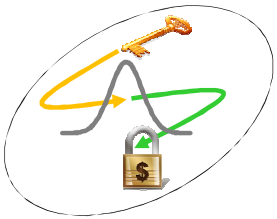
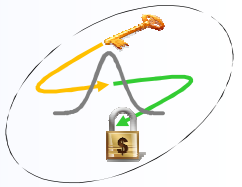
Critical Parameter Development & Management

The 12 Step Process to Develop Critical Parameters

PDSS
Product Development Systems & Solutions

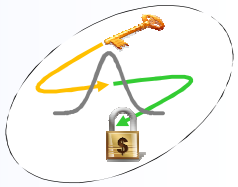


Defining a process for CPD&M



- Post-launch Production & Ongoing Life cycle Management out to Discontinuance…
- The 12 Step process is designed to be used by Teams that are supporting products and services that are already in the field.
  - Development of CPs that are currently unknown
    - Reverse engineering of CPs
    - Can start at any focus point you want & develop CP data up & down the product & process relationship structure you need

Example of the General Flow Down Structure for Critical Parameter Management



VOC:
Needs…

System Level:
Reqts…

System Level:
CFRs…

Subsystem Level:
Reqts…

Subsystem Level:
CFRs…

Subassembly:
Reqts…

Subassembly:
CFRs…

Components:
CTF Rqts…

Components:
CTF Specs…

Mfg. Process:
Reqts…

Mfg. Process:
CFRs…

Cp

Cp

Cp

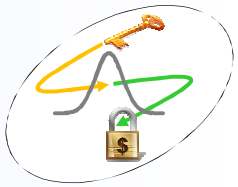
Cp

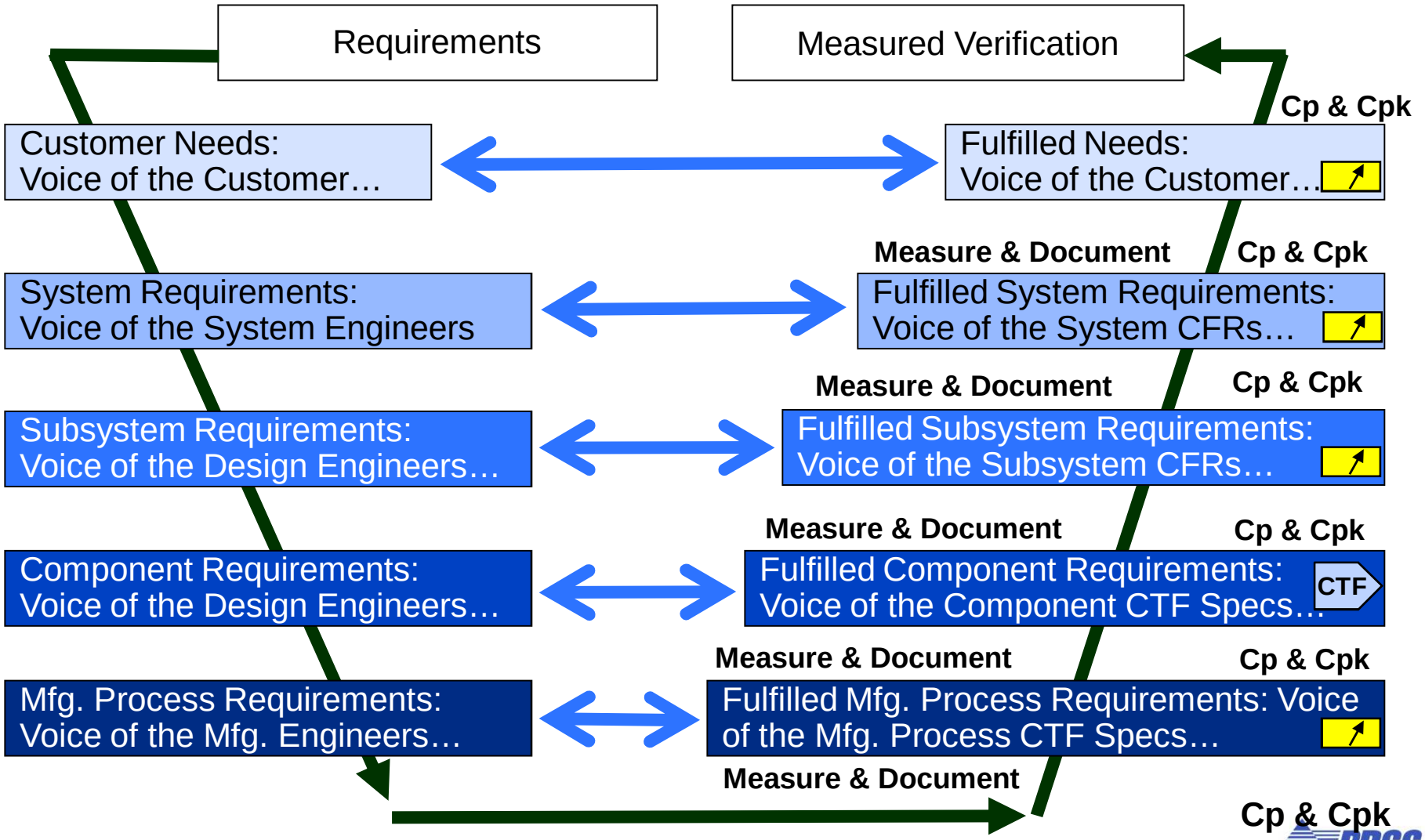
Flow down of the Voice of the Customer…requirements to be fulfilled through the measurement of CFRs & CTFS…

