Quality Assurance
Charting for QC Data

September 2018

Iowa's Environmental & Public Health Laboratory

Agenda

- Introduction
- Pre-Quiz
- Key Practices
- Post-Quiz
- Questions

60 Minute Schedule

- Introduction 5 min
- Pre-Quiz 5 min
- Key Practices
  - Standard Work 20 min
  - Quality Control 15 min
- Post-Quiz 5min
- Questions (10 min float)

Introduction

Mark Pendergast

- 15 years as an analytical chemist
  - GCMS, HPLC, Nutrients
  - Microscopist
- 2015 to Present
  - Manager, Quality Systems
  - Advisor to SHL Director
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Quality Control

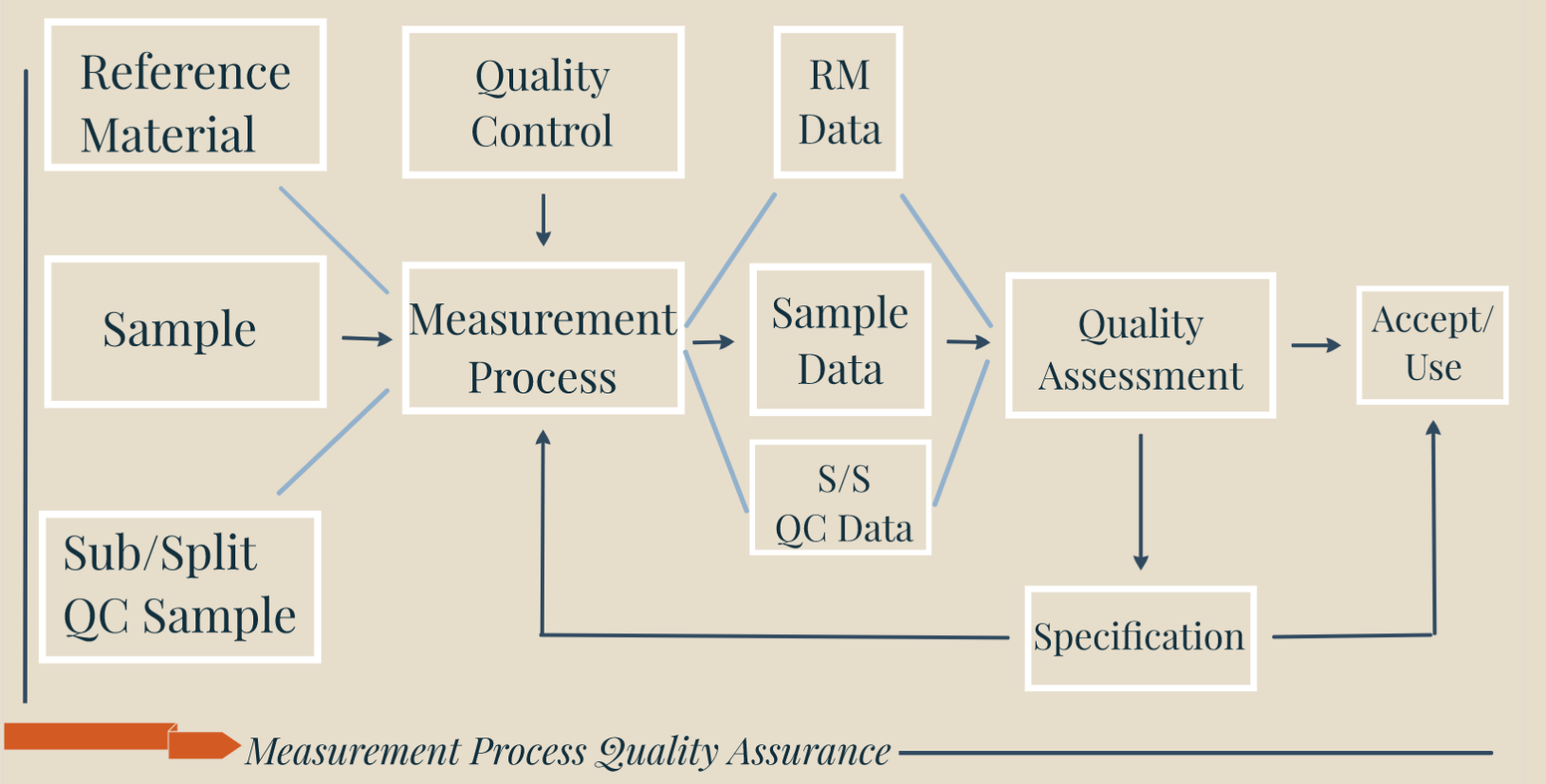
1. DOC
2. MDL
3. LRB
4. LFB
5. MS/MSD
6. ISTD
7. CCV
8. Control Charts
9. Corrective Action
10. QC Acceptance Criteria
11. Definitions
12. Minimum Frequency for QC

