Control Charts

What they are and how to use them

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- The control chart is one of the most important tools of quality control for laboratory data.

- A control chart is a specific kind of run chart that allows unusual change to be differentiated from the normal variability that can routinely occur with the method

- A control chart gives you a visual display of method stability or instability over a period of time.

- Every method has normal variation.

- Some variation is simply the result of numerous, ever-present differences in the method.
- This is **common cause variation.**

Examples of common causes

- Chance occurrences
- Random issues that can't be controlled

- Some variation may be the result of causes which are not normally present in the method.
- This could be **special cause variation.**

Examples of special causes

- Incorrect reagents
- Expired reagents
- Inaccurate measurements
- Dirty glassware

- Control Charts differentiate between these two types of variation.

- A corrective action investigation will isolate the possible special causes of a set of data

- **Control charts**, also known as **Shewhart charts**, are tools used to determine whether or not an analytical process is in a state of statistical control, or stability.

- Stability is defined as the state in which a method has displayed a degree of consistency in the past and is expected to continue to do so in the future.

- This consistency is demonstrated by a stream of data falling within **control limits** based on **plus or minus 3 standard deviations** of the calculated centerline

- Control charts help monitor the method over time to allow you to determine if the method is in control or not.

- If analysis of the control chart indicates that the method is currently under control then data from the method can be reported with reasonable certainty.

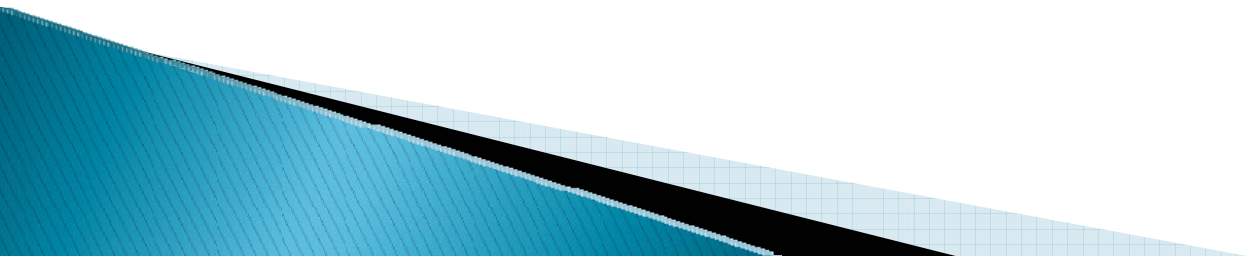
- If the chart indicates that the method is not in control, a corrective action investigation can be conducted to determine the source of error and correct it.

- The control chart is part of an objective and disciplined approach that enables correct decisions regarding control of the method, including whether or not to report the data generated.

- Control chart parameters should never be adjusted to generate data, as this will result in incorrect or skewed results (reporting false data to the regulatory agency)

Chart Construction

- Points representing the statistic
- Mean of the data
- Center line
- Standard deviation of the data
- Control limits
- Warning limits
- Chart Zones



Points representing a statistic

- measurements of a quality characteristic in samples taken from the process at different times [the data]
- Should be a minimum of 20 data points

-57.5	-58.8	-54.7
-59.2	-60.0	-60.5
-58.8	-60.0	-59.7
-58.3	-58.7	-59.8
-56.0	-58.5	
-56.7	-61.0	
-58.4	-60.0	
-58.6	-62.6	

Sample Data Points

Slope for Ammonia samples, Multiple Known Additions using Ion Selective Electrode

Calculate the mean

- The mean of the specific parameter using all the samples is calculated

- Add up the data points and divide by the number of points used to find the “mean” (average)

- −58.89

Mean (also known as average)

Slope for Ammonia samples, Multiple Known Additions using Ion Selective Electrode

Calculate the standard deviation

- The standard error (e.g., standard deviation) for the mean) of the parameter is also calculated using all the samples

