

Fall Technical Conference

Statistics & Quality: Riding the Big Data Wave



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A Recommended Set of Indices for Evaluating Process Health

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Last year...



Stability Assessment with the Stability Index

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The ultimate process goal

Processes are meeting customer needs (based on specifications), stable, and on-target with minimum variation and an adequate measurement system

Problem statement

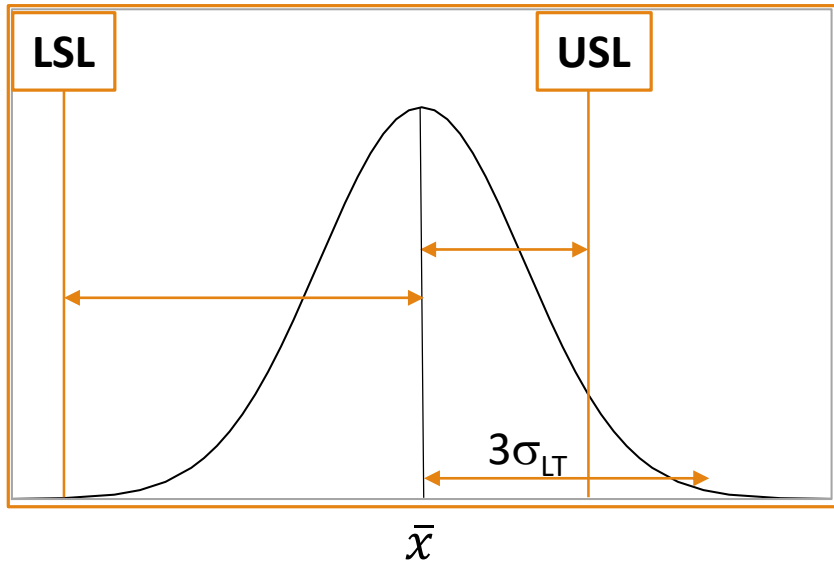
A quality or manufacturing manager oversees multiple processes and wants to evaluate the process health to identify areas for improvement

In light of the ultimate process goal...

- What set of indices is best to assess performance?
- How can these indices be used to quickly evaluate many processes?
- Can these indices provide clues to the type of improvement needed?

Start with P_{pk}

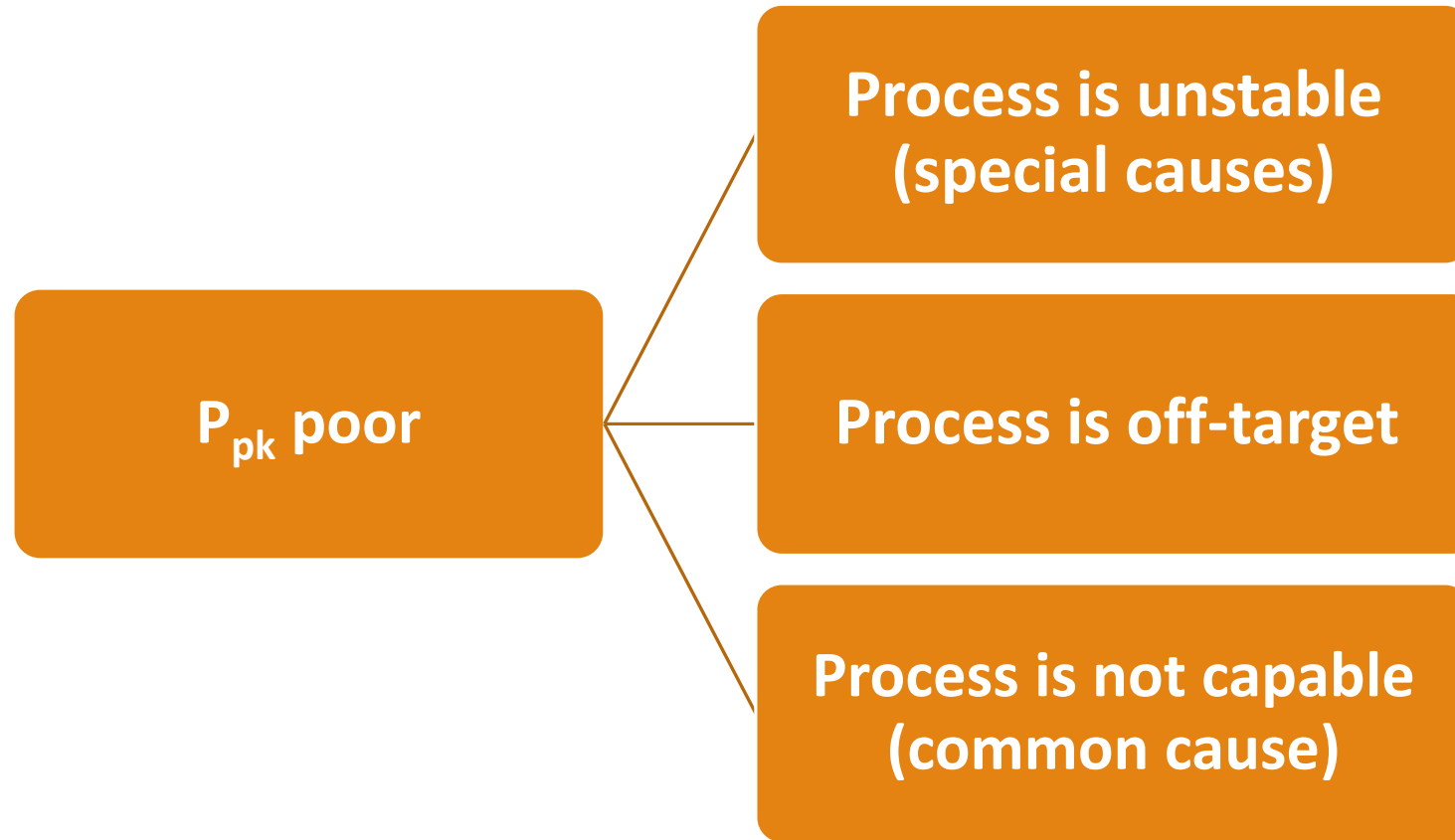
P_{pk} is a good indicator of actual process performance compared to specifications because it considers the long-term variability and the process average.



$$P_{pk} = \frac{\min(USL - \bar{x}, \bar{x} - LSL)}{3\sigma_{LT}}$$

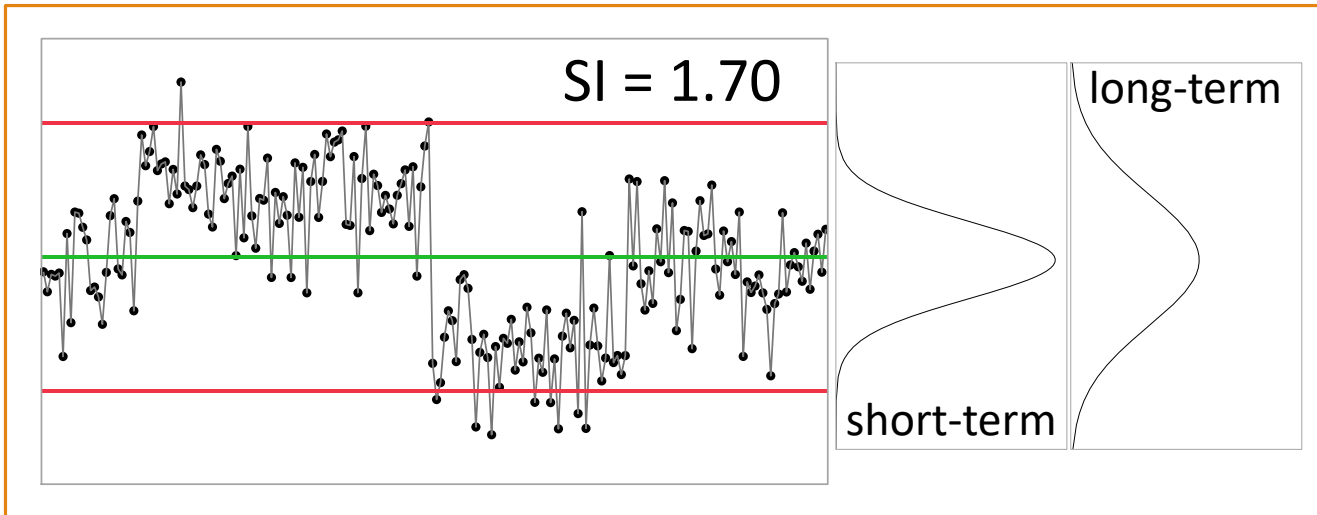
Rule of Thumb	P_{pk}
Adequate	>1.33
Marginal	1.00-1.33
Poor	<1.00

Three reasons for an unhealthy process



Stable?

