Control chart methods –

a practical statistical tool for quality control (Part I)

Quality control methods are widely used to monitor the laboratory analysis process.

An analytical system where all the factors affecting the magnitude of errors are kept constant is said to be in "statistical control". Under these conditions, we can assume that results obtained by repeated analysis of a single test material would resemble independent random values taken from a normal distribution $N(\mu, \sigma^2)$.

A convenient way to monitor a measurement system is via a control chart. This is based on the results obtained by the analysis of one or more special test materials that have been homogenized and tested for stability. These 'control materials' must be typical of the material under routine test and are analyzed exactly as if they were normal samples in every run of the analytical system.

The results are then plotted on a chart that shows the results as a function of run number or time. This type of chart is called Shewhart chart. See Figure 1.

Statistically speaking, we expect in the long period, about 95% of test results to fall within a range of $\mu \pm 2\sigma$ and about 99.7% to fall within the range $\mu \pm 3\sigma$. These two equations actually are originated from the equation of the confidence interval of the mean for large number of samples:

$$\mu = \bar{x} \pm z\frac{s}{\sqrt{n}} \quad \text{or} \quad \mu = \bar{x} \pm z\sigma$$

where the value of z depends on the degree of confidence required, such as:

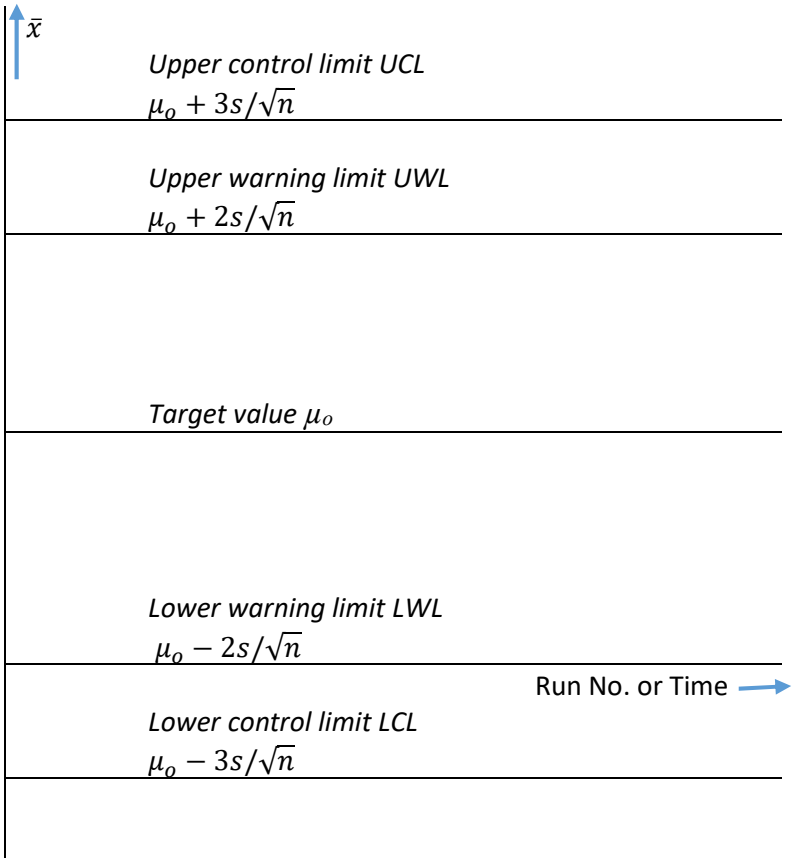
For 95% confidence limits, z =1.96 ≈ 2.0

For 99% confidence limits, z =2.58

For 99.7% confidence limits, z =2.97 ≈ 3.0

The Shewhat control chart conventionally uses lines at μ_o, $\mu_o \pm 2\sigma$(Warning limits) ad $\mu_o \pm 3\sigma$(Action or control limits) to monitor the data collected.

Figure 1: Shewhart chart for mean values

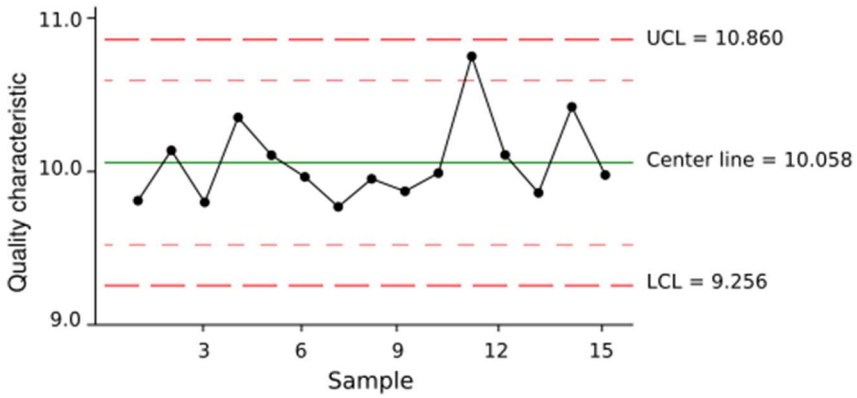


Under statistical control, a result is very unlikely to fall outside these action limits. But, if this situation does happen, it shows the system is 'out of control' and requires the results obtained in that run to be regarded as suspect. The analytical system is to be halted until the root cause has been identified and corrective actions have been made, i.e., the statistical control has been restored.

The Shewhart chart is good for detecting abrupt changes in the measurement system. Warning signs for potential out-of-control situation are to be noted when the following scenarios are observed:

- Continuous 9 data points at one side of the central line
- Continuous 7 data points showing an increasing or decreasing trend
- Continuous 5 data points lying on one side and beyond standard deviation $s_{R'}$
- 2 of the 3 continuous data points lying on one side and beyond $2s_{R'}$ *(i.e. UWL or LWL).*

A visual presentation of Shewhart quality control chart is shown in **Figure 2**.



In order to ensure the data collected for control charting are randomly distributed and independent, an Anderson-Darling test statistic can be carried out, as discussed previously: https://consultglp.com/2016/08/28/how-to-use-excel-spreadsheet-for-anderson-darling-ad-test-statistic/. A Microsoft Excel® spreadsheet template had been made available before: https://consultglp.com/2016/08/28/an-excel-template-for-evaluation-of-anderson-darling-test-statistic/