Quality Control

1. DOC
2. MDL
3. LRB
4. LFB
5. MS/MSD
6. ISTD
7. CCV
8. **Control Charts**
9. **Corrective Action**
10. **QC Acceptance Criteria**
11. Definitions
12. **Minimum Frequency for QC**

Process

- **Measurement Process**



Quality Assurance of Chemical Measurements – John Keenan Taylor

Quality Control

Meet the needs of the users

- Satisfactory
- Adequate
- Dependable
- Economic

Quality Control

40 CFR 136.7

The permittee/laboratory shall use suitable QA/QC procedures when conducting compliance analyses with any part 136 chemical method or an alternative method specified by the permitting authority. These QA/QC procedures are generally included in the analytical method or may be part of the methods compendium for approved Part 136 methods from a consensus organization. For example, Standard Methods contains QA/QC procedures in the Part 1000 section of the Standard Methods Compendium. The permittee/laboratory shall follow these QA/QC procedures, as described in the method or methods compendium. If the method lacks QA/QC procedures, the permittee/laboratory has the following options to comply with the QA/QC requirements:

12 Elements

Quality Control

40 CFR 136.7

- **Use suitable QA/QC procedures**
- **Standard Methods contains QA/QC procedures (part 1000)**
- **The permittee/laboratory shall follow these QA/QC procedures, as described in the method or methods compendium.**
- **If the method lacks QA/QC procedures, the permittee/laboratory has the following options to comply with the QA/QC requirements:**
  - **12 Elements**

Quality Control

Standard Method 1020 B.

Include in each analytical method or SOP the minimum required QC for each analysis.

14 Elements

Control Charts

- Present a graphical Record over time
- Demonstrate Statistical Control
- Detect changes in analytical process
- Accuracy & Precision of the test

Control Charts for Individuals

- Often based on single QC result per batch
- Accept or reject that batch may depend on this one result

Control Chart Types

- Accuracy (means) chart
- Precision (range) chart

Accuracy Control Chart

Accuracy (means) chart

- The accuracy chart for QC samples is constructed from the average and standard deviation of a specified number of measurements of the analyte of interest.

Accuracy Control Chart

- Reagent blanks
- LCSs
- Calibration check standards
- LFBs
- LFMs
- Surrogates

Accuracy Control Chart

Accuracy (means) chart

- Set up using calculated values for:
  - Mean & standard deviation or
  - Percent recovery (if concentration varies)
- Construct a chart for each analytical method
- May need to be matrix specific
- Enter each time QC sample is analyzed
- Re-calculate standard deviation ~20-50 results

Accuracy Control Chart

- Mean & standard deviation or
- Percent recovery (if concentration varies)

