# Hierarchical, Statistical Approach to Model Based Development for Medical Imaging Device Development

*5th Annual INCOSE Great Lakes Regional Conference*
*November 2011*

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*GE Healthcare*

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# Agenda / Abstract

Introduction to GE Healthcare

Design Challenges for GE Healthcare

What is Six Sigma?  How Does Modeling Fit?

Hierchical Modeling Example: CT Detectors

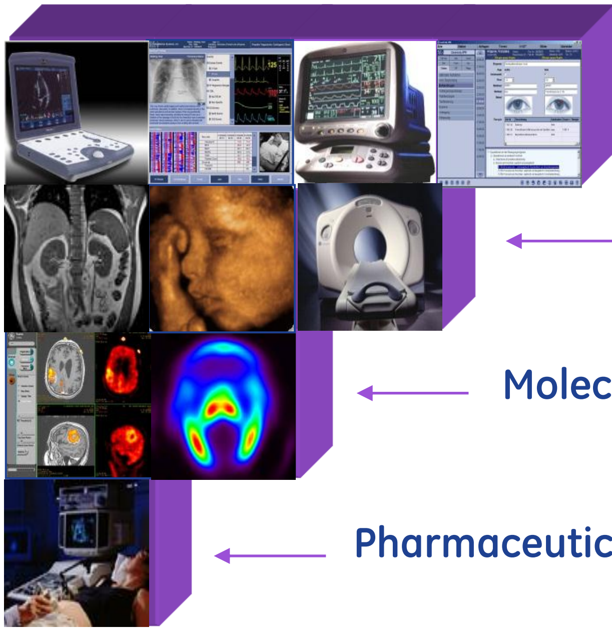
Statistical Cost Modelling: CT Detectors

Monte Carlo Example: CT Xray Source

# The world's best diagnostics company

## Technologies

## Bio-Sciences

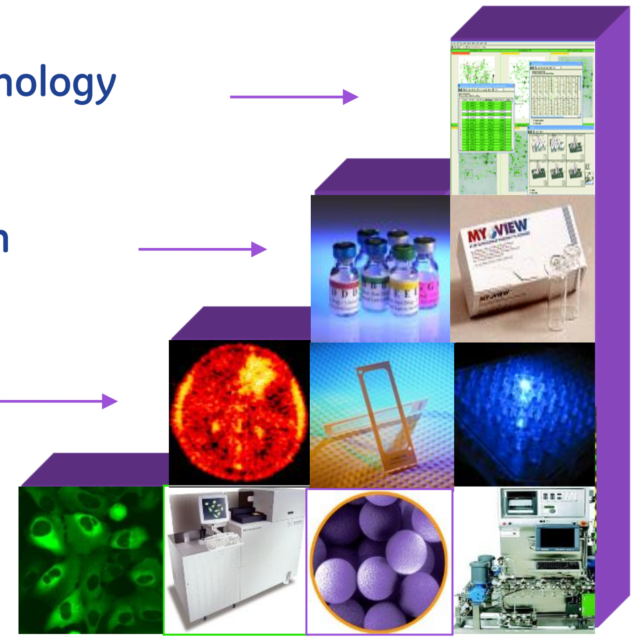


Information Technology

Imaging and Intervention

Molecular Diagnostics

Pharmaceutical Solutions




### *Our Core Competencies…*

- ✓Engineering / Physics
- ✓Information Technology
- ✓Chemistry
- ✓Biology

### *Serves Demand…*

- ✓Application/Disease Focused… New Indications
- ✓Customer Driven… New Products

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# Materials Enables Improved Imaging

**1913**

**XR Tube**

Vacuum Tube, Ductile Tungsten

$1^{st}$ Medical XR tube…

GE #1 Worldwide XR Tube Supplier

**1970's**

**CT HiLight Detector**

Scintillator – Lumex

1975 Intro, 1987 HiLight…

GE #1 Worldwide CT supplier

**1980's**

**MR Supercon Magnets**

Superconductivity

1983 $1^{st}$ 1.5T MRI…

GE #1 Worldwide MR supplier

**1990's**

**Flat Panel XR Detector**

$\alpha$-Si Panel
CsI Scintillator

$1^{st}$ Flat Panel Digital

GE #1 Worldwide FPD Supplier

***Amazing Future!***

**Molecular Medicine**

Chemistry, Functional Imaging

**Nanotechnology**

Material Sciences

**Information Quality**

Algorithms, CAD, Information Everywhere…

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# The Challenge… Energy Conversion & Detection

