

Appendix 1: Control Charts for Variables Data – classical Shewhart control chart:

When plate counts provide estimates of large levels of organisms, the estimated levels (cfu/ml or cfu/g) can be considered as variables data and the classical control chart procedures can be used. Here it is assumed that the probability of a non-detect is virtually zero. For these types of microbiological data, a log base 10 transformation is used to remove the correlation between means and variances that have been observed often for these types of data and to make the distribution of the output variable used for tracking the process more symmetric than the measured count data¹.

There are several control charts that may be used to control variables type data. Some of these charts are: the X_i and MR, (Individual and moving range) \bar{X} and R, (Average and Range), CUSUM, (Cumulative Sum) and \bar{X} and s, (Average and Standard Deviation).

This example includes the X_i and MR charts. The X_i chart just involves plotting the individual results over time. The MR chart involves a slightly more complicated calculation involving taking the difference between the present sample result, X_i and the previous sample result, X_{i-1} . Thus, the points that are plotted are: $MR_i = X_i - X_{i-1}$, for values of $i = 2, \dots, n$. These charts were chosen to be shown here because they are easy to construct and are common charts used to monitor processes for which control with respect to levels of microbiological organisms is desired.

X_i and MR Chart: The example briefly described here is for $\log_{(10)}$ transformed generic *E. coli*.

Steps required for developing X_i and MR charts are:

1. Define the characteristic Generic *E. coli* levels measured from a 25 gram sample, using 3M Petrifilm™
2. Determine sample size (number of samples) 1 for X_i and 2 for MR charts
3. Log(10) transform the data
4. Calculate mean from control data
5. Calculate Moving Ranges
6. Calculate X_i and MR control limits
7. Place control limits on charts with baseline data
8. Plot baseline data and connect consecutive points with a line
9. Place control limits on a blank chart
10. Collect new data
11. Plot new X_i and MR values as they are collected
12. Connect each point to the previous point with a straight line.
13. View both the X_i and MR charts after each point for out of control signals.

After defining the characteristic and deciding that the X_i and MR is the appropriate chart for one's particular situation, baseline data are collected. Baseline data, both X_i

values, (Log(10) transformed) and MR values are placed on a baseline control chart prior to calculating control limits, (Figure 1).

After collecting about 30 X_i values and 29 MR_i values, (there is one less MR than X_i since the first MR is not calculated until the second X_i is collected), one can calculate control limits. Before calculating control limits one must first calculate the average moving range, (\overline{MR}) and the average of the X_i values, (\overline{X}).

$$\overline{MR} = \frac{\sum MR's}{(Number_of_Xi) - 1} = \frac{27.11}{29} = 0.93$$

$$\overline{X} = \frac{\sum Xi's}{(Number_of_Xi)} = \frac{42.78}{30} = 1.426$$

Note: For computing the standard deviation, σ , needed to establish upper and lower control limits, or other criteria used for evaluating a process, a relationship between \overline{MR} and σ when the results are distributed as a normal distribution. The relationship is simply $\sigma = \overline{MR} / d_2$, where d_2 is a constant = 1.128. Thus, for example, the upper Shewhart control limit is the mean plus 3 times an average \overline{MR} divided by 1.128.

MR Chart Control Limit Formulae:

$$UCL_{MR} = D_4 \times \overline{MR} = 3.267 \times 0.93 = 3.04$$

$$LCL_{MR} = D_3 \times \overline{MR} = 0 \times 0.93 = 0$$

$$\text{Center Line, } (\overline{MR}) = 0.93$$

Values of D_4 and D_3 , can be found in material on quality control published by professional organizations, for example as given in the endnotes².

X_i Chart Control Limit Formulae:

$$UCL_{X_i} = (\overline{X} \text{ or Target}) + (3 \times (\frac{\overline{MR}}{d_2})) = 1.43 + (3 \times (\frac{0.93}{1.128})) = 3.90$$

$$LCL_{X_i} = (\overline{X} \text{ or Target}) - (3 \times (\frac{\overline{MR}}{d_2})) = 1.43 - (3 \times (\frac{0.93}{1.128})) = -1.06$$

$$\text{Center Line, } (\overline{X}) = 1.43$$

$$(3 \times (\frac{\overline{MR}}{d_2})) \text{ may be replaced with } (2.66 \times \overline{MR})$$

Note: If data are put into a computer, calculator, or spreadsheet, it might be simpler to

compute the sample standard deviation, using the “usual” formula, $s = \left[\frac{\sum_{i=1}^n (X_i - \overline{X})^2}{n - 1} \right]^{1/2}$

where n is the number of samples ($n = 30$). The upper and lower limits are set at $(\bar{X} \pm 3s)$. However, this method may provide wider limits than those calculated using the first method (Wheeler and Chambers, 1992).

After calculating control limits and the central value (the mean), horizontal lines at these values are placed to the control chart and the baseline data are plotted, X_i and MR_i versus i (Figure 2).

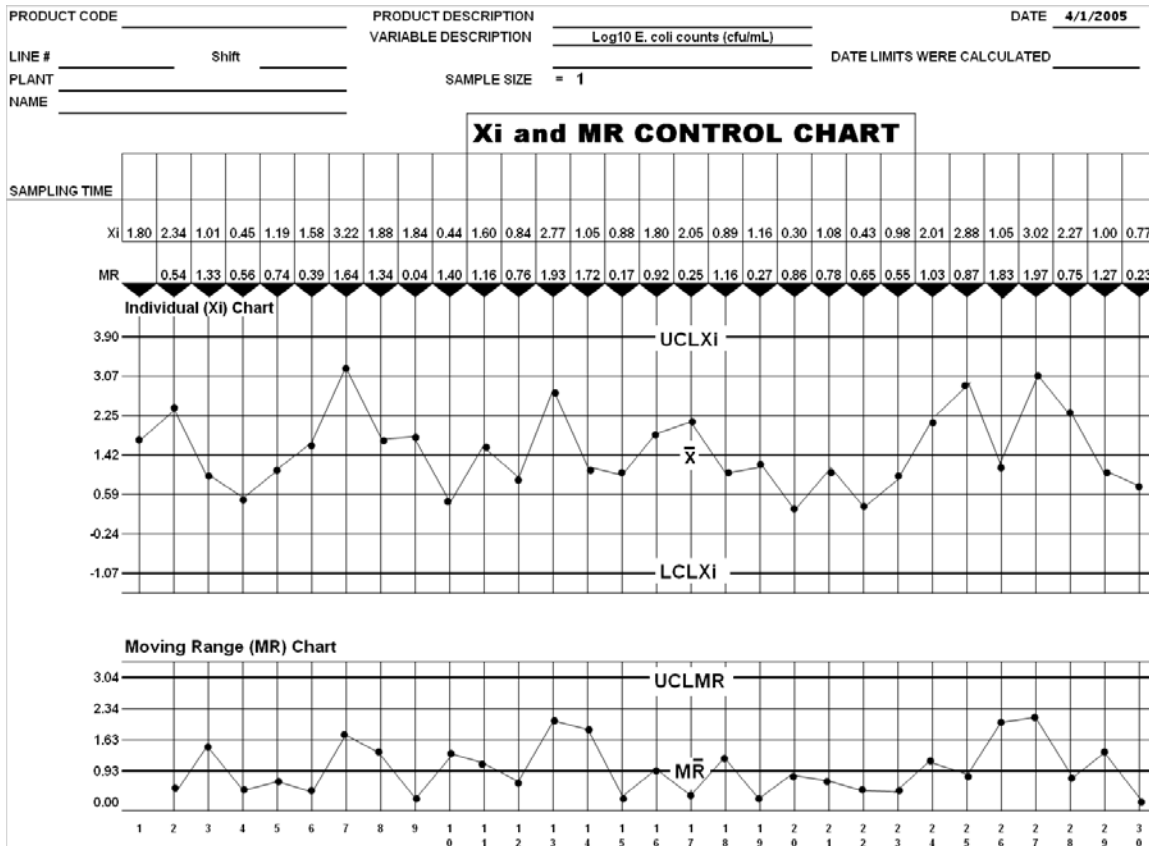


Figure 1: Baseline data plotted on the control charts with limits derived from the baseline data.

The baseline data, when plotted, produce a “stable appearing” process. The limits are then transferred to a blank control chart and X_i and MR_i values are plotted as they are collected. After the X_i and MR_i are plotted and connected to the previous point with a straight line, both the X_i and MR charts are viewed for out of control sequences. Pyzdek (1974) suggests the following out of control rules be used:

X_i Chart:

1. Any point exceeding a control limit
2. Eight consecutive points on the same side of the average, (\bar{X})

MR Chart:

1. Any point exceeding a control limit
2. Eight consecutive points on the same side of the average, (\overline{MR})

Figure 2 demonstrates a process with a positive shift in *E. coli* counts. At about point number 19 the process showed a positive shift. This was identified after the eighth consecutive point above average on the X_i chart, and confirmed by the out of control point exceeding the UCL_{X_i} on point number 27. Although the process average had shifted up there is no indication that the variation had increased, (Figure 2). If this were the case, then the reason for the out of control pattern would be systemic, affecting the processing within the plant, and would not be from a source which would only affect a portion of the process output, such as a supplier effect. That is, certain possible causes could be eliminated from consideration.

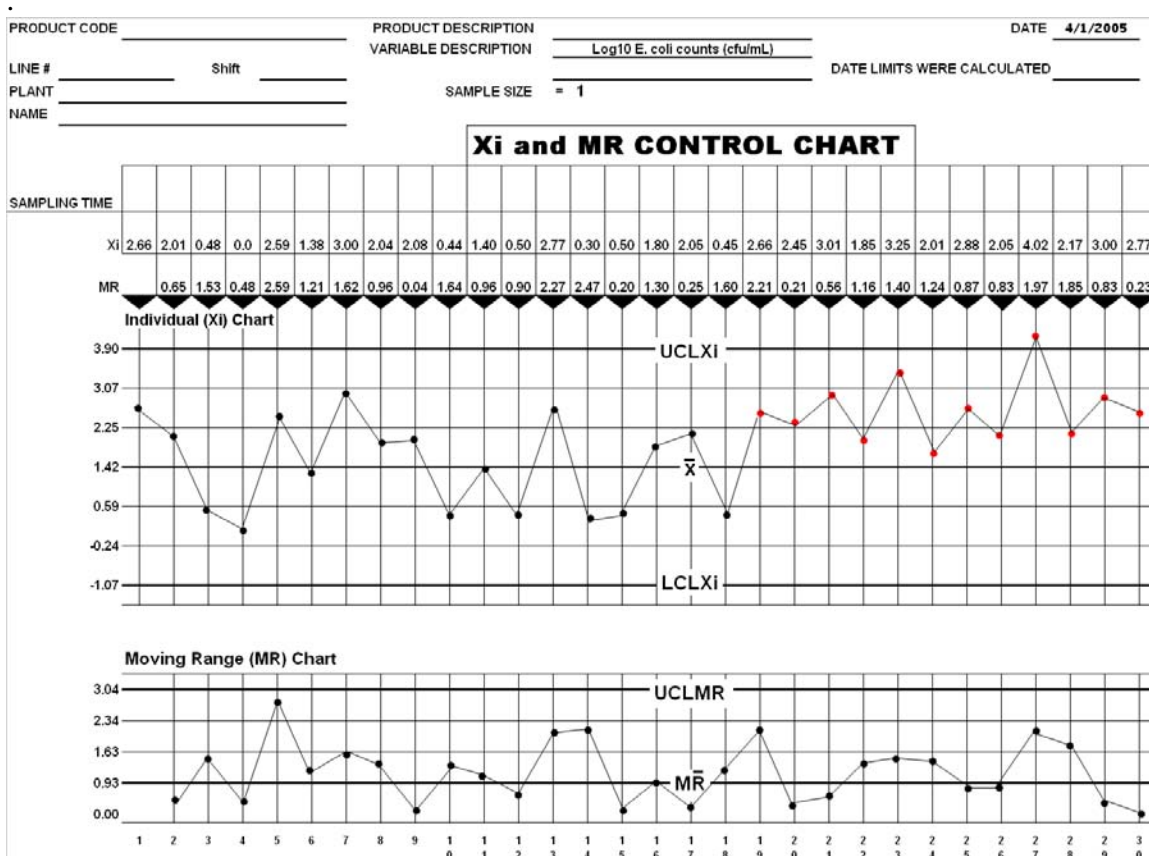


Figure 2: Log(10) *E. coli* counts illustrating an increase in CFU per ml

A large “movement” between two consecutive sample values in the X_i chart may cause the MR chart to exceed the UCL_{MR} while both X_i points were within the control limits on the X_i chart. Such a signal may signify a shift in the process mean: a positive shift if the latter result were the large one, for example, (see Figure 3). Or, if a shift in the mean did not occur, then the signal in the MR chart could imply that, while in a systematic way the process is not out of control, there could still be some factor associated with one of the two samples affecting results. Consequently, an investigation of the sources associated

with the two samples might provide a clue of an uncontrolled factor that could be contributing to process variation or could lead to actions that could lead to an improvement of the process. If this were to happen with some regularity, the motivation to investigate would be increased.

If possible a moving range average using more than 2 results might provide a more accurate detection of short term variation. The more terms used though the harder it would be to identify probable causal factors. With computers, it is possible that more than one type of moving range could be computed; for example the two-term moving range, and a 5-term moving range. The ideas presented here remain the same regardless of the number of terms used in the moving range – just different parameters values for D_4 and D_3 would be used.

