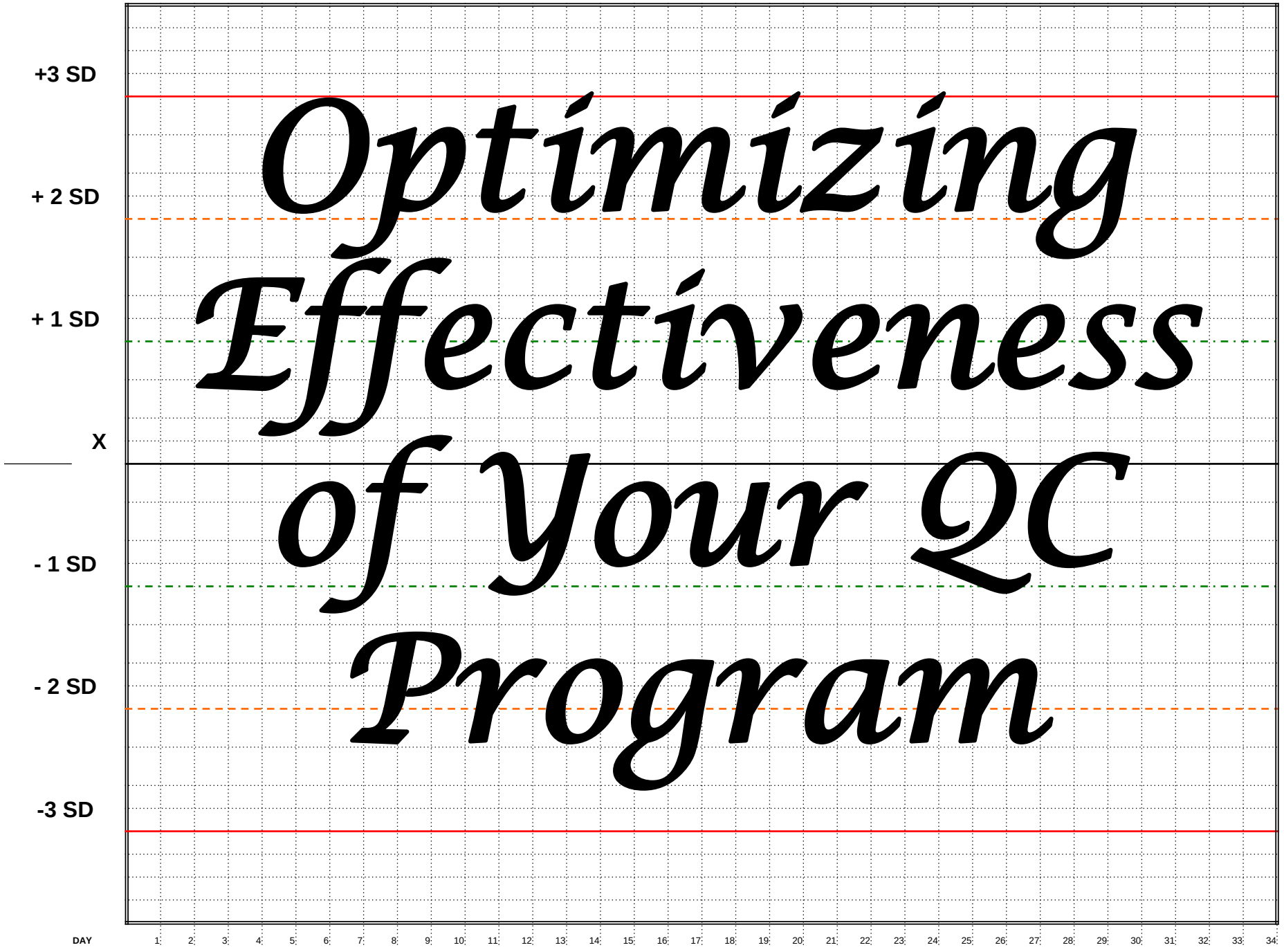

+3 SD
+ 2 SD
+ 1 SD
X
- 1 SD
- 2 SD
-3 SD
DAY
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34
Optimizing Effectiveness of Your QC Program

"Theoretically, laboratory QC is easy. Simply calculate the mean and SD for a set of data and use one or more QC rules to warn when data fall outside the acceptable range."

"Unfortunately, many pitfalls exist that may lead to incorrect conclusion about method performance."

Zoe Brooks

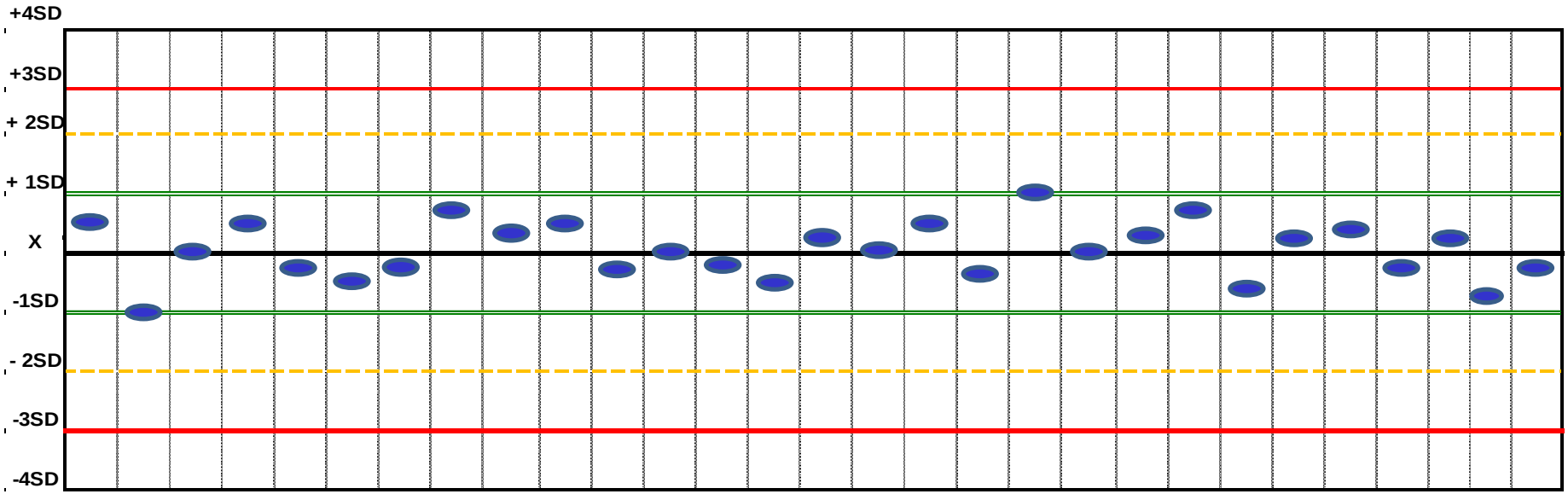
Brooks, Zoe C. *Performance-Driven Quality Control*, 2001, p 70.

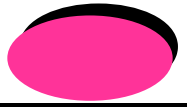
"It [QC] still relies on the right mean, the right SD, the right control limits, the right rules and numbers of control measurements, and the right interpretation of control data points."

