

Control Charts in Environmental Chemistry

Establishing Control Limits
And
Trend Analysis

Goal of this Discussion

- Start to figure out how to move from the theoretical to the practical.
- Begin building a list of items that should be considered in establishing procedures for creating and using control charts.
- I have no answers, only questions.



Outline

- What a control chart does and doesn't tell you.
- What data should be used to build a control chart.
- What do you do with a control chart once you have one.

References

- SW 846 Method 8000B
- Standard Methods for the Examination of Water and Wastewater, 20th ed, Method 1020
- NIST/SEMATECH e-handbook of Statistical Methods, Chapter 6, Section 3
<http://www.itl.nist.gov/div898/handbook/>

What a Control Chart tells you

- Identifies variations from your routine performance
 - Common Variation (normal precision)
 - Special Variation (theoretically attributable to specific event)

What a Control Chart doesn't tell you

- A Control Chart does not necessarily tell you if you are doing good or doing bad

What data should go in a Control Chart?

- All results? Just those passing QC?
Something in between?
- Laboratories need to develop a policy on what data does and does not go in control charts

Item 1 to Consider

- 8000B 8.7.7 Results used to develop acceptance criteria should meet all other QC criteria associated with the determinative method. For instance...recoveries...should be generated from samples analyzed after a valid GC/MS tune and a valid initial calibration.
- 8270D (11.3.4.2) allows up to 10% of compounds to exceed 20%RSD in ICAL. Should QC from these compounds be in control charts?