The Stability Index (SI) is the ratio of the long-term standard deviation to the short-term standard deviation

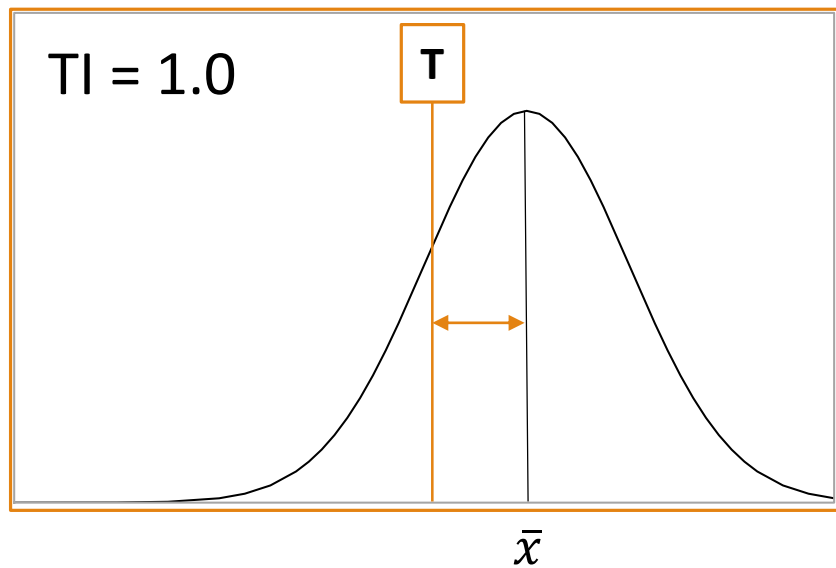


$$SI = \frac{\sigma_{LT}}{\sigma_{ST}} = \frac{C_{pk}}{P_{pk}} = \frac{C_p}{P_p}$$

Rule of Thumb	SI
Adequate	<1.25
Marginal	1.25-1.50
Poor	>1.50

Off-target?

The Target Index (TI) is the number of short-term standard deviations the process average is from target

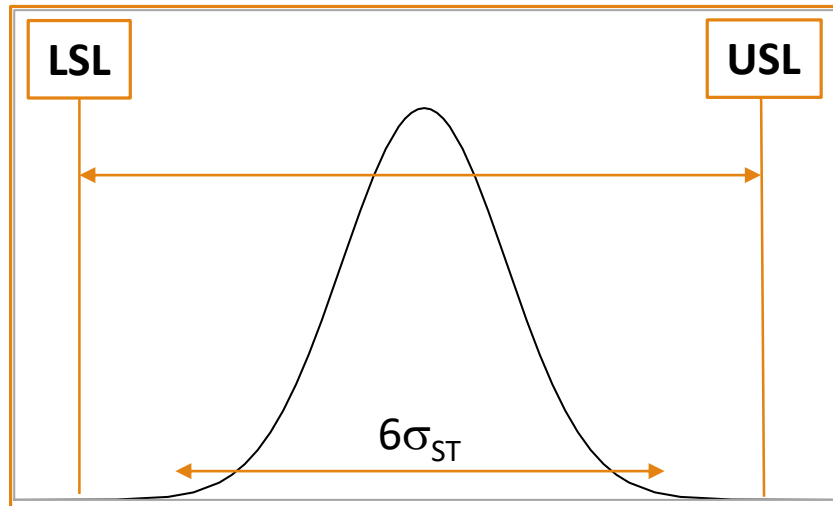


$$TI = \frac{|\bar{x} - T|}{\sigma_{ST}} = 3(C_p - C_{pk})$$

Rule of Thumb	TI
Adequate	<0.5
Marginal	0.5-1.0
Poor	>1.0

Common cause capable?

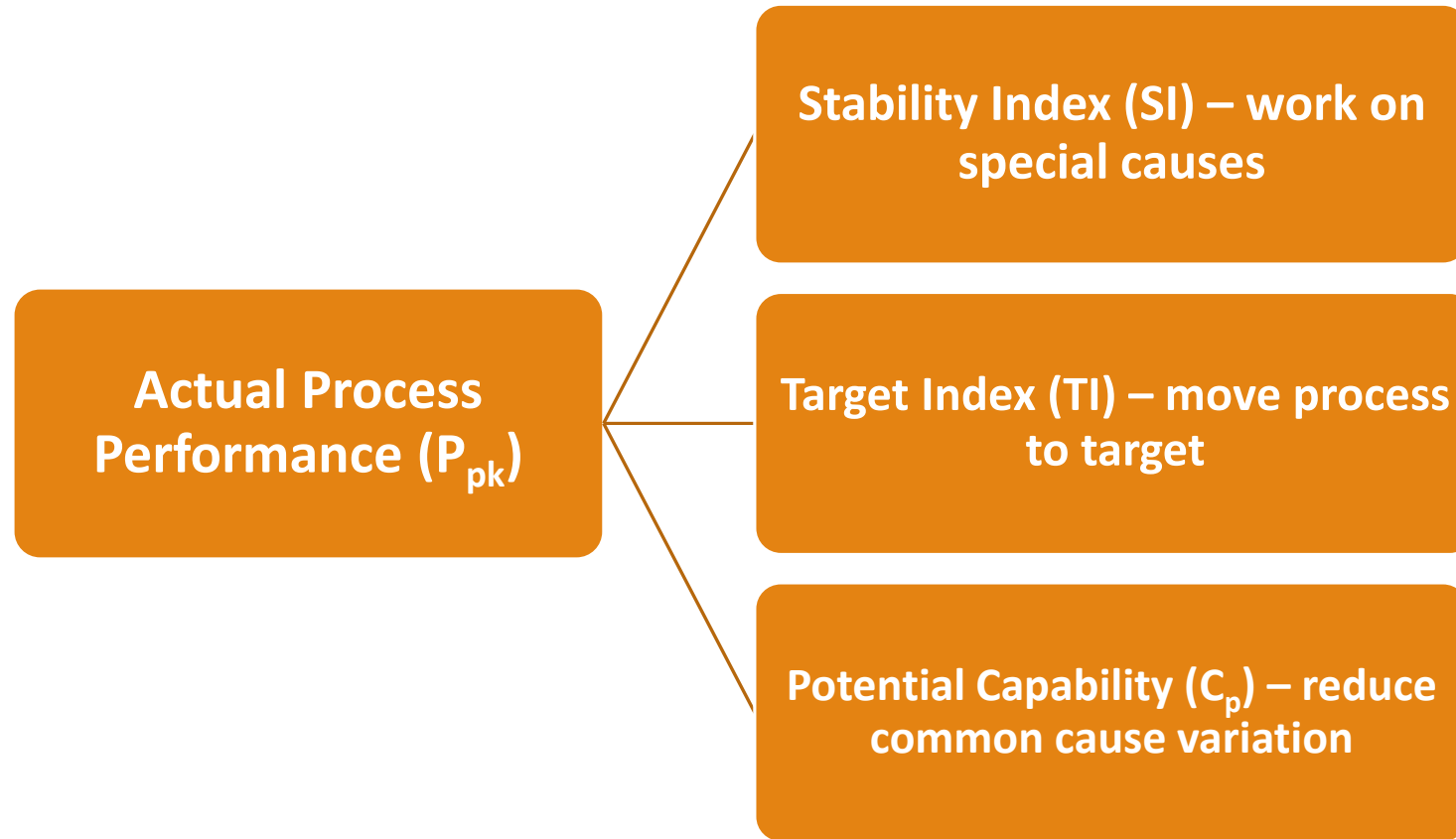
C_p is a good indicator of potential process performance because it only considers the short-term variability due to common cause



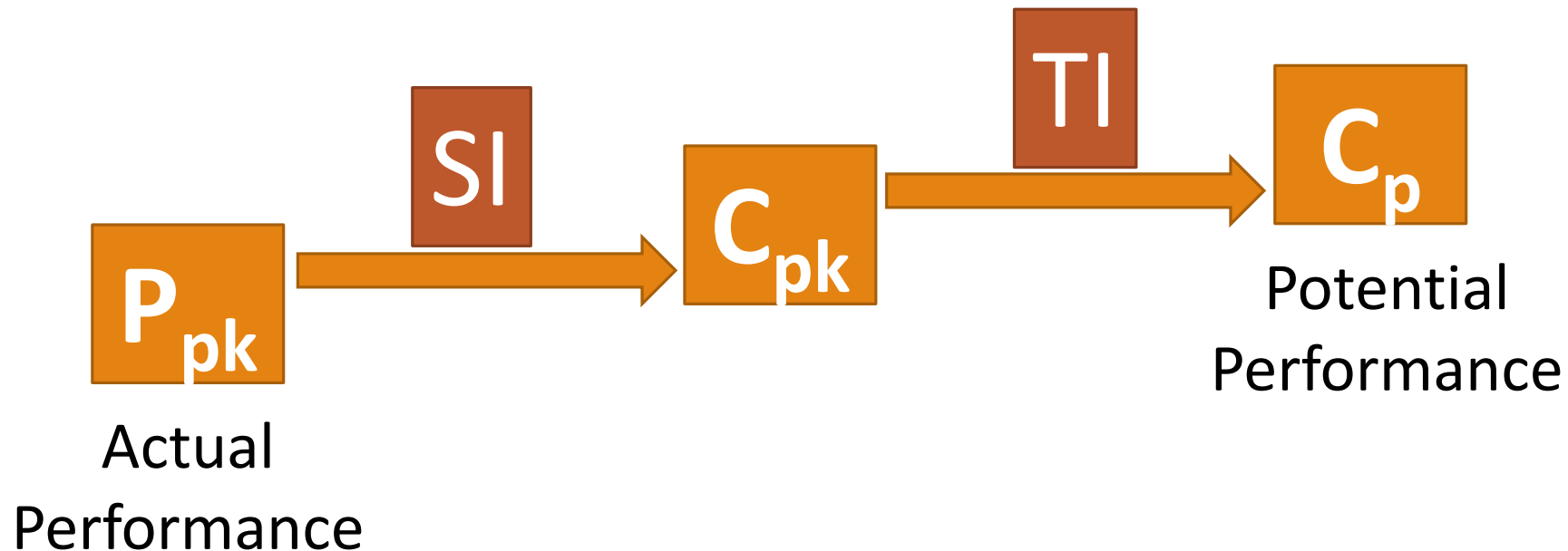
$$C_p = \frac{USL - LSL}{6\sigma_{ST}}$$