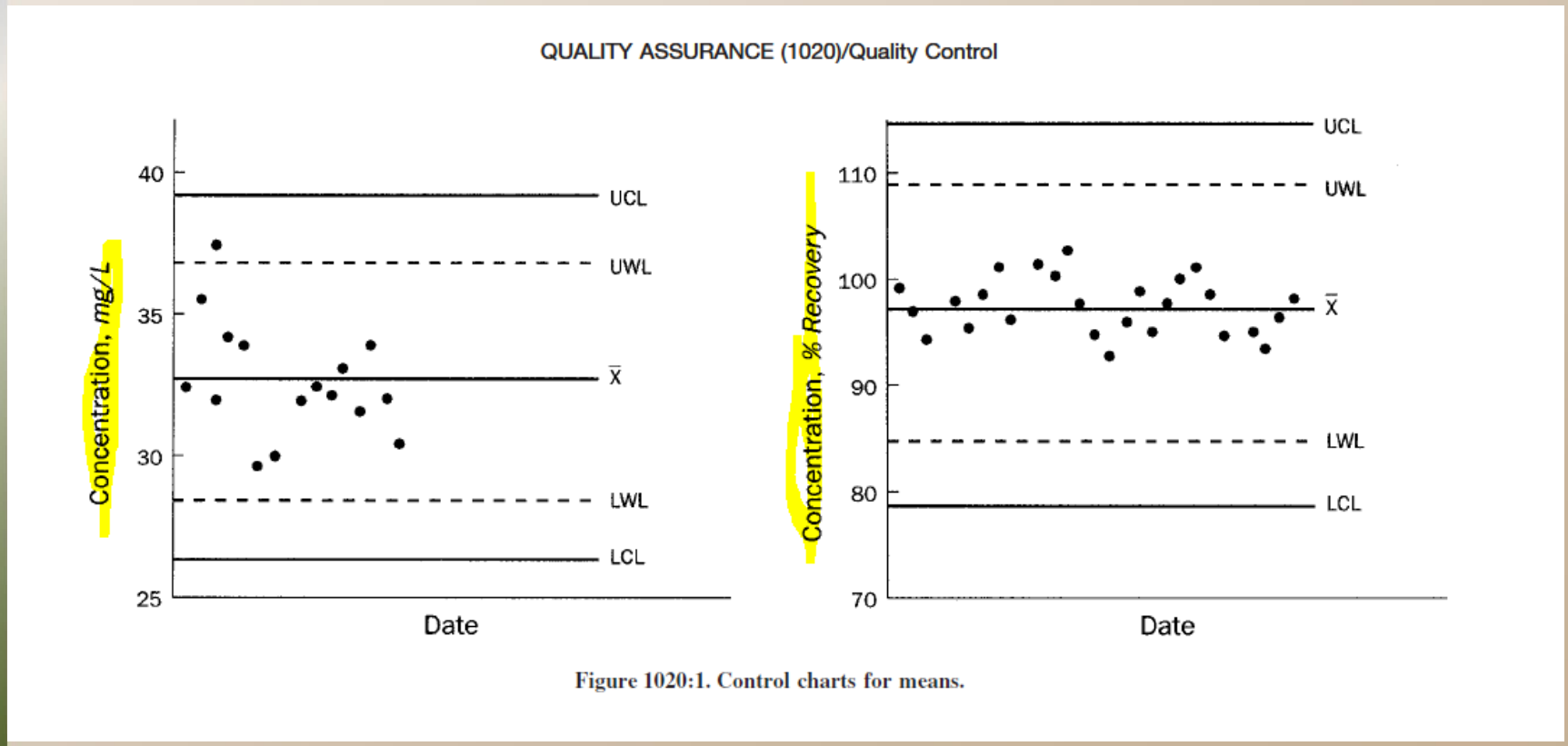


Figure 1020:1. Control charts for means.

Hand Out – Accuracy Control Chart

1. Plot 10 data points along X axis using % recovery data displayed (next slide)
2. Plot Average
3. Plot Warning Limits (2x standard deviation)
4. Plot Control Limits (3x standard deviation)

Note: Excel will be displayed during this process

Calculate Average & Plot

X	y
1	96
2	103
3	92
4	85
5	101
6	
7	
8	
9	
10	

1. Calculate Average = sum of y / # of data points
2. Plot as straight line on your chart

Standard Deviation

X	y
1	96
2	103
3	92
4	85
5	101
6	
7	
8	
9	
10	

Standard Deviation = 7

Warning Limit & Plot

X	y
1	96
2	103
3	92
4	85
5	101
6	
7	
8	
9	
10	

Standard Deviation = 7

1. Calculate Warning Limit = 2 x Standard Deviation
2. Add to average as high WL
3. Subtract from average as low WL
4. Plot both straight lines across your chart