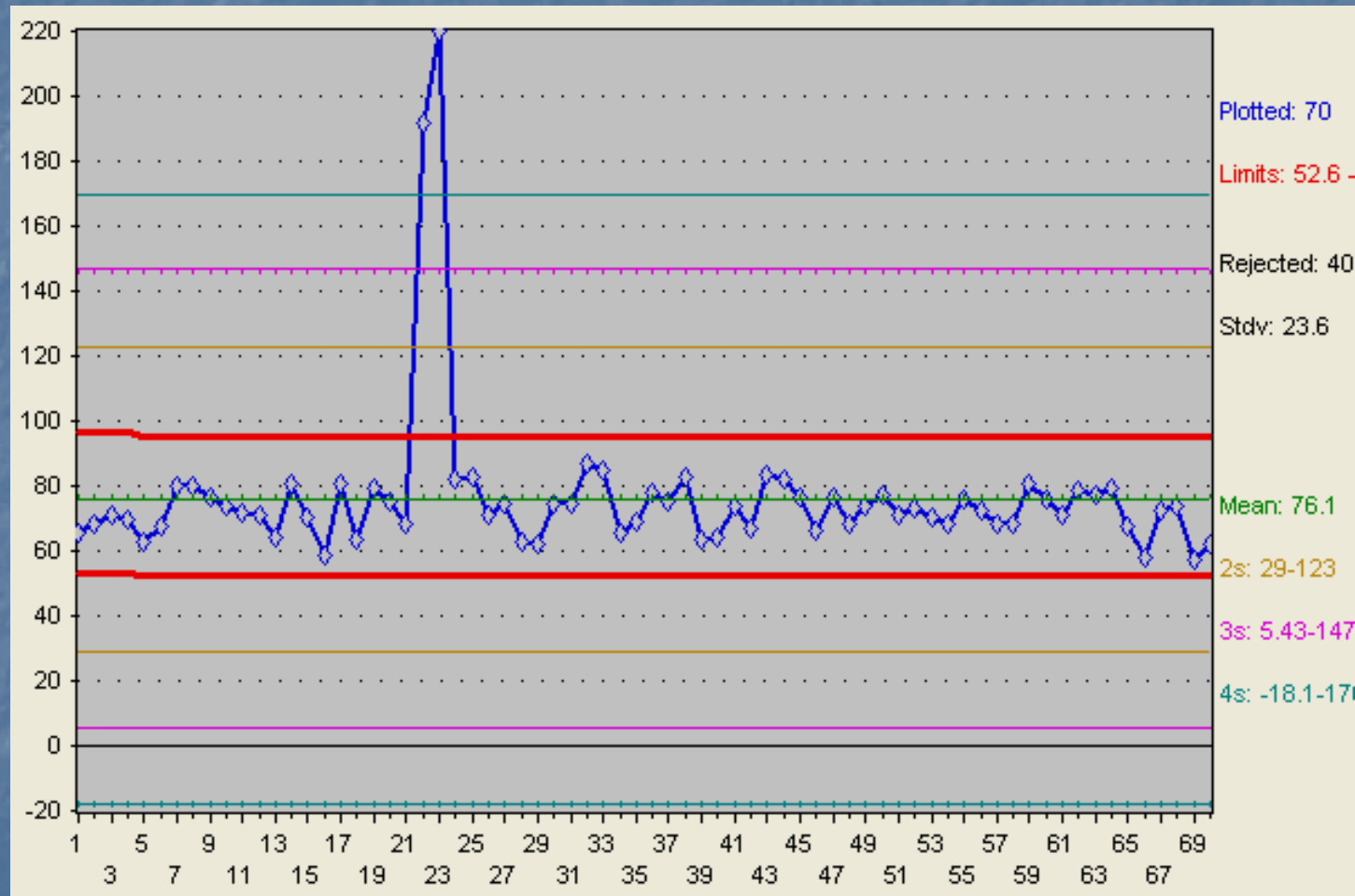
Item 2 to Consider

- Analysis of an LCS (LFB) fails. A re-analysis passes. Should first, second, or both of these analyses go in control chart?
 - An LCS represents the entire system (both prep and analysis). Both analyses represent just one prep.
 - What about Volatiles or AutoAnalyzers?

Item 3 to Consider

- Should MS recoveries used in control charts be limited to a minimum spike/background ratio? e.g. 1/5
- 8000B (8.5.4.1 and 8.7.8)
 - (8.5.4.1) Acceptance criteria are a function of spike concentration.
 - (8.7.8) Spiking Levels should be within a factor of 2.