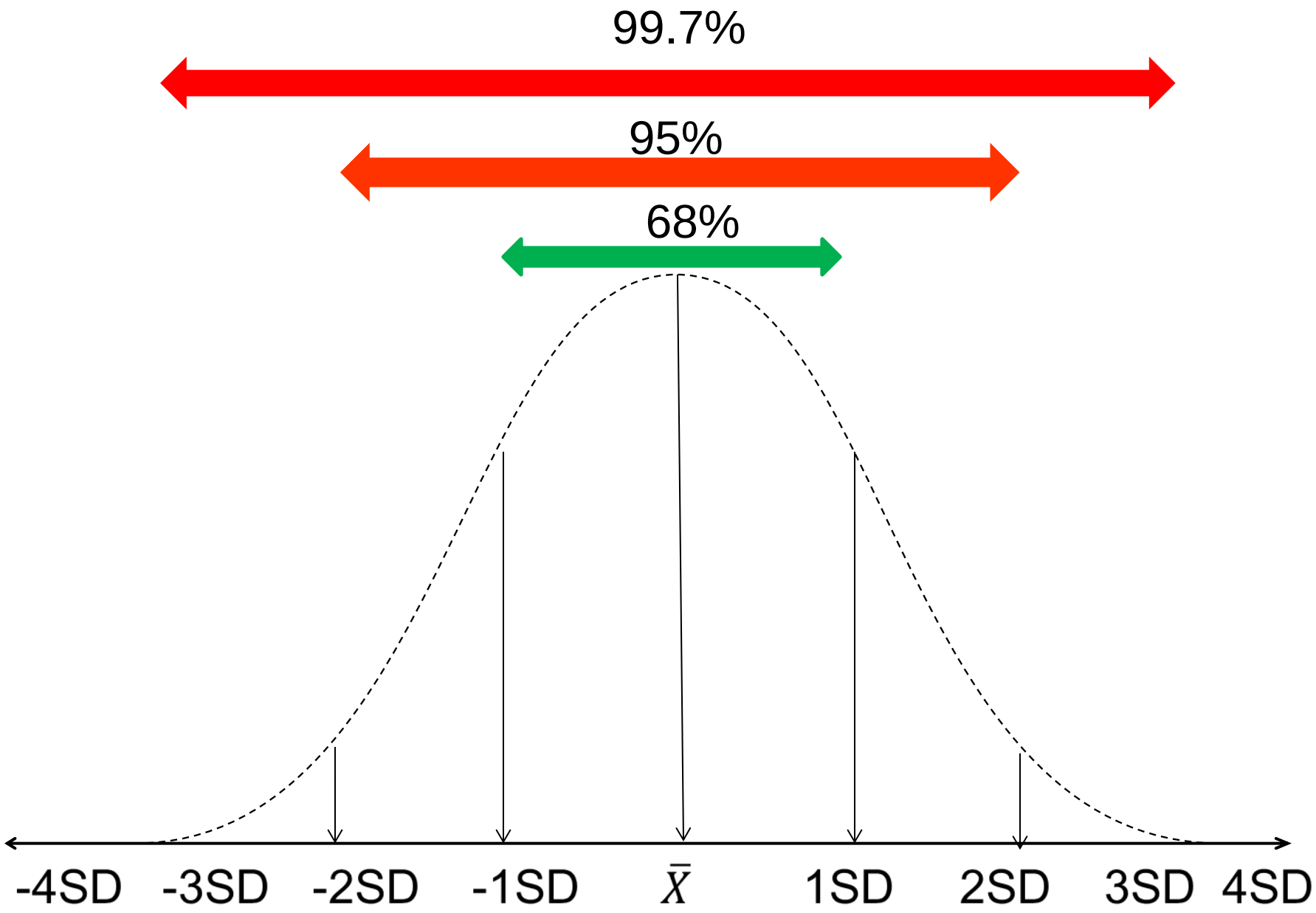
"If you get one part of this system wrong, it can throw off the correct implementation."

Dr. James Westgard

Is this the right L-J chart for this method?