**MR 3T**

30 MJ

**Performix Pro**

40 kJ

**Gradient Coil**

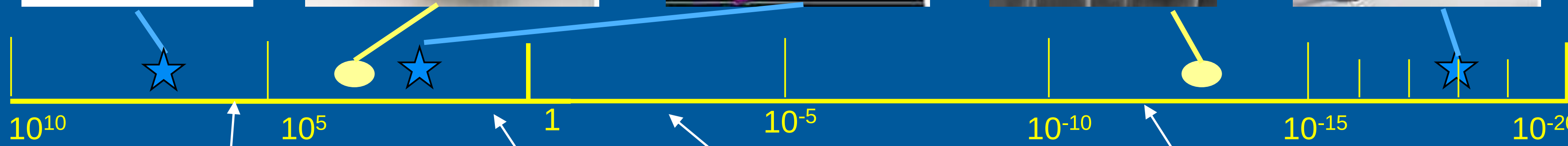
1 kJ

**$e^-$ Noise**

8 fJ

**MR Min Signal**

$10^{-18}$ J




1MJ

**Hummer @ 50 mph**

400 J

**Climbing 1 Step**

2 mJ

**Pin Dropping**

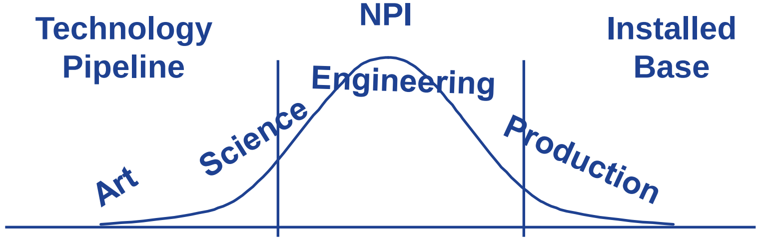
1 pJ

50 um Particle

**Grain of Sand Falling off Another**

# T-Milestones and Technology Readiness Levels

## Resource Profile




- Materials
- Simulations
- Dream Machine

- CTQ Predictability
- Global Platforms
- DFR / DFM

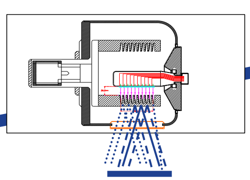
- Field robustness
- VCP
- Yield

## Four Critical Milestones in Technology Development

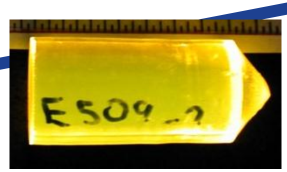
- **T0**: Technology Investigation Launched
- **T1**: Technology Investigation Plan Complete
- **T2**: Technical Feasibility Demonstrated
- **T3**: Technical Feasibility Demonstrated and Transition Complete

## Platform Breakthrough Lifecycle…

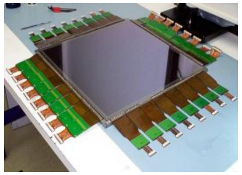
**Art…**
New Way Everyday



**Science…**
It Almost works




**Engineering…**
Cause/Effect Understood



**Production…**
Producing in Volume

1-2 years → 2-4 years → 1-2 years → 10+ years but declining

Technology Pipeline Keeps Platform Development Off The Critical Path

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# Evolution of Design Technology

Trial & Error | Empirical | Mathematical | Probabilistic

Random Experimentation

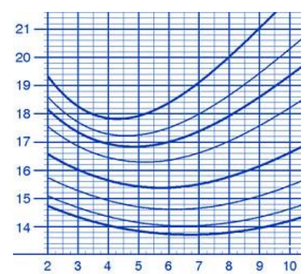
Experience-based

Deterministic

(Factors of Safety)

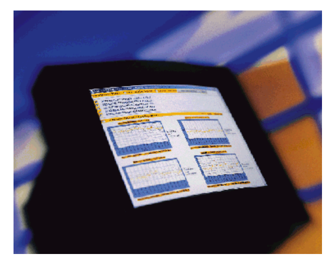
Stochastic

(Risk Quantified)



