DATA QUALITY REPORT SERIES

PRINCIPLES
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PRINCIPLE OF CONTROL CHARTING

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The Principle of Control Charting

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Abstract

The purpose and objectives of control charting are reviewed. Control is defined as proper action in response to the observation of unexpected behaviour relative to defined limits about an expected value or mean. Precision and accuracy control are differentiated and discussed in terms of simple and complex statistical control. The advantages of a dual control system for verifying calibration control status between-run are presented. With the aid of two control standards proper control action can be taken based on knowledge of proper system function and experience with respect to probable cause and most appropriate solution.

The Principle of Control Charting

Introduction

Control carries with it the implication of action in response to an observation. It is something that is imposed rather than mere happenstance. Control implies the existence of an expected value and of some limitation to the amount of deviation from expected. A simple temperature measurement device connected to a digital display would not be a control device. Even when it is connected to a strip chart recorder it is still not considered a control device until mechanical limits are put in place which cause an alarm to sound whenever the pen deflection exceeds a predefined amount. And if no one is around to hear and react to the alarm there is still no control.

In the same way, an analytical process may be in a state of control, but it cannot be considered to be under control until the observations made have been plotted on a chart, and considered in the light of predefined limits. Even then, control has not been exerted until the human operator has made a decision based on the combination of observed fact, defined limits, and most importantly, other relevant factors.

The strip chart temperature recorder on an incubator is required, not because it is connected to a control device, nor yet because it records individual values. but because it provides a performance record for later review and evaluation. Trends, or chronic malfunctions can be seen at a glance. The frequency, as well as the magnitude, of unexpected values is a valid indication of control status. Obviously deviations caused by someone opening the door cannot be considered as indicative of a control problem unless it is opened too frequently or left open too long. It is the supervisor's responsibility to decide correctly whether to call the serviceman or to speak to the staff.

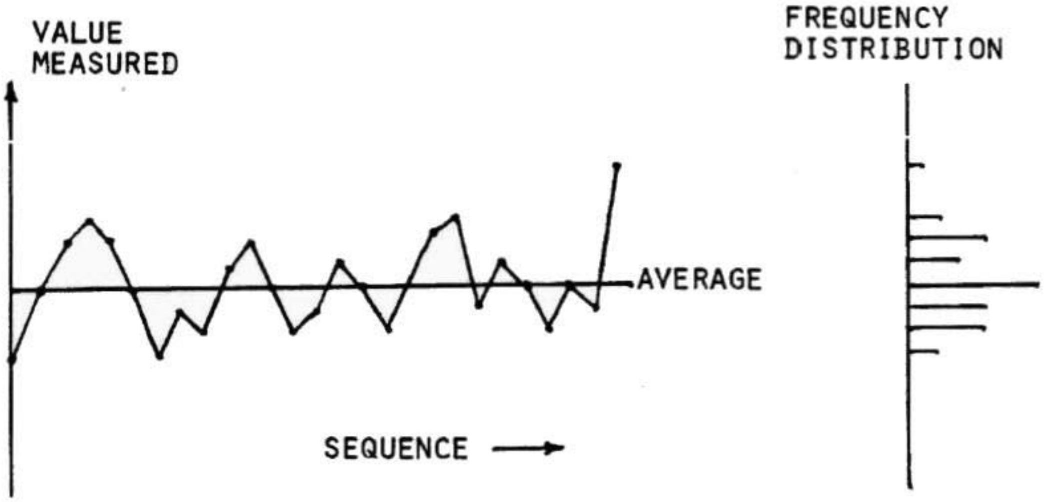


FIGURE 1: A record of observations will reveal trends and variability relative to an average value.

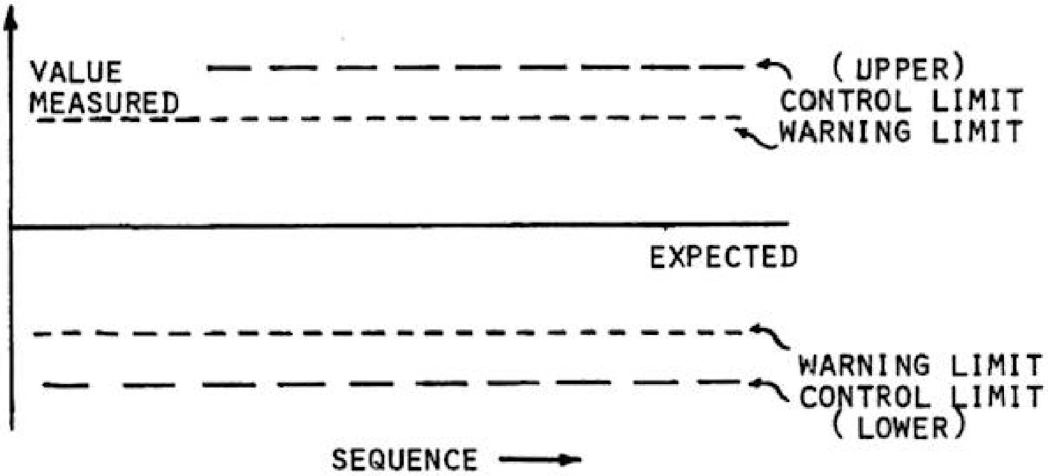


FIGURE 2: A control chart defines the limits of acceptable deviation from an expected value.

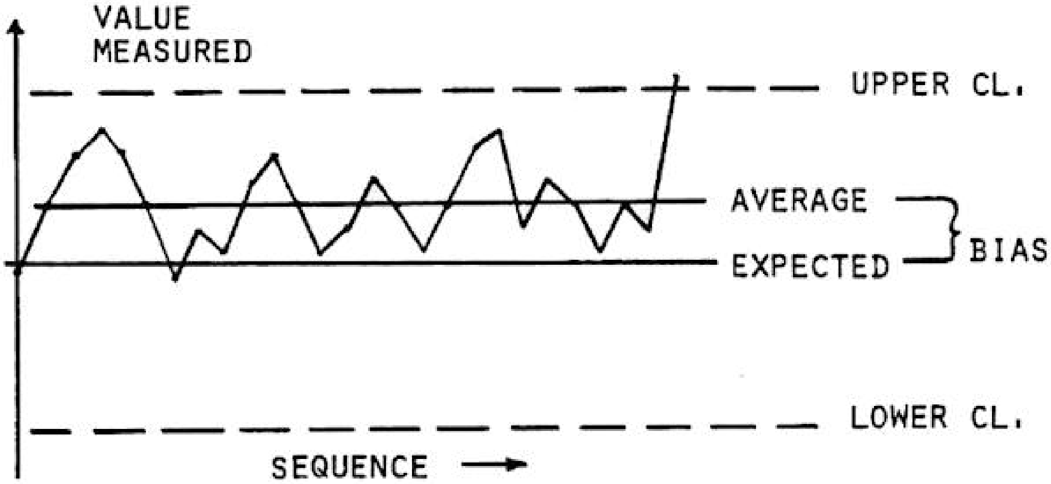


FIGURE 3: Control status is assessed by combining observations and control chart limits. The validity of the current limits should be evaluated in addition to data repeatability and bias of the average.

Clearly there is a difference between a data chart and a control chart. Figure 1 represents a series of observed results plotted in time sequence. Figure 2 is a control chart. It includes an expected value and control limits. By imposing Figure 2 on Figure 1 (see Figure 3) we obtain an impression of relative Control Status.

Figure 3 suggests that there is more involved to Control than simply calculating a control limit and plotting data. As shown, the limits seem far too wide compared to the current data set, and the average seems to be displaced from the expected value. One might (correctly) conclude that control is required over both the range of variation of individual values (precision), and the variation or drift of averages (accuracy). However before we discuss how to control, we should know

a) what control means,
b) what we are trying to achieve by control and control charting,
c) the areas of operation that should be considered for control, and
d) the relative priority of these areas in assuring final measurement quality.

Definition of Control

Control arises from Proper Action in Response to the Observation of Unexpected Behaviour Relative to Defined Limits about an Expected Value or Mean.

Proper action will be based on Knowledge of Proper System Function and Experience with respect to Probable Causes and the Most Appropriate Solutions.

