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Combined Shewhart–Cusum Control Chart for Improved Quality Control in Clinical Chemistry

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We describe the adaptation of the decision limit cumulative sum method (cusum) to internal quality control in clinical chemistry. With the decision limit method, the cusum is interpreted against a numerical limit, rather than by use of a V-mask. The method can be readily implemented in computerized quality-control systems or manually on control charts. We emphasize the manual application here and demonstrate how the technique can be implemented on existing Shewhart or Levey–Jennings control charts. This permits both cusum and Shewhart control rules to be used simultaneously on a single control chart and also minimizes the data calculations necessary for the cusum method. Computer simulation studies are used to determine the performance characteristics of several different cusum rules, alone and in combination with a Shewhart rule. These studies indicate that improvements in existing quality-control systems should be possible by addition of this simple cusum method and by use of a combined Shewhart–cusum control chart. This should be particularly advantageous when introducing the cusum method in laboratories with manual quality-control systems.

Application of the cumulative sum quality-control method (hereafter called "cusum") has been limited in clinical chemistry, even though the method appears to have advantages in detecting systematic changes in the analytical process. This lack of acceptance is partly due to the additional effort required to calculate and maintain the cusum control chart, but also due to the qualitative manner in which the cusum chart is generally interpreted. There are techniques for quantitative interpretation, most notably by use of "V-masks," which are templates that can be overlaid on the control charts. These masks can be designed so that the control procedure provides a particular probability for detecting a systematic change in the analytical process, as well as providing a suitably low probability for rejection when analytical disturbances are absent. However, their use has not been readily accepted in clinical chemistry laboratories, leaving the analyst to make some qualitative judgment by visual inspection of the control chart.

There exists an alternative quantitative method for interpreting the cusum control procedure, called the "decision limit method" (*1*). In this method, the cusum is interpreted against a numerical limit. The decision limit method provides equivalent interpretation to that by use of a V-mask, and in fact the performance characteristics of a given V-mask can be transferred to provide a comparable decision limit method. But use of a numerical limit makes the interpretation easier, both in computerized and manual applications.

Implementation in computerized quality-control systems is simple and straightforward. Implementation in manual systems can be aided by use of a combined Shewhart–cusum control chart (S-CS control chart). Using this approach, the decision limit cusum method can be implemented by simple modifications of existing Shewhart (*2*) or Levey–Jennings (*3*) control charts.[4] Both the Shewhart and decision limit cusum methods can be plotted simultaneously on this one control chart and both are interpreted similarly against limit lines drawn on that chart. Use of both methods on a single control chart minimizes the work effort in introducing and maintaining the decision limit cusum technique.

Use of the combined Shewhart–cusum control system would be expected to provide an improved system for internal quality control. The performance of a proposed quality control system can be studied by determining the probability for rejection in situations where different amounts of analytical error are present. However, the probability calculations become very complex when combinations of control rules are considered. In studying the performance of the combined Shewhart–

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[4] The term "Shewhart control chart" is used here to refer to the commonly used control chart in which the concentration measured for a control solution is plotted on the y-axis vs. time (often the day) on the x-axis. Shewhart actually introduced two charts, one for plotting the mean of a group of observations and the other for plotting the range of the observations. As applied in clinical chemistry, often only a single control measurement is made and therefore only one control chart is used.

Table 1. Example Cusum Calculation and Tabular Record for the Case where $\bar{x}_a = 100$, $s = 5.0$, $k_u = 105$, $k_l = 95$, $h_u = 13.5$, and $h_l = -13.5$

Control observation no.	Control value	d_i	CS_i	Comment
1	104			
2	98			
3	102			
4	108	3	3	Start cusum calcn
5	109	4	7	
6	106	1	8	
7	96	−9	−1	End cusum calcn
8	104			
9	98			
10	89	−6	−6	Start cusum calcn
11	92	−3	−9	
12	92	−3	−12	
13	94	−1	−13	
14	93	−2	−15	Out-of-control

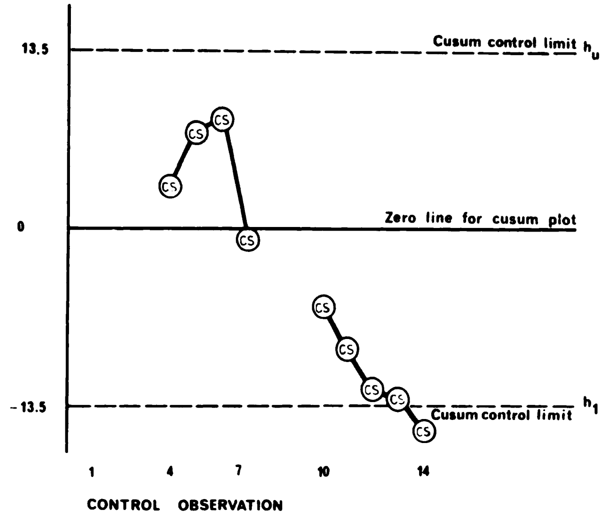

Fig. 1. Decision limit cusum control chart for example data given in Table 1

The cusum plot is initiated when a control observation exceeds $\bar{x}_a \pm 1.0s$. The analytical method is declared out-of-control when the cusum exceeds $\pm 2.7s$

