12 Steps for a Critical Parameter Development Project (incl. 6 Check Points)

Step 1: Create a CP Project Charter

- establish goal, objectives, team members, roles & responsibilities, time line & scope
- define clear, specific & measurable CP project results

Scope of CP Activity

Step 2: Create a cross-functional team of experts to help ID a thorough set of CPs

- make sure they are well balanced, right mix of people (experience & judgment)
- good at mistake-proofing the list of parameters (methods for mistake-proofing)

Step 3: Generate / Assess Requirement Clarity, Classification & Flow-down

- define Critical System level functional Reqts & their tolerance limits (USL & LSL)
- define NUD (Critical) & ECO (non-Critical) requirements as they flow down to subsystems, subassemblies, parts, materials and mfg. /assy./ packaging processes

Step 4: Generate I-O-C Diagrams, P – Diagram, Noise Diagrams & the Boundary Diagram

- identify high level mass, energy & information flows into and out of the system, subsystems & subassemblies
- identify candidate Critical functions, inputs, outputs, controllable parameters & noises
- Define leading and lagging indicators & their units of measure
- identify unit-to-unit, external / environmental & deteriorative noise parameters
- preliminary documentation of required measurement systems

Step 5: Structure a Critical Parameter Flow-down Tree

CP candidate structure & prioritize for focus areas

- Define the relationships between Y, ys & their controlling xs
  - Function Trees & Functional Flow Diagrams
  - Math Models
- Define macro-relationships aligned with Critical noise parameters; which are NUD?
- Plan to separate which xs dominate & control the mean & which control σ for each Y & sub-y
- Conduct Potential Problem Prevention & Impact Mitigation Analysis (P^3IMA Table aka FMEA)
  - Laws of Unintended Consequences (unwanted functions)

Step 6: Identify unique sub-areas of focus; lean out, rank & prioritize the areas to work on

- Group prioritized CP flows with the biggest impact on the reqts; apply 6 Step Prevention Process
- Select the appropriate groups of flows that matter the most; again – which are NUD?
- Align critical noise parameters with the appropriate sub-groups

Step 7: Prove measurement systems are capable

- MSA & Gage R&R Studies for Critical Ys, sub-ys & controlling Xs (for both leading & lagging indicators)

Step 8: Design & conduct experiments (problem ID & prevention!)

- screening experiments (separate signal from random noise)
- modeling experiments (linear & non-linear effects plus interactivity)
- noise parameter strength experiments (what shifts the mean or spreads the variance?)
- robustness experiments
- tolerance sensitivity experiments

Step 9: Analyze data using ANOVA & other statistical methods that identify sensitivities & level of capability

- define statistical significance (p values)
- $MS_{parameter}$ / MS_{total}
- Cp & Cpk values
- Capability Growth Indices (CGI maturation by development process phase)

Facts database of CPs & their relationships

Step 10: Establish & Verify tolerance ranges & % contribution to variation of critical Ys & sub-ys

- USL & LSL for both nominal conditions & stressful conditions (robust tolerances)
- establish variance role-up model ($s^2_{total} = s^2_1 + s^2_2 + \ldots + s^2_n$)
- verify & validate final design & processing set points

Documented CP set points

Step 11: Mfg. & Production Implementation Plan for Critical Parameters

- Establish production & assembly data requirements & data utilization plan
  - Agreement on what constitutes a production or assembly CP
    - In-process CPs on the process itself
    - Within-process or post-process CPs (on parts, sub-assy, sub-system or system during mfg., assembly, packaging or upon receipt)
  - Requirements/Specifications to measure production & assembly CPs against
  - SPC & Cp/Cpk Study requirements & procedures
    - Frequency of measurements & action based upon data
    - Critical Cpk>>>Cp Adjustment parameters (mean shifters)
  - Measurement system requirements & acceptable signal/noise resolution
  - Contingency & Corrective Action plans
    - Alternative action plan
    - Process specific LSS-based corrective action process plan
      - Kaizen event or 6σ Project?

Conduct CP summary reviews & make Cpk>>>Cp adjustments as needed during steady state mfg.