Objectives of Control Charting

1. To make You more familiar with the Actual Operating Characteristics of Your System, as operated by You.

2. To provide a Readily Interpretable Record of the performance level achieved, for internal and external evaluation.

Control Areas

1. Equipment

   - regular inspection and maintenance
   - passive control (self-limiting)

2. Analytical Precision

   - well-defined procedures
   - properly trained staff
   - passive control (self-limiting)

3. Analytical Accuracy

   - properly prepared, traceable standards
   - well-defined calibration and standardization procedures
   - active control of standardization by means of control standards

4. Analytical Recovery

   - known sample processing efficiency
   - well characterized samples
   - active control of sample processing by means of control samples

Priorities for Control

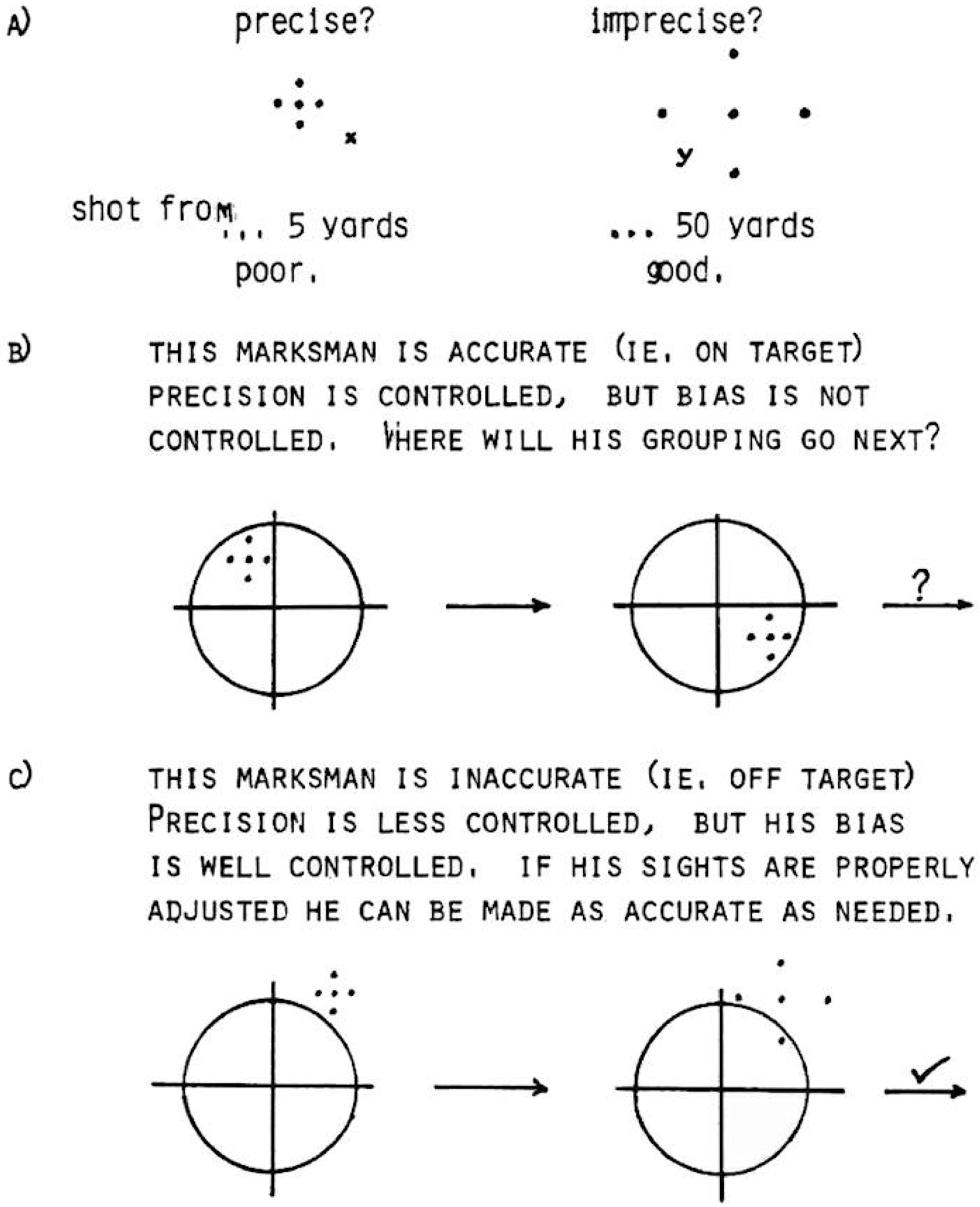
Measurement theory suggests that results obtained within a short period of time under standardized conditions will show a central tendency. They will not deviate excessively from this central value with more than a defined probability. It is not the point of this discussion to describe how these limits are calculated or how the probability of exceeding a limit is determined. In the end it is essentially an arbitrary decision based on statistical theories which may, or may not, be appropriate. It is more important that we discuss the nature of control as it relates to measurement and to the decision making process. In particular the difference between precision and accuracy control must be clearly appreciated.

Precision is a measure of the spread of individual values. Accuracy is a measure of the deviation of an average from an expected value. Ability to detect inaccuracy is limited by the precision available only when insufficient data is included in the average. No statement can be made about either precision or accuracy given only a single value. Recent and historical patterns are essential to evaluating control status.

As shown in Figure 4A, precision and accuracy statements are always relative. Information is required as to what is acceptable, not only on an instantaneous but also on a continuous basis. Five shots closely spaced in a target may give an impression of precision. But if the marksman was only five yards from the target this may be unacceptable.

If five shots are closely spaced and the sixth is not (e.g. point marked X) one must consider the marksman somewhat erratic. The point marked y is obviously not erratic. The more precise a procedure becomes the easier it is to identify suspect values. Fewer repeat measurements are required to confirm an outlier.

It should be apparent from Figure 4B that it is not sufficient to be able to place shots precisely. One must be able to repeat this performance on successive trials.



THIS MARKSMAN IS ACCURATE (IE. ON TARGET) PRECISION IS CONTROLLED, BUT BIAS IS NOT CONTROLLED. WHERE WILL HIS GROUPING GO NEXT?

THIS MARKSMAN IS INACCURATE (IE. OFF TARGET) PRECISION IS LESS CONTROLLED, BUT HIS BIAS IS WELL CONTROLLED. IF HIS SIGHTS ARE PROPERLY ADJUSTED HE CAN BE MADE AS ACCURATE AS NEEDED.

FIGURE 4: Precision, Bias, and Accuracy can only be assessed in terms of past experience, continuing control, and a definition of what is considered acceptable.

PRECISION

A MEASURE OF THE SPREAD OF INDIVIDUAL VALUES DUE TO

- INHERENT WITHIN-RUN VARIATION OF MEASUREMENT PROCESSES
- CONTROLLABLE BETWEEN-RUN VARIATION CAUSED BY THE STANDARDIZATION PROCESS

REPEATABILITY = WITHIN-RUN EFFECTS ONLY
REPRODUCIBILITY = BOTH WITHIN RUN AND BETWEEN RUN

BIAS

VARIATION OF AN AVERAGE, EITHER OVER TIME
OR BETWEEN OPERATORS
OR BETWEEN SYSTEMS / METHODS
OR RELATIVE TO AN EXPECTED VALUE

THE EXPECTED VALUE MAY BE DERIVED FROM A LONG TERM AVERAGE OR A BETWEEN-METHOD OR A BETWEEN-LAB AVERAGE.

INACCURACY

DEVIATION OF A LONG TERM (ETC.) AVERAGE FROM A DEFINED TRUE VALUE.

THE DEFINED TRUE VALUE IS FREQUENTLY AN EXPECTED VALUE MADE OFFICIAL BY DECREE. IT'S VALIDITY WILL THEREFORE OFTEN BE METHOD DEPENDENT.

NOTE

REPEATED MEASUREMENT WILL INCREASE ONE'S CONFIDENCE IN THE AVERAGE VALUE OBTAINED. IT HAS NO EFFECT ON THE TRUTH OR ACCURACY OF THE AVERAGE. IT MAY IN FACT VERIFY ANY BIAS WHICH MAY BE PRESENT.

ACCURACY IS NOT AN ABSOLUTE. IT DEPENDS UPON WHAT ONE CONSIDERS ACCEPTABLE. THEREFORE THE PHRASE 'ON-TARGET'.

However, even if the precision can be maintained it is not good enough if the next grouping of shots is located at a different spot on the target.

Bias is usually introduced through operator error. If the gun sights are not adjusted correctly one will not expect the shots to arrive at the same location. If a different gun is used, a standard setting of the sights may not work. Calibration adjustments are always susceptible to Type I and Type II errors. The first is a failure to make an adjustment when one is required. The second involves failure to make a correct adjustment particularly when one is not required.

In Figure 4B we assume the marksman is accurate because he is on target. His ability to control bias is not being tested sufficiently. If the target were smaller, or further away, he might have problems with accuracy.

In Figure 4C we see a marksman who is inaccurate (off-target) but who is bias controlled. Readjustment of the sights would keep him on center. His precision is somewhat variable but this has little or no effect on the determination of bias or accuracy.

It should be clear at this point that precision control and bias control are independent factors. One's ability to become and remain accurate depends more on the size of the target then anything else. However if the target is small, bias control becomes critical. Precision is relatively unimportant. Its importance increases as fewer and fewer shots are taken per grouping.

