

SOP 22

Preparation of control charts

1. Scope and field of application

This procedure details the preparation and use of property (\bar{X}) and range (R) control charts. The \bar{X} chart is used to demonstrate whether a measurement mean is in control, the R chart is used to demonstrate whether measurement variability is in control. Such charts are basic tools for the quality assurance of analytical measurements. They can be used to document measurement uncertainty and to monitor a variety of aspects of a measurement process, such as blank levels or instrument sensitivity.

2. Principle

The construction of a control chart is based on statistical principles, specifically on the normal distribution. The control limits are based on considerations of probability; thus decisions that a system is in control are supported. Similarly, the control limits can be used to warn of potential problems and reveal the need for corrective action. Control charts should be kept in real time so that such corrective action is taken promptly.

3. Procedures

3.1 *Statistical calculations*

SOP 23 of this handbook provides all the necessary information to carry out the statistical calculations needed in this SOP.

3.2 *The \bar{X} chart*

Values obtained for repetitive measurements of a control sample are plotted sequentially to evaluate the stability of the measurement process (see figure 1). Such control samples must be very similar to the test samples of interest, otherwise it is not

possible to draw conclusions about the performance of the system on test samples from this information.

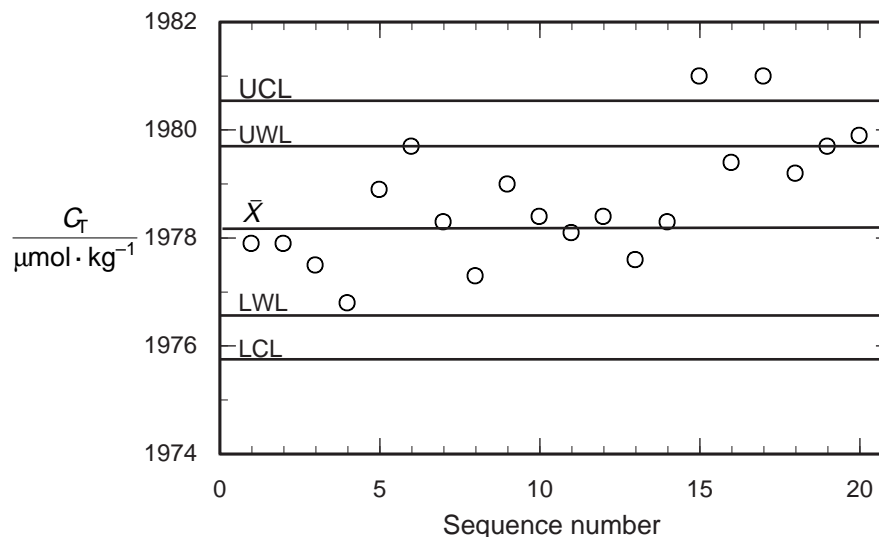


Figure 1. Example of a property control chart showing a trend in the data with time; control limits were calculated from the first 12 points. This chart indicates that the measurement process is not in control.

The results from at least twelve measurements—with never more than one measurement made on the same day—are used to compute estimates of the mean and standard deviation of the data in accordance with the standard expressions (SOP 23).

The central line is the mean value, \bar{x} , the control limits are based on the sample standard deviation, s :

upper control limit	$\text{UCL} = \bar{x} + 3s$
upper warning limit	$\text{UWL} = \bar{x} + 2s$
lower warning limit	$\text{LWL} = \bar{x} - 2s$
lower control limit	$\text{LCL} = \bar{x} - 3s$

When so set, approximately 95% of the plotted points should fall between the warning limits (UWL and LWL) and rarely should any fall outside the control limits (UCL and LCL).

3.3 The R chart

The absolute differences (R) of duplicate measurements are plotted sequentially to evaluate the precision of the measurement process (see figure 2). The average range \bar{R} is related to the short-term standard deviation (or repeatability, s_R) of the measurement

process (SOP 23). At least 12 measurements should be used to compute \bar{R} . The control limits for duplicate measurements are

$$\text{UCL} = 3.267 \bar{R}$$

$$\text{UWL} = 2.512 \bar{R}$$

$$\text{LWL} = 0$$

$$\text{LCL} = 0 .$$

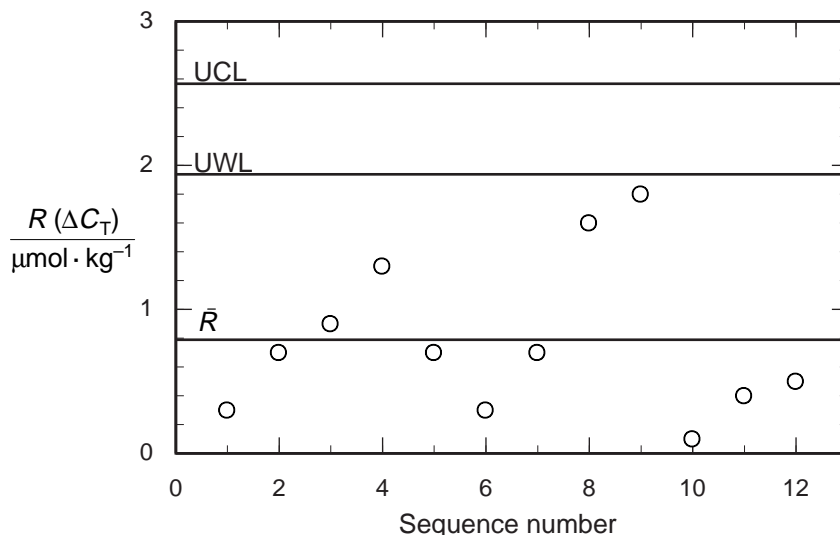


Figure 2. Example of a range control chart; control limits were calculated using all the data shown. The measurement precision is in control.

3.4 Updating control charts

After additional control data have been accumulated—at least as much as was used originally—the control limits may be updated. A t test is made to assess whether \bar{x} for the second set of data is significantly different from that for the first (SOP 23). If not, all the data may be used to compute a new estimate of \bar{x} , otherwise only the second set of data should be used to revise the control chart.

The value of the sample standard deviation, s , should also be calculated for the second set of data. It should be compared with the estimate from the first set of data, using the F test (SOP 23) to decide whether to pool it with the first, or to use it separately in setting new control limits.

If the values of R show no significant trends and if \bar{R} has not changed significantly, all of the values of R should be combined to obtain an updated estimate of \bar{R} from which updated control

limits can be computed. Judgement of the significance of changes in \bar{R} are best judged by computing the corresponding values of the short-term standard deviation (the repeatability) and conducting an F test.

3.5 Interpretation of control chart data

Points plotted on a control chart should be randomly distributed within the warning limits when the system is in a state of statistical control. If a plotted point lies outside of the warning limits, a second set of measurements should be made. If this point also lies outside the warning limits, corrective action is required and demonstrated attainment of control is necessary before measurements may be reported with confidence. Barring blunders, one point outside of the control limits is reason for corrective action. The nature of the corrective action to be taken will depend, in either case, on the kind of measurement made. If the X point is outside the limits but the R point is not, a source of bias should be sought and eliminated. If the R point is outside of limits, X probably will be as well. Sources of extraordinary random error should be sought and eliminated before any possible bias can be detected.

Control charts may be used to evaluate the uncertainty of measurement in some cases. When an appropriate control chart is maintained, an \bar{X} chart may be used to evaluate bias and to document the standard deviation of the measurement process. Then the values of s on which the control limits are based may be used in calculating confidence limits for measurement values.

References

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