Understanding Quality Control:

A Process Improvement Perspective

Robert L. Schmidt MD, PhD, MBA
Lauren N Pearson DO, MPH

DISCLOSURE: Robert Schmidt

In the past 12 months, I have not had any significant financial interest or other relationship with the manufacturers of the products or providers of the services that will be discussed in my presentation.

DISCLOSURE: Lauren Pearson

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Understanding Quality Control

A process improvement perspective

Inspecting poor quality out

Building quality in

Compliance:

Inspecting poor quality out

Improvement:

Building quality in

Compliance: **Immediate perspective**

Inspecting poor quality out

Improvement:

Long-term perspective

Building quality in

What you will learn:

Knowledge	Skills
Key Concepts Underlying QC Stability Capability Common Cause Variation Assignable Cause Variation Long vs Short Term Variation Controllability	How to calculate control limits correctly
The improvement cycle	How to assess patterns in a control chart
Compliance vs Improvement	How to tell whether your control plan can detect important errors

Background and Motivation

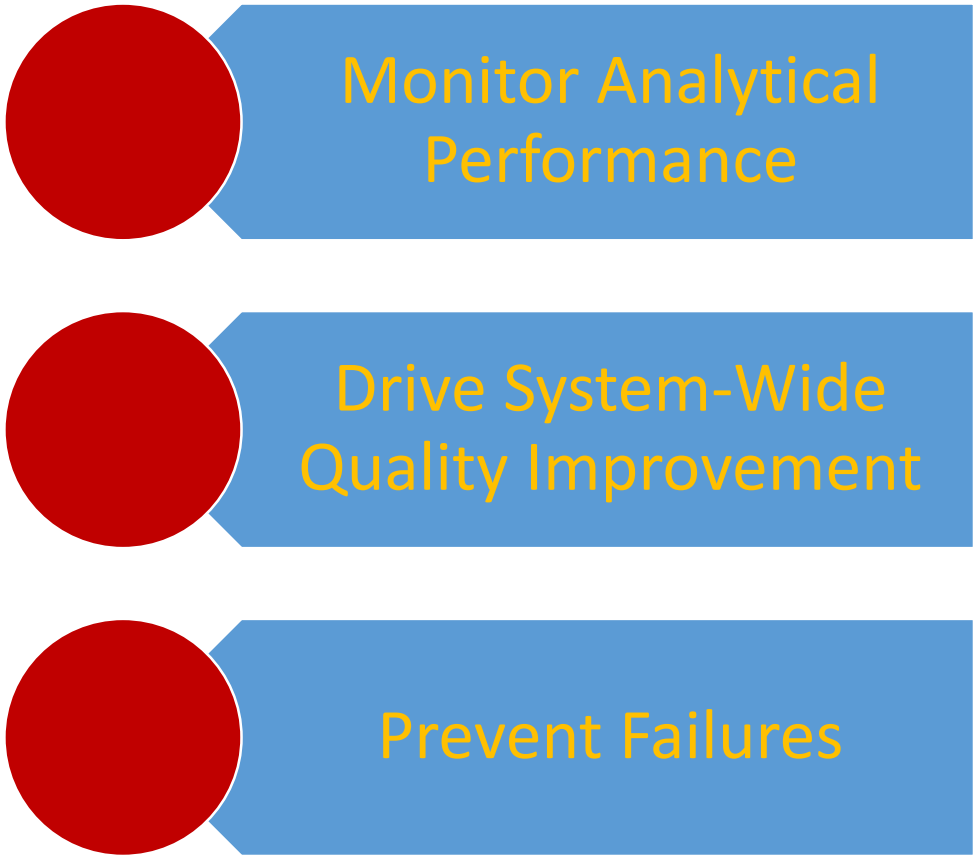
Impact of QC Improvement TTE Lab

- 74.5% Reduction in Troubleshooting Time
- 43% Reduction Labor Cost
- 50% Improvement in Turnaround Time

How did they do it?

QC- Opportunity for Process Improvement?

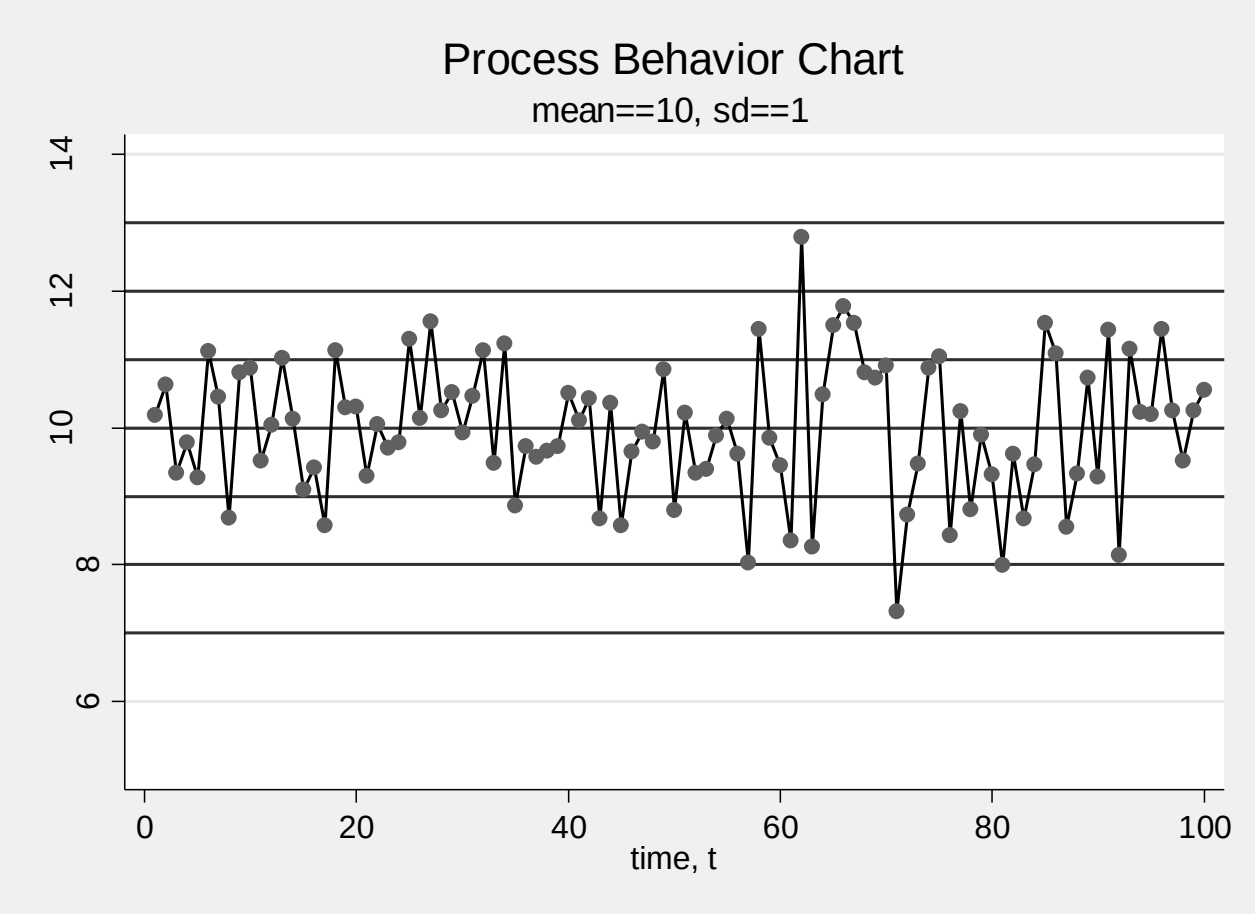
- Compliance versus process improvement
  - Remove bad quality
  - Reduce variation
  - Reduce costs
- Toxicology and Trace Elements (TTE) provides an example at ARUP
  - Reduced costs, increased capacity



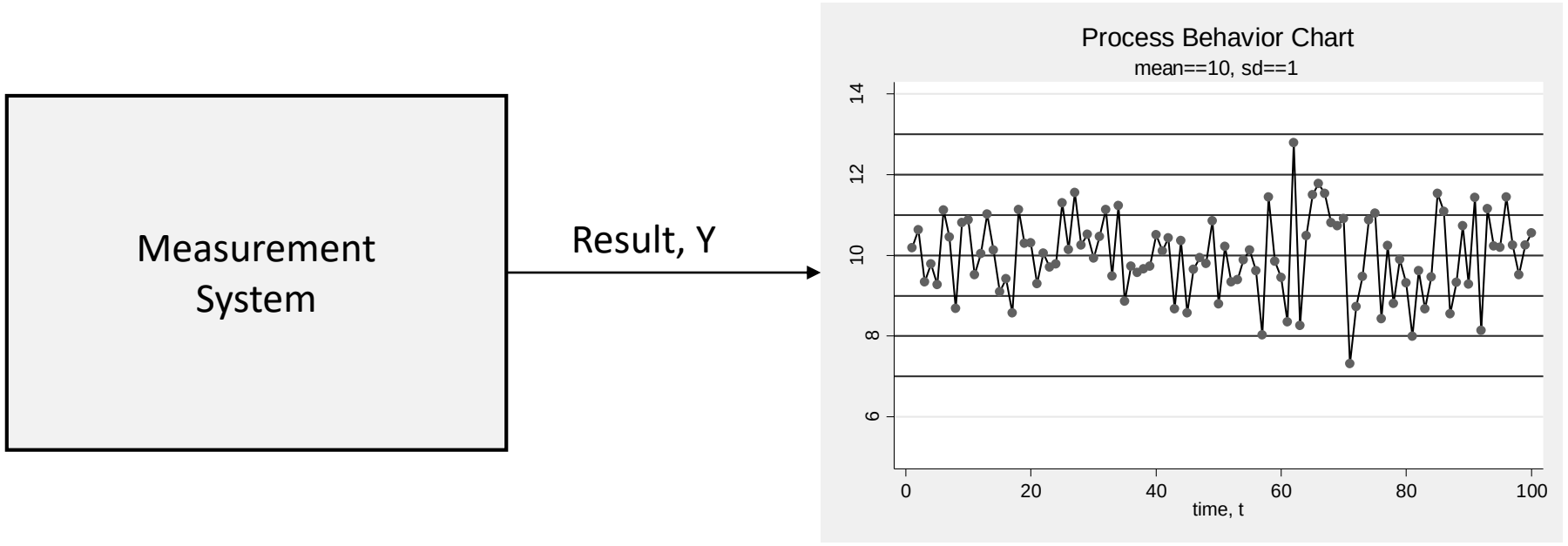
Three key questions:

1. Stable?
2. Capable?
3. Controllable?

Process behavior chart answers this question:
Is this process stable?



Why do measurements vary?



Inputs

Output

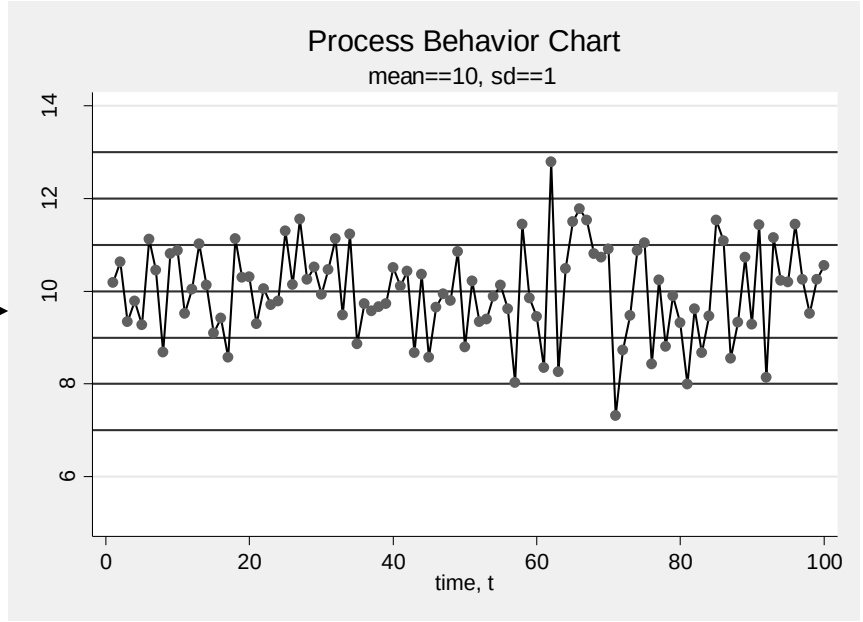
X_1

X_2

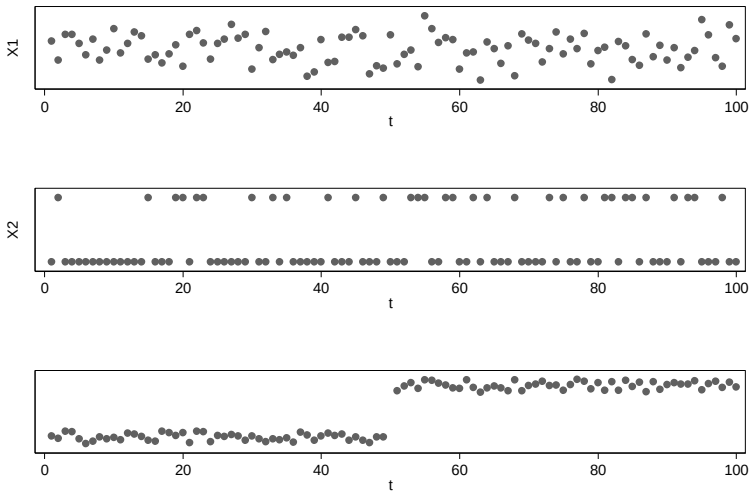
X_{137}

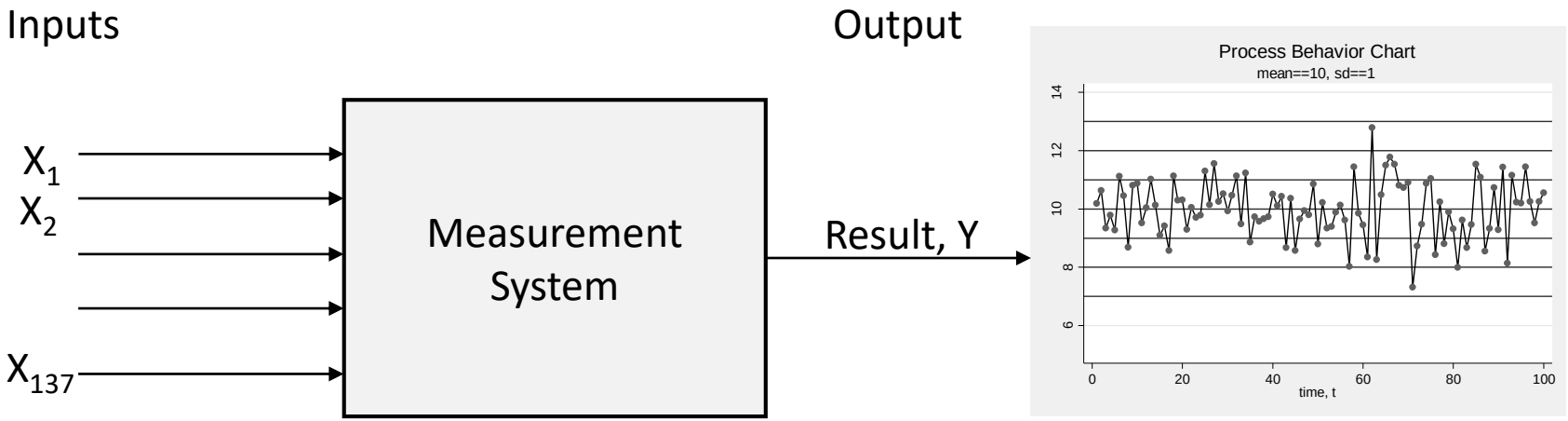
Measurement System

Result, Y



Input variation→ Output variation

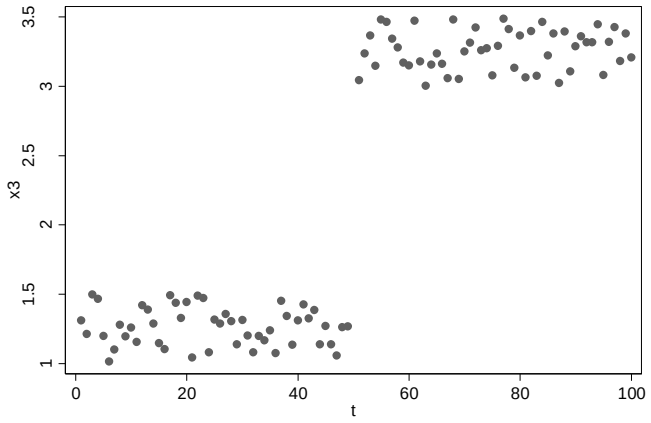




- Multiple inputs combine to produce the final result
  - Temperatures, concentrations, etc.
  - Most are unobserved but usually cause small variation
- This variation is intrinsic to the process and causes the natural variation in QC results
  - Best achievable assay performance
  - Exhibits no patterns e.g. shifts or trends
  - Output is random but predictable

Input variation→ Output variation

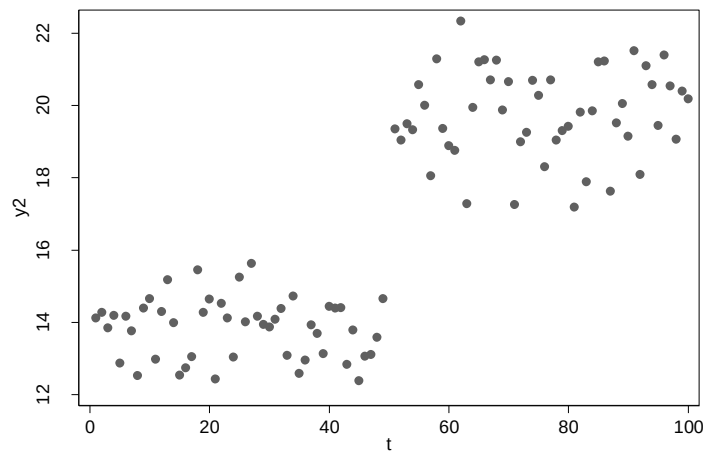
Input



Measurement System

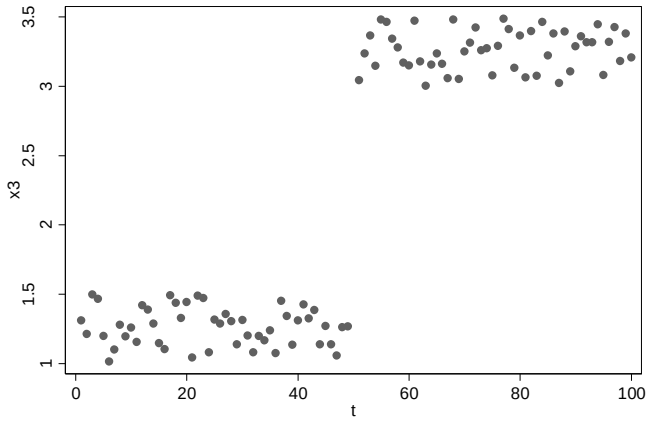
Result, Y

Output



Assignable Cause Variation

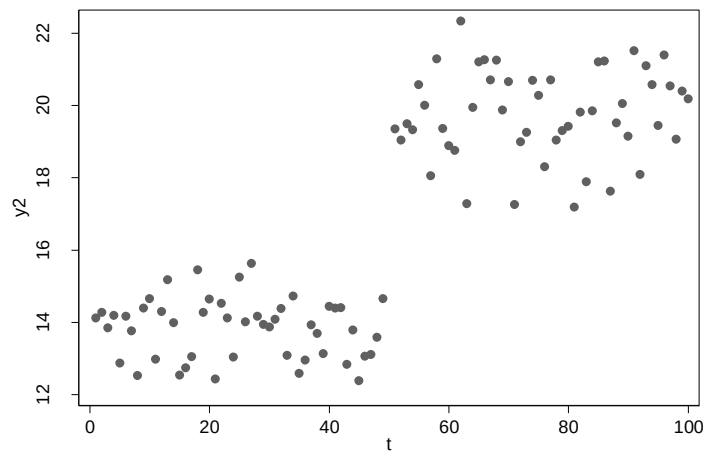
Input



Measurement System

Result, Y

Output



Assignable Cause Variation

- A process becomes unstable and produces results that are unusual or contain a pattern
  - The output no longer represents common cause variation
  - Input is extrinsic to the process and reflects a change that is outside the normal operation of the process
- Change in output can be linked (in theory) to a particular input, or assignable cause
  - Challenge is to identify that input or cause!
- When present, the process is not operating as designed and is unstable

How do you achieve process control?