Simple Statistical Control: Precision

As long as we do not interrupt a measurement process by re-calibration, or otherwise change the conditions of measurement, and as long as the process has been demonstrated to be rugged (i.e. relatively unaffected by small changes in procedure), it is safe for us to "act for the moment as if the process is in a state of statistical control". Every time we repeat the process we can expect more or less the same result. Small changes at various stages in the process will tend to have random small effects on the result. On average these will tend to cancel out.

Statistically this means that any given average calculated from a small amount of data will tend to be a good estimate of the 'true average' under existing conditions. It also implies there is a low probability that any given result will differ greatly from the average. The range of deviation likely to be observed can be estimated as some factor (often 3) times the 'standard deviation' (s). Given a series of repeated measurements (X_1, X_2, - - - X_n), s is calculated by the formula

$$s^2 = \frac{\Sigma X_i^2 - (\Sigma X_i)^2 /n}{n - 1}$$

Given a series of duplicate results s can also be calculated by

$$s^2 = \frac{\Sigma (X_1 - X_2)_i^{\,2}}{2k} = \frac{\Sigma (D)^2}{2k}$$

where k is the number of duplicate pairs and D is the difference between the paired values.

It is important to realize that s can be calculated for any available data set. However, its suitability for predicting the likely range of deviation from an average requires that all results were determined under identical conditions and that the distribution of repeated results is approximately 'normal'. In other words the system must be in control.

Demonstrating Simple Statistical Control

The essential ingredient in Simple Statistical Control is repeatability. The actual value measured is not a concern at this point. Analysis is usually performed as a batch process. As long as the same reagents, digestion equipment, etc., are used and as long as the measurement instrumentation is stable and drift free there is no reason to believe that the average analytical response will change. Duplicate analysis of selected samples which represent the type routinely received can be used to demonstrate that Simple Statistical Control is actually occurring.

A common approach to evaluating within-run control status from duplicates is to define an acceptable degree of difference (e.g. 10% or 0.25 mg/L) irrespective of the actual performance being achieved. This represents an acceptance limit approach. The alternative is to calculate of the standard deviation under routine conditions based on recent duplicate results. The control limit is then some factor times this standard deviation. Both approaches may permit a system to operate 'out-of-control' for significant periods of time, since data obtained under uncontrolled conditions will not yield a valid control limit.

A prime requisite for establishing a proper control limit is a system that is demonstrably in-control. Demonstration is most readily achieved by graphical techniques. A day to day plot of the difference between duplicates will indicate not only the instantaneous variability of differences but also, over the long-term, will show periods of time when differences are on average smaller than previously. At such times, a higher degree of control is being achieved. This is usually related to the use of a different batch of reagents, re-serviced equipment, or staff rotation. Once this has been observed, control can be exerted over the factor that has been identified and more appropriate control limits can be determined.

It should be clear that both acceptance limits and control limits are useful. The former ensures a guaranteed level of service to the laboratory client while the latter ensures that periods of poorer control status are identified so that remedial action can be undertaken. There are dangers in the use of acceptance limits related to maintaining accuracy. This will be discussed later. When used in the context of precision based on repeatability of duplicates this is not a problem.

Outliers on a day to day basis, as defined by the control limits, will occur

a) because the sample is atypical of the routine for which the performance criterion was defined.

b) the criterion is actually dependent on concentration and this factor has not been considered in defining it.

c) an unusually large deviation has occurred, as expected (e.g. 1 in 20 or 1 in 200).

d) an unusually large deviation has occurred because of an error in the analytical process, operational or instrumental problems, or individual sample processing error.

If we can "act for the moment" as if the system is capable of control, and if we know that it has been in-control, and that no changes have been introduced a single instance of outliers must be carefully evaluated in terms of alternative explanations before one concludes that the process itself has failed. It is a characteristic of standard analytical procedures that gross total failure is highly unlikely. The judgement error of unnecessarily re-analyzing large numbers of samples because of a single instance of suspect repeatability is as serious an error as ignoring a control problem by failing to look for it. If the cause of the suspect data cannot be identified there can be no reason to believe that automatic re-analysis will provide data any more repeatable than that already available. It could provide worse data if the system is indeed on the verge of failure.

One should always be cautious when responding to control problems identified by use of duplicate (or replicate) analyses, especially when they are borderline. Acceptance limits based on actual client needs should always be incorporated into the control program action plan to avoid unnecessary or incorrect control response. Repeatability control is properly a passive activity. It documents the performance level achieved, good or bad. It does not provide solutions.

Figure 5 demonstrates a mechanism for observing the distribution and dependence of difference between duplicates on concentration. It usually reveals that a single criterion for controlling repeatability is inappropriate. It can indirectly monitor the effect of time as points are added to the diagram on a day by day basis. Figure 6 demonstrates the Range control chart approach based on time sequence. In both cases control limits are defined as a factor times the average range (difference between duplicates). However Figure 5 accounts for the effect of concentration.

Complex Statistical Control: Accuracy

In order to report a result two principles are involved. There must be a measured response. But there must also be a calibration equation for converting the response to a concentration or other usable value. As already indicated, response can be assumed, for the moment, to vary in a statistically random fashion. However, it is not proper to make the same assumption with respect to calibration factors, because of the human element involved in deciding to accept or reject the data used to calibrate. Figure 7 shows how the response factor (sensitivity) might change from day to day. As shown, errors can be made in concluding that a significant change has, or has not occurred.

When the same solution is measured on several different occasions the variation between results will be larger than predicted by random chance alone, because the

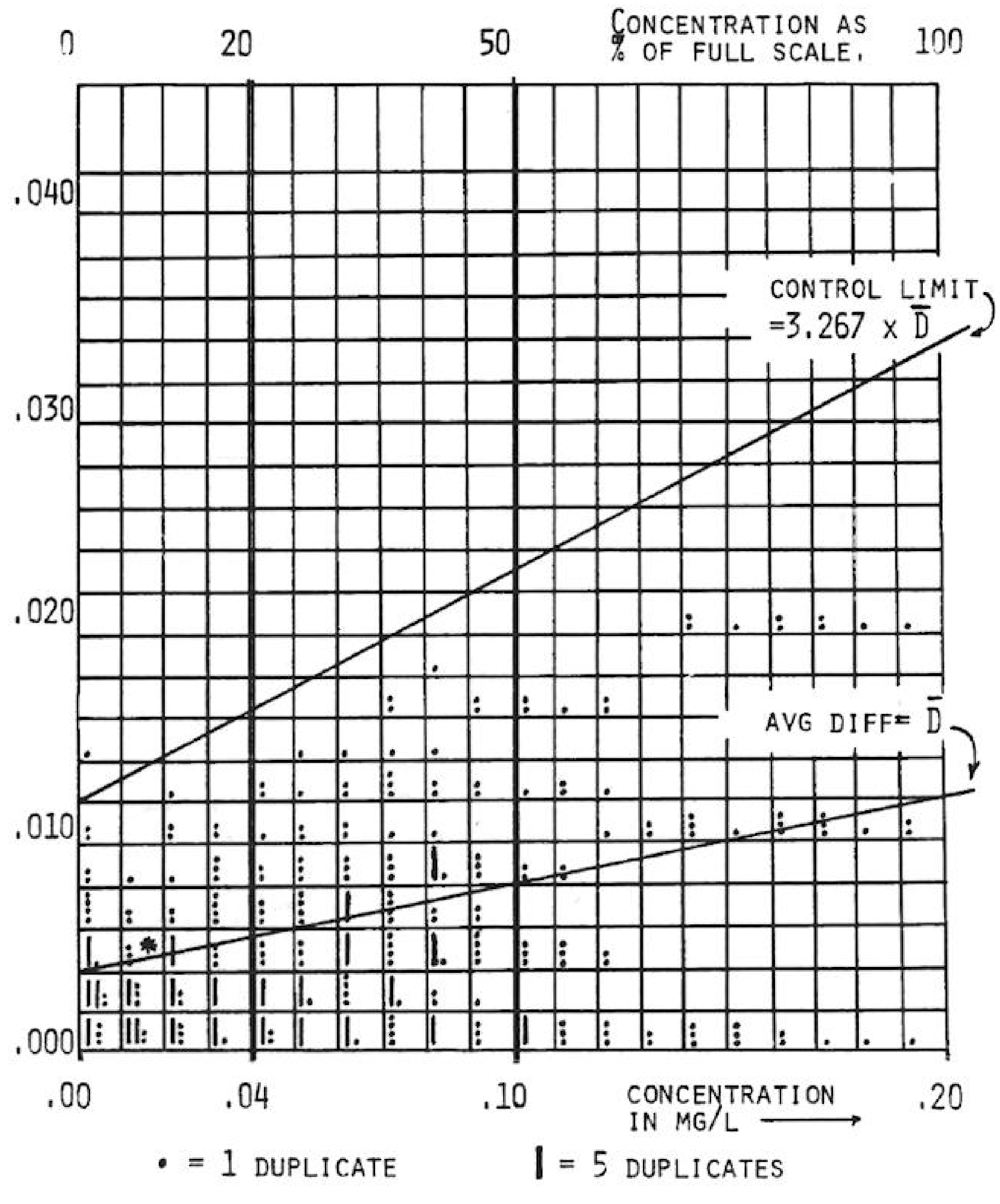


FIGURE 5: The range of difference between duplicates is usually somewhat dependent on concentration. This method of accumulating data helps to show how control limits can be adjusted for this effect. A duplicate pair 0.017 and 0.021 would be added as a point in the box marked *. note the effect of rounding-off results on the apparent differences.