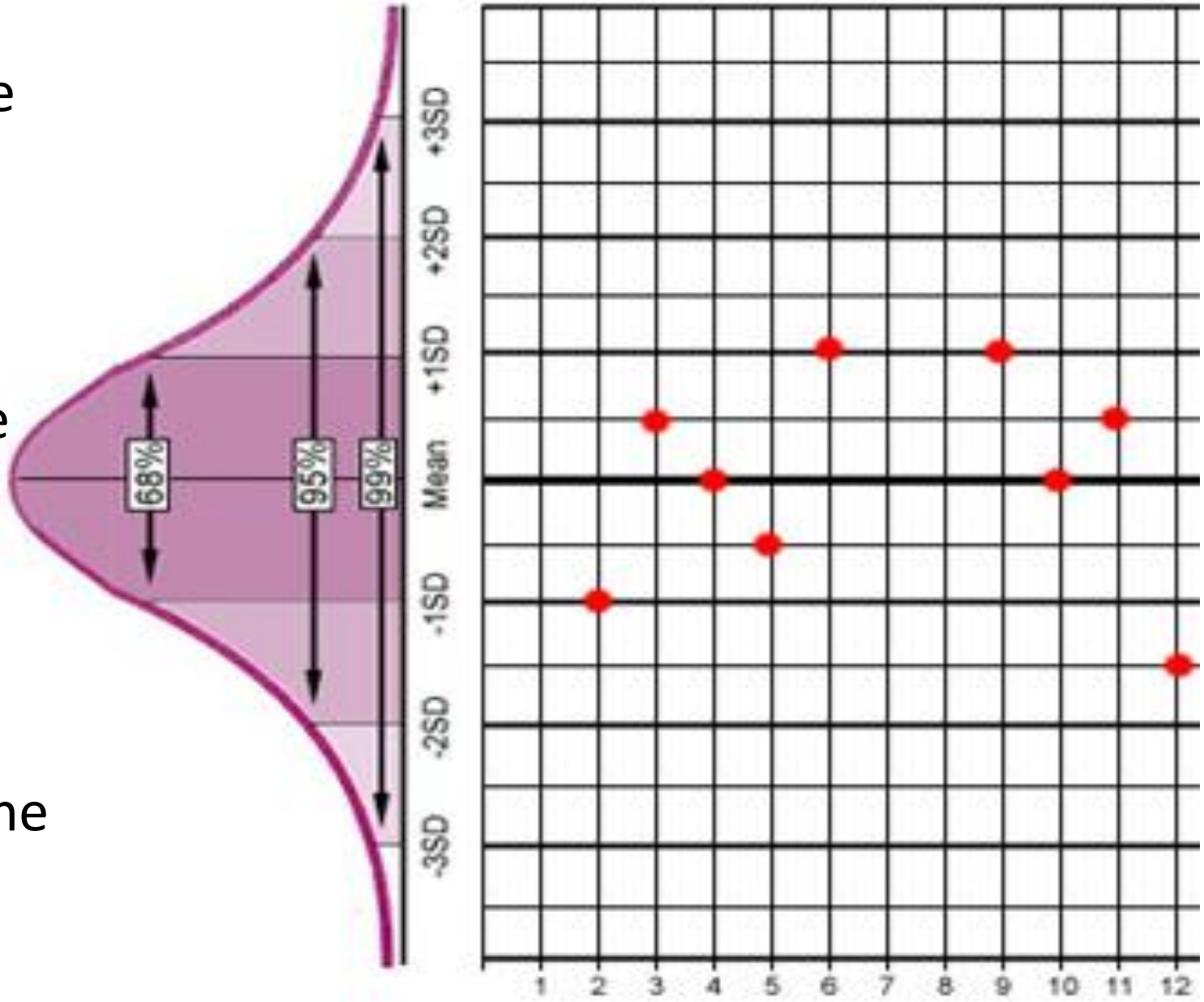


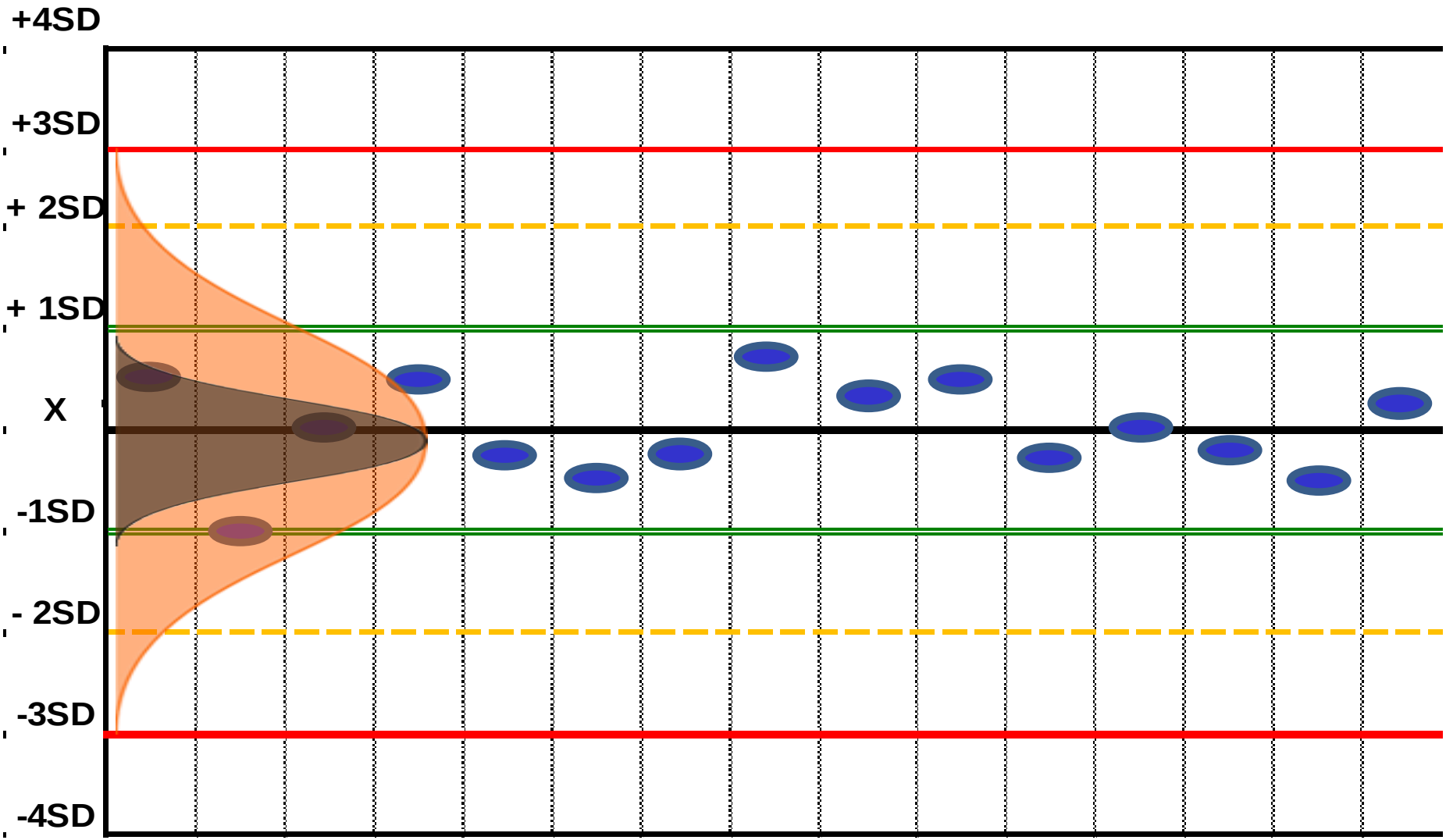
	YES – Move your LEFT hand forward
	NO – Move your RIGHT hand forward


99.7%
95%
68%
-4SD
-3SD
-2SD
-1SD
$\bar{X}$
1SD
2SD
3SD
4SD

Levey-Jennings Chart

QC analysis relies on the ability to predict that any stable system will produce the same distribution of data on both the Gaussian curve and the QC chart.



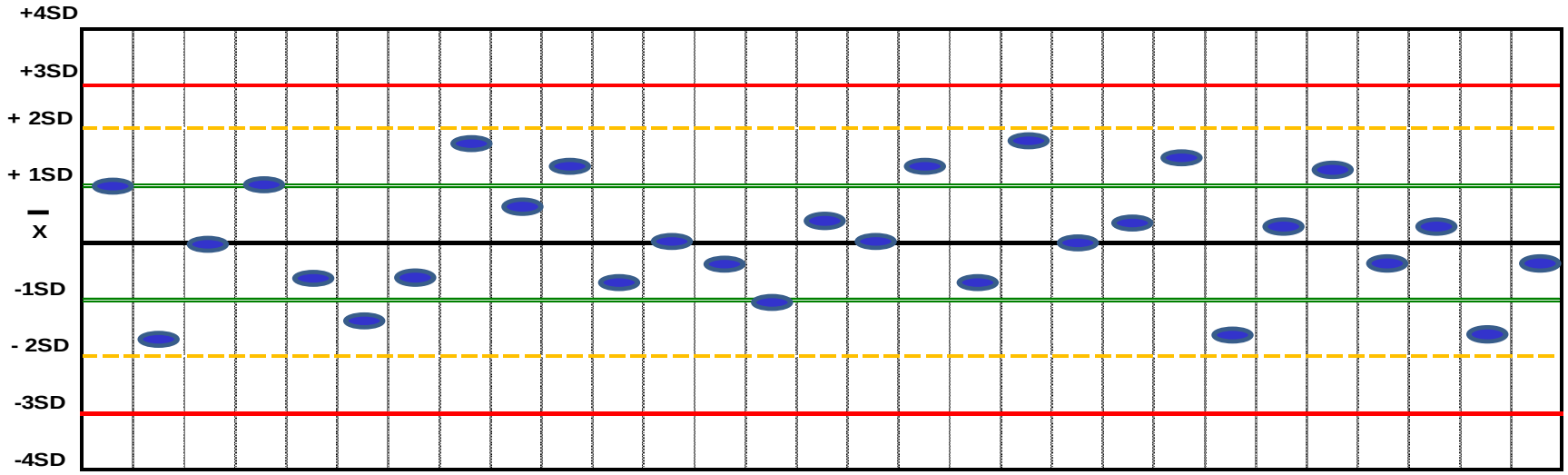

+4SD
+3SD
+ 2SD
+ 1SD
X
-1SD
- 2SD
-3SD
-4SD

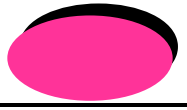
QC Problem #1

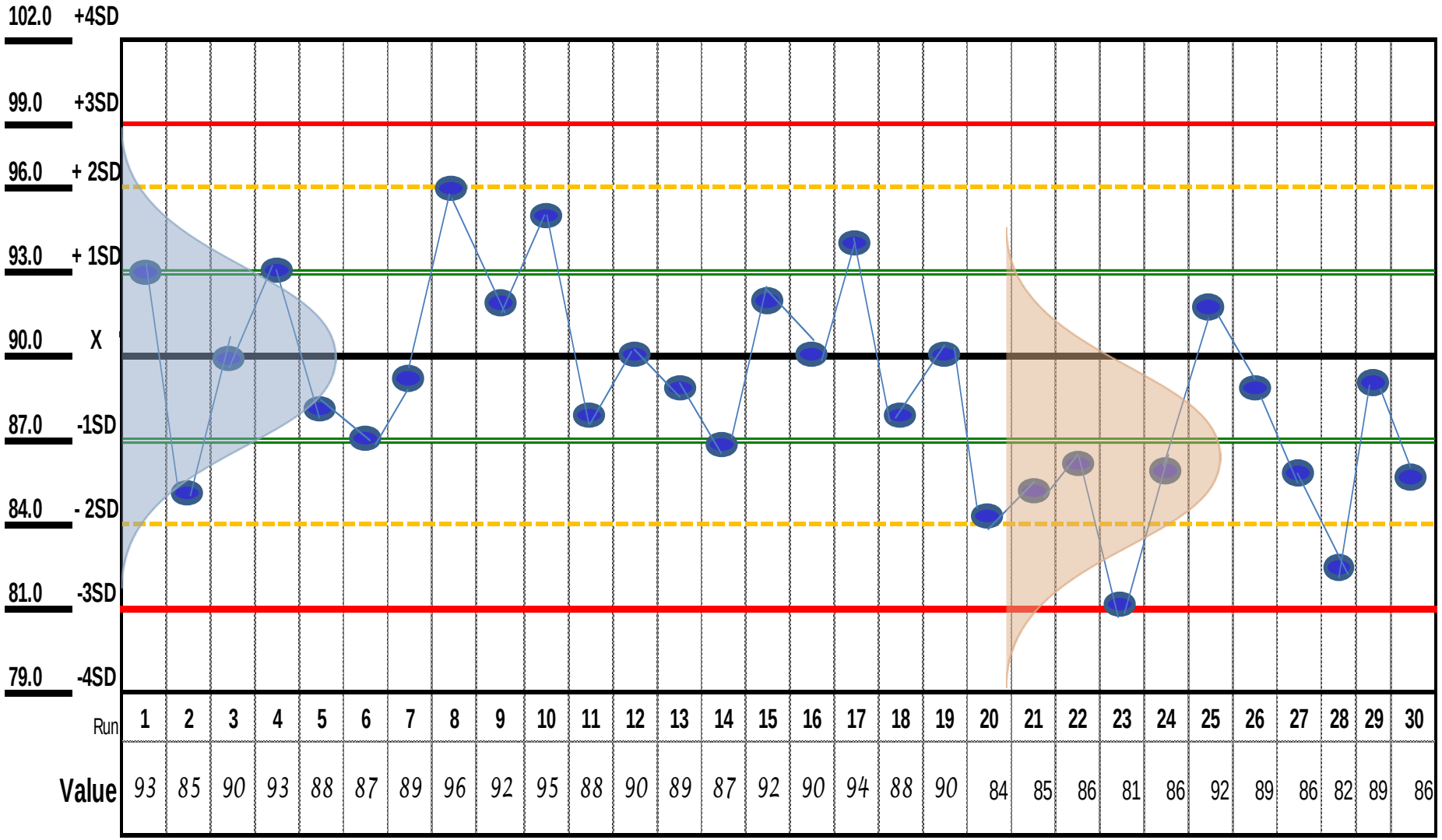
The Gaussian distribution of the current stable method is not correctly captured on the L-J chart.