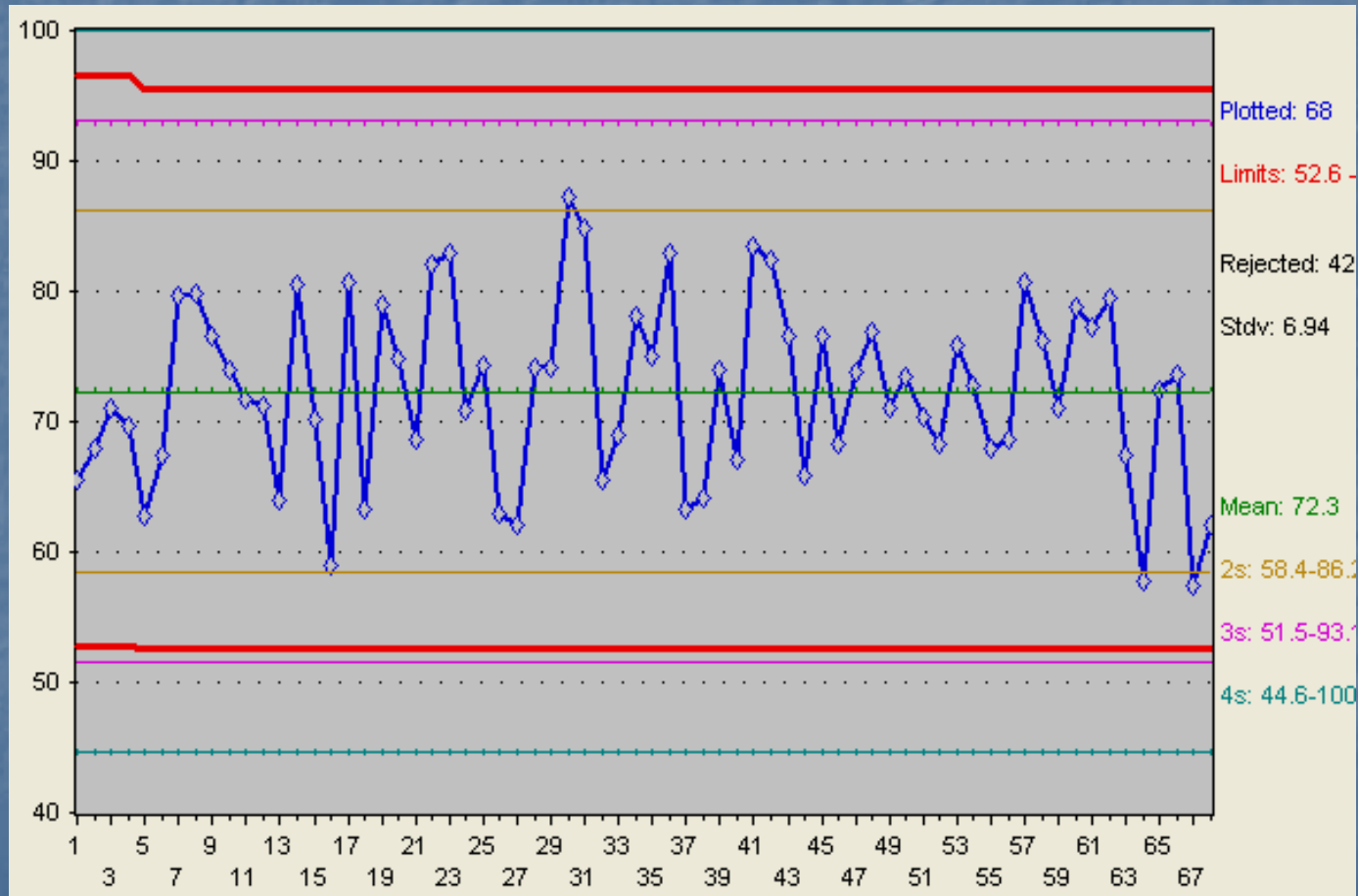
2-Methylnaphthalene MS recoveries



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MS/MSD with High Background Removed