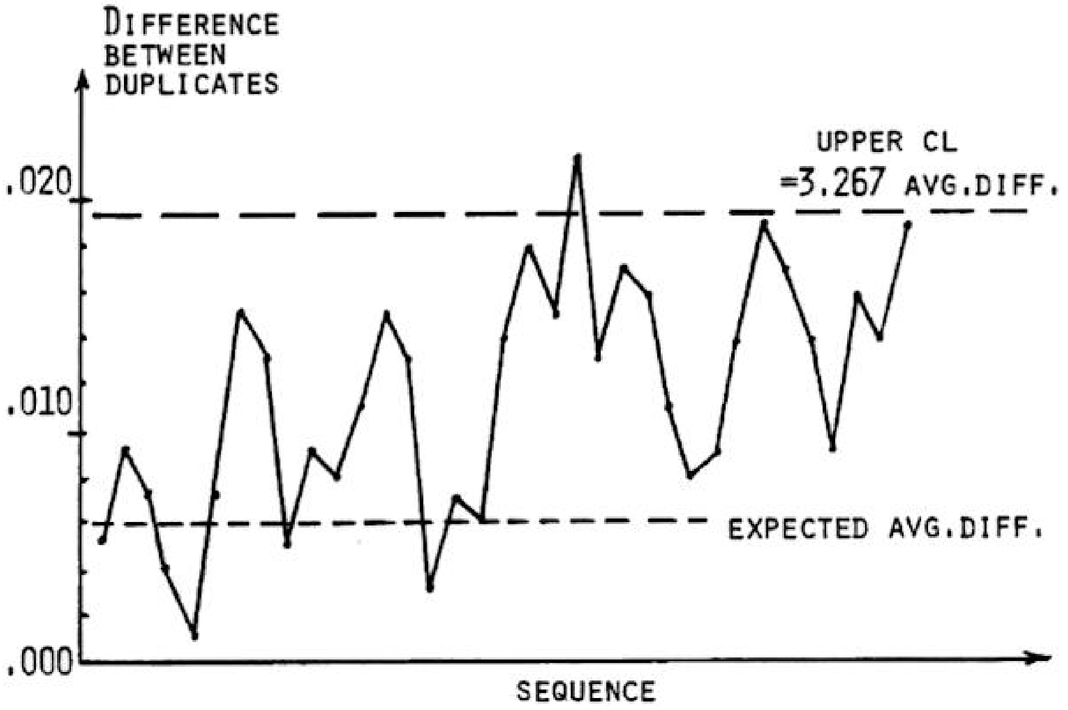


FIGURE 6: Typical range control chart, there is no allowance for the effect of concentration on difference, true control status is difficult to evaluate, has the observed average difference changed recently? Or have we been analysing a larger than usual number of high level samples?

PRECISION CONTROL

- ASSUMES THAT ANALYTICAL CONDITIONS INCLUDING SYSTEM CALIBRATION REMAINS UNCHANGED
- DEMONSTRATED BY ABILITY TO REPEAT ANALYSIS AND OBTAIN THE SAME RESULT WITHIN A NARROW RANGE OF VARIATION
- SELF-LIMITING CHARACTERISTIC OF ALL "STANDARD" MEASUREMENT PROCESSES
- LOW PROBABILITY THAT ANY REPLICATE RESULT WILL DIFFER GREATLY FROM THE AVERAGE
- LOW PROBABILITY THAT CONTROL ACTION WILL BE REQUIRED UNLESS THE SYSTEM FAILS COMPLETELY
- PASSIVE DATA COLLECTION AND EVALUATION IS USUALLY SUFFICIENT

> WE CAN ACT FOR THE MOMENT AS IF THE PROCESS IS IN A STATE OF "SIMPLE" STATISTICAL CONTROL. THEREFORE THE USE OF A CONTROL CHART IS HELPFUL BUT NOT ESSENTIAL.

ACCURACY CONTROL

- ASSUMES THAT ANALYTICAL CONDITIONS HAVE CHANGED AND THAT RE-STANDARDIZATION IS REQUIRED
- DEMONSTRATED BY A LARGER RANGE OF VARIATION BETWEEN RESULTS FROM DIFFERENT "RUNS"
- INCORPORATES THE ERRORS IN PREPARING AND PROCESSING STANDARDS
- THE RANGE OF VARIATION IS NOT LIMITED BY CHANCE
- HIGH PROBABILITY THAT ACTION WILL BE REQUIRED IN ORDER TO MAINTAIN CONTROL
- REQUIRES ACTIVE DATA COLLECTION AND EVALUATION

> A CONTROL CHART IS REQUIRED TO KEEP THE PROCESS IN A STATE OF "COMPLEX" STATISTICAL CONTROL.

OBJECTIVES IN CONTROL CHARTING ACCURACY

- TO ENSURE CONTROLLED BETWEEN-RUN VARIATION
- TO IDENTIFY UNUSUAL CALIBRATION CHANGES WHICH COULD AFFECT ACCURACY
- TO RECORD THE LEVEL AND STATUS OF CONTROL BEING MAINTAINED
- TO DETERMINE AND CHARACTERIZE THE PARTICULAR TYPES OF CALIBRATION PROBLEMS TO WHICH THIS PROCESS IS SUSCEPTIBLE

TO MAKE YOU
FAMILIAR WITH THE ACTUAL
OPERATING CHARACTERISTICS OF
YOUR SYSTEM AS
OPERATED
BY YOU

CALIBRATION PROBLEMS

- ZERO ADJUSTMENT AND CONTROL
- BLANK CORRECTION AND CONTROL
- SLOPE ADJUSTMENT AND CONTROL
- ERROR IN PREPARATION OF STANDARDS
- UNCERTAINTY IN MEASUREMENT OF STANDARDS
- CURVATURE IN USUALLY LINEAR SYSTEMS
- INSTABILITY IN CURVED SYSTEMS
- ILL-ADVISED ADJUSTMENT OF INSTRUMENT OR SYSTEM CONTROLS

calibration curve must be re-standardized day by day. One cannot automatically assume that the materials used as 'standards' are correct or have been prepared without contamination or loss, or have been measured without error. Therefore once the calibration curve has been re-standardized, deliberate action must be taken to ensure that today's 'true average' will be not significantly different from its previous value. This introduces the concept of Complex Statistical Control.

It should be noted that analytical recovery from individual samples is not under discussion here, although it may have some impact on the result in less 'rugged' analytical processes. Rather, we are concerned with ensuring that standards are used and interpreted properly, to avoid introducing bias between 'true averages' from day to day. It must always be kept clear that 'simple statistical control' determines only the range of variability expected. It defines the precision of the method. On the other hand, 'complex statistical control' addresses the variability of the 'true average'. It therefore maintains a degree of accuracy.

Demonstrating Complex Statistical Control

Whenever a system is re-standardized there is always a significant probability that bias will be introduced. A check is required which will help to limit the range of this error. This is achieved by use of a control standard. The data in Figure 7 is basically the same as Figure 3) except that not only the range of variation but also the variation relative to an expected value must be examined. This difference represents the bias for that day's run. From day to day this bias will change. It may or may not be significant. It is the function of the control standard to monitor these changes.

