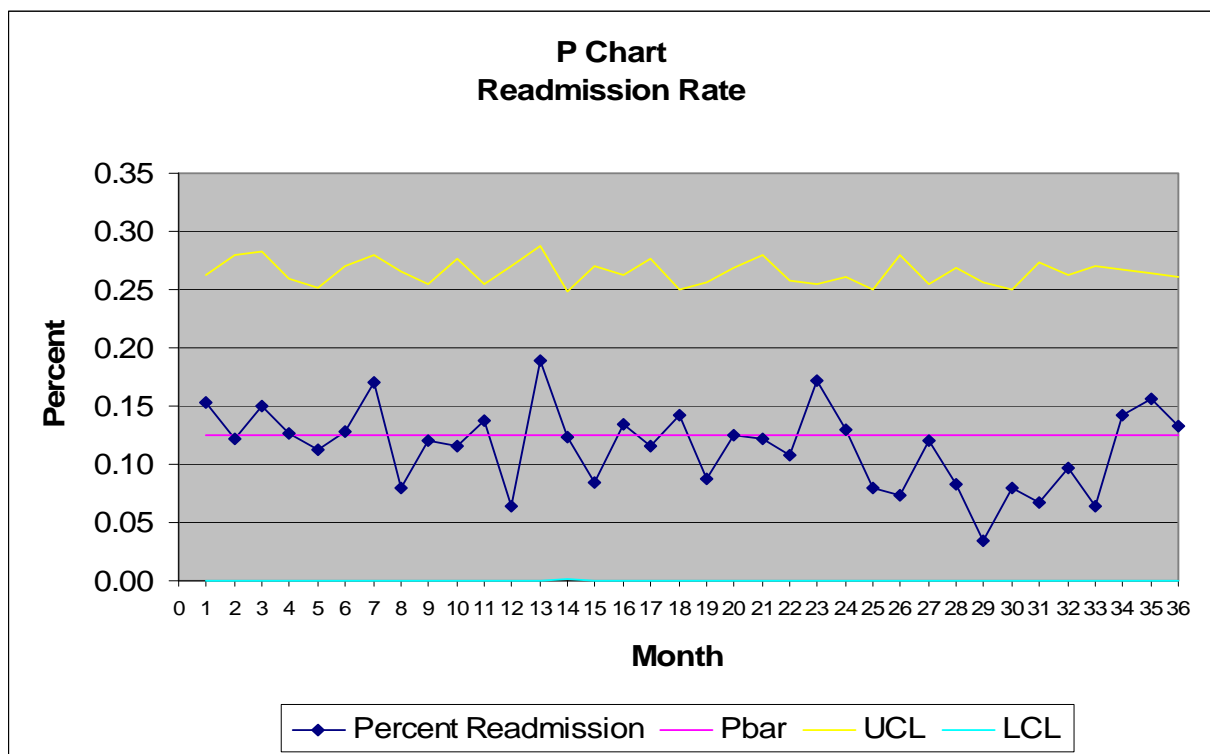


Again things look pretty stable. In practice one would first want to look at the s-chart to make sure the process was stable, and then go to the xbar chart, but both can help identify abnormalities in the process. *A good way to think about it is that the xbar chart looks at variations overtime (or across subgroups) while the s chart looks at variation within groups.*

### Control Charts for Count or Attribute Data

P-chart The p-chart is probably the easiest to deal with. In this case we have a percentage or proportion of something that we are tracking over time. On the worksheet titled “p-chart” data for Readmission Rates after Congestive Heart Failure 1998-2000. In January 2000 an intervention occurred (a case management protocol), and so we want to know if things have improved.

So we know how many patients were admitted for heart failure and how many of them were later readmitted, and thus we know the proportion of readmit for each month. To construct the control chart, we first calculate the total proportion of readmission for the period prior to the intervention (1998 and 1999) this is  $\bar{p} = .125$ , then to construct the UCL and LCL we calculate  $\text{Sigma} = \sqrt{[(p) \cdot (1-p)] / (n)}$ . This should look somewhat familiar (think back to the standard error when doing hypothesis tests on a proportion). Note that the  $n$  is the sample size for each period which varies, thus the UCL and LCL will vary across the chart. So the UCL is  $\bar{p} + 3$  times the sigma for each month and the LCL is the maximum of  $\bar{p} - 3$  sigma and zero.