Rule of Thumb	C_p
Adequate	>1.33
Marginal	1.00-1.33
Poor	<1.00

Three reasons for an unhealthy process



Connecting to process capability and performance indices



Example

17 quality measures to evaluate the process health

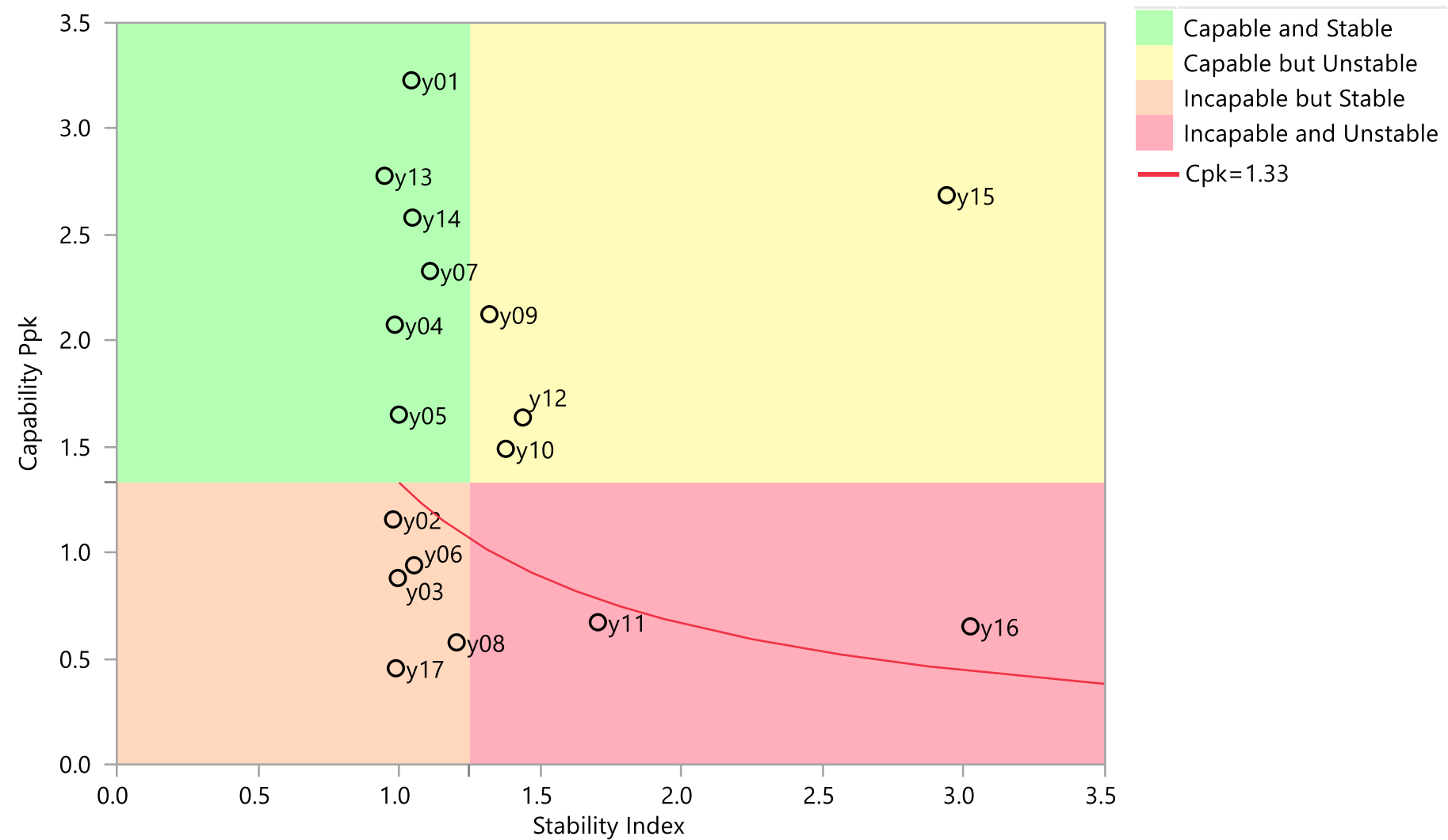
Where are the biggest improvement opportunities?

What type of improvement is required?

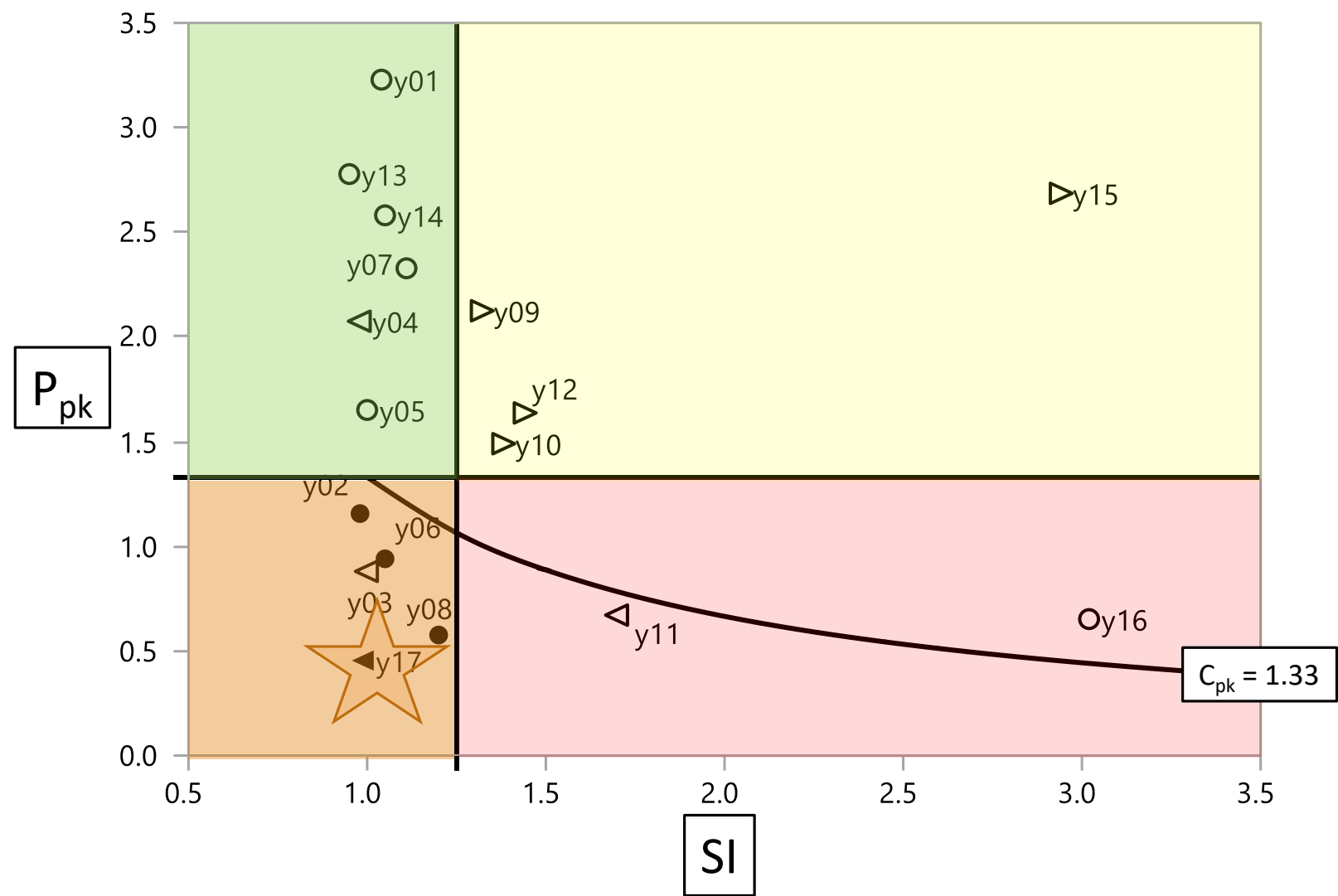
Summary report

Column	Variability			Summary	Capability		
	Stability Index	Within Sigma	Overall Sigma		Ppk ^	Cp	Target Index
y17	0.99	0.30652	0.30301	2.01262	0.454	0.870	1.264
y08	1.20	0.28977	0.3488	1.95288	0.576	0.748	0.163
y16	3.02	0.63253	1.91214	38.7377	0.652	2.108	0.415
y11	1.70	12.0155	20.4724	61.2177	0.671	1.387	0.731
y03	1.00	0.96173	0.95735	16.5268	0.880	1.386	1.532
y06	1.05	1.31126	1.38092	49.8942	0.940	1.017	0.081
y02	0.98	0.99252	0.97137	70.1302	1.156	1.175	0.131
y10	1.38	2.65564	3.65867	28.6505	1.490	2.510	1.375
y12	1.44	1.95919	2.81774	1.15858	1.637	2.552	0.591
y05	1.00	0.99995	0.99901	70.0519	1.651	1.667	0.052
y04	0.98	0.09922	0.09771	0.80836	2.075	2.688	1.931
y09	1.32	3.82862	5.05307	37.7919	2.125	3.047	0.729
y07	1.11	0.31858	0.35347	9.9691	2.328	2.616	0.097
y14	1.05	0.00491	0.00514	0.0498	2.581	2.716	0.042
y15	2.94	1.16829	3.43357	82.328	2.686	8.560	1.993
y13	0.95	27.3877	25.9691	223.573	2.778	2.678	0.130
y01	1.04	0.1974	0.20598	97.9951	3.229	3.377	0.025

