Confidence Bound Capability Measurements

Purpose:

This memo is being issued to document a change to current methodology for establishing acceptance criteria for process validation. Since no formal procedure covering this subject exists, this memo shall be used until a formal procedure has been released for the Spinal & Biologics organization.

Discussion:

The main criteria used for conducting process validation/qualification is the confidence and reliability (C/R) level that we establish in the risk assessment. For Example: 95/95 establishes that we are 95% confident that 95% of our parts meet specification. The C/R level is then used to determine sample size using MedStat.

Table 1: Risk to Confidence/Reliability Conversion

Risk	Severity Rating	Confidence	Reliability
Low	1	95	80
Medium	2-4	95	95
High	5	95	99

Once sample size has been determined, the acceptance criteria for the protocol is established. Historically, we have used a standard capability requirement (Cpk >=1.33) as this acceptance criteria. As with all statistical techniques, this value is an estimate of the true process capability. The accuracy of this estimate is influenced by the number of samples used in the calculation and the overall (pooled) standard deviation.

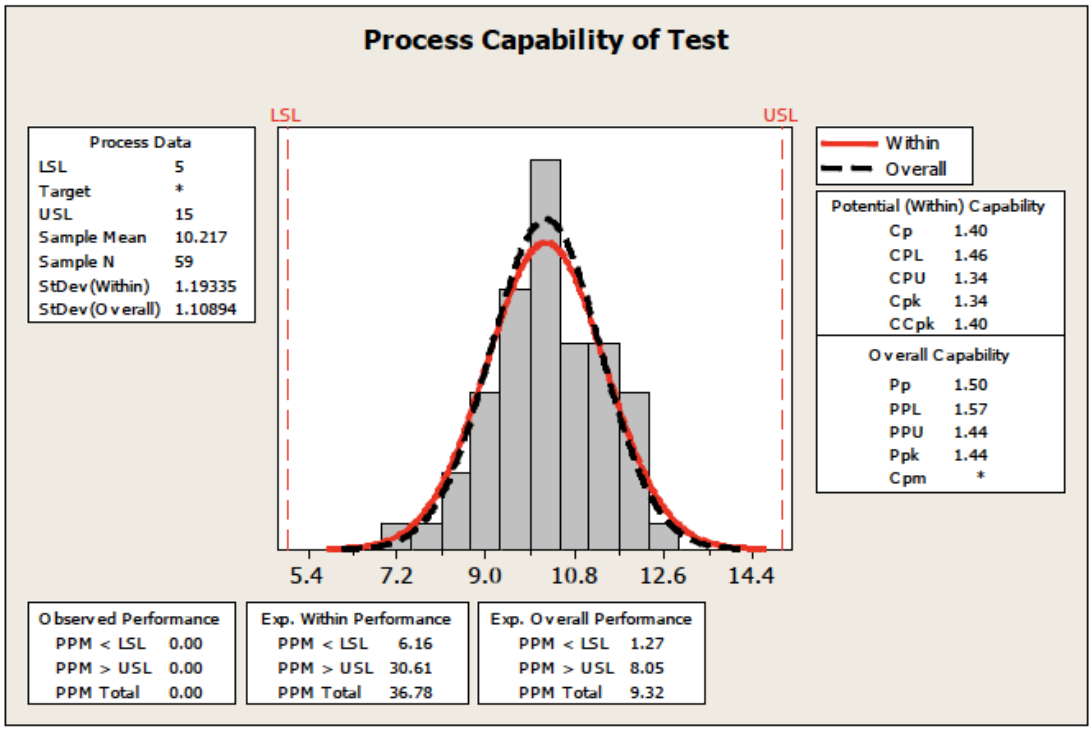

Figure 1 - Standard Capability Analysis (Minitab)

Using the Cpk from a standard process capability analysis only has a 50% chance of accurately predicting that the true capability (long-term) will meet (or exceed) the pre-determined acceptance criteria. This prediction does not meet the C/R level established during the initial risk assessment.

To properly apply the C/R level we must first start with the reliability portion of this criteria. Using standard statistical techniques, reliability can be translated into a Cpk measurement.

Table 2 - Reliability Converted to Cpk

Reliability	Minimum Cpk
80	0.8
95	1.0
99	1.3

With minimum Cpk determined, we now apply the other portion of the C/R level. This establishes with 95% confidence that our process will meet or exceed this minimum Cpk (aka ***lower limit confidence bound capability***).

To calculate this using Minitab, select the following options:

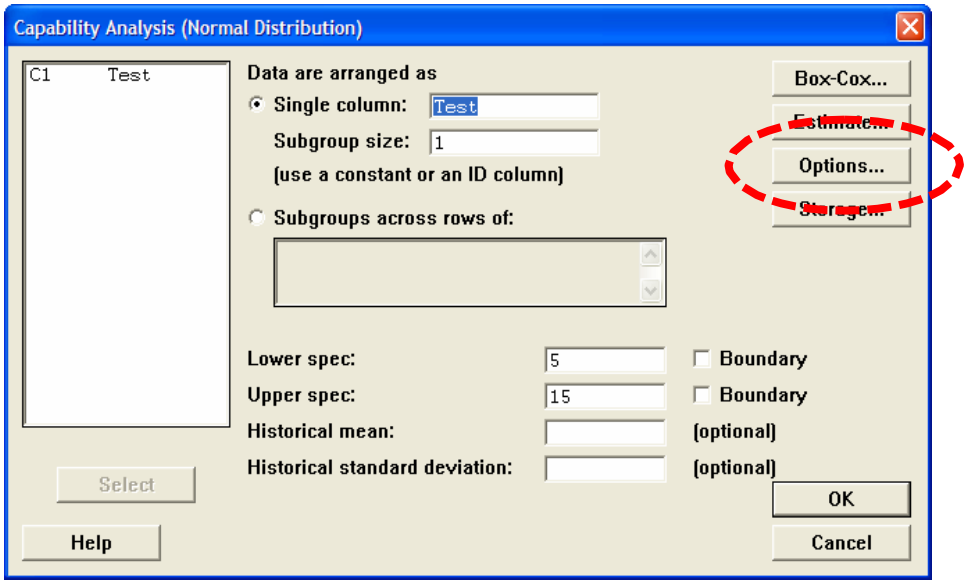

Figure 2 - Capability Analysis Dialog Box (Minitab)