So note that prior to the intervention there is only common cause variation (all the variation is noise), but after month 24 we get 9 consecutive months below the centerline (test 3) and so conclude that the plan seems to have been successful – at least for a while.

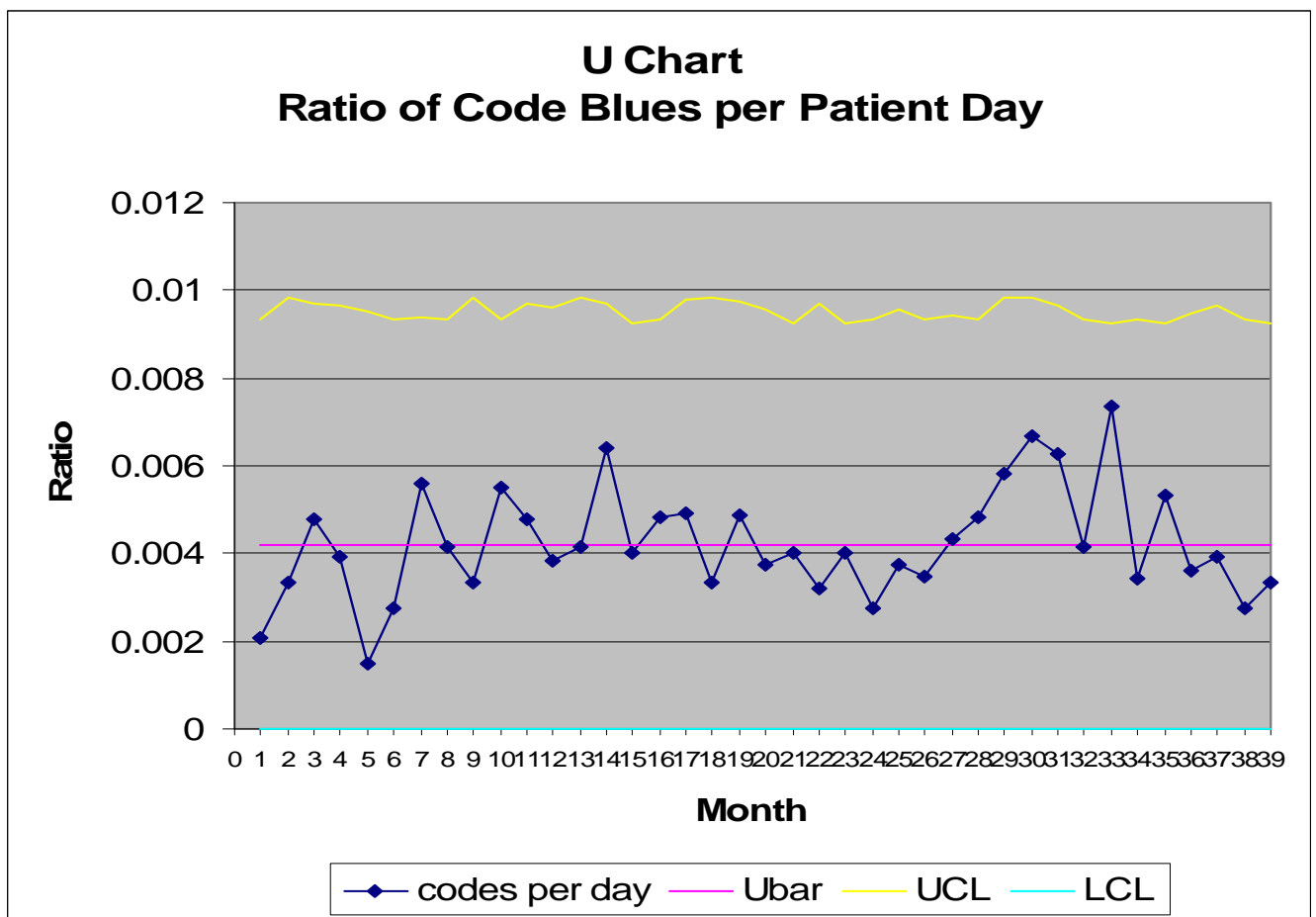
Note that the last 3 months of 2000 show a percentage back above the centerline. So further tracking would be needed before concluding things were better.