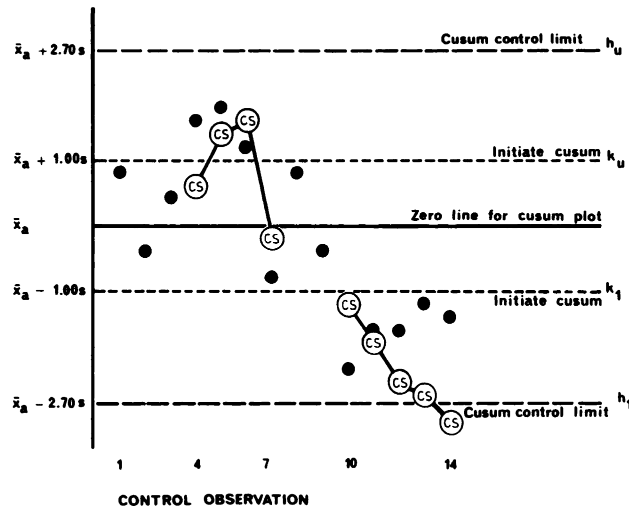

Fig. 2. Decision limit cusum control chart for which a tabular data record is not required

cusum control system, we use a computer simulation approach (*4*) to estimate the probability for rejection (*a*) when there are no analytical errors present except for the inherent random error or imprecision of the analytical method, (*b*) when there is a systematic shift equivalent to 1.0*s*, where *s* is the standard deviation for the control solution when analyzed by the analytical method, (*c*) when there is a systematic drift equivalent to 1.0*s* by the end of the analytical run, and (*d*) when there is a 50% increase in random error. We use the terms *probability for false rejection* in discussing situation *a* and *probability for error detection* for situations *b–d*.

Methods and Materials

Development of the Combined Shewhart–cusum Control Chart

The decision limit cusum method is described in detail in the *Appendix*. The method requires that values be defined for the mean, $\bar{x}_a$, and standard deviation, s, for a particular control solution when analyzed by the analytical method of interest, and also for the level at which the cusum calculations are initiated, k, and the numerical control limit for the cusum, h.

To illustrate how the decision limit cusum method works, an example set of data is given in Table 1. Here $\bar{x}_a$ is 100, s is 5.0, the k-values are 95 (lower level, k_l) and 105 (upper level, k_u), and the control limits are ±13.5 (upper and lower control limits, h_u and h_l). The cusum calculation is first initiated when a control observation exceeds a k-value, in this example when the 4th observation is obtained. The difference (d_i) between the control value and the k-value is calculated, and then successive differences are summed to give the cusum (CS_i). When the cusum changes sign, as for the 7th observation in Table 1, the cusum calculation is terminated until one of the k-values is again exceeded. At the 10th observation, the cusum is initiated again and at the 14th observation, the cusum exceeds the control limit ($h_l = -13.5$). The analytical method should be declared out-of-control. When the disturbance is corrected and the method re-started, the cusum would start over again at zero.

The cusum values can be plotted on an individual cusum control chart such as the one shown in Figure 1. This control chart must be used together with a tabular record such as that shown in Table 1. Implementation of this control chart is simple, but it does require considerable work to maintain both the tabular record and the control chart. This would be particularly noticeable when the cusum method is added to an existing control system where Shewhart charts are already used.

However, the cusum method can be implemented without need for a separate tabular record by use of a control chart such as that in Figure 2. Here the control

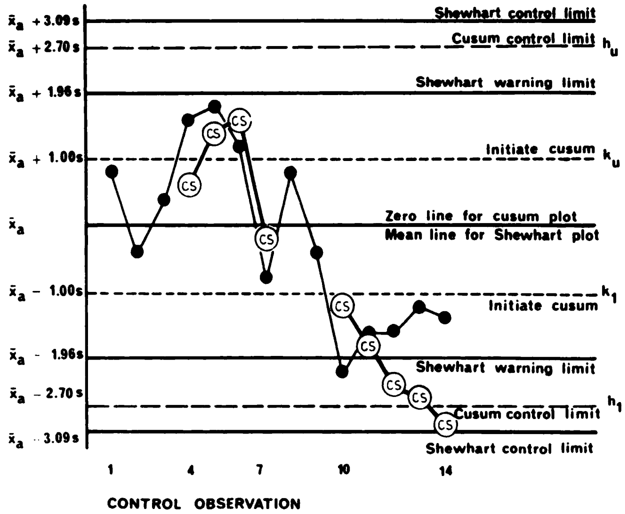

Fig. 3. Combined Shewhart–decision limit cusum control chart (*S-CS* chart)