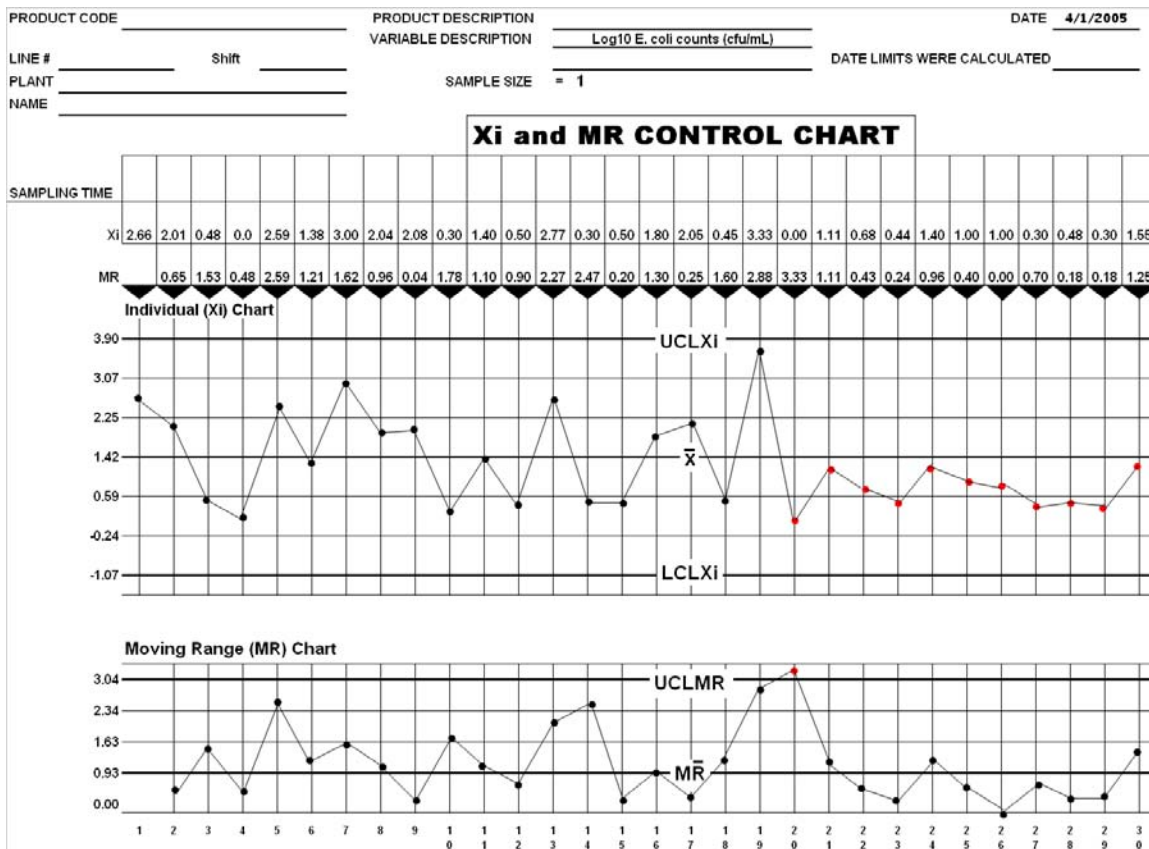


Figure 3: A down shift in CFUs per ml. first picked up by an out of control signal on the MR chart.

Appendix 2: Control Chart for Poisson Distributed Characteristics, with one sample size - the C Chart

When counts are not high and there is a non-trivial probability of not detecting any colony forming units (recorded as ND), the counts seen on a plate can not readily be considered as variable data, as in the previous example (Appendix 1). In this case, a discrete distribution, such as a Poisson distribution or negative binomial distribution can be considered de modeling the distribution of counts (where ND is zero). Microbiological examples which fit Poisson-like probability distributions are not as common as those which lend themselves to the binomial or normal distributions. The Poisson distribution is characterized completely by the value of one parameter, which is the expected value of the distribution. The variance of the Poisson is equal to the expected value, and since the lowest possible value is zero, and there is no limit for the highest values, the distribution is positive skewed. Poisson distributions arise under very specialized conditions, when an assumption of “pure” or simple uniformity is appropriate. However, often this assumption is not appropriate; rather there are many factors that can affect the results, all acting simultaneously so that pure or simple uniformity is not appropriate. Consequently, two parameter distributions such as a negative binomial or even binomial distribution, under certain circumstances can fit data well (Appendix 3). However, the Poisson distribution is an important one, and in some circumstances it might provide a good fit to the data. Thus, this example is being given.

Data for this example were generated using a Poisson distribution, so the Poisson distribution will provide a good fit to the data. A procedure for determining this is given. The example continues with a retrospective analysis, demonstrating one of the features (and possible pitfalls) of such an analysis.

The C chart is used when sample size (number of units or amount of material, being sampled for one analysis) is constant for all samples; the U chart is used for circumstances where sample size may vary. Without loss of generality, it is assumed that the sample size is 1; that is, the direct counts for some material are being recorded.

A word of caution: the Poisson distribution is a skewed distribution, thus α - and β -probabilities need to be calculated taking into consideration when the probability of being above or below the target value is not 50%.

Control Chart for Poisson distribution with a constant sample size=1

For this example the number of organisms that appear on an aerobic plate count (APC), Petrifilm™, from pre-operational food contact surfaces swabs, (1 square inch, 2.54 cm x 2.54 cm) are counted and expressed as Colony forming units, (CFUs), per square inch, (sampling area). For this example the area is swabbed with moistened cotton tipped swab. The swab is used to plate the results on Petrifilm™. The number of colonies is counted after a 48 hour incubation period.

The data from the one hundred swabs are given in Table 1. (Note: these data are not actual data, but were generated using a Poisson distribution). The table includes the observed frequency of results, the predicted frequency assuming a Poisson distribution estimated from the data using the maximum likelihood estimate (MLE)³; the likelihood ratio contribution for the observed result, the likelihood ratio contribution for the observed result when combining the results greater than 6 into one category, and the chi-square statistic for the observed result, which is the square of the difference between the observed and expected frequencies divided by the expected frequencies, $(f-e)^2/e$, where f is the observed frequency, e is the expected or predicted frequency derived from, using the estimated Poisson distribution. The likelihood ratio contribution is minus twice the product of the observed frequency and the difference of the natural logarithms of the observed and expected frequencies, or, symbolically:

$$-2f[\ln(f) - \ln(e)],$$

where “ln()” is the natural logarithm.

The sum of the chi-square and likelihood-ratio contributions are statistics that are asymptotically distributed as a chi-square with k-1 degrees of freedom, where k is the number of distinct results (or categories) for which estimates are made. The likelihood ratio when combining results greater than 6 has 8 categories so that the chi-square approximation is based on 7 degrees of freedom. The results do not indicate any severe lack of fit, notwithstanding the 13 negative results that were observed when only 9 were predicted, and the large observed value of 11, which would not be predicted to be seen very often.

Table 1: Results from the 100 preoperational swab, counts, frequency of results, and predicted frequency using maximum likelihood estimate for Poisson distribution

count	observed frequency	predicted frequency	likelihood ratio	likelihood	chi
				ratio combined 7 df	square 7 df
0	13	9.1	9.35	9.35	1.701
1	20	21.8	-3.40	-3.40	0.144
2	27	26.1	1.78	1.78	0.029
3	19	20.9	-3.62	-3.62	0.173
4	10	12.5	-4.53	-4.53	0.515
5	6	6.0	-0.04	-0.04	0.000
6	2	2.4	-0.74	-0.74	0.069
7	1	0.8	0.38	5.70	1.129
8	0	0.2	.	.	.
9	1	0.1	5.43	.	.
11	1	0.0	11.33	.	.
sum	100	100	16.0	4.50	3.76

Accepting that the underlying distribution of results is a Poisson distribution with expected value of 2.4, the steps involved in using a C control chart are:

1. Define the characteristic... APC counts per sampling location
2. Determine sample size 1 square inch area, 1 sampling area
3. Collect baseline data
4. Calculate Control Limits
5. Place Control Limits on chart of baseline data
6. Plot the baseline data
7. Connect consecutive plotted points with a straight line
8. Place control limits on a new chart
9. Collect and plot data as collected
10. Connect each point to previous point with a straight line
11. Observe chart for out of control signals after each point

The formula for C Center line and control limits are:

$$\text{Average Count} = \bar{C} = \frac{\text{Total_Number_of_CFUs}}{\text{Number_of_Samples}}$$

where: Sample_size = 1 and Number_of_Samples = k = 100 (in this example).

$$\bar{C} = \frac{240}{100} = 2.40$$

$$\text{Center Line} = \bar{C} = 2.40$$

Control Limit Calculations:

Standard Deviation: $\sigma = \sqrt{\bar{C}}$ - that is, it is assumed that the distribution is a Poisson distribution.

Upper Control Limit C:

$$UCL_c = \bar{C} + (3 \times (\sqrt{\bar{C}}))$$

$$UCL_c = 2.40 + (3 \times (\sqrt{2.40})) = 7.05$$

Lower Control Limit C:

$$LCL_c = \bar{C} - (3 \times (\sqrt{\bar{C}}))$$

$$LCL_c = 2.40 - (3 \times (\sqrt{2.40})) = -2.25 \text{ so } LCL_c = 0$$

For the upper limit, if the underlying distribution was a Poisson with expected value equal to 2.40, then the probability of a result greater than 6 is 1.16%; and greater than 7 is 0.334%. This depending upon the α -probability desired, either a result greater than or equal to 7 or 8 would be considered as presumptive evidence of an out of control process.

For the lower limit, the probability of 0 is 9.1%, which for the α -probability (in this document) would be considered as too high. Thus, a single value of 0 would not, by itself be considered as an indication of a process change.

If an actual Poisson distribution was not assumed or any other distribution could not be found to fit the data, then the square root transformation, or its variations $(x+3/8)^{1/2}$, could be used for plotting and construction a control chart.

In this example, the SPC chart of Figure 1 is constructed, with the upper limit of 7 and the lower limit of 0, derived assuming that the results are distributed as a Poisson distribution. The last 40 points are shown on the chart.

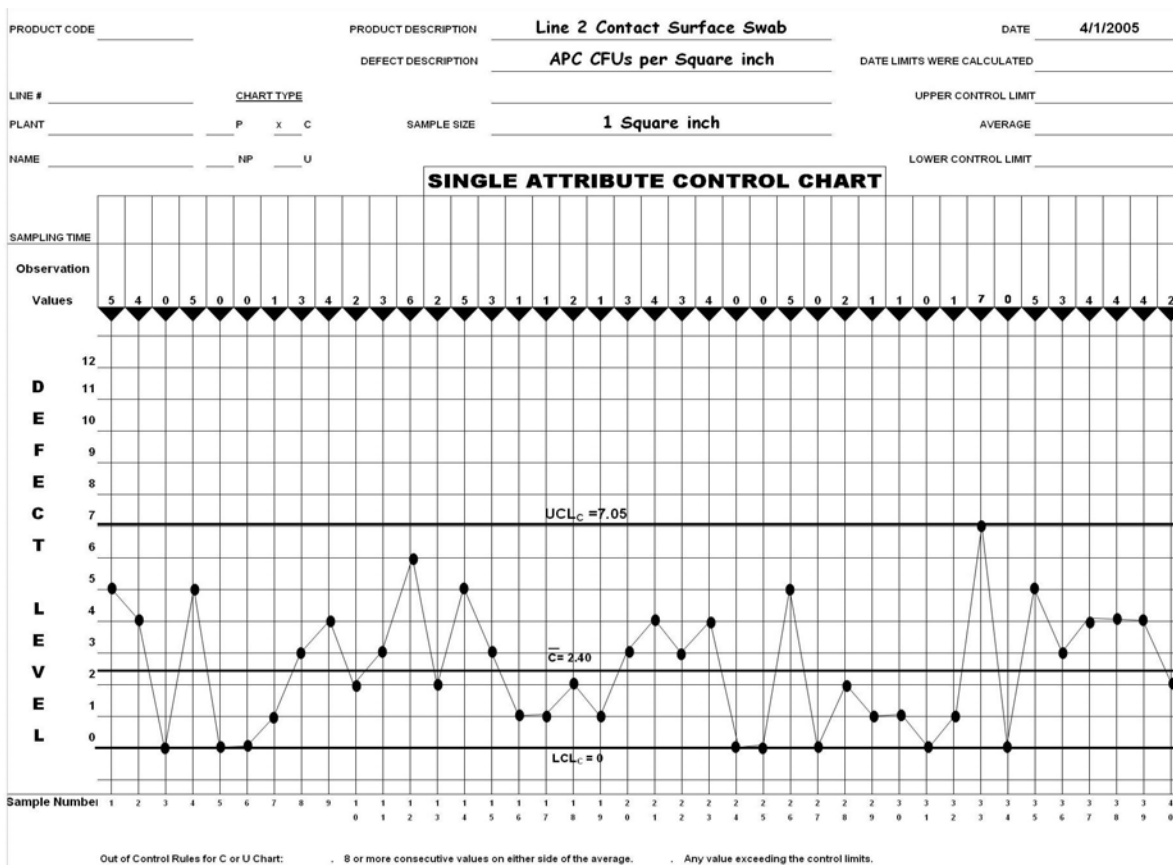


Figure 1: A C chart showing the last 40 data points of the baseline data plotted

Upon an examination of this chart, out of the 40 points, only one had a value of 7 (or more), and there were 8 zero results. Moreover there does not seem to be a consistent trend (in actuality CUSUMS or moving averages would be computed as well to judge trends). By these usual rules, it might be reasonable to conclude that the 40 points plotted represent a set of data for which the process is in control. Only one result reached the value of 7, but that, by itself, would not be a reason to suspect an out-of control situation.

However, a further examination might lead to some questions and further exploration of the process. The probability of 8 or more zero results from 40, when the underlying distribution is Poisson is about 2.5%; however, what may be of interest is that the 8 values seemed to be “clustered” with respect to time, where 3 zero results occurred within the first 6 times of sampling, and the other 5 zero results occurred within a span of 11 samples 18 samples later.