**Subgroup sizes for P-charts.** P charts are likely to be especially sensitive to small sample sizes. One simple rule is that the subgroup size should be big enough such that there is at least one event or occurrence in every subgroup – so there are no zero percent occurrences. Alternatively, some argue it should be large enough to get a positive LCL. The American Society for Testing and Materials (ASTM) has set guidelines for p-charts: The lower limit on subgroup size for p-charts may not yield reliable information when:

1. Subgroups have less than 25 in the denominator, or
2. the subgroup size  $n$  multiplied by  $\bar{p}$  is less than one.

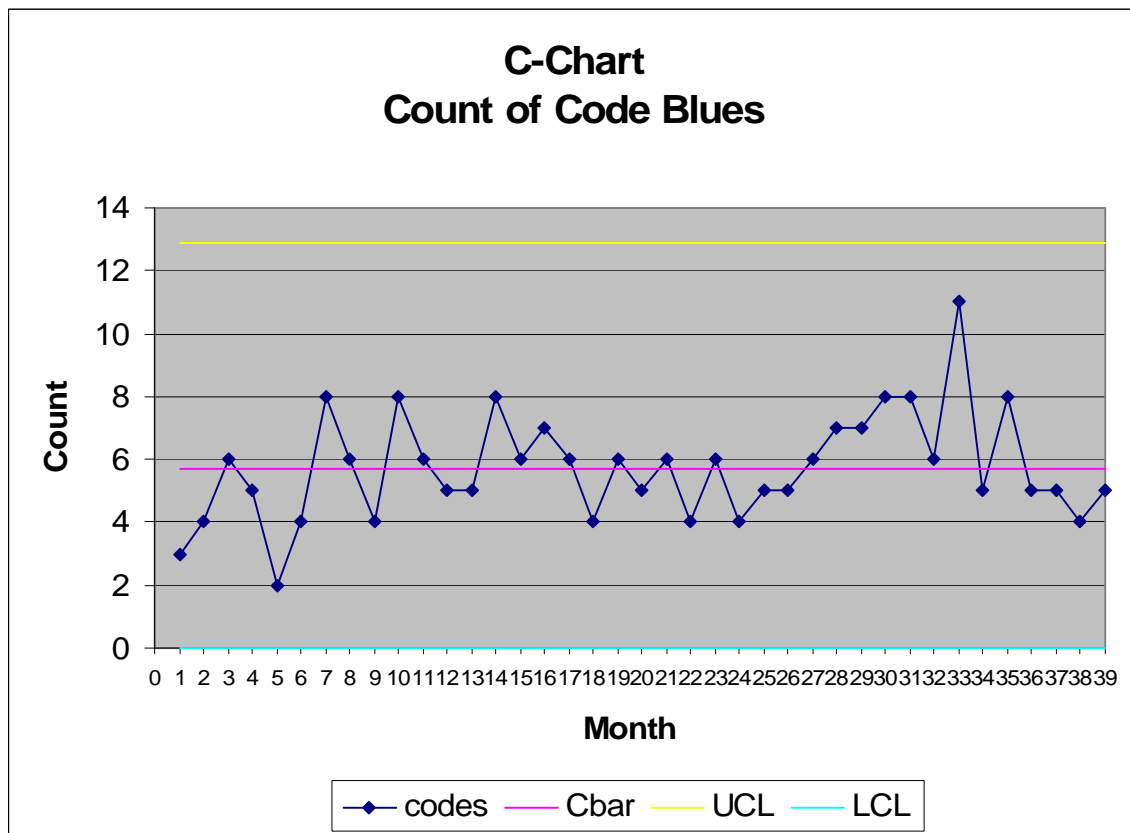
U-Chart. When we have count data and different sample sizes for each period – where there is an unequal area of opportunity. For example on the worksheet labeled U-chart are data that show the number of code blues as well as the number of patient days per month, from April 1992 to June 1995. Note that you have a count -- the number of code blues and you also have a varying number of patient days. In months with a higher census you'd expect more codes even if things were still "normal" so you want to account for this to the extent you can. Also an x-bar chart probably would not be appropriate since the count is not really normally distributed. Likewise one could calculate the proportion of code blues and do a pchart, but since codes are such rare events most of the proportions would be close to zero and so it would be difficult to pick up any action. A U-chart is generally more powerful than the pchart since it will take all this information into account.