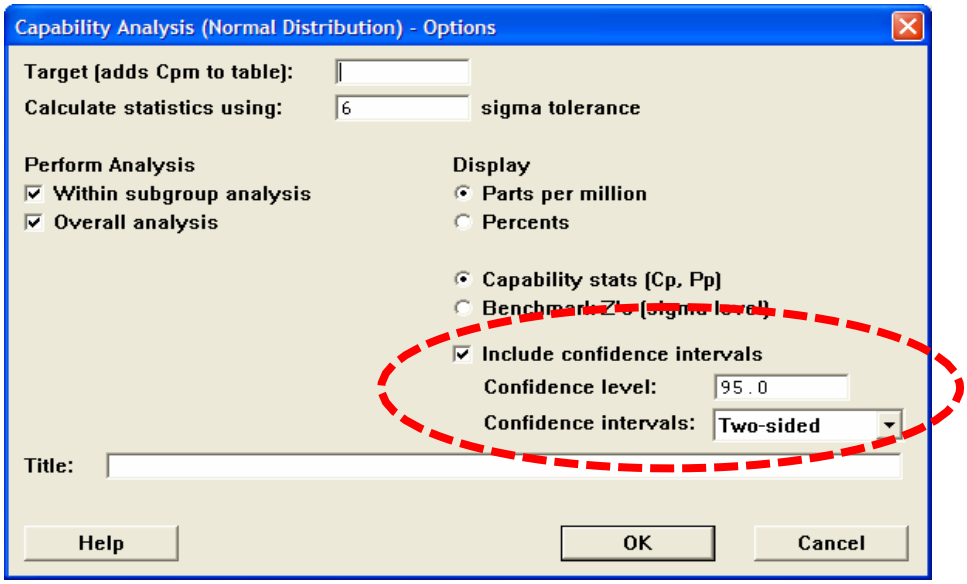

Figure 3 - Options Dialog Box (Minitab)

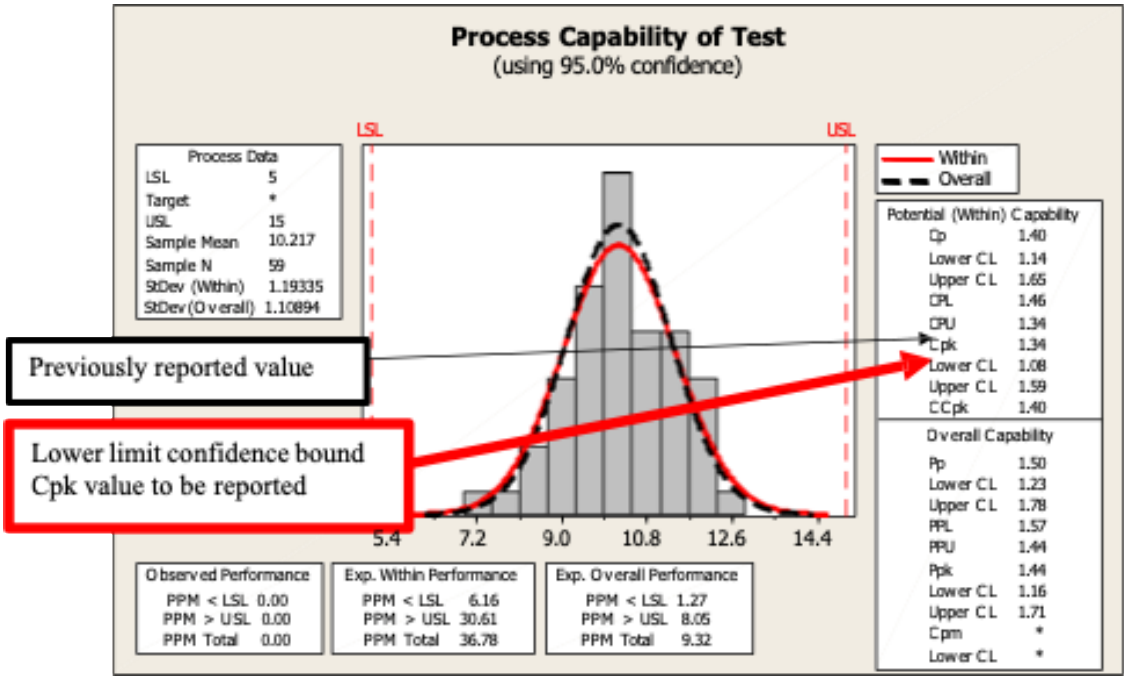

Figure 4 - Capability Analysis with Confidence Intervals (Minitab)

The output of the analysis will display both the standard Cpk measurement as well as the lower confidence interval bound Cpk. This lower limit value should be used to determine if the process has met the pre-determined acceptance criteria.

Conclusion:

Based on the information above, acceptance criteria for variables data should now be written as follows:

"Process shall exhibit, with 95% confidence, a lower bound process capability (Cpk) limit equal to or greater than a *XX*% reliability level. Minimum Cpk >= *Y.Y*"

Where XX and Y.Y come from the table above.