Control Limit

X	y
1	96
2	103
3	92
4	85
5	101
6	
7	
8	
9	
10	

Standard Deviation = 7

1. Calculate Control Limit = 3 x Standard Deviation
2. Add to average as high CL
3. Subtract from average as low CL
4. Plot both straight lines across your chart

Plot next 5 data points along X axis using % recovery data displayed

X	y
1	96
2	103
3	92
4	85
5	101
6	120
7	122
8	115
9	112
10	113

Plot next 5 data points along X axis using % recovery data displayed

X	y
1	96
2	103
3	92
4	85
5	101
6	120
7	122
8	115
9	112
10	113

Points 6 to 10 are now using the WL & CL set by points 1 to 5.

Recap– Accuracy Control Chart

1. Plotted 10 data points along X axis using % recovery data displayed
2. Plotted Average
3. Plotted Warning Limits (2x standard deviation)
4. Plotted Control Limits (3x standard deviation)
5. Compared daily QC value to WL & CL

Precision (range) Control Chart

- Constructed from average and standard deviation of a specified number of measurements.
- Replicate & Duplicate analysis
- %RSD or relative percent different (RPD)
- Baseline is set at zero
  - Only upper WLs & CLs

Precision (range) Control Chart

- Baseline is set at zero
- Only upper WLs & CLs
- Duplicate

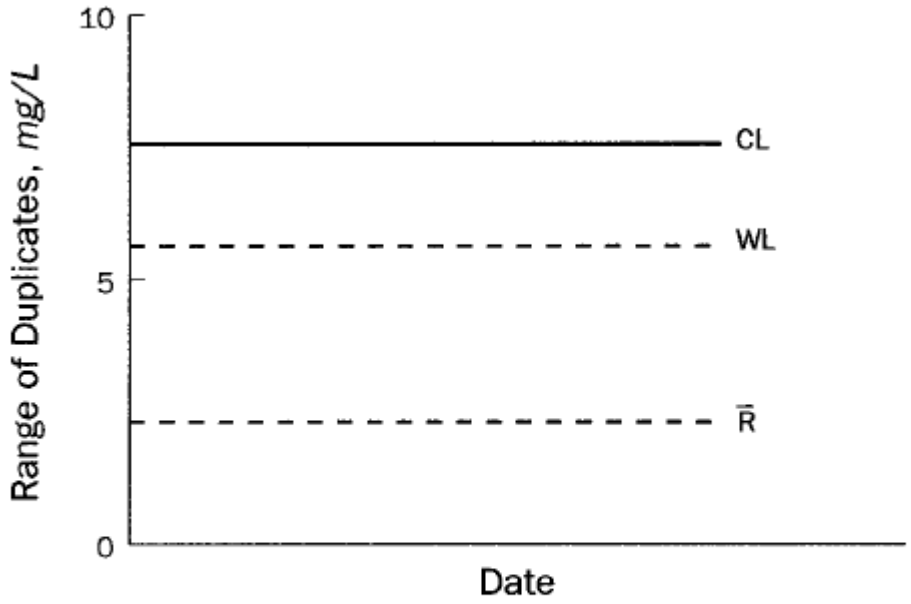


Figure 1020:2. Duplicate analyses of a standard.