First we calculate  $\bar{U}$  – the average proportion of codes per patient day:  $\bar{U} =$  number of defects for all subgroups/total number of observations in all subgroups. In this example we get  $\bar{U} = .0042$  or about 4 codes per 1,000 patient days. Then the sigma =  $\sqrt{\bar{U}/n}$  where  $n$  is the number of observations in each period. So sigma will vary across subgroups. Then the control limits =  $\bar{U} \pm 3 * \text{Sigma}$ . Then we get:



Looking at the graph does not reveal any special causes – but it is close to test #4 where we have a trend of 5 in a row of increasing, but officially you need 6 in a row.

C-Chart The final case to discuss is the c-chart. This is an alternative to the U-chart, but when there is equal opportunity for defects (or when the opportunity is unknown). So suppose on the code blue data we only knew the total number of codes per month, but not the patient days. Now we have to assume that codes are equally likely across months and we look at how the actual counts vary across months. This is done on the C-chart worksheet. Now we first calculate  $Cbar = \text{average number of defects over the period}$ ,  $cbar = 5.72$ . Then the standard deviation =  $\text{sqrt}(cbar)$  This is assumes the count data follows the hypergeometric distribution. So now we get the following C-chart. Note that the UCL no longer varies across the sample but is constant.



We generally get the same picture here, but the U-chart generally is more powerful than the C-chart since it has more information in it. Similarly the Xbar chart is more powerful than the I chart. But sometimes you just don't have the information needed to do the U chart or Xbar chart.

**Subgroup sizes for C-charts and U-charts.** The ASTM suggests that, to provide reliable information, the subgroup size for U-chart should at least be equal to one divided by the average of nonconformities ( $\bar{U}$ ), but will be "most useful" when the subgroup is at least equal to four divided by  $\bar{U}$ . For example, if the average number of medication errors at a hospital is four per 1000 (.004), The U-chart would be most useful when the subgroup size (the number of medication orders) was at least  $4/.004$  or 1000.