Step 12: Evaluate Quality and Implement Changes in a Control plan

- Develop and submit alternate acceptance plans that maintain or improve functional quality with reduced acceptance costs
  - Select acceptance plan that meets overall program needs
  - Verify performance of selected plan
  - Implement changes as supported by data per the control plan

Change Implementation and Document Ongoing Control Plan

CP Step	Enabling Tools, Methods or Best Practices
Step 1: Create a CP Project Charter	Project Planning tools (MS Project); Monte Carlo Simulations of Critical the Path of Task Flows (@Risk Software Tool; Palisades), Cost Estimation, SMART Problem & Goal Identification, Intro. to CP Module
Step 2: Create a cross-functional team of experts to help ID a thorough set of CPs	Specific Experience, Technical Expertise & Judgment, Prefer DFLSS trained individuals on the IPT; can be trained and mentored JIT as required
Step 3: Generate / Assess Requirement Clarity, Classification & Flow-down Documentation	Customer/Stakeholder ID, Interviewing Methods, KJ Method, NUD vs. ECO Classification, Kano Method, Quality Function Deployment (QFD) & the Houses of Quality, DOORS Reqts. Software Tool, CP Reqt. Database Documentation, CP Reqts. Worksheets
Step 4: Generate I-O-C Diagrams, P-Diagrams, Noise Diagrams, Boundary Diagrams & Math Models	I-O-C Diagramming, P-Diagramming, Noise Diagramming, System Noise Mapping, Boundary & Interface Diagramming, 1^{st} Principles Modeling & Simulations
Step 5: Structure a Critical Characteristics Flow-down Tree	Functional Diagramming, FAST Diagramming, Tree Diagramming, Flow Diagramming, CocCPit CPM Software Tool (Cognition), CP Data Base Construction Module, CP Score Card Structuring Module, CP Reqts. & Measured Y Worksheets
Step 6: Identify unique sub-areas of focus; lean out, rank & prioritize the areas to work	NUD vs. ECO Classification, Kano Classification, Pareto Process, QFD Reqts. Ranking & Prioritization, Function Trees, Noise Diagrams, FMEAs
Step 7: Prove measurement systems are capable	Measurement System Analysis, Gage R&R Studies

Step 8: Design & conduct experiments	SPC Studies, Capability Studies, Sample-size Determination, Sample Data Parameter & Distribution Characterization Studies, Multi-vari Correlation Studies, t-Tests for 2 Way Comparisons, DOE Methods: Full & Fractional Factorial Designs, Screening Experiments, Modeling Experiments, Optimization Experiments, Mixture Experiments, Robustness Development Experiments, System Integration Sensitivity Experiments, Tolerance Balancing Experiments, ALT, HALT & HAST, Duane Plotting
Step 9: Analyze data using ANOVA & other statistical methods that identify sensitivities & level of capability	Descriptive, Graphical & Inferential Statistical Data Analysis Methods, Confidence Interval Analysis, ANOVA, Regression, Main Effects & Interaction Plotting, CP Documentation & CP Scorecards
Step 10: Establish & Verify tolerance ranges & % contribution to variation of critical Ys & sub-ys	Screening DOEs (Plackett-Burman Arrays), ANOVA, Taguchi Loss Function, Additive Variance Modeling, SPC & Capability Studies, CP Documentation & CP Scorecards
Steps 11-12: Mfg. & Production Implementation Plan	Control Planning, Quality Planning, SPC Studies, Capability Studies, CP Allocation for Production & Assembly Processes, CP Documentation & CP Scorecards, CP Deployment in Production & Supply Chain Environments Module

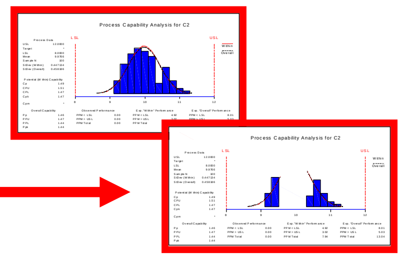
Recommendation for linking NUD requirements to CPs for Capability tracking

What is Required?		**What is Measured?**
Customer Level (USL – LSL)	⟷	Customer Level (Avg & σ)
System Level (USL – LSL)		System Level (Avg & σ)
Subsystem Level (USL – LSL)		Subsystem Level (Avg & σ)
Subassembly Level (USL – LSL)		Subassembly Level (Avg & σ)
Component Level (USL – LSL)		Component Level (Avg & σ)
Mfg. Process Level (USL – LSL)		Mfg. Process Level (Avg & σ)