To explore the possibility that this pattern represents a possible source of unexplained variation, consider a one-sided CUSUM for the occurrence of negative results. That is, consider a CUSUM, S_k , where, $S_0 = 0$, $S_k = \max(0, S_{k-1} + \delta_k - p)$, δ_k is the Kronecker delta function for a negative result for the k^{th} sample ($= 1$ when the result is negative, otherwise equal to 0), and p is a constant equal to the probability of a negative result ($= 0.091$). Let the signal for “out of control” – meaning that the probability of a negative, somewhere, was greater than 9.1% - be 5. That is, when the CUSUM value is equal to or greater than 5 the CUSUM signals and the null hypothesis that the probability of a negative was equal to or less than 9.1% over the 40 samples would be rejected in favor of the alternative hypothesis that for some time the actual probability was greater than 9.1%. The reason for selecting the signal limit of 5 is: the ARL for this CUSUM with a signal limit of 5 is about 346 when the underlying probability of a negative result is 9.1%, as predicated from the assumed Poisson distribution with parameter value equal to 2.4. Thus, if this CUSUM rule had been constructed before the samples were being collected, the one sided α -probability would have an assigned value of 0.29%.

Calculating this CUSUM with these 40 samples, at the 34th sample, the CUSUM exceeded 5.0 so that a signal would have occurred. Table 2 provides an example of a spread sheet that can be used for the calculations of CUSUM. The above formula for the CUSUM implies that the CUSUM value at the k^{th} sample depends on the CUSUM value for the $(k-1)^{\text{th}}$ sample and an increment value, which is the value of the k^{th} sample minus the target constant, μ . The updated value of the CUSUM for the k^{th} sample is the sum of the previous CUSUM value plus the increment, provided this sum is not less than zero; otherwise it is set equal to zero. Thus the formula for the CUSUM can be written as:

$$\text{CUSUM}_k = \max(0, \text{CUSUM}_{k-1} + \text{increment}_k)$$

where the value of the increment $= \delta_k - p$. Table 2 presents the calculations of the CUSUM for the 40 samples using the above formula.

As can be seen from Table 2, the CUSUM value exceeds the value of 5 at the 34th sample, thereby suggesting that the process mean probability of a negative exceeded its target value of 9.1% at least some time at or before the 34th sample. However, the probability of a Type 1 error with respect to the statistical question, given the 40 data points, is not the same as the assigned α -error probability given above (based on the ARL). The statistical question involves deciding between two hypotheses: the null hypotheses, H_0 : the probability of negative results is never larger than 9.1% over the period of time that the samples were collected; versus the alternative, H_A , that at some time, the probability exceeded 9.1%. To help evaluate possible answers, the probability of seeing a signal

within 40 samples is needed, when the probability of a negative is equal to 9.1% over the 40 samples, thereby assuming that the null hypothesis is true. The 2nd percentile of the distribution of run lengths (estimated by simulation using the binomial random generator for SAS[®], release 8.0) is about 40 samples, indicating that the retrospective α -probability of a Type 1 error is about 2% (that is, of having a signal within the first 40 samples when the probability was 9.1% of a negative result).

Table 2: Calculation spreadsheet for CUSM.

sample number	sample result	target fraction positive	increment (result-target)	CUSUM
1	0	0.09	-0.09	0.00
2	0	0.09	-0.09	0.00
3	1	0.09	0.91	0.91
4	0	0.09	-0.09	0.82
5	1	0.09	0.91	1.73
6	1	0.09	0.91	2.64
7	0	0.09	-0.09	2.55
8	0	0.09	-0.09	2.46
9	0	0.09	-0.09	2.36
10	0	0.09	-0.09	2.27
11	0	0.09	-0.09	2.18
12	0	0.09	-0.09	2.09
13	0	0.09	-0.09	2.00
14	0	0.09	-0.09	1.91
15	0	0.09	-0.09	1.82
16	0	0.09	-0.09	1.73
17	0	0.09	-0.09	1.64
18	0	0.09	-0.09	1.55
19	0	0.09	-0.09	1.46
20	0	0.09	-0.09	1.37
21	0	0.09	-0.09	1.28
22	0	0.09	-0.09	1.18
23	0	0.09	-0.09	1.09
24	1	0.09	0.91	2.00
25	1	0.09	0.91	2.91
26	0	0.09	-0.09	2.82
27	1	0.09	0.91	3.73
28	0	0.09	-0.09	3.64
29	0	0.09	-0.09	3.55
30	0	0.09	-0.09	3.46
31	1	0.09	0.91	4.37
32	0	0.09	-0.09	4.28
33	0	0.09	-0.09	4.19
34	1	0.09	0.91	5.09
35	0	0.09	-0.09	5.00
36	0	0.09	-0.09	4.91
37	0	0.09	-0.09	4.82
38	0	0.09	-0.09	4.73
39	0	0.09	-0.09	4.64
40	0	0.09	-0.09	4.55

Retrospective analyses such as this one are fraught with problems regarding the “true” magnitude of the α - and β - probabilities. The only reason that this CUSUM was designed, after the fact, was because of the pattern of negative results that were observed and the higher than expected frequency of them in the 40 samples. However, any truly “random” sequence of numbers could turn up patterns that are suggestive of possible non-randomness suggesting a more complex generator (of the numbers), which, when statistically tested for, would result in a low calculated α -probability. Notwithstanding these types of problems, the results of this analysis might suggest or provide evidence of the existence of a factor that is causing excess process variation, and that further examination of the process would be worthwhile; for example, the producer might explore to see if there were any common sources peculiar to the initial 6 and the later 11 data points. If there were, then particular sharper criteria or rules related to the possible common sources could be constructed; if there were not, then the observed pattern could be considered as arising due to statistical variation.

Appendix 3: Count Data that is not Poisson distributed, with many non-detect values.

This example presents data that do not seem to have arisen from a Poisson distribution.

Table 1: Obtained counts, together with goodness-of-fit statistics for a Poisson distribution.

count	observed frequency	predicted frequency	likelihood ratio	likelihood ratio combined 7 df	chi square 7 df
0	15	4.9	33.39	33.39	20.576
1	19	14.8	9.40	9.40	1.168
2	22	22.3	-0.65	-0.65	0.005
3	15	22.4	-12.0	-12.0	2.447
4	10	16.9	-10.4	-10.4	2.790
5	6	10.1	-6.31	-6.31	1.696
6	4	5.1	-1.93	-1.93	0.234
7	2	2.2	-0.36	13.68	2.643
8	0	0.8	.	.	.
9	1	0.3	2.58	.	.
10	3	0.1	21.53	.	.
11	1	0.0	7.57	.	.
15	1	0.0	19.55	.	.
20	1	0.0	37.40	.	.
Sum	100	100	99.68	25.10	31.56

With 7 degrees of freedom, the likelihood ratio test and the chi-square test for lack of fit are significant, with significance levels less than 0.01, suggesting that the fitted Poisson distribution does not fit the data well.

A two parameter distribution, the negative binomial is a distribution which is often used to model the distribution generating the data when the Poisson does not provide a good fit. The probability density, $f(k|p, n)$ of the negative binomial is:

$$f(k | p, n) = K(n, k)p^n(1 - p)^k, \quad k=0,1,\dots$$

where n and p are parameters whose values are to be estimated and $K(n, k)$ is a binomial-like coefficient. The above data were fit to a negative binomial, using a maximum likelihood estimates (MLE) of the parameter values. The MLE of p and n were 0.3655 1.7342, respectively. Table 2 provides summary statistics for the MLE fitted negative binomial. The likelihood ratio with 8 degrees of freedom was obtained by pooling all the results greater than 7 into one category.

Table 2: Obtained counts, together with goodness-of-fit statistics for a negative binomial distribution

count	observed frequency	predicted frequency	likelihood ratio	likelihood ratio combined 8 df	chi square 8 df
0	15	17.5	-4.56	-4.56	0.347
1	19	19.2	-0.42	-0.42	0.002
2	22	16.7	12.23	12.23	1.709
3	15	13.2	3.93	3.93	0.257
4	10	9.9	0.24	0.24	0.001
5	6	7.2	-2.17	-2.17	0.197
6	4	5.1	-1.97	-1.97	0.245
7	2	3.6	-2.34	-2.34	0.704
8	0	2.5	.	-1.38	0.075
9	1	1.7	-1.07	.	.
10	3	1.2	5.69	.	.
11	1	0.8	0.48	.	.
15	1	0.2	3.69	.	.
20	1	0.0	7.84	.	.
sum	100	100 ^a	21.57	3.55	3.54

^a) The sum includes predicted numbers for counts not shown, for example, a count of 12, up to a count of 20.

From Table 2 it appears that the fitted negative binomial distribution fits the data well. Assuming that the distribution generating the count data is the estimated negative binomial distribution, the probability that an individual count would be greater than or equal to 18 is 0.133%. Thus, the individual limit, corresponding to the Shewhart limit of 3 standard deviation units above the mean for a normal distribution, would be 18, using the negative binomial distribution.

The assumption that these data were collected for a process under control is important here. The 15 non-detects may suggest a measurement problem, insofar as the number of these seems high compared to what might have been expected if it were believed the distribution of counts would be Poisson distributed. This might be one area of further, retrospective, exploration. Many other distributions could be fit to these data directly, for example Poisson with added zeros, or other types of distributions.

As suggested in this document, another possible way of constructing a SPC plan and chart is to consider transformations of the data in an attempt to make the data more symmetric and nearly normal. Figure 1 is a comparison of the box-plots, of the square root transformed counts with the raw counts. The square root transformed counts are multiplied by 2, so that the means of the two sets of numbers are nearly the same. As is clearly seen, the square root transformed results provide a more symmetric distribution than that of the raw counts. The means and standard deviations for the raw counts and twice the square root of the counts, and the control limits derived from them are given in Table 3.

Table 3: Means, standard deviations and control limits when using raw counts and square root transformed counts.

type	mean	std dev	limit: 3 std dev above mean	limit using square root
raw counts	3.01	3.20	12.62	.
twice square root	2.97	1.79	8.36	17.47

The Shewhart limit of 3 standard deviations above the mean using the square root transformation is 18 (rounding up from the 17.47 given in Table 3), the same as that derived using the fitted negative binomial. From the 100 raw counts, only 1 was above 18.

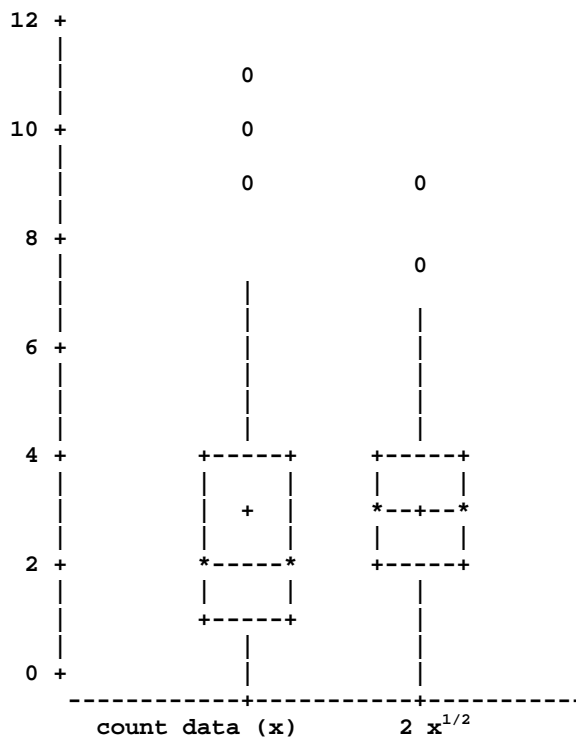


Figure 1: Box-plots of counts and twice the square root of the counts. The high values of 15 and 20 for the count data are not shown.

Appendix 4 - Control Chart for Binomially Distributed Data, with one sample size

This example is a very important one since often qualitative analyses, looking just for the presence of some pathogen in samples, are performed. A chart that can be used to track the control of a process with respect to the presence of some pathogen on samples is called a “NP” - control chart. Generally such charts can be used for a binomially - like distributed characteristics (a two-class attribute test), for example, the detecting of *Salmonella* spp on samples. One of the classifications is assigned the name “defective” or positive, and it is that classification for which process control is measured. P refers to the percentage or probability of “defective” units (positive units of some product); the magnitude of P is to be controlled (usually to be low as possible).

The letters “NP” are used as a mnemonic for the plotting of the number of “positive results”; the expected value of the number of positive results is equal to the sample size, N, times the assumed proportion of positive samples, P – or, symbolically, NP.

In this example, it is assumed a sample size of 50 product tests, constituting one sample, for which the number of positive results is the output. A NP-chart is a plot of the number of “positive” test results within a sample over time. The example given in Appendix 5 provides methodology that can be used when the sample sizes are not the same (using a P-chart or a transformation of the results).

Control Chart for Binomially Distributed Data Plotted as the Number of Positive Outcomes from an Inspection

For the NP - control chart, “N” indicates sample size, (often an upper case N is used to symbolize population size, but it is the SPC convention to use an upper case N which stands for sample size – the number of units being considered together as one sample), and P represents the proportion of the units that are “defective,” as described above. The set of N units is referred to as a “sample”, so that the first N-unit set is labeled sample 1; the second N-unit set is labeled sample 2, and so forth. An NP-chart is simply a plot of X_i = the number of defective units in the i^{th} sample, versus sample index value (or some other appropriate time measure), with lines connected between successive data points. The steps involved in determining the control limits for a NP-control are:

1. Define the characteristic... Presence of *Salmonella* spp. in 25 grams of product
2. Determine sample size..... Sample size = 50, 25-gram units
3. Collect baseline data
4. Calculate Control Limits
5. Place Control Limits on chart of baseline data
6. Plot the baseline data
7. Connect consecutive plotted points with a straight line
8. Place control limits on a new chart
9. Collect and plot data as collected
10. Connect each point to previous point with a straight line
11. Observe chart for out of control signals after each point

For this example, Figure 1 is the number of *Salmonella* spp. positive units identified in a sample of 50 units of product is plotted versus sample number (or time of sampling) on the NP control chart. After about 30 data points have been collected, (a rule of thumb for normal or nearly normal data is that about 30 data points should be used for control limit calculations) the control limits are ready to be calculated.

