be considered inclusive. There may be other situations in which it is appropriate to report the data. When encountered, these should be described and added to the list.

Discussion

Examples of Interpretations

Figure 3 shows some control data that could have been obtained when applying the control procedure recommended here. The top control chart is for a high concentration control material and the bottom chart is for a low concentration material. The observations charted are structured to illustrate how the control rules should be interpreted in many different situations.

Day 5: The control observation on the high material is within 2*s* limits. The control observation on the low concentration material exceeds the $-3s$ control limit. The analytical run should be rejected. There is likely to be a random error occurring.

Day 6: The control observation on the high material exceeds the $+2s$ limit, but the observation on the low material is within 2*s* limits. There is a warning of possible problems. Inspection of the control data using the 2_{2s}, 4_{1s}, R_{4s}, and $10_{\bar{x}}$ control rules does not confirm a problem. The run should be accepted.

Day 8: The control observations on both materials exceed their respective $+2s$ control limits, thus the run should be rejected according to the 2_{2s} control rule (applied across control materials). There is likely to be a systematic error occurring throughout the concentration range covered by these control materials.

Day 11: The control observations on both materials exceed 2*s* control limits, but in opposite directions. The run should be rejected by the R_{4s} rule. There is likely to be random error occurring.

Day 13: The observation on the high-concentration material exceeds the $-2s$ control limit. This is a warning of possible problems. Inspection of the control data with use of the 2_{2s}, 4_{1s}, R_{4s}, and $10_{\bar{x}}$ rules does not confirm a problem. The run should be accepted.

Day 14: The observation on the high-concentration material again exceeds the $-2s$ control limit. The run should be rejected according to the 2_{2s} control rule (applied within one control material). There is likely to be a systematic error occurring in the high concentration range.

Day 17: The observation on the low-concentration control material exceeds its $+2s$ control limit. The warning of a potential problem is confirmed by application of the 4_{1s} rule across control materials. The last two observations on each material exceed their respective $+1s$ control limits, giving a total of four consecutive observations exceeding the $+1s$ limit. The run should be rejected. There is likely to be a systematic error occurring throughout the concentration range covered by the controls.

Day 25: The observation on the low control material exceeds the $-2s$ control limit. Inspection by the other control rules does not provide grounds for rejection. The run is accepted.

Day 27: The observation on the low control material exceeds the $-2s$ control limit. Inspection reveals that the last 10 observations on that material have fallen below the mean. The run is rejected according to the $10_{\bar{x}}$ control rule. There is likely to be a systematic error occurring in the low concentration range.

Day 29: The observation on the high control material exceeds its $+3s$ control limit, and the observation on the low material exceeds its $+2s$ control limit. The run can be rejected by applying either the 1_{3s} or 2_{2s} control rule. There is likely to be a systematic error occurring throughout the concentration range covered by the control materials because both materials are exceeding their respective $+2s$ control limits.

Resolving Control Problems

When the control system gives a rejection signal, a problem-solving procedure should be initiated. Often the first response by the analyst seems to be to prepare and analyze new samples of the control materials. This may not be the most productive response for the control procedure here because (*a*) the level of false rejections has been kept low by the choice of control rules, and (*b*) the difficulties with control materials themselves should have been decreased by including two different concentrations of the analyte each time the analytical method is tested for statistical control. Investigation of the analytical method itself may be a more productive response.

As a starting point when investigating the analytical method, the particular control rule violated may give an indication of the type of error that is occurring. Violation of the 2_{2s}, 4_{1s}, or $10_{\bar{x}}$ control rules suggests a systematic error, whereas violation of the 1_{3s} and R_{4s} control rules suggests a random error. Interpretation of the 1_{3s} rule can be somewhat more difficult, because it will also respond to a large systematic error. A review of the other control observation will be helpful in assessing whether the 2_{2s} rule is also being violated, in which case it is likely that there is a systematic error occurring.

The control rule violated suggests the type of analytical error that is occurring, which in turn may suggest possible cause for that problem. For example, violation of the 2_{2s} control rule, such as occurs in Figure 3 on day 8, suggests a systematic error. When the violation occurs on the two different concentrations of control material within a single run, it is unlikely to be a problem with the control materials. It is more likely to be a problem with the standards, instrument calibration, reagent blanks, or similar factors that will affect all measurements in the same direction.

When a random error occurs such as suggested by violation

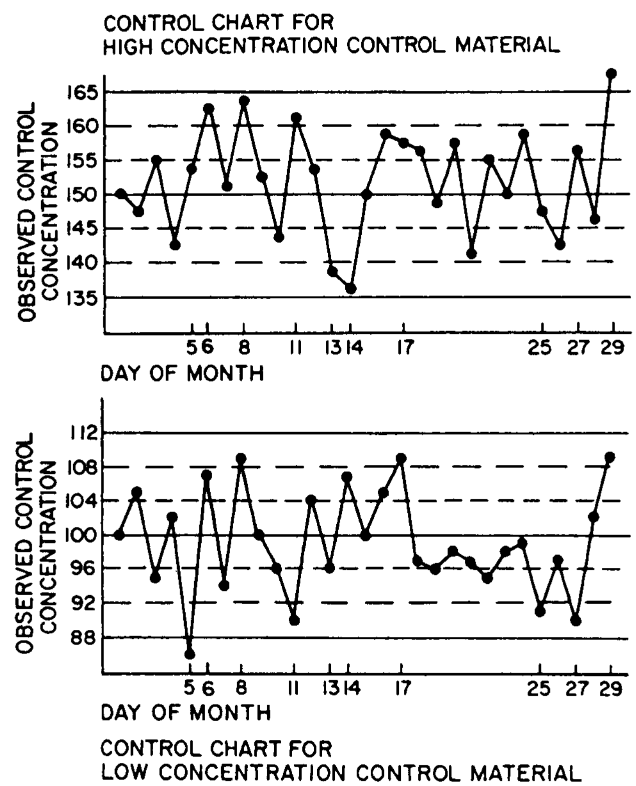

Figure 3. Example application of the multi-rule Shewhart procedure

Control charts are shown for both a high concentration control material (*top chart*) and a low concentration control material (*bottom chart*). See text for interpretation