When only one analysis of a single control standard is available, it is clearly difficult to distinguish between the precision variability and the accuracy variability. However, the use of a control chart with limits based on within-run estimates of standard deviation will reveal,

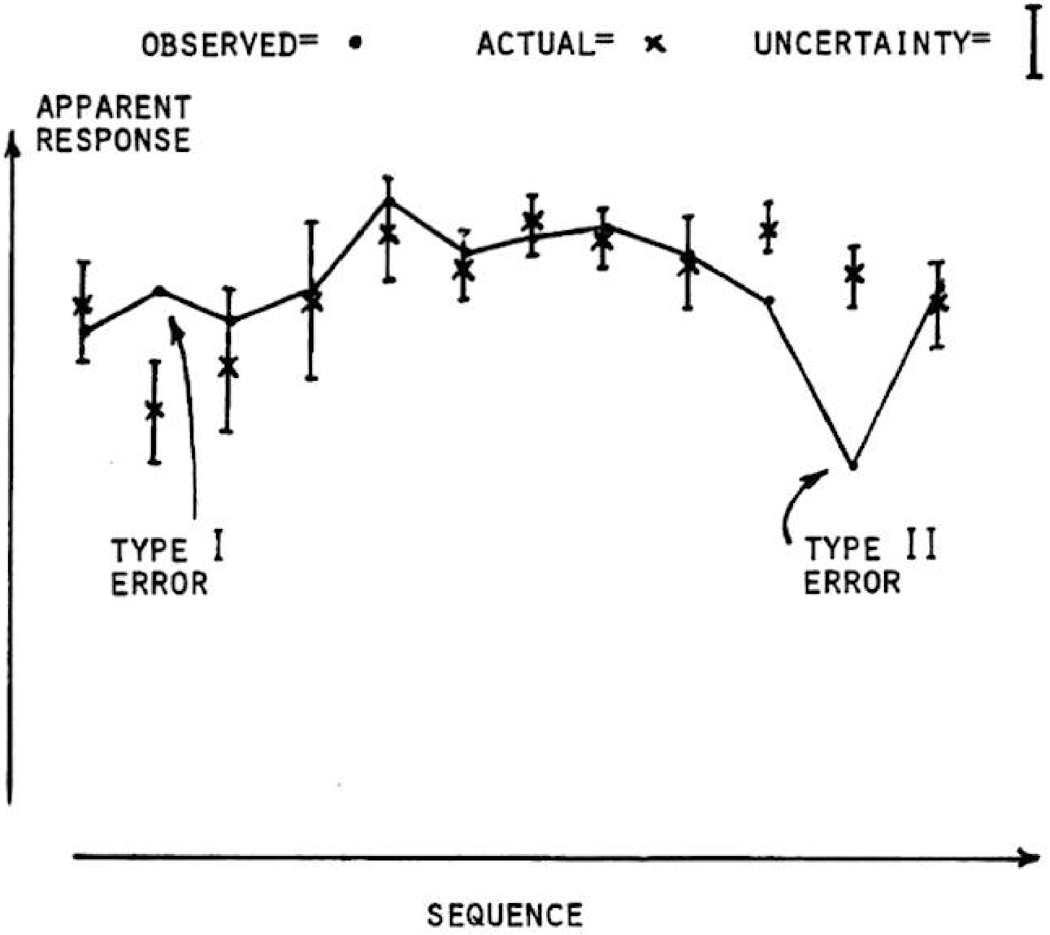


FIGURE 7: Instrumental response factors usually vary somewhat from day to day. Calibration adjusts for this. But analytical errors in the standards can lead to incorrect calibration decisions which will affect all measurements in that run.

a) an unexpected number of values outside the control limits but not grossly outside. These we may have to live with since they represent an acceptable level of between-run control.
b) trends in the apparent average over short periods of time. These we should eventually correct since trends are a sign of determinate error rather than chance.
c) occasional gross outliers beyond the level defined by a). These we must prevent from affecting calibration on a day-to-day basis.

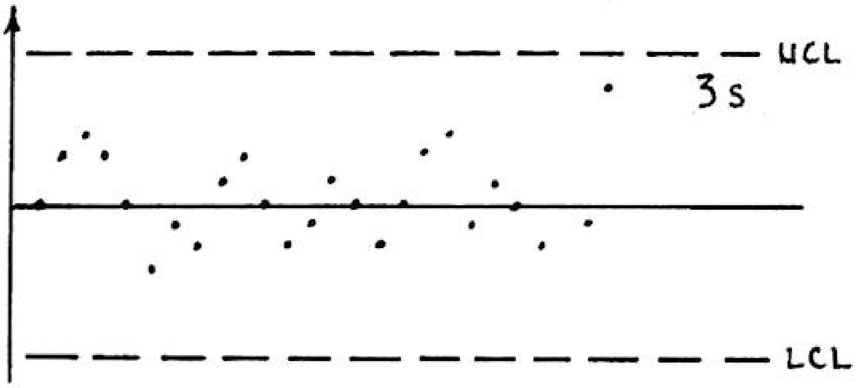
Extraordinary deviations may occasionally reflect an error in analysis of the control standard. But more frequently they are a direct indication of calibration bias influencing today's 'true average'.

The data in Figure 8A might generate the control limit estimates shown. However this control status cannot be assumed to be good. This data may have been actually generated over several runs where the within-run standard deviation was known to be significantly better. As shown in Figure 8B the system appears to be out-of-control relative to within-run performance. But is it really? Is there a criterion for establishing an acceptable level of control over between-run variation?

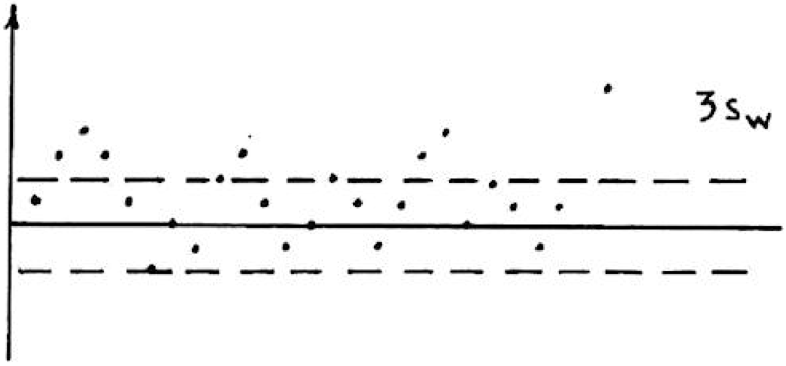
Control limits are often set at 3 times the standard deviation. In setting control limits for between-run performance it should be obvious that within-run standard deviation is too tight a basis. On the other hand, between-run standard deviations will reflect the current control status. If the process is not in good control, between-run standard deviations will be too loose to exert control.

As a general rule of thumb, a ratio greater than 1.3 for between-run versus within-run standard deviation would be considered 'statistically significant' (based on the f-test for ratios of variance for about 30-60 degrees of freedom). While statistical significance is not directly indicative of practical significance, in this case it provides a basis for establishing control. Our experience indicates that the simple use of a control chart often has the effect of reducing the ratio of between-run to within-run standard deviation below this value.

A) BETWEEN-RUN STD DEV. YIELDS LOOSE CONTROL LIMITS



B) WITHIN-RUN STD DEV. YIELDS EXCESSIVELY TIGHT LIMITS



c) 1.3 X WITHIN-RUN STD DEV. EXERTS CONTROL

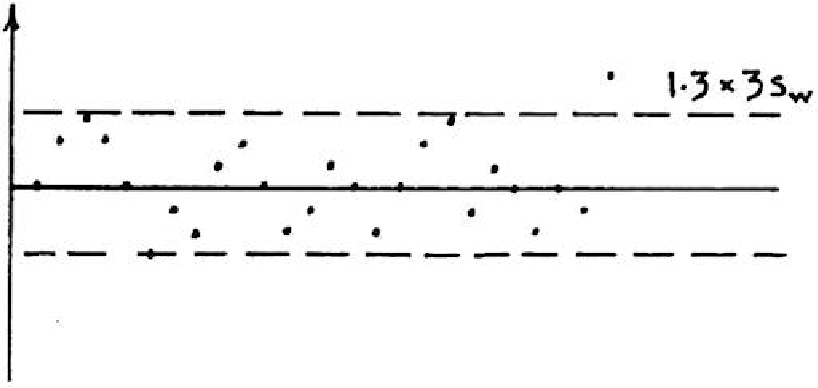


FIGURE 8: If between-run effects are not controlled then control limits based on such data can not exert control, a factor of 1.3 times the known within-run standard deviation will provide a better estimate of between-run standard deviation for use in defining more appropriate control.

Therefore, in establishing control limits for between-run performance, it is better to determine the within-run standard deviation and apply a factor of 1.3, than to use the actual between-run standard deviation. This allows room for short-term drift as well as imprecision and yet establishes active control.

It is always possible to apply an acceptance limit approach for determining when action is absolutely required. This usually implies relaxing the control limit somewhat. However, it must be kept in mind that accuracy is at stake here, not just precision. It may be permissible to allow replicate results to vary by plus or minus 10% or 20%. But, the client does not expect the 'true average' to change by this amount. When a single control standard is being used, it is impossible to determine how much of today's deviation is random and how much represents a bias. It is even less possible to determine the source of this bias.