Precision (range) Control Chart

- Duplicate analyses of a standard (easier):

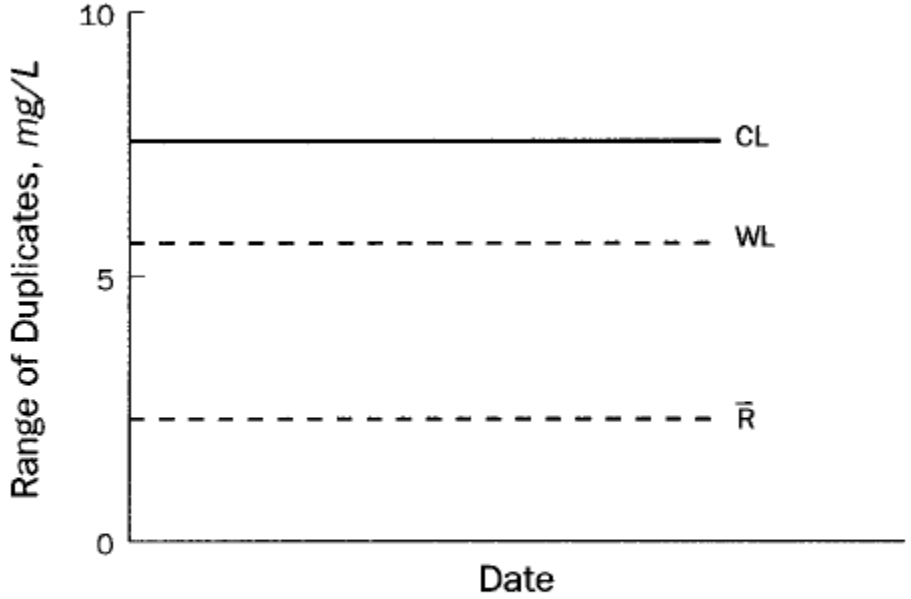


Figure 1020:2. Duplicate analyses of a standard.

Precision (range) Control Chart

- Duplicate analyses of samples (variation in sample concentration)

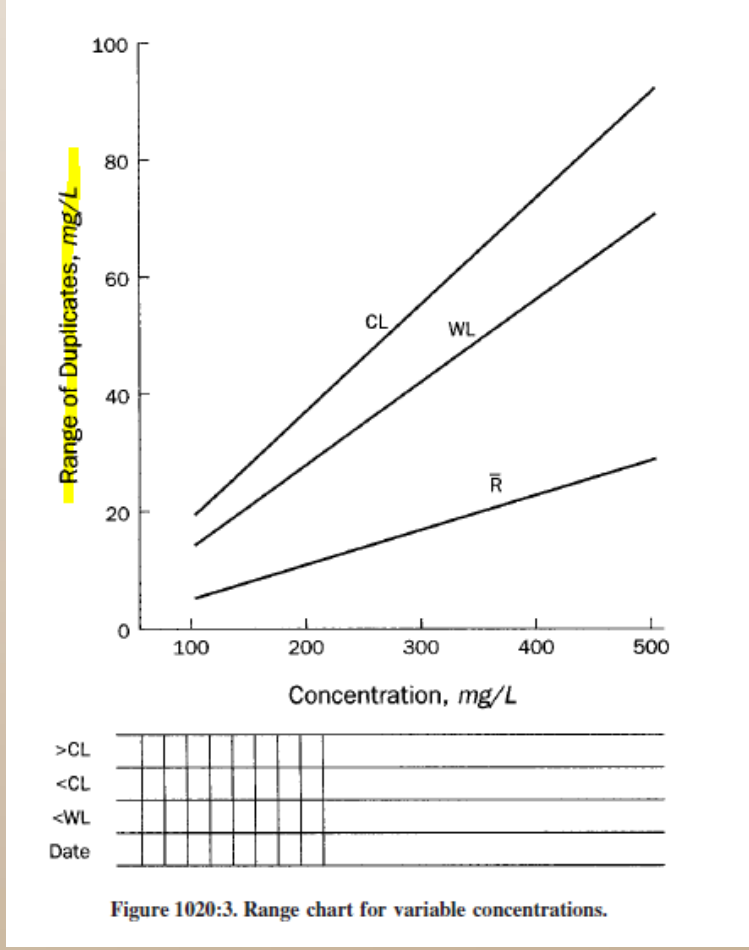


Figure 1020:3. Range chart for variable concentrations.