The analytical method is declared out-of-control when a single control observation exceeds $\bar{x}_a \pm 3.09s$ or when the cusum exceeds $\pm 2.7s$

chart is prepared by drawing a line for the mean ($\bar{x}_a$), k-lines ($\bar{x}_a \pm 1.0s$ in this example), and lines for the control limits (conveniently drawn at $\bar{x}_a \pm 2.7s$ for this example). The y-axis is given in concentration units, so that the observed control values can be plotted directly on the chart. For the example set of data in Table 1, the control values are shown in Figure 2 by the solid black circles or points. When a control value first exceeds a k-line, then the distance of the point from the k-line can be measured with a ruler or a compass, or counted in arbitrary chart units. This distance (actually d_i) is then plotted taking the mean line ($\bar{x}_a$) as the zero line for the cusum plot. For each additional point, the distance from the k-line is added or subtracted from the previous distance, giving a total distance that represents the cusum (CS_i). When this distance exceeds the distance of the control line from the mean line, which is $2.7s$, then the method is declared out-of-control.

This control chart really has two scales on the y-axis, the first for plotting the absolute control values and the second for plotting the cusum. However, it is not actually necessary to use the second scale because no numerical calculations or numerical values are required when the cusum is measured graphically in terms of distance.

The similarity between this control chart and the commonly used Shewhart chart is readily apparent. The decision limit cusum method can be implemented on existing Shewhart charts by drawing the additional k-lines and cusum control limits. Figure 3 shows such a combined Shewhart–cusum control chart (*S-CS* chart) which will permit the use of both shewhart and cusum control rules simultaneously on one control chart. This *S-CS* control chart initially appears somewhat complicated because of the many lines; however, the use of appropriate color coding will serve to separate the Shewhart and cusum data and to identify their respective control limits. It may also be possible to eliminate some of the lines, perhaps by removing the $2s$ warning limits, or using a common control line for both the Shewhart and cusum methods (see *Discussion* section).

Table 2. Decision Limit Cusum Rules Tested via Computer Simulation Studies

Symbol	k-lines	Control limits	SE_d
$CS1^{1.0s}_{2.7s}$	$\bar{x}_a \pm 1.0s$	$\pm 2.7s$	$2.0s$
$CS1^{1.0s}_{3.0s}$	$\bar{x}_a \pm 1.0s$	$\pm 3.0s$	$2.0s$
$CS1^{0.8s}_{3.0s}$	$\bar{x}_a \pm 0.8s$	$\pm 3.0s$	$1.6s$
$CS1^{0.6s}_{3.0s}$	$\bar{x}_a \pm 0.6s$	$\pm 3.0s$	$1.2s$
$CS1^{0.5s}_{5.1s}$	$\bar{x}_a \pm 0.5s$	$\pm 5.1s$	$1.0s$

Control Rules Studied

Several different decision limit cusum rules were studied by use of computer simulation in order to compare their performance. The different rules are listed in Table 2. The rules are identified by symbols which have the general format $CSn_h{}^k$. Here CS stands for a cusum rule, n is the number of control measurements included in the control observation that is tested (which is 1 for all the rules studied here), k is the level at which the cusum is initiated, and h is the control limit.

Combinations of cusum and Shewhart rules were studied, and Shewhart rules are identified by similar though simpler symbols. The symbol 1_{3s} refers to the Shewhart rule where the method is declared out-of-control when one observation exceeds a 3.09s limit. The symbol $1_{2.7s}$ has similar meaning, except that the control limit is $2.7s$. The symbol $1_{0.01}$ refers to a control rule where the control limit has been calculated at each N in order to maintain a constant probability of 0.01 for false rejections (4).

Cusum rules $CS1^{1.0s}_{2.7s}$ and $CS1^{0.5s}_{5.1s}$ were chosen to have a low probability for false rejections, approximately 0.002. The other rules were selected because they would be simpler to adapt to existing Shewhart control charts.

Computer Simulation Studies

Sixteen hundred analytical runs were simulated for estimating the probability for false rejections and 400 for estimating the probability for error detection (for each type of error studied). The proportion of runs rejected was calculated and this was taken as the estimate of the probability for rejection (p). Repeated simulations of a systematic shift equivalent to 1.0s showed that the probability estimates had a standard deviation of approximately 0.005 to 0.03, depending on the magnitude of p itself. For higher p's, s tended towards the higher values. For four simulations, the average p's for the 13 points used to draw the p vs. N response curves were 0.417, 0.409, 0.408, and 0.402. The computer simulation procedure itself is described in more detail in reference *4*.