Establishing Calibration Control

Control can only be exerted when both a cause and a solution can be determined. It is always important to realize that excessive control may not only create bias, it may also prevent the cause of the problem from being identified. Figure 9 shows a few of the different types of problems that can be revealed by a control chart. Since this chart provides no solution, proper action cannot be taken. Therefore this process must remain out-of-control.

In addition to curvature, a calibration will show variation in both slope and intercept over time. Figure 8 showed that changes were occurring but the operator had to guess the cause. More often than not this type of behaviour is not even apparent because the 'control' date is not plotted even if the control material analyzed and measured. The assumption is often made that this data reflects the capability of the process rather than lack of control over it.

IS THIS SYSTEM UNDER CONTROL?

1. THE CONTROL LIMITS WERE DETERMINED DURING THIS PERIOD.

2. THIS ERRATIC POINT MAY OR MAY NOT REFLECT A CALIBRATION ERROR, IT COULD BE AN ANALYTICAL OR MEASUREMENT ERROR.

3. BETWEEN-RUN PRECISION HAS IMPROVED. THE CURRENT CONTROL LIMITS ARE TOO LOOSE BUT ARE RETAINED AS ACCEPTANCE LIMIT: UNTIL A REASON CAN BE FOUND FOR CHANGING THEM.

4. IS THIS DRIFT CAUSED BY BLANK OR SLOPE EFFECTS. ARE THE STANDARDS CHANGING OR IS IT THE INSTRUMENT?

5. DRIFT HAS STABILIZED. ACCEPTANCE LIMITS ARE PERMITTING A SIGNIFICANT BIAS GIVEN THE APPARENT BETWEEN-RUN PRECISION.

6. ALTHOUGH THIS RESULT LOOKS GOOD, IT IS ERRATIC RELATIVE TO RECENT VALUES, SOMETHING IS WRONG.

7. THE BIAS HAS BEEN ELIMINATED DELIBERATELY BY ADJUSTING THE SLOPE. HOW DO WE KNOW THIS WAS CORRECT? PERHAPS THE BLANK CORRECTION HAS BEEN INCORRECT?

8. NEW CONTROL LIMITS WERE FINALLY ESTABLISHED. THE CAUSE OF THE CYCLICAL DRIFT CANNOT BE DETERMINED AT THIS TIME BUT THE VARIATION IS TOLERABLE FOR THE INTENDED DATA USE.

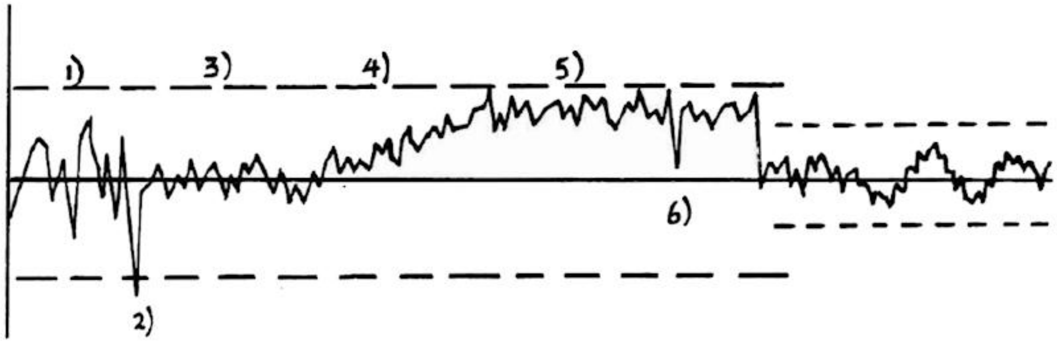


FIGURE 9: Several types of control problems seem to be occurring, are they within or between-run? Are they blank, slope or sample related? Were proper adjustments made, and on what basis?

When two control solutions are analyzed and measured it becomes possible to evaluate the nature of the change. If they differ in strength, so as to cover the bottom and top of the calibrated range, several factors can be evaluated over time by plotting a control chart, not just for the individual control standards but, more importantly, for their sum and difference values. If the variability of the high standard is greater than for the low standard, an overall lack of slope control is indicated. Intercept problems will be masked. Once this situation is controlled then;

1) Their difference monitors slope trend control as long as the variation in slope from day to day is controlled.

2) The variability of their difference monitors within-run precision as long as the slope is in-control.

3) The pattern of variation in the sum of the two control values will indicate between-run control problems. If the slope is in-control these problems will be related to intercept or blank determination errors.

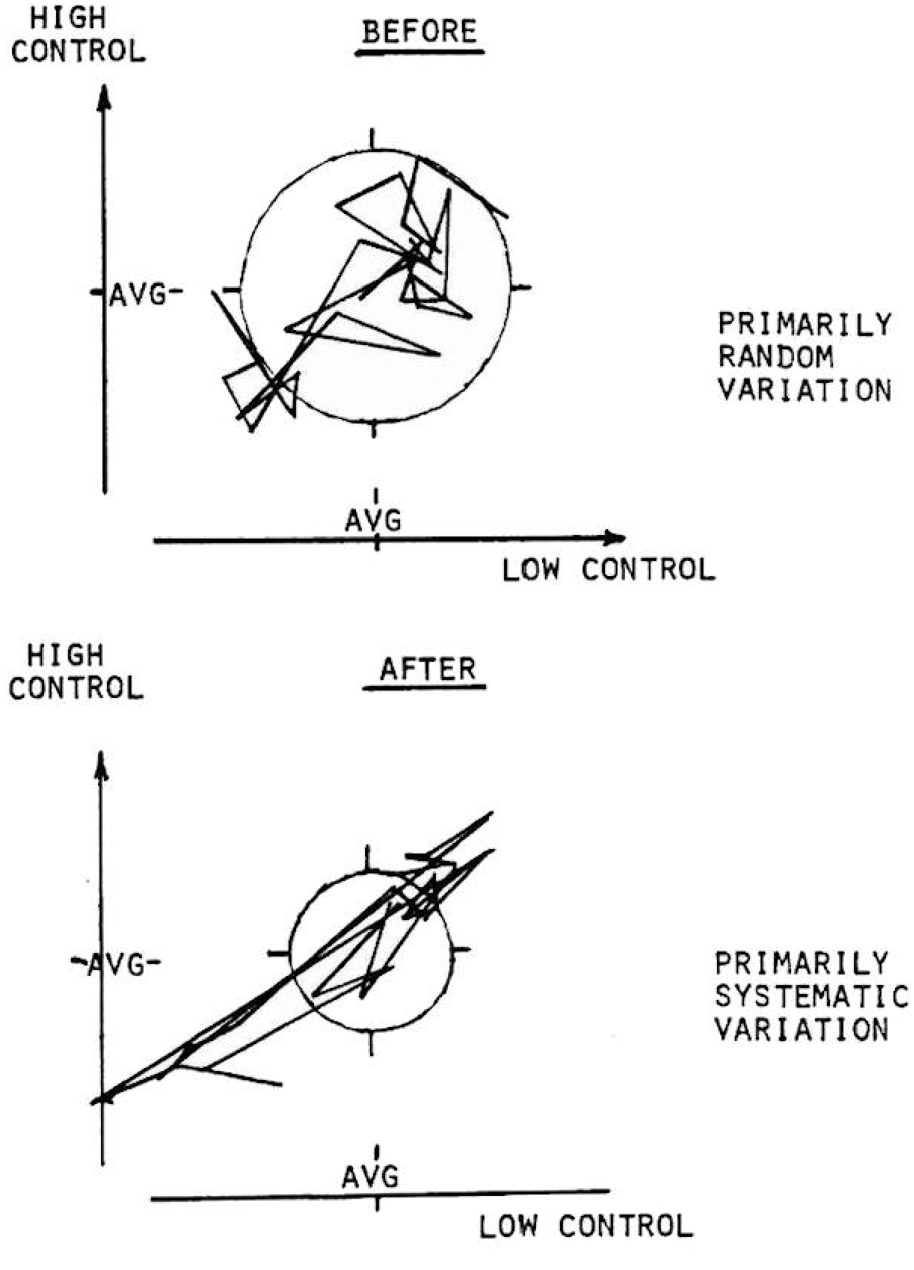
4) If the blank is normal, an intercept problem suggests chronic curvature at the top end of an otherwise normally linear relationship.

These patterns are demonstrated in Figures 10 (and following). They reflect the calibration problems shown beside them.