$$Cp = \frac{VOC}{VOP} = \frac{USL-LSL}{6\sigma}$$

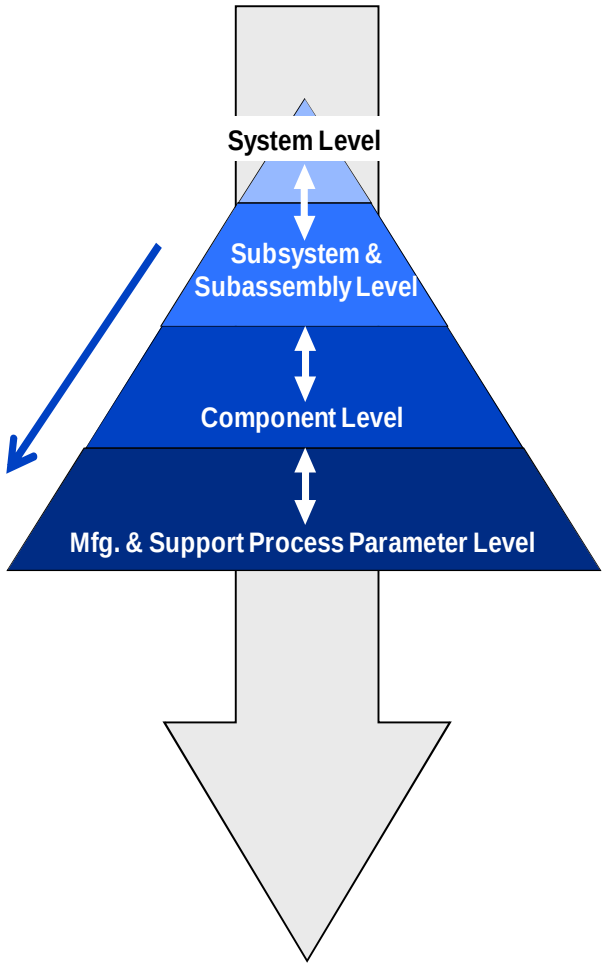
Roll-up of the Voice of the Design & Mfg. Critical Parameters…through the actual measurement of CFRs & CTFS

