Division of Consolidated Laboratory Services (DCLS)
Virginia Environmental Laboratory Accreditation Program (VELAP)

Technical Assistance Document

Using Statistical Control Limits and Control Charts for the Generation of Control Limits and for Trend Analysis

This is a Technical Assistance Document prepared by the Laboratory Certification Group of the Virginia Division of Consolidated Laboratory Services. This document is meant to be used as an advisory tool to assist laboratories in understanding the use of statistical control limits and control charts for the generation of control limits and for trend analysis. Laboratories are directed to 1VAC30-45, 1VAC30-46 and the reference method, as appropriate, to determine regulatory compliance.

I. UNDERSTANDING VARIABILITY

"Variability" refers to the amount of *spread* or *scatter* in a data set. Every process has variability. An environmental analysis is a process which may be complex and which may have potential for a large amount of variability, or variability from multiple sources.

Variability in any process is from either a *natural cause* or a *special cause*. It is important for laboratory analysts to understand the difference in *natural cause* and *special cause* variability.

- ***Natural cause* variability** is the expected variability in a process. It is the variability within expected and acceptable limits for a process. In laboratories this is usually called "**in control**" variability.
- ***Special cause* variability** is variability that is not usual or acceptable for a process. In laboratories this is usually called "**out of control**" variability. Generally there is a specific cause for this variability and this cause can usually be determined and addressed through corrective action. Environmental data which demonstrates special cause variability must be identified as having unknown certainty, by being flagged or qualified.

The acceptable amount of variability for a laboratory analysis may be specified in a permit, in specific data quality objectives for a project, in the analysis method, in national standards, and/or in regulations. Frequently, statistical methods are used to calculate limits for variability. When statistical limits and control charting are used appropriately, it is possible to discern natural (in control) variability from special cause (out of control) variability.

The most critical QC sample, used to validate whether or not a method is in control, is the Laboratory Control Sample (LCS), also called the Laboratory Fortified Blank (LFB). This matrix-specific sample is handled through all preparation and analysis steps. The analysis batch cannot be accepted if this sample exceeds established evaluation criteria (i.e., control limits). Establishing statistical limits for this parameter and performing trend analysis to identify and predict method performance issues are critical steps to well-managed data generation and avoiding repeat

analyses or qualified data. Laboratories effectively applying control charting procedures for the LCS, and for other key quality control samples, benefit from the information gained through the control charting process on an ongoing basis.

II. UNDERSTANDING THE PURPOSE AND VALUE OF CONTROL CHARTING

Control charts help you:

- ✓ **Pay attention** to variability;
- ✓ **Notice** variability before it impacts your data;
- ✓ **Notice** variability before it impacts your customer;
- ✓ **Identify and address the cause** for the change before the amount of variability is outside of acceptable limits;
- ✓ **Capture data** for review and for limit calculation**;** and
- ✓ **Quickly determine** when variation is not a natural (i.e., expected or in control) amount of variability.

Control charts are most beneficial when they are used on a day-to-day or "real time" basis and are used to evaluate acceptability of data.

- Laboratories are encouraged to implement control charting practices that are managed on a real-time basis for maximum benefit.
- Control charts generated infrequently provide 'after the fact' data analysis. In this case the laboratory loses the opportunity to perform preventive action to avoid an out-of-control situation when a bias in the data begins.
- *Standard Methods for the Examination of Water and Wastewater* (*Standard Methods*), states: "Construct a chart for each analytical method. Enter results on the chart **each time** the QC sample is analyzed."[SM 1020 B 13 a (2011); see also 1020 B sections 13 c and 15, in full, for additional information on real-time control charting.]

III. UNDERSTANDING HOW TO CONSTRUCT A CONTROL CHART

Control charts are easy to generate and easy to use.

- The Quality Assurance Section of *Standard Methods*, SM 1020, has information and tips regarding control charting.
- The internet has many helpful videos, instructions, tips, and templates for control charting.
  - Internet searches using key phrases like "control charts", "control chart template", and "how to make a control chart" yield educational and informative websites and videos.
- Control charts can be made most easily with the aid of computers and common software.
  - Many laboratory information management systems (LIMS) and many instruments have control charting capabilities.
  - Common spreadsheet programs, for example Microsoft Excel, have tools for generating charts and statistical parameters.
- Control charts can be made from day-to-day data *without computers*.