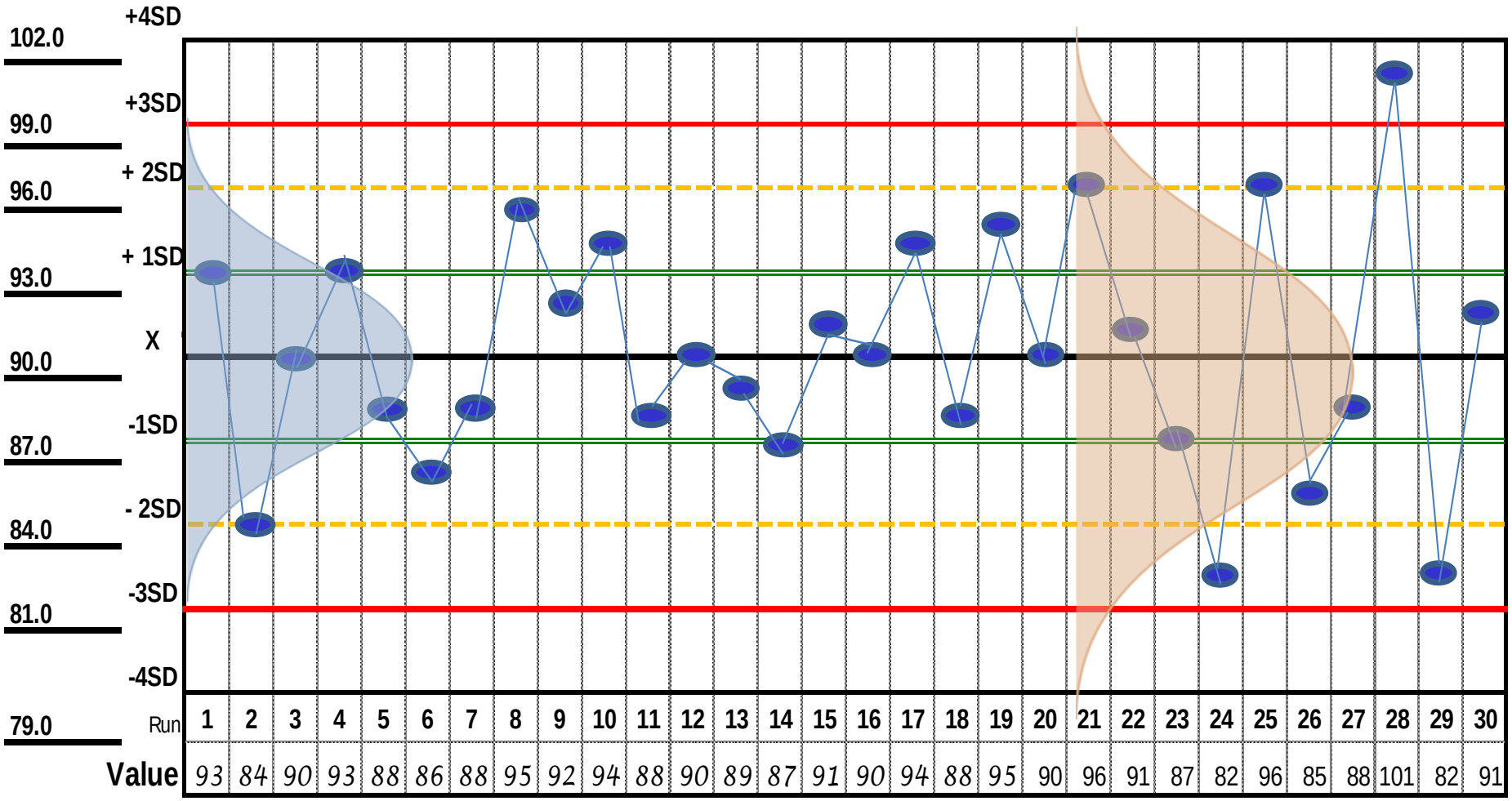
When the wrong mean and/or wrong SD is assigned to the chart it renders our QC rules **ineffective**. Therefore, effective monitoring begins with the right chart.

From this L-J Chart, we can conclude the method is good?



	YES – Move your LEFT hand forward
	NO – Move your RIGHT hand forward


102.0 +4SD
99.0 +3SD
96.0 + 2SD
93.0 + 1SD
90.0 X
87.0 -1SD
84.0 - 2SD
81.0 -3SD
79.0 -4SD
Run 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
Value 93 85 90 93 88 87 89 96 92 95 88 90 89 87 92 90 94 88 90 84 85 86 81 86 92 89 86 82 89 86


+4SD
102.0
+3SD
99.0
+ 2SD
96.0
+ 1SD
93.0
X
90.0
-1SD
87.0
- 2SD
84.0
-3SD
81.0
-4SD
79.0
Run 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
Value 93 84 90 93 88 86 88 95 92 94 88 90 89 87 91 90 94 88 95 90 96 91 87 82 96 85 88 101 82 91

QC Problem #2

The L-J chart cannot tell you about the acceptability of the method's performance.

L-J charts can only tell you if the method remains stable or has undergone a change in accuracy or an increase in imprecision.

“If you cannot specify the quality requirement, there is no point to quality control”

Dr. James Westgard

For Quality, you will need 4 Key Numbers

Mean

SD **WHERE WE ARE**

True Value

WHERE WE WANT TO BE

Total Allowable Error (TE_A)

$TE < TE_A$

TE is the total variation of our value from the true value

TE_A specifies the **maximum** acceptable variation from the true value.

ISO 15189

Standard: *The specified requirements (performance specifications) for each examination procedure shall relate to the intended use of that examination.*