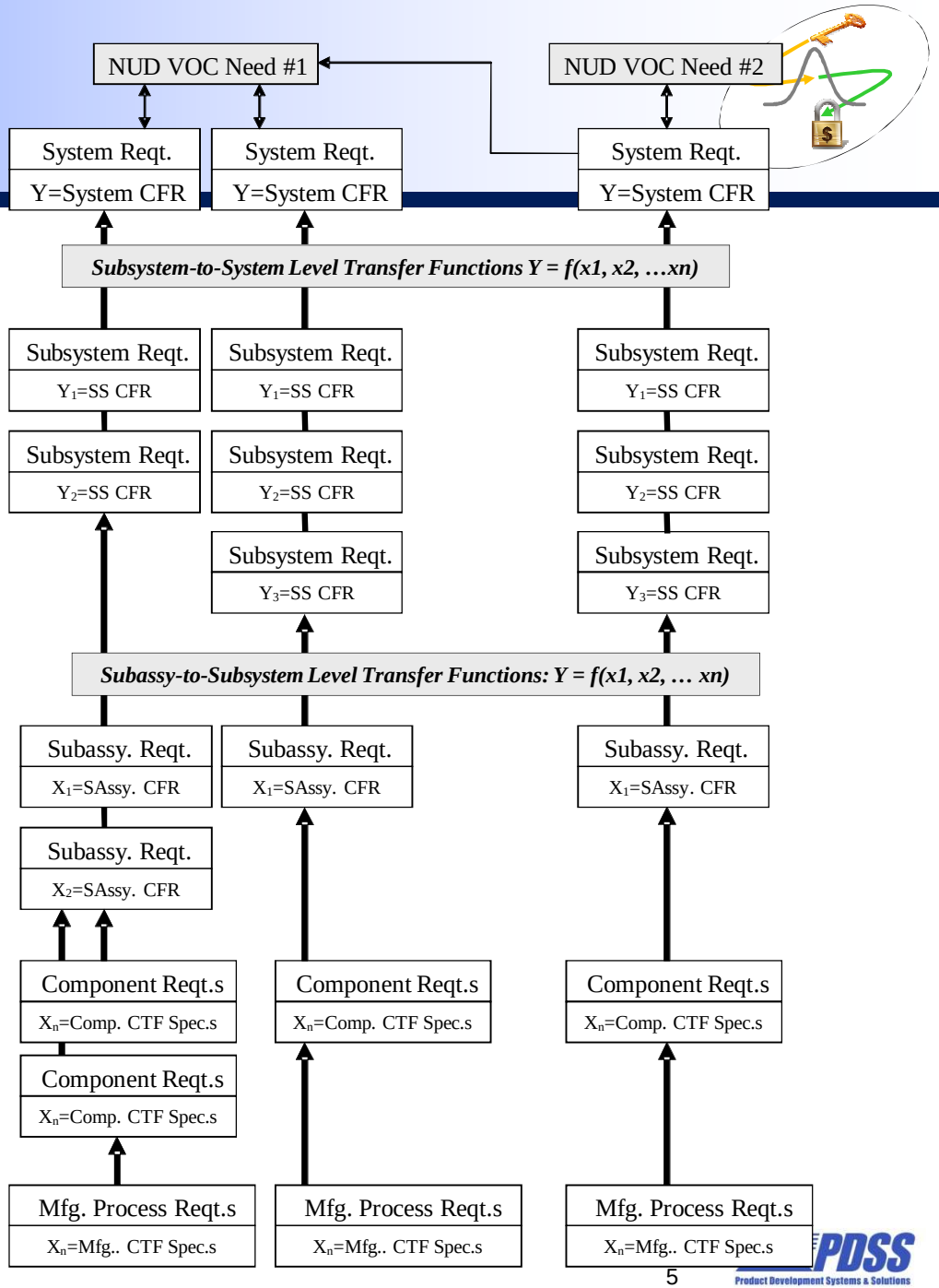
Requirements Flow Down and Capability Flow-Up