- Use extra care when calculating parameters manually, and maintain records for traceability of all values derived from manual calculations.

Control charts use the mean and standard deviation of the data set to generate and display warning and control limits.

- For the purposes of basic determination of control limits, laboratories use two statistical parameters: **mean** (also called average) and **standard deviation**.
- Formulae for these parameters are readily available in texts and from online resources. More commonly, these parameters are calculated by using basic software tools or a calculator with statistical functions.
- Once these statistical parameters are used to determine control limits, data points are plotted on a graph. This process provides visual representation of data in comparison to those control limits for effective and efficient analysis.

- **Evaluating BIAS:**
  - **WARNING LIMITS: the historical mean recovery ± 2 standard deviations**
    - The statistical chances or "odds" of a data point with only natural variability being outside of 2 standard deviations (but within 3 standard deviations) are 1 in 20. These are called warning limits because if a data point falls outside of 2 standard deviations it is a warning that the variability in the process may not be "natural."
  - **CONTROL LIMITS: the historical mean recovery ± 3 standard deviations**
    - The statistical chances or "odds" of a data point with only natural variability being outside of 3 standard deviations are less than 1 in 100. These are called control limits because if a data point falls outside of 3 standard deviations, the variability in the process is not "natural", but instead is "special cause" or out of control.
    - **When a value exceeds the control limits, something is affecting the analysis other than the expected variables. The cause for the variability must be identified and corrected.**
    - The analysis must be repeated, if possible, after the problem is corrected; alternatively, the data must be qualified as having increased uncertainty because quality control criteria were not met.

- **Evaluating PRECISION:**
  - WARNING AND CONROL LIMITS: the historical data for %RSD or RPD is used to calculate the mean range and upper warning limits and control limits; perfect agreement between replicates or duplicates results in a difference of zero, so the baseline of the chart is zero; see SM 1020 B 13 b or other applicable resource for precision formulae and definitions of RSD and RPD.
    - The statistical chances or "odds" of a data point with only natural variability being outside of the control limits are less than 1 in 100.
    - When an analysis fails the control limits, **something is affecting the analysis other than the expected variables**. The cause for the variability must be identified and corrected.
    - **The analysis must be repeated, if possible, after the problem is corrected; alternatively, the data must be qualified as having unknown uncertainty.**

- **Refer to the individual method for expected precision and for information on the determining the evaluation criteria.**
- As an example of method specifications for precision evaluation for those laboratories using *Standard Methods*, SM 1020 B-2011 Section 8, (applicable to chemistry *Standard Methods*) allows for the Minimum Reporting Limit (MRL) to be used as the control limit for the maximum difference between two duplicates (i.e., "range"), when one or both samples in the duplicate pair are less than or equal to 5 times the MRL, and for these data NOT to be used to make determinations of data acceptability.
    - For example, if the MRL = 0.1 mg/L, then samples with a concentration less than 0.5 mg/L may be discounted for the purpose of evaluation of duplicate precision.
    - Precision evaluation is a key aspect of establishing data defensibility. If duplicate samples analyzed by Standard Methods are frequently below 5x the MRL, the practice of evaluating **matrix spiked duplicates** may be routinely used to evaluate precision.

Tips for Getting Started:

How many data points are used?

- Frequently, statistics are generated with a minimum of 10-20 data points.
- Some methods specify this information.
- The number of data points used may be related to the frequency of analysis.

Do the limits change with each new additional data point?

- Typically, a data set (with at least 20 points) is used to characterize "typical" performance. Once that data is collected, the limits calculated from the data set are "locked" and then future data values are evaluated against those limits.
- Ideally, control limits should only be recalculated when you have made a process change that *improves* the process by either moving the average or reducing the variation.
- Limits are re-evaluated periodically to determine if the limits should be replaced with a re-calculated value. (Example: Results rarely, if ever, exceed the control limit.)

How often must control limits be re-evaluated?