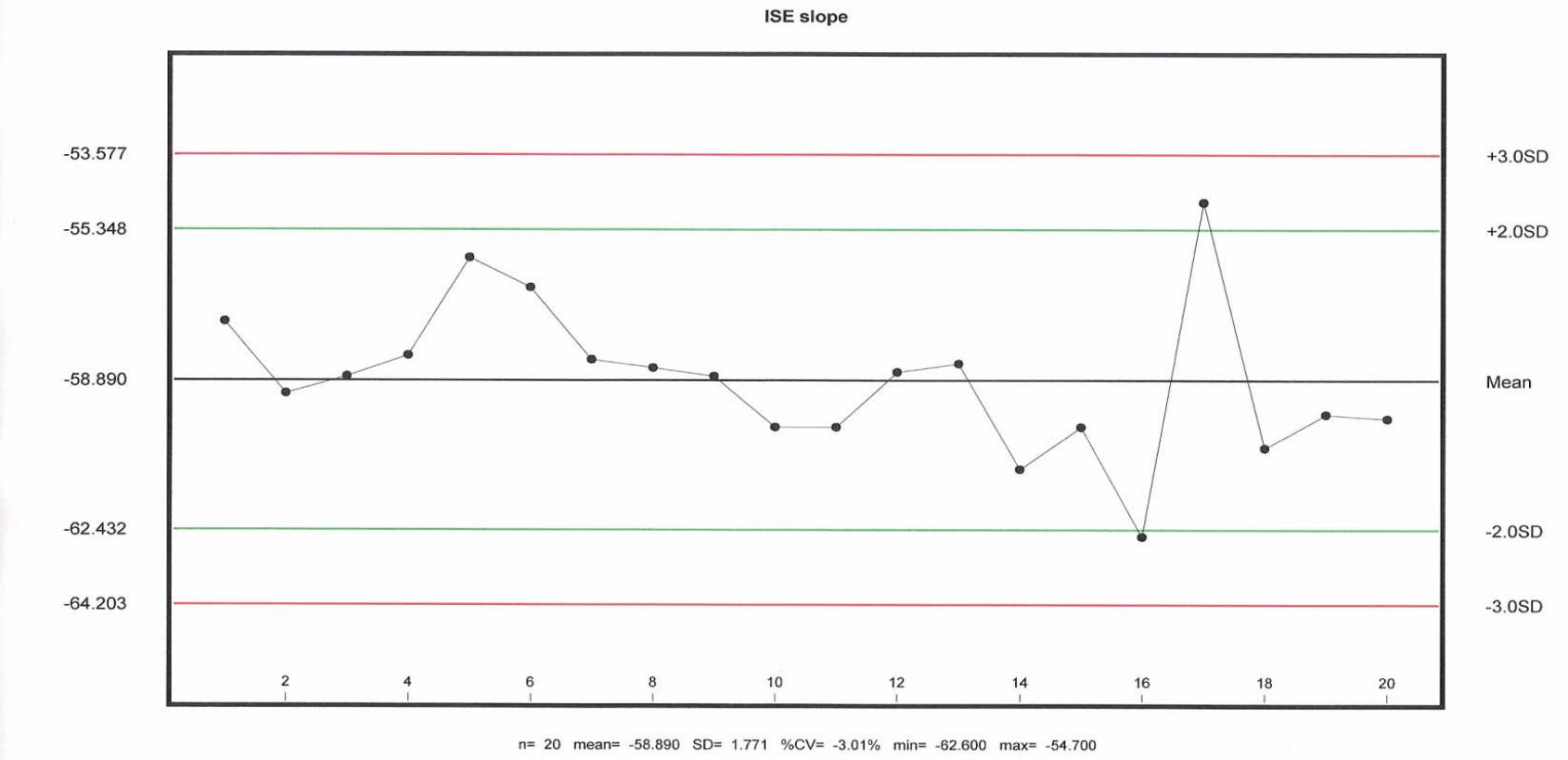
Calculate control limits

- Upper and lower control limits that indicate the threshold at which the method result is considered statistically 'unlikely' are drawn typically at 3 standard errors from the center line

Calculate warning limits

- Upper and lower warning limits, drawn as separate lines, typically two standard errors above and below the center line

- Plot the data on a graph
- Draw the Center Line (mean)
- Draw in the Warning limits
- Draw in the Control limits



Basic chart for the slope for ammonia ISE

Slope for Ammonia samples, Multiple Known Additions using Ion Selective Electrode

