# Control and Specification Limits

## Factors that Help with Setting Limits

By Peter Fortini

**Q How many batches do we need to evaluate a control or specification limit?**

A Numbers of observations are the most characteristic questions to which statistics is turned for answers. The considerations that govern them include factors that are within the scope of statistics, and factors that are external to it. Statistical factors include the typical values of characteristics to be controlled or specified, how variable they are, and the accuracy of measurements. External factors include the amount of effort and time available before limits must be provided, the effort that can reasonably be devoted to maintaining the process within the limits, and the expected causes and consequences of violating them.

We consider here only limits that would apply to individual values. The classical $\bar{X}$/R chart control limits apply to subgroup averages, and not to the results of individual items at all. Traditional advice for control charts is that 25-30 observations should be available for setting control limits. The practice for use of control charts in statistical process control (E2587) recommends that a minimum sample size of 30 be used to construct a Shewhart chart for individuals. The statistical reason for the number, 30, has been described in previous Data Points articles.[1,2] The standard deviation of a process is a key input to control imits. Essentially, 30 is the sample size we need for an estimate of the standard deviation to be reliable enough for the purpose.

We consider here other factors that also come into play when setting limits.

### RATE OF PRODUCTION

When the rate of production is low, a smaller sample is appropriate. The traditional advice was offered in the setting where product was measured frequently, twice a shift or every hour, so that the time required to accumulate the 30 is not long. However, the production rate for many materials and processes is only a few batches per year. When limits are required in a short time, there is no choice but to base them on smaller numbers of observations.

### EFFORT TO MAINTAIN A PROCESS WITHIN LIMITS

There may be an effective handle in production that can maintain values of the property within limits, and perhaps to control its variability. Such properties pose relatively few issues for the provision of limits, and setting them based on a relatively small amount of data is feasible. The process will evolve and be maintained to meet them. An automated feedback control system, properly tuned, can maintain a material property within very narrow limits if that is desired. In other cases, there will not be effective handles that control a characteristic; it is the result of a large number of influences, including measurement error. Reliance on statistics to define the range that can be met then requires larger sample sizes.

### CONSEQUENCES OF EXCEEDING LIMITS: SPECIFICATION VERSUS CONTROL LIMITS

Setting specification limits poses some problems compared to control limits. The consequences of violating specification limits are more severe, up to rejection of the product, than for control limits. The processes for changing them are also more difficult.

The fundamental basis for specifications is, of course, what is required of the item or material. Specifications required for fit, assembly, or function are seldom the cause of trouble, as attention is paid to these properties and nonconformance is accepted as fatal. For other properties, the actual service need is not well-defined, or there may be a gray zone between what is wanted (and thus made a requirement) and what is really needed.

Nonetheless, the methodology designed for control limits has been applied to development of specifications. Based on the practice that control limits are set at the mean plus or minus three standard deviations, the same mean plus or minus three standard deviation limits have been given the name "natural tolerance limits" and proposed as specifications. There is some justification for going about setting limits by such a procedure. The material may have been selected for use based on development testing. The goal is to ensure that changes do not occur that might compromise the design or formulation. Therefore, the requirement is that future material be the same, within limits, as that supplied initially. A specification serves to enforce constancy to manufacture.

### USE OF THE TOLERANCE INTERVAL IN SPECIFICATION SETTING

An approach that has been adopted to reduce the risk that limits based on limited data sets are too narrow is to apply tolerance intervals to the setting of specifications. The tolerance interval for a population, based on a sample, is an interval with the property that, with a stated confidence level, usually 95 percent, the interval contains a given fraction of the whole population. For a normal distribution, the tolerance interval takes the form $\bar{x} \pm ks$, where $\bar{x}$ is the mean and *s* is the standard deviation for a sample of size *n*.

Taking as a point of departure the idea that specifications might be set at the mean plus or minus three standard deviations for the population, $\mu \pm 3\sigma$, the effect of using a tolerance interval increases the "3" to account for uncertainty in the mean and standard deviation. Table 1 gives values of the multiplier *k* to provide an interval containing [$\mu$-3$\sigma$, $\mu$+3$\sigma$] with 95 percent confidence. For a property with a normal distribution, that would guarantee that the middle 99.73 percent of the distribution is included. Values of *k* in the range from 12 to 30 samples are between 4 and 5. The table illustrates that, when sample data are used to set limits, wider limits are appropriate for smaller sample sizes.

The approach does not provide a complete answer to the problem of generating limits based on limited data. The result is still an allowance of only a multiple of the standard deviation, and a modest increase in the multiple does not change the fact that the available standard deviation might underestimate long-term process variability.

### REVIEW OF LIMITS

Setting either control or specification limits based on limited data can pose risks. The risks can be mitigated by instituting a procedure for review and, if necessary, adjusting the limits. Recalculation of limits, periodically and following process changes, is part of the ongoing operation of a statistical control program. Specification limits that have been set based on limited data, too, should be re-evaluated after a larger number of lots (again, at least 30) have been produced.

**Table 1 — Multiplier of *s* for a Tolerance Interval to Contain $\mu \pm 3\sigma$ for a Normal Distribution**

| n | k |
|---|---|
| 5 | 8.023 |
| 6 | 7.003 |
| 7 | 6.376 |
| 8 | 5.947 |
| 9 | 5.634 |
| 10 | 5.395 |
| 11 | 5.205 |
| 12 | 5.050 |
| 13 | 4.920 |
| 14 | 4.811 |
| 15 | 4.716 |
| 16 | 4.634 |
| 17 | 4.562 |
| 18 | 4.497 |
| 19 | 4.440 |
| 20 | 4.388 |
| 21 | 4.341 |
| 22 | 4.298 |
| 23 | 4.258 |
| 24 | 4.222 |
| 25 | 4.188 |
| 26 | 4.157 |
| 27 | 4.128 |
| 28 | 4.101 |
| 29 | 4.076 |
| 30 | 4.052 |

**REFERENCES**

1. Bzik, Thomas J., "Shewhart Individuals Control Charts, Part 1: Sample Size and Chart Reliability," *Standardization News*, Vol. 40, No. 1, Jan./Feb. 2012, p. 14.

2. Lau, Alex T. C., "Why 30? A Consideration for Standard Deviation," *Standardization News*, Vol. 45, No. 4, July/Aug. 2017, p. 47.

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