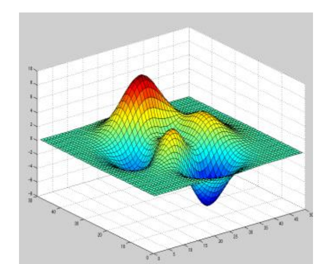

Graphical Approaches

Systematic Experimentation



Computer simulations based on system physics

Point estimates



Computer simulations based on system physics

Robust Solutions

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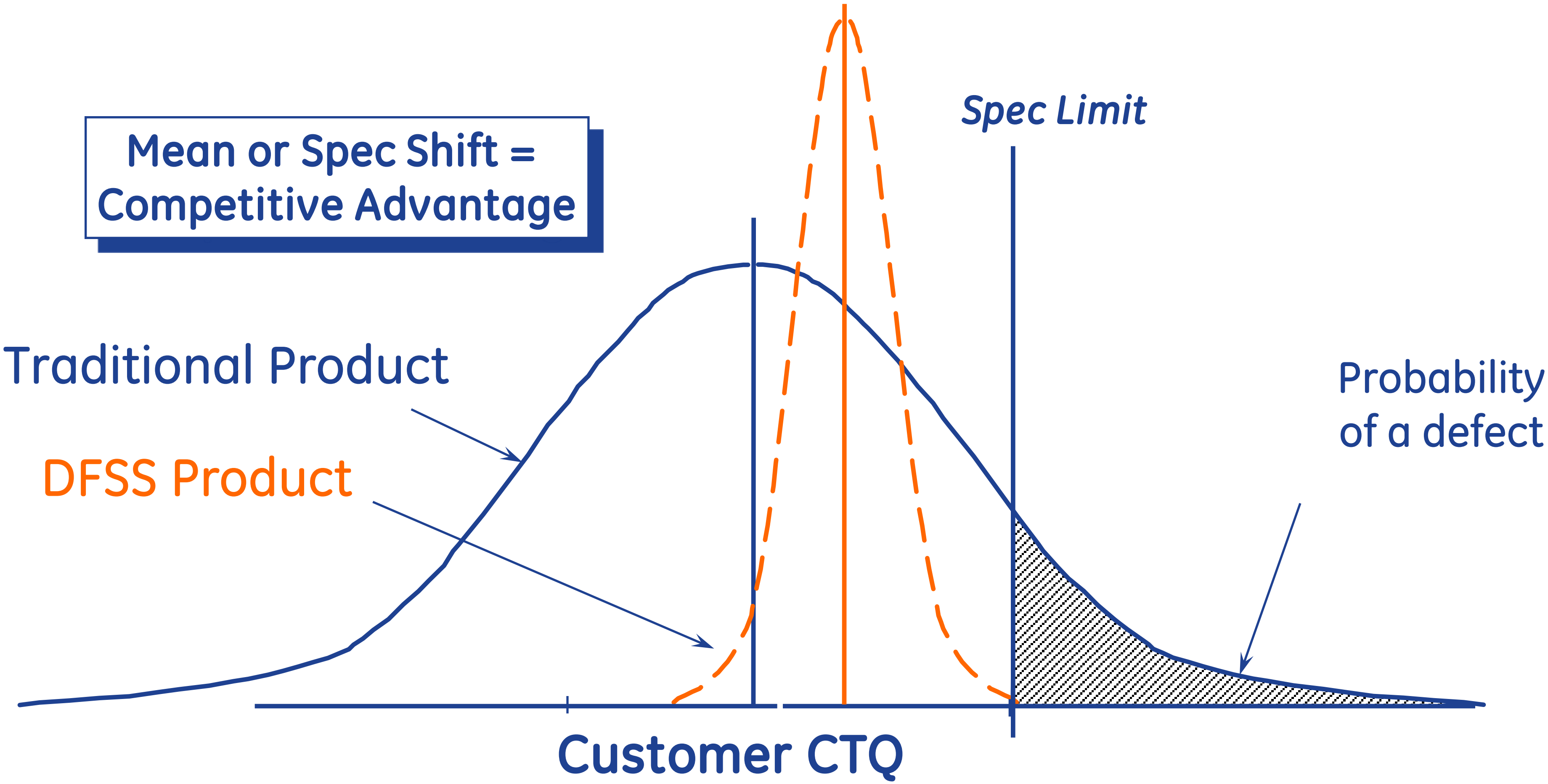
# What is Design for Six Sigma (DFSS)?