- Inside the warning limits means the method is running well

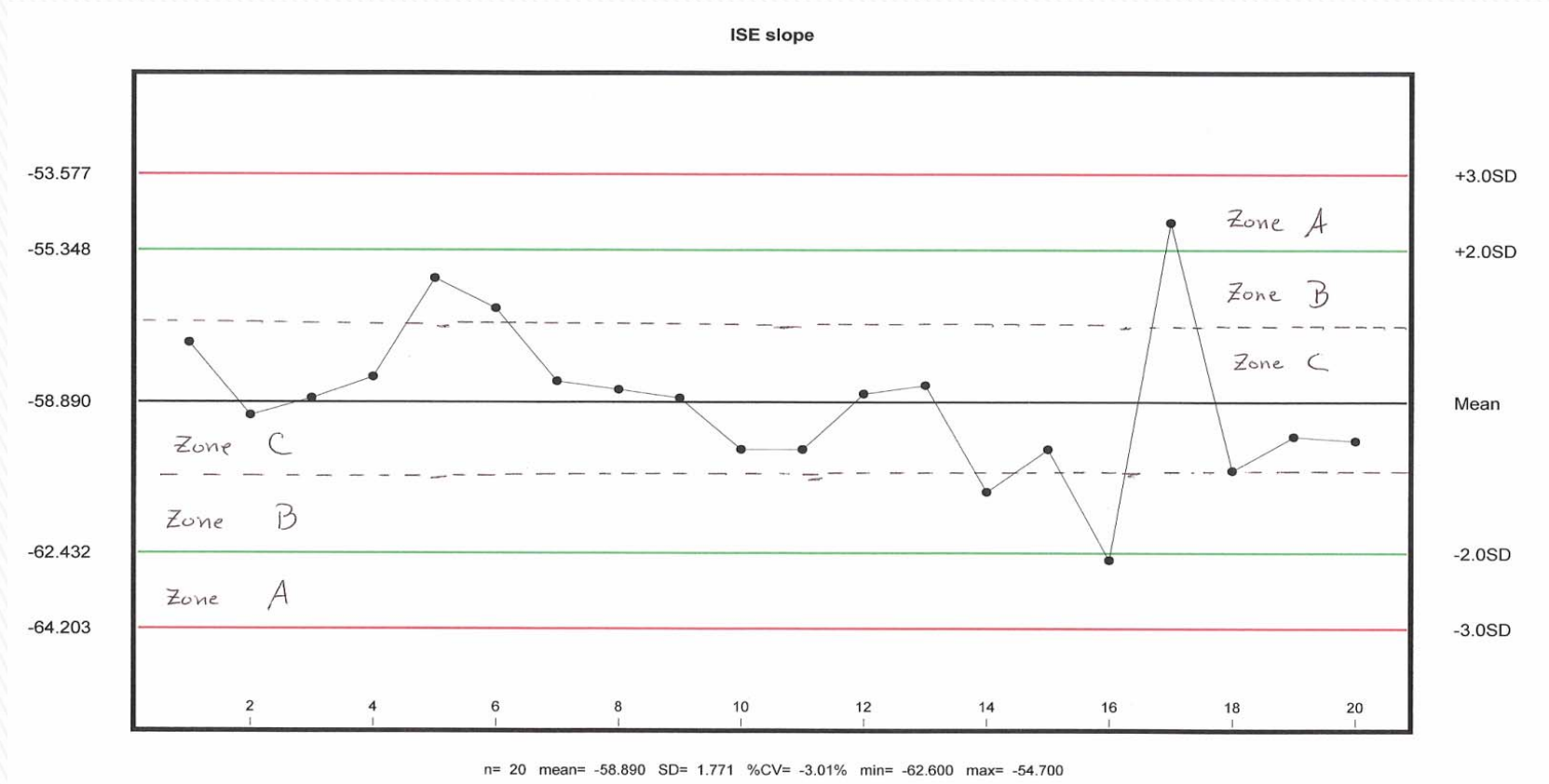
- Between the warning limits and the control limits means check for possible problems

- Outside the control limits means the parameter is “out of control”

- Set up the chart with “zones” based on the calculated std deviations

- These will be used to “test” the data for outliers later.

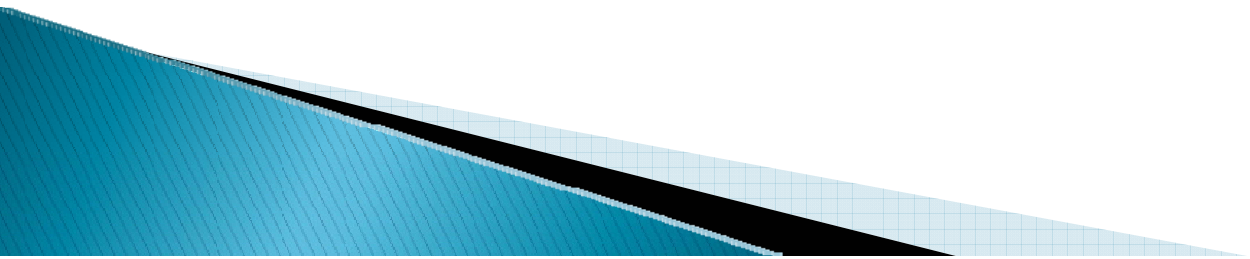
- Zone A is between 2 and 3 std deviations
- Zone B is between 1 and 2 std deviations
- Zone C is +/- 1 std deviation