1. Identify causes of assignable cause variation

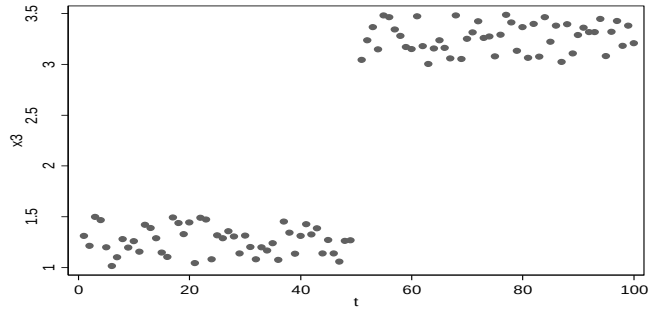
2. Eliminate variation in key inputs (control)

Requires process knowledge

Ability to relate output signals to inputs

Process Behavior Chart is the key

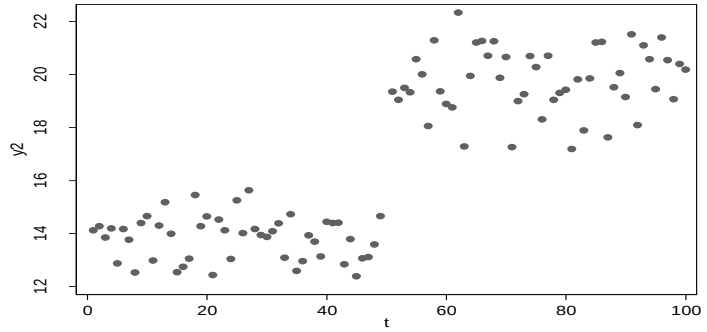
Input



Measurement System

Result, Y

Output

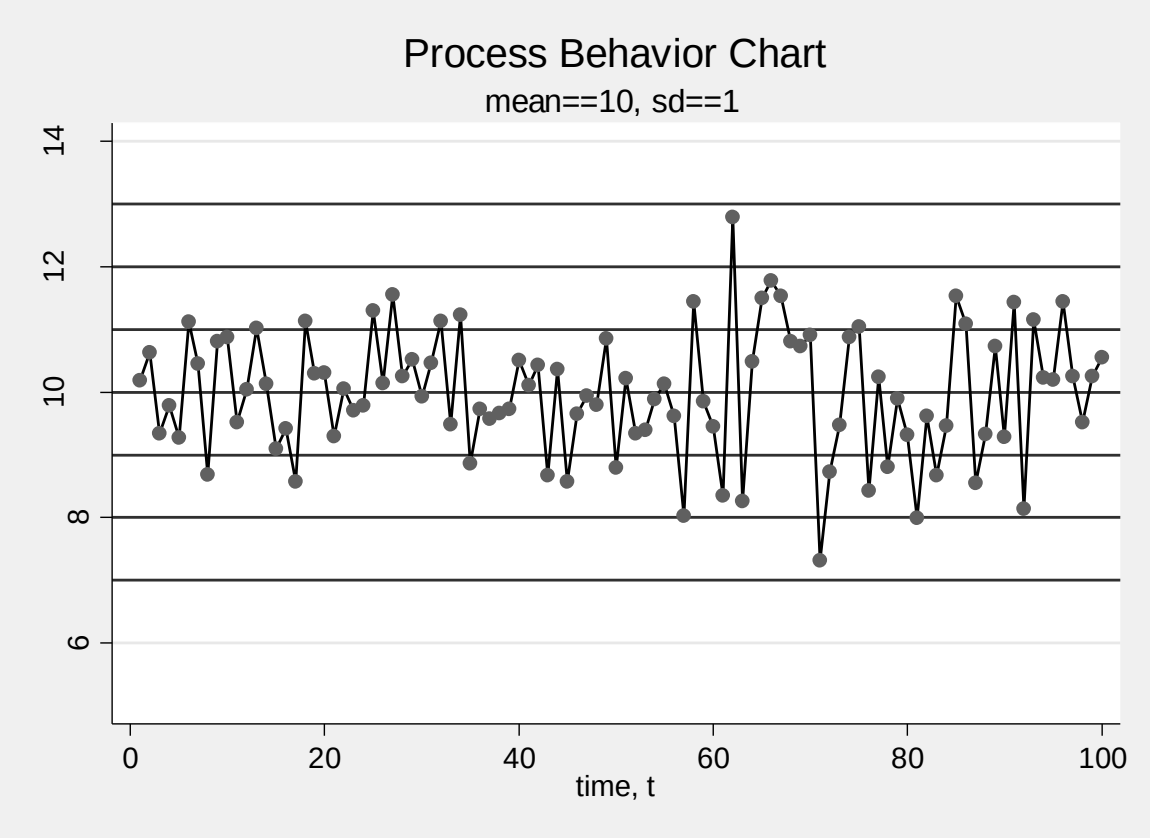


Signal

Process Monitoring

Process Knowledge

What does a controlled process look like?



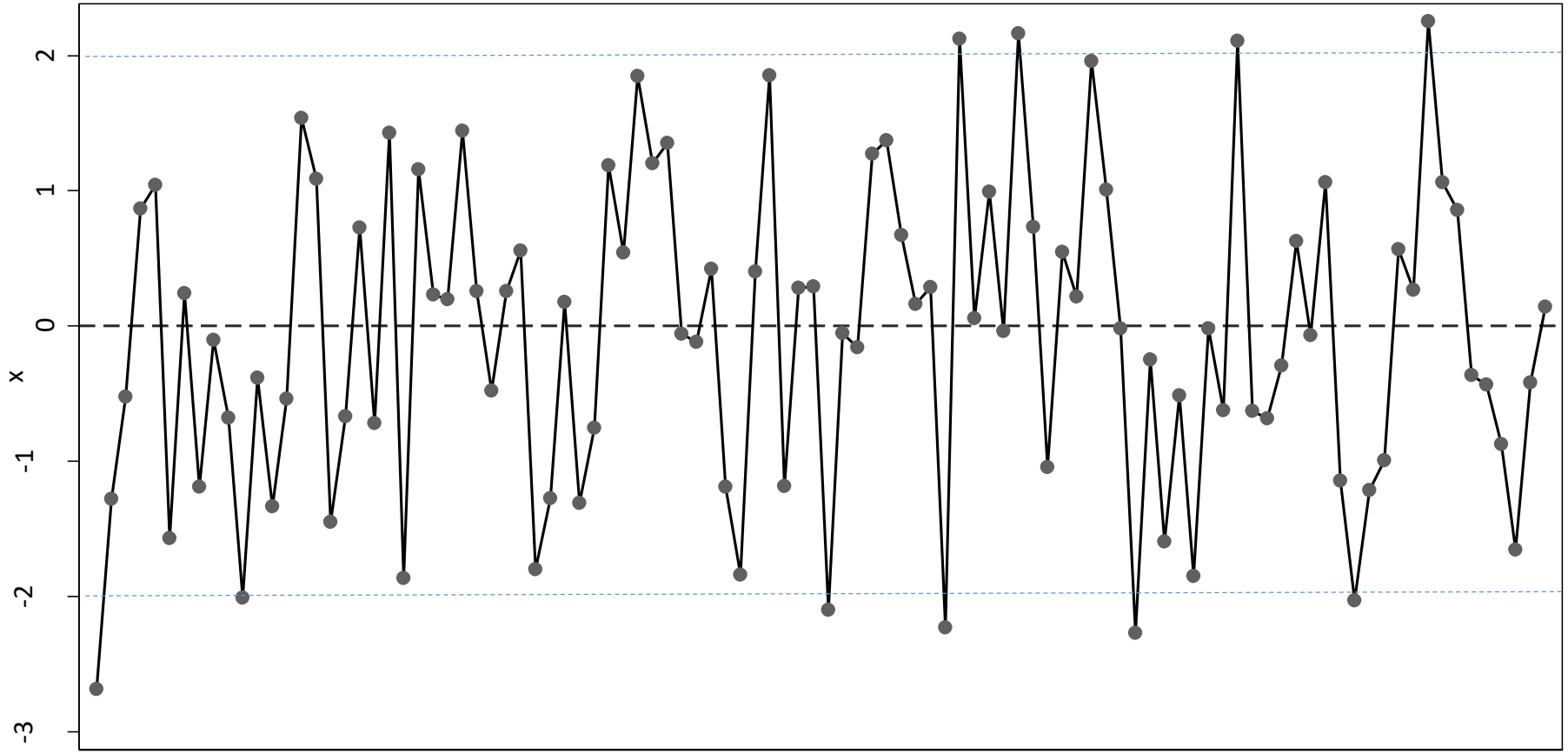
Common Cause Variation

- Process is stable
- No assignable causes
- No pattern in the data
- Process is in “statistical control”
- Basis for control chart

Stability Assessment

Short-term vs Long term Variation

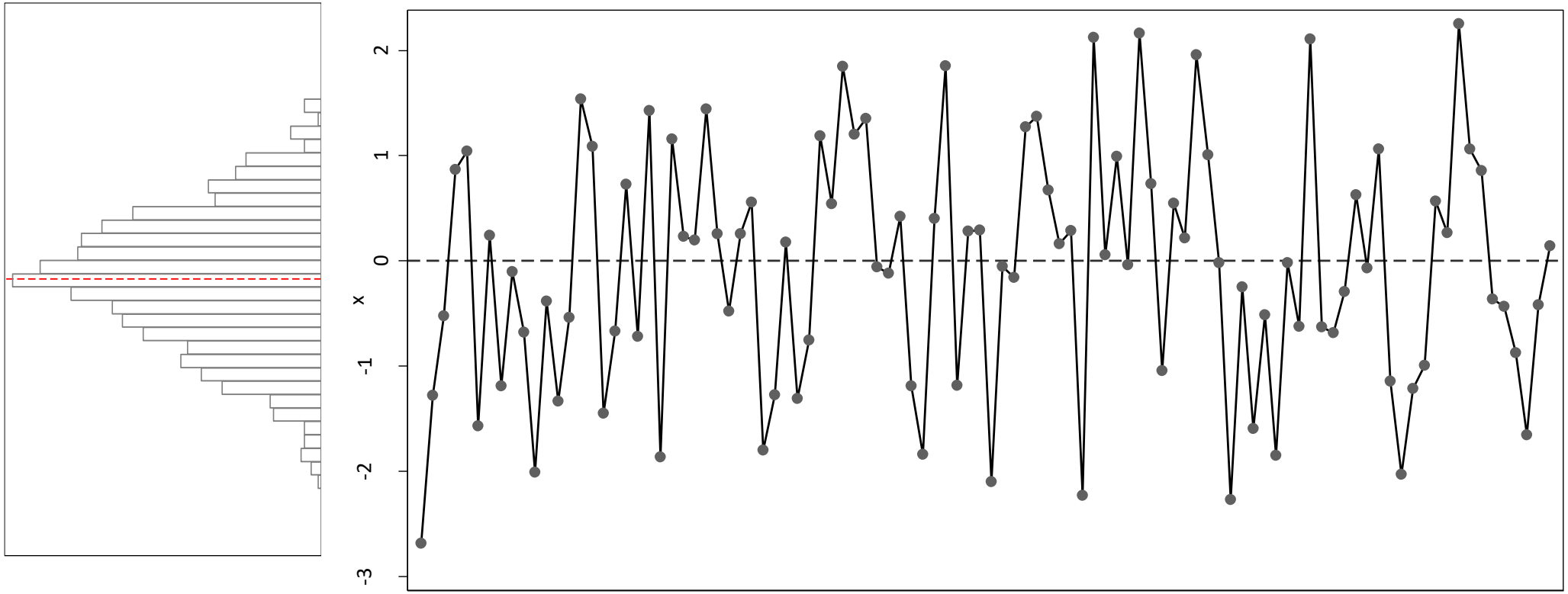
Control Chart: Basic Tool for Stability Assessment

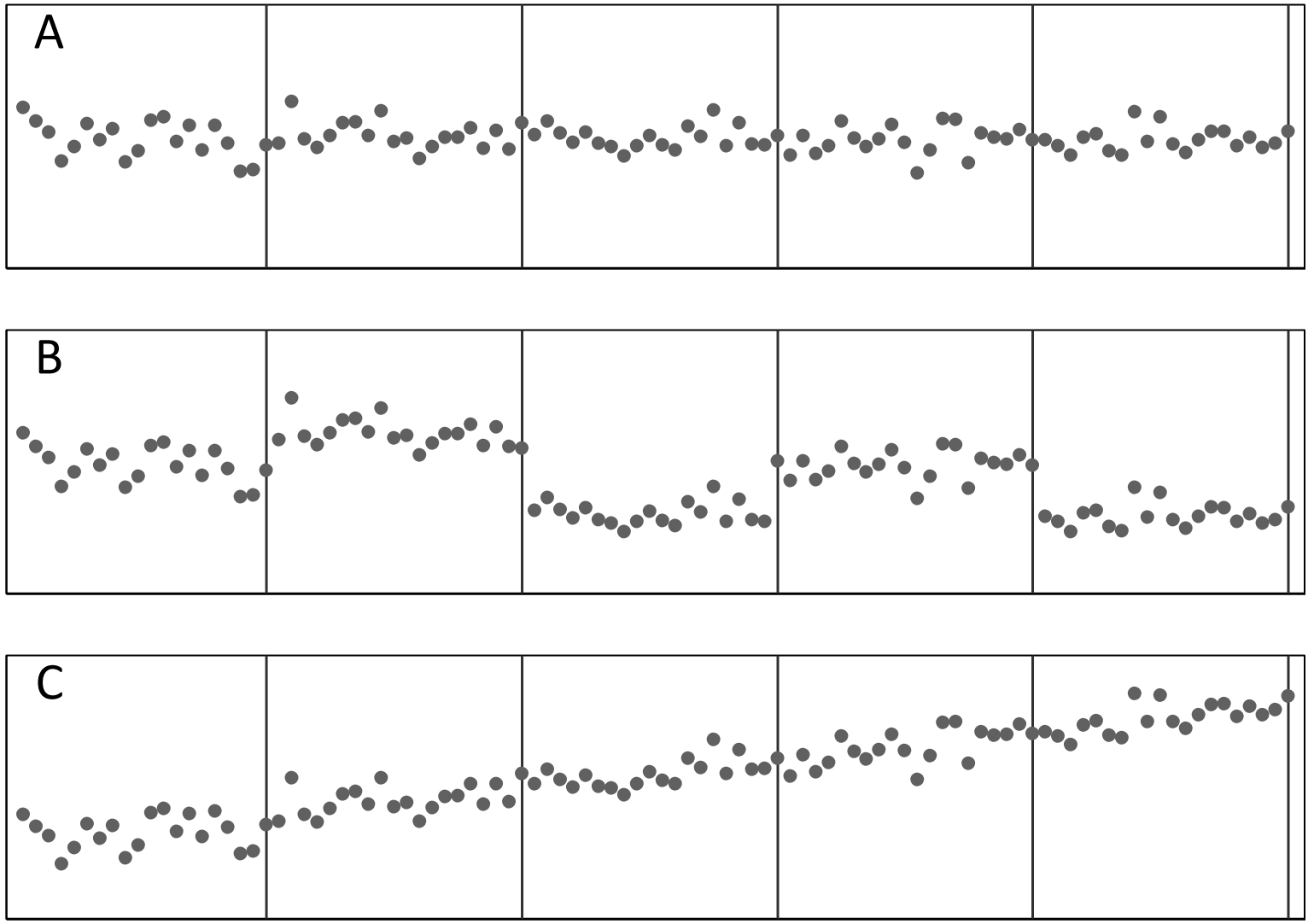


Two parameters of interest:

1. Location

2. Dispersion

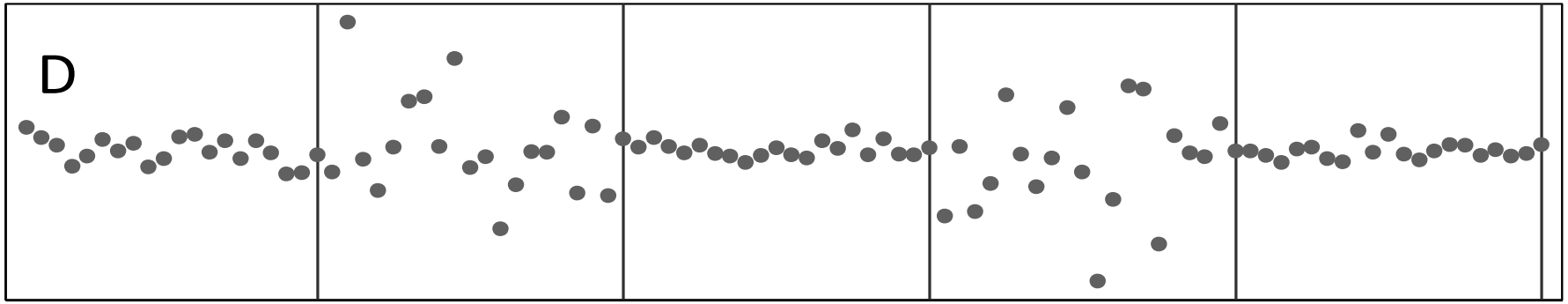




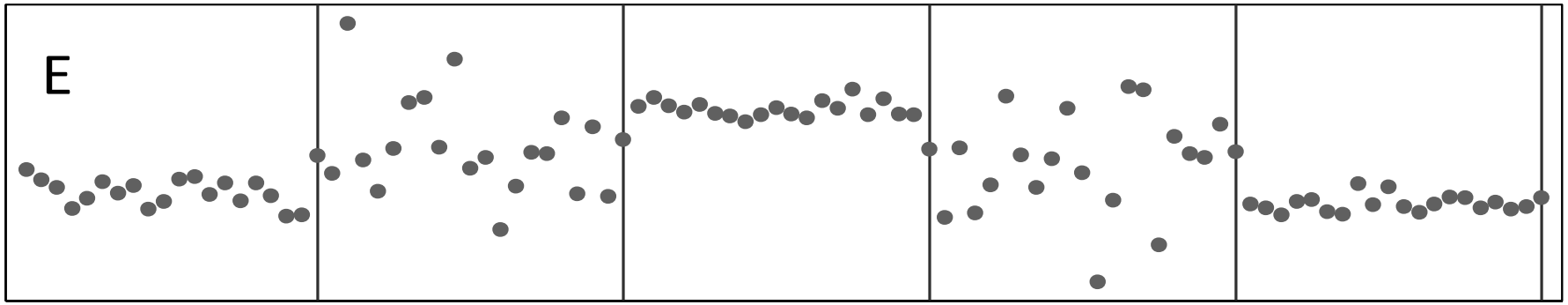
Stable process

Unstable process: shifts

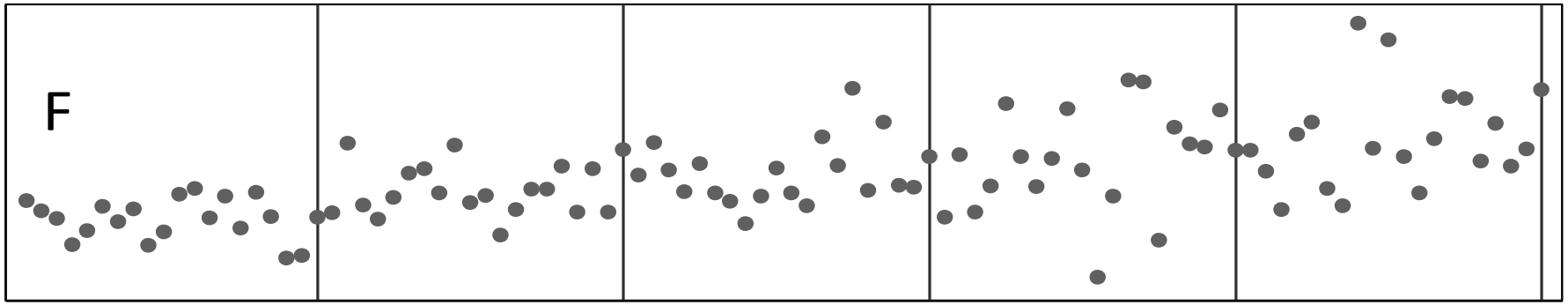
Unstable process: drift



Stable mean
Unstable variance

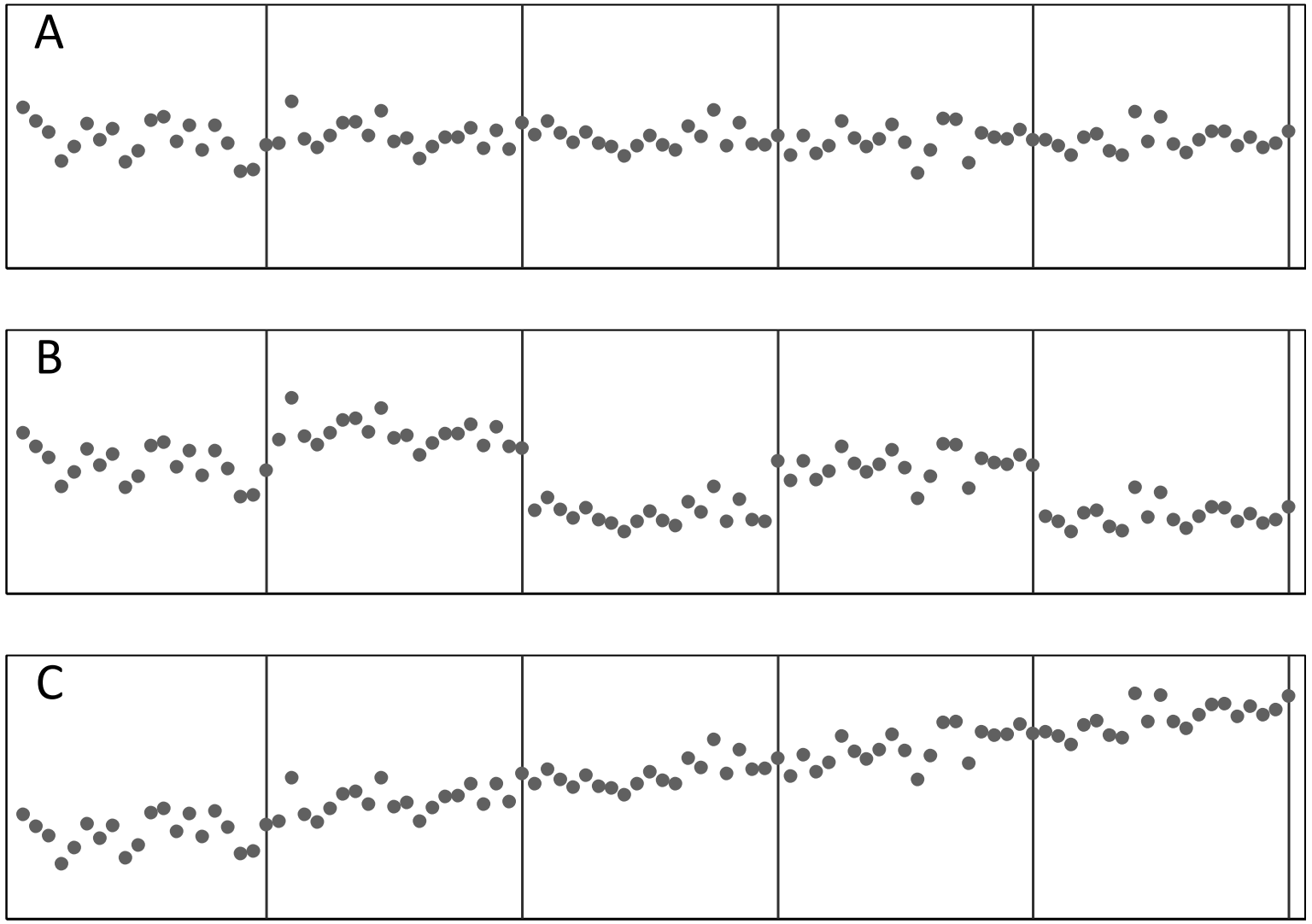


Unstable mean
Unstable variance



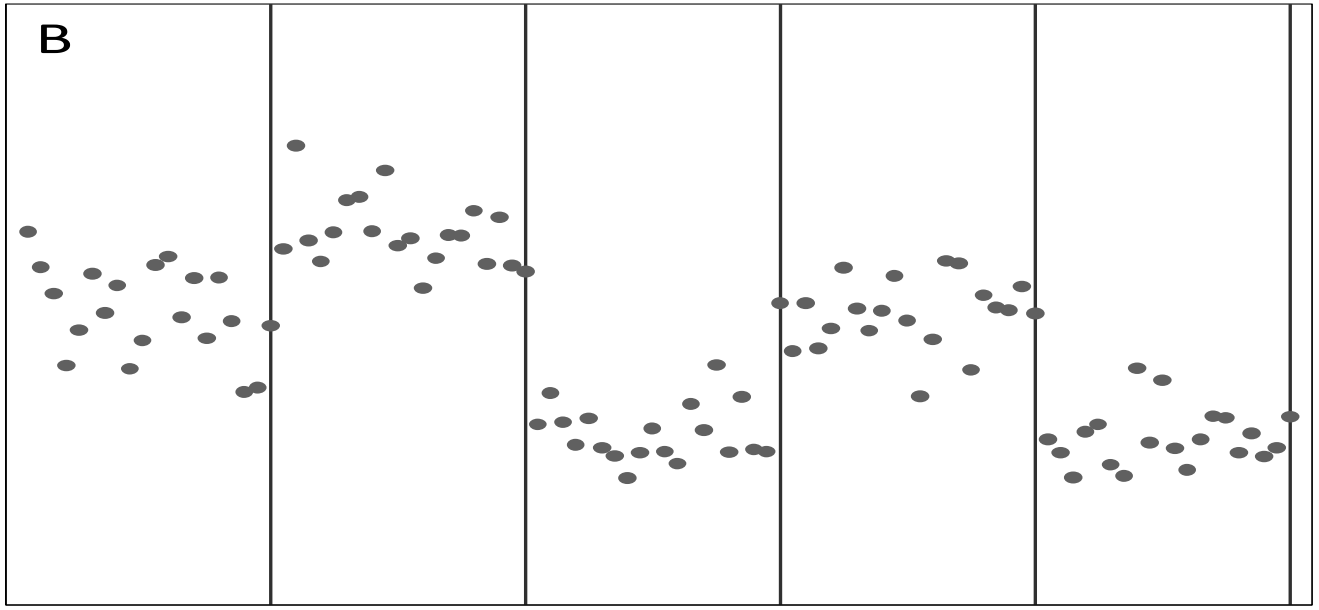
Unstable mean
Unstable variance

Short-term vs long-term variation



Variance estimate	
short	long
1	1
1	2.4
1	3.1

Measuring Short Term Variability



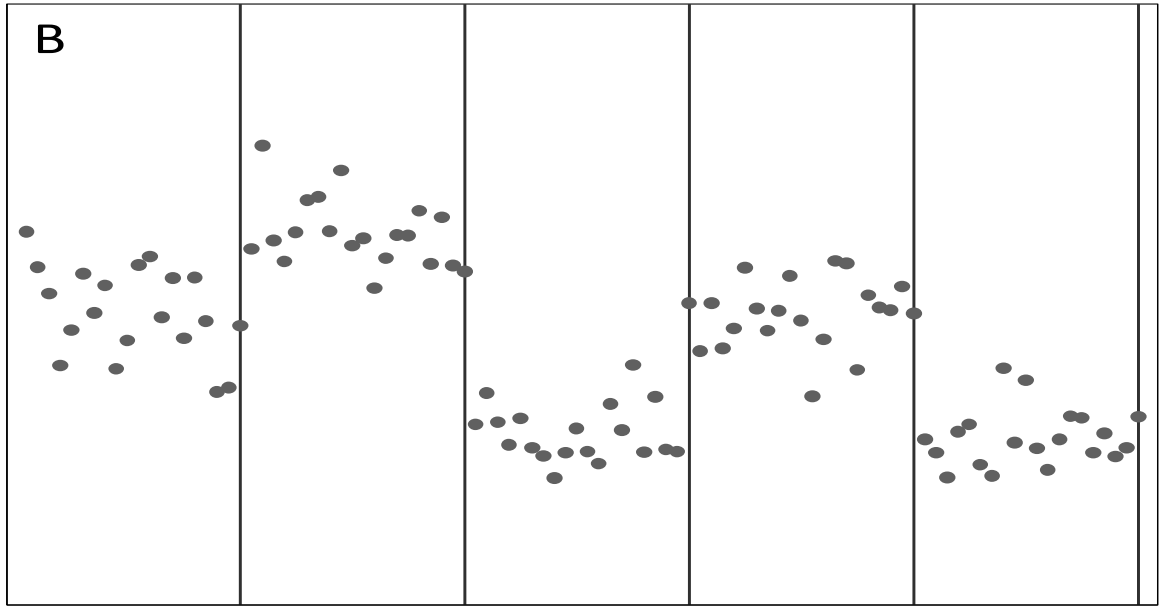
Form “rational subgroups”

1. Measure sd for each group

2. Measure range for each group

$$sd = \frac{\bar{R}}{d_2}$$

Measuring Short Term Variability



Form groups using successive values (moving range)

$$R_i = |X_i - X_{i-1}|$$

$$sd = \frac{\bar{R}}{d_2}$$

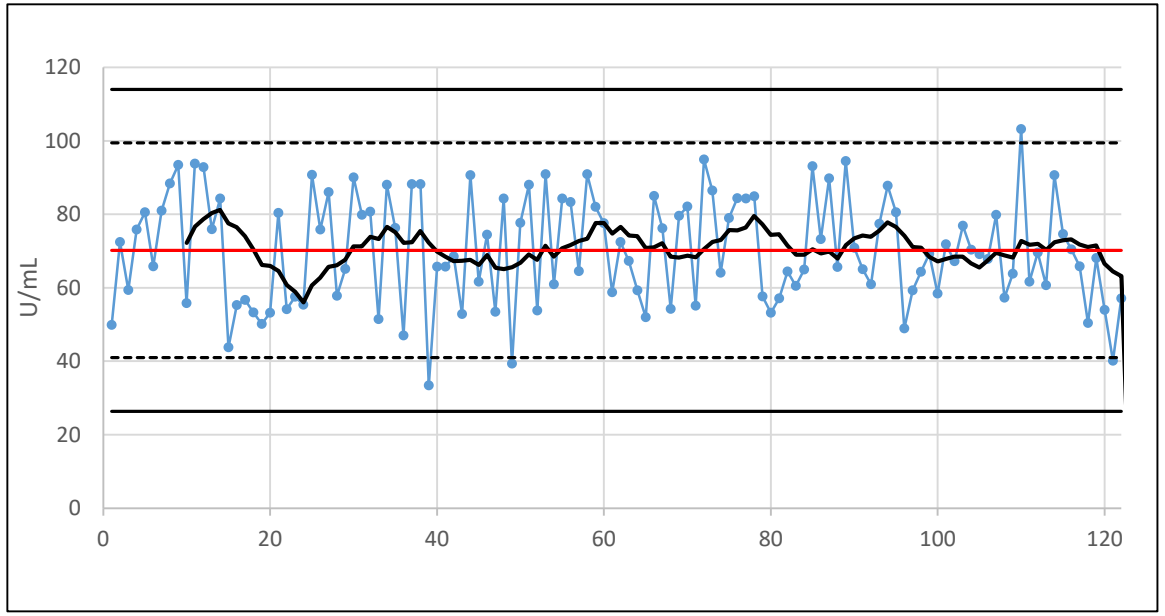
Actual short-term sd = 1.0

Estimated short-term sd 1.06

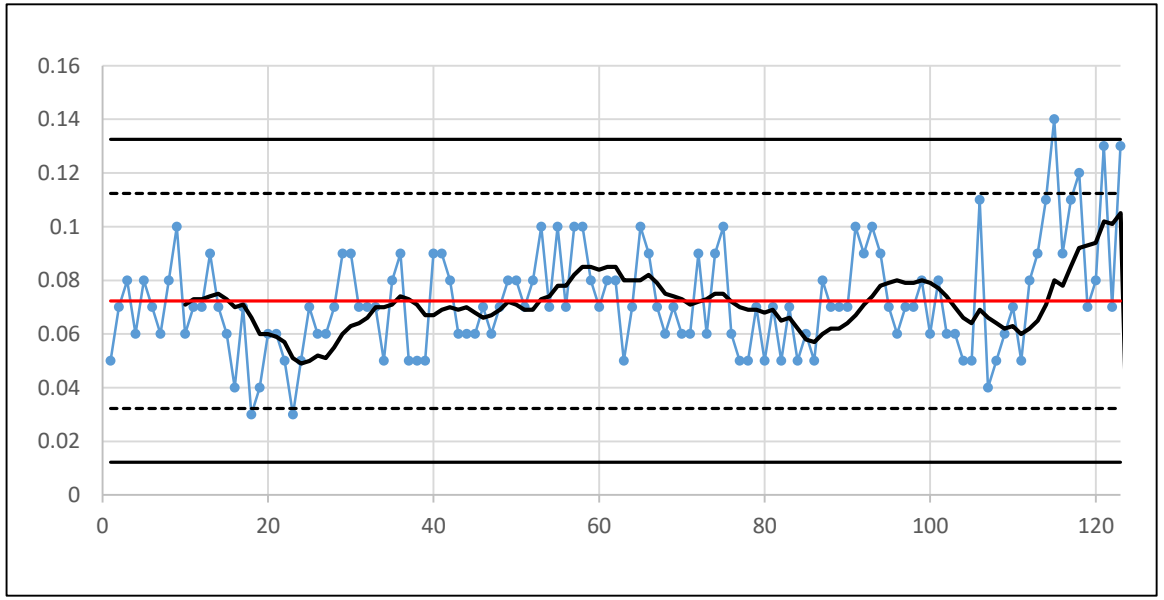
Long-term sd= 2.4

$$\text{SR Ratio} = \frac{long\ term\ variation}{short\ term\ variation}$$

Assay X – in control



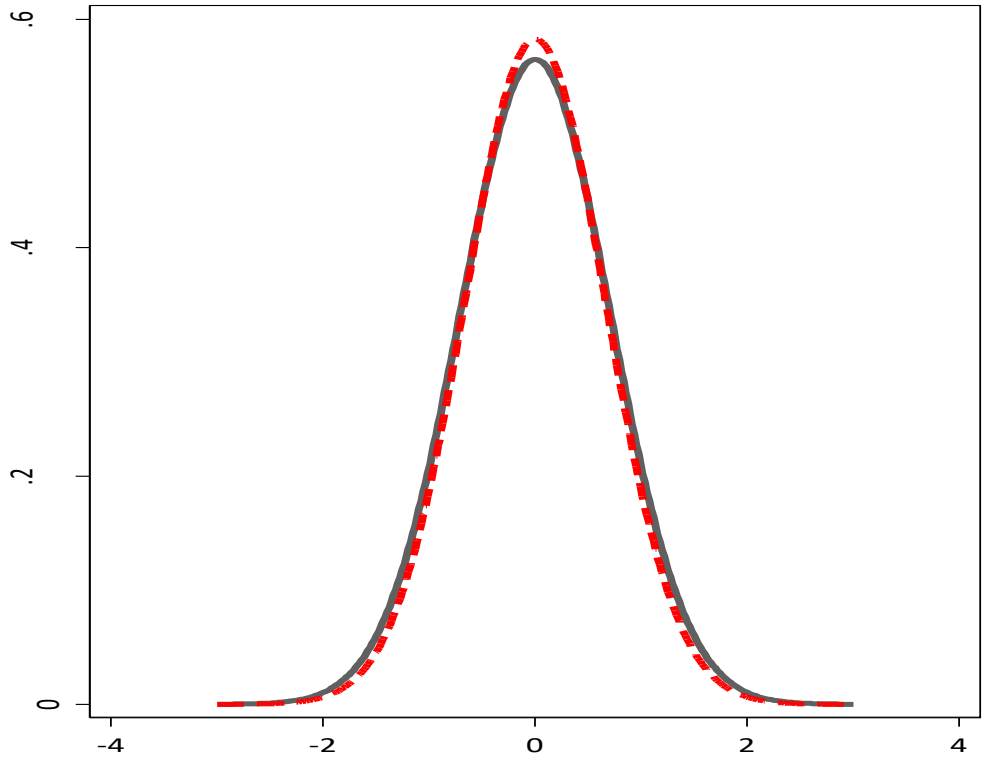
Assay Y – out of control



Statistic	**Assay X**	**Assay Y**
Number of observations	123	123
mean	69.6	0.072
Average moving range ($\bar{R}$)	16.8	0.021
Short-term (ST) standard deviation (df)	14.9 (76)	0.015 (76)
Long-term (LT) standard deviation (df)	15.9 (122)	0.020 (122)
Ratio LT/ST	1.07	1.30
F statistic (SR statistic)	1.13	1.69
P value	0.27	0.007

Which assay can we improve?

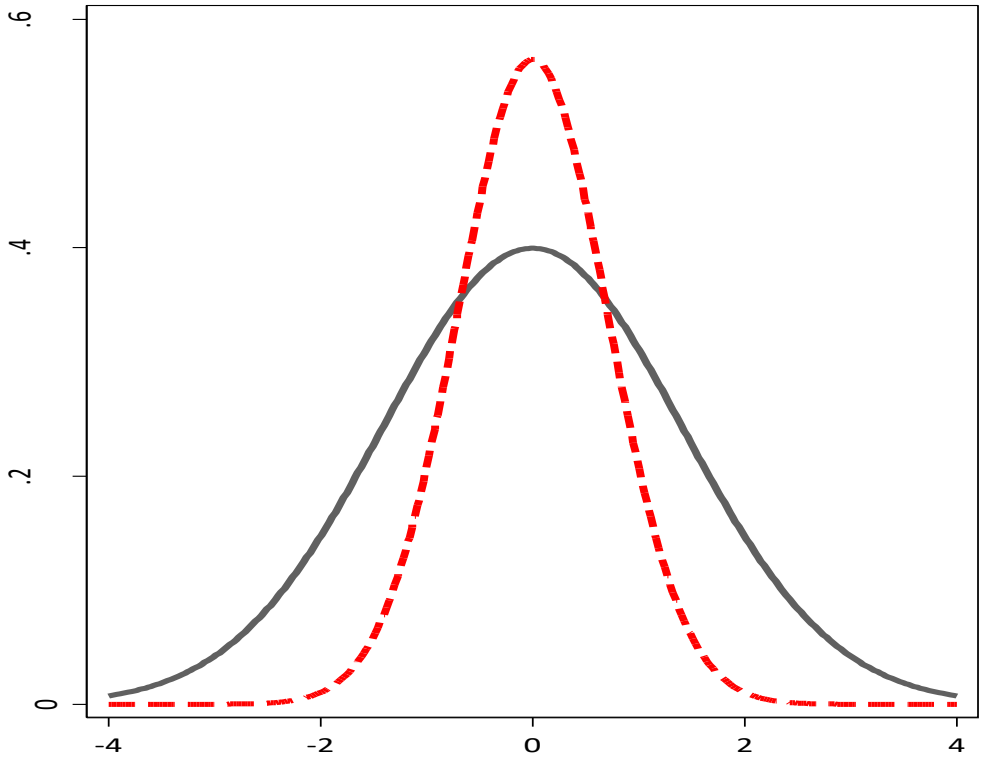
Assay X



NO!

$$\frac{long-term}{short-term} \sim 1.0$$

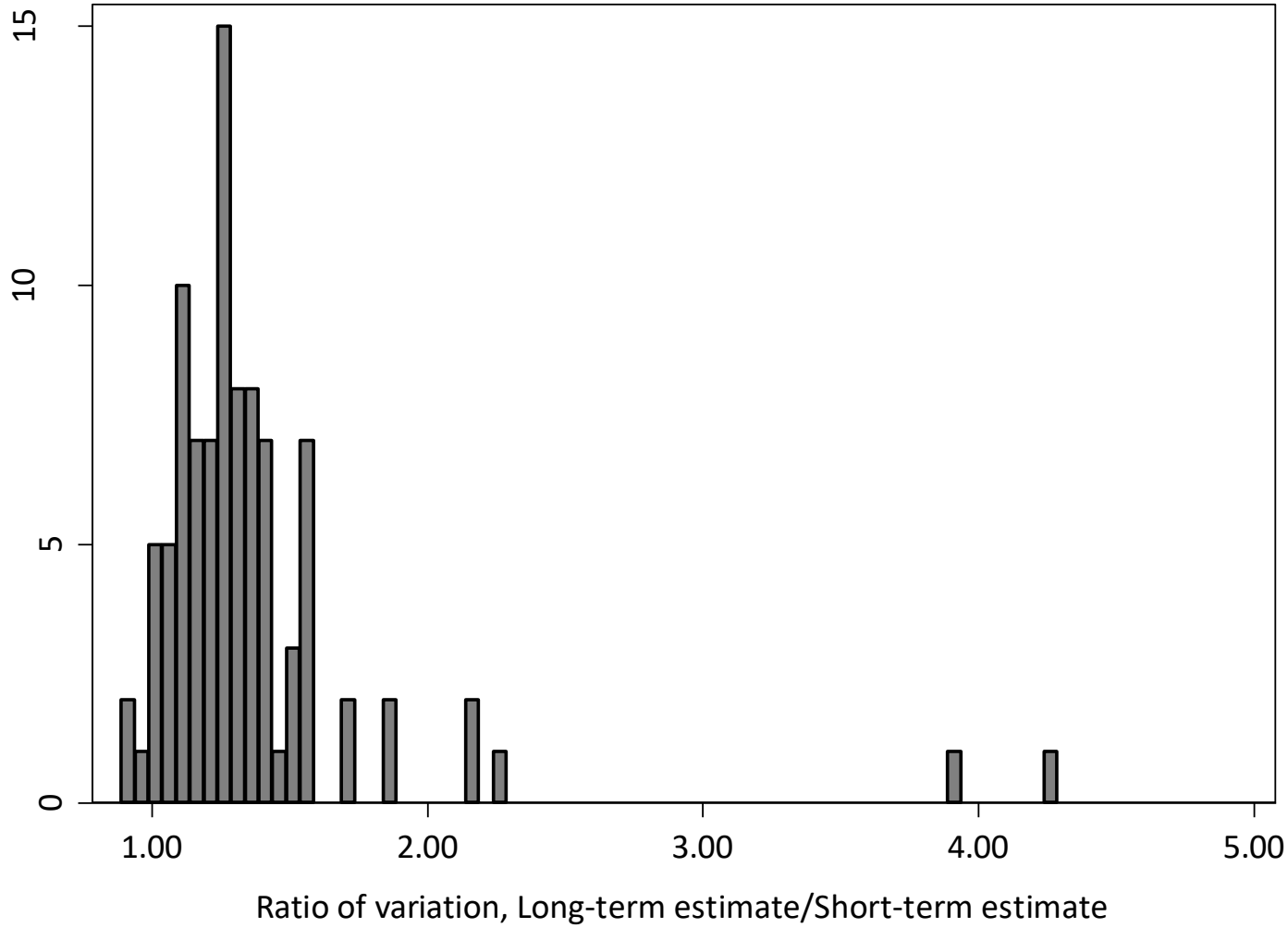
Assay Y



YES!

$$\frac{long-term}{short-term} \sim 1.3$$

$\frac{long-term}{short-term}$ for 95 assays ……



Control charts should be based on short-term variation!!