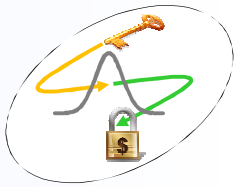


CPD&M Flow-Down Map





General Steps in Critical Parameter Development to prevent problems…



CPD&M Process Step	Enabling Tools, Methods & Best Practices
Step 1: Create a CPD&M Project Charter	➢ Project Planning & Mgt., Monte Carlo Sim., Cost Estimation, SMART reqts. & goal ID, Intro to CPD&M Module
Step 2: Create a cross-functional team of experts to help ID a thorough set of CPs	➢ Specific, in-depth experience; Technical expertise & judgment, DFLSS training, JIT training & mentoring in CP tool sets
Step 3: Generate / Assess requirement clarity, classification & flow-down	➢ Customer/Stakeholder ID, Interviewing Methods, KJ Analysis, NUD vs. ECO classification, Kano Analysis, QFD & HOQs, Doors, Relational data base
Step 4: Generate I-O-C-Diagrams, P-Diagrams, Noise & Boundary Diagrams	➢ I-O-C Diagramming, P-Diagm'g, Noise Diagm'g, System Noise Mapping, Boundary & Interface Diagm'g, 1st Principles Modeling & Simulation
Step 5: Structure a Critical Parameter Flow-down Tree & Relational Data base	➢ Functional Diagm'g, Flow Diagm'g, Cockpit SW, CP Data base dev., CP Scorecards, CP Reqts. & Measured Y worksheets
Step 6: ID unique sub-areas of focus; lean out, rank & prioritize the areas to work on	➢ NUD vs. ECO classification, Kano Analysis, Pareto process, QFD ranking, Function Trees & Flow Diagm'g., Noise Diagm'g, FMEAs
Step 7: Prove measurement systems are capable	➢ Measurement Systems Analysis, Gage R&R Studies
Step 8: Design & conduct experiments on candidate Critical Parameters & Noises	➢ Hypothesis formation, SPC & Cp/Cpk studies, DOEs, t-Tests, ALT, HALT, HAST, Duane Plotting
Step 9: Analyze data using ANOVA & other statistical methods to ID sensitivities & Cpk	➢ ANOVA, Descriptive & Inferential Statistical methods, Regression Analysis, Correlation Analysis, Confidence Intervals, Main effects & interaction plotting
Step 10: Establish & verify tolerance ranges & % contribution to variation of Critical Ys	➢ Screening DOEs, ANOVA, Taguchi's Loss Function, Additive Variance Modeling, SPC & Cp/Cpk Studies, F Ratios
Step 11: Create a Mfg. & Production implementation plan for CPs	➢ SPC & Cp/Cpk Studies, CP documentation, CP relational data base & Score cards
Step 12: Evaluate Quality and Implement Changes in a Control Plan	➢ Control Planning, SPC & Cp/Cpk Studies, CP Documentation

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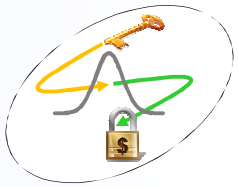
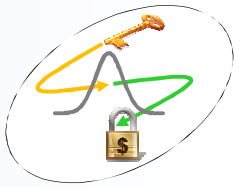
What makes a parameter Critical?



- Is it **measurable**?
- Is it **stable**?
- Is it **adjustable**?
- Is it **interactive & statistically significant**?
- Is it **sensitive**?
- Is it **robust**?
- Is it **capable**?

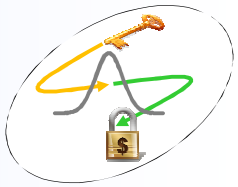
If any one or more of these is a significant problem or a shortfall – then the parameter is Critical & needs the extra effort to make it ECO!

Step 1: Create a CP Project Charter



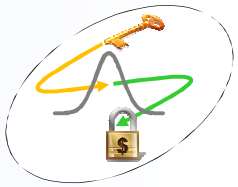
- ✓ Establish the primary goal 1st then…
  - ✓ Specific objectives (CP Project **requirements**)
  - ✓ Essential team members
  - ✓ Roles & responsibilities
  - ✓ Project time line
  - ✓ Scope
- ✓ CP project results
  - ✓ clear, specific & measurable **deliverables**

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



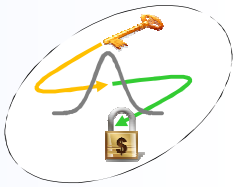
- Make sure they are well balanced
  - right mix of people (experience & judgment)
- Good at mistake-proofing the list of candidate Critical parameters