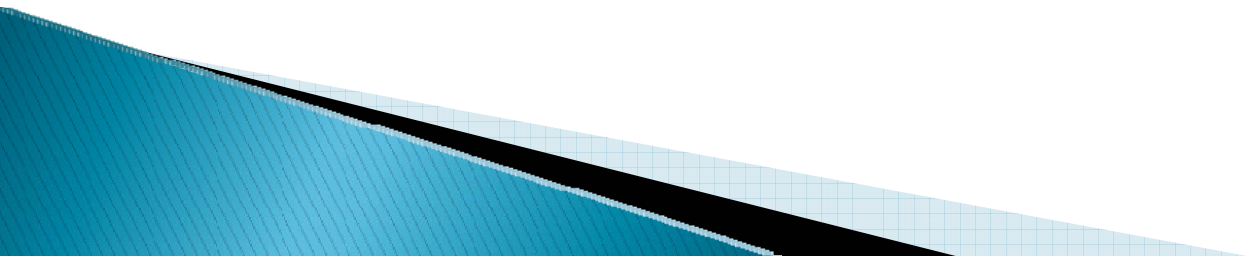
Basic chart with zones identified

Slope for Ammonia samples, Multiple Known Additions using Ion Selective Electrode

When to Update the charts



- Ideally, charts should be continuous for the method, adding the data to the existing stream already plotted.

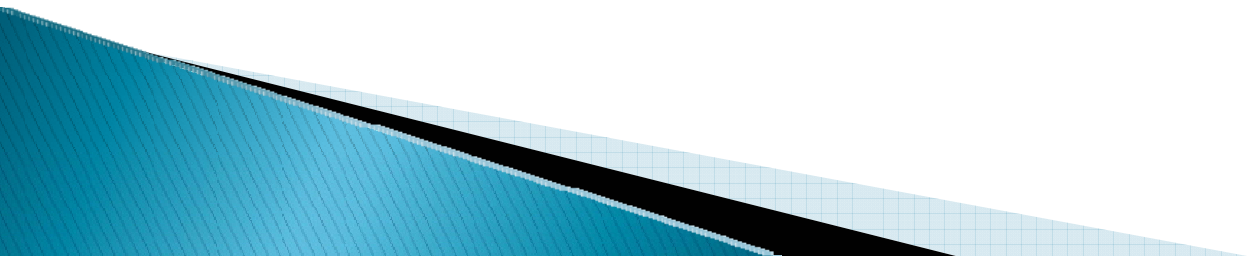


- The more points included in the evaluation, the more “realistic” the results will be

- New charts should be started for new methods, or for current methods that undergo a significant change in equipment or method modification.

- Add data points to the plotting system as they accumulate

- Update charts no more often than when 20 new data points have been added.