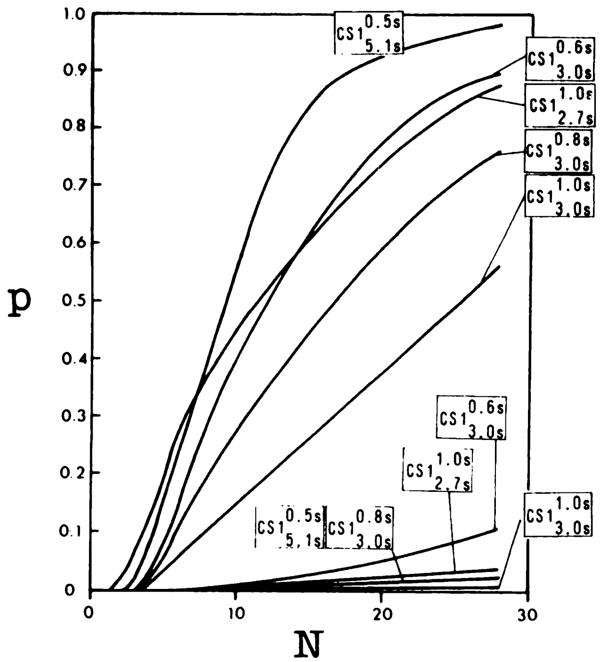

Fig. 4. Responses of individual decision limit cusum control rules to a *systematic shift equivalent to 1.0s* (top part of figure) and *when no analytical errors are present* (bottom part of figure)
In Figures 4–9, the probability for rejection (p) is plotted vs. the number of control observations (N)

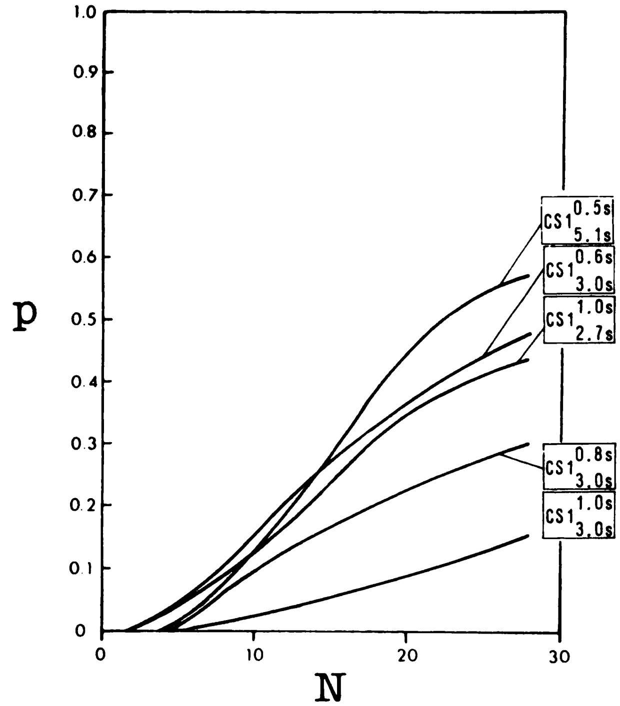

Fig. 5. Responses of individual decision limit cusum control rules to a *systematic drift equivalent to 1.0s*

Results of Simulation Studies

The results are presented graphically in Figures 4–8, where the probability for rejection (p) is plotted on the y-axis vs. the number of control observations (N) on the x-axis. Figures 4–6 present the results for the individual cusum rules and different error situations. Figures 7 and 8 present results for combination rules, where a cusum rule has been combined with a rule for a Shewhart control chart.

The lower part of Figure 4 shows the probability for false rejections (p_{fr}), i.e., the probability for rejection when the analytical process is running acceptably and there are no analytical errors present except for the inherent random error or imprecision of the analytical method. It is desirable that this be low. All rules except $CS1^{0.6s}_{3.0s}$ show p_{fr} to be 0.05 or less for N up to 28. This means that when 25 or so observations are collected, there is a 5% chance that there will be an out-of-control indication. This is about comparable to the level of false rejections observed when using $\pm 3.09s$ limits on a Shewhart control chart (*4*, see Figure 1).

The upper part of Figure 4 shows the probability for error detection (p_{ed}), in this case for a systematic shift equivalent to $1.0s$. When N is high, rule $CS1^{0.5s}_{5.1s}$ has the highest probability for detecting the error. Rules $CS1^{0.6s}_{3.0s}$ and $CS1^{1.0s}_{2.7s}$ show good responses, and at low N, $CS1^{1.0s}_{2.7s}$ is actually more sensitive. Rules $CS1^{0.8s}_{3.0s}$ and $CS1^{1.0s}_{3.0s}$ show the lowest responses.