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



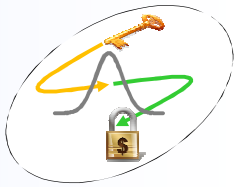
- Define Critical System level functional Requirements & their tolerance limits (Target + USL & LSL)
  - "Big" Ys
- Define NUD (Critical) & ECO (non-critical) requirements as they flow down to subsystems, subassemblies, parts, materials and mfg. /assy./ packaging processes

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



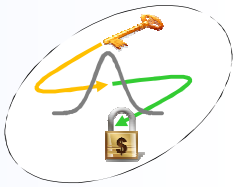
- Identify high level mass, energy & information flows into and out of the system, subsystems & subassemblies
  - Define candidate System level CFRs = Ys to be measured
- Identify Critical functions, inputs, outputs, controllable parameters & noises
  - Define subordinate CFRs = ys to be measured
- Define leading & 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



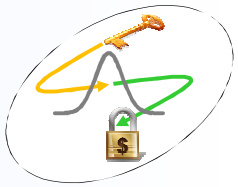
- Define the relationships between Y, ys & their controlling xs
  - Function Trees & Functional Flow Diagrams
  - 1st Principles Math Models (***how*** does it work?)
- Define macro-relationships aligned with Critical noise parameters; which are NUD?
- Plan to separate & define which Xs dominate & control the mean & which control s (or both!) for each Y & sub-y
  - Y as a function of the Xs
- Conduct Potential Problem Prevention & Impact Mitigation Analysis on the Functions
  - (P^3IMA Table aka *Functional* FMEA)

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



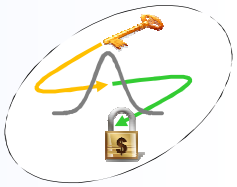
- Group prioritized CP flows with the biggest impact on the Project Goal & Objectives (reqts);
  - apply 6 Step Prevention Process to your Project Tasks
  - Mistake-proof your CP project plan!
- Select the appropriate groups of flows that matter the most; again – which are NUD?
- Align *candidate* Critical noise parameters with the appropriate sub-groups

Step 7: Prove measurement systems are capable



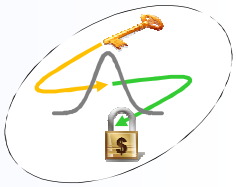
- Conduct Measurement Systems Analysis (MSA)
  - Gage R&R Studies for Critical Ys, sub-ys & controlling Xs (for both leading & lagging indicators)
  - Destructive & Non-destructive forms for measurable samples
    - what am I measuring?... mass?, energy? Information?)

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



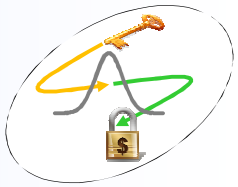
- screening experiments (separate signal from random noise)
- modeling experiments (linear & non-linear effects plus interactivity)
- noise parameter strength experiments (what shifts the mean or spreads the variance?)
- robustness experiments
- tolerance sensitivity experiments

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



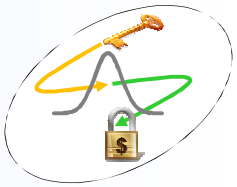
- define statistical significance (p values)
- $MS_{parameter}$ / MS_{total}
- Cp & Cpk values
- Capability Growth Indices (CGI maturation by development process phase)

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



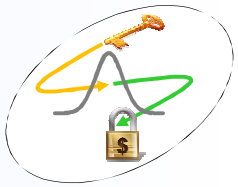
- USL & LSL for both nominal conditions & stressful conditions (robust tolerances)
- Documented CP set points
- establish variance role-up model
  - ($s^2_{total} = s^2_1 + s^2_2 + \ldots + s^2_n$)
  - verify & validate final design & processing set points

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
- Conduct CP summary reviews & make Cpk>>>Cp adjustments as needed during steady state mfg.
  - Kaizen event or 6s Project?

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

ESD.33 Systems Engineering

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