Process performance graph



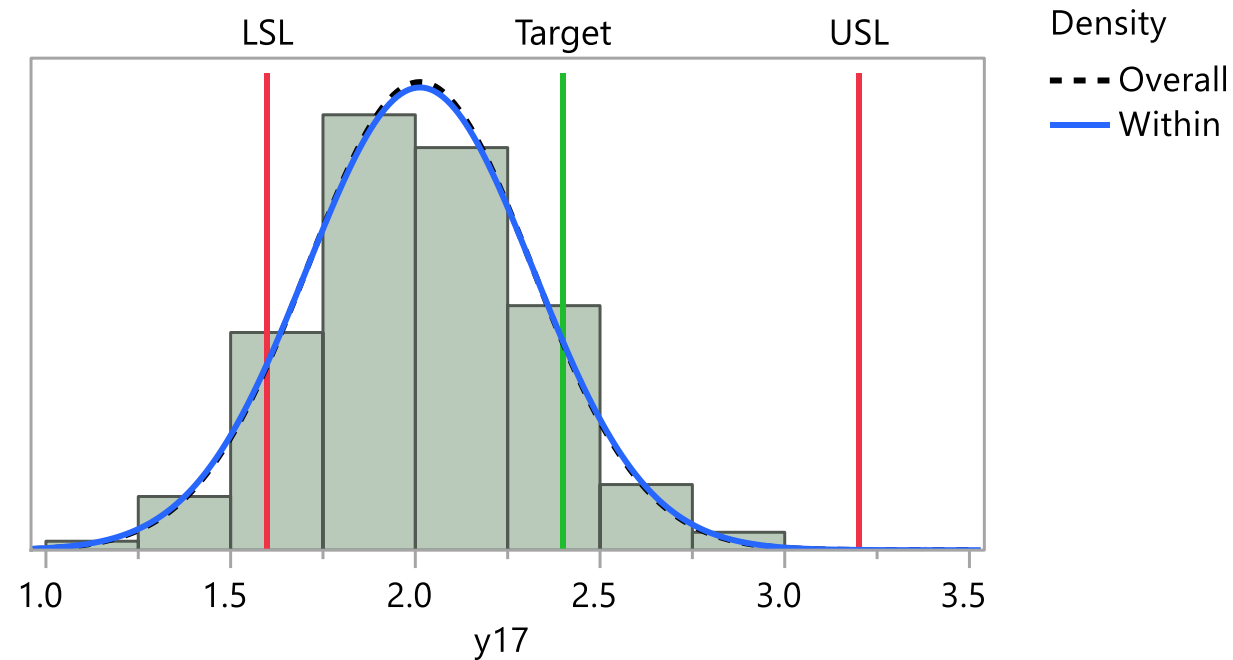
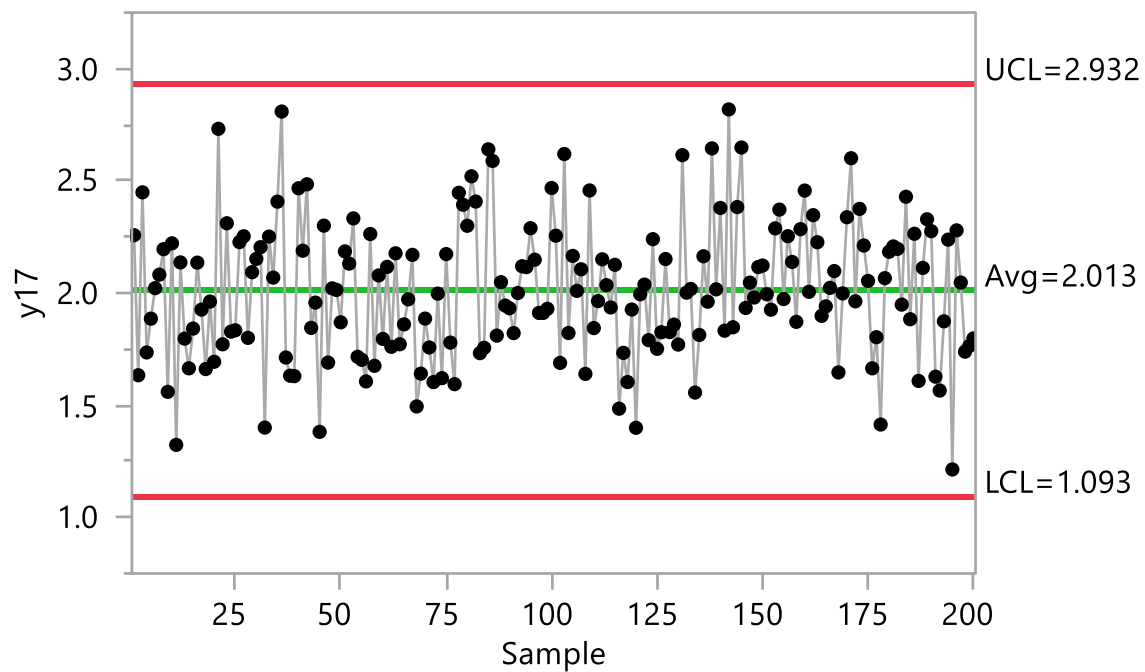
4D process performance graph



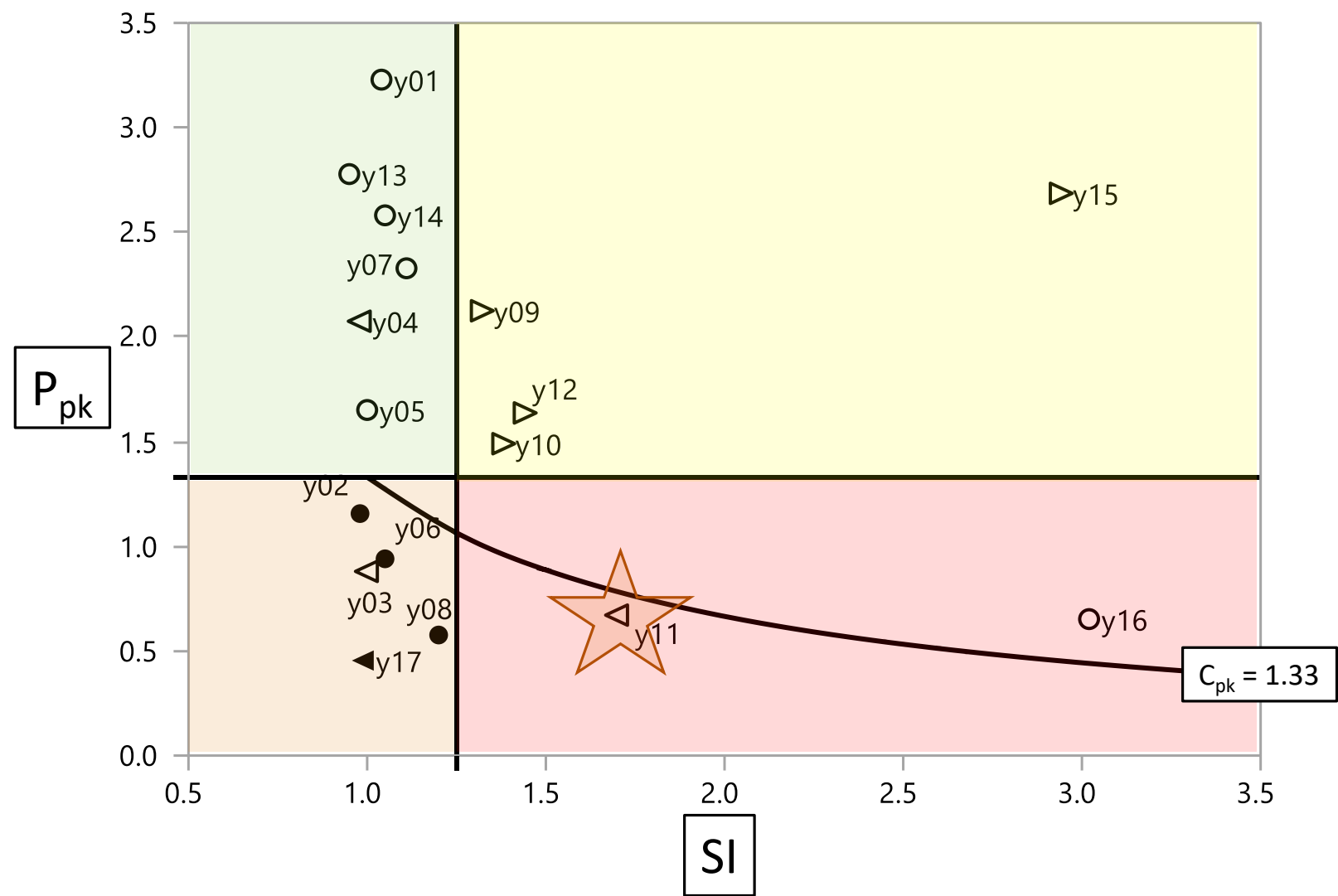
Graph Marker	TI	C _p
○	Adequate	Adequate
●	Adequate	Not Capable
▷	Above Target	Adequate
◼	Above Target	Not Capable
◁	Below Target	Adequate
◼	Below Target	Not Capable