ISO 15189: 5.5.1.1

ISO 15189 in Layman's Terms

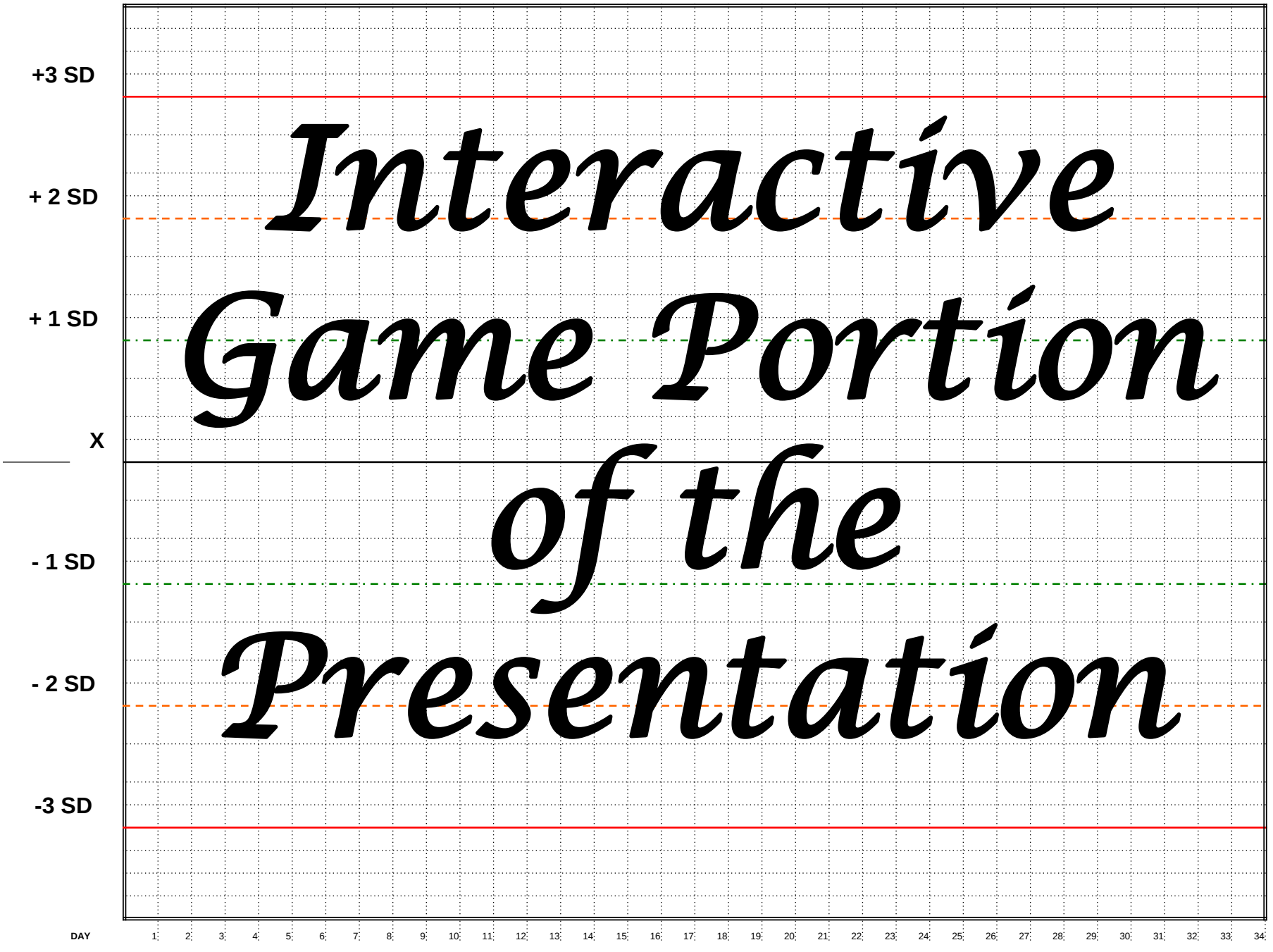
Standard: *The specified requirements (WHERE WE ARE) for each examination procedure shall relate to WHERE WE WANT TO BE.*

ISO 15189: 5.5.1.1

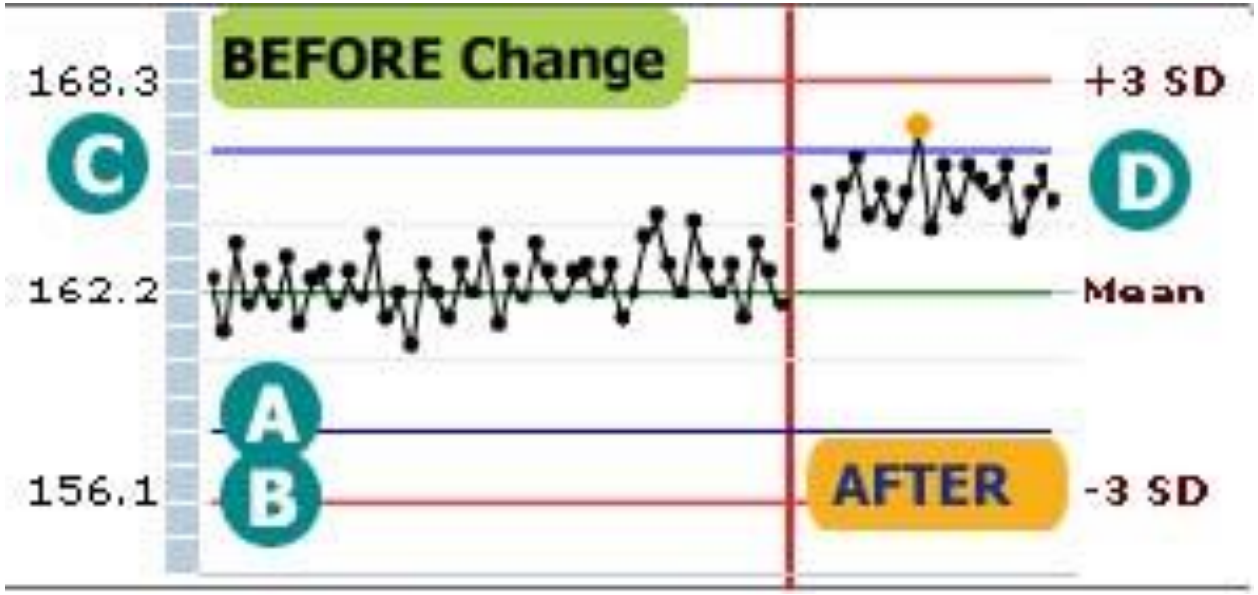
QC Problem #3

Without first setting quality goals, you are only practicing arbitrary control and not quality control.

Performance-driven QC (applying quality goals) is required for today's top laboratories seeking distinction through accreditation.


+3 SD
+ 2 SD
+ 1 SD
X
- 1 SD
- 2 SD
-3 SD
DAY
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34
Interactive Game Portion of the Presentation

Each chart shows 50 stable results before the line, and 20 points after a simulated change.

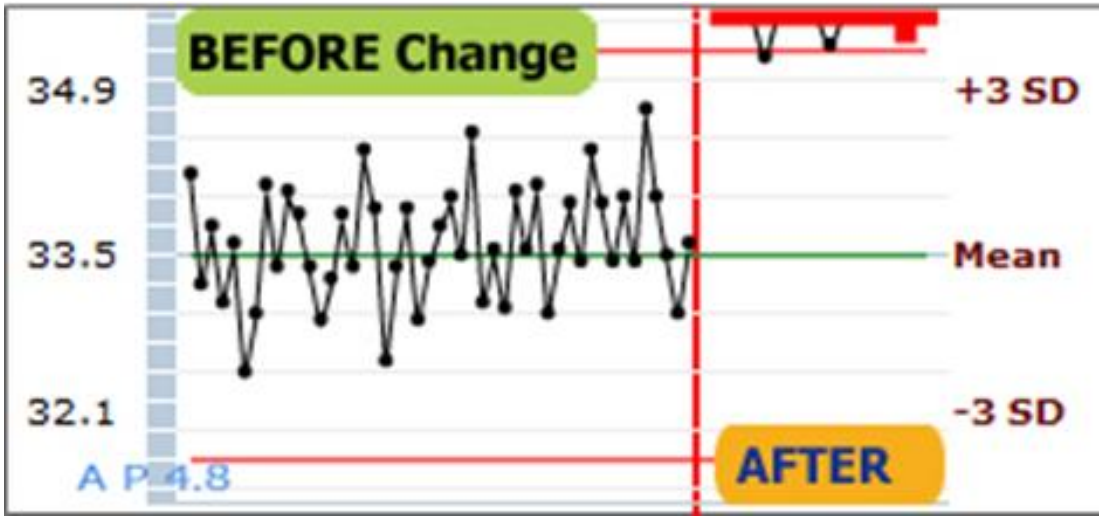


A. Blue lines are drawn at ± 2SD
B. Red lines show reject rules (e.g. ± 3SD)
C. The numbers show the mean and ± 3SD limit
D. Labels show mean and ± 3SD limits

1:3s – rejection
1:2s – warning

Each QC chart if based on actual laboratory data!