- Some methods specify the frequency.
    - *Standard Methods* 1020 B.13.c states, "If measurements never or rarely exceed the WL [warning limits] in the accuracy and precision charts, recalculate the WL [warning limits] and CL [control limits] using the 10 to 20 most recent data points."
- If not specified by the method or by Data Quality Objectives, establishing a routine for re-evaluating limits is strongly recommended.
    - Establishing and keeping a schedule for re-evaluation of control limits (such as quarterly, semi-annually, after 100 data points, etc) creates an additional aspect of data review that can provide trend analysis opportunities for the laboratory by reviewing the change in calculated limits over time.

May I use fixed limits as evaluation criteria rather than calculated limits?

- VELAP sought clarification from the *Standard Methods* (SM) committee of the statement from SM 1020 B 13 C, "As an alternative to constructing control charts, use fixed limits from a database or list for WLs, CLs, and trends." SM has clarified as follows: "*The intent was to allow creation of fixed limits using the foregoing methods, and then using those limits as a static trigger for WL, CL, etc., rather than using each new data point to continuously construct charts.* ***It's an alternative to creating charts, not an alternative for creating the limits."***
- Based on the clarification offered by the *Standard Methods* committee, VELAP will assess to this requirement; i.e. control or acceptance limits will be calculated from laboratory data <u>whenever required by the method</u>.
- Should the laboratory opt for the use of more stringent fixed limits than those calculated by statistical means, the laboratory's records must provide validation that the fixed limits are more stringent than the calculated limits.
- <u>*Continued and careful charting and trending of data may help the laboratory track, diagnose, and address with corrective or preventive action the causes of systematic error which may be causing the laboratory's calculated limits to be broader than either the method's stated accuracy and precision or the customer's stated DQOs.*</u>
- Control charting is a beneficial practice even when fixed limits are used for evaluation criteria, because charting facilitates trend analysis.
- ***Many methods provide defined control limits, or suggest limits which have been established by pooled data from multiple labs. It is generally expected that a laboratory's own statistical limits will not be broader than method defined or pooled limits. Should the lab's limits be broader, then a careful root cause analysis should be done to look for the reasons that the laboratory cannot meet the method's projected limits. In such cases, it is appropriate to utilize the stricter fixed limits until the laboratory's control charting process has helped align the laboratory's precision and accuracy with the method's expected limits.***

IV. UNDERSTANDING HOW TO INTERPRET A CONTROL CHART

"Statistics 101"

- If warning limits are set at ± 2 standard deviations, this is called the "95% confidence interval". On average, 1 out of 20 points (95%) would exceed that level when data demonstrates 'natural variability'.
- If control limits are set at ± 3 standard deviations, this is called the "99% confidence interval". On average, less than 1 out of 100 points (99.7%) would exceed that level when data demonstrates 'natural variability'.

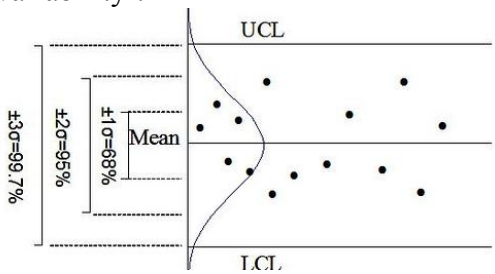
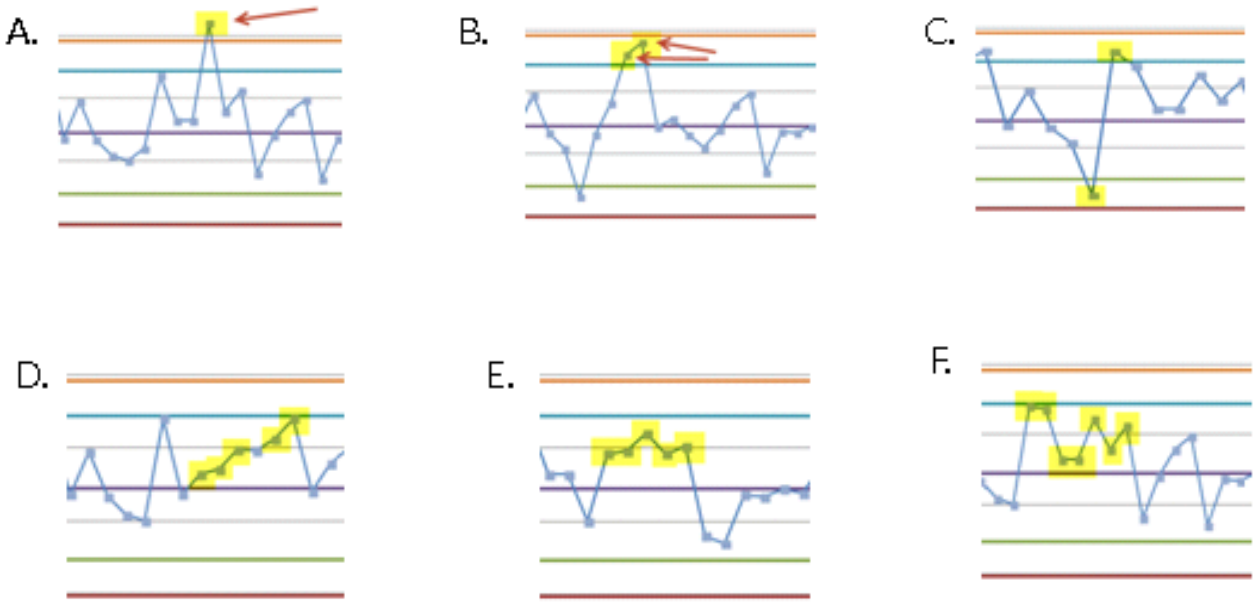