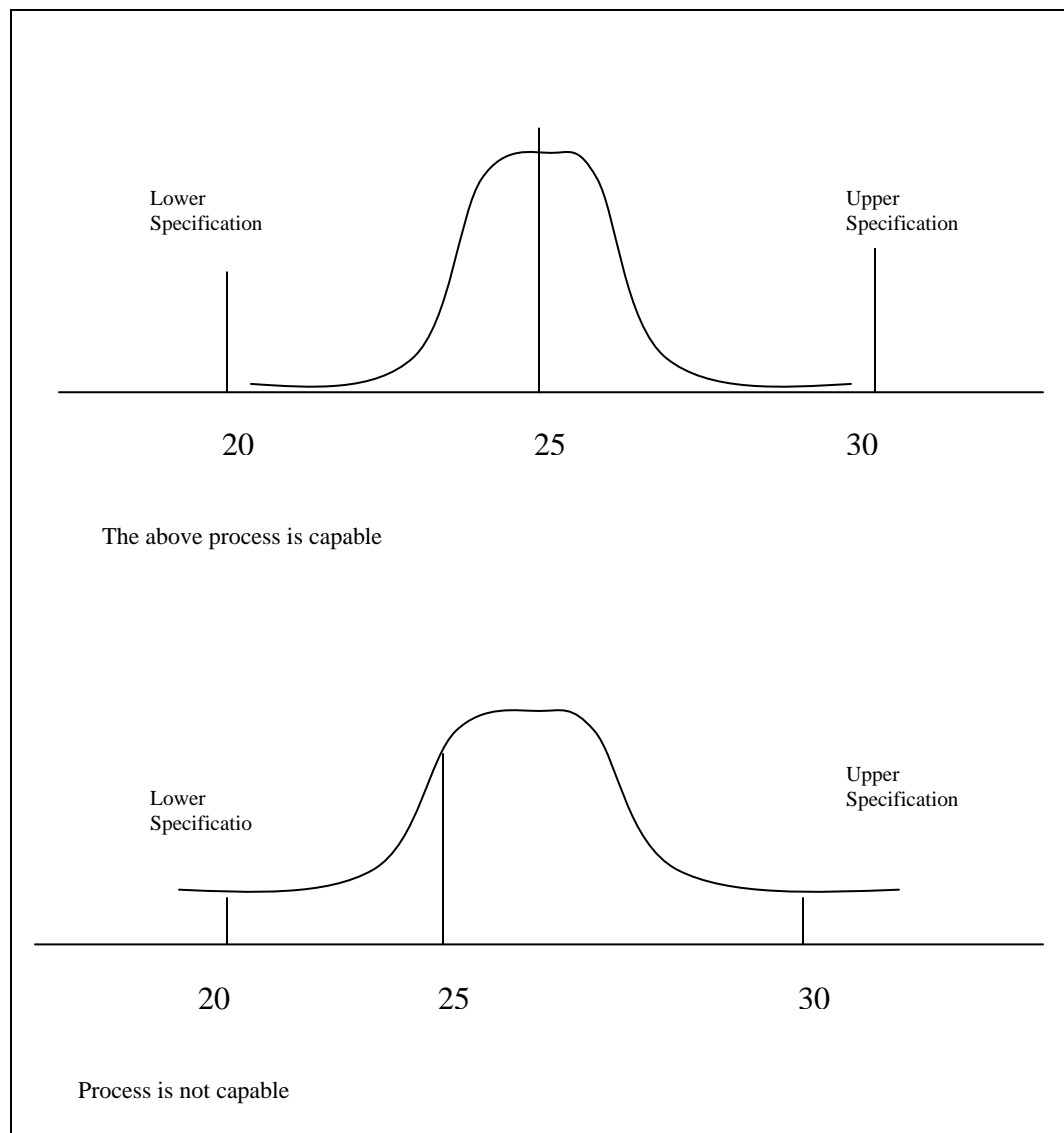
For C-charts the subgroup size should be large enough that the average count of nonconforming items ( $\bar{c}$ ) is at least greater than one, but preferably greater than 4.

### **III. Process Capability**

Statistical process control helps managers achieve and maintain a process distribution that does not change in terms of its mean and variance. The control limits on the control charts signal when the mean or variability of the process changes. A process that is in statistical control, however, may not be producing services or products according to their design specifications because the control limits are based on the mean and variability of the *sampling distribution*, not the design specifications.

Process Capability refers to the ability of the process to meet the design specifications for a service or product. Design specifications often are expressed as a target and a tolerance. For example, the administrator of an ICU lab might have a target value for the turnaround time of results to the attending physicians of 25 minutes and a tolerance of  $\pm 5$  minutes because of the need for speed under life-threatening conditions. The tolerance gives an upper specification of 30 minutes and a lower specification of 20 minutes.

The administrator is also interested in detecting occurrences of turnaround times of less than 20 minutes because something might be learned that can be built into the lab process in the future.



The idea here is kind of in reverse from the control charts. There we let the data decide what the limits were and looked to see if there were any outliers. But now we are saying, “lets define what our limits are and then see if our data fit into them”. If they do not, then we change the process until they do. The above diagrams show one process that is “capable”, that is, it is working within the specifications. The bottom diagram is not.