#1 AO4



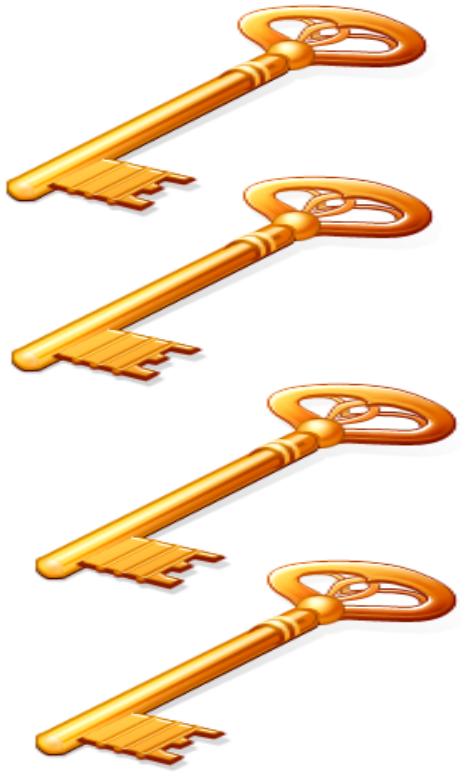
BEFORE the change at the **red** line, this chart shows:

a. acceptable precision and accuracy
b. a positive bias
c. a negative bias
d. a problem with precision
e. The chart does not convey the answer

AFTER the change at the **red** line on chart, I would:

a. consider results OK to report
b. stop to investigate after 1 run
c. stop after 2-5 runs
d. stop after >5 runs
e. not stop now, but investigate later
f. chart does not convey the answer

You need 4 Key Numbers to Evaluate Method Performance



Mean

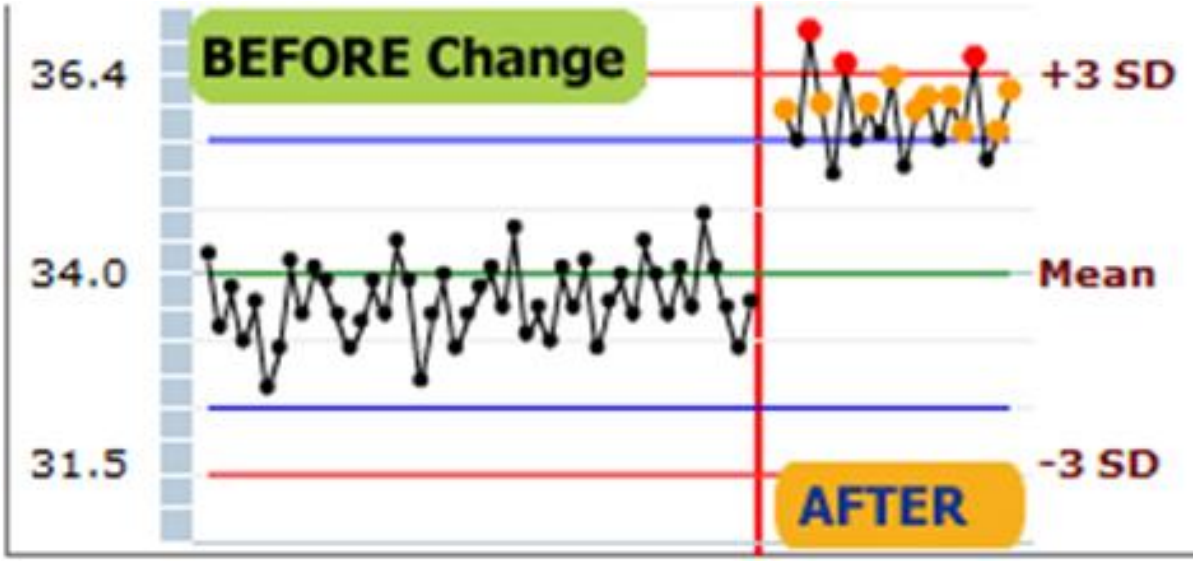
SD

True Value

Total Allowable Error (TE_A)

Acceptable Performance $TE < TE_A$

#2 A2L



BEFORE the change at the **red** line, this chart shows:

a. acceptable precision and accuracy
b. a positive bias
c. a negative bias
d. a problem with precision
★ e. The chart does not convey the answer

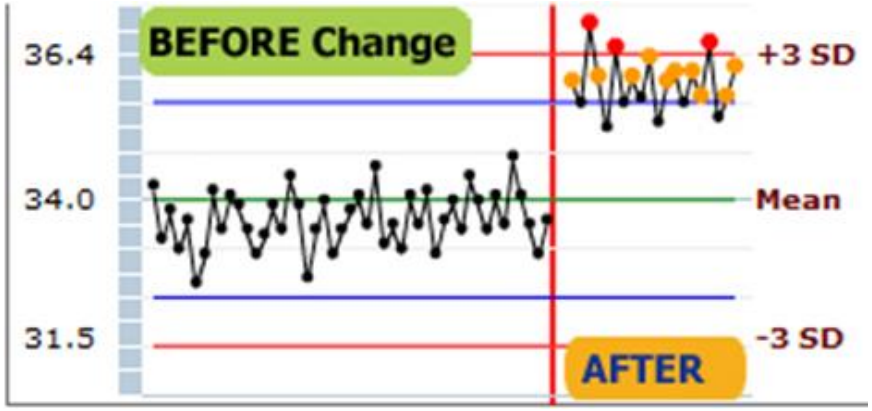
AFTER the change at the **red** line on chart, I would:

a. consider results OK to report
b. stop to investigate after 1 run
★ c. stop after 2-5 runs
d. stop after >5 runs
e. not stop now, but investigate later
f. chart does not convey the answer