y17

Column	Variability			Summary	Capability		
	Stability Index	Within Sigma	Overall Sigma		Ppk ^	Cp	Target Index
y17	0.99	0.30652	0.30301	2.01262	0.454	0.870	1.264



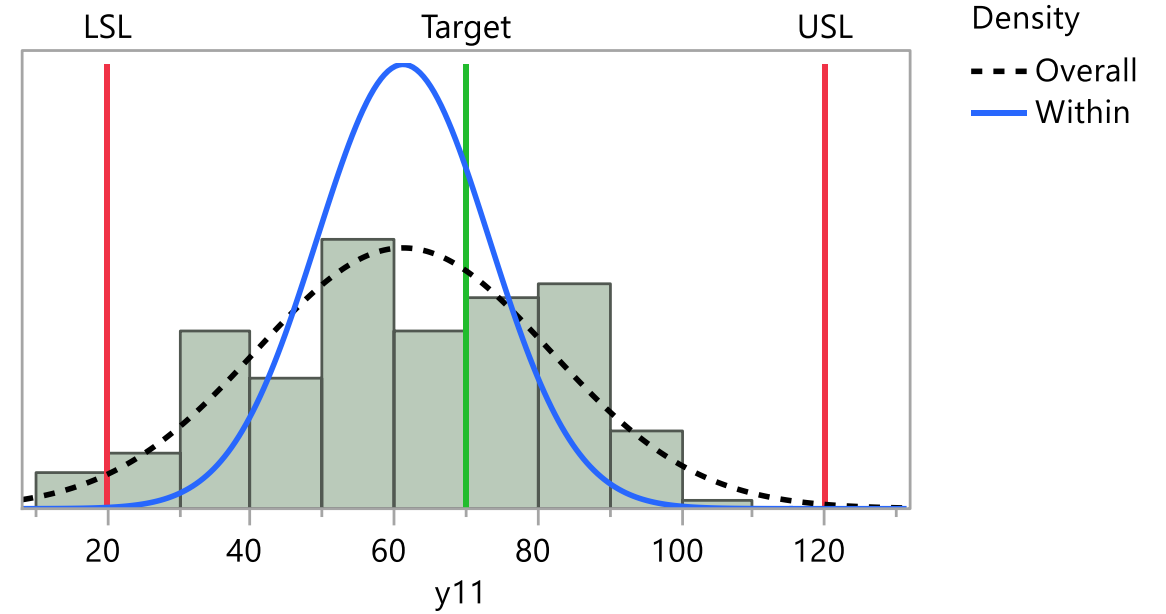
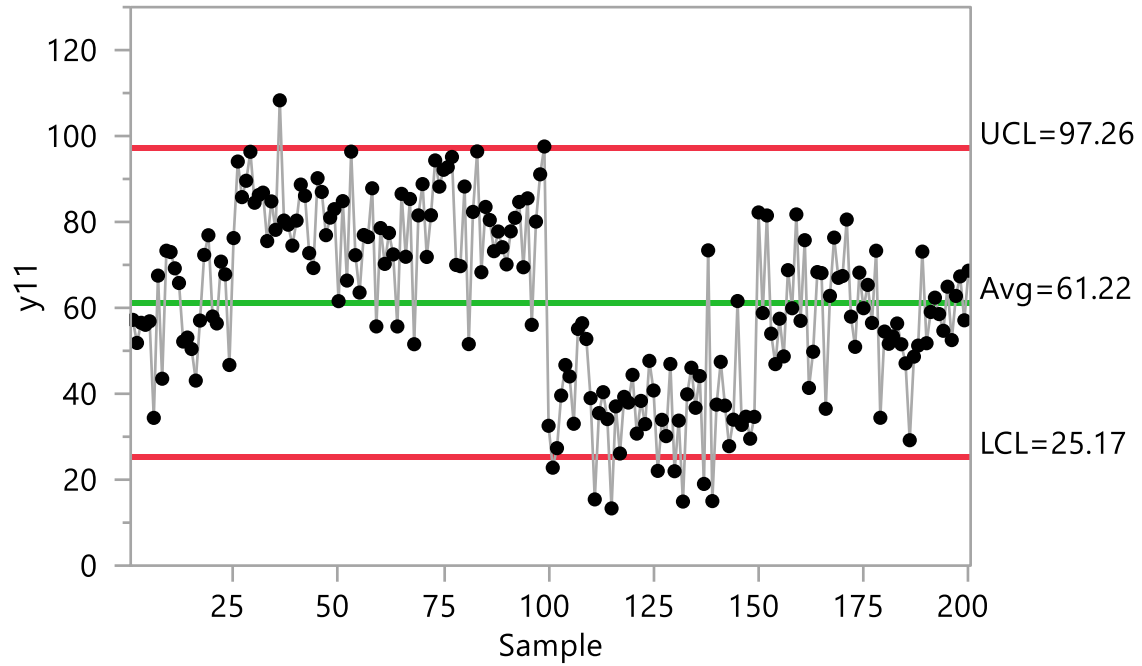
4D process performance graph



Graph Marker	TI	C _p
	Adequate	Adequate
	Adequate	Not Capable
	Above Target	Adequate
	Above Target	Not Capable
	Below Target	Adequate
	Below Target	Not Capable

y11

Column	Variability			Summary	Capability		
	Stability Index	Within Sigma	Overall Sigma		Ppk ^	Cp	Target Index
y11	1.70	12.0155	20.4724	61.2177	0.671	1.387	0.731



What about the measurement system?

When the process is not capable ($C_p < 1.33$), a frequent next step is to understand how much of the variability is due to the measurement system

$$\sigma_t^2 = \sigma_p^2 + \sigma_{ms}^2$$

σ_t – observed standard deviation

σ_p – process standard deviation

σ_{ms} – measurement system standard deviation

Percent of variation due to the measurement system

$$\%MS = \frac{\sigma_{ms}^2}{\sigma_t^2} \times 100$$

What should we use for σ_t ?
 σ_{ST} or σ_{LT} ?

$$\%MS = \frac{\sigma_{ms}^2}{\sigma_{ST}^2} \times 100$$

Percent of the short-term
(common cause) variability due
to the measurement system

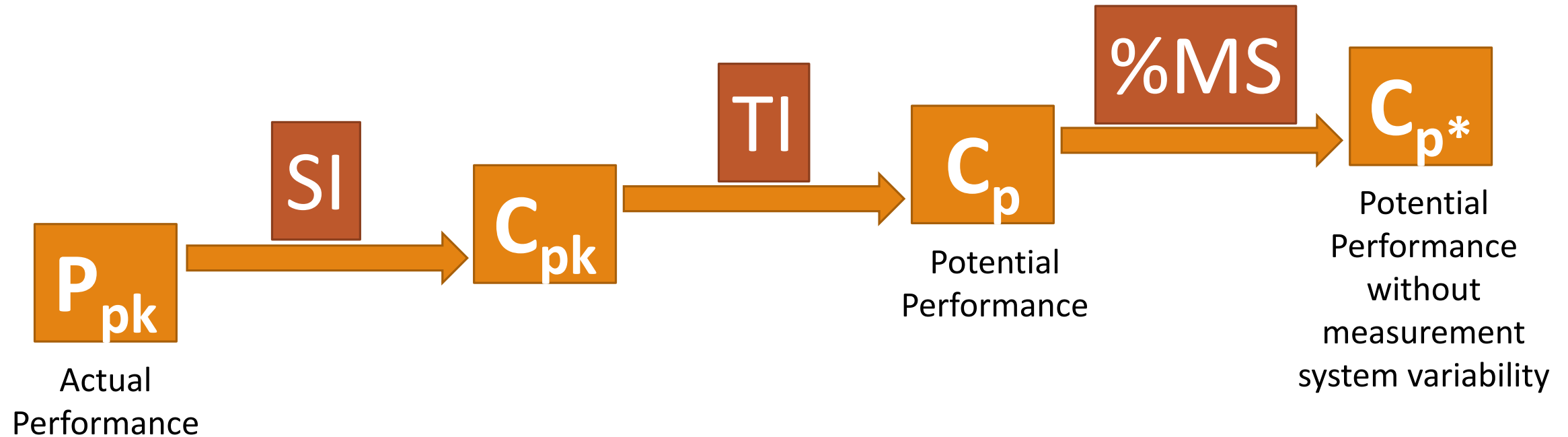
Impact of measurement on capability

How good could the process be if there was no measurement variability?