Accuracy Control

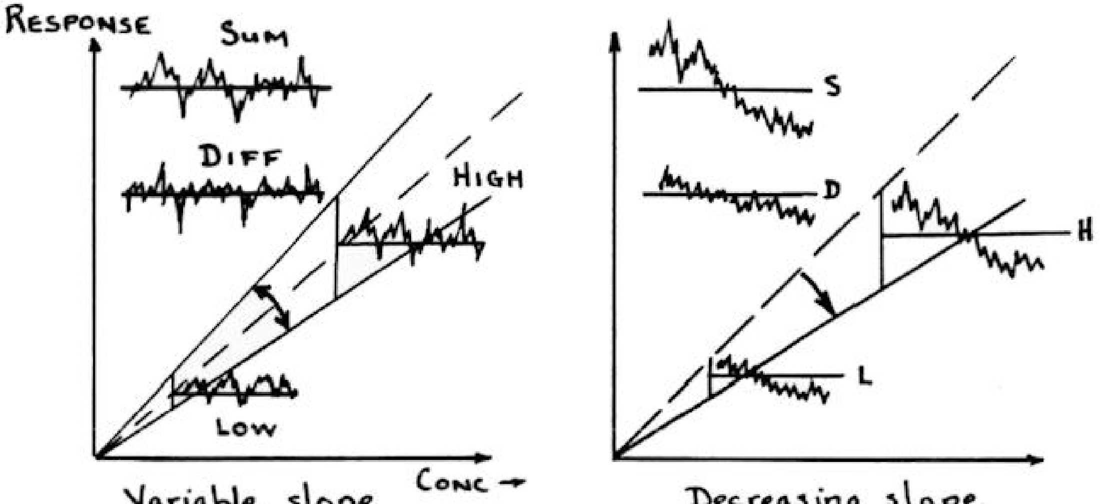
We have indicated that repeatability is essentially process controlled (3 times the within-run standard deviation). Further we have shown that between-run bias can be placed under control (based on a factor of 1.3 times the within-run limits or about 4 S_w.) However the question of accuracy control has not been resolved.

It is important to realize that between-run variability usually reveals trends. i.e. drifting of the average over time. While it is acceptable for individual points to



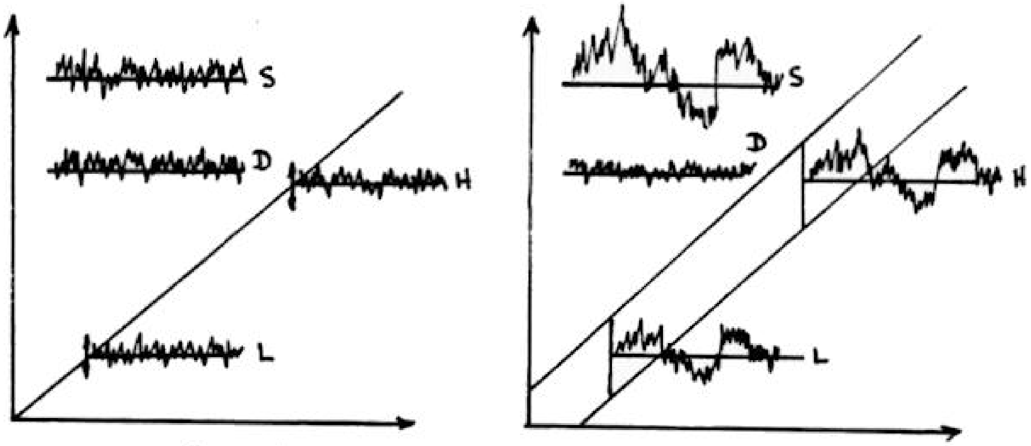
CIRCLE REPRESENTS 2X CALCULATED IN-RUN STD. DEVIATION

FIGURE 10: The results for two control standards can be plotted versus each other, the dots are joined in sequence to reveal systematic versus random patterns, systematic errors cause both results to increase or decrease together causing lines from lower left to upper right, these two patterns were obtained from the same system before and after a major instrument overhaul.



Variable slope

Decreasing slope



No systematic error

Drifting blank

FIGURE 11: Two control standards or samples can be used to monitor the top and bottom of the calibrated range, their difference monitors slope control and is used to estimate within-run std, deviation. Their sum accentuates systematic changes if they are present and can be used to estimate the between-run standard deviation. If the system is in-control the ratio of these estimates should not exceed 1.3 to 1.5.

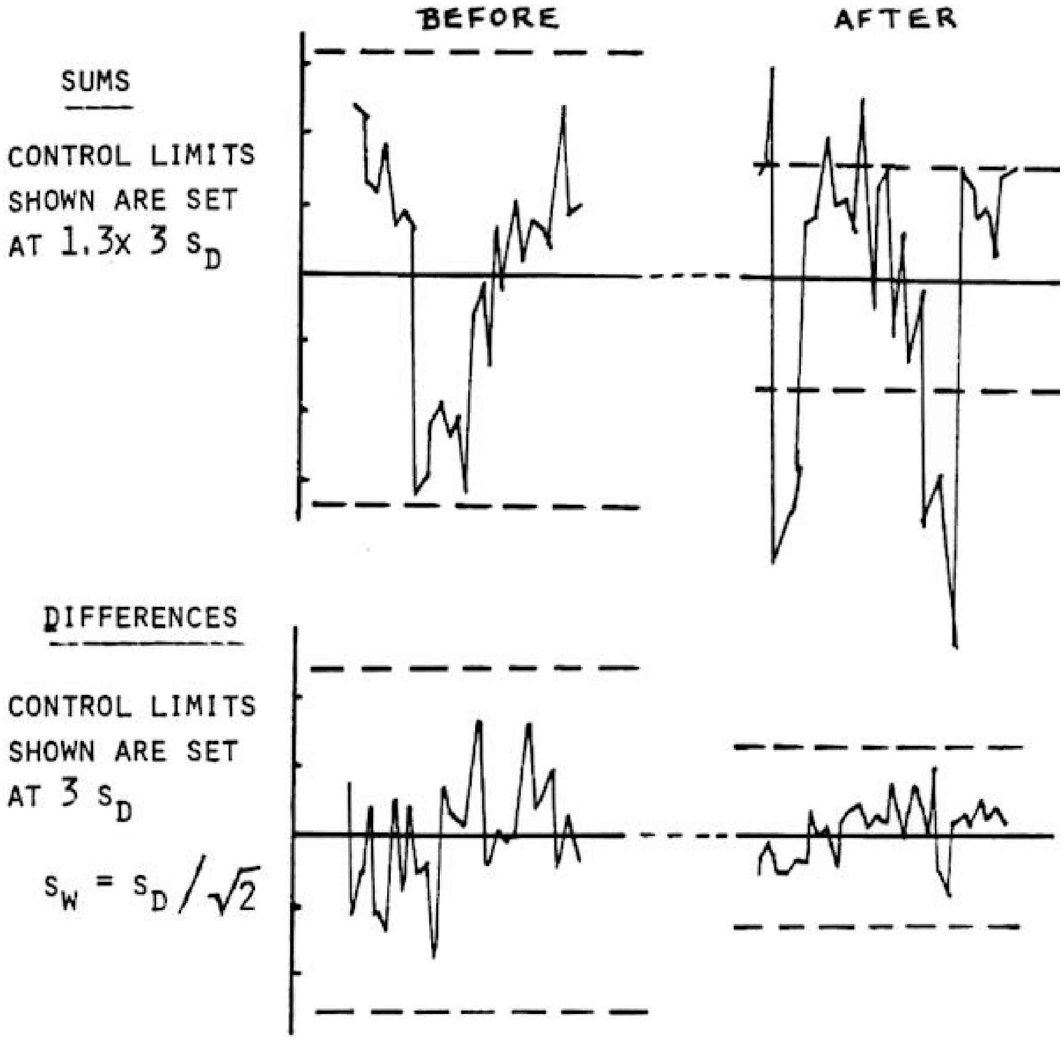


FIGURE 12: Time sequence plots of the high and low controls and of their sums and differences reveal that after the overhaul the slope variation has stabilized. The large variation in the sums must be due to lack of control over the blank or intercept correction.

deviate by as much as 4 times S_w from expected, the average should not. Confidence in an average increases as the number (n) of values incorporated in it increases. The 'standard error' of an average is given by $s/\sqrt{n}$. Therefore, if the average is based on eight results, the standard error will be about 0.38 times the standard deviation.

Therefore, given that the bias control limit for individual values is 4 times S_w, it can be determined that the control limit for an average of eight results in sequence will be about 1.5 times S_w. If the recent trend of control data is such that the addition of today's result will cause the average to differ from expected by more than this amount, it is reasonable to conclude that long-term accuracy is being affected even if today's result is still in control.

Figure 13 reviews the various control limits that have been discussed. Their basis on the known within-run standard variation ensures control action will be taken, when necessary, to permit limited drift in bias while ensuring control of accuracy.