From this comparison we can document performance Capability

$$C_p = \frac{USL - LSL}{6\sigma}$$

$$C_{pk} = Min\left(\frac{\bar{X} - LSL}{3\sigma}, \frac{USL - \bar{X}}{3\sigma}\right)$$



Summary of Critical CPM Actions:

CPM Actions	**Reliability Actions**
Metrics: scalars & vectors; continuous variables	Metrics: time-based failures; discrete events
Y=f(x) physics –based models	Additive / Product Functions; serial / parallel Time-To-Failure models
P-Diagrams	Reliability Block Diagrams
Noise Diagrams	FMEA, FMECA & Fault Tree Analysis
Function Trees	Duane Reliability Growth Plots
Functional Flow Diagrams	Normal Reliability Tests
Form Hypotheses & prioritize evaluations	Accelerated Reliability Tests
Screening & Modeling DOEs under nominal conditions	HALT, HASS & HAST evaluations
Robustness experiments under stressful conditions	FRACAS
Tolerance balancing experiments under nominal & stressful conditions	

Problem Prevention Steps:

The 6 Steps for Problem Prevention:

Plan & Rank Tasks
- **Design a Diagram** of detailed functions in their serial & parallel flows
- These are value-added functions that possess inherent robustness
- Rank & prioritize the value of each function relative to one another

Define Potential Problems
- **Define potential problems** that can occur within & between the functions
- A statement of the mistakes or errors that characterize the problem
- Identification of Leading Indicators that measure the on-set of a problem

Evaluate Causes
- **Evaluate & document the root causes** of the potential problems
- Understand the mechanisms behind all impending problems

Define Preventive Actions
- **Define preventive actions** for effectiveness & value
- Finalize, measure & track leading indicators – be proactively efficient

Define Contingent Actions
- **Define contingency plans** if the problem actually occurs
- Finalize, Measure & track leading & lagging indicators – be reactively effective after indicators reach a trigger point.

Re Use Learning
- **Re-use the lessons learned** for future use & reactivity
- Continuously improve the problem prevention process

The P³IMA Table to help with the Problem Prevention Steps

The Potential Problem Prevention & Impact Mitigation Analysis (P³IMA) (a derivative of FMEA)

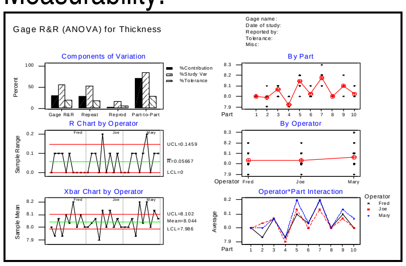
Critical Function	Potential Problem	Likely Causes	Probability of Occurrence	Preventive Action	Ability to Detect Onset	Severity of Impact	Contingency Action

What do I keep track of? & how do I do it? **7 Things** to prove you are ok!

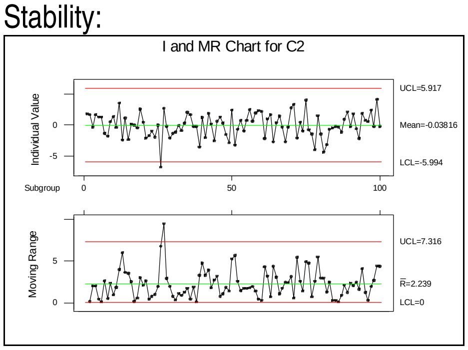
Measure	How?
Measurability	MSA: Gage R&R Study
Stability	SPC Chart: I & MR
Tunability	DOE, RSM, Regression Y=F(CAPs)
Sensitivity & Stat. Significance	DOE, p-Value, ANOVA:DY/DX
Interactivity	DOE, ANOVA: Xa * Xb
Capability	Capability Indices: Cp & Cpk
Robustness	DOE, S/n: COV, std. deviation

If these items are problematic and not in control then these are NUD parameters that are very good candidates for Critical Parameter status… until proven under control and able to be re-classified as Easy, Common & Old.