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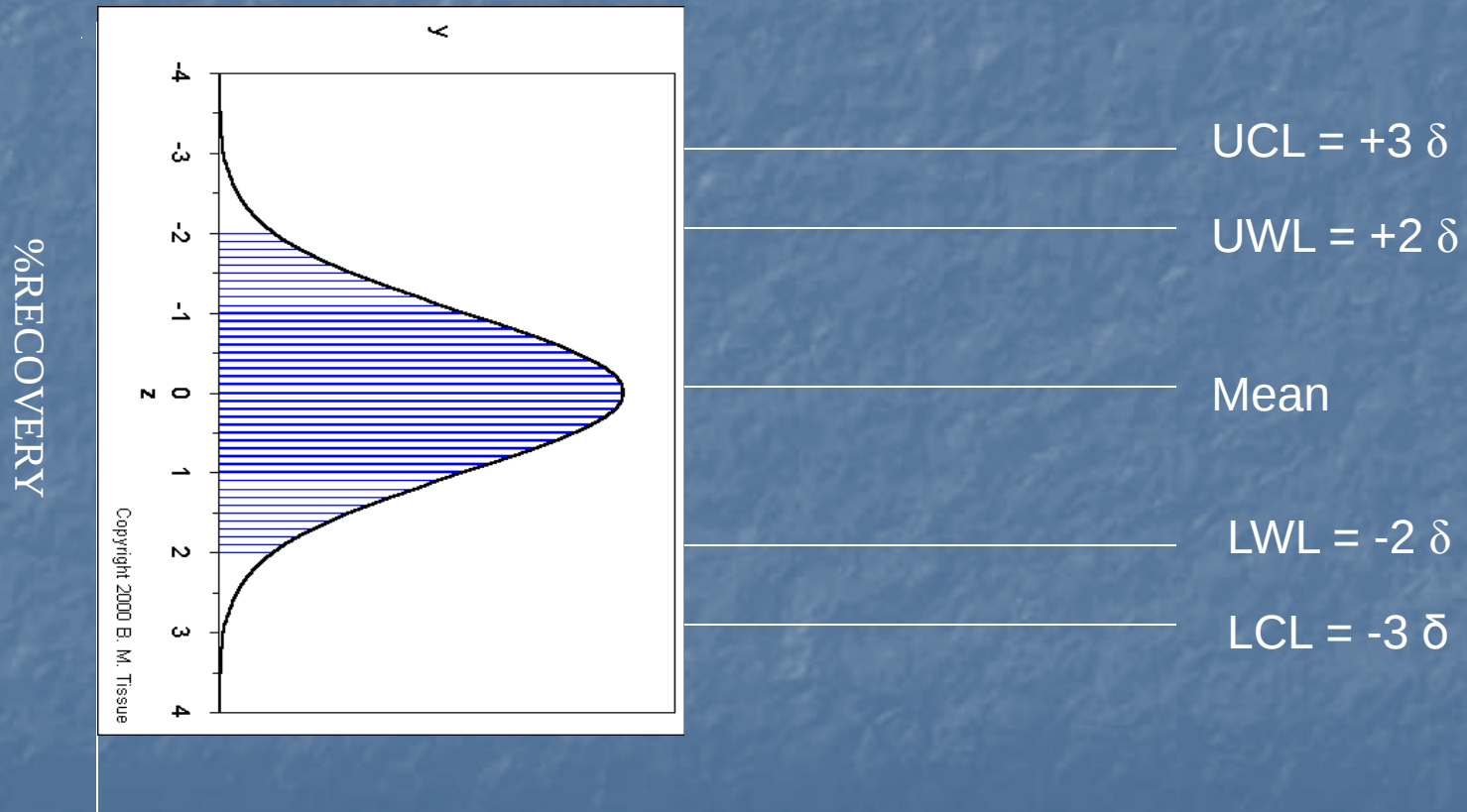
Item 4 to Consider

- Should 'wild' recoveries be excluded from control charts? e.g. $>200\%$ or $<0\%$
- 8000B (8.7.9) Don't discard data that doesn't meet preconceived notion of acceptable. Use an outlier test.

Item 5 to Consider

- Should MSDs and LCSDs be included in MS and LCS charts?
 - How would outlier tests be impacted if they are included or excluded?

Establishing In-House Limits



Item 6 to Consider

- Should there be a limit to in-house limits?
- 8000 8.5.4 Recoveries should be 70-130
 - Are limits of 63% to 114% OK?
 - Are limits of 5% to 180% OK?

Evaluating Data from 3s Control Charts

- 1 in 371 observations will fall outside control limits with no assignable cause. (NIST Handbook Section 6.3.2.1)
Otherwise, a special variation is the cause. (SM 1020 states 1/100)
 - This is true only when using 3s limits (as opposed to method defined) that accurately represent the random variability of the method.

Evaluating Data with Control Charts

- Exceeding a Control Limit:
 - SM 1020 12 (c) Discontinue analysis and correct the problem.
 - SM 1020 14 Qualifying data does not eliminate the need to take corrective actions...
 - Method 8000B 8.7.4. Once the problem has been identified and addressed ...

WECO Rules

(from NIST Handbook)

What are the WECO rules for signaling "Out of Control"?