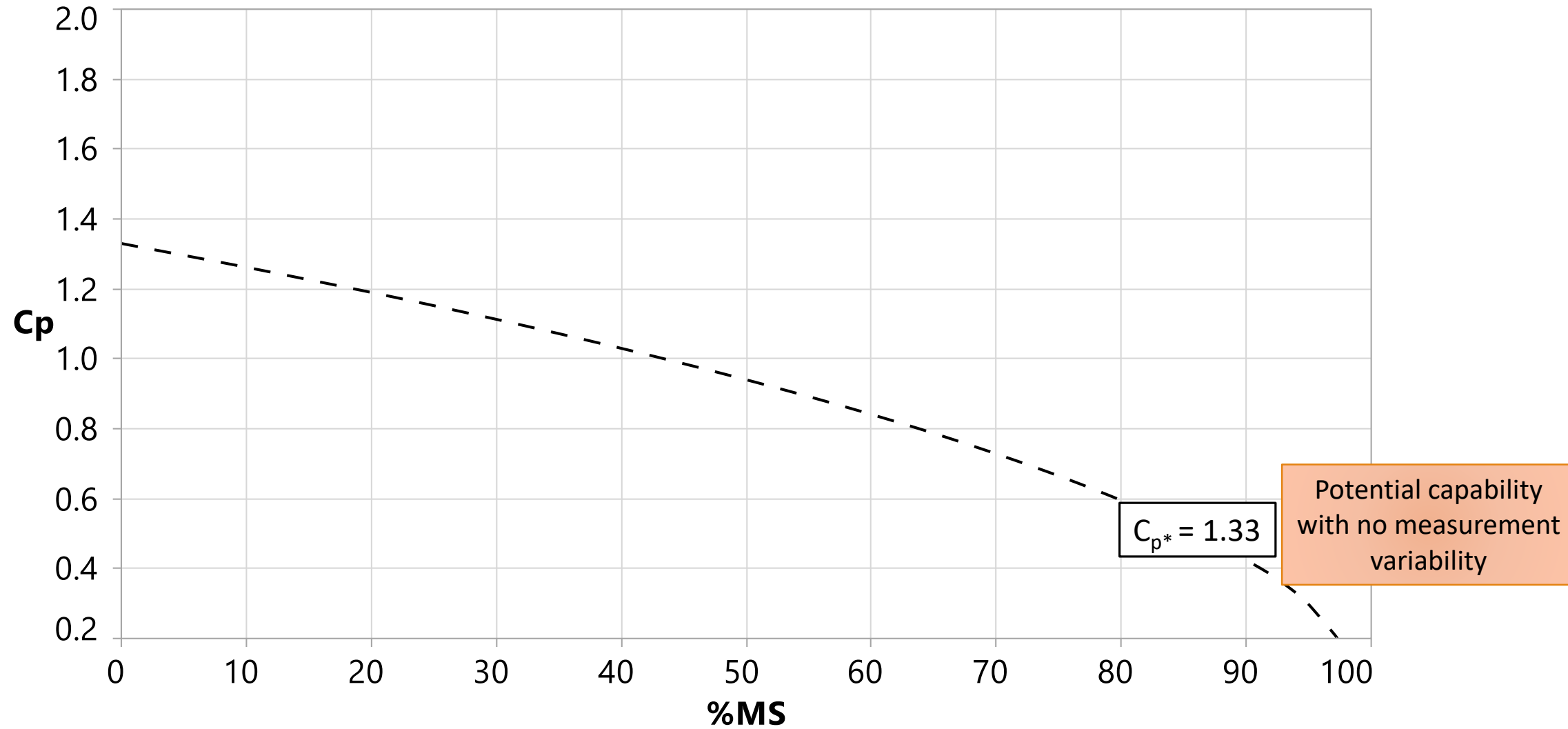
$$C_{p*} = \frac{USL - LSL}{6\sigma_p} = \frac{C_p}{\sqrt{1 - \frac{\%MS}{100}}}$$

When there is a “large” difference between C_p and C_{p*} , it indicates there is an opportunity to work on the measurement system

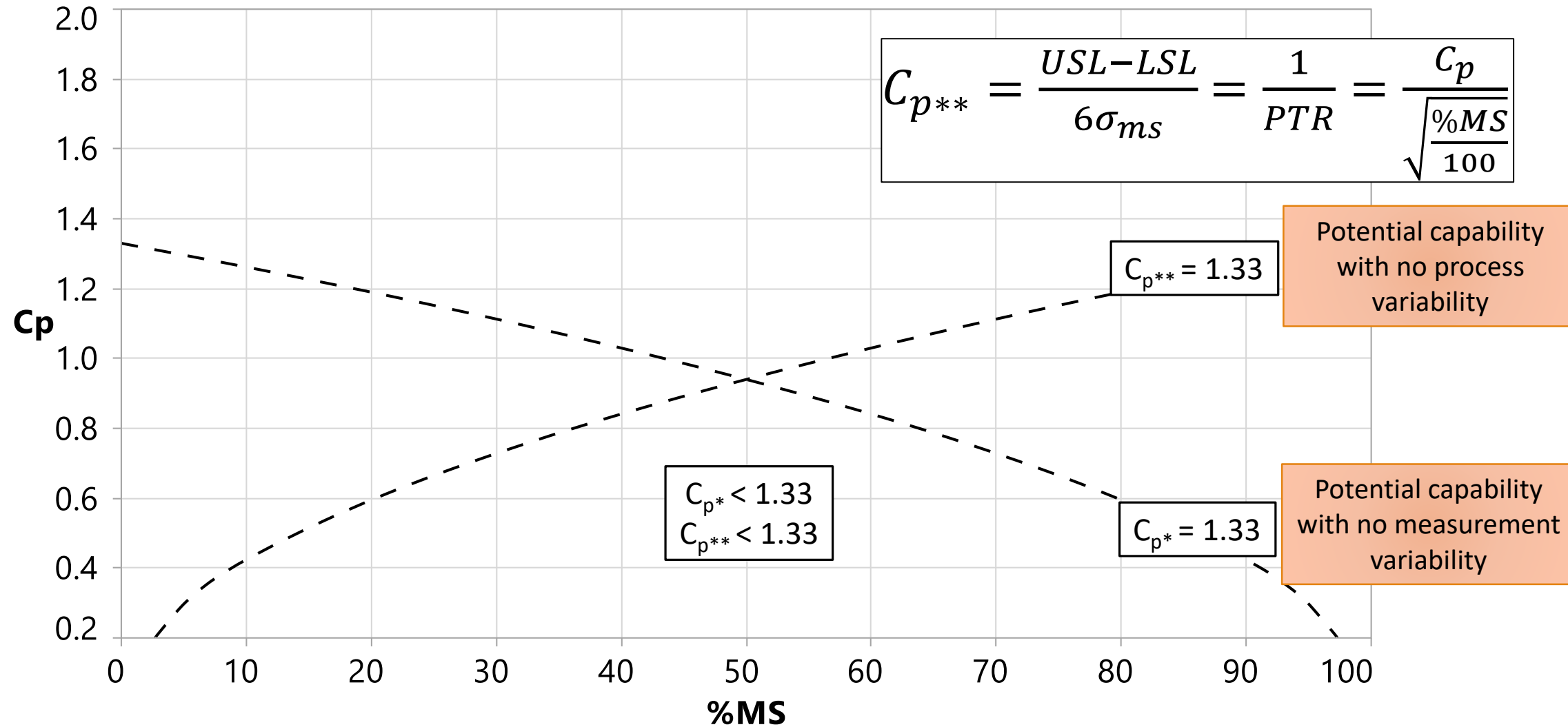
Connecting to process capability and performance indices