Chart Analysis:

The greatest value in control chart evaluation and trend analysis is promoting the laboratory's awareness of the *type of variability* that generated data demonstrates. ***All data has variability***, but when the variability of data is ***not natural***, the laboratory has evidence of unacceptable error in the analytical process. This unacceptable error may be identified by use of rules for identification of ***special cause (or, out of control) data variability***. When variability is not natural and instead caused by special influences, the data may exhibit characteristic patterns. Common "Rules" used in chart evaluation and trend analysis have been developed by numerous sources (for example, Standard Methods [SM 1020 B.13.c-2011], Westgard, Western Electric, Nelson, etc.) to describe patterns which would indicate non-random variability. **Refer to these or similar resources for descriptions of specific trend analysis rules.**

Example Illustrations of Chart Analysis Issues or Trends:

Control charting facilitates recognition of special cause variability by providing a quick visual indication of the patterns characteristic of non-random variability, as illustrated below. These notable patterns are generally more recognizable in a control chart than in a data table format; these patterns are examples of issues or trends typically identified by rules such as those in SM 1020 B or other resources for statistical trending rules.



A. 1 data point outside of the control limits
B. 2 consecutive data points outside of the warning limits, on the same side of the mean
C. 2 consecutive data points outside of the warning limits, on different sides of the mean
D. 5 of 6 data points in ascending (or, descending) order
E. 5 consecutive points outside of 1 standard deviation on the same side of the mean
F. 7 consecutive points on 1 side of the mean

Refer to the resources stated above, for example, SM 1020 B.13.c-2011, for the full text describing specific trend analysis rules and appropriate actions when trends are noted.

Trending Requirement:
The regulatory requirement for trend analysis is as follows: *"The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results."* [2003 NELAC 5.5.9.1 or 1VAC30-45-750 A]

V. NEXT STEPS

Congratulations! If you've worked through sections I through IV, then you have reviewed the fundamentals of control charting and the purpose and value of control charting for environmental laboratories. What's next?

- *CONTROL CHARTING IS A PARTICIPATION EVENT … the maximum value is gained when control charting is done in real-time by the folks closest to the analysis. If the analyst who performs the test is responsible for charting the data as soon as it is generated, the likelihood of detecting trends before data is impacted is greater. Control charting done after-the-fact has less value to the organization.*
- *ALWAYS REMEMBER THE PURPOSE → to facilitate the detection of variability in the analytical system before data is impacted! For this reason, there is not a one-size-fits-all answer to some questions, such as, "How many data points do I use?" and "How often do I re-calculate limits?" The laboratory may need to adjust its responses to these questions based on the data available and the guidance provided by the published methods and "best practice" resources.*
- ***It is generally expected that a laboratory's own statistical limits will not be broader than method defined or pooled limits which may have previously been used. Should the lab's limits be broader, then a careful root cause analysis should be done to look for the reasons that the laboratory cannot meet the method's projected limits. In such cases, it is appropriate to utilize the stricter fixed limits until the laboratory's control charting process has helped align the laboratory's precision and accuracy with the method's expected limits.***