Conclusion

The important thing to keep in mind when considering use of control charts is not how they should be drawn, nor even how the control limits should be defined. If the objectives of a 'control chart' are not understood, it will not be plotted. These objectives include mechanisms for

1) determining when calibration errors between-run are affecting the accuracy of sample results.
2) characterizing the most significant sources of between-run problems.
3) limiting between-run variation and yet retaining control over it.
4) permitting trends and yet identifying unusual individual errors.
5) demonstrating the level and nature of control being maintained.

The most important objective, however, is to become familiar with the characteristics of this particular analytical process as operated by you.

A control chart need not be complicated by statistics. Its primary purposes are to identify outliers and to detect trends. Obviously once this has occurred, a solution is required. But, blind action is to be avoided at all cost. It is far worse to take the wrong action than to take no action at all. The more information that is recorded to assist in finding the right solution the better. Two controls are much more informative and useful than one.

If resources are tight, precision control is less critical. It is already limited by the analytical process and technical proficiency. Accuracy however requires active control because of the nature of the human decision-making process. It needs you. It needs a control chart.

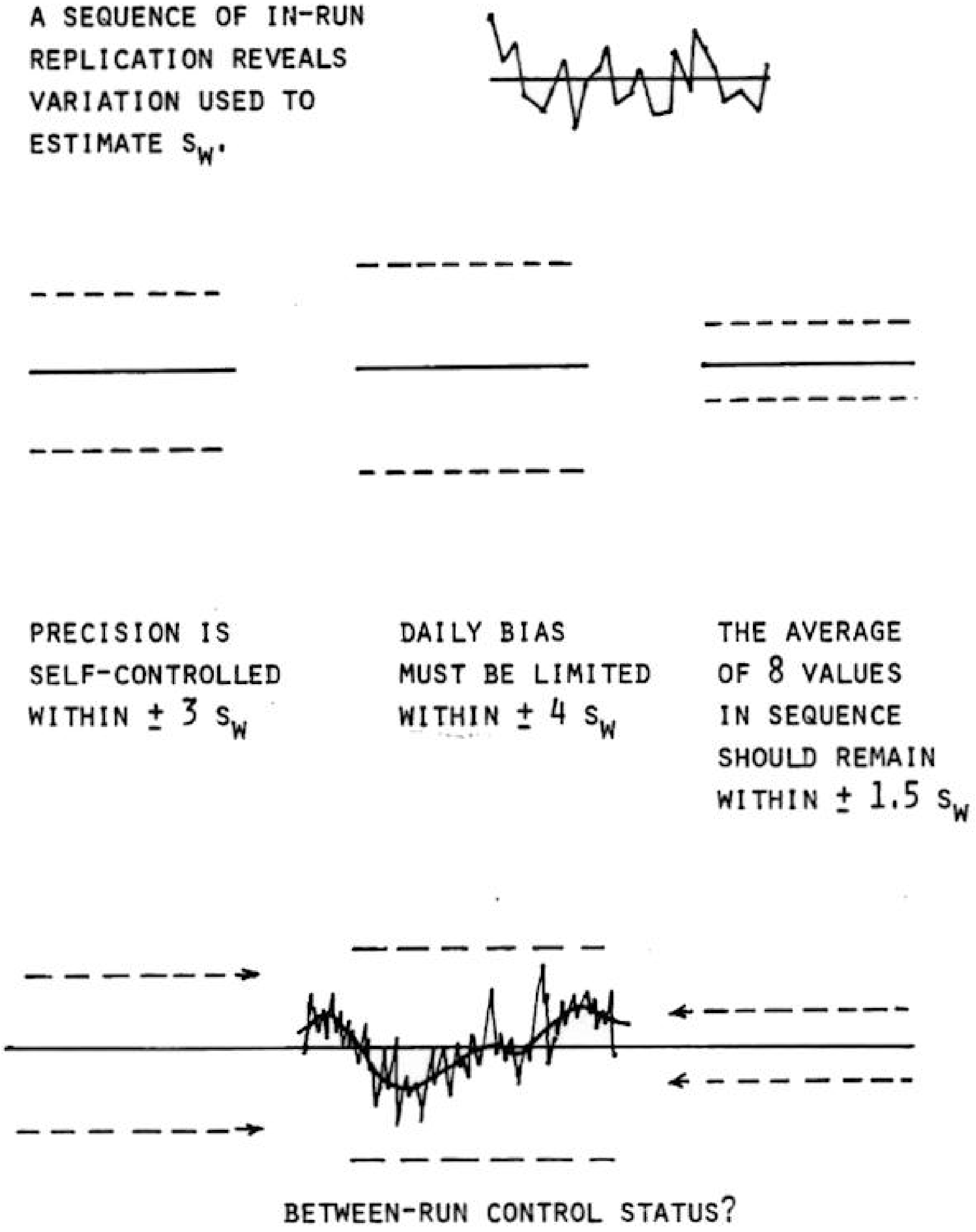


FIGURE 13: Differentiation Between Control Limits For Precision ($3S_w$) , Bias ($4S_w$) , and Accuracy ($1.5\ S_w$).

CONTROL

PROPER ACTION TAKEN IN RESPONSE
TO THE OBSERVATION OF
UNEXPECTED BEHAVIOUR RELATIVE TO
DEFINED LIMITS ABOUT AN
EXPECTED VALUE OR MEAN

PROPER ACTION

ACTION BASED ON KNOWLEDGE
OF PROPER SYSTEM FUNCTION, AND
EXPERIENCE WITH RESPECT TO
PROBABLE CAUSES AND
MOST APPROPRIATE SOLUTIONS

If you don't know what went wrong ....
DON'T FIX IT.
If you don't have all the facts ....
DON'T MAKE DECISIONS.
If you're absolutely sure you can fix it ....
THINK IT OUT AGAIN.
When you think it has been fixed ....
PROVE IT.

THEN.......... DOCUMENT THE PROBLEM
AND YOUR SOLUTION

AND.... UPDATE THE CONTROL CHART.

References

A. General Texts

1. Inhorn , S.L, 1978. Quality Assurance Practices for Health Laboratories (chapters 1-4 and 15). APHA, Washington, D.C.

2. US Dept. Commerce, NBS 1969. Precision Measurement and Calibration. NBS Spec. Pub 300 - Vol 1. USGPO Washington, D.C. (particularly articles by Youden, W.J.)

3. US EPA 1979. Handbook for Analytical Quality Control in Water and Wastewater Laboratories.

4. Youden, W.J., Statistical Techniques for Collaborative Tests, AOAC. Washington D.C. (1967)

B. Articles

1. Hunter, J.S., The National System of Scientific Measurement, Science. 210,869 (1980).

2. Delury, D.B. Computations with Approximate Numbers, The Mathematics Teacher. Nov.(1958) (reprinted in text 2 above, p 392).

3. Natrella, M.G. and Eisenhart, C. Some Basic Statistical Concepts and Preliminary Considerations (see text 2 above, p277) (particularly chapter 1-9, Using Statistics to Make Decisions).

4. Youden, W.J., Ranking Laboratories by Round-Robin Tests (see text 2 above p 165).

5. King, D.E. Detection of Systematic Error in Routine Trace Analysis. Proc. 7th Materials Research Symp. NBS Spec. Pub. 422 p 141 (1976).

6. King, D.E., Evaluation of Interlaboratory Comparison Data by Linear Regression Analysis. Proc. 8th Materials Research Symp. NBS Spec. Pub. 464 p 581 (1977).

7. Klein, R. Jr and Hach C, Standard Addition Uses and Limitations in

Spectrophotometric Analysis. Proc 8th Materials Research Symp. NBS Spec. Pub. 464 p 61 (1977).

8. Wilson, A.L. Minimizing and Estimating Analytical Errors Part 1: Simple Statistical Techniques for Analysis. Water Research Assoc. TM55 (1970).
Part 2: Estimation of Precision and Bias of Analytical Results, Wat. Res. Assoc. TM56 (1970).

9. Wilson, A.L. The Nature and Importance of Errors in Chemical Analysis, Wat. Res. Assoc. TM52 (1970).

10. Wilson, A.L. Precautions to be Considered in Establishing Collaborative Programs of River Quality Measurement. Wat. Res. Assoc. TM71 (1972).

11. Cheeseman, R.V. Analytical QC for a group of Collaborating Laboratories: Interlaboratory tests. Wat. Res. Centre TM96 (1974).

12. McDonald, R.H. and Reilly P.M, Precision Accuracy and Significant Figures. Chem. in Can. p13 Jan 1975.

C. Environment Ontario - Laboratory Services Branch

1. Outlines of Analytical Methods, June 1981.

2. Data Quality Report Series

   - Quality Control and Data Evaluation Procedures
   - Performance Reports 1975 (Water Quality Labs)
   - Data Quality Summary 1975
   - Quality Control Procedures and Objectives 1976
   - Microbiology Quality Assurance Programs 1976