Same Data Points Used in All 3 Charts

#2 A2L

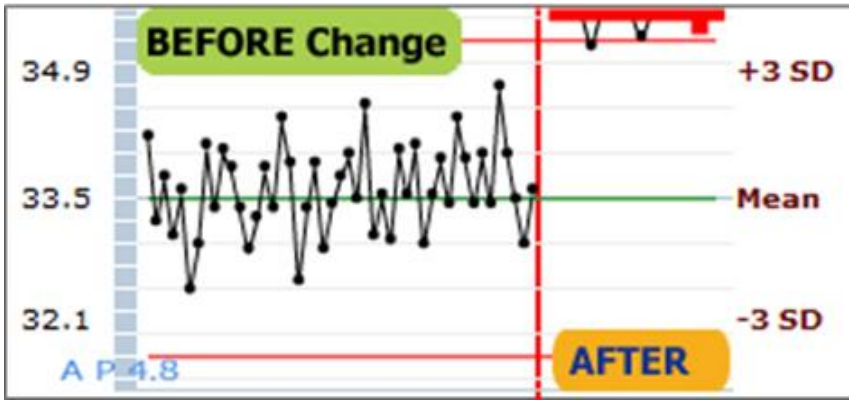
Wrong mean and SD assigned to chart



stop after **2-5** runs

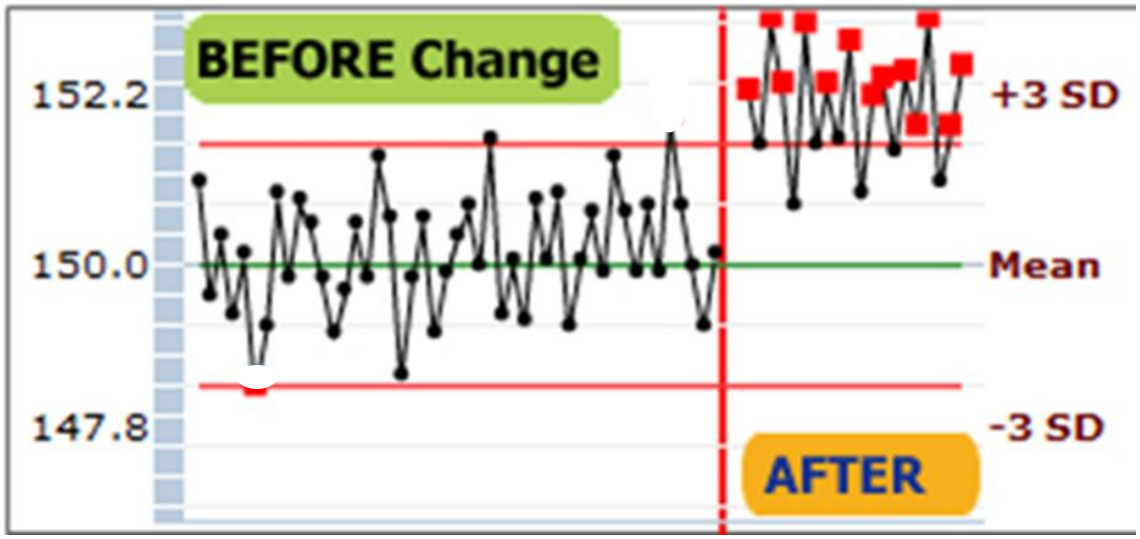
#1 AO4

Observed mean and SD assigned to chart



stop to investigate after **1** run

#3 N1O



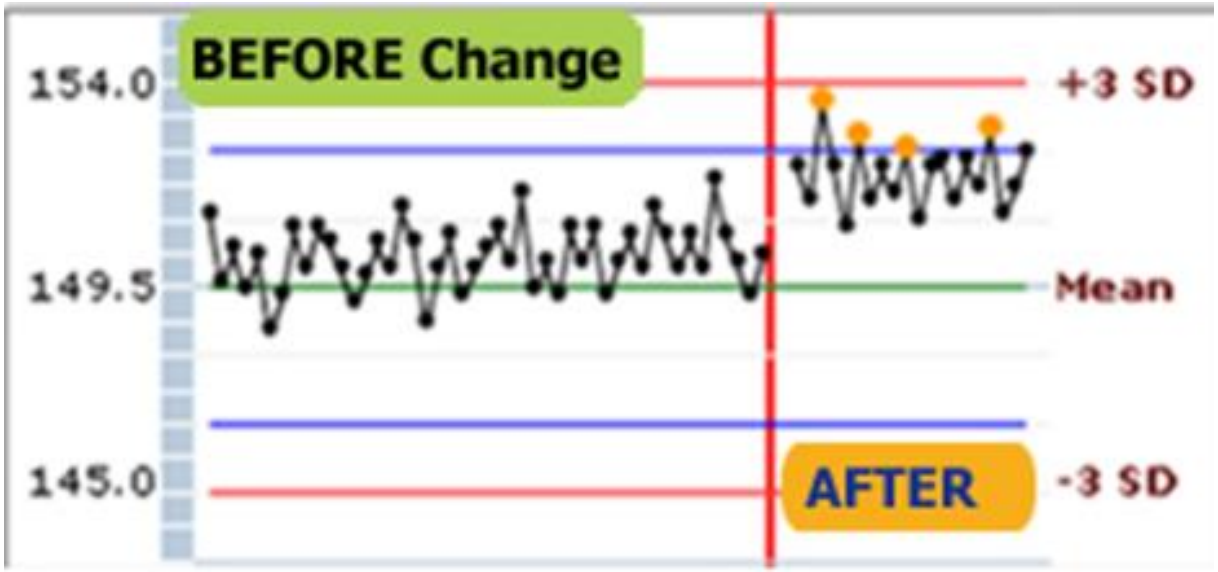
BEFORE the change at the **red** line, this chart shows:

a. acceptable precision and accuracy
b. a positive bias
c. a negative bias
d. a problem with precision
e. The chart does not convey the answer

AFTER the change at the **red** line on chart, I would:

a. consider results OK to report
b. stop to investigate after 1 run
c. stop after 2-5 runs
d. stop after >5 runs
e. not stop now, but investigate later
f. chart does not convey the answer

#4 NLR



BEFORE the change at the **red** line, this chart shows:

a. acceptable precision and accuracy
b. a positive bias
c. a negative bias
d. a problem with precision
e. The chart does not convey the answer

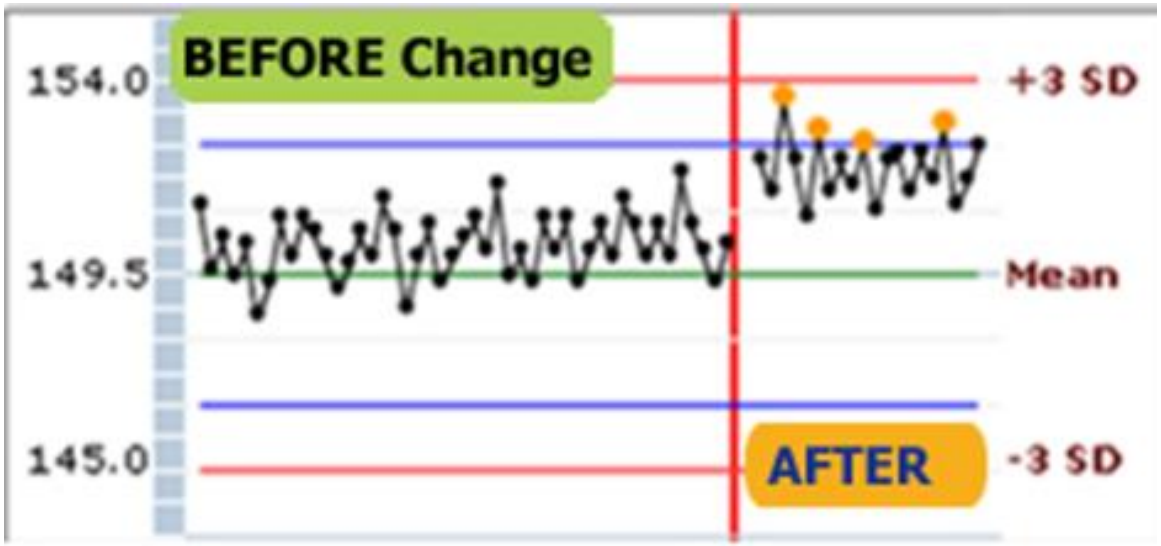
AFTER the change at the **red** line on chart, I would:

a. consider results OK to report
b. stop to investigate after 1 run
c. stop after 2-5 runs
d. stop after >5 runs
e. not stop now, but investigate later
f. chart does not convey the answer