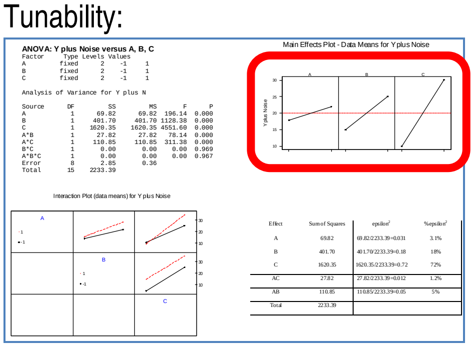
Measurability:

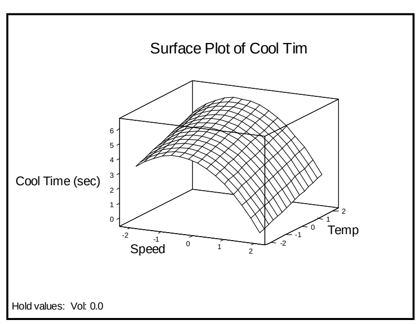


Stability:

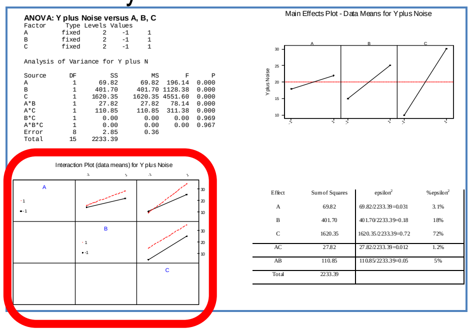


Tunability:





Interactivity:

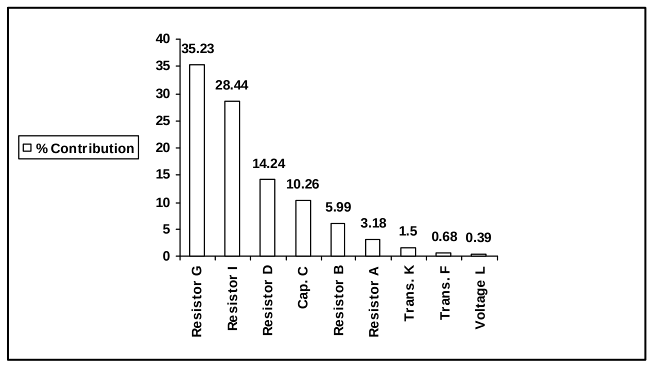


Sensitivity & Statistical Significance:

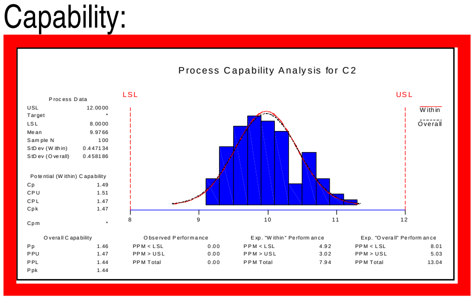
- Resistor G [36,960/**105,227**] x [100] = **35%**
- Resistor I [29,843/**105,227**] x [100] = **28%**
- Resistor D [14,945 /**105,227**] x [100]= **14%**
- Capacitor C [10,764/**105,227**] x [100]= **10%**
- Resistor B [6,281/**105,227**] x [100]= **6%**
- Resistor A [3,335/**105,227**] x [100]= **3%**
- Transistor C [1,580/**105,227**] x [100]= **1.5%**
- Transistor F [716/**105,227**] x [100]= **0.68%**

Source	DF	Seq SS	Adj SS	Adj MS	F	P
Res A	1	3335	3335	3335	24.88	0.002
Res B	1	6281	6281	6281	46.85	0.000
Cap C	1	10764	10764	10764	80.29	0.000
Res D	1	14945	14945	14945	111.48	0.000
Trans F	1	716	716	716	5.34	0.054
Res G	1	36960	36960	36960	275.69	0.000
Res I	1	29843	29843	29843	222.60	0.000
Trans K	1	1580	1580	1580	11.79	0.011
Error	7	938	938	134		
Total	15	105361		105227		

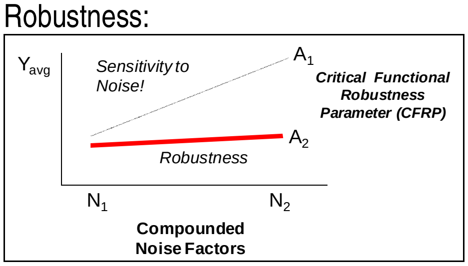
Total MS



Capability:



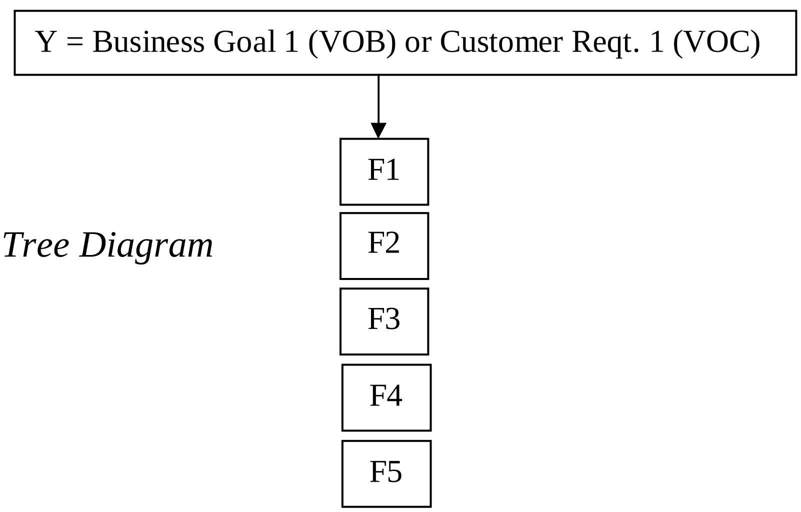
Robustness:



Example of getting Functions right and driving your CP development methodology:

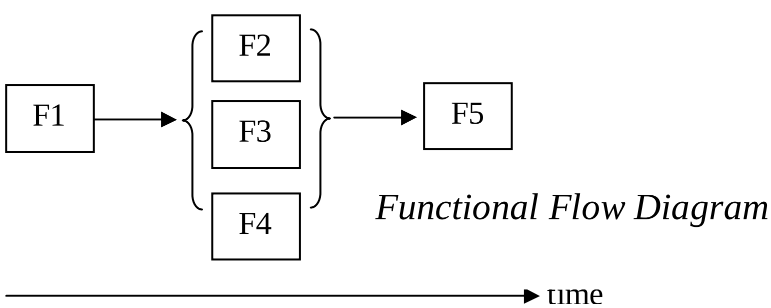
If I have 5 Functions, then I have at least 5 measurable **y**s.
Each **y** variable is dependent on one or more **X** variables.

First, we define all 5 functions verbally using verb-noun pairs on Post It notes. This results in vertical branches of lists of functions called Function Trees. The top of the tree is a big Y, which is your business or VOC based requirement. This is usually not stated in physics terms but rather quality, financial or some other non-physics form of units of measure. We MUST state our functions in fundamental units of physical measure. You can have multiple branches of functions coming from multiple Voice of Business (VOB) goals or Voice of Customer (VOC) requirements…

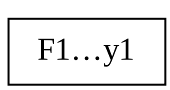


Function Tree Diagram

Next, we rearrange the Post It notes containing the Functions into their horizontal flow relationships over time. This will result in a serial-parallel flow diagram of exactly how the functions occur over time.



Each function is quantified as a y variable and is stated in its physics-based units of measure (a scalar or vector). We add the y variables and their units of physical measure to the Post It notes.



Next we must define each X variable that controls or influences each y…

X variables come in 4 varieties:

$\mathbf{X}_{\text{mean shifter}}$ = controllable parameter that has a strong ability to move the mean of **y**
$\mathbf{X}_{\text{std. dev. shifter}}$ = controllable parameter that has a strong ability to move the value of $\boldsymbol{\sigma}$
$\mathbf{X}_{\text{COV shifter}}$ = controllable parameter that has a strong ability to move both the mean of **y** and the value of $\boldsymbol{\sigma}$ (a coupled affect on both statistical parameters! Called the Coefficient of Variation: **COV** = (σ/mean)
$\mathbf{X}_{\text{noise inducer}}$ = an uncontrollable parameter that has a strong ability to either move the mean of **y**, the value of $\boldsymbol{\sigma}$ or the **COV**. They come from either External, Unit-Unit or Deteriorative sources.