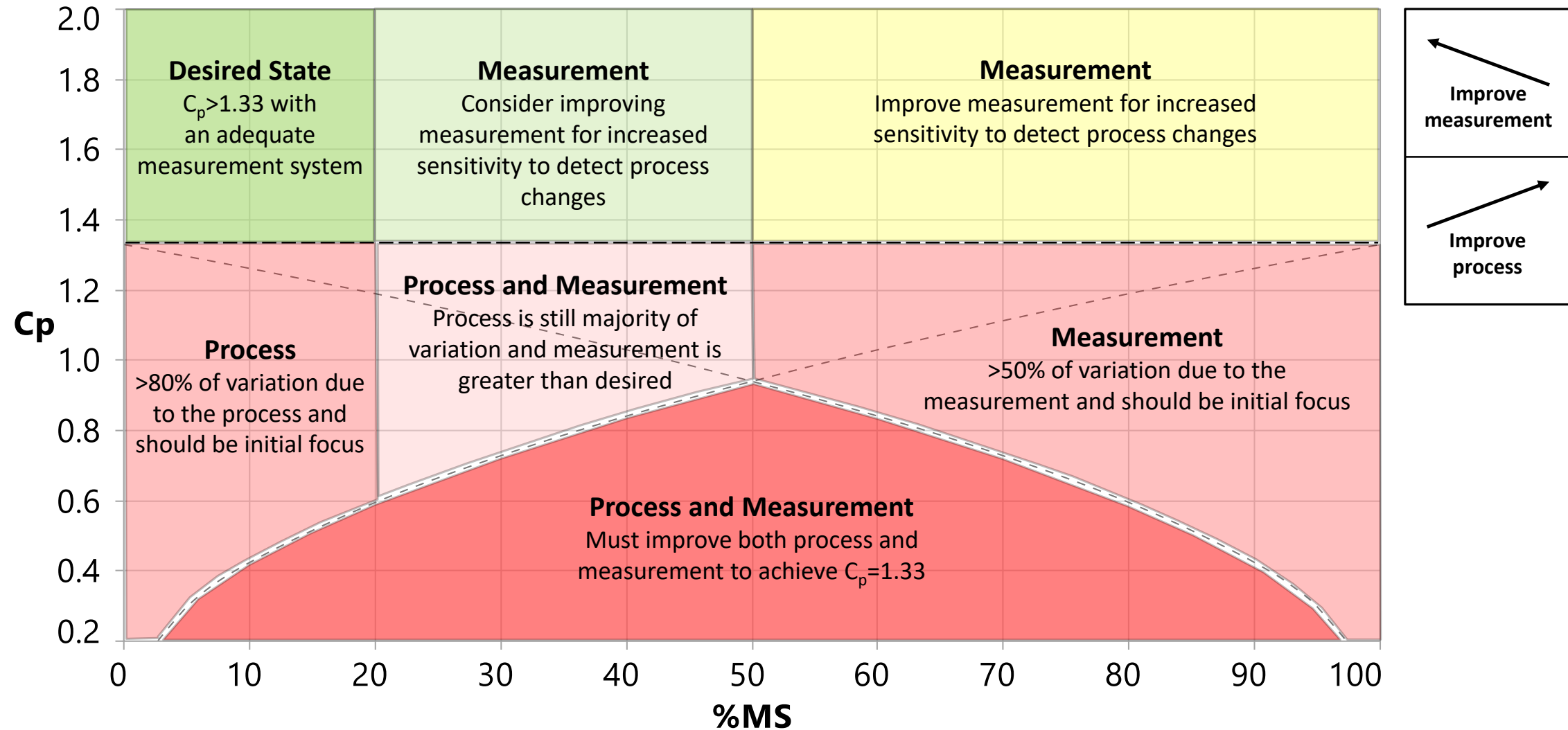
Process potential graph



Process potential graph



Process potential graph

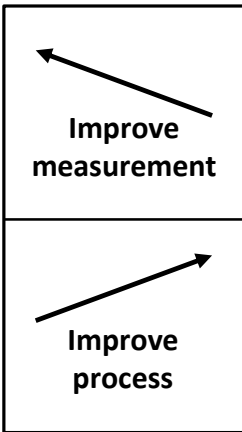
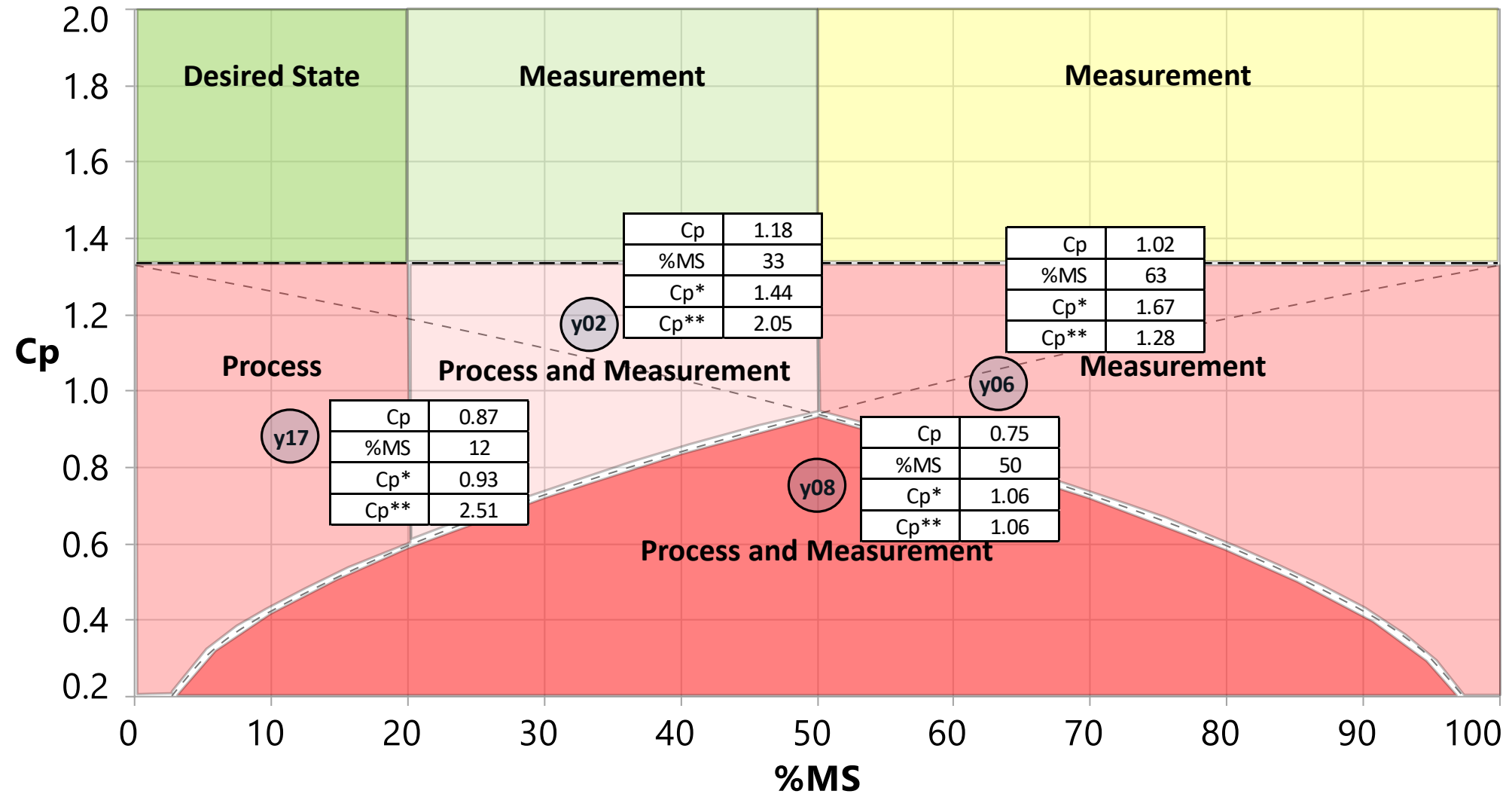


Example continued

In the earlier example, there were four quality measures with a $C_p < 1.33$

Column	Variability			Summary	Capability			%MS	Cp*	Cp**
	Stability Index	Within Sigma	Overall Sigma		Ppk	Cp ^	Target Index			
y08	1.20	0.28977	0.3488	1.95288	0.576	0.748	0.163	50	1.06	1.06
y17	0.99	0.30652	0.30301	2.01262	0.454	0.870	1.264	12	0.93	2.51
y06	1.05	1.31126	1.38092	49.8942	0.940	1.017	0.081	63	1.67	1.28
y02	0.98	0.99252	0.97137	70.1302	1.156	1.175	0.131	33	1.44	2.05

Process potential graph



Special Cases

- Two-sided specification with an off-center target
- One-sided specification with a defined target
- One-sided specification without a defined target

P_{pk} – use P_{pl} or P_{pu} for one-sided cases

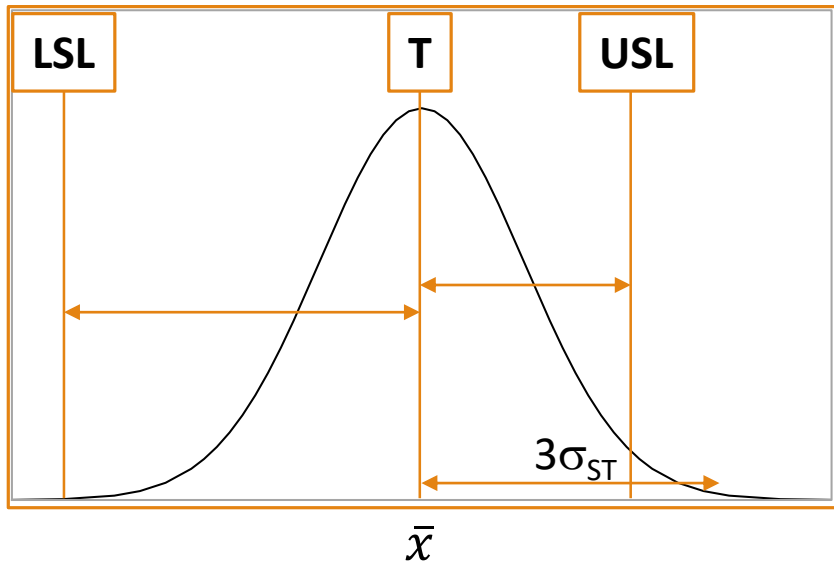
SI – not affected

TI – not affected if target defined

LSL only	$P_{pk} = P_{pl} = \frac{\bar{x} - LSL}{3\sigma_{LT}}$
USL only	$P_{pk} = P_{pu} = \frac{USL - \bar{x}}{3\sigma_{LT}}$