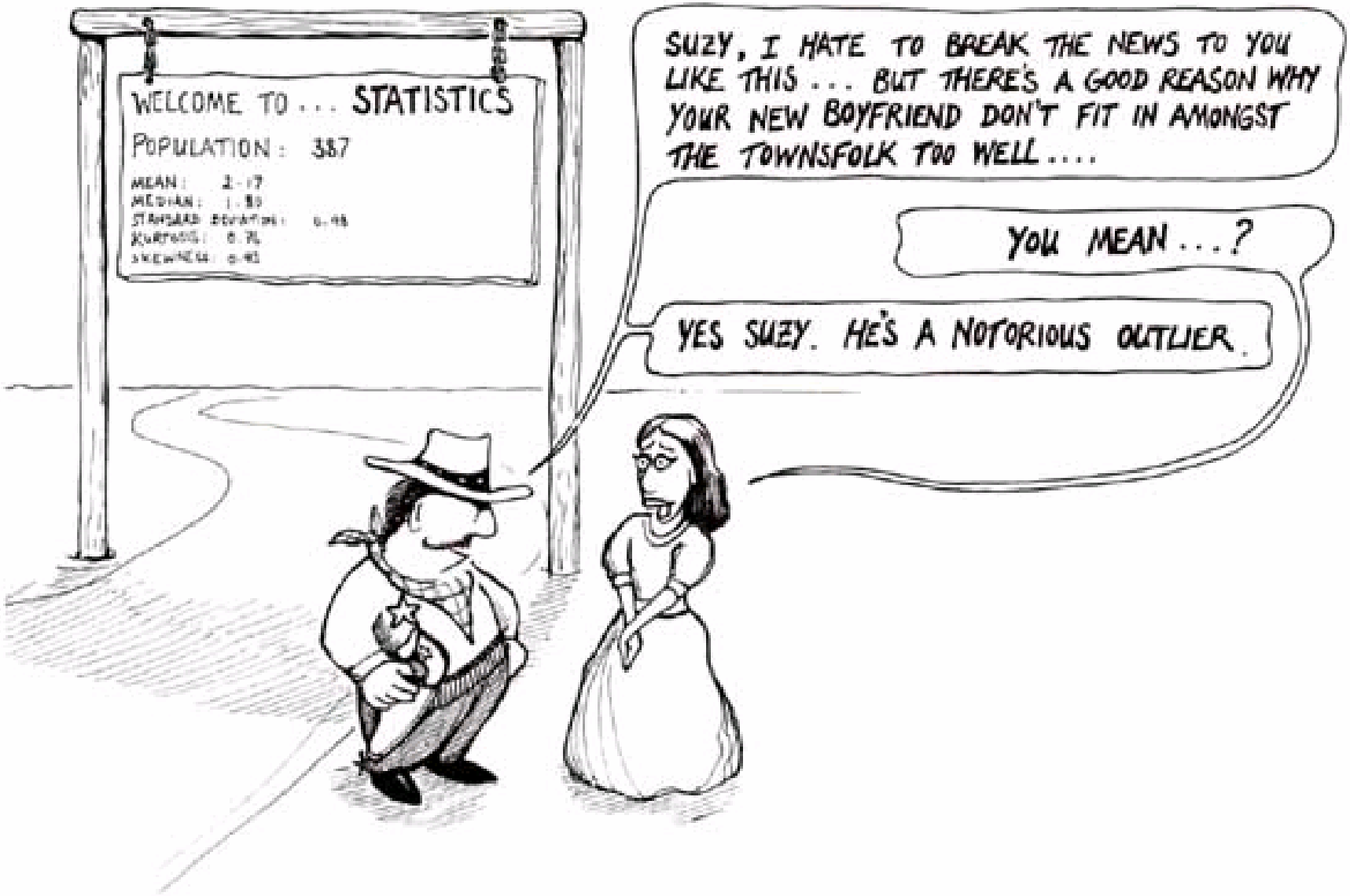
What's "IN" and What's "OUT"

- All data points should be included in the initial charts.

- Data that is affected by “normal” variability should be left in use.

- Data should ideally only be excluded if and when it can be linked to a specific cause variability.

- Specific cause variability would be something linked directly to an error in the method:
- Incorrect reagents
- Dirty glassware
- Poor technique


WELCOME TO ... STATISTICS
POPULATION: 387
MEAN: 2.17
MEDIAN: 1.89
STANDARD DEVIATION: 0.98
KURTOSIS: 0.76
SKEWNESS: 0.92
SUZY, I HATE TO BREAK THE NEWS TO YOU LIKE THIS ... BUT THERE'S A GOOD REASON WHY YOUR NEW BOYFRIEND DON'T FIT IN AMONGST THE TOWNSFOLK TOO WELL....
YOU MEAN...?
YES SUZY. HE'S A NOTORIOUS OUTLIER.

- There are other factors, or trends, that must be taken into consideration as well as whether the data is inside or outside the control limits to determine if a method/ data is in control:

- look for systematic patterns of points (e.g., means) across samples, because such patterns may indicate that the process average has shifted.

- A run of 9 consecutive points on the same side of the mean indicates the method is “out of control”

- probability of this happening statistically is .00195 – same probability that a point will fall outside the 3 std deviation line

- **9 points in Zone C or beyond (on one side of central line).**

- if this pattern is detected, then chances are the average has probably changed.

- Successive samples with less-than-average variability may be worth investigating, since they may provide hints on how to decrease the variation in the method.

- Note that it is assumed that the distribution of the data points will be symmetrical around the mean.

- **6 points in a row steadily increasing or decreasing.**

- This also signals a drift in the average.

- Often, such drift can be the result of equipment wear, deteriorating maintenance, improvement in skill, etc. (Nelson, 1985).

- **14 points in a row alternating up and down.**

- If this trend is present, it indicates that two systematically alternating causes are producing different results.

- **2 out of 3 points in a row in Zone A or beyond.**

- This provides an "early warning" of a process shift.