So for each **X** we can create a Post It note to align with each **y**…

Xa = …	Xb = …	Xn = …

To define the candidate critical parameter **y**s & **X**s; we lay out the functional relationships

F1…y1	Xa = …	Xb = …	Xn = …

For each function you develop a Y = f(X…) model. This is a set of “hypotheses” that must be proven to be complete and true. DOEs will answer the following questions…

y1 = f(Xa, Xb, …) **Δy1 = f(ΔXa, ΔXb, …); σ^2 of y1 = f(σ^2 from ΔXa, σ^2 from ΔXb,…)**
y2 = f(Xa, Xb, …) **Δy2 = f(ΔXa, ΔXb, …); σ^2 of y2 = f(σ^2 from ΔXa, σ^2 from ΔXb,…)**
y3 = f(Xa, Xb, …) **Δy3 = f(ΔXa, ΔXb, …); σ^2 of y3 = f(σ^2 from ΔXa, σ^2 from ΔXb,…)**
y4 = f(Xa, Xb, …) **Δy4 = f(ΔXa, ΔXb, …); σ^2 of y4 = f(σ^2 from ΔXa, σ^2 from ΔXb,…)**
y5 = f(Xa, Xb, …) **Δy5 = f(ΔXa, ΔXb, …); σ^2 of y5 = f(σ^2 from ΔXa, σ^2 from ΔXb,…)**

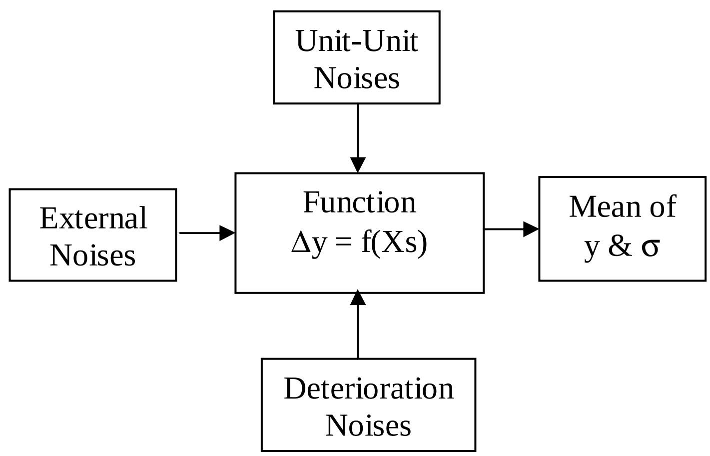
We will know the model is complete by developing both analytical & empirical models. If our correlation coefficient ($\mathbf{R}^2$) for the empirical model is high, then we know very little of the data is attributable to missing Xs and in fact the error on the model is due to random effects and not missed X parameters. If random error is small, then our model is good and our data acquisition system is too. If random error is high and our GR&R is over 10-20% we have a measurement system problem to correct!

We will know the model is true because the terms, coefficients, linearity or curvature in the analytical and empirical models are in agreement and that the X parameters are all statistically significant – a *parsimonius* or efficient model! Assumptions will have been proven or corrected.

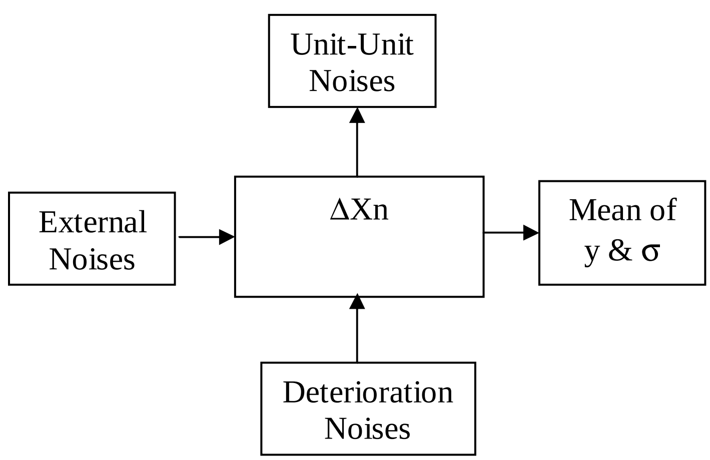
What about Noise and its affect of the Functions (**y**s) and the relationship of (X * Noise) interactions.

The Noise Diagrams:

For the Function, what noises cause it to vary?



For any X variable that is not a Noise Parameter, what noises cause it to vary? X variations



We must know what noise parameters really affect our Xs & Ys so we can conduct robust design experiments to assess interactivity between the Xs & the Noises. These noises will also impact k in Cpk assessment because they are able to cause both mean shifts and variance growth.

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