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Quality control limits: Are we setting them too wide?

Robert L. Schmidt[a], Brandon S. Walker[b], Lauren N. Pearson[a,*]

[a] Department of Pathology, ARUP Laboratories, University of Utah, Salt Lake City, UT, United States
[b] ARUP Laboratories, Salt Lake City, UT, United States

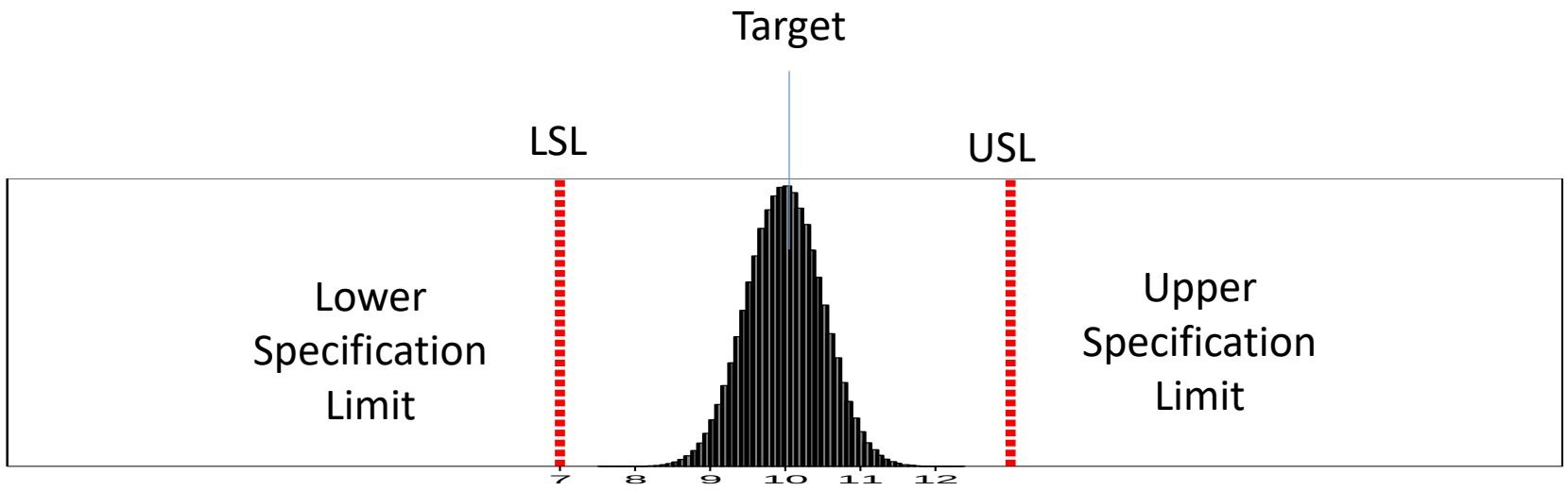
Stability - Key Ideas

- Variation
  - Assignable Cause
  - Common Cause
- How to assess stability
- How to assess potential for improvement
- How to construct control charts
  - Short term or common cause variation

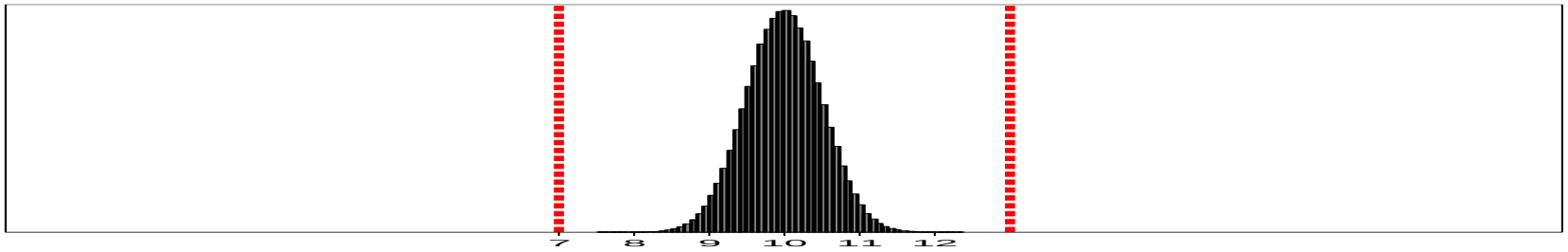
Three key questions:

1. Stable?
2. Capable?
3. Controllable?

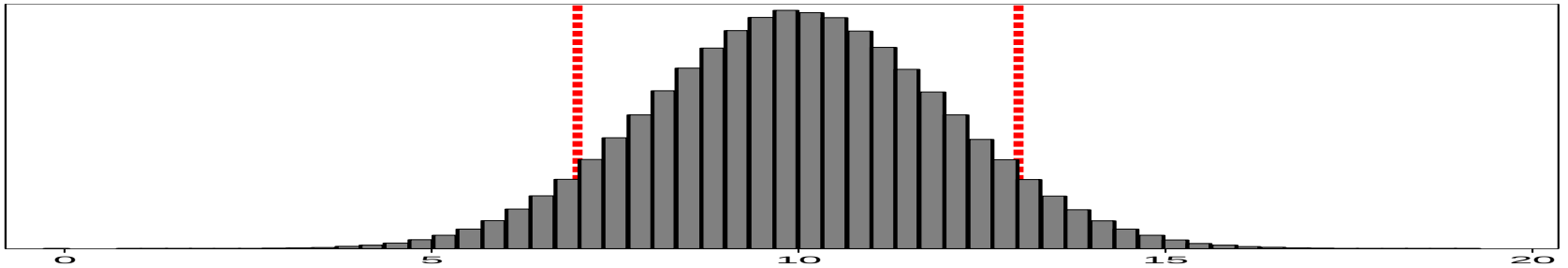
$$\text{Process Capability} = \frac{allowable\ variation}{actual\ variation} = \frac{USL-LSL}{\sigma}$$



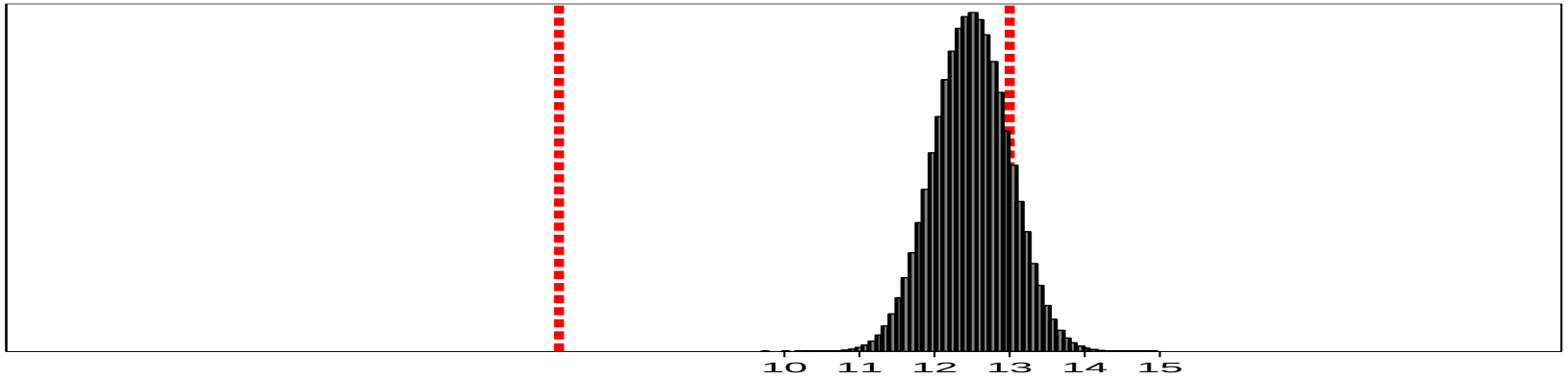
Process Capability



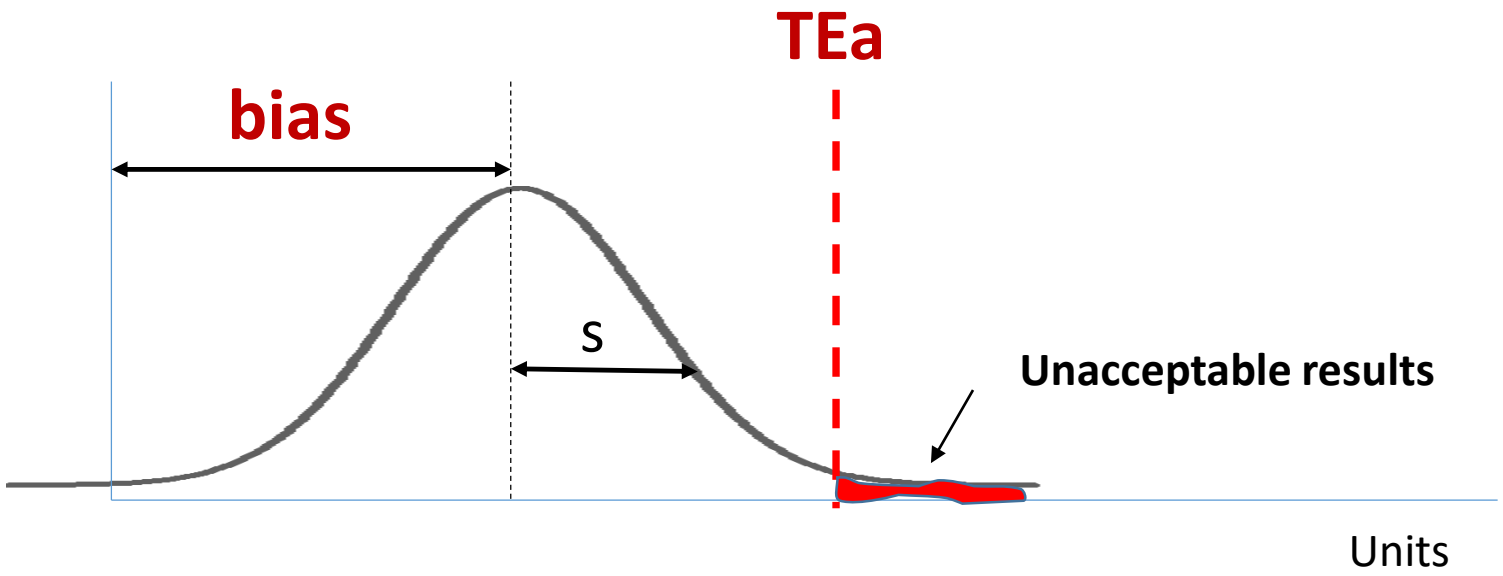
Capable



Not Capable (imprecision)



Not Capable (bias)



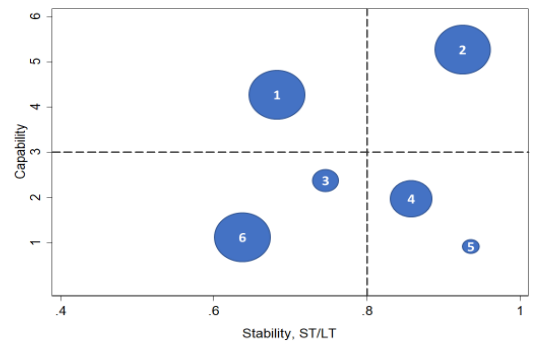
$$Capability = sigma = \frac{(TE_a - bias)}{s} = \frac{allowable\ variation}{actual\ variaion}$$

Capability tells us whether a stable process can perform according to requirements

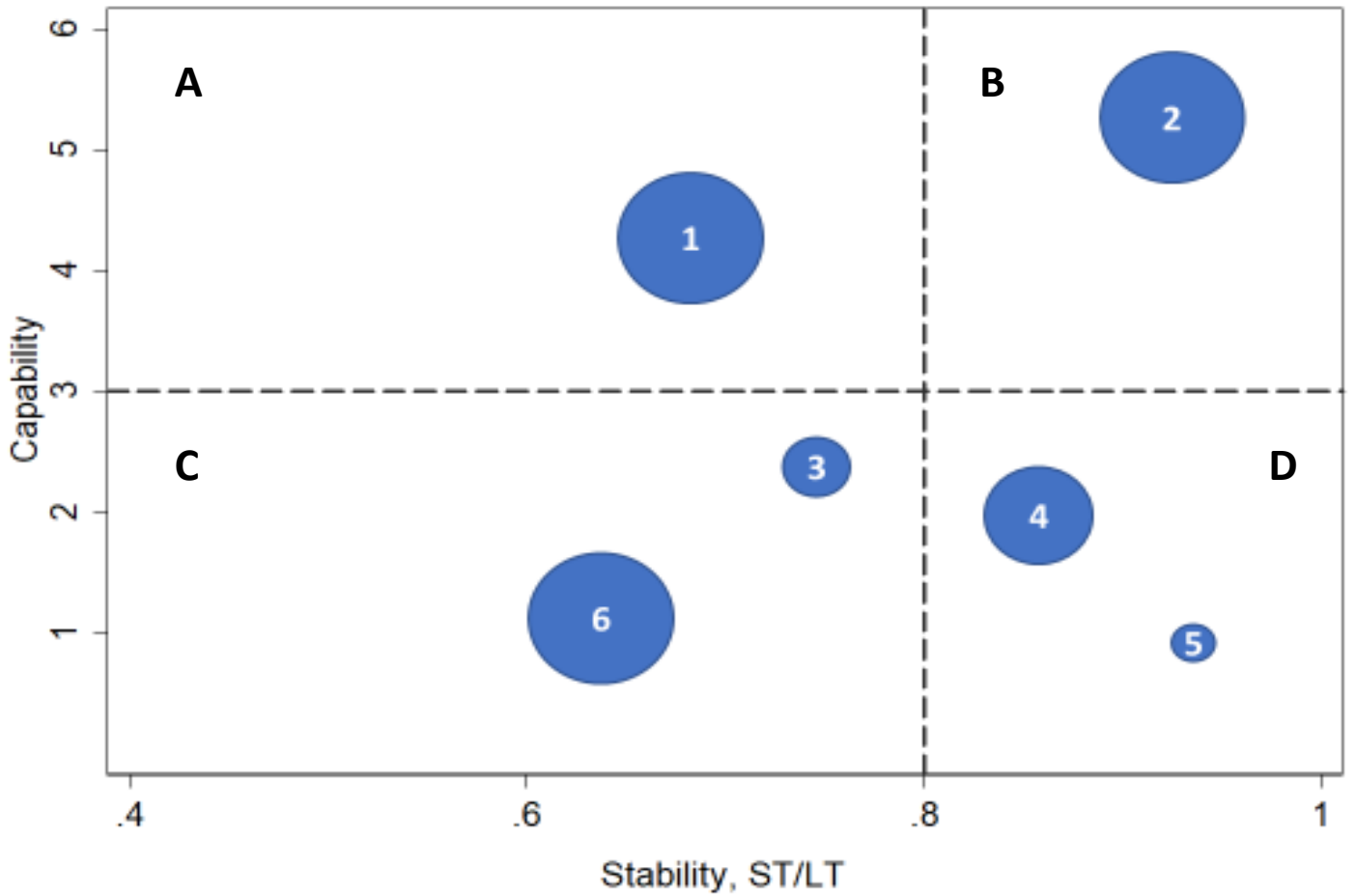
Capability (sigma)	errors > TEa
1	35%
2	16%
3	3.3%
4	0.3%
5	0.01%
6	0.00015%

Prioritizing Improvement Projects:

The Capability-Stability Matrix

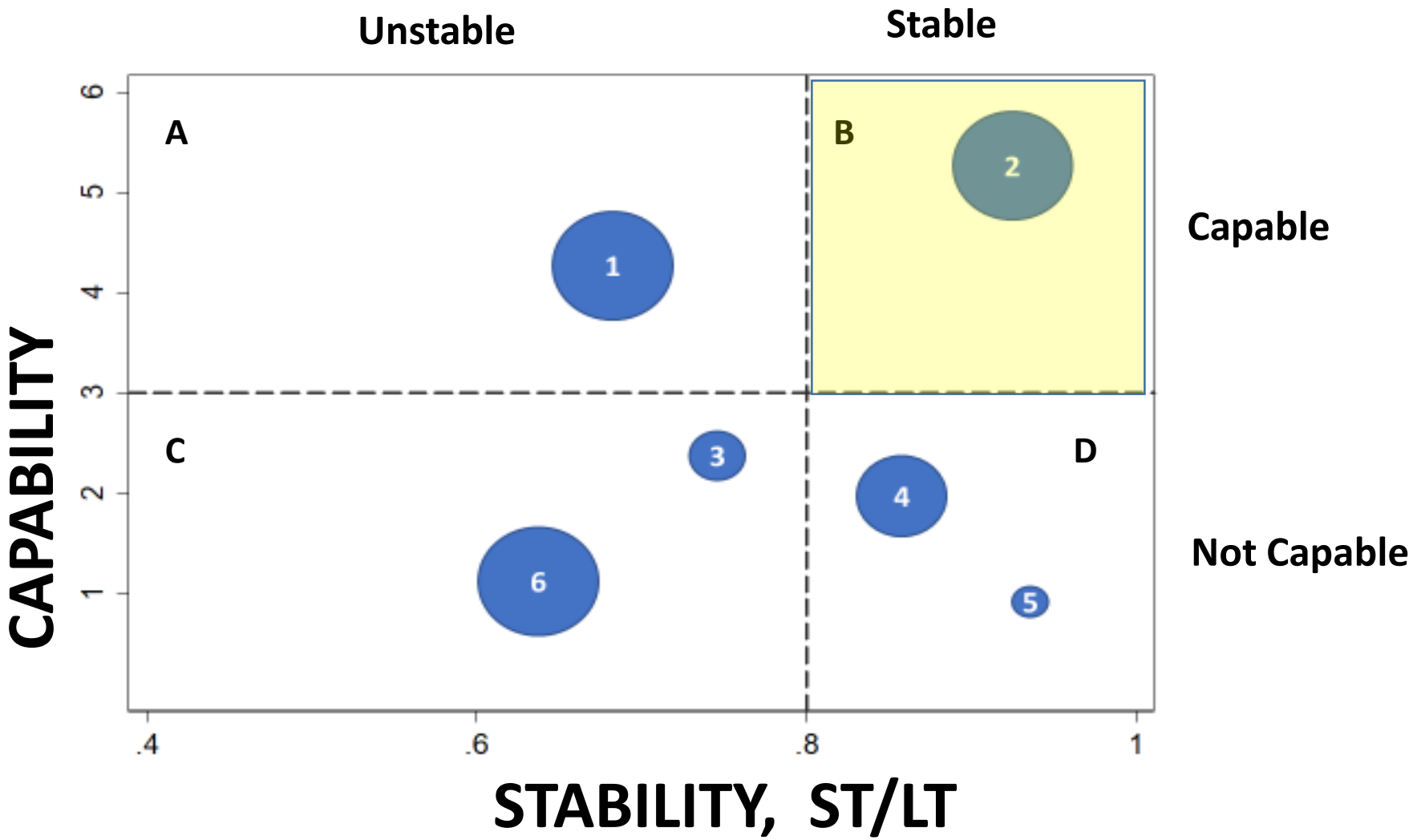


The Stability-Capability Matrix

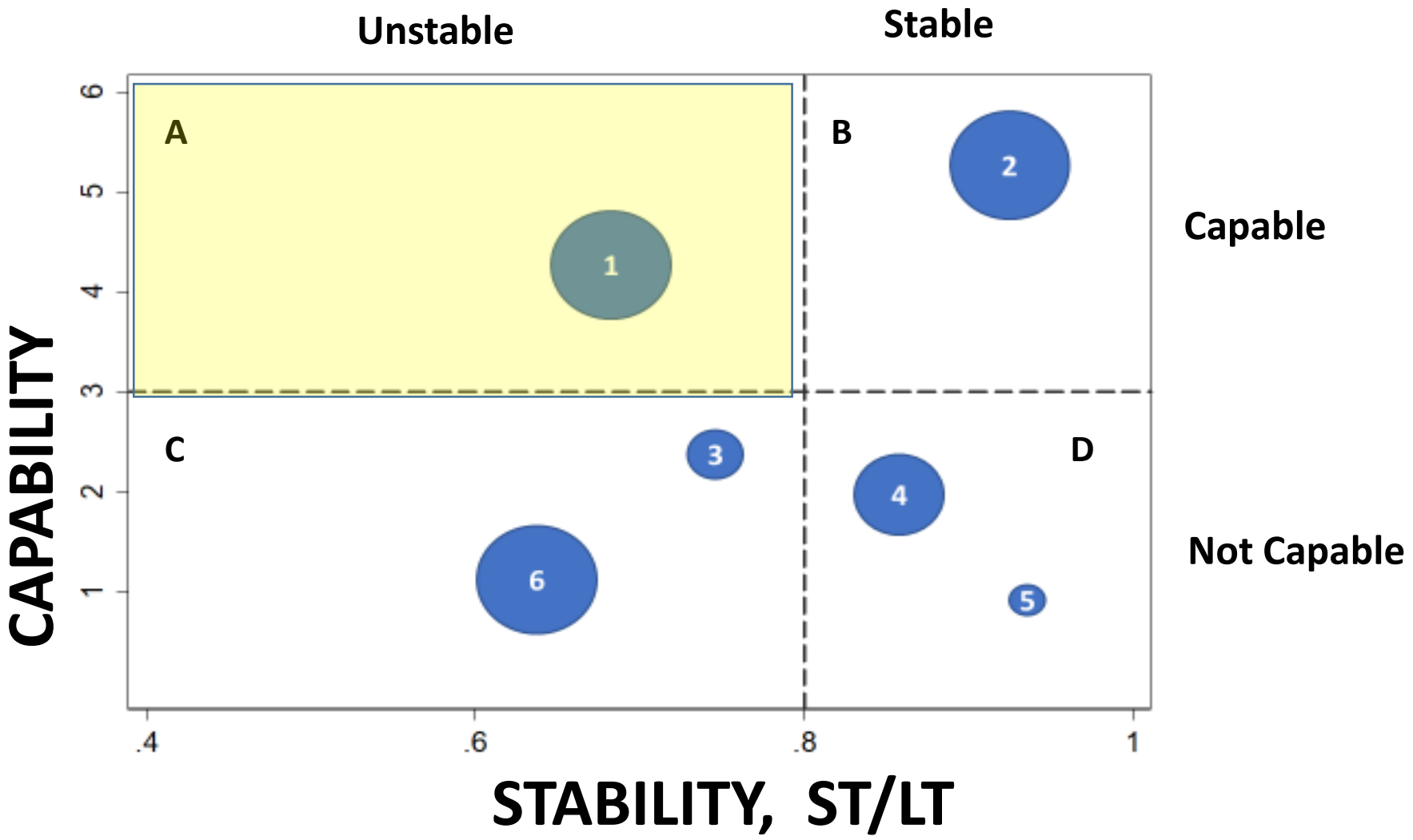


The dotted lines represent acceptable levels of stability and capability. Each circle represents an assay (numbered 1 to 6). The size of the circle corresponds to the annual volume of the assay.