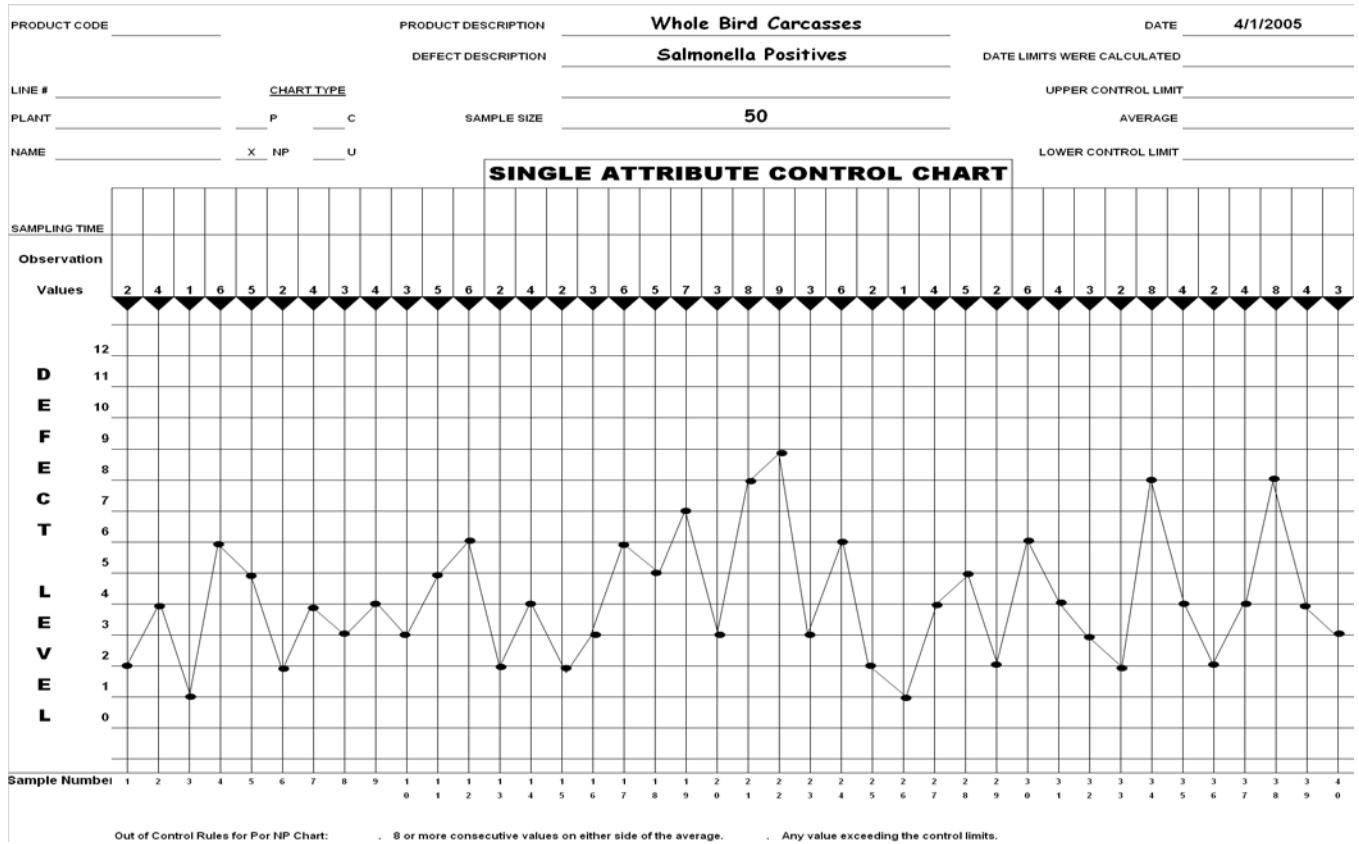


Figure 1. Base line *Salmonella* spp. data collected in sample size = 50.

The formula for NP Center line and control limits are:

$$\text{Average Proportion Positive} = \bar{P} = \frac{\sum_{i=1}^k X_i}{\text{Sample_size} \times \text{Number_of_Samples}}$$

where Sample_size = N = 50; and Number_of_Samples = k = 40 (in this example).

$$\bar{P} = \frac{165}{50 \times 40} = 0.0825 = 8.25\%$$

$$\text{Center Line} = N\bar{P} = \text{Sample Size} \times \bar{P} = 50 \times 0.0825 = 4.125$$

(This gives the expected number of positive results per sample).

Control Limit Calculations:

Standard Deviation: $\sigma = \sqrt{N\bar{P} \times (1 - \bar{P})}$ - that is, it is assumed that distribution is a binomial distribution. In actuality this may not be true even when the process is in control because of inherent intra-sample correlations that would cause the expected value of the number of positive results to vary by sample.

Note: An estimate of the standard deviation can be computed as: $\sigma = \sqrt{\frac{N \sum_{i=1}^k (P_i - \bar{P})^2}{k - 1}}$,

where k is the number of samples (= 40) and P_i is the fraction of positive results (of the N analyses) for the i^{th} sample.

In this example, it is assumed that “the best” control is achieved so that the deviations from the expected value follow a binomial distribution, implying that the standard deviation is proportional $(p(1-p))^{1/2}$, where p is the expected percentage of positive units. If this assumption is incorrect and that the expected value of the probability of defects on a unit changes from day to day or sample to sample, a condition known as over-dispersion may exist. In this case, the standard formula for standard deviation, or the MR statistic discussed in Appendix 1, could be used, for the number of positive results, or for the arc-sine transformation: $y_i = N \sin^{-1}(P_i^{1/2})$. Evidence of this condition may be identified by plotting the baseline data on the chart with control limits calculated in the manner shown and observing many point either “out of control” or at least near the extremes, but that the deviations seem random and symmetric. More formal statistical tests for “over-dispersion” can be made using statistical programs such as PROC GENMOD of SAS⁴. Such a pattern might arise, when there are uncontrollable factors, such as day-to-day variations attributable to environment or slight, but uncontrollable differences, of supply input quality. In this case, the process standard deviation can be computed using the above standard formula. However, if this case does exist, the producing establishment should strive to eliminate some of these sources that contribute to the variability of the process, particularly when the establishment determines that the characteristic should be binomially distributed. Obtaining better control and eliminating factors that cause over dispersion usually leads to improvements, (reduction in percentage of defective units in this example) which means new control limits will need to be calculated once the improvement is documented.

In the following it is assumed a binomial distribution describes the number of positive results.

Upper Control Limit NP:

$$UCL_{NP} = N\bar{P} + \left(3 \times \left(\sqrt{N\bar{P} \times (1 - \bar{P})}\right)\right)$$

$$1 - \bar{P} = 1 - 0.0825 = 0.9175$$

$$UCL_{NP} = 4.125 + \left(3 \times \left(\sqrt{4.125 \times 0.9175}\right)\right) = 9.96$$

Lower Control Limit NP:

$$LCL_{NP} = N\bar{P} - \left(3 \times \sqrt{N\bar{P} \times (1 - \bar{P})}\right)$$

$$LCL_{NP} = 4.125 - \left(3 \times \sqrt{4.125 \times 0.9175}\right) = -1.71 = 0$$

From the above data, the average proportion of *Salmonella* spp. positive was 0.0825. If the expected proportion of positive results for each 50-set sample was 8.25%, then the average or expected number of positive results in a 50-set sample is 4.125, ($N\bar{P} = 4.125$), and the control limits would be 9.96 and 0 for the UCL_{NP} and LCL_{NP} , respectively. A value of 10 then would be considered as out of control. (The actual probability of 10 or more positive units in 50 units, when the probability of a positive is 8.25 % and the true underlying distribution is binomial, is 0.70%, which provides a reasonably low α -error rate.) Since the calculated value of LCL_{NP} is a negative value and since one can never find fewer than zero positives in a sample, the LCL_{NP} defaults to zero. (A result of zero may not be considered by itself to be an out of control event, since the probability of no positive results from 50 samples, given a true percentage of 8.25% and a binomial distribution, is 1.35 %, which is substantially larger than the nominal value of α of 0.135% used by Shewhart, when the underlying distribution is normal). By placing the control limits and center line on the baseline data run chart a control chart is produced (Figure 2).

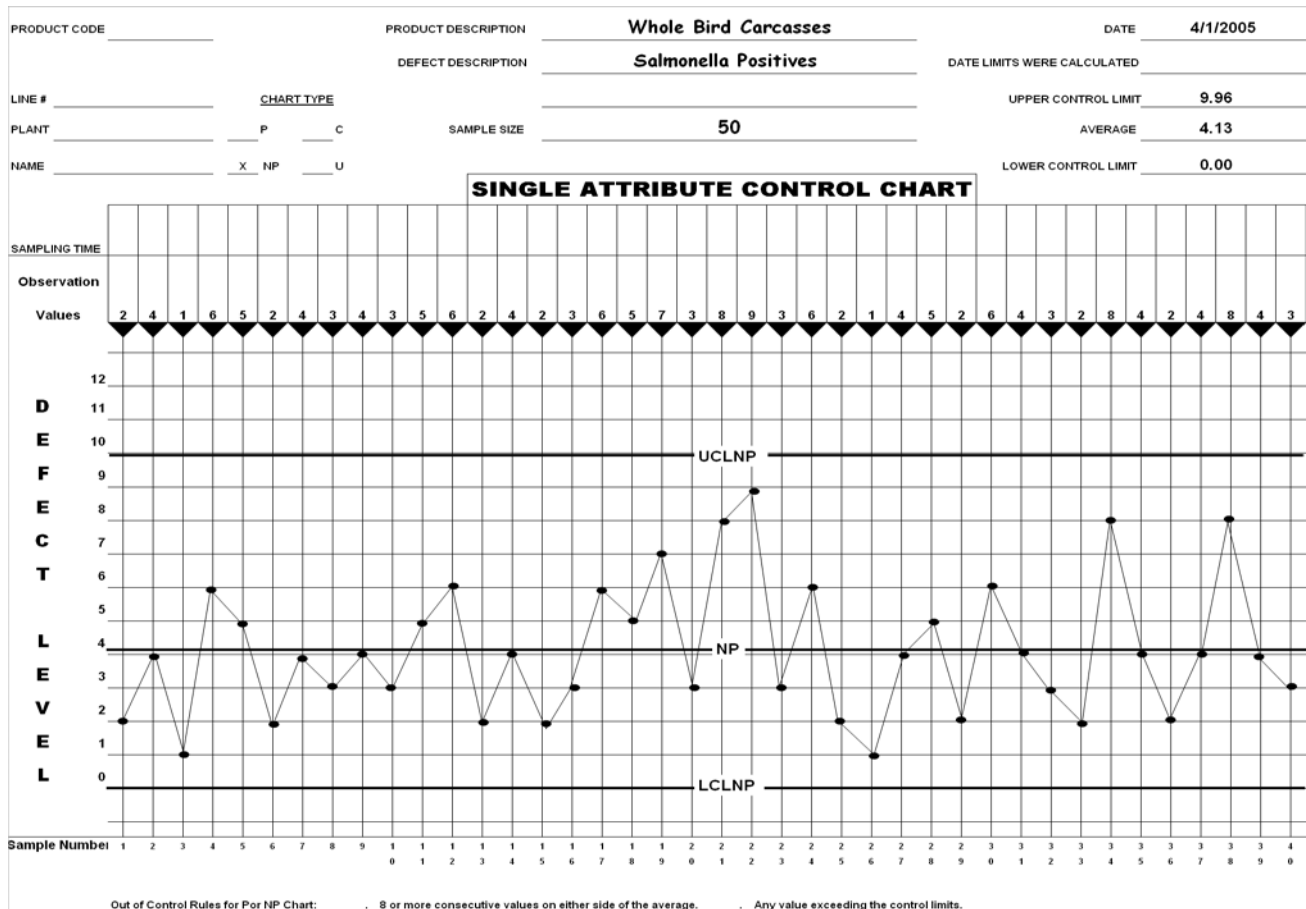


Figure 2. NP control chart of baseline data

The control limits are calculated and the plot of the baseline data confirms the control limits appear reasonable, as in Figure 2. The control limits are then transferred to a blank control chart, or extended from the control chart containing the baseline data, and data points are plotted and connect to the previous plotted point with a straight line. Figures 3 and 4 demonstrate two control charts that show a period of expected performance followed by an out of control period. Figure 3 shows a process with the incidence of *Salmonella* spp. increasing, while Figure 4 shows a reduction in *Salmonella* spp. Both of the charts thus show out of control conditions, because both of these red point series are ‘unexpected’ from what would be seen, based on the baseline data and the assumption that the process was in control.