Figure 5 shows the probabilities for detecting a systematic drift equivalent to $1.0s$ by the end of an analytical run. Rule $CS1^{0.5s}_{5.1s}$ again is most sensitive for high N. For low N, rules $CS1^{0.6s}_{3.0s}$ and $CS1^{1.0s}_{2.7s}$ are somewhat more sensitive. Rules $CS1^{0.8s}_{3.0s}$ and $CS1^{1.0s}_{3.0s}$ again show relatively poor performance.

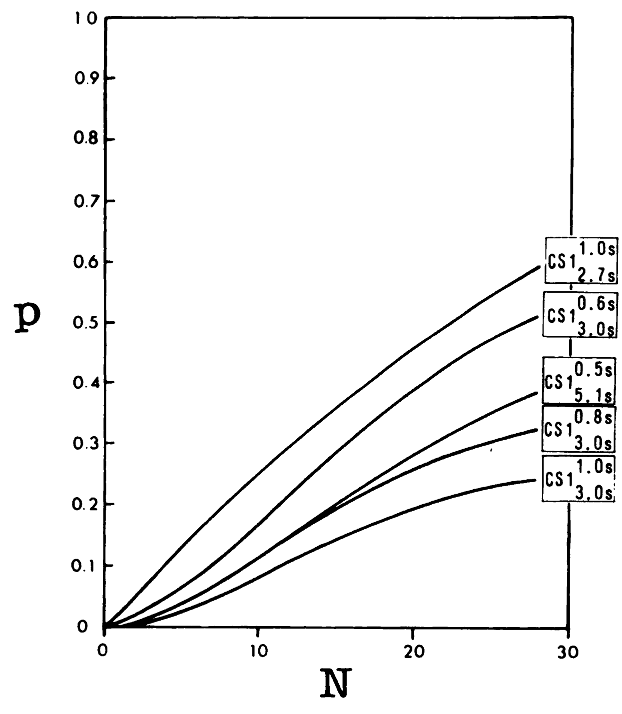

Fig. 6. Responses of individual decision limit cusum control rules to a *50% increase in random error*

Figure 6 shows the responses to a 50% increase in random error. The cusum rules are seen to be quite responsive to an increase in random error, even though they are usually of interest for detecting systematic errors.

The lower part of Figure 7 shows the probability for false rejection for the combination rules. The combinations $1_{2.7s}/CS1^{1.0s}_{2.7s}$ and $1_{3.0s}/CS1^{0.6s}_{3.0s}$ show the highest probability for false rejections, exceeding 0.10 or 10% as 20 or so control observations are accumulated.

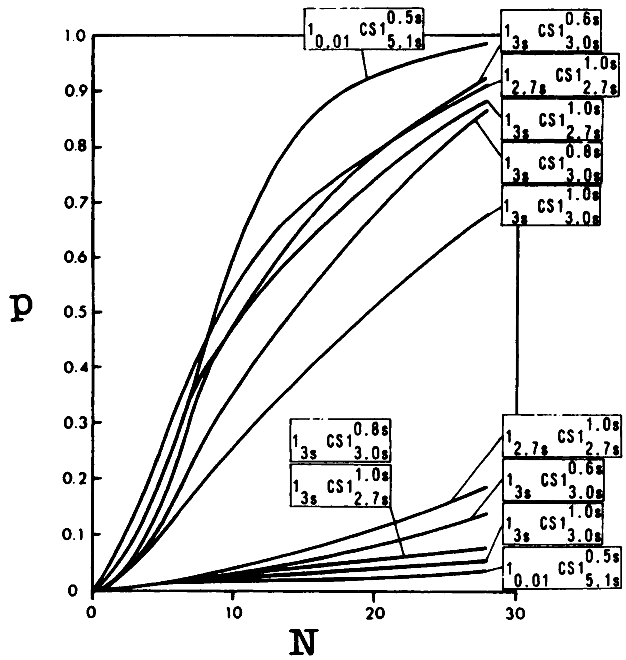

Fig. 7. Responses of combination Shewhart–decision limit cusum rules to a *systematic shift equivalent to 1.0s* (top part of figure) and *when no analytical errors are present* (bottom part of figure)