- 15 points in a row in Zone C (above and below the center line).
- This test indicates a smaller variability than is expected (based on the current control limits).

- 8 points in a row in Zone B, A, or beyond, on either side of the center line (without points in Zone C).

- This indicates that different samples are affected by different factors, resulting in a bimodal distribution of means.

- This may happen, for example, if different samples were processed by two different techs, where one follows good measurement protocol and the other doesn't.

Using the control chart for data reporting

- When evaluating the run, look at the QC from that run as it relates to the parameters generated from the control chart

- If the data is in control, report the results
- If a data point is out of control, look for special causes and re-analyze the sample(s) affected

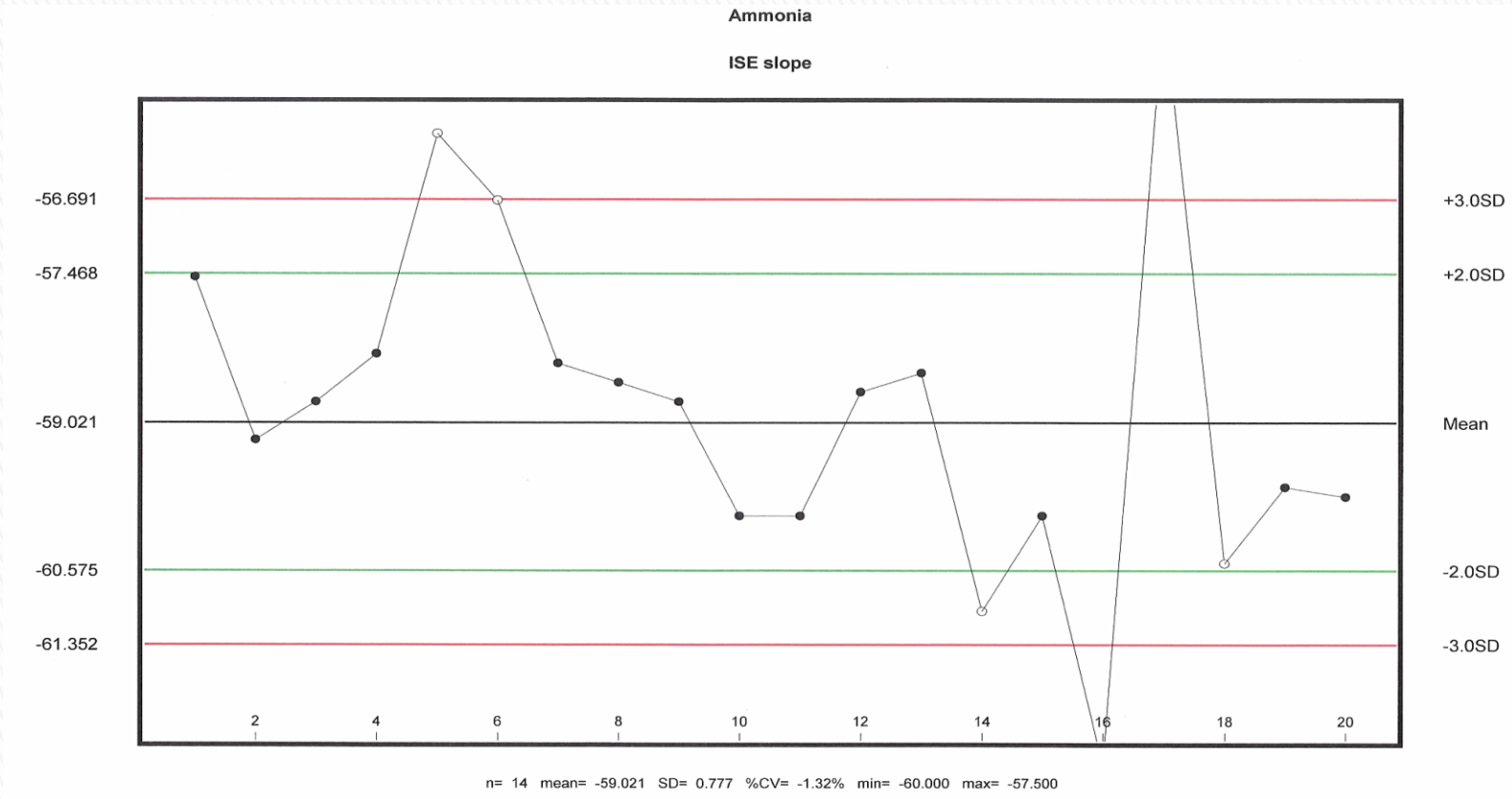
- If comparing results from 2 different labs, review all of the QC generated in comparison to their control charts

- Select the data from the most reliable QC source

- If the lab can not provide QC results, and their control charts – consider the data invalid until it can be proven otherwise

- Good data is data that is accurate and precise – and can be documented to demonstrate those characteristics.