There are two measures commonly used in practice to assess the capability of a process: Process capability ratio and process capability index.

Process Capability Ratio. A process is capable if it has a process distribution whose extreme values fall within the upper and lower specifications for a service or product. As a general rule, most values of any process distribution fall with  $\pm 3$  standard deviations. [Specifically 68.26% are within one SD, 95.44 are within two, and 99.73 are within 3] In other words, the range of values of the quality measure generated by a process is approximately 6 standard deviations of the process distribution. Hence if a process is capable, the difference between the upper and lower specification, called the tolerance width, must be greater than 6 standard deviations. The process capability ratio,  $C_p$  is defined as:

$$C_p = \frac{\text{Upper Specification} - \text{Lower Specification}}{6\sigma}$$

where  $\sigma$  is the standard deviation of the process distribution.

A  $C_p$  value of 1.0 implies that the firm is producing three-sigma quality (.26 percent defects) and that the process is consistently producing outputs within specifications even though some defects are generated. Values greater than 1 imply higher levels of quality achievement. Firms striving to achieve greater than three-sigma quality use a critical value for the ratio greater than 1. A firm targeting six-sigma quality will use 2.0, a firm targeting 5 sigma quality will use 1.67, etc.

Process Capability Index. The process is capable only when the capability ratio is greater than the critical value and the process distribution is centered on the nominal value of the design specification. For example, the lab process may have a process capability ratio greater than 1.33 for turnaround time. However, if the mean of the distribution of process output,  $\bar{x}$ , is closer to the upper specification, lengthy turnaround times may still be generated. Likewise if  $\bar{x}$  is closer to the lower specification, very quick results may be generated. Thus, the capability index measures the potential for the output of the process to fall outside of either the upper or lower specifications.

The process capability index,  $C_{pk}$ , is defined as:

$$C_{pk} = \text{Minimum} : \left[ \frac{\bar{x} - \text{lower specification}}{3\sigma}, \frac{\text{upper specification} - \bar{x}}{3\sigma} \right]$$

We take the minimum of the two ratios because it gives the worst-case situation. If  $C_{pk}$  is greater than the critical value (say 2 for six sigma quality) and the process capability ratio is also greater than the critical value, we can say the process is

capable. If  $C_{pk}$  is less than the CV, either the process average is close to one of the tolerance limits and is generating defective output, or the process variability is too large.

Example:

The intensive care unit lab process has an average turnaround time of 26.2 minutes and a standard deviation of 1.35 minutes. The target value for this service is 25 minutes with an upper specification limit of 30 minutes and a lower specification limit of 20 minutes. The administrator of the lab wants to have four-sigma performance for her lab. Is the lab process capable of this level of performance?

The first step is to check to see if the process is capable by applying the process capability index:

$$\text{Lower Specification} = (26.2-20)/3(1.35) = 1.53$$

$$\text{Upper Specification} = (30-26.2)/3*(1.35) = .94$$

So the minimum is .94

Since the target value for four-sigma is 1.33 ( $4\sigma/3\sigma$ ), the process capability index tells us the process is not capable. But note this doesn't tell us if the problem was the variability of the process, the centering, or both.

Next we look at the process variability with the process capability ratio:

$$C_p = (30-20)/6(1.35) = 1.23$$

So this does not meet the four-sigma target of 1.33. Thus, there is too much variability. Suppose the administrator initiated a study and found that two activities: report preparation and specimen slide preparation were identified as having

inconsistent procedures. When these procedures were modified to provide more consistent performance, new data were then collected and the average turnaround was now 26.1 minutes with a sd of 1.2.

$$\text{Now: } C_p = (30-20)/6(1.20) = 1.39$$

So we have process capability.

But note the capability index still has problems:

$$\text{Lower: } (26.1-20)/3(1.2) = 1.69$$

$$\text{Upper: } (30-26.1)/3(1.2) = 1.08$$

Thus we have 3 sigma capability, but not 4 sigma. The variability is OK, but we are off center – 26.1 is still too high.