Precision (range) Control Chart

- Duplicate analyses of samples (variation in sample concentration)
- Relative Percent Difference (RPD)

$$\%RPD = \frac{|(sample\ -duplicate)|}{(sample + duplicate)/2}\ x\ 100$$

  - Normalizes the data

Precision (range) Control Chart

- Duplicate analyses of samples (variation in sample concentration)

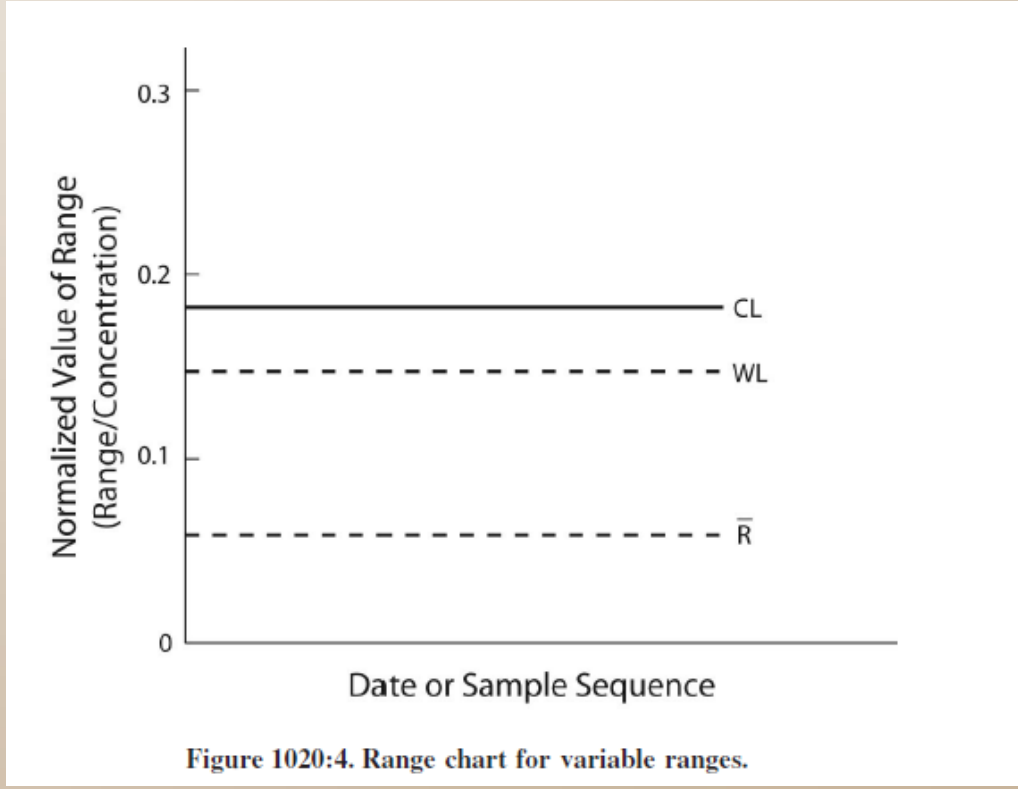


Figure 1020:4. Range chart for variable ranges.