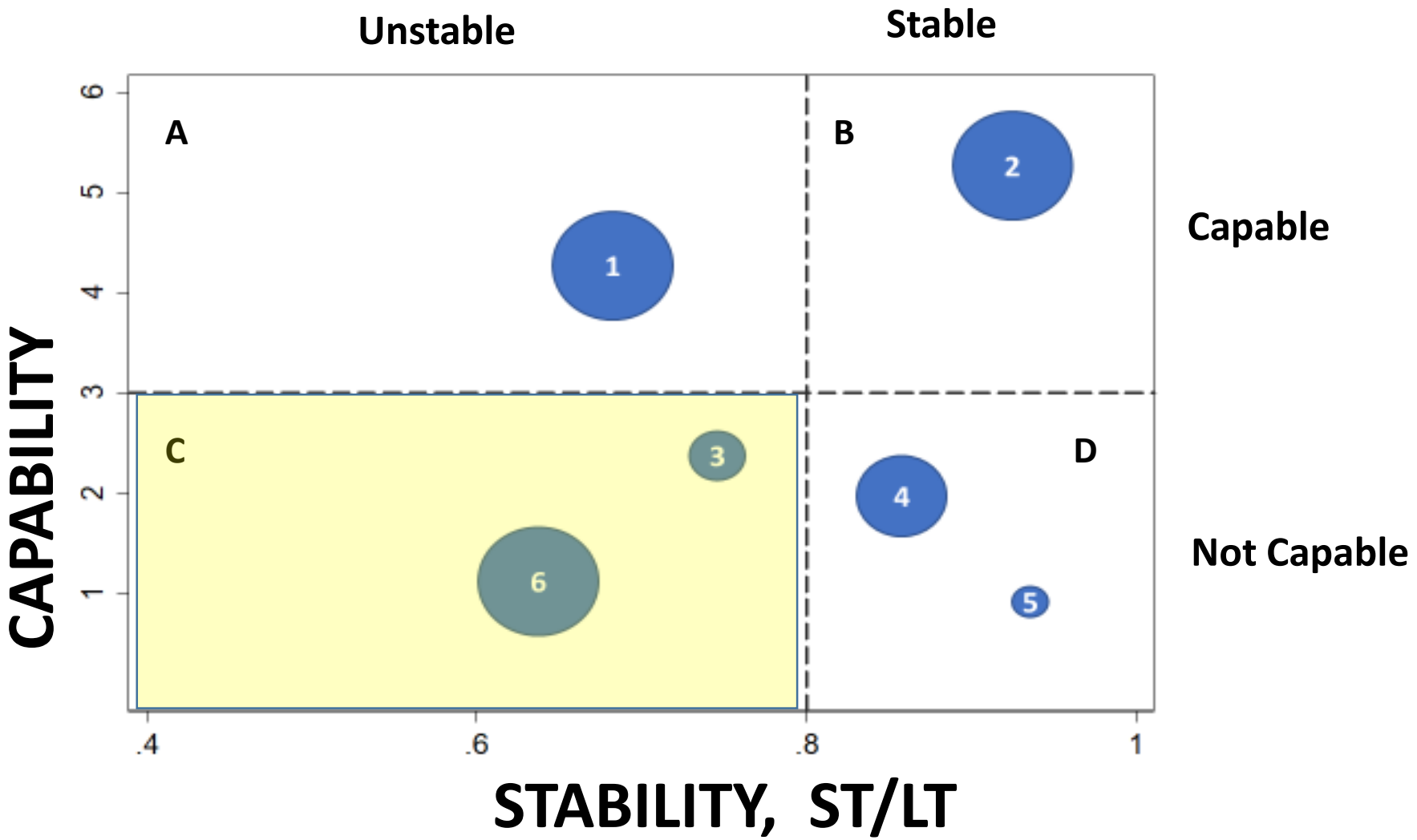
Stability-Capability Matrix



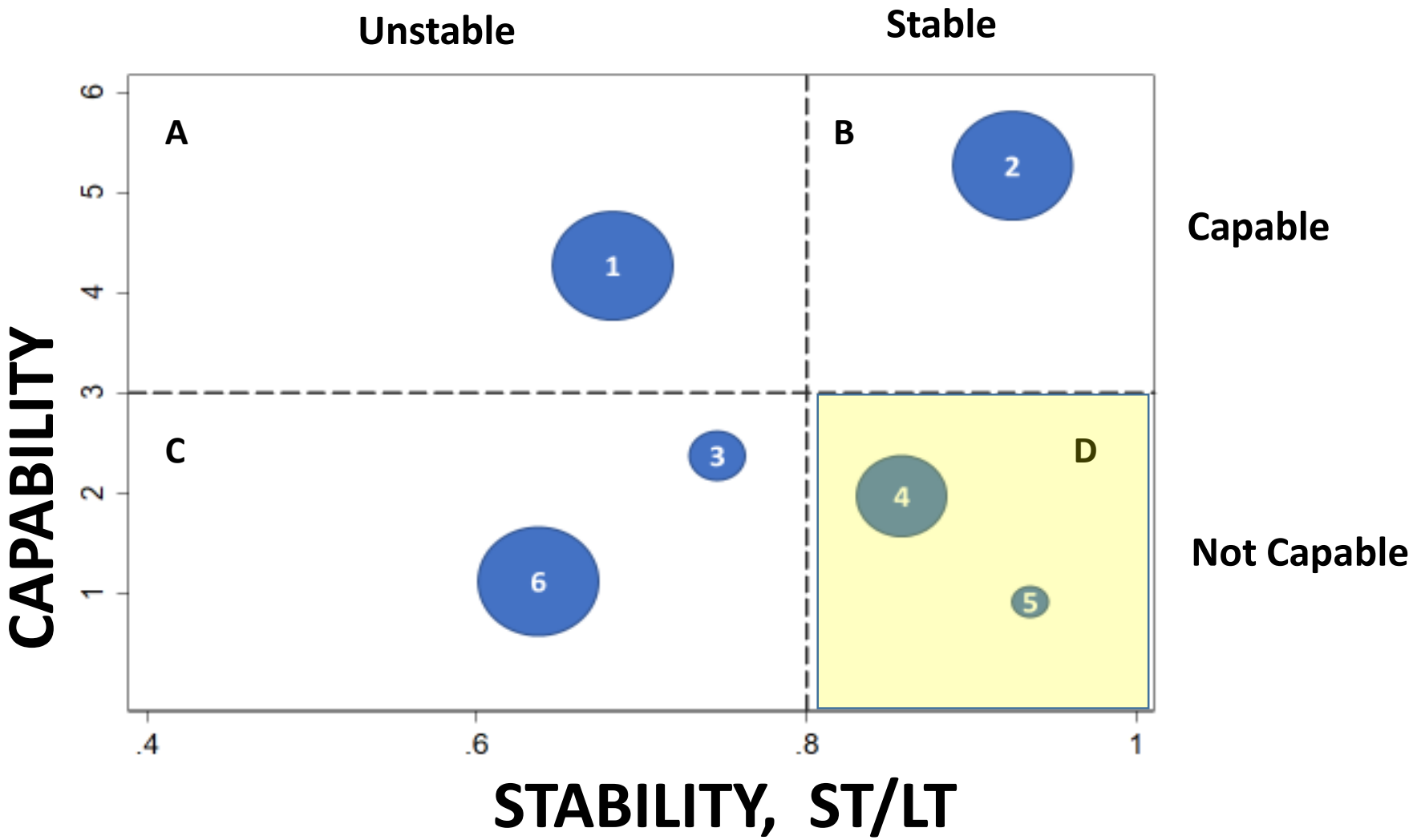
Stability-Capability Matrix



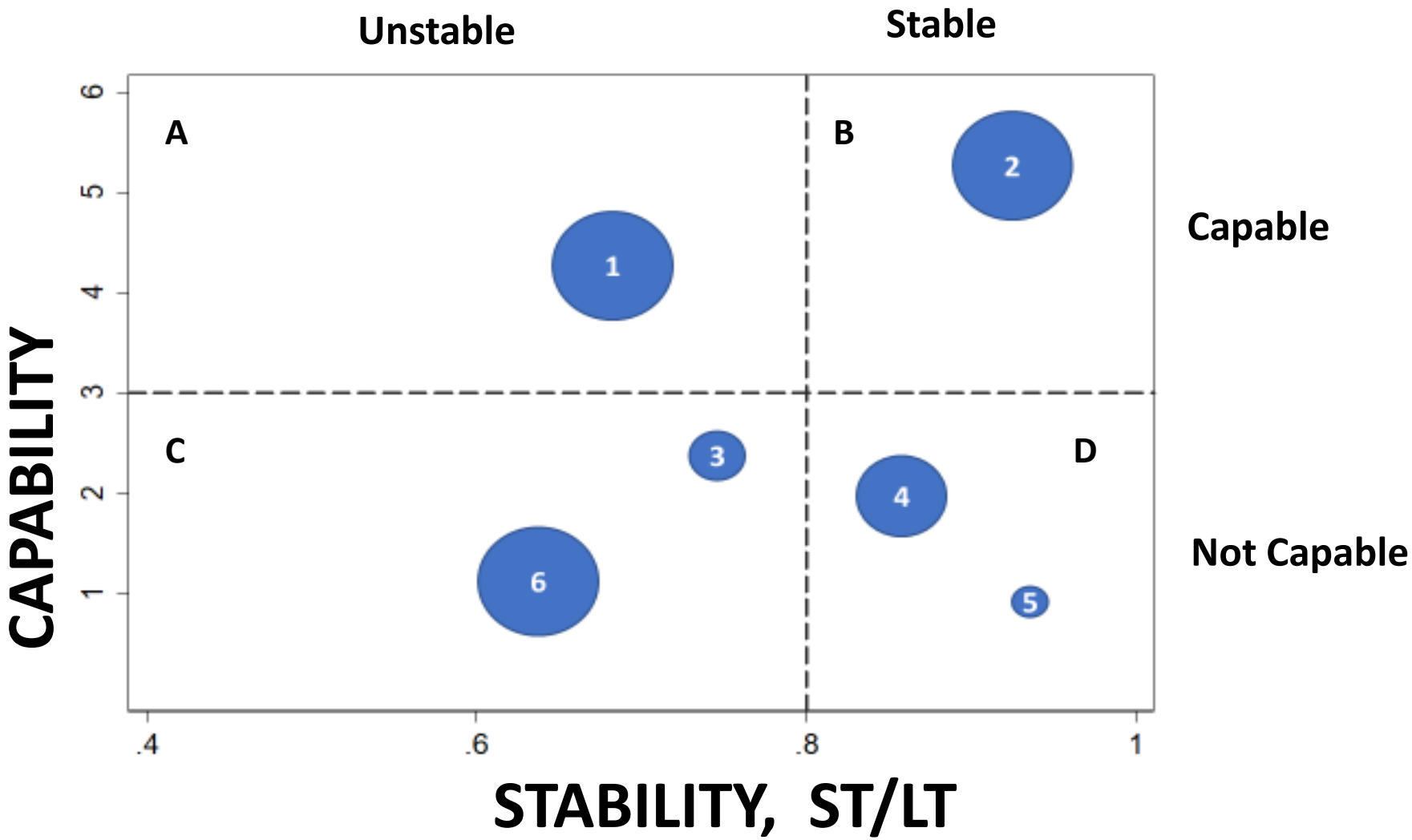
Stability-Capability Matrix



Stability-Capability Matrix



Stability-Capability Matrix



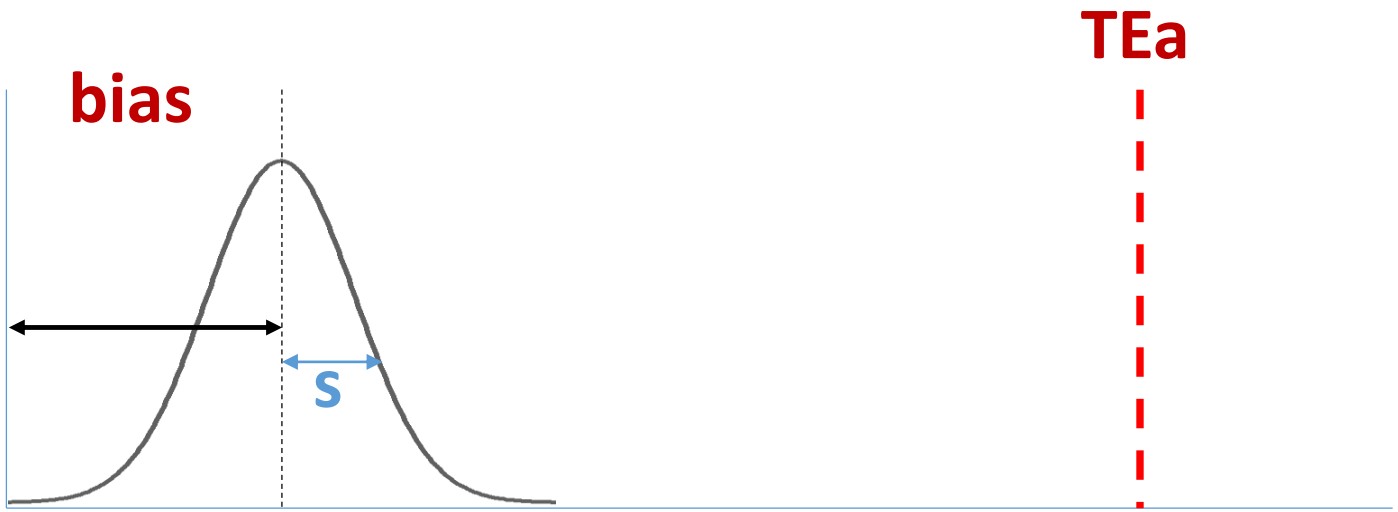
Three key questions:

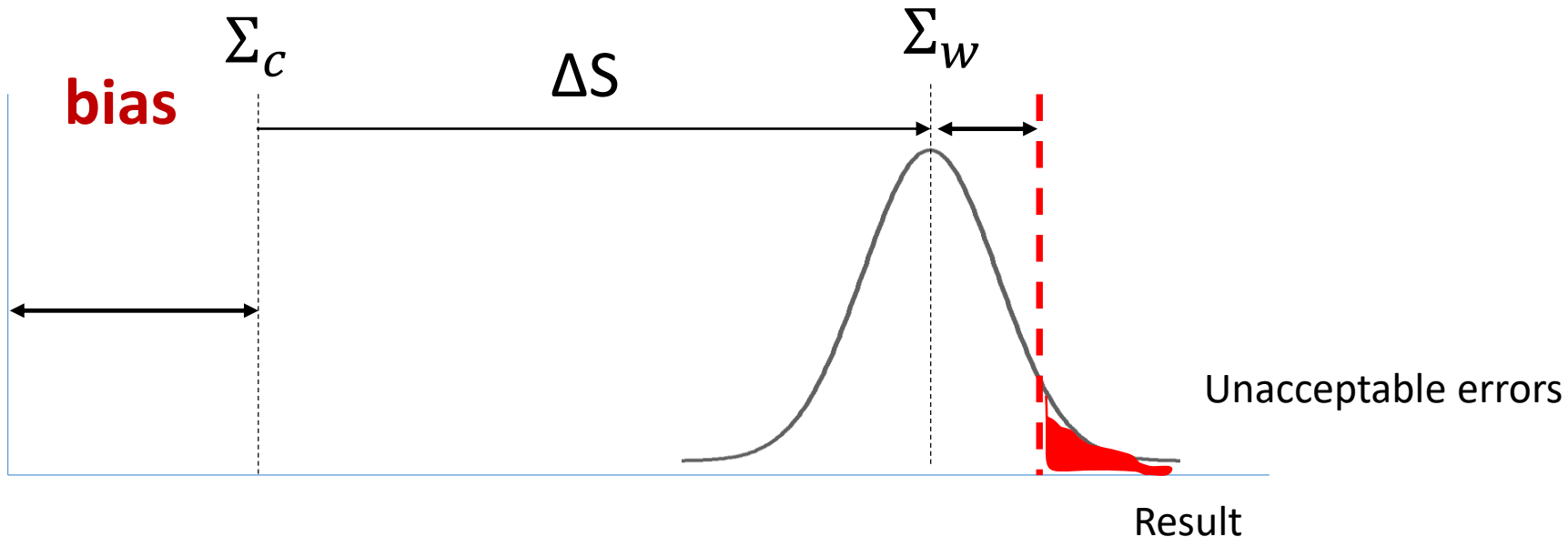
1. Stable?

2. Capable?

3. Controllable?

What is the maximum shift we can accept?

