For example, it is inappropriate to use statistical approaches that rely on normally distributed data to analyze for trends in Grades A and B count data, where the majority of counts are zeros. Second, after a statistical tool is chosen, establish trend targets (i.e. control levels) by analyzing at least a year of historical data. This will ensure a more accurate target that is free of short-term bias.

Percentage Nonconforming.
It is well known that EM count data can be widely variable and statistical treatments that rely on counts are unreliable at best. Therefore, one method for identifying long-term trends is to examine the proportion (i.e. percentage) of nonconforming EM results. This method merely puts a statistical foundation under what many plants are already doing to identify trends and is analogous to using *p* charts for controlling processes that yield attribute data[3].

One benefit of using this method is that the definition of nonconforming results is flexible. They can be alert level excursions, identification of certain genera or groups (e.g. Bacillus, Gram negatives), or both. In other words, both qualitative and quantitative trends can be analyzed with this tool.

Another significant benefit is that determining control levels and generating *p*-charts are relatively straightforward and require no special statistical analysis software. Assuming the process is constant, the underlying distribution of percent nonconformities will be the binomial distribution. Using this technique, historical data is analyzed for the percentage of EM samples that produced nonconformities, or *p*.

Then, an upper control level can be established based on the chosen standard deviation (e.g. +2σ or +3_). Control levels are set with the following formula:

$$p + \sigma\sqrt{\frac{p(1-p)}{n}}$$

$$\frac{(ppp)1(-+\sigma)}{n}$$

where,

p = proportion nonconforming (from historical data)
σ = standard deviation
n= sample size

Since sample sizes are rarely identical from one time period to the next, the upper control level can be established once using an average sample size or with each trend analysis using the sample size for the time period in question. Once the upper control level is established, it can be compared to the percentage of EM data points that do not conform to the chosen attribute.

Further, it is possible to construct a control chart consisting of the predetermined percent non-conforming, upper control levels, and each data point representing the percentage non-conforming from a particular time point. This will provide a visual