Plot 5 data points on the Precision Chart using %RPD data displayed

X	y
1	22
2	10
3	14
4	18
5	20
6	
7	
8	
9	
10	

Calculate Average & Plot

X	y
1	22
2	10
3	14
4	18
5	20
6	
7	
8	
9	
10	

1. Calculate Average = sum of y / # of data points
2. Plot as straight line on your chart

Standard Deviation

X	y
1	22
2	10
3	14
4	18
5	20
6	
7	
8	
9	
10	

Standard Deviation = 5

1s & Plot

X	y
1	22
2	10
3	14
4	18
5	20
6	
7	
8	
9	
10	

Standard Deviation = 5

1. Calculate 1s= Standard Deviation + Mean
2. Plot straight line across your chart
3. Label line as 1s

Warning Limit & Plot

X	y
1	22
2	10
3	14
4	18
5	20
6	
7	
8	
9	
10	

Standard Deviation = 5

1. Calculate WL= 2 x Standard Deviation + Mean
2. Plot straight line across your chart
3. Label line as WL

Control Limit & Plot

X	y
1	22
2	10
3	14
4	18
5	20
6	
7	
8	
9	
10	

Standard Deviation = 5

1. Calculate CL= 3 x Standard Deviation + Mean
2. Plot straight line across your chart
3. Label line as CL

Plot next 5 data points along X axis using % RPD data displayed

X	y
1	22
2	10
3	14
4	18
5	20
6	23
7	24
8	28
9	25
10	23

Plot next 5 data points along X axis using % recovery data displayed

X	y
1	96
2	103
3	92
4	85
5	101
6	120
7	122
8	115
9	112
10	113

Points 6 to 10 are now compared to the 1s, WL, & CL set by points 1 to 5.

Recap -Control Charts & QC Limits

1. Percent Recovery (unknown compared to known)
2. Relative Percent Difference (duplicate samples comparing two values)
3. X Control Chart

Control Charts & QC Limits

X Control Chart

1. Mean (establish from 20 data points)
2. Warning Limits (2 standard deviations)
3. Control Limits (3 standard deviations)

Control Charts & QC Limits

Control Limits

- Control charts utilize a central line to define and provide the best estimate of the variable plotted.
- Control limits define the bounds of virtually all values produced and in statistical control.

Control Charts & QC Limits

Standard Deviation

- Standard deviation is only an estimate based on limited data.
- Represents the spread around the mean. Is used to establish control of a measurement.

QC Frequency

- Follow your method requirements
- If in doubt contact lab certification program

Chart Analysis

At the 95% confidence level, on average:

- 1 out of 20 exceed the WL
- 1 out of 100 exceed the CL

Chart Analysis

What to do to examine apparent out-of-control changes in method performance?

Chart Analysis

What to do to examine apparent out-of-control changes in method performance?

- **Tradeoff**
  - **Missing a change in method performance (false negative)**

Chart Analysis

What to do to examine apparent out-of-control changes in method performance?

- **Tradeoff**
  - Missing a change in method performance (false negative)

  VERSUS

  - Investigating and acting on an apparent change in method performance when nothing actually changed (false positive)

Chart Analysis

Guidelines from Standard Methods:

- **Control Limit**
- **Warning Limit**
- **Standard Deviation**
- **Trending**

Chart Analysis

Review Accuracy Chart

- **Control Limit** – if 1 measurement exceeds the CL, repeat the analysis immediately.
- If the next sample:
  - within the CL, continue
  - exceeds the CL, discontinue analyses and correct the problem.

Chart Analysis

Review Accuracy Chart

- **Warning Limit** – if 2 of 3 successive points exceed the WL, analyze another sample.
- If the next sample:
  - within the WL, continue
  - exceeds the WL, evaluate bias and correct problem

Chart Analysis

Review Precision Chart

- **Standard Deviation** – if 4 of 5 successive points exceed 1s, or are in decreasing or increasing order, analyze another sample.
- If the next sample:
  - Less than 1s, or changes order, continue
  - Otherwise correct the problem

Chart Analysis

Review Precision Chart

- **Trending** – 7 successive samples are on the same side of the central line
  - Discontinue analyses and correct the problem

Chart Analysis

- **Remember Tradeoff**
  - Missing a change in method performance (false negative)

  VERSUS

  - Investigating and acting on an apparent change in method performance when nothing actually changed (false positive)

Chart Analysis

- Improvement in method precision
  - Never exceed WL
    - Recalculate WL & CL using 10-20 most recent data.
  - Trends in precision can be detected sooner if running averages of 10-20 are kept
  - Trends indicate systematic error
  - Random error is revealed by random exceedance of WLs & CLs.

Corrective Action

Document

Record of action relating to non-conforming event (NCE)

Next Steps

Plan, Do, Check, Analyze

1. Review your policy, process, procedure, and forms
2. Improve and Repeat

QUESTIONS?

Acknowledgements

- CFR
- Standard Methods
- Quality Assurance of Chemical Measurements – John Keenan Taylor
- CLSI – QMS11-A Management of Nonconforming Laboratory Events; Approved Guideline