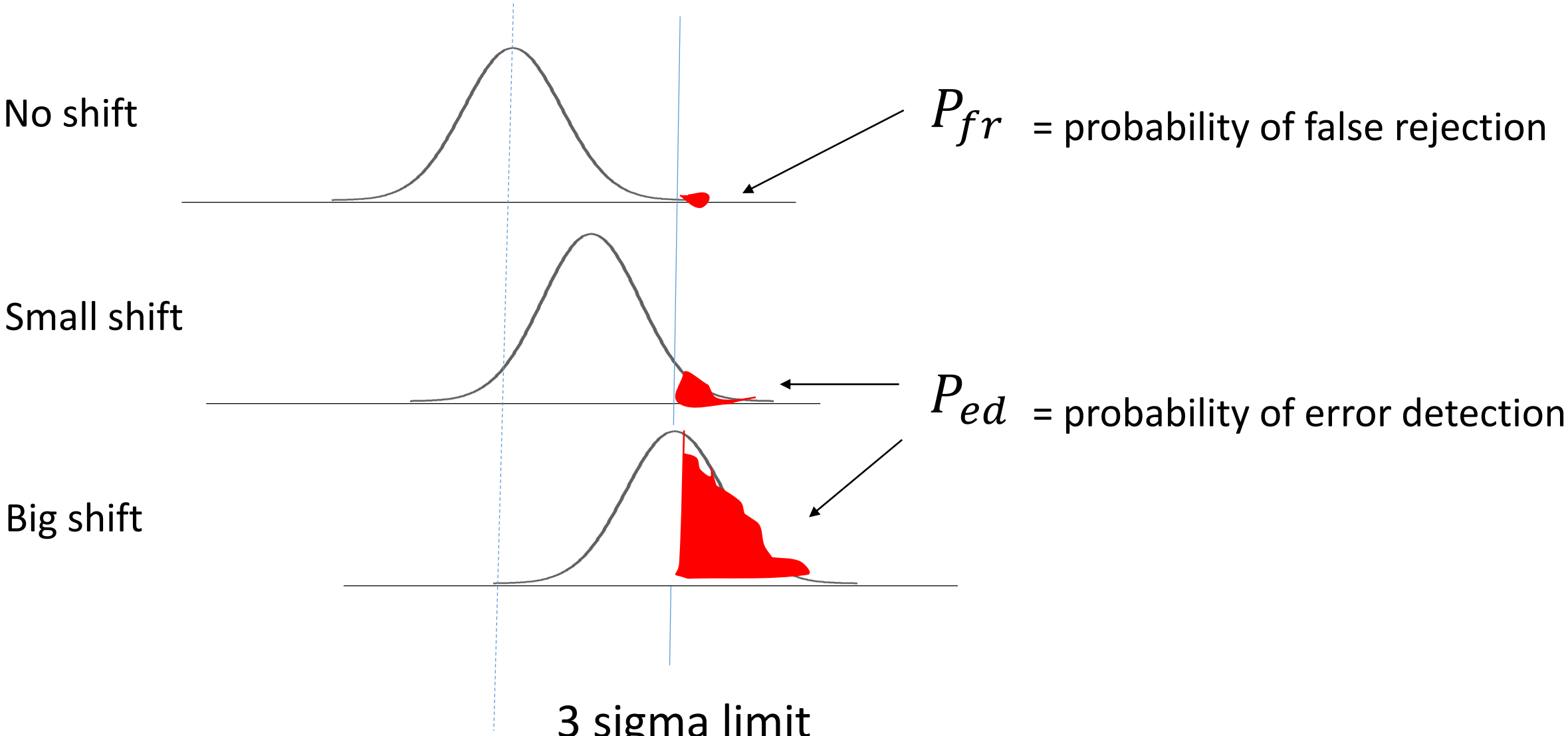


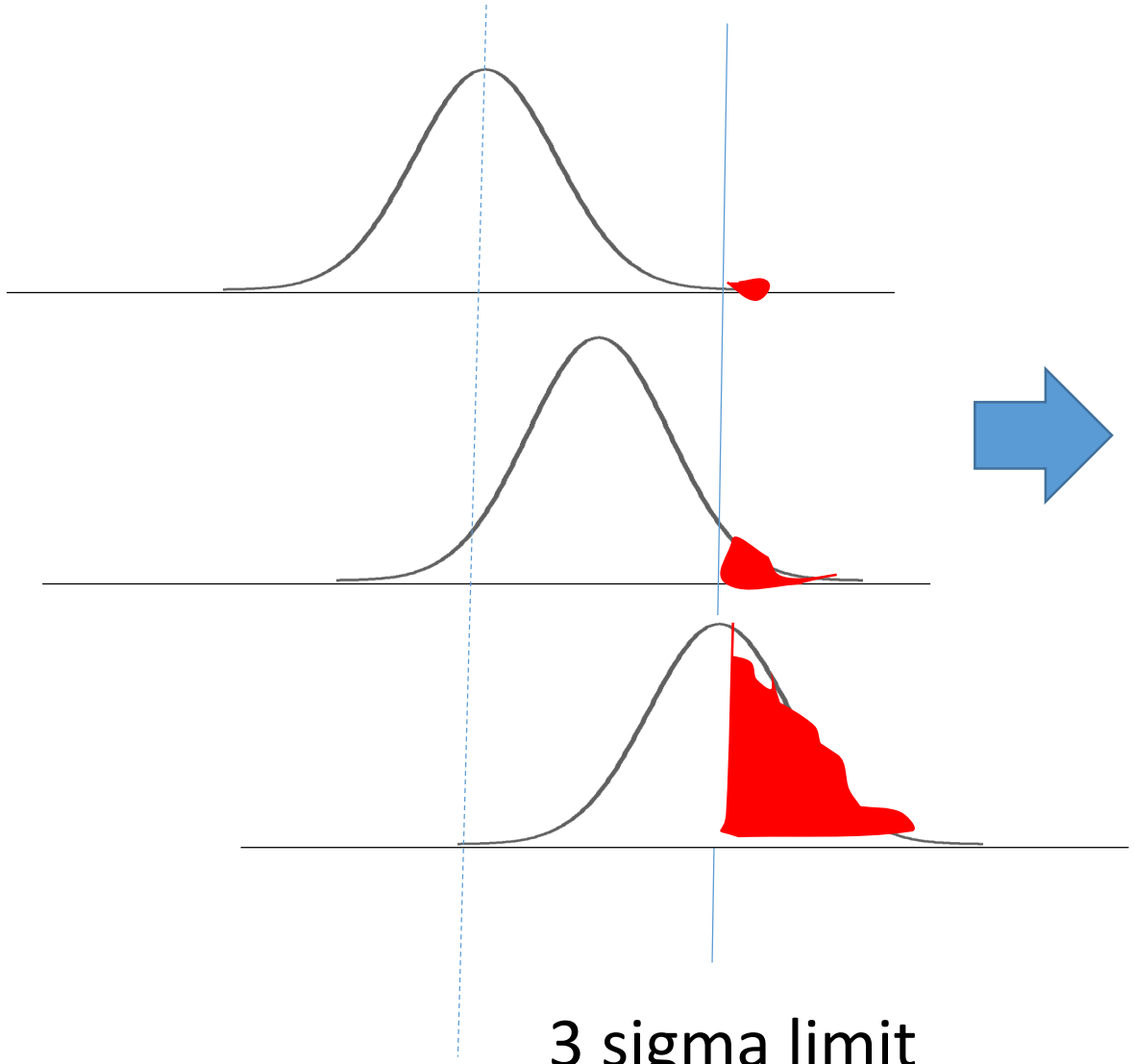


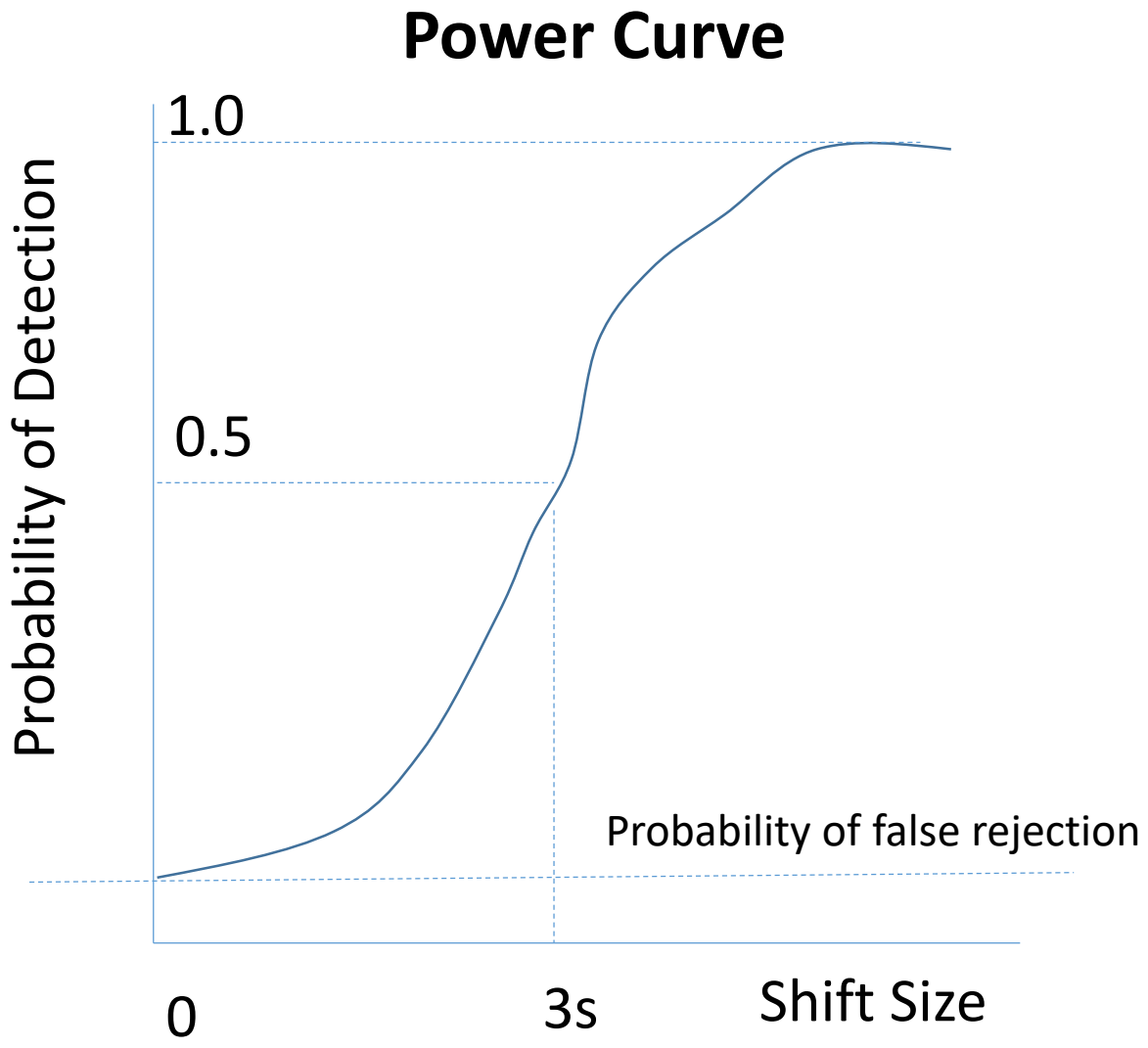
Controllability

- Ability to detect an important shift in the mean

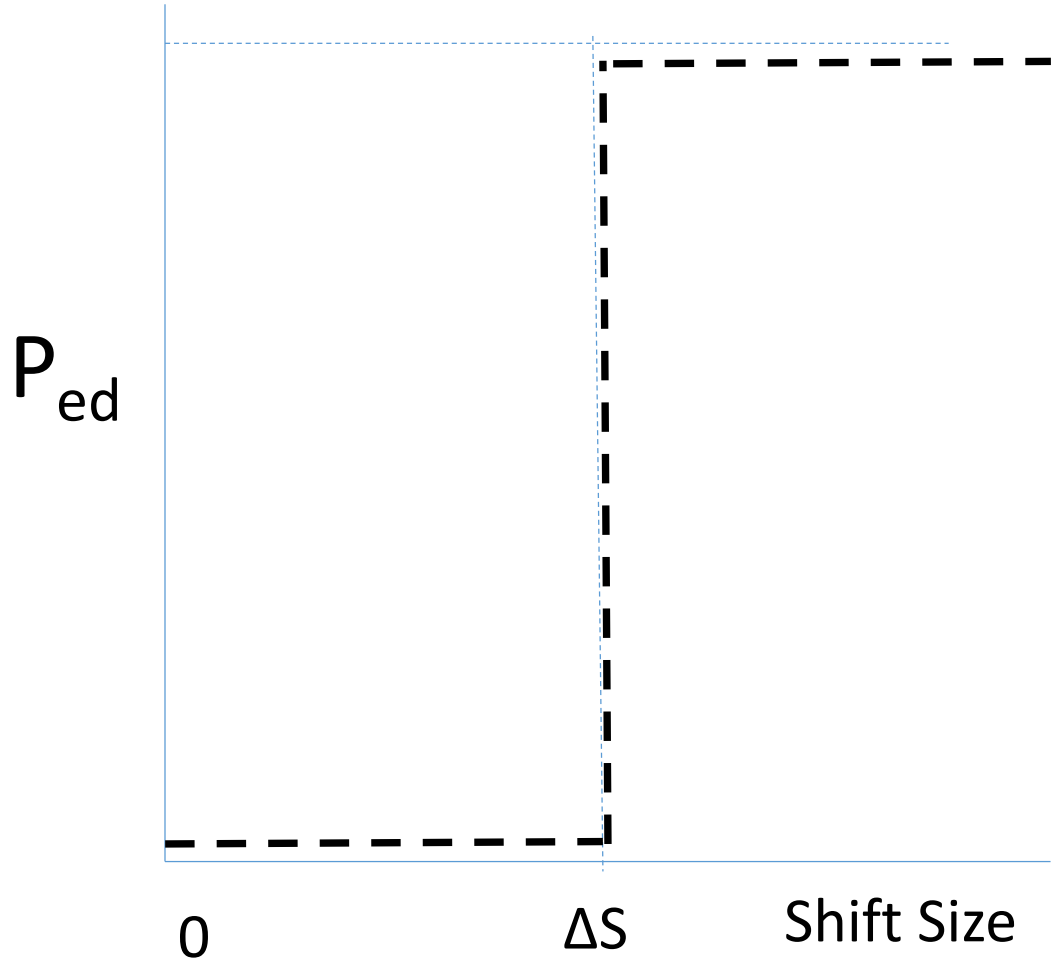
Big shifts are easier to detect



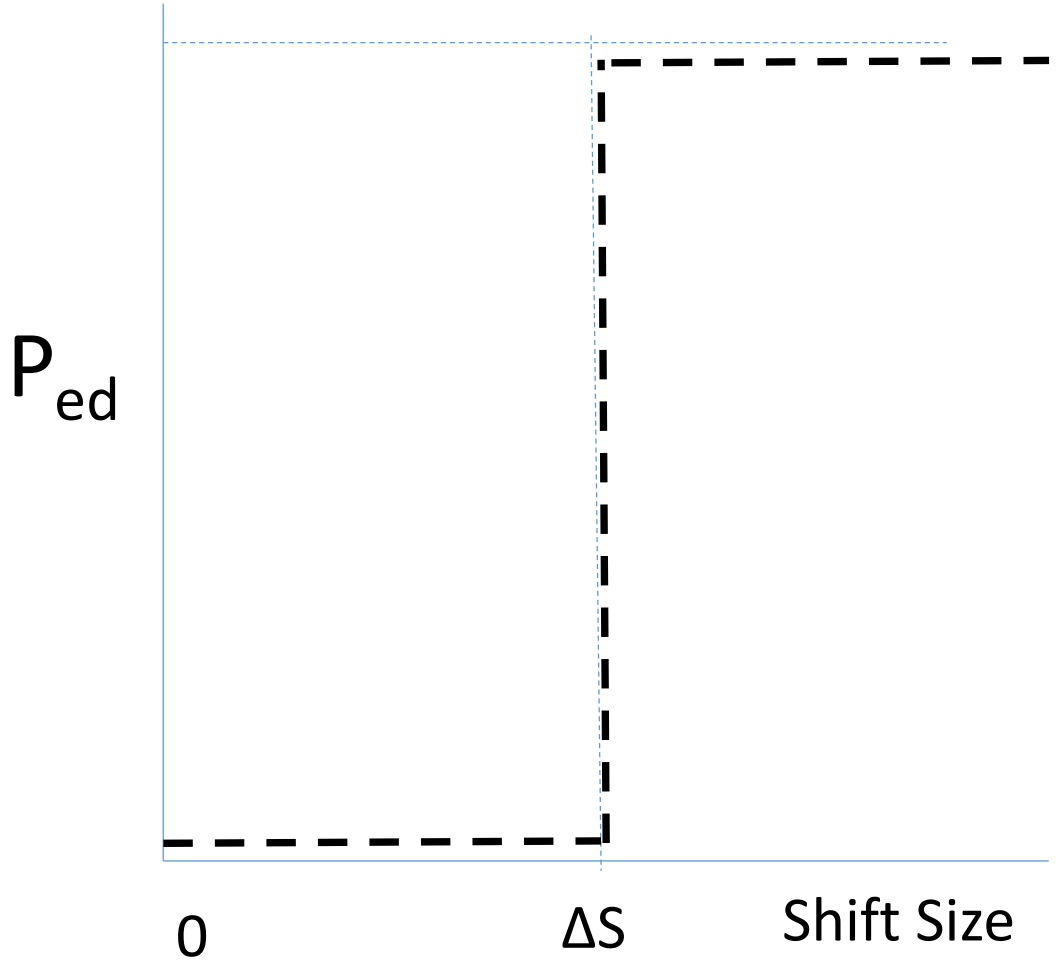

3 sigma limit


Power Curve
1.0
0.5
Probability of Detection
Probability of false rejection
0
3s
Shift Size