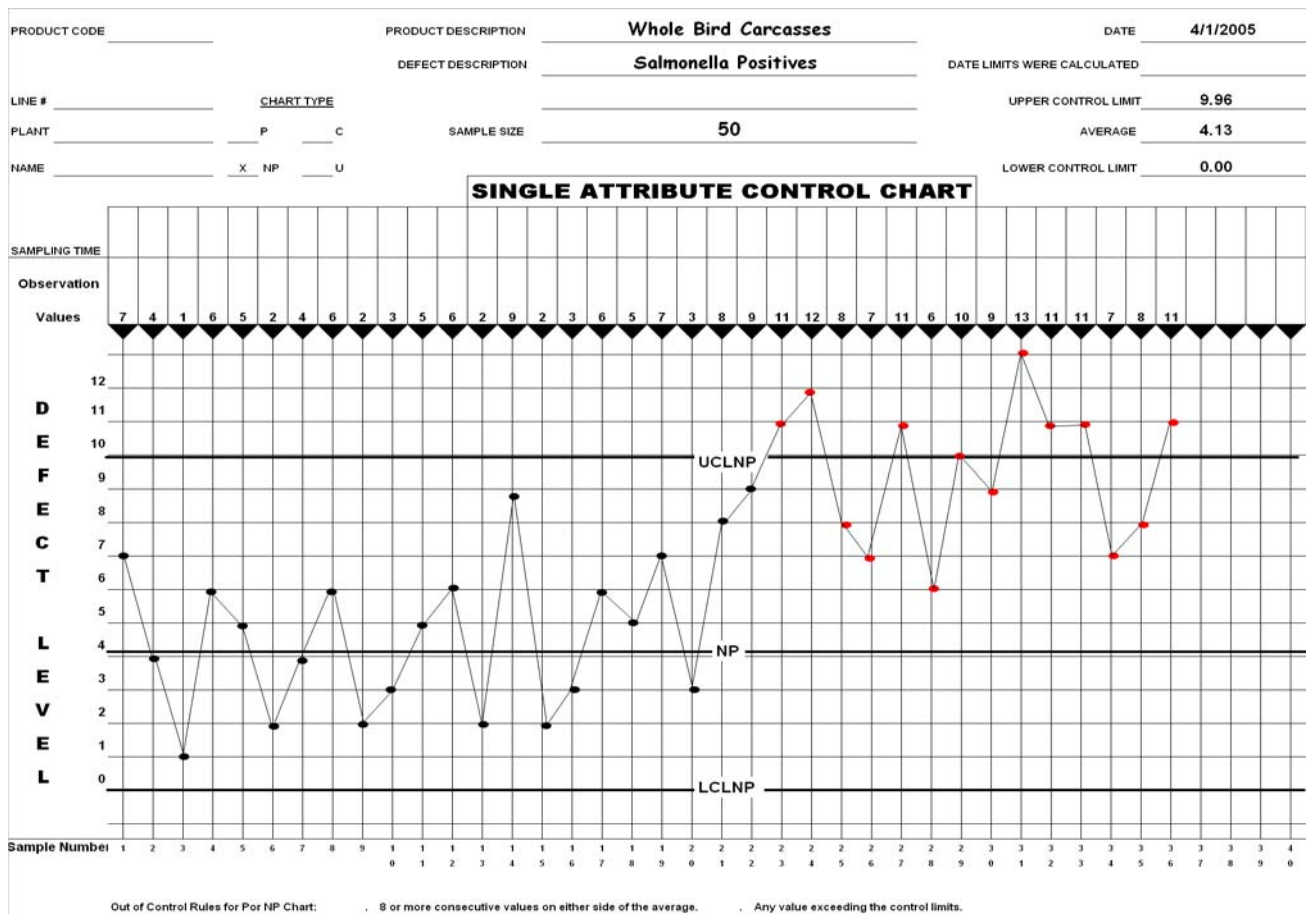


Figure 3. NP chart showing an increase in *Salmonella* spp.

The identification of the out of control signal suggests an investigation as to what caused the out of control condition. It is through the identification and control of factors that adversely affect the process that leads to process improvement. Once these are controlled often a new level of quality is achieved. A new level of quality in this case can be identified by an “out of control” condition where an unexpectedly high number of consecutive points fall below average (Figure 4). The informed manufacturer at this point would identify the

conditions required to produce these better results and after a brief time calculate new control limits based on the new level of quality that the process is producing. There are methods described for computing new control limits, see Wheeler and Chamber, 1992⁵, for examples.

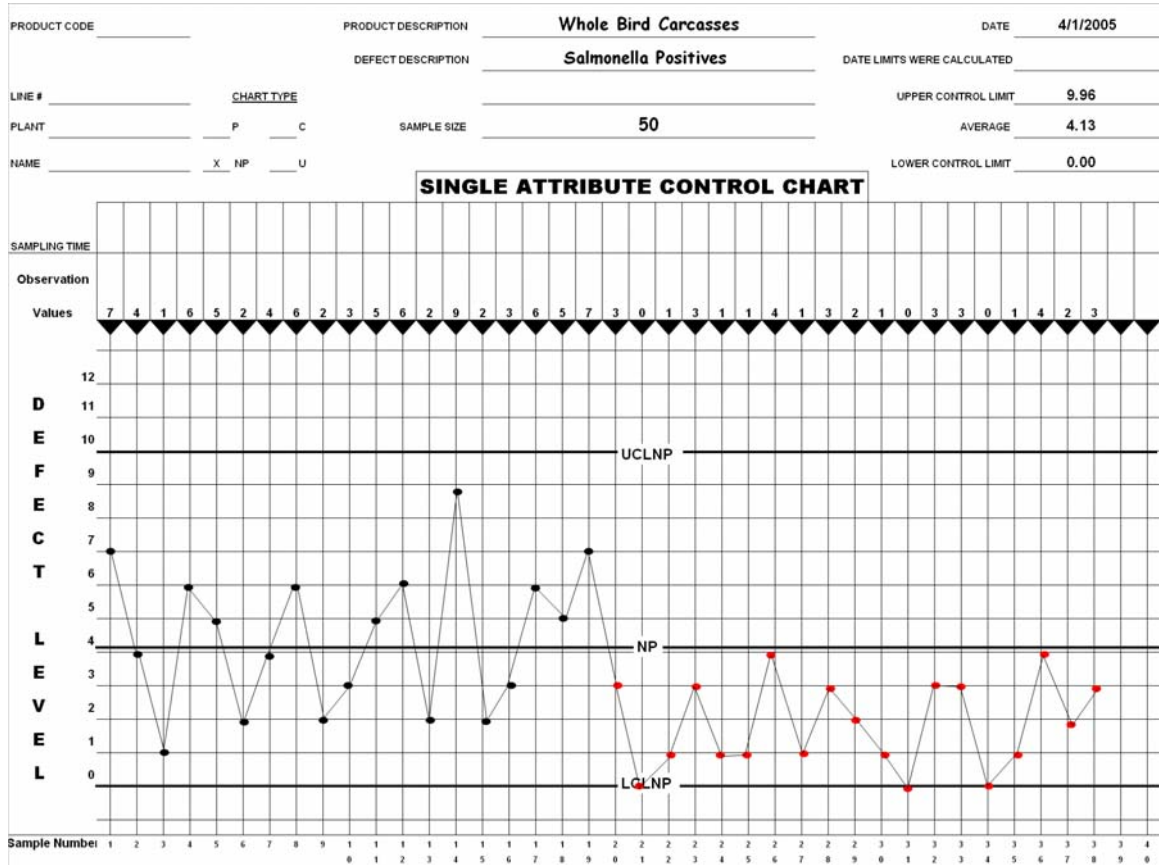


Figure 4. NP chart showing a reduction in *Salmonella* spp.

Appendix 5 - Control Chart for Binomially Distributed Data Plotted as Proportions (P Chart), with varying sample sizes

The example given in Appendix 4, of the binomial control chart plotted the number of positive results out of a sample of 50 units. The characteristic feature in that example was that the number of units per sample was fixed (= 50), so that the expected number of positive results per sample (of 50 units) was the same. However, in many situations the sample size is not the same and thus the expected number of positive results would not be the same. Thus plotting the number of positive results is not appropriate for a control chart since the underlying assumption for the data to be used for plotting, namely, that the results are from a common distribution when the process is under control, would not be satisfied.

A simple adjustment might be to plot the proportion of positive results, P_i rather than the number of positive results; however, while the expected value would be same for all samples, the expected variances of the results will no longer be the same. Thus, such data would not be usable for plotting for the reason given above. However, one possible way of correcting this is to plot: $Z_i = \sqrt{N_i} (P_i - P)$, where P is the assumed true proportion of positive results and N_i is the sample size for the i^{th} sample. In this case, the expected value of Z is zero, and the standard deviation of Z is $[P(1-P)]^{1/2}$. For sufficiently large N_i , the distribution would be the same (approximately normal) for each plotted data point, so that the Z_i could be used for plotting a control chart. A control chart for Z would have Shewhart control limits of $\pm 3[P(1-P)]^{1/2}$. CUSUMS and moving averages could be constructed with the Z_i values. Or, if the sample sizes were not that large, an arcsine transformation: $y_i = \sin^{-1}(P_i^{1/2})$ could be used, setting $Z_i = \sqrt{N_i} (y_i - \bar{y})$.

If the number of distinct values of N_i is small (say two or three) it would be possible to just plot the P_i , and have two or three Shewhart limits depicted on the same chart. The following is an example of a P-chart with two Shewhart limits for two values of N_i (= 50 or 100).

Similar as above for the other charts, the steps involved are:

1. Define the characteristic..... Presence of *Salmonella* spp.
2. Determine sample size or sizes ... Sample size = 50 or 100 25-gram units
3. Collect baseline data
4. Calculate Control Limits
5. Place Control Limits on chart of baseline data
6. Convert observations to proportions
7. Plot the baseline data
8. Connect consecutive plotted points with a straight line
9. Place control limits on a new chart
10. Collect and plot data as collected
11. Connect each point to previous point with a straight line
12. Observe chart for out of control signals after each point

For this example, Figure 1 is the number of *Salmonella* spp. positive units identified in a sample of 50 units of product is plotted versus sample number (or time of sampling) on the NP control chart. After about 30 data points (results from 30 samples) have been collected, (a rule of thumb for normal or nearly normal data is that 20-30 data points should be used for control limit calculations) the control limits are ready to be calculated. These data will be used to calculate control limits when these values are converted to proportions.

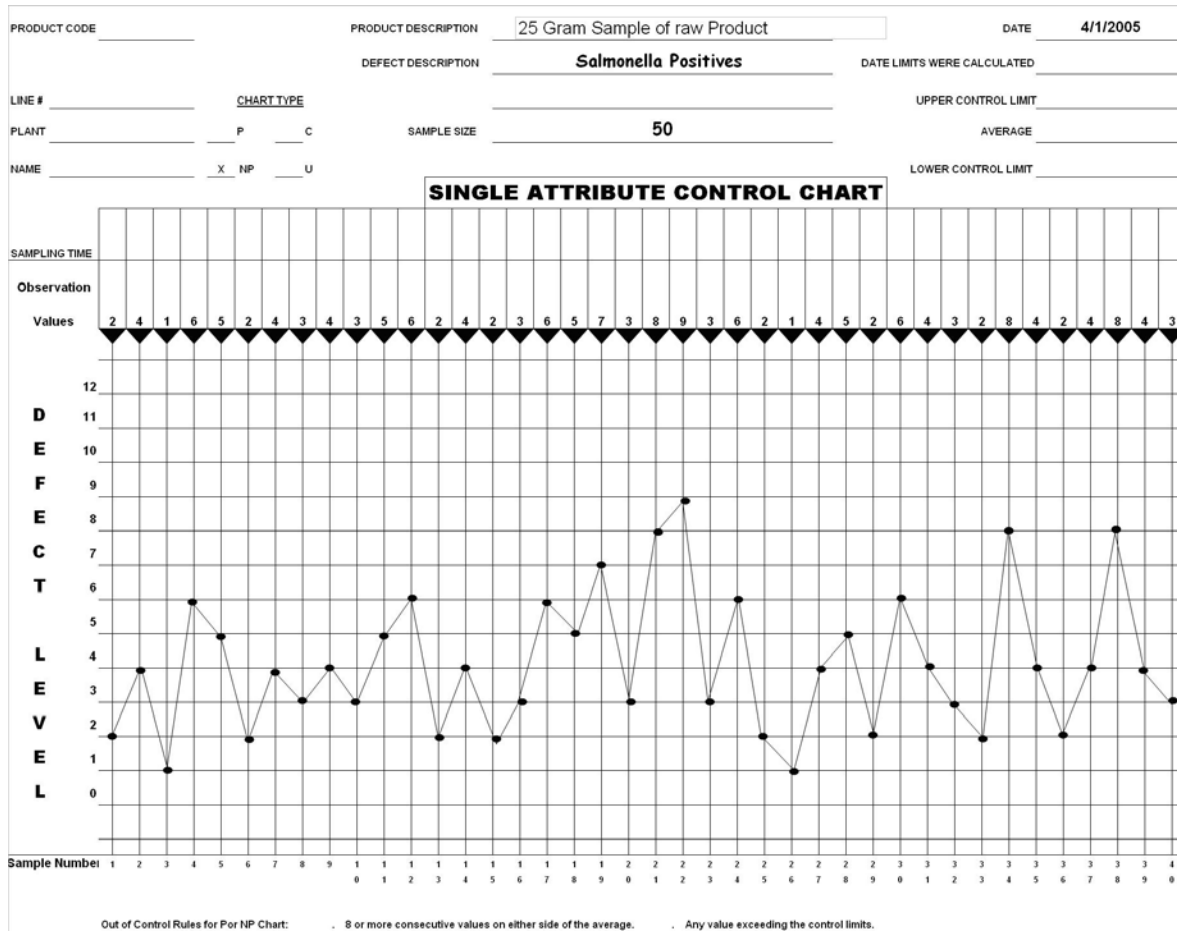


Figure 1. Base line *Salmonella* spp. data collected in sample size = 50

The formula for P Center line and control limits are:

$$\text{Average Proportion Positive} = \bar{P} = \frac{\sum_{i=1}^k X_i}{\text{Sample_size} \times \text{Number_of_Samples}}$$

where Sample_size = N_i = 50; and Number_of_Samples = k = 40 (in this example).

$$\bar{P} = \frac{165}{50 \times 40} = 0.0825 = 8.25\%$$

Center Line = $\bar{P} = 0.0825$

Control Limit Calculations:

Standard Deviation: $\sigma = \sqrt{\frac{\bar{P} \times (1 - \bar{P})}{n}}$ - that is, it is assumed that distribution is a binomial distribution.