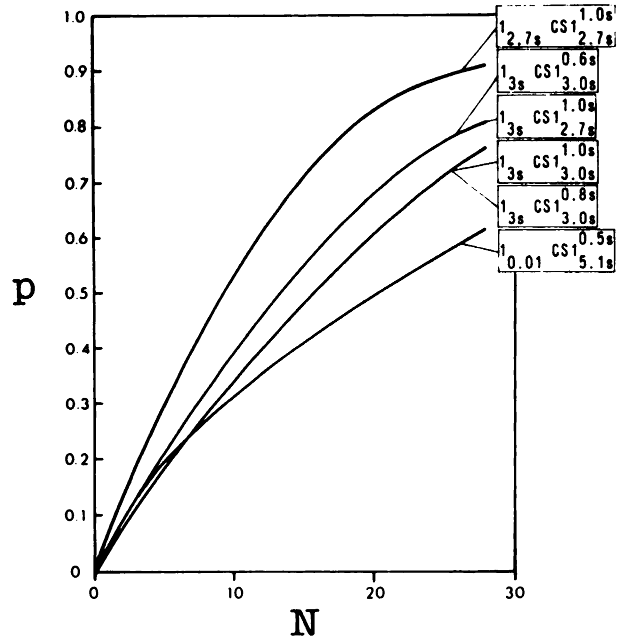

Fig. 8. Responses of combination Shewhart–decision limit cusum rules to a *50% increase in random error*

The upper part of Figure 7 shows the responses of the combination rules to a systematic shift equivalent to 1.0*s*. The combination rules show the same relative order of ability to detect the systematic error as observed in Figure 4, though the absolute values are somewhat higher for some of the rules. For a systematic drift equivalent to 1.0*s*, the responses were very similar to those shown earlier in Figure 5.

Figure 8 shows the responses to a 50% increase in random error. The combination rules show higher probabilities for detecting the analytical disturbance because all the individual rules have some ability to detect increases in random error.

Discussion

Use of a combined Shewhart–cusum control chart (*S-CS* chart), such as the one shown in Figure 3, provides improved detection of systematic errors. The amount of improvement over the commonly used Shewhart method with a 1_{3s} rule is shown by the simulation results in Figure 9. The probability for detecting systematic shifts and drifts equivalent to 1.0s should be about doubled by use of the *S-CS* chart (compare the *S-CS* 1.0*s* shift line with the 1_{3s} shift line, and the *S-CS* 1.0*s* drift line with the 1_{3s} drift line). This is achieved at a relatively small increase in the probability for false rejections (compare the no-error lines for *S-CS* and 1_{3s}).

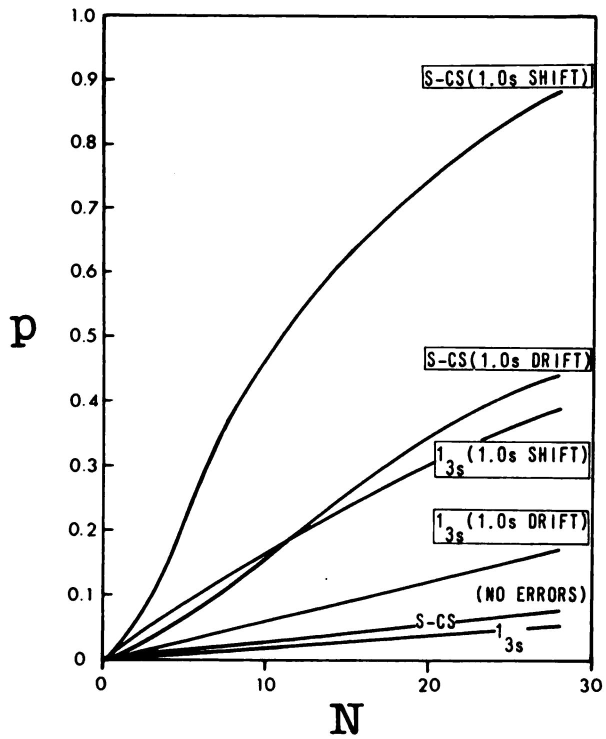

Fig. 9. Comparison of the responses of the combination $1_{3s}/CS1^{1.0s}_{2.7s}$ Shewhart–cusum rules (*S-CS*) with the Shewhart 1_{3s} rule alone for different error situations: *no analytical errors, a systematic drift equivalent to 1.0s,* and *a systematic shift equivalent to 1.0s*

Similar, though not identical, improvements in performance can be expected from use of some of the other cusum rules studied here. The choice between these rules depends on the particular laboratory application.

The rule $CS1^{0.5s}_{5.1s}$ appears to offer the best performance, having a low probability for false rejections and a high probability for error detection. However, it would probably be difficult to implement this rule on existing Shewhart charts because the large values for the control limits would be unlikely to fit on the charts. It could be implemented by using separate cusum control charts, but this is unlikely to be accepted in busy clinical laboratories. It is obvious that this rule could be readily

