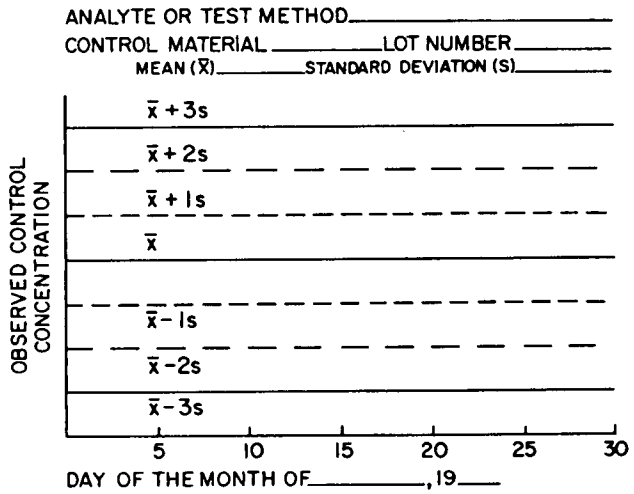

Fig. 2. Control chart for use with the multi-rule Shewhart procedure

Ordinate: concentration; abscissa: time. Control limits are drawn at $\bar{x} \pm 3s$, $\bar{x} \pm 2s$, and $\bar{x} \pm 1s$

range from $\bar{x} - 4s$ to $\bar{x} + 4s$. The x-axis should be scaled to provide the time period of interest, usually one month. Horizontal lines should be drawn corresponding to $\bar{x} + 3s$, $\bar{x} + 2s$, $\bar{x} + 1s$, $\bar{x}$, $\bar{x} - 1s$, $\bar{x} - 2s$, and $\bar{x} - 3s$. See Figure 2 for an example control chart (note that these control limits could be color coded for easier use—for example, green for $\bar{x}$, blue for $\pm 1s$, orange for $\pm 2s$, and red for $\pm 3s$). For the control procedure recommended here, it is convenient to prepare the two control charts on a single page (see Figure 2, for example).

Control Procedure

1. Analyze samples of two different control materials. Make one measurement on each control material each time when testing for statistical control.[2] Record those observations and plot them on the control charts.
2. Test the control data, using the 1_{2s} rule. *Accept* the run when both control observations are within $\bar{x} \pm 2s$ limits. Report patients' results. When at least one control observation exceeds the $\bar{x} \pm 2s$ limits, hold the patients' results and inspect the control data further, using additional control rules.
3. Inspect control data within the run.
   (*a*) Test with the 1_{3s} rule. *Reject* the run when one control observation exceeds $\bar{x} \pm 3s$ limits. Do not report patients' results.
   (*b*) Test with the 2_{2s} rule across control materials. *Reject* the run when both control observations exceed the same $\bar{x} + 2s$ or $\bar{x} - 2s$ control limit. Do not report patients' results.
   (*c*) Test with the R_{4s} rule, within the run, across control materials. *Reject* the run when one control observation exceeds a $\bar{x} + 2s$ limit and the other exceeds a $\bar{x} - 2s$ limit. Do not report patients' results.
4. Inspect control data across runs.
   (*a*) Test with the 2_{2s} rule within the control materials. *Reject* when the previous observation on the same control material exceeded the same $\bar{x} + 2s$ or $\bar{x} - 2s$ control limit. Do not report patients' results.
   (*b*) Test with the 4_{1s} rule across control materials. *Reject* when the last four consecutive control observations exceed the same $\bar{x} + 1s$ or $\bar{x} - 1s$ limit. Do not report patients' results.
   (*c*) Test with the 4_{1s} rule within control materials. *Reject* when the previous three control observations on the same control material exceeded the same $\bar{x} + 1s$ or $\bar{x} - 1s$ control limit. Do not report patients' results.
   (*d*) Test with the $10_{\bar{x}}$ rule across control materials. *Reject* when the last 10 consecutive observations fall on the same side of $\bar{x}$. Do not report patients' results.
   (*e*) Test with the $10_{\bar{x}}$ rule within control materials. *Reject* when nine previous observations on the same control material fall on the same side of $\bar{x}$. Do not report patients' results.
5. *Accept* the run when none of the rules indicates a lack of statistical control. Report patients' results.
6. When the analytical method is out-of-control:
   (*a*) Determine the type of errors occurring (random, systematic, or both) based on the control rules being violated. Note that when either the 1_{3s} or R_{4s} control rule is violated, it is more likely random error than systematic error. When systematic error is present, it is more likely to be detected by the 2_{2s}, 4_{1s}, or $10_{\bar{x}}$ rules. A review of control data on both control materials (across materials) will help detect errors that occur throughout the concentration range tested by those controls. A review of control data on a single control material (within control materials) will help detect errors in a particular concentration range.
   (*b*) Refer to a troubleshooting guide to inspect the components of the method or instrument that contribute to the type of error observed.
   (*c*) Correct the problem, then re-analyze the patients' samples and control samples, testing for statistical control by the same procedure. In assessing control of the new run, do not include the control data from the previously rejected run.
   (*d*) Consult a supervisor for any decision to report data when there is a lack of statistical control (i.e., when any of the control rules here give a rejection signal).
7. The supervisor may make a decision to report data when there is a lack of statistical control in the following situations:
   (*a*) The control problem can be shown to be due to the control materials themselves.
   (*b*) The control problem can be shown to have resulted from an isolated event that would not have affected the rest of the run (e.g., an interchange of two samples or a clerical transcription error).
   (*c*) The control problem occurs in a concentration range that is different from the concentrations of the patients' samples. The method is in-control in the range of the patients' samples.
   (*d*) The size of the analytical error is judged to be small relative to the medical usefulness requirements.[3]

Note: Reviewer R.B. noted that this list (in 7 above) should not

[2] These two samples can be analyzed each day, each shift, or each analytical run, whatever is most appropriate for the analytical method and its application. Rigorous definition of the locations, sequences, intervals, or times depends on the particular analytical methods and the laboratory application. It may sometimes be appropriate to assign the control samples randomly to positions in a run and other times to place them in specific locations that bracket the patients' samples. In some situations it may also be justifiable to analyze control samples before analyzing patients' samples, to establish that the analytical method is in a state of statistical control and can be used for patient testing.

[3] The quality of laboratory service is related not only to the size of analytical errors, but also to other factors such as the time required to obtain the result. There may be situations that require a relative judgment of the importance of the various factors involved in quality, thus it may be necessary to overrule the statistical control system. This is a professional judgment requiring knowledge of medical usefulness limits of error, an understanding of the use and interpretation of the analytical results, and experience.