When $N_i = 50$

Upper Control Limit P:

$$UCL_P = \bar{P} + \left(3 \times \left(\sqrt{\frac{\bar{P} \times (1 - \bar{P})}{n}} \right) \right)$$

$$1 - \bar{P} = 1 - 0.0825 = 0.9175$$

$$UCL_P = 0.0825 + \left(3 \times \left(\sqrt{\frac{0.0825 \times 0.9175}{50}} \right) \right) = 0.1992$$

Lower Control Limit P:

$$LCL_P = \bar{P} - \left(3 \times \left(\sqrt{\frac{\bar{P} \times (1 - \bar{P})}{n}} \right) \right)$$

$$LCL_P = 0.0825 - \left(3 \times \left(\sqrt{\frac{0.0825 \times 0.9175}{50}} \right) \right) = -0.0342 \text{ so } LCL_P = 0$$

For the process that the data were collected from above the average proportion of *Salmonella* spp. positive was 0.0825. The average or expected proportion of positive samples in a sample size of 50 is 0.0825, ($\bar{P} = 0.0825$), and the control limits calculate to be 0.1992 and 0 for the UCL_P and LCL_P , respectively. By placing the control limits and center line on a P control chart and then transforming the actual baseline data into proportion by dividing by the sample size, (50 for the baseline data) and plotting these data on the control chart, the baseline data can be viewed for stability (Figure 2). Figure 3 gives a schematic showing the relationship of NP-charts and P-charts when the sample size is the same (=50).

When the sample size is 100, the Shewhart control limits are determined using the same formulas as above, expect substituting the sample size 100 for 50. The target mean remains the same at 0.0825; the upper limit decreases to 0.165; and the lower limit would be zero. For a sample size of 100, the probability of no positive samples is 0.018%, well below the α -probability of 0.135%. The probability of one or zero positive results in a 100-sample set is 0.18%, so that even one positive result could be used as the lower limit when the sample size is 100.

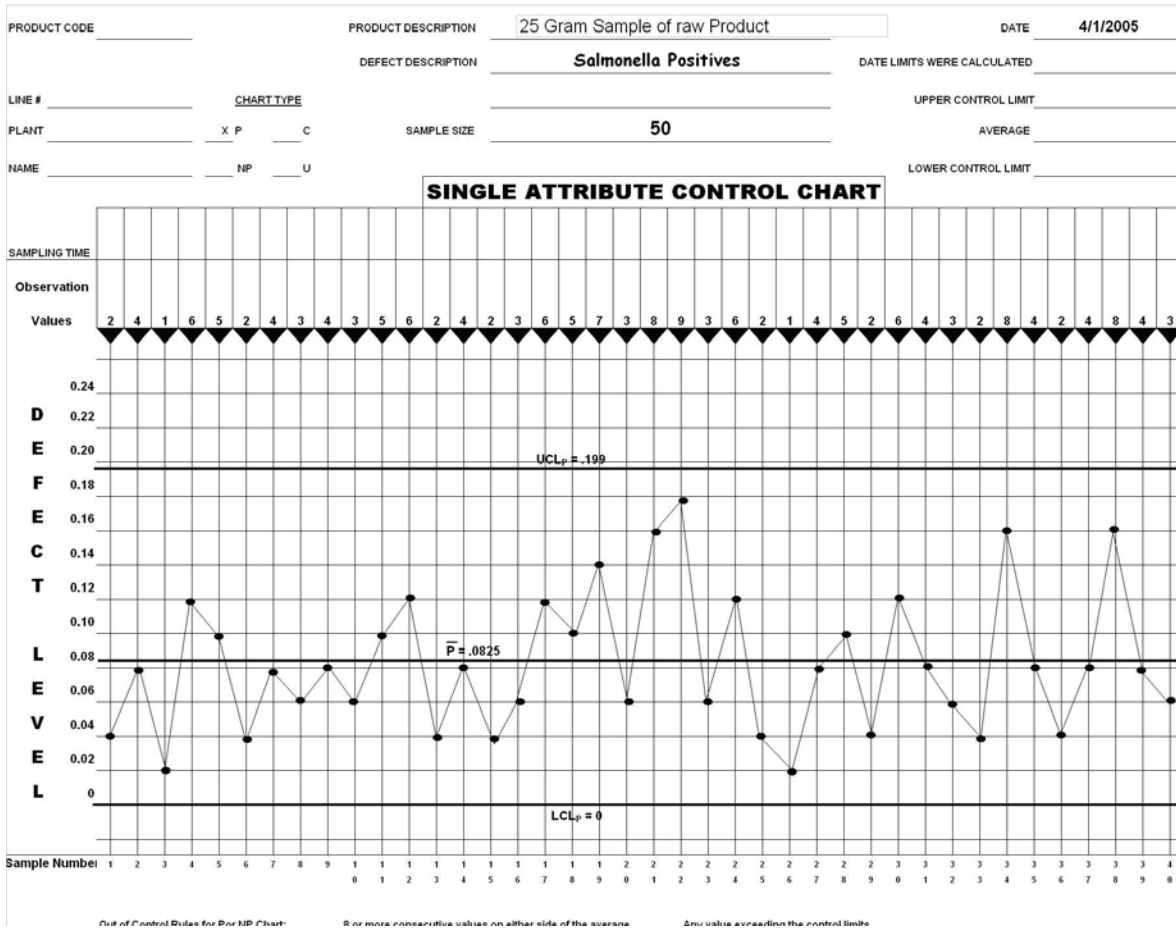


Figure 2. P control chart of baseline data

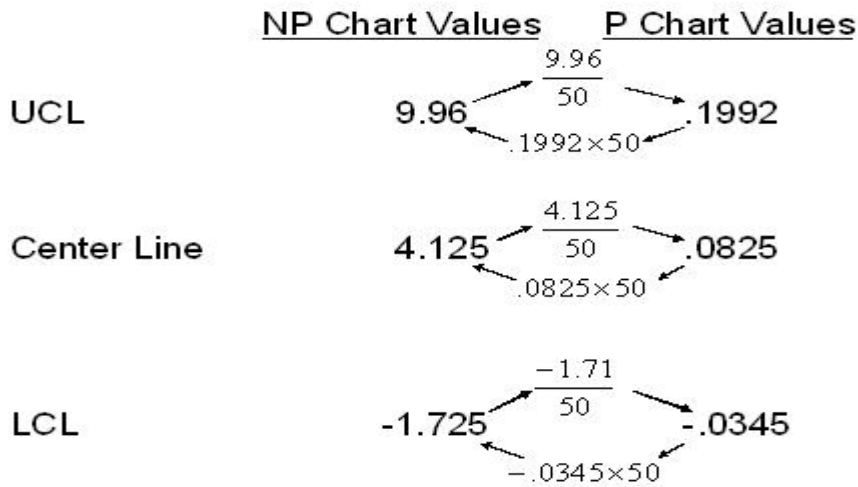


Figure 3. A comparison of center line and control limits for an NP and P-charts.

A control chart can be set up to accommodate two sample sizes. The new control chart has one lower control limit, (zero), one center line and two upper control limits, one for sample size 50 and one for sample size 100 (Figure 4). Data for both sample sizes are plotted on the chart. On this chart observations from a sample of size 50 are shown in black and observations from a sample size of 100 are shown on blue. All observed values are divided by their respective sample sizes before plotting. Notice how the data are connected in chronological order and sample size differences can be handled.

An interpretation of this chart is as follows: 1. the process was operating in a relatively stable manner for the first third of the chart. The result at sample number nine, where the data point fell between the two control limits, does not indicate an out of control signal since this point is associated with a sample size equal to 50 and this point is below the UCL_P for sample size 50. 2. Even though the criteria for declaring a process out of control did not occur, the pattern of results suggested that improvements could be made. Suppose such an attempt to change the process was made in order to try to decrease the process mean, and the data points when the processing was conducted after the change was plotted. In this example (Figure 4), the change seems to have made a difference as the level of positives dropped after the change was made. 3. Further suppose that after additional data were collected so that there are about 30 values (in this example 28) new control limits were established for this process. Then the (data corresponding to the points in the circle would be used for the calculations of new control limits using the above formulas with sample size equal to 100 or 50).

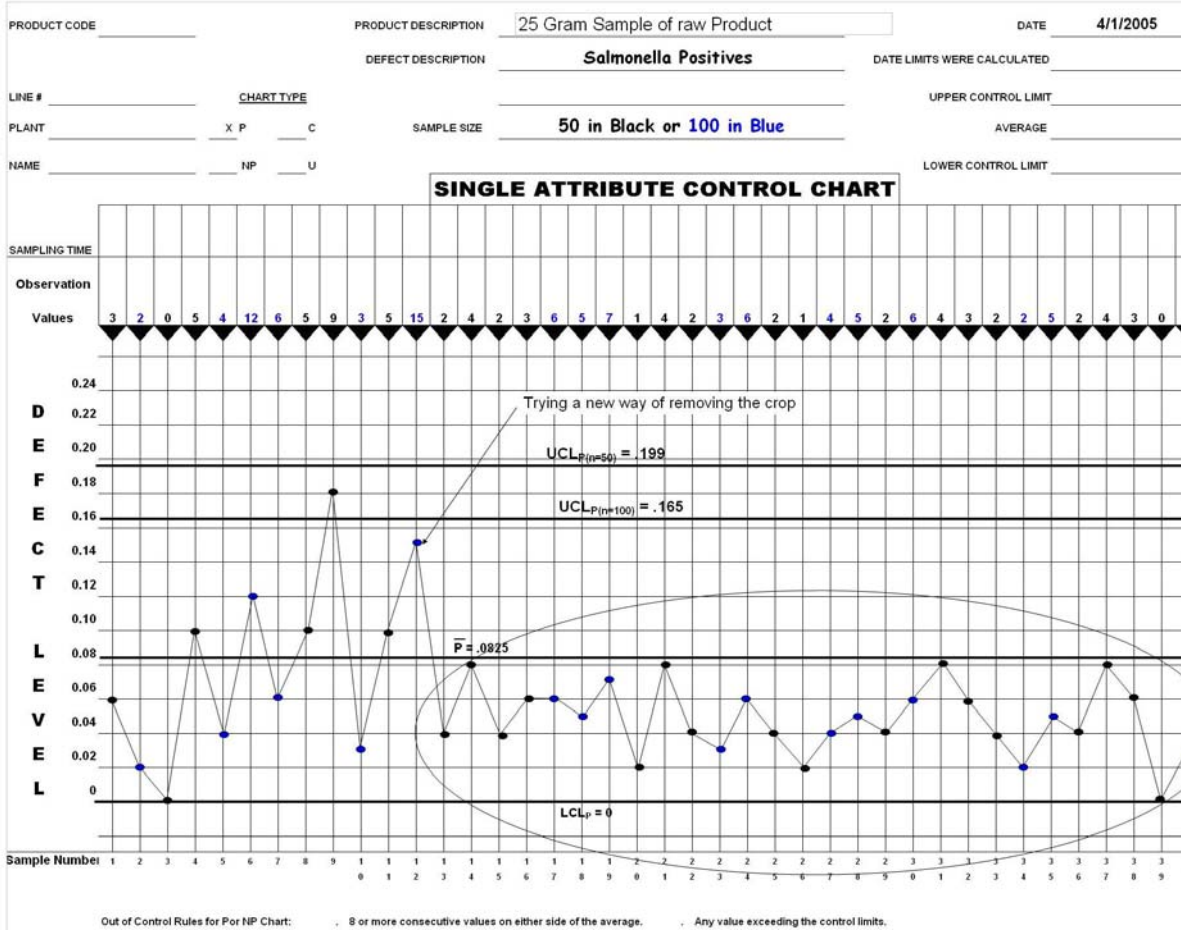


Figure 4. P Chart developed to accommodate two sample sizes

Appendix 6: Control Chart for Poisson distribution for more than one sample size or when one expresses results in a unit size not equal to sample size - the U Chart

When data are collected using more than one sample size (amount of material sampled) and an underlying Poisson – like distribution can be assumed, a U chart may be used to do process control. A U chart is a plot of observation per sample, normalized to a fixed unit size.

In this example APC counts are measured for a fully cooked product. Briefly, a 10 % dilution is prepared by removing 10 grams of fully cooked product from post-packaged product aseptically and placing it in 90 ml of diluent, stomached for 60 seconds and then 1 ml is plated and incubated for 48 hours. After the incubation CFUs are counted and data are reported as CFUs per gram. Since the actual amount of product in the one ml of plated diluent is actually 0.10 gram a situation is presented where count data are reported in units other than that equal to the sample size, and counts are low. At later time, the size if the same changes to a value different than 0.10 grams. In this case, all data could be standardized to be expressed in per gram units, where control limits would depend on the same size, in a similar fashion as given in Appendix 4, for P- charts. The standardization is just dividing the counts by the sample size: $U = C/\text{sample size}$. For these reasons a U chart is chosen as the chart to use for process control for this characteristic.