Use Caution on Removing points from chart

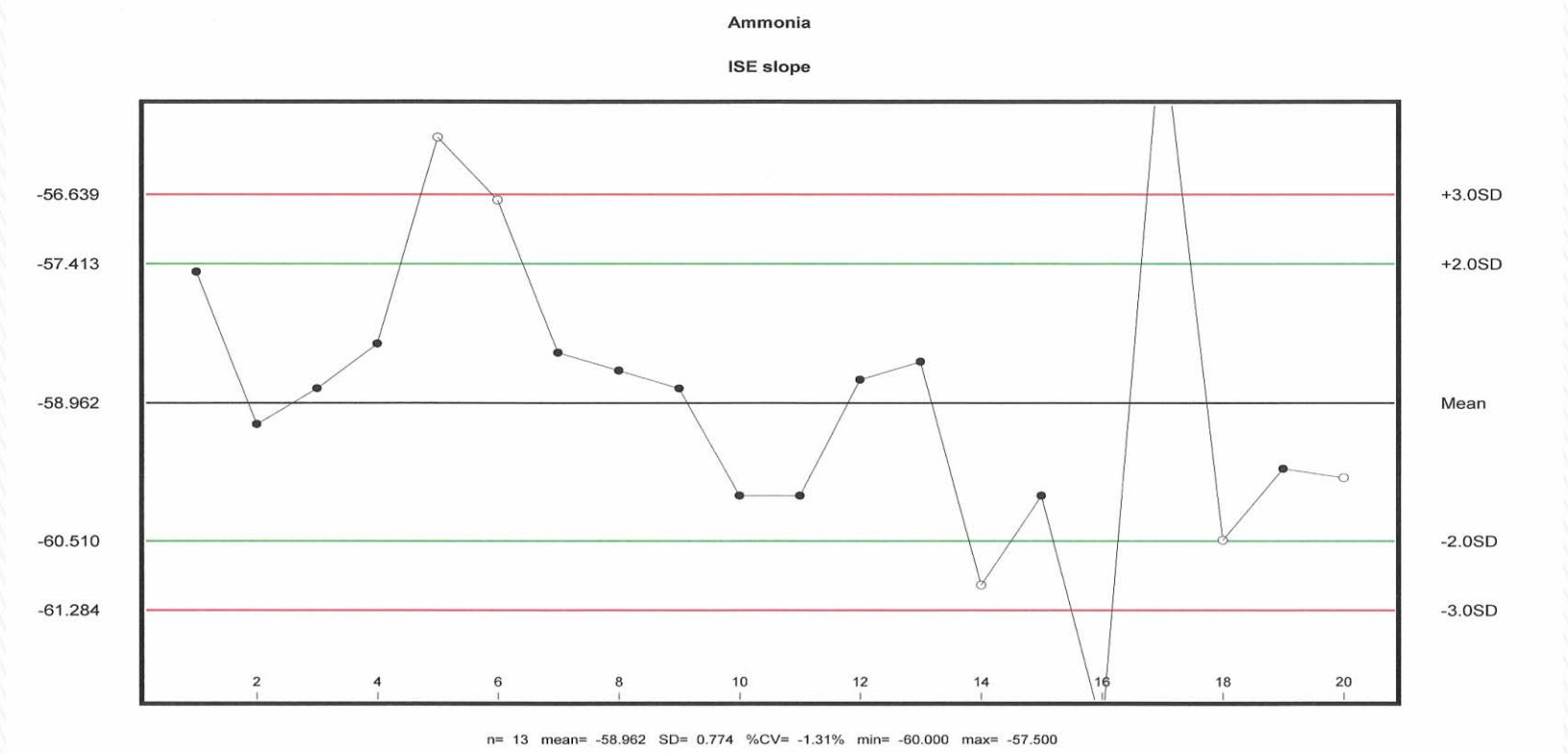


Basic chart with QC parameters applied

Original mean was -58.89

Warning limits were: -55.348 and -62.432

- Points eliminated from original chart were:
- -56 and -62.6 because they were outside the warning limits
- -60.5 because there 4 out 5 successive points outside 1 std dev
- -54.7 because there were 2 out of 3 successive points outside of 2 std dev