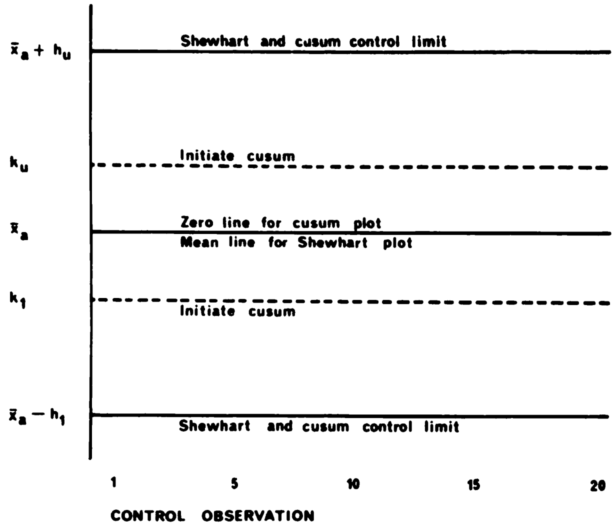

Fig. 10. A simplified combined Shewhart–decision limit cusum control chart (*S-CS* chart) where the same control limits are used for both the Shewhart and cusum methods

implemented in quality-control systems having computerized data calculations, as could rules where more than one control measurement is averaged to give the control observation to be tested. In computerized systems, the cusum could be used along with rules for the mean and range, and it would be expected to offer similar improvements in detecting systematic errors. Our concern here has been for implementation in quality-control systems where data handling is performed manually.

In applications where a simpler appearing control chart is desired, a chart like the one in Figure 10 could be used. The *S-CS* chart then only needs the mean line, k-lines, and one set of control limit lines. One possibility is to set the k-lines to $\bar{x}_a \pm 1.0s$ and the control limits at $\bar{x}_a \pm 2.7s$, as is done in Figure 2. This gives a $1_{2.7s}/CS1^{1.0s}_{2.7s}$ Shewhart–cusum combination that would provide an improved probability for error detection, particularly when it is also of interest to detect random as well as systematic errors. This combination has a higher probability for false rejections and its practicality depends on whether this is tolerable in the particular application of interest.

In applications where the existing Shewhart control charts have 3.0s control limits, it would be easiest to use a cusum rule with a 3.0s limit, particularly when first introducing the method. The probabilities for false rejection and error detection will depend on where the k-lines are drawn. The closer the k-lines are to the mean line, the higher are the probabilities for false rejection and error detection. Again, choice of the cusum rule is likely to depend on the level of false rejections that is tolerable. It may be desirable to start initially with k-lines at $\bar{x}_a \pm 1.0s$, then lower the lines to $\bar{x}_a \pm 0.8s$ and $\bar{x}_a \pm 0.6s$ in succeeding months.

In addition to improvements in the ability to detect systematic errors, use of the *S-CS* control chart should also help distinguish between random and systematic errors. This additional information would be useful in solving out-of-control problems. When the cusum limit alone is exceeded, the error is more likely to be systematic in nature. When the Shewhart limit alone is exceeded, the error is more likely to be random in nature. When both are exceeded, visual inspection of the plotted data should be helpful. A relatively smooth cusum line suggests a mainly systematic error, whereas a cusum line with many abrupt changes suggests that random error is large. Such problem solving will be greatly aided by familiarity with the analytical method and by experience with the *S-CS* control chart.

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Appendix

Description of the Decision Limit Cusum Method

In this technique, a reference point k is chosen to be halfway between the mean ($\bar{x}_a$), where the process is in stable or acceptable operation, and the mean ($\bar{x}_r$), where the process is considered to be disturbed and the analytical run should be rejected.

$$k = \frac{\bar{x}_a + \bar{x}_r}{2} \tag{1}$$

The cusum calculation is initiated when a control observation first exceeds k. For this particular observation, called x_j, and for succeeding observations, called x_i, the individual differences, d_i, are calculated.

$$d_i = x_i - k; i = j, j + 1, \cdots \tag{2}$$

They are summed to give the cusum (CS_i).

$$CS_i = d_j + d_{j+1} + \cdots + d_i \tag{3}$$

This continues until one of the following two situations occurs: (a) The sign of the cusum changes, indicating that the process has changed direction, in which case the process is considered to be "in-control" and the cusum calculation is stopped. (b) The cusum exceeds a control limit h, in which case the process is declared "out-of-control" and should be stopped.

Notice that no cusum calculations are performed until an initial control observation exceeds k. Calculations are started when the process starts to show some deviation from the process mean ($\bar{x}_a$). No effort is required when the process is running in good control.