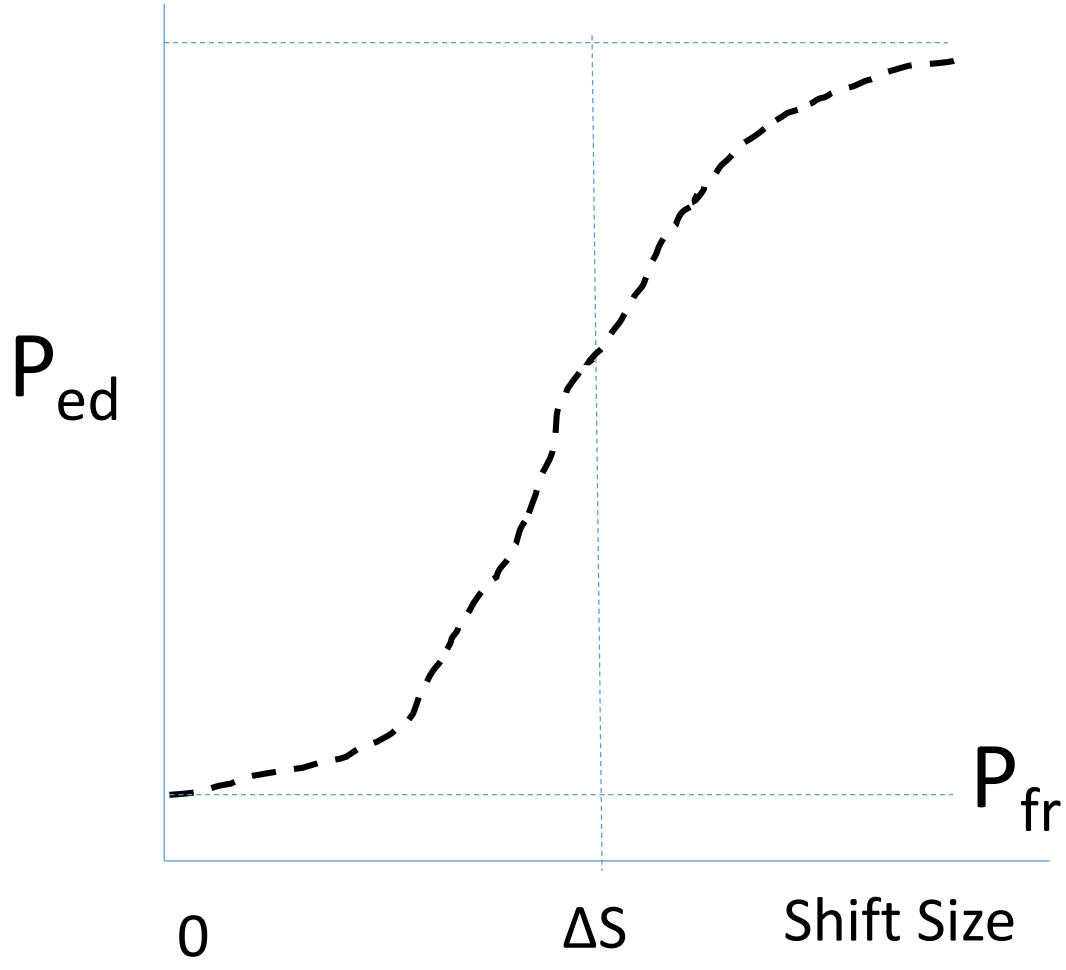
Perfect Power Curve



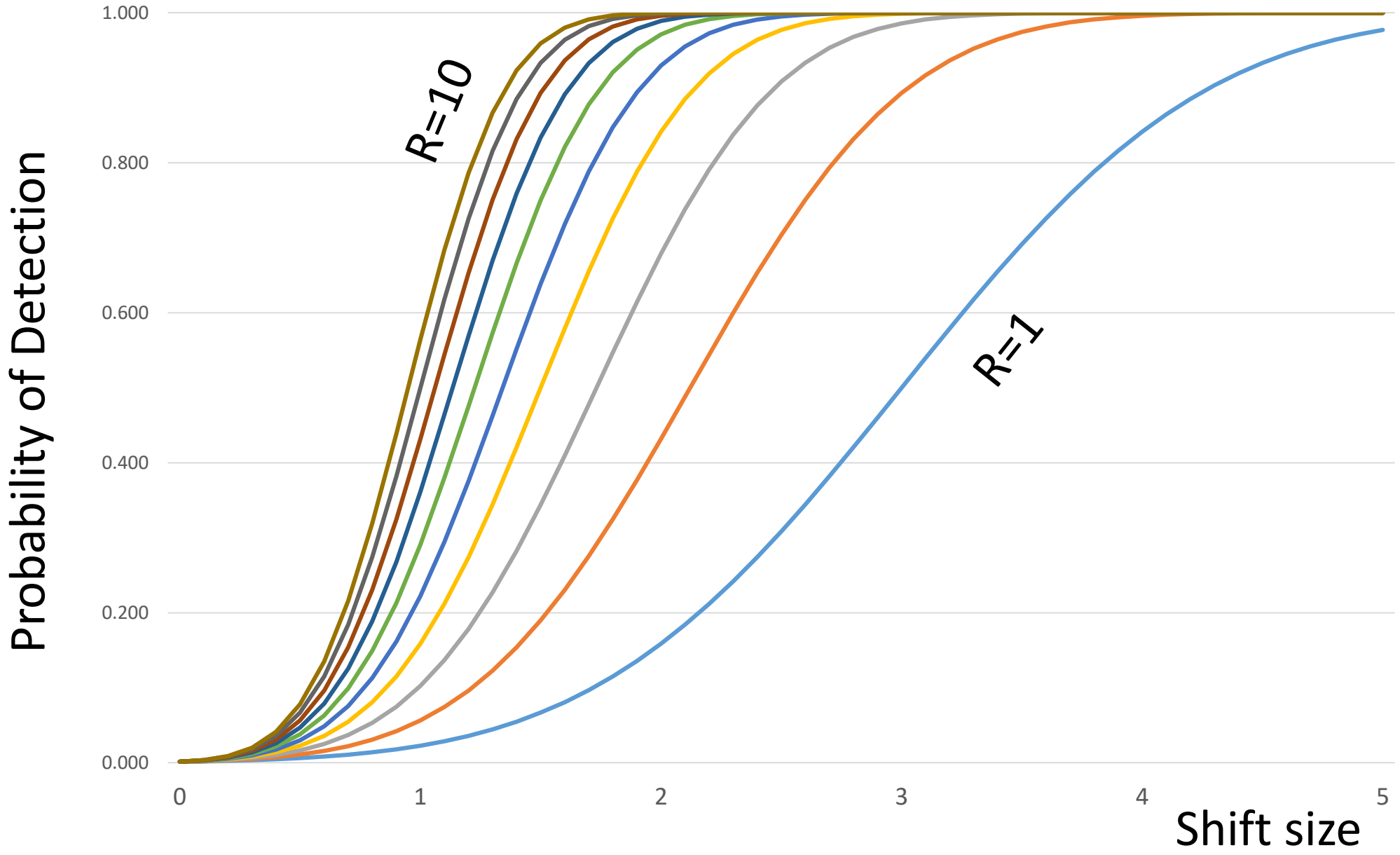
Perfect Power Curve



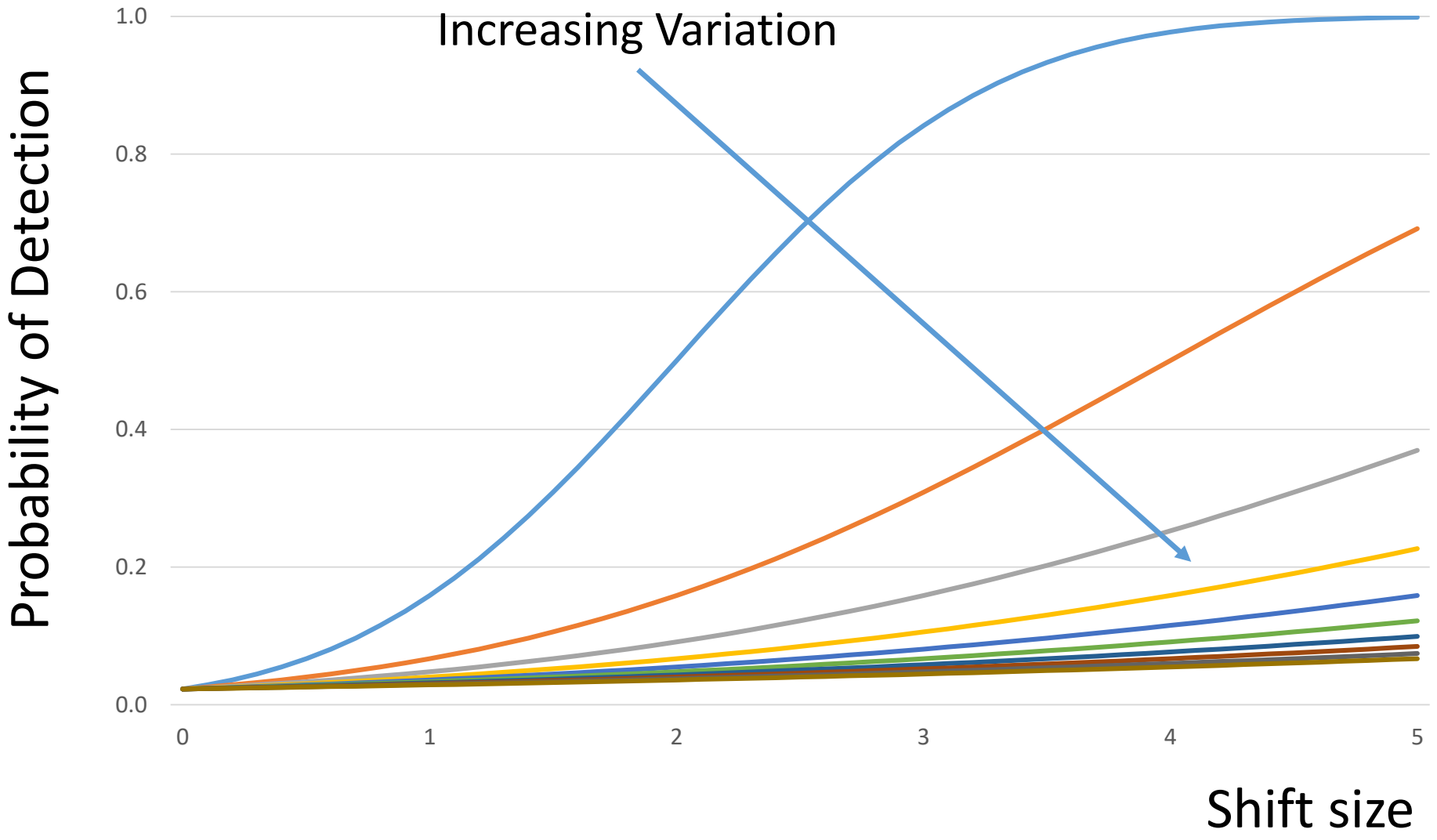
Actual Power Curve



Effect of repeat controls



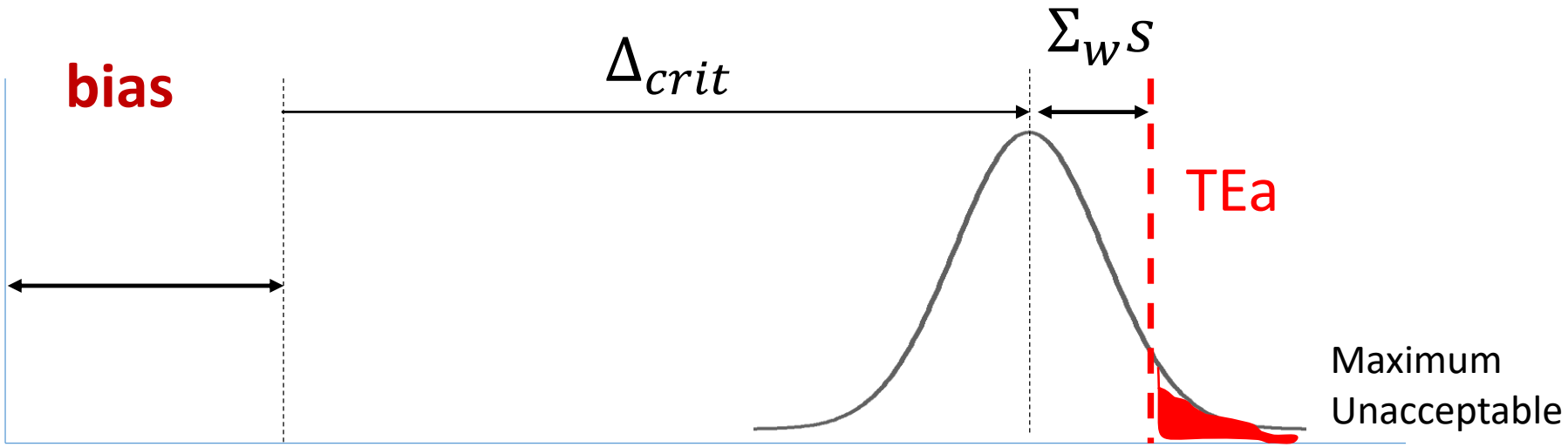
Effect of Variation on Power (R =1)

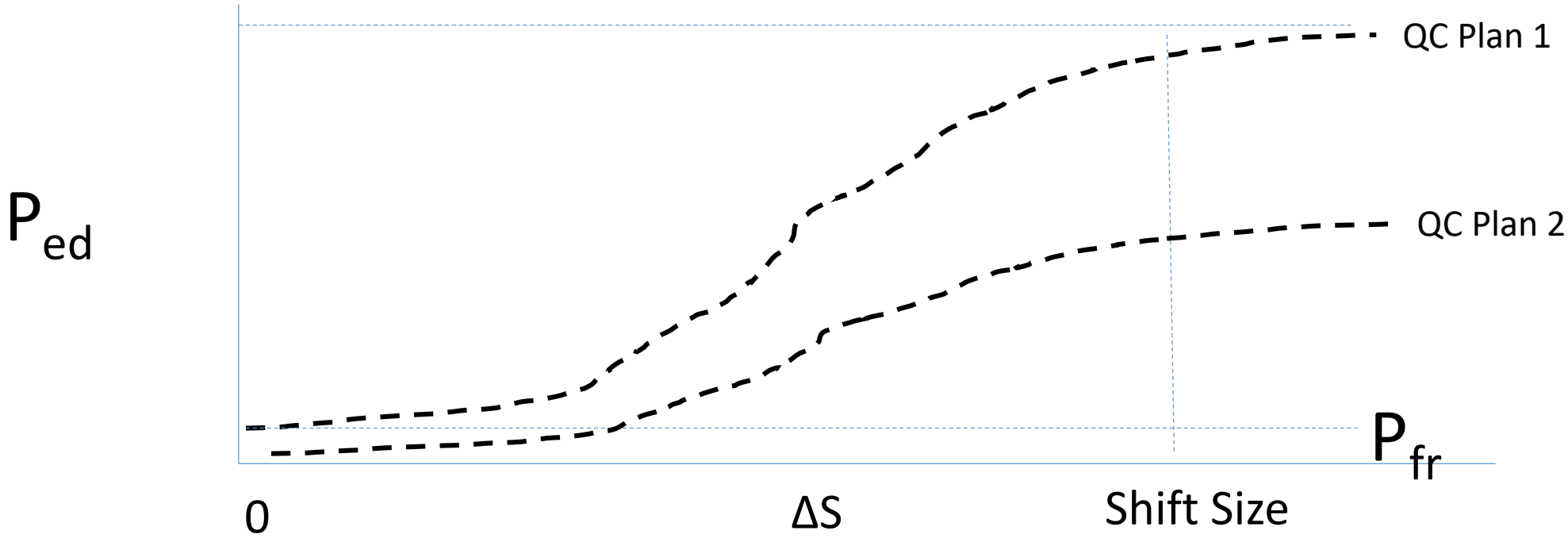


Levers for statistical power

- Number of levels
- Number of repeats
- Selection of Signal (2 sd, 3 sd, Westgard Rules, CUSUM, EWMA)
- Process variation

Can we detect this shift?

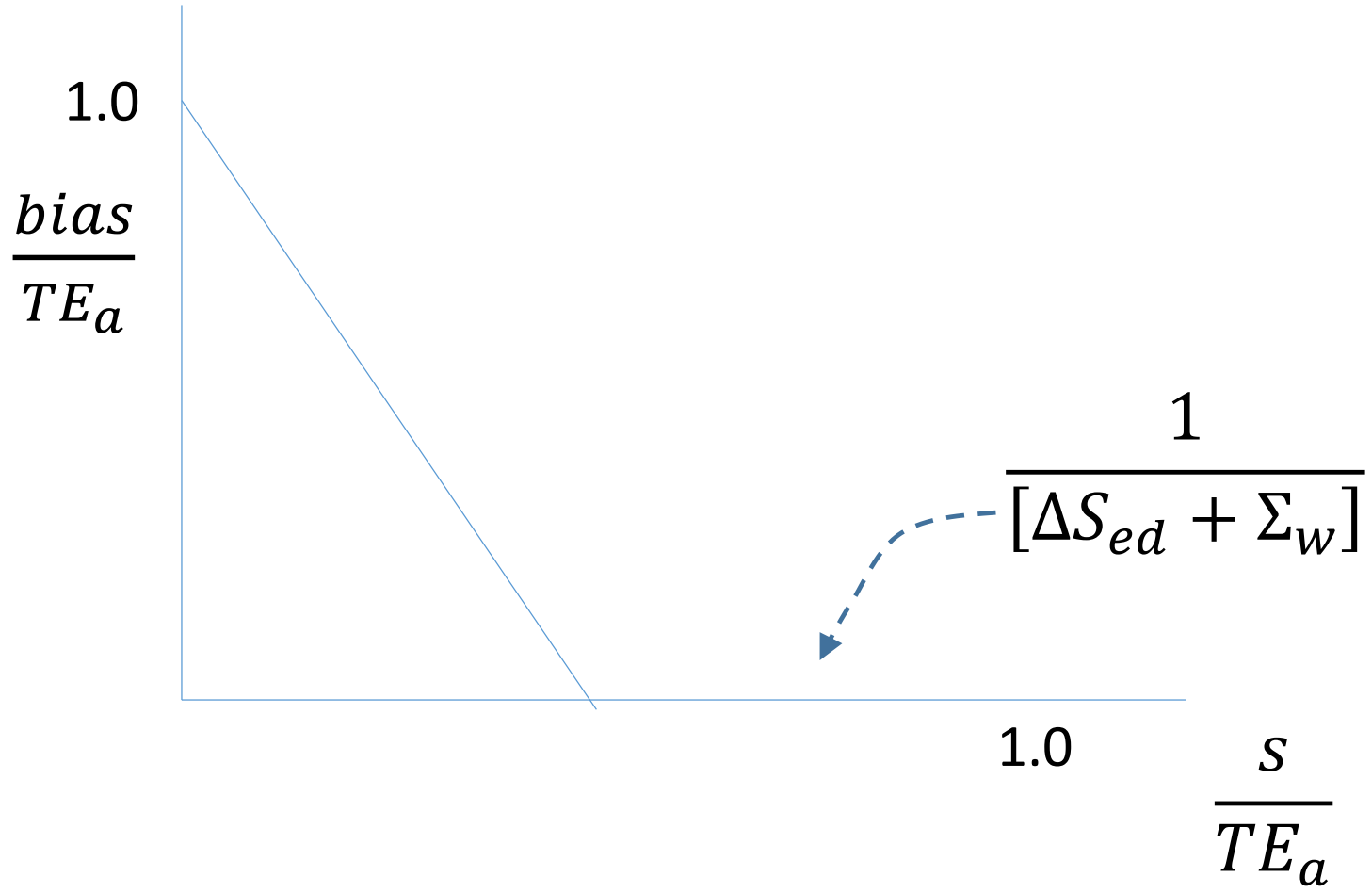




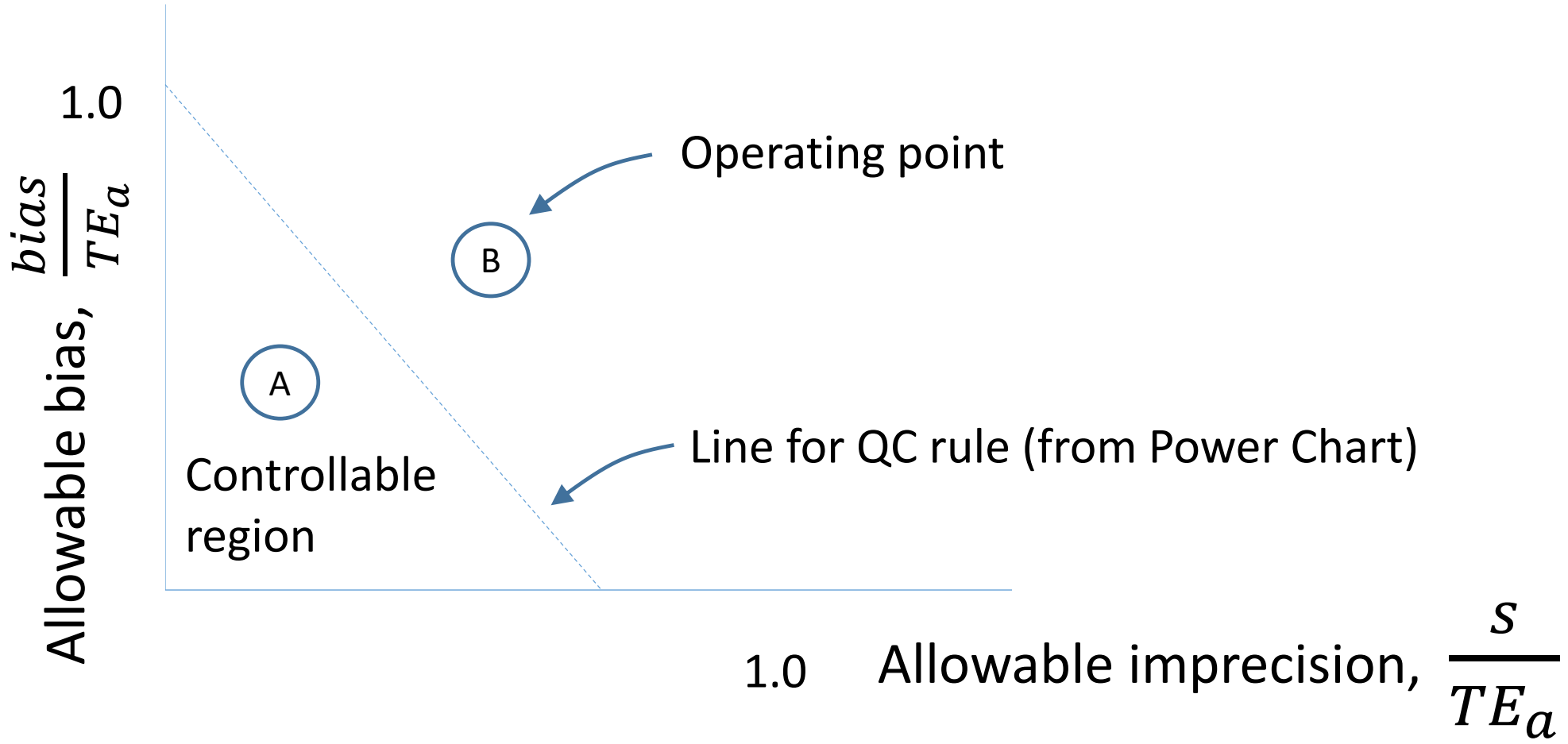
Criteria for controllability

you can detect the changes you need to detect

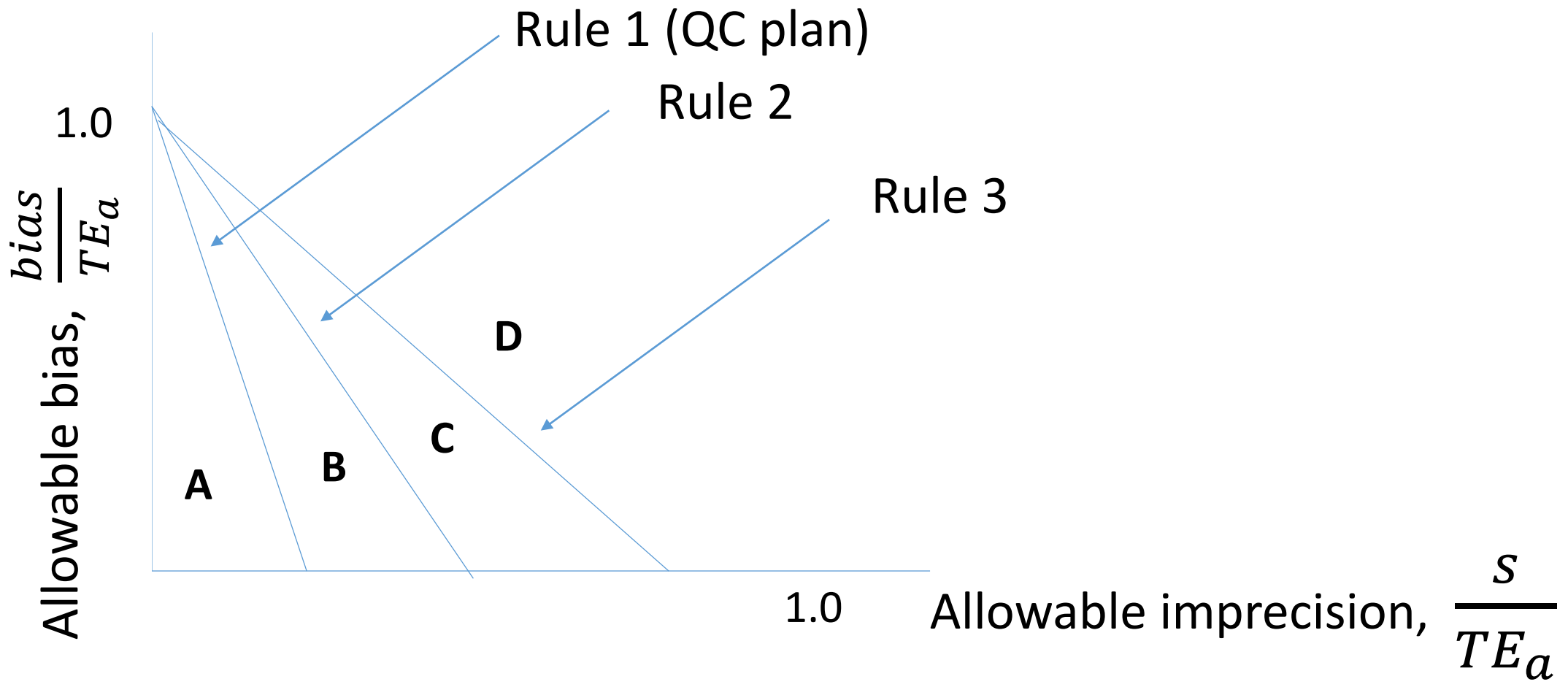
OPSpec chart



OPSpec chart



OPSpec chart



Key Points:

- Every QC plan has a controllable region
- Every testing process has an operating point
- A QC plan can control a testing process if the operating point is in the controllable region
- You can change the operating point

QC Optimization at ARUP

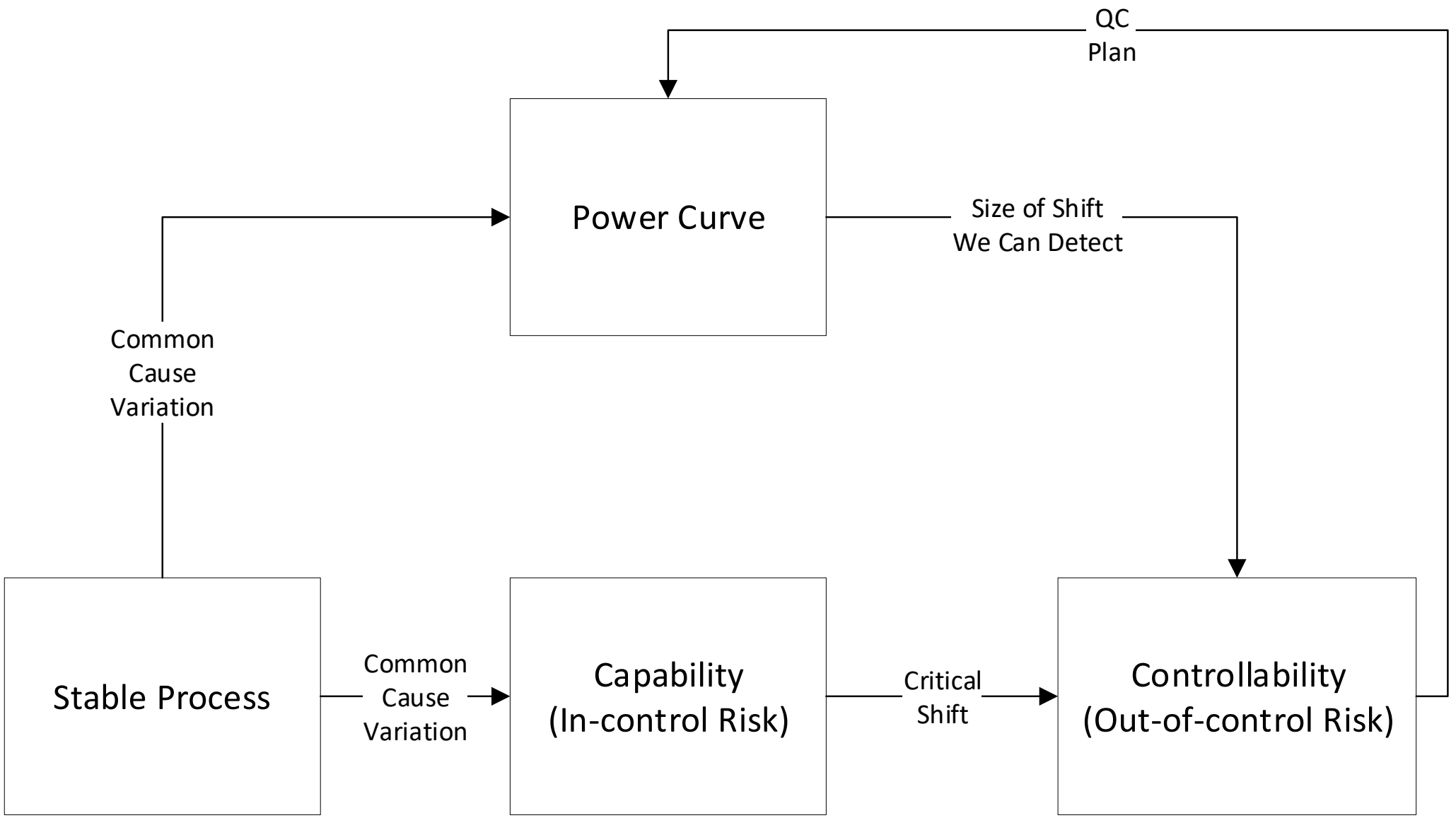
Three key questions:

1. Stable?

2. Capable?

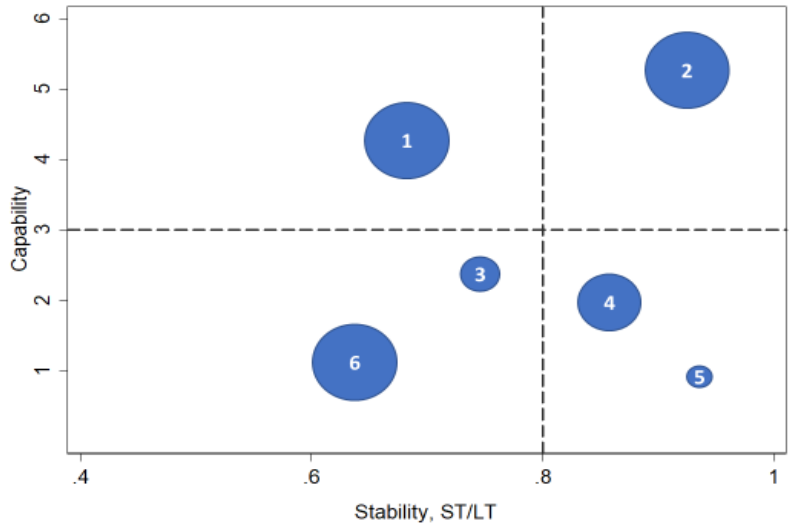
3. Controllable?

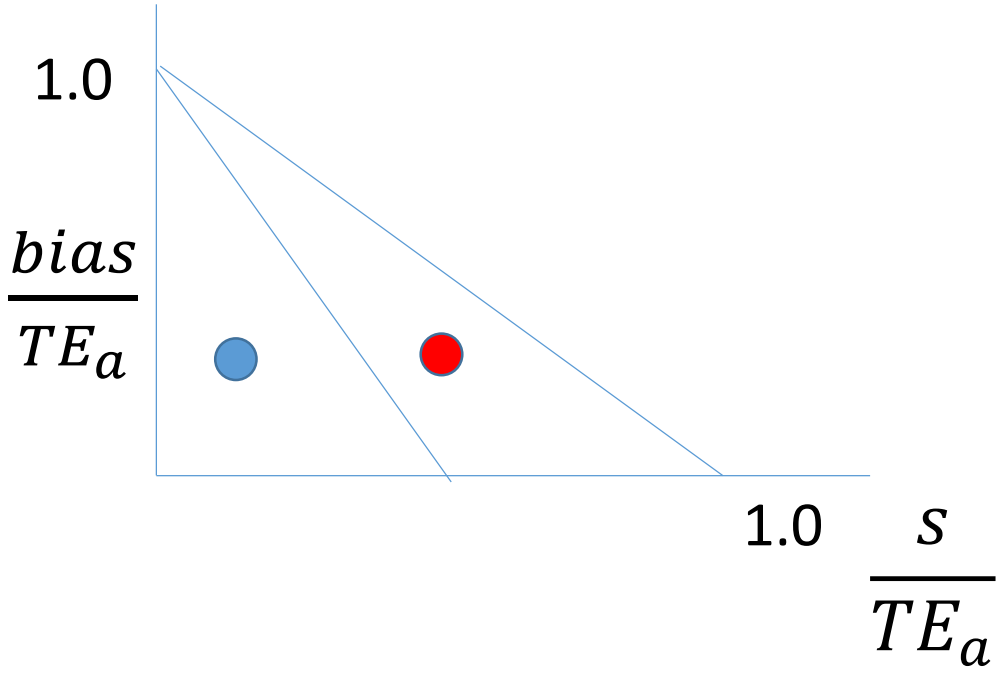
Summary


QC
Plan
Power Curve
Size of Shift
We Can Detect
Common
Cause
Variation
Stable Process
Common
Cause
Variation
Capability
(In-control Risk)
Critical
Shift
Controllability
(Out-of-control Risk)

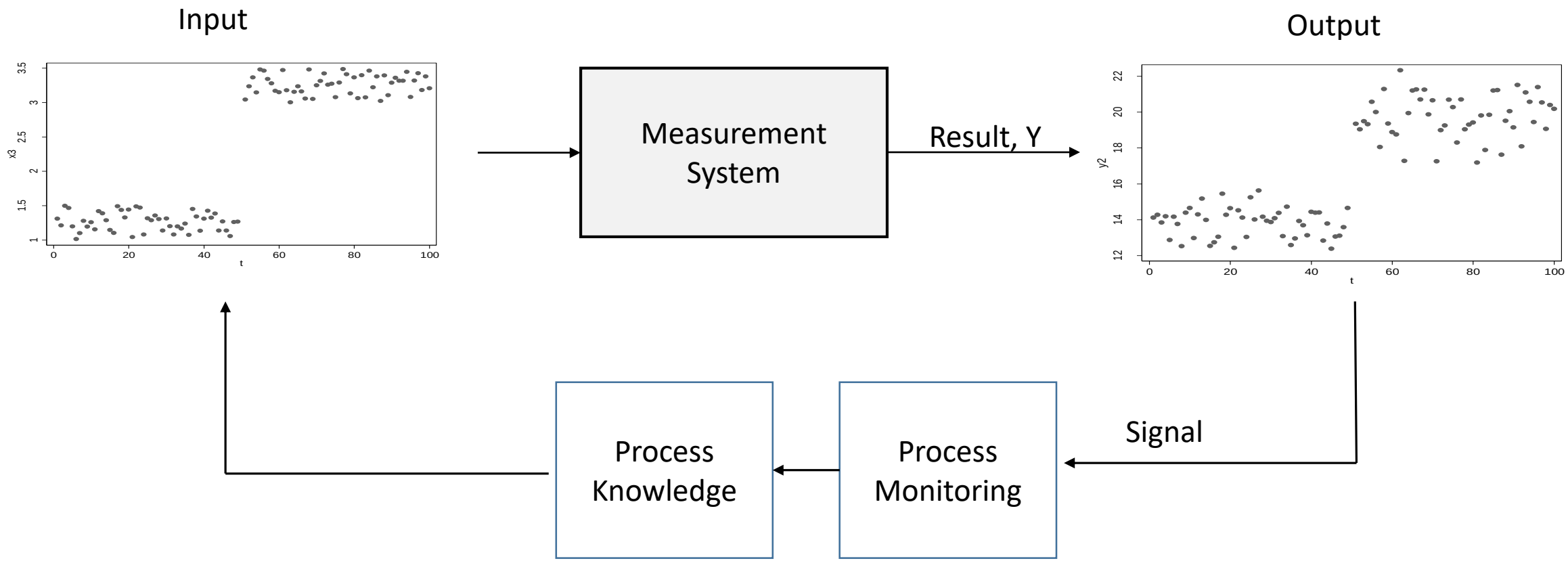
Assay Assessment:

- stable?
- capable?
- controllable?





Goal: Process Knowledge and Variance Reduction



How to reduce long-term variation
(increase stability)

- Use control charts effectively
  - Quality tools
  - Root cause analysis
  - Correct control limits
- Failure Modes and Effects Analysis (FMEA)
- Experiments

Variation is the enemy

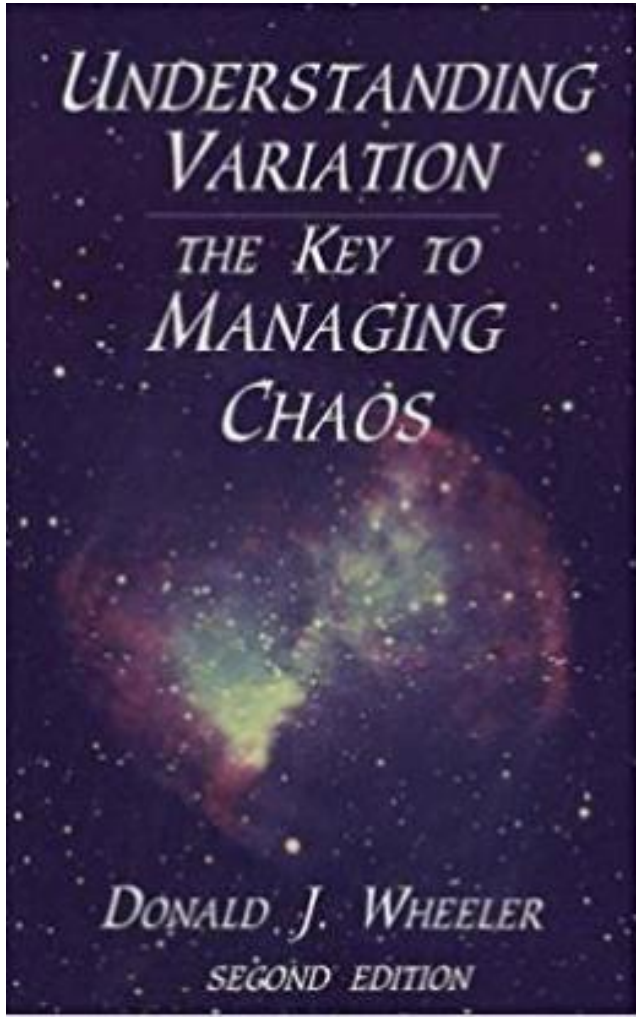
- Hard to detect change
  - Harmful change
  - Beneficial change
- Reduces process capability
  - Unacceptable results
- Increases cost
  - Run failures
  - Need expensive control plan

Impact of QC Improvement TTE Lab

- 74.5% Reduction in Troubleshooting Time
- 43% Reduction Labor Cost
- 50% Improvement in Turnaround Time

Understanding Quality Control

A Process Improvement Perspective



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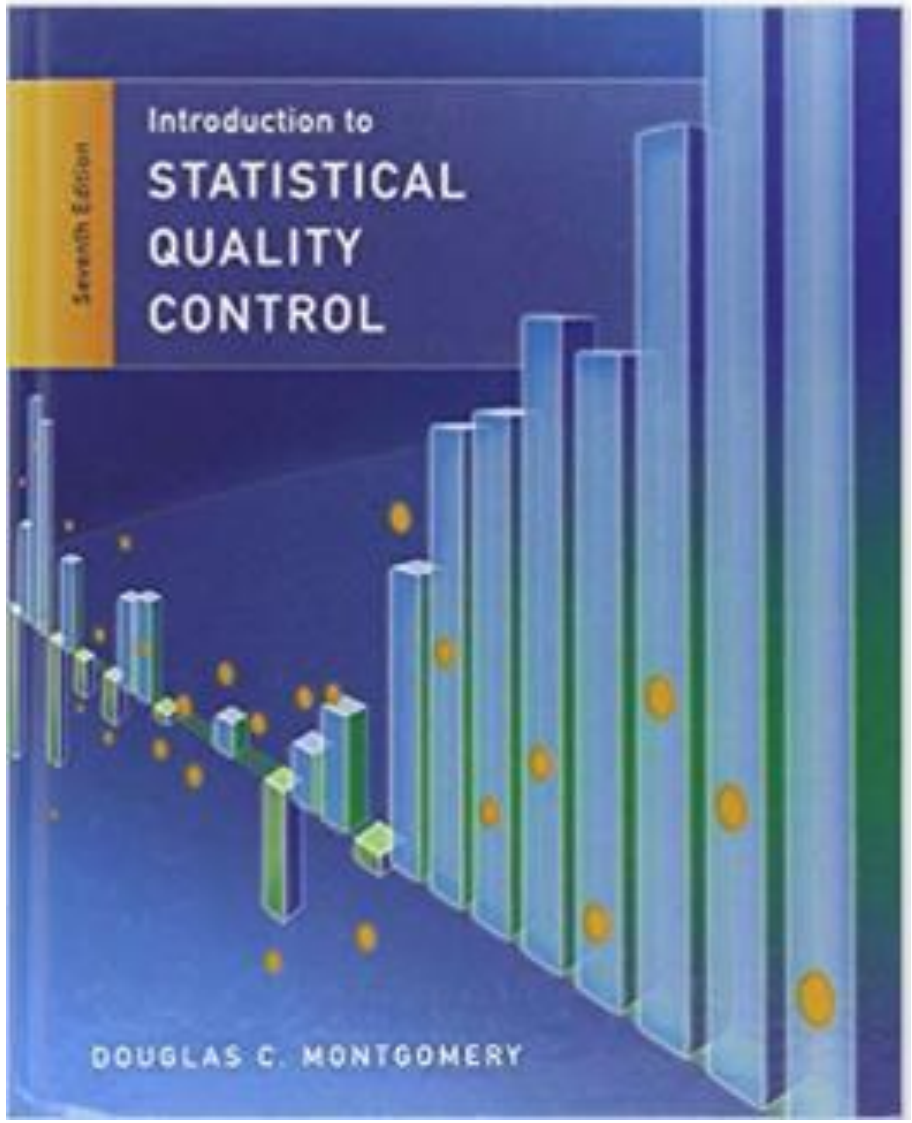

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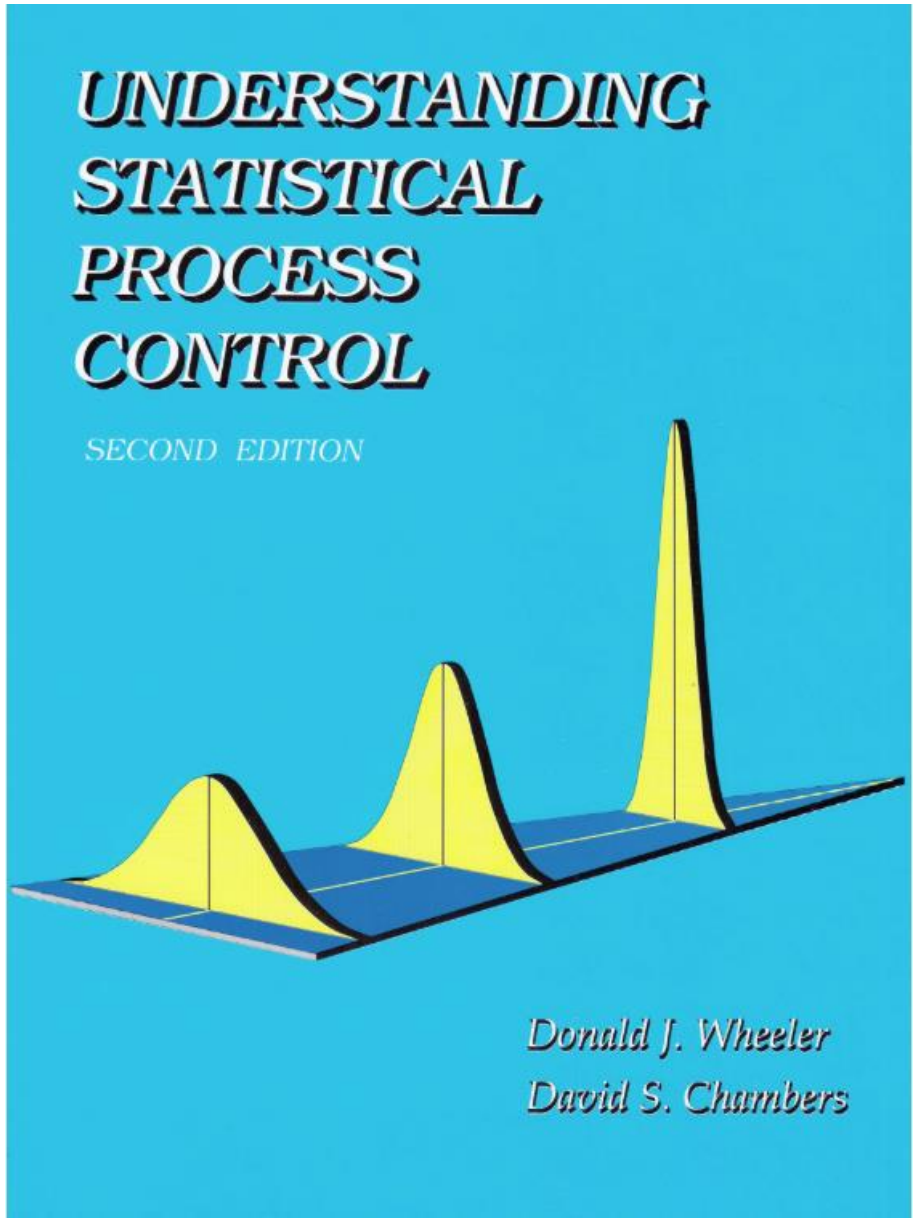

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Questions?

Robert.Schmidt@hsc.utah.edu

Lauren.Pearson@aruplab.com

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