Actual Counts of the last 100 samples were:

Table 1. Results from the previous 100 APC, (CFUs) per ml and the frequency of results

<u>Count per ml.</u>	<u>Frequency</u>
0	49
1	29
2	13
3	3
4	3
5	1
8	1
11	1

For graphing purposes, each observation is divided by the sample size to express the results as CFUs per ml, (a 1 CFU outcome is reported as $1/.1 = 10$ CFUs per ml)

The steps involved in using a U control chart are:

1. Define the characteristic... APC counts per gram
2. Determine sample size 1 ml, .1 gram
3. Collect baseline data
4. Calculate Control Limits
5. Place Control Limits on chart of baseline data
6. Standardized the data by dividing by sample size
7. Plot the baseline data

8. Connect consecutive plotted points with a straight line
9. Place control limits on a new chart
10. Collect and plot data as collected
11. Connect each point to previous point with a straight line
12. Observe chart for out of control signals after each point

The formula for U Center line and control limits are:

$$\text{Average Count} = \bar{U} = \frac{\text{Total_Number_of_CFUs}}{\text{Sample_Size} \times \text{Number_of_Samples}}$$

Where: Sample_size = 0.1 and Number_of_Samples = k = 100 (in this example).

$$\bar{U} = \frac{100}{0.1 \times 100} = 10 \text{ CFUs per ml}$$

$$\text{Center Line} = \bar{U} = 10$$

Control Limit Calculations:

Standard Deviation: $\sigma = \sqrt{\frac{U}{n}}$ - that is, it is assumed that distribution is a Poisson distribution.

The control limits for the U chart are calculated as:

Upper Control Limit U:

$$UCL_U = \bar{U} + \left(3 \times \left(\sqrt{\frac{\bar{U}}{n}} \right) \right)$$

$$UCL_U = 10 + \left(3 \times \left(\sqrt{\frac{10}{0.1}} \right) \right) = 40$$

Lower Control Limit L:

$$LCL_U = \bar{U} - \left(3 \times \left(\sqrt{\frac{\bar{U}}{n}} \right) \right)$$

$$LCL_U = 10 - \left(3 \times \left(\sqrt{\frac{10}{0.1}} \right) \right) = -20 \text{ so } LCL_U = 0$$

These control limits were then placed on a single attribute, (U) control chart and the last 40 data points are plotted to view how some of the baseline fit on the chart (Figure 1).

The control chart illustrates how the user divides each observation by the sample size and plots the standardized results, (for the first observation 1 CFU is divided by 0.1 gram which provides a value of 10, so 10 is plotted as the first point, representing 10 cfu/g).

If the sample were to change to 0.5 instead of 0.1, then the control limits would change: the upper control limit would equal: $10 + 3(10/0.5)^{0.5} = 23.4$, and the lower control limit would equal 0, since $10 - 3(10/0.5)^{0.5} < 0$.

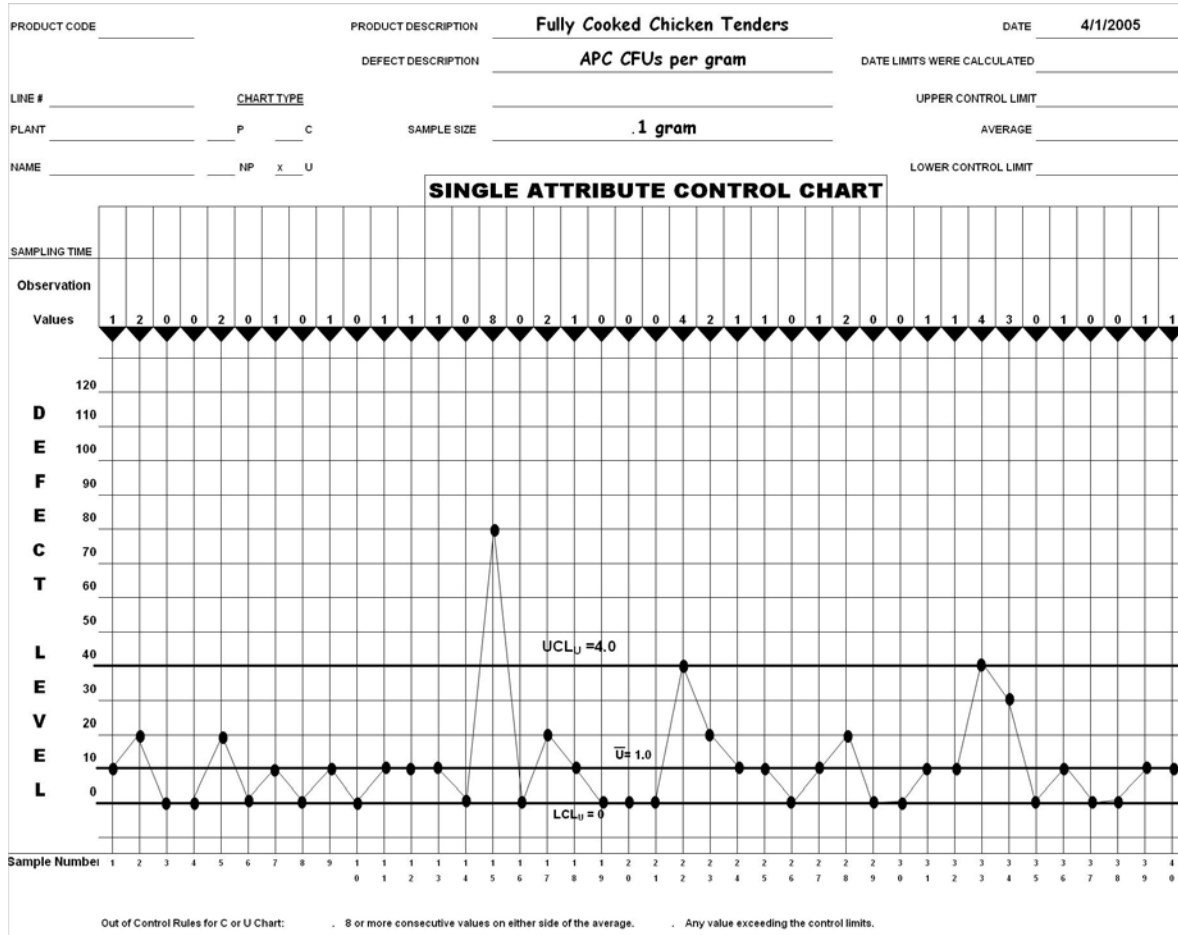


Figure 1: U Chart of CFUs per gram of fully cooked product

As with the P chart, a U chart can also accommodate more than one sample size, and, as with the P chart, the larger the sample size the closer the control limits are to the center line.

Appendix 7: Control Charts for Rare Events:

The Failure Control Chart, F Chart:

For events that are rare, to the extent that reasonable subgroup sample sizes would yield many zero values, a Failure Control Chart (F Chart) is an effective method for gaining an understanding as to whether the rate of the event is increasing, decreasing or remaining approximately stable. This particular chart was in fact developed to help answer this question. When the process is in control, the duration of time between events would be expected to follow an exponential probability distribution, which is described by a single parameter, given everything else being equal. In other words, it can be assumed that the number of failures expected over any number of times would be proportional to the number of samples, and the distribution of the number of failures would be binomial. The approximation made for determining the control limits is that the number of samples can be considered a continuous variable, associated with time. This assumption is reasonable when it is assumed that the failure rate is small. When the process is in control, it is assumed that the value of the failure rate parameter is constant over time.

In order to develop an F Chart the average time (number of samples) between events must be estimated. After an event, the time or number of samples since the last event are determined. The distribution of the times between events is assumed to be exponential distribution when the process is under control. Again the rule of thumb of observing 20- 30 or more events, to obtain a good estimate of the average time between events is recommended. The average time is referred to as “Mean Time Between Failure,” MTBF, to keep consistent with reliability engineering convention. The probability of having not failed based on the current MTBF is calculated as follows:

Reliability: $R = \text{Probability of not failing} = e^{-\frac{t}{MTBF}}$ where t is the number of samples since the previous failure.

High values of R imply low values of t, which would be undesirable.

The follows from the definition of the exponential distribution, which has the cumulative distribution function, $\text{cdf}(t) = 1 - \exp(-t/\beta)$, where β is a constant. The expected value of a random variable distributed as an exponential distribution with parameter β is β . Thus the value of MTBF is estimated from baseline data consisting of many samples by just dividing the number of samples by the number of failures, assuming that this last value is not zero. To get a reasonable accurate estimate of MTBF, following the normal convention, the number of samples collected should provide about 20-30 failures. However, the standard error of this estimate assuming that the number of samples between failures is distributed as an exponential distribution is $MTBF/n^{0.5}$, where n is the number of failures. The error CV thus is $100\%/n^{0.5}$. To have an error CV of less than 20% would require more than 25 failures; to have CV of less than 10% would require more than 100 failures. If it is anticipated that the failure rate would be low, so that MTBF would be large, this latter number of failures might be difficult to obtain. However, an error CV larger than 20% could impact on the accuracy of the control charting. Thus it seems that at

least 20-30 positive results, and possibly more, should be used when computing MTBF for a control chart

For example, during a previous year, a plant collected 4,400 *E. coli* 0157:H7 samples, of those samples, 44 samples tested positive. The MTBF can be determined by dividing the number of sample by the number of positives:

$$\text{MTBF} = \frac{4400}{44} = 100$$

Time is a continuous variable and sample number is a discrete variable. This discrepancy may cause some problems when the MTBF is “small.” In the example being presented, MTBF = 100, so that the probability $t=1$ is 1%, since $R = e^{-1/100} = 0.99$ is the probability of not failing, so that the probability of a positive sample is $1-0.99 = 0.01$. The implication of this is that two consecutive positive samples, providing an observation of $t = 1$, is not enough to signal “out of control” if the control limits are set where the α -probability is to be low, about 0.135%, based on the normal distribution assumption for the Shewhart (one-sided) control limit of $\mu + 3\sigma$. In order to have a α -probability that low or lower, the MTBF must be no less than 750 samples.

There are many ways this “problem” can be dealt with. The easiest is just to count the number of samples between positive results, exclusively, so that the above example would provide an observation of $t = 0$, (two consecutive events would mean no negative results between events), and thus would automatically (regardless of the value of MTBF) provide an “out of control” signal. This is a “conservative” approach insofar as it assigns the number of days the minimum it could be assuming that time was a continuous variable and what is being measured is that time when a “failure” takes place. In practice this should not create a serious bias in the α - and β -probabilities, but has the effect of increasing the α -probability slightly while decreasing the β -probability slightly over actual values. Thus, the time, t in the above formula is, (t) , equal to number of samples since last positive -1.

Steps required to develop an effective F Charts are:

1. Define the event of interest.....Positive finding of *E. coli* 0157:H7
2. Calculate the MTBF From last 20- 30 events
3. After an event determine the time or number of samples since the last event.
4. Determine t , by subtracting 1 from the answer in 3.
(or combining 3 and 4, determine the number of samples between positive events , exclusive of the positive samples)
5. Determine the ‘probability’, R , of having not failed, using t , computed in 4.
6. Plot this probability of having not failed.
7. Connect the plotted point to the previously plotted point.
8. Review the chart for out of control signals after each point.

Note that the MTBF is not directly placed on the F-Chart, rather the F-chart is scaled from zero to 100% with limits set at a probability equal to those historically set by Shewhart at 0.13% and 99.87%. These probabilities correspond closely to the upper and lower control limits set at $\mu \pm 3\sigma$ for the usual Shewhart control chart, discussed above. The target line corresponding to the mean is at 50% (labeled \tilde{F}). When the times between events are distributed as an exponential distribution, the probabilities, R, will be distributed as a uniform distribution between 0 and 1, and thus the data points, R, would be randomly distributed around the center line (0.5) rather than being distributed non-symmetrically as would be the case if the times themselves were plotted. Thus R could be used for constructing moving averages, CUSUMS, or other trend statistics, keeping in mind though that the underlying assumption is a uniform distribution rather than a normal distribution.

After each event, the time since the last event or number of samples since the last event are placed in the space labeled, Time Since Last Failure - 1 (t), and the probability of not having a failure is calculated and entered in the space labeled Probability of not Having a Failure (R). An F Chart with a MTBF of 100 may look like that illustrated in Figure 1.