Two-sided specification with an off-center target

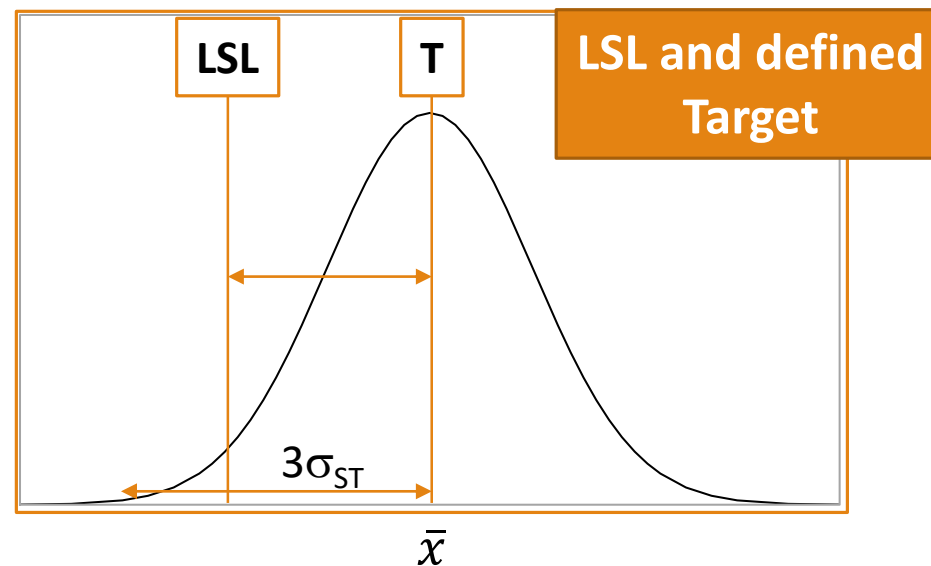
For C_p calculation, need to ensure that the common cause variability is sufficient for the minimum of $USL - T$ or $T - LSL$



$$C_p = \frac{\min(USL - T, T - LSL)}{3\sigma_{ST}}$$

One-sided specification with a defined target

C_p needs to consider the distance between T and LSL or USL and T.

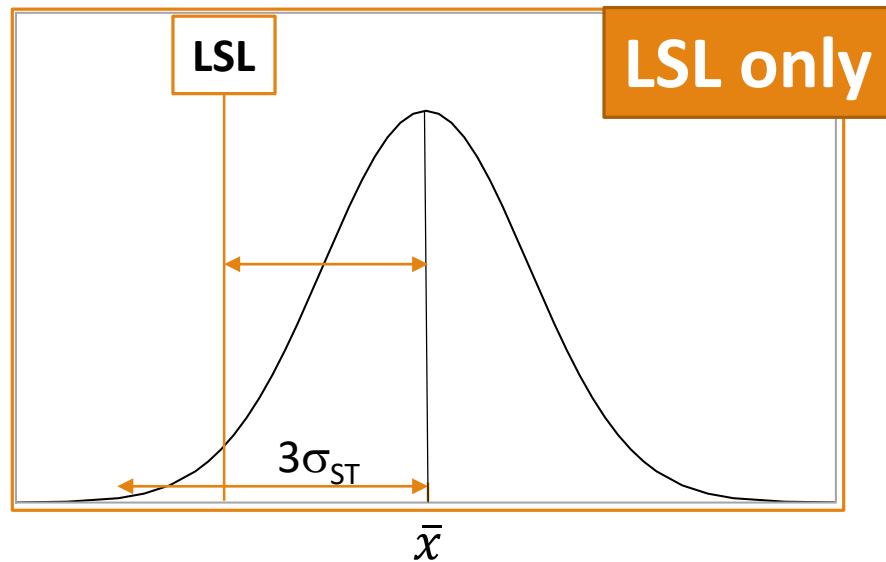


$$C_p = \frac{T - LSL}{3\sigma_{ST}}$$

$$C_p = \frac{USL - T}{3\sigma_{ST}}$$

One-sided specification without a defined target

If a target cannot be defined, use C_{pk} in place of Tl and C_p . The process location effect and the short-term capability effect become “confounded” when there is not a defined target.



$$C_{pk} = C_{pl} = \frac{\bar{x} - LSL}{3\sigma_{ST}}$$

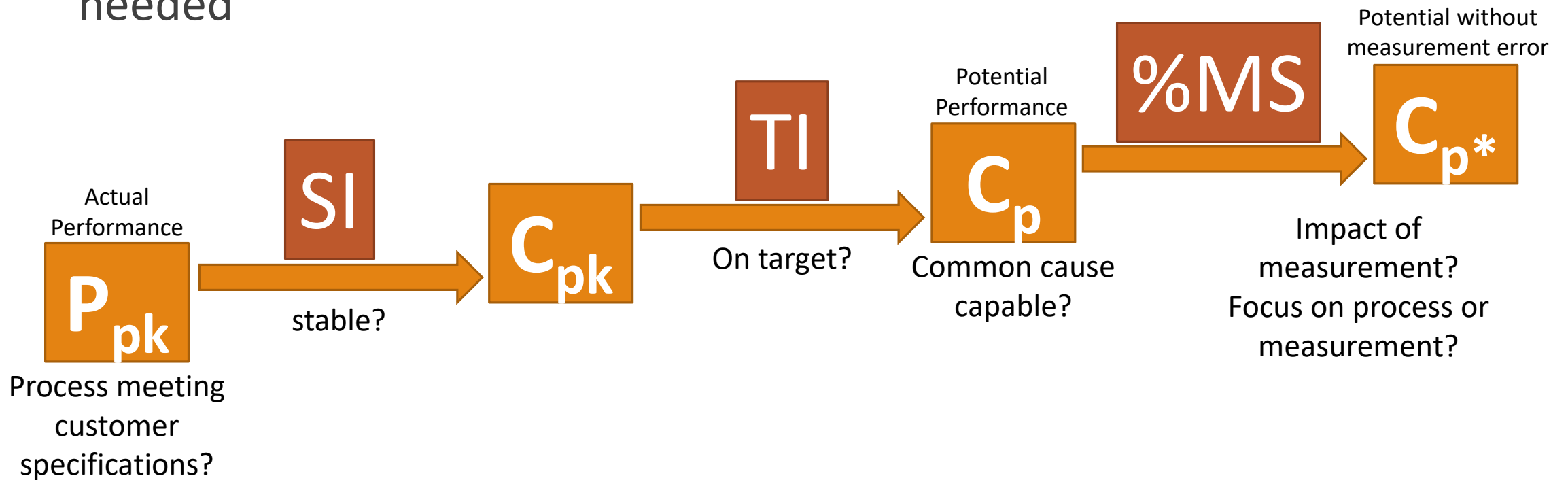
$$C_{pk} = C_{pu} = \frac{USL - \bar{x}}{3\sigma_{ST}}$$

Special cases summary

Case	Actual Performance	Stability	Target	Potential Performance
Two-sided specs with centered target	P_{pk}	SI	TI	C_p
Two-sided specs with off-center target	P_{pk}	SI	TI	$C_p = \frac{\min(USL - T, T - LSL)}{3\sigma_{ST}}$
One-sided specs with a defined target	P_{pl} or P_{pu}	SI	TI	$C_p = \frac{T - LSL}{3\sigma_{ST}}$ or $\frac{USL - T}{3\sigma_{ST}}$
One-sided specs without a defined target	P_{pl} or P_{pu}	SI		$C_{pl} = \frac{\bar{x} - LSL}{3\sigma_{ST}}$ or $C_{pu} = \frac{USL - \bar{x}}{3\sigma_{ST}}$

Conclusions / Take Home Message

The right set of process indices and graphs can quickly identify improvement opportunities as well as the type of improvement needed



For more information

Britt, K.A., Ramírez, B. and Mistretta, T. (2016). Process monitoring using statistical stability metrics: Applications to Biopharmaceutical Processes. *Quality Engineering*, 28(2), pp. 193-211.

Jensen, W., Szarka, J. and White, K. (2018). Stability assessment with the stability index. *Quality Engineering*, to appear.

Ramírez, J. G. (2016). A health screening for your processes. JMP Foreword, 11-12.

Sall, J. (2018) Scaling up process characterization. *Quality Engineering*, 30(1) pp. 62-78 with discussion on pp. 79-93

Wheeler, D. J. (2006), *EMP III Using Imperfect Data*. Knoxville, TN: SPC Press

White, T.K. and Borrer, C.M. (2011). Two-Dimensional guidelines for measurement system indices. *Quality and Reliability Engineering International*, 27(4), pp. 479-487.

Thank you

Questions?