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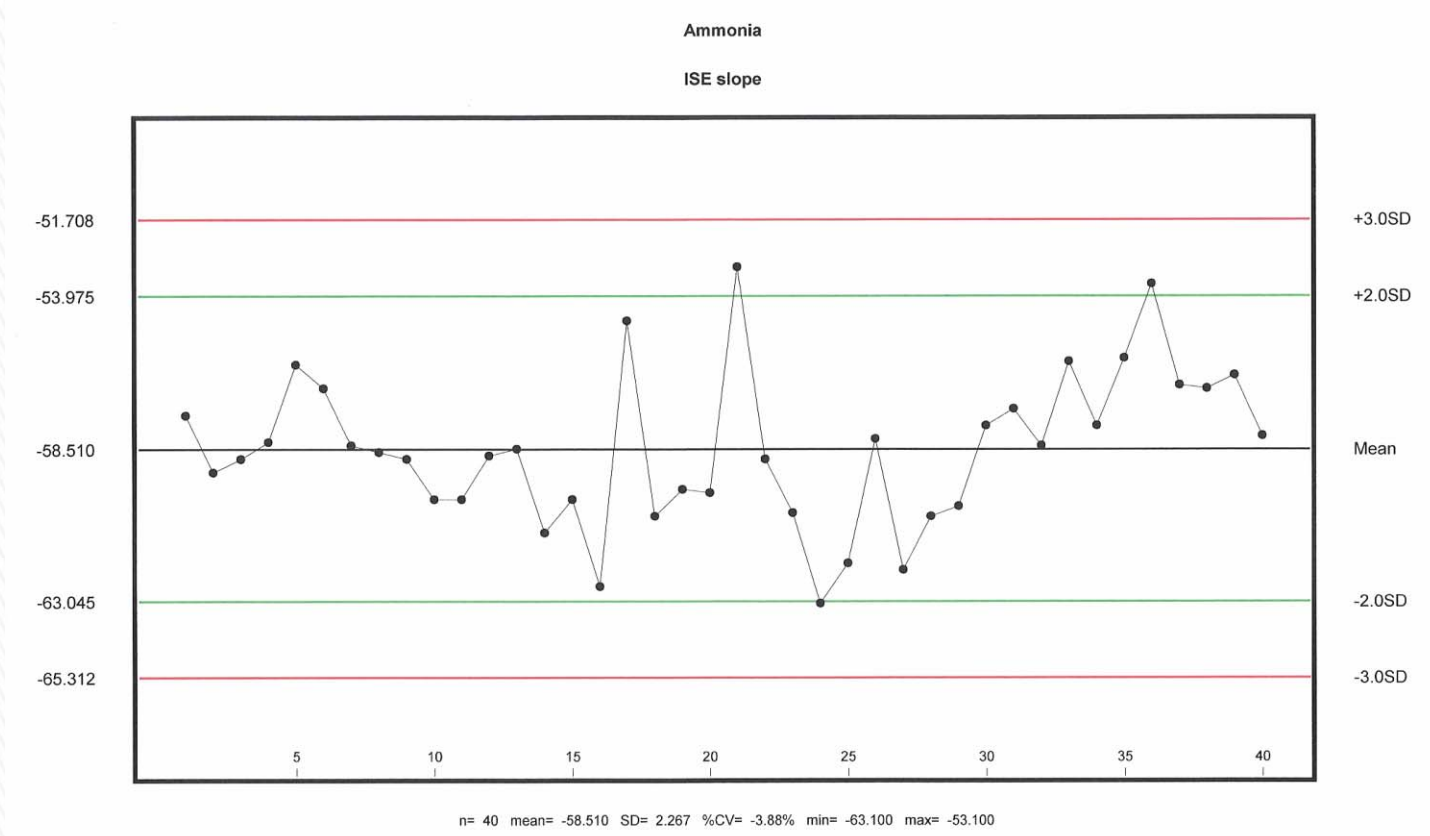
Previous chart with QC applied

Last mean was at -59.021

Warning limits were at -56.691 and - 61.352

- Additional points that were eliminated were:
- -56.7 because there were 2 out of 3 successive points outside the new 2 std dev
- -61 because it was outside the new warning limits
- -59.8 because there were 4 out of 5 successive points outside the new 1 std dev

- If you continue to eliminate points like this without confirming there was special cause for them to occur, you will eventually end up with a control chart so tight you will almost always be “out”



Ammonia Chart with 40 data points

The more points you incorporate, the more realistic the control parameters

- Questions?

- Contact info:

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