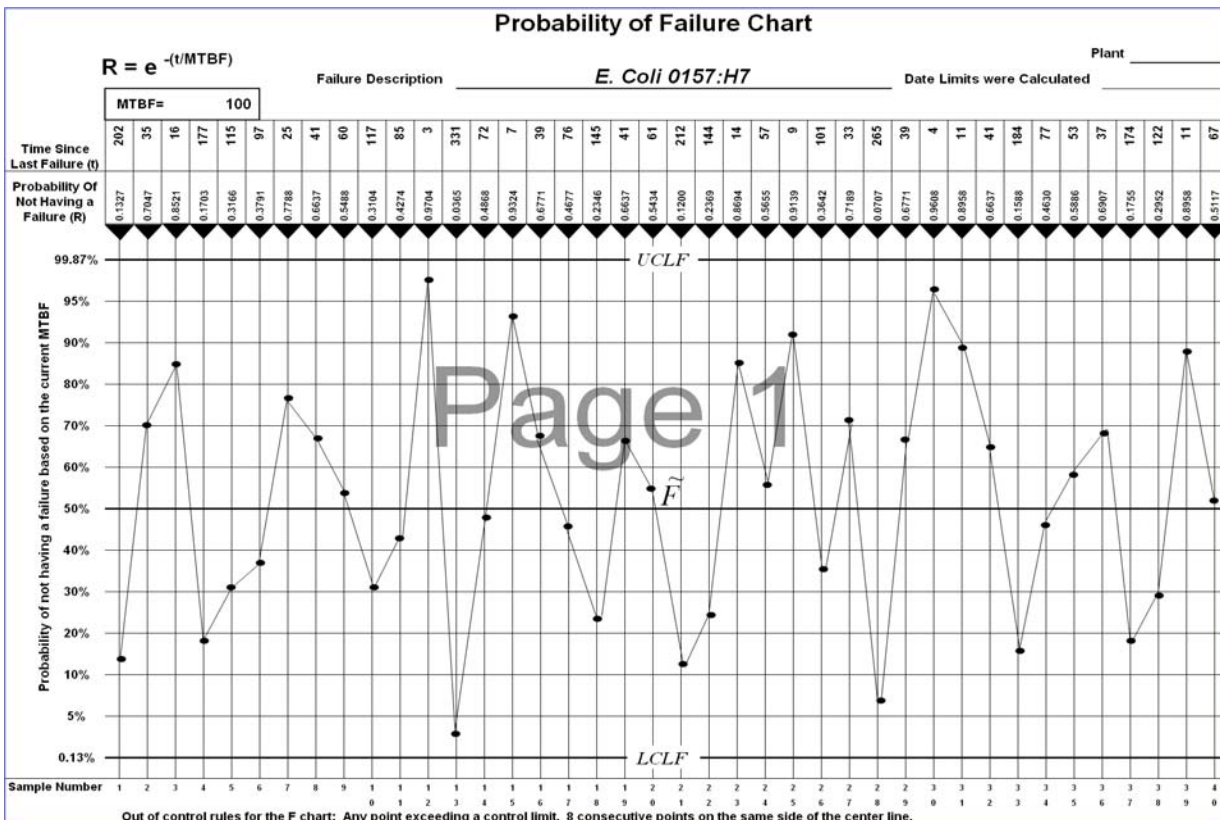


Figure 1. An F Chart of *E. coli* 0157:H7 events for a process with a MTBF of 100 samples

For this example, with a MTBF of 100 samples, the first event on this chart occurred after 202 samples (actually the 203rd sample). This corresponds to a probability of not having a failure of 0.1327 because

$$R = e^{\frac{-t}{MTBF}} = e^{\frac{-202}{100}} = 0.1327.$$

Stated another way the process had about an 87% chance of having an event before it did. In setting the chart up in this manner, it allows one to look at the graph of events in a similar fashion that one would look at a single attribute, such as, the NP chart discussed in Appendix 4. For example, eight consecutive points below \tilde{F} (Figure 2) would indicate an increase in MTBF and eight consecutive points above \tilde{F} (Figure 3) would indicate the MTBF is decreasing. Other indicators that the MTBF is increasing or decreasing would be a single point below the LCL_F or a single point above the UCL_F , respectively. Figure 4 illustrates a process with a point below the LCL_F . (Note, as discussed above, that because the MTBF is only 100, for a point to exceed the UCL_F requires two consecutive positive samples, or zero samples between failures.)

Of course, as with all SPC charts, an out of control signal should be investigated. An investigation of points above the UCL_F or eight consecutive points above $\tilde{F} = 0.5$ would help one identify processing conditions which raise the probability of an event. Removal of the conditions which raise the probability of an event could lower the probability of the event. This would in turn cause an increase in the MTBF, resulting in either a point below the LCL_F or eight consecutive points below \tilde{F} .

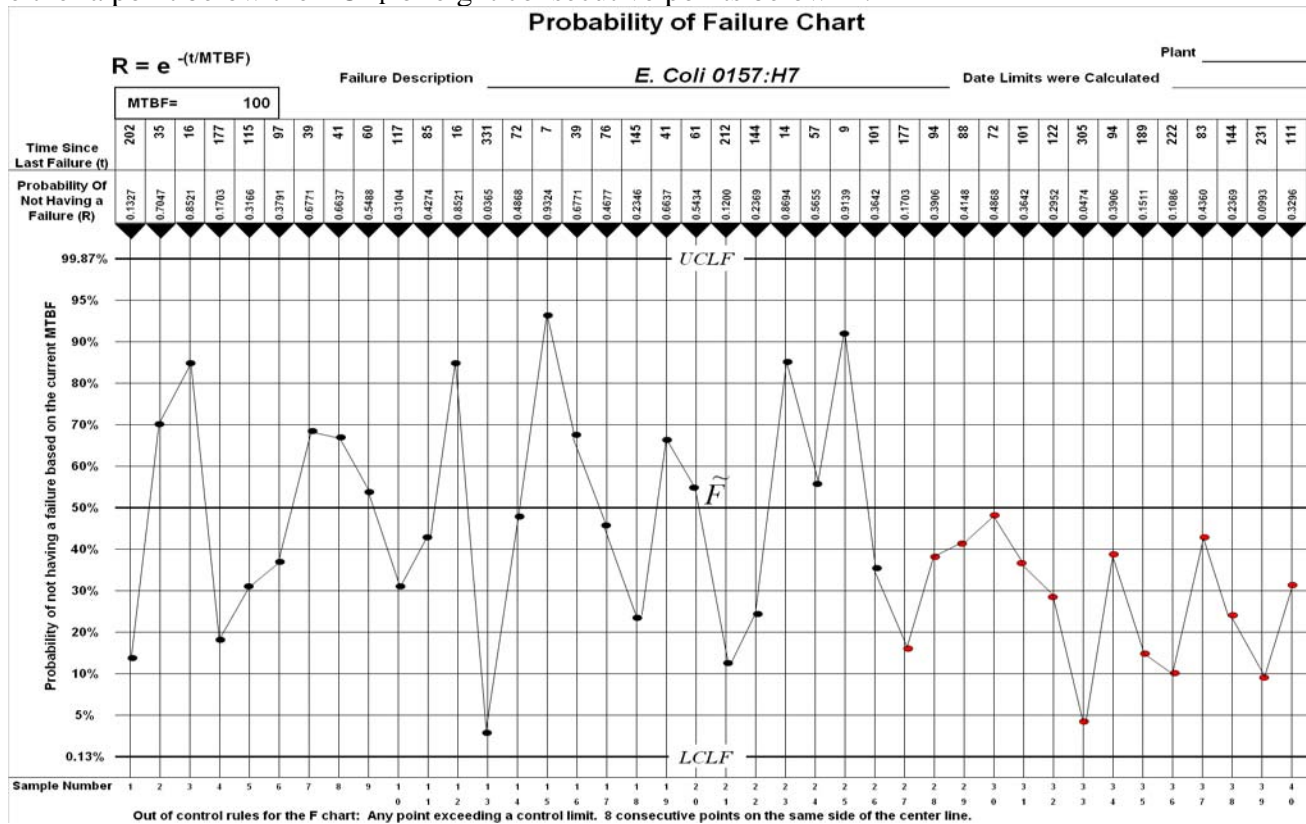


Figure 2. An F Chart showing an increase in the MTBF

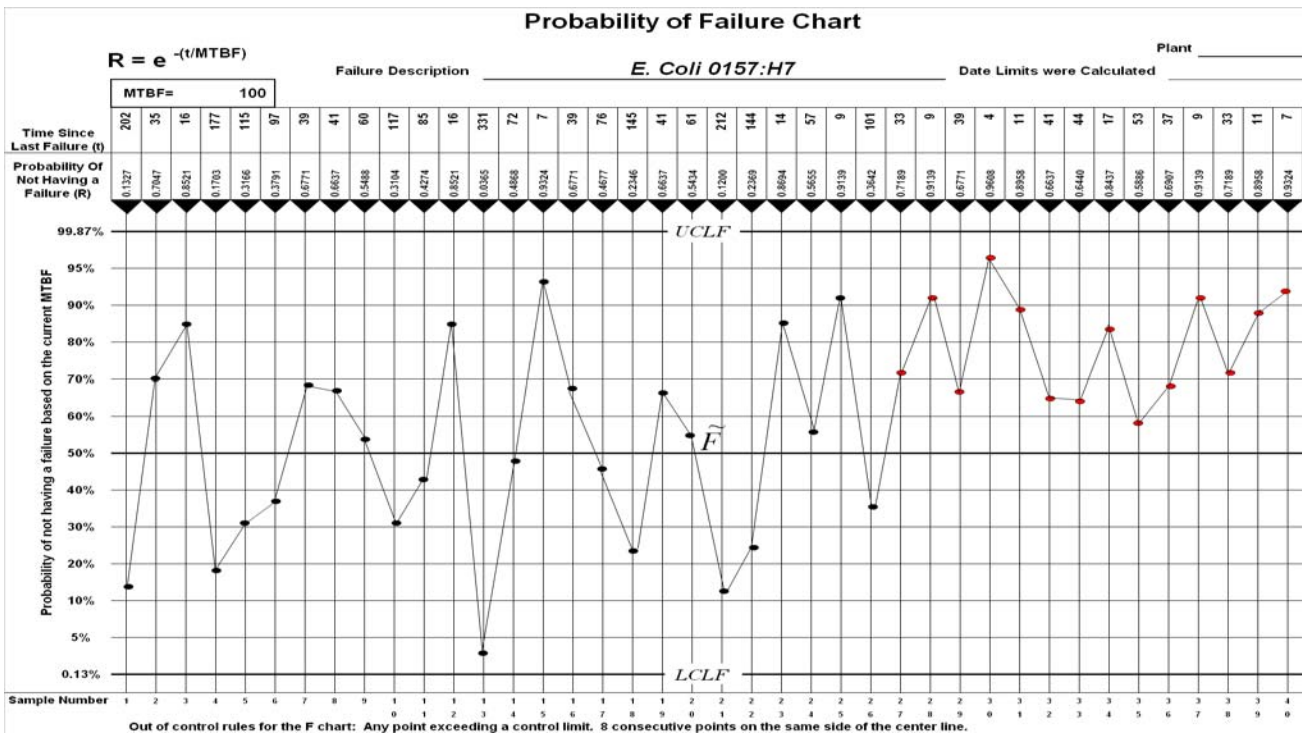


Figure 3. An F Chart showing a decrease in the MTBF

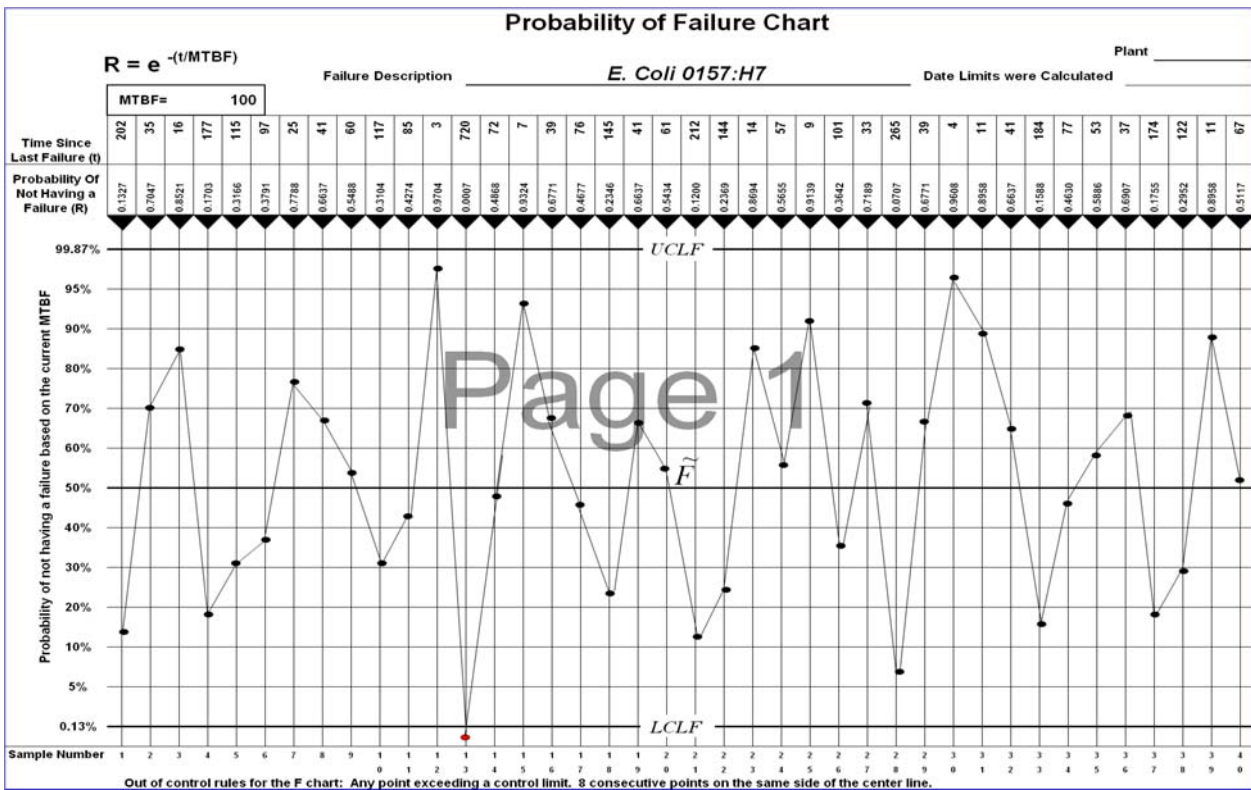


Figure 4. An F Chart showing a point below the LCLF, indicating the MTBF may be increasing

¹ Almost any microbiological data set of counts will have a distribution that is skewed so that a log transformation would make the distribution more symmetric. See for example the USDA Food Safety Inspection microbiological baseline surveys for counts of generic E. coli and other organisms. In fact this seems to be mostly true for any population data of living things. Part of the reason might be due to the inherent randomness associated with growth or cell division that “pure living” systems exhibit – namely an exponential growth.

² American Society for Testing Materials, from ASTM Manual on Quality Control of Materials, Philadelphia, January 1951, p. 115.

³ Discussion of maximum likelihood estimation, and maximum likelihood ratio and chi-square statistics can be found, in: Kendall and Stuart’s The advanced theory of statistics, vol. 2. Charles Griffen and Company Limited, London.

⁴ SAS, SAS Institute Inc. , Cary NC.

⁵ Wheeler, Donald J. and Chambers, David S. 1992 “Understanding Statistical Process Control. 2nd edition.” SPC Press, Inc.