Setting Control Limits

The Roles of Data and Subject Matter Experts

BY JOSEPH S. KOSLER

Q: How are limits set?

A. Setting limits depends on what you are doing. Since the purpose of a limit and the methodology for constructing a limit are specific to its application, this article will not attempt to describe the solution for a specific problem. Instead, this article describes considerations made when someone is asked to produce a limit, set of limits or system of limits.

CONSEQUENCES OF EXCEEDING THE LIMIT

The primary considerations are the consequences and planned reaction for exceeding the limit. This may be negotiated with the client as potential limits and flexibility in reaction are balanced. The negotiation may reveal what is driving the request for the limit: usually process control, process monitoring for quality assurance and quality control, regulation, physical science or customer specifications. An observation that falls outside a limit is perhaps out of control or OOC (i.e., exceeds control limits), out of trend or OOT (i.e., exceeds trend limits), out of specification or OOS (i.e., exceeds specification limits) or perhaps just interesting (i.e., exceeds alert limits). The reaction to an observation that falls outside a limit may be reporting only, but generally there is a stronger consequence to company resources (e.g., compliance) or an operational consequence such as a change to the process (e.g., process control). The reader should attempt to match the methodology for constructing the limit to expected consequences within the context of the client's request.

INTERACTION WITH EXPERTS

Data-driven decisions require substantive knowledge of the context and mechanism(s) for generating the data. In psychiatric research, a subject may be excluded from an analysis used to set limits on normative psychophysiological function due to nutritional or medical history, yet included in another analysis that compares individual results to those limits. In pharmaceutical manufacturing, a test result observed by a QC laboratory may be excluded from the process history used to calculate control limits if the batch record confirms that the material tested was not representative of the process.

Input from subject matter experts is needed when an initial limit is required for a new production process or when an updated limit is required following a major change to an existing process. Two years of process history is desirable, yet uncommon, for calculating control limits. If the process is new, few sources of variation will have the opportunity to manifest in the small number of observations, *n*, available for the calculation. Consequently, limits regularly require adjustment as the number of data points (information) increases. Input from subject matter experts is needed to characterize processes with few observations (small *n*) due to infrequent output (e.g., four batches per year). A calculated limit may be adjusted by a process engineer or a physical scientist to a value known by other means as meeting production needs.

DATA, FREQUENCY AND INFERENCE

Limits on a process may be set at the minimum and maximum of observed process history (two years recommended). The minimum and maximum are data points, but they also have a frequency interpretation: the 0th and 100th percentiles, where *n* = 100 observations. With sufficient information about a process (large *n*), other percentiles of the data may be calculated directly or estimated using nonparametric procedures.[1] The 0.25th and 99.75th percentiles capture extremes at the rate of 1 in 400 each and may provide a useful screen. Alert limits (e.g., minimal reaction) and action limits (e.g., strong reaction) may be staged percentiles, such as the 95th and 99th percentiles (or 5th and 1st percentiles, respectively).

Percentiles used as limits may be computed by statistical inference. For example, it is known by the central limit theorem that process observations will conform to the normal (Gaussian) distribution over time if the observations (e.g., QC lab test results) are constructed as means or totals (sums). It is also known that this actually works.[2] With normality, it is known that $k\sigma$ limits (calculated as the product of a multiplier k and an estimated standard deviation s, or ks) cover about 95 percent of possible results when $k = 2$, and 99.73 percent when $k = 3$, assuming that you have an adequate estimate s of the total variance σ. Without normality, the limits widen to obtain similar coverage: At least $(1 - 1/k^2) \times 100\%$ of the data fall within k standard deviations of the mean, symmetry not required (Chebyshev's theorem), providing at least 94 percent coverage with $k = 4$ and at least 96 percentage coverage with $k = 6$. Inferential confidence bounds meeting highly prescribed criteria might be found in such books as Hahn and Meeker's *Statistical Intervals: A Guide for Practitioners*.[3]

AUTOMATION OR MANUAL PRODUCTION OF CALCULATED LIMITS

It is easy to automate the routine calculations needed to maintain a system of limits using all available data. However, input from subject matter experts regarding exclusions and process issues cannot be automated. A system of limits for an automated significance editing procedure called the SignEdit System[4] is planned for agricultural surveys in the Research and Development Division of the National Agricultural Statistics Service, U.S. Department of Agriculture. The SignEdit System includes a system of action limits and alert limits on process behavior. For farms included in every reporting period of a survey cycle, current values are compared to previously reported values to check for outliers that might reflect processing errors. A ratio comparison attributed to Hidiroglou and Berthelot of Statistics Canada was used.[5] The distributional properties of the H-B effects are unknown, so a manual approach was used to set initial limits across roughly one year of process history for development purposes.[6] For purposes of automation, action limits at the 0.25th and 99.75th percentiles were planned with annual recalculation based on two years of process history. The action limits indicate an automated restriction of OOT farm reports from the donor pool for donor imputation. The alert limits were planned at the 1st and 99th percentiles. The alert limits indicate an automated notification for manual review where the H-B effects will be studied further and where the performance of the action limits may be evaluated. Automation was adopted as hundreds of limits were required to control potential outliers from each survey question of each participating survey.

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JOSEPH S. KOSLER, *Ph.D., a statistician in the Research and Development Division of the National Agricultural Statistics Service at the U.S. Department of Agriculture in Fairfax, Va., is the secretary of ASTM Committee E11 on Quality and Statistics and an appointee to U.S. Food and Drug Administration advisory committees on clinical pharmacology and pharmaceutical science.*

DEAN V. NEUBAUER, *Corning Inc., Corning, N.Y., is an ASTM fellow; he serves as chairman of Committee E11 on Quality and Statistics, chairman of E11.90.03 on Publications and coordinator of the DataPoints column.*

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