## Design For Six Sigma

| Define | Measure | Analyze | Design | Optimize | Verify |
|---|---|---|---|---|---|
| Set quality goals<br><br>Flow down requirements | Analyze measurement system<br><br>Assess reliability of current products | Develop conceptual designs<br><br>Risk Assessment<br><br>Initiate design quality scorecards | Build system models<br><br>Statistical analysis of variation<br><br>Process capability flow-up | Design for Reliability<br><br>Robust design<br><br>Tolerancing | Design verification<br><br>Develop control plans<br><br>Transition |

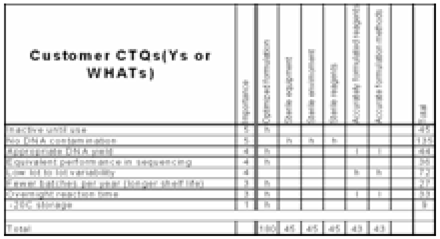
- Tools, training & metrics
- Products that meet Customer expectations
  - Technical Requirements
  - Reliability
  - Producibility (cost)
- Predict and improve quality before building prototypes
- Verify using pilot runs, pre-production and production units

# Why is DFSS Important?

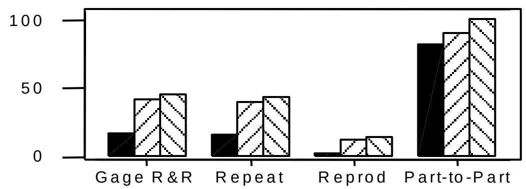



Reduced Variation Yields Customer Benefit and Competitive Advantage

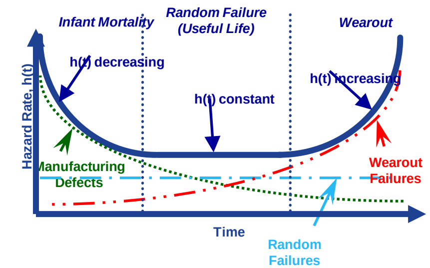
# A few tools in the DFSS toolkit




QFD: Translate Customer needs to product reqmts

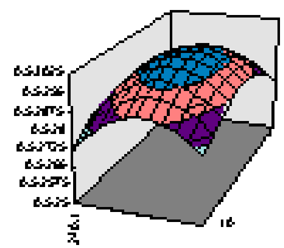



Measurement System Analysis

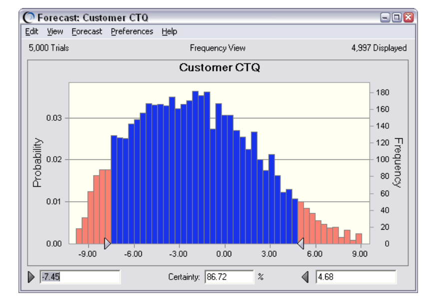



Reliability Modeling

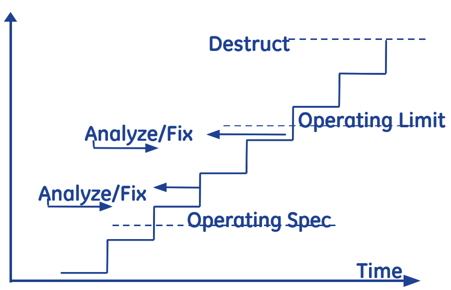
Scorecards



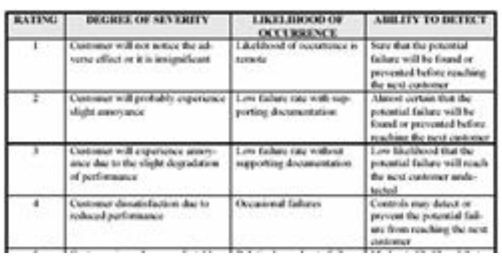
Design Of Experiments (DoE)




Monte Carlo Simulation (MCS)

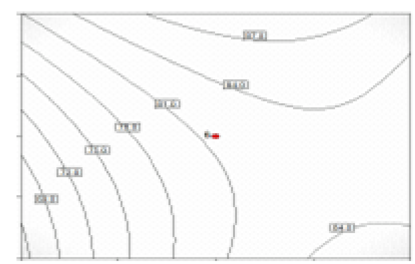



Accelerated Life Tests



| RATING | DEGREE OF SEVERITY | LIKELIHOOD OF OCCURRENCE | ABILITY TO DETECT |
|---|---|---|---|
| 1 | Customer will not notice the adverse effect or it is insignificant | Likelihood of occurrence is remote | Sure that the potential failure will be found or prevented before reaching the next customer |
| 2 | Customer will probably experience slight annoyance | Low failure rate with supporting documentation | Almost certain that the potential failure will be found or prevented before reaching the next customer |
| 3 | Customer will experience annoyance due to the slight degradation of performance | Low failure rate without supporting documentation | Low likelihood that the potential failure will reach the next customer undetected |
| 4 | Customer dissatisfaction due to reduced performance | Occasional failures | Controls may detect or prevent the potential failure from reaching the next customer |

Failure Modes & Effects Analysis



Optimization

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