WECO stands for Western Electric Company Rules

Any Point Above +3 Sigma

----- +3 σ LIMIT

2 Out of the Last 3 Points Above +2 Sigma

----- +2 σ LIMIT

4 Out of the Last 5 Points Above +1 Sigma

----- +1 σ LIMIT

8 Consecutive Points on This Side of Control Line

===== CENTER LINE

8 Consecutive Points on This Side of Control Line

----- -1 σ LIMIT

4 Out of the Last 5 Points Below - 1 Sigma

----- -2 σ LIMIT

2 Out of the Last 3 Points Below -2 Sigma

----- -3 σ LIMIT

Any Point Below -3 Sigma

Trend Rules: 6 in a row trending up or down. 14 in a row alternating up and down

SM 1020 Section 12c

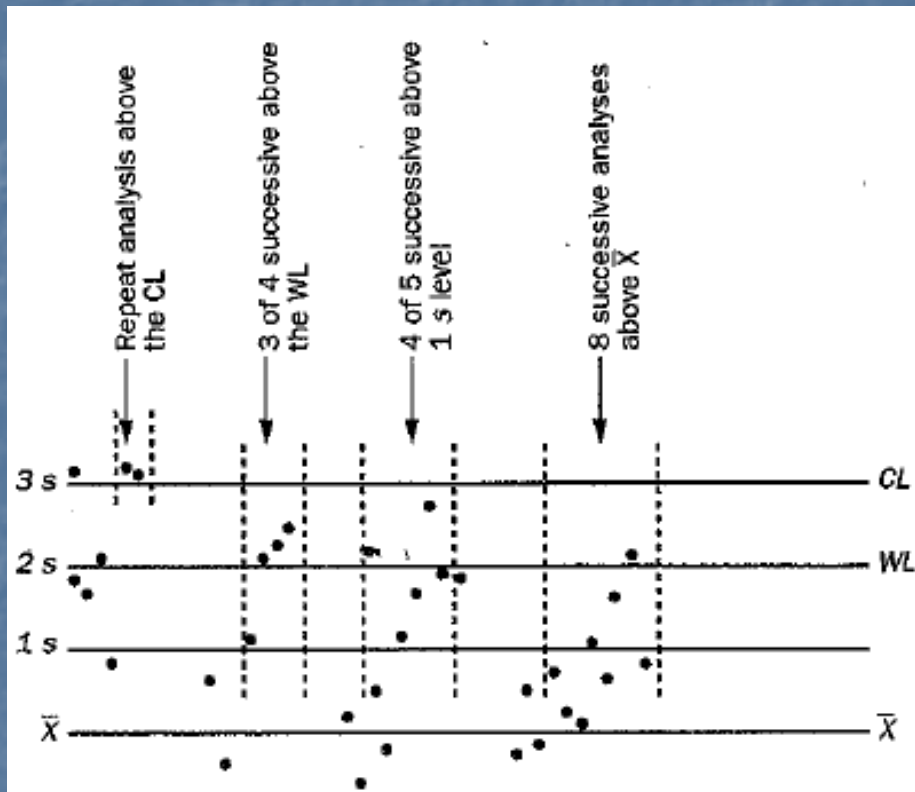
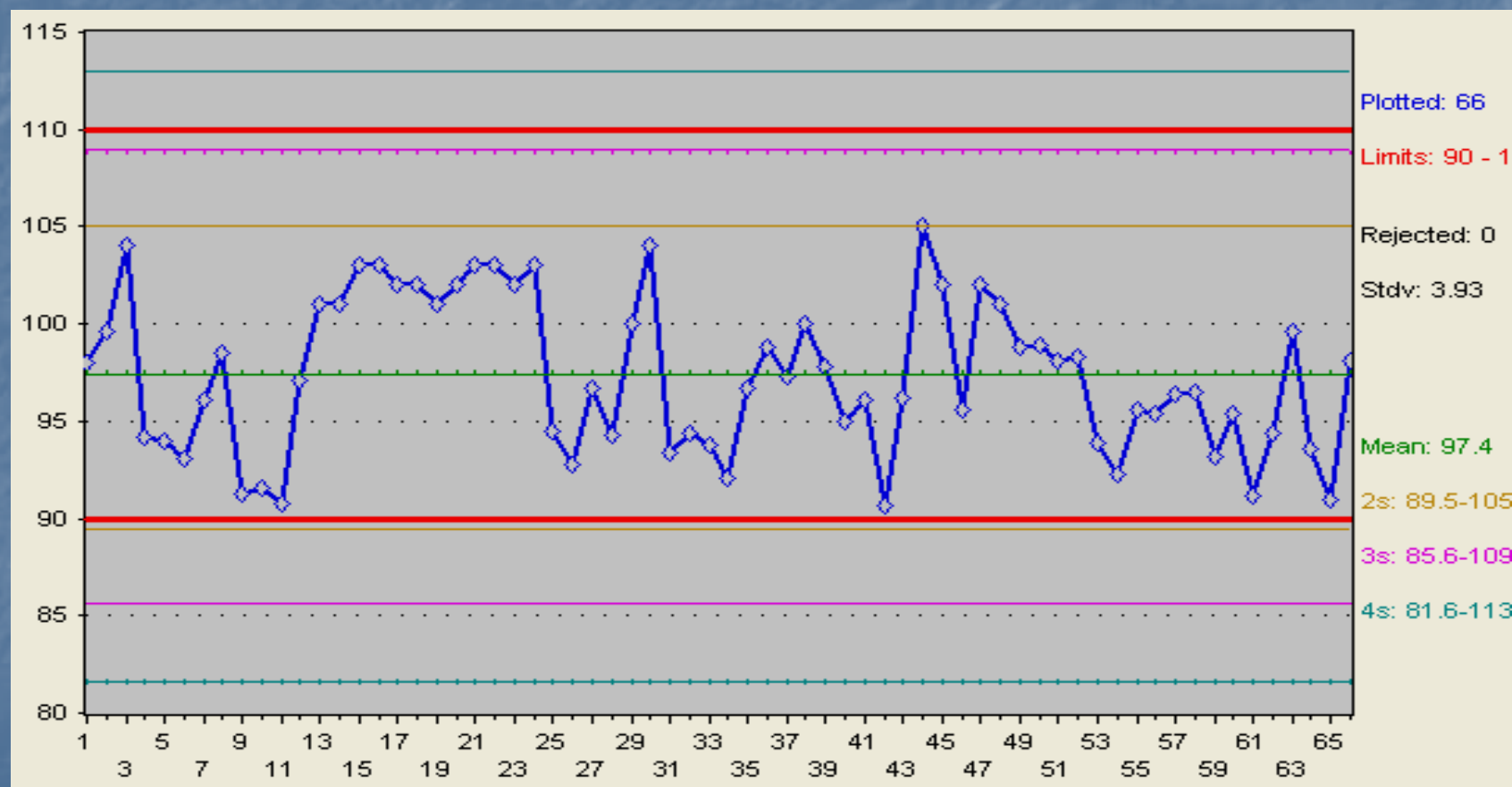
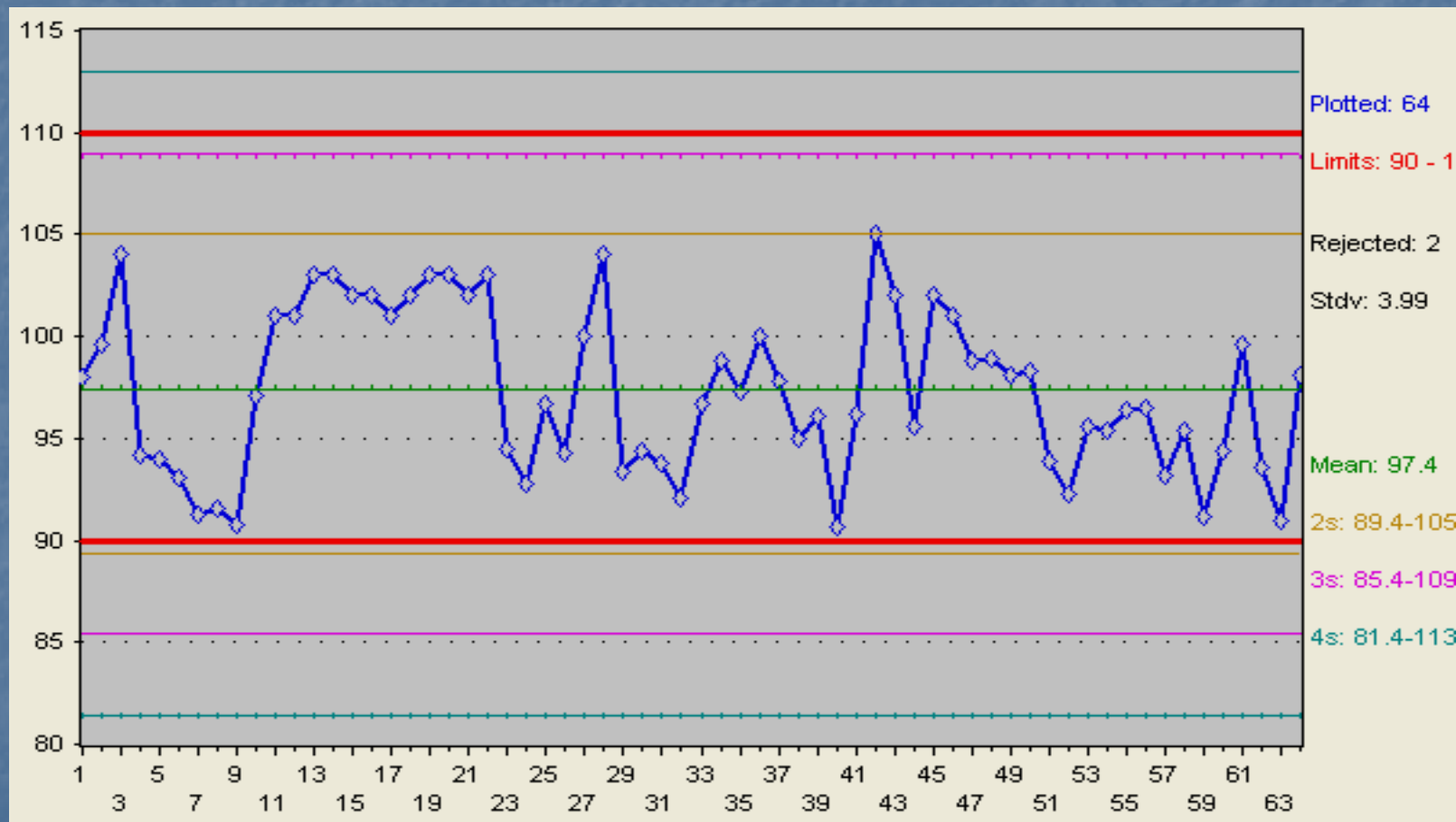


Figure 1020:5. Means control chart with out-of-control data (upper half).

Cyanide LCS Recovery (are all out of control situations really out of control?)



Preventive Action from Trend Analysis



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Item 7 to Consider

- Clearly identify when a corrective action (root cause analysis) is required. (or at least try to.)

Item 8 to Consider

- Should an LCS (LFB) failure outside of method defined acceptance criteria receive the same level of corrective action as perhaps required by an LCS failure of in-house limits at 3s limits?
 - Method defined limits may be tighter or wider than 3s the normal variation of the data.
 - Usually optional to calculate in-house limits

Summary

- Establish procedures to define what data goes into control charts
 - Control charts should include all data that represent the normal variation of the method
 - Control charts should not include data generated when a known problem (special variation) is present. (8000B 8.7.7)

Summary

- Develop procedures to define how control charts are evaluated.
 - When is corrective action, beyond re-analysis or qualifying data required?
 - Are results from in-house 3s limits evaluated differently than those from methods with defined limits?
 - Don't box yourself in with too restrictive corrective actions beyond those defined by the method or accreditation standard.