Same Data Points Used in Both Charts

#4 NLR

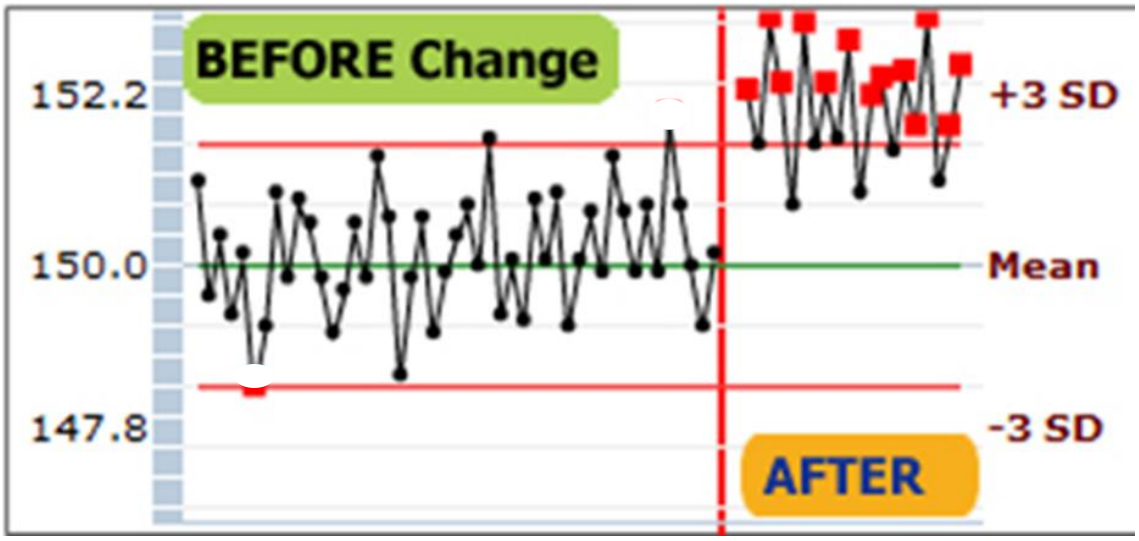
Wrong mean & SD assigned to chart



not stop now, but investigate later

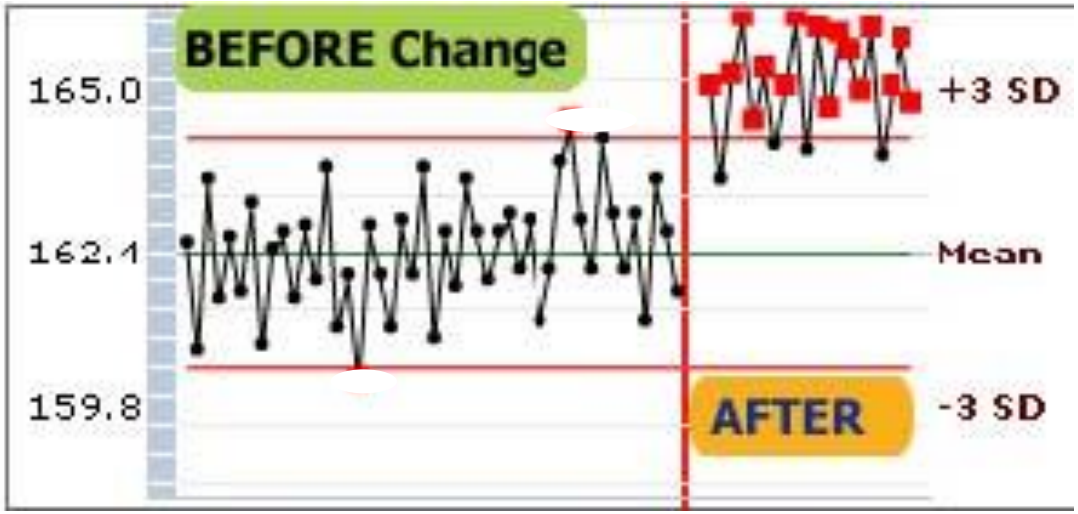
#3 N1O

Observed mean & SD assigned to chart



stop to investigate after **1** run

#5 2NO



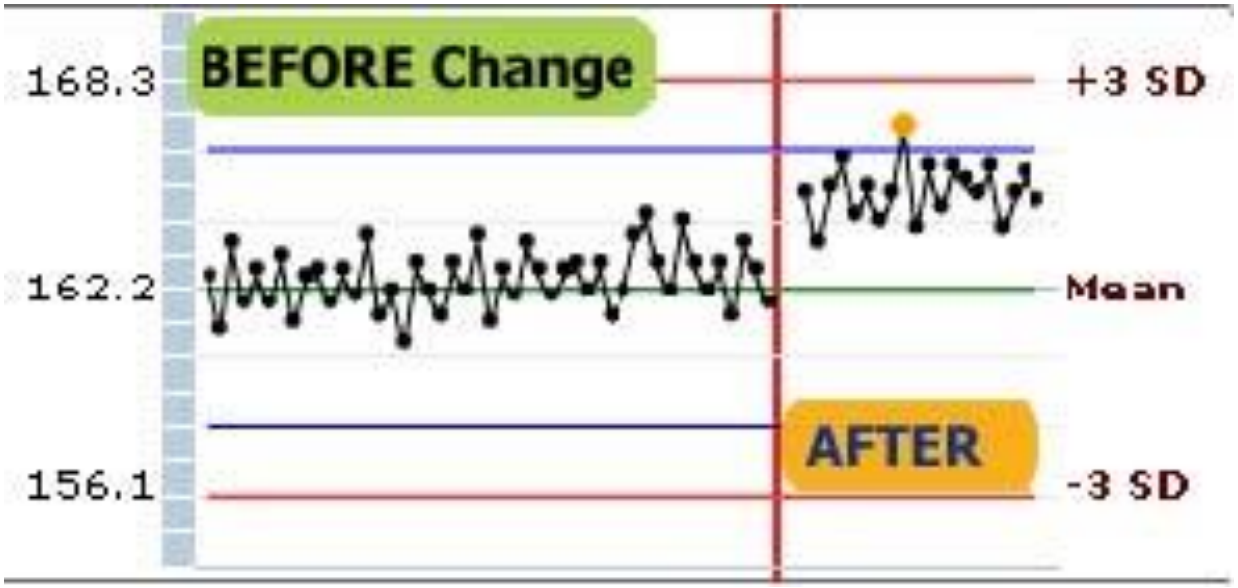
BEFORE the change at the **red** line, this chart shows:

a. acceptable precision and accuracy
b. a positive bias
c. a negative bias
d. a problem with precision
e. The chart does not convey the answer

AFTER the change at the **red** line on chart, I would:

a. consider results OK to report
b. stop to investigate after 1 run
c. stop after 2-5 runs
d. stop after >5 runs
e. not stop now, but investigate later
f. chart does not convey the answer

#6 N2L



BEFORE the change at the **red** line, this chart shows:

a. acceptable precision and accuracy
b. a positive bias
c. a negative bias
d. a problem with precision
e. The chart does not convey the answer

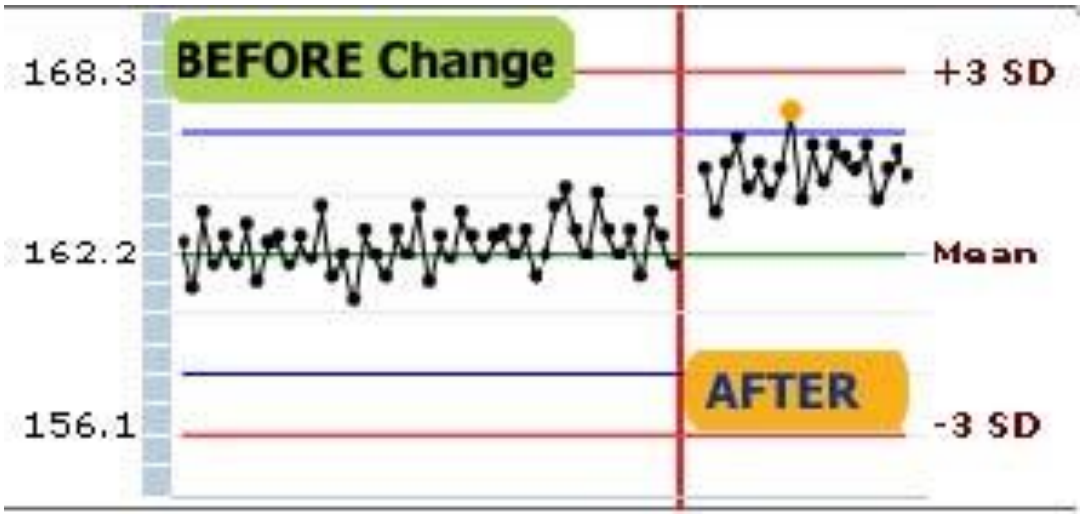
AFTER the change at the **red** line on chart, I would:

a. consider results OK to report
b. stop to investigate after 1 run
c. stop after 2-5 runs
d. stop after >5 runs
e. not stop now, but investigate later
f. chart does not convey the answer

Same Data Points Used in Both Charts

#6 N2L

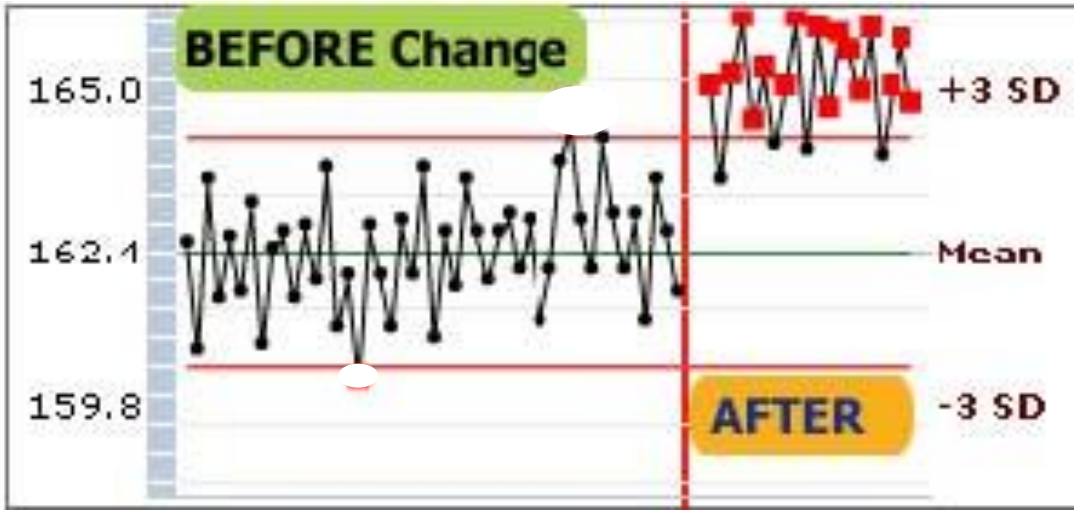
Wrong SD assigned to chart



consider results **OK** to report

#5 2NO

Observed SD assigned to chart



stop to investigate after **1** run

Key Points to Remember

- ✓ Effective QC monitoring begins with the right L-J chart.
- ✓ L-J charts can only tell you if the method remains stable or has undergone a change in accuracy or an increase in imprecision.

  The L-J charts <u>cannot</u> tell you if the method is good or not.

- ✓ To practice Quality Control, you must first define the acceptable quality limits.

Thank You!