In designing a decision limit cusum scheme, values must be obtained for k and h. To define k, it is necessary to state the process mean at which the quality is considered unacceptable and the output should be rejected ($\bar{x}_r$). This may more easily be done by considered the systematic error that one wishes to detect (SE_d), which is equal to the difference between the two means ($SE_d = |\bar{x}_a - \bar{x}_r|$). It is convenient to then express SE_d in terms of s, which is the inherent random error or imprecision of the analytical method, and n, which is the number of measurements included in the control observation that is to be tested. An upper limit for k is given by

$$k_u = \bar{x}_a + \frac{\mathrm{SE_d}}{2\sqrt{\mathrm{n}}} \tag{4}$$

A lower limit for k is given by

$$k_l = \bar{x}_a - \frac{\mathrm{SE_d}}{2\sqrt{\mathrm{n}}} \tag{5}$$

For example, if $\mathrm{SE_d}$ were equivalent to 2.0s and n were 1, then k would be $\bar{x}_a \pm 1.0s$. If $\mathrm{SE_d}$ were 1.0s and n were 4, then k would be $\bar{x}_a \pm 0.25s$.

The value for h is obtained from a nomogram, such as the ones provided by Davies and Goldsmith (*5*) and Duncan (*6*). These nomograms give h as a function of $\mathrm{SE_d}$, n, and the performance characteristics of the control scheme. We call these characteristics (a) the *probability for false rejection*, p_{fr}, and (b) the *probability for error detection*, p_{ed} (*4*). In the statistical literature, the terminology for these characteristics is (a) the probability for an α or type I error, and (b) 1 minus the probability for a β or type II error, also known as the "power of the test." In the quality-control literature, these characteristics are called (a) the probability for rejection when quality is acceptable, p_a, and (b) the probability for rejection when quality is rejectable, p_r. It is also common in the quality-control literature to express these characteristics in terms of the average number of control observations that will be accumulated before the analytical run is rejected. This is called the *average run length* (ARL), and it can be specified for both situations. $\mathrm{ARL_{fr}}$ is given by $1/p_{\mathrm{fr}}$ and $\mathrm{ARL_{ed}}$ is given by $1/p_{\mathrm{ed}}$. The nomograms given in the references (*5, 6*) present the performance characteristics in terms of average run lengths.

In using these nomograms, values must be chosen for $\mathrm{SE_d}$, n, and $\mathrm{ARL_{fr}}$, then the nomogram provides an estimate of $\mathrm{ARL_{ed}}$ and gives a factor $h\sqrt{\mathrm{n}}/s$. The upper and lower control limits (h_u and h_l, respectively) can then be calculated as follows.

$$h_u = (\text{nomogram factor})(s/\sqrt{\mathrm{n}}) \tag{6}$$

$$h_l = -(\text{nomogram factor})(s/\sqrt{\mathrm{n}}) \tag{7}$$

To give a specific example of how a decision limit cusum technique can be set up, the nomogram provided by Davies and Goldsmith (*5*) will be used. Note that this nomogram is for a one-sided control scheme, whereas the interest in clinical chemistry applications is for a two-sided scheme because process deviations both above and below the mean are important. The $\mathrm{ARL_{fr}}$ for a two-sided scheme will be one-half that given in the nomogram; thus when $p_{\mathrm{fr}} = 0.002$ is desired, an $\mathrm{ARL_{fr}}$ of 1000 should be used instead of 500. The $\mathrm{ARL_{ed}}$ or p_{ed} given by the nomogram will still be approximately correct for a two-sided scheme.

This particular nomogram has $(|\mathrm{SE_d}|\sqrt{\mathrm{n}})/s$ plotted on the y-axis and $(|h|\sqrt{\mathrm{n}})/s$ plotted on the x-axis, though the terminology is different from that used here. Given $\mathrm{SE_d}$ as 2.0s and n as 1, the y coördinate is 2.0. For $p_{\mathrm{fr}} = 0.002$, the $\mathrm{ARL_{fr}}$ line for 1000 is used (instead of the line for 500, see discussion above). The intersection of this line and the y-coördinate of 2.0 gives an x coördinate of 2.7, which means that h is 2.7s. For this point of intersection, the nomogram also indicates that $\mathrm{ARL_{ed}}$ should be 3 to 4; i.e., on the average, it will take three to four control observations to detect a systematic change equivalent to 2s.

For this example, the decision limit cusum technique would operate as follows.

(1) Obtain estimates of $\bar{x}_a$ and s from previous control data.

(2) Calculate the k-values ($k_u = \bar{x}_a + 1.0s$, $k_l = \bar{x}_a - 1.0s$) and the control limits ($h_u = 2.7s$, $h_l = -2.7s$).

(3) When a control observation is between the k-values (i.e., within $\bar{x}_a \pm 1.0s$), do nothing.

(4) When a control observation exceeds k_u or is less than k_l, initiate the cusum calculation. Calculate $d_j = x_j - k = CS_j$.

(5) For each additional point, continue calculating d_i and CS_i.

(6a) When CS_i changes sign, stop calculating until such time as step 4 above again applies.

(6b) When CS_i exceeds one of the control limits, declare the run out-of-control.

To illustrate how this technique works, an example set of data is given in Table 1 and discussed in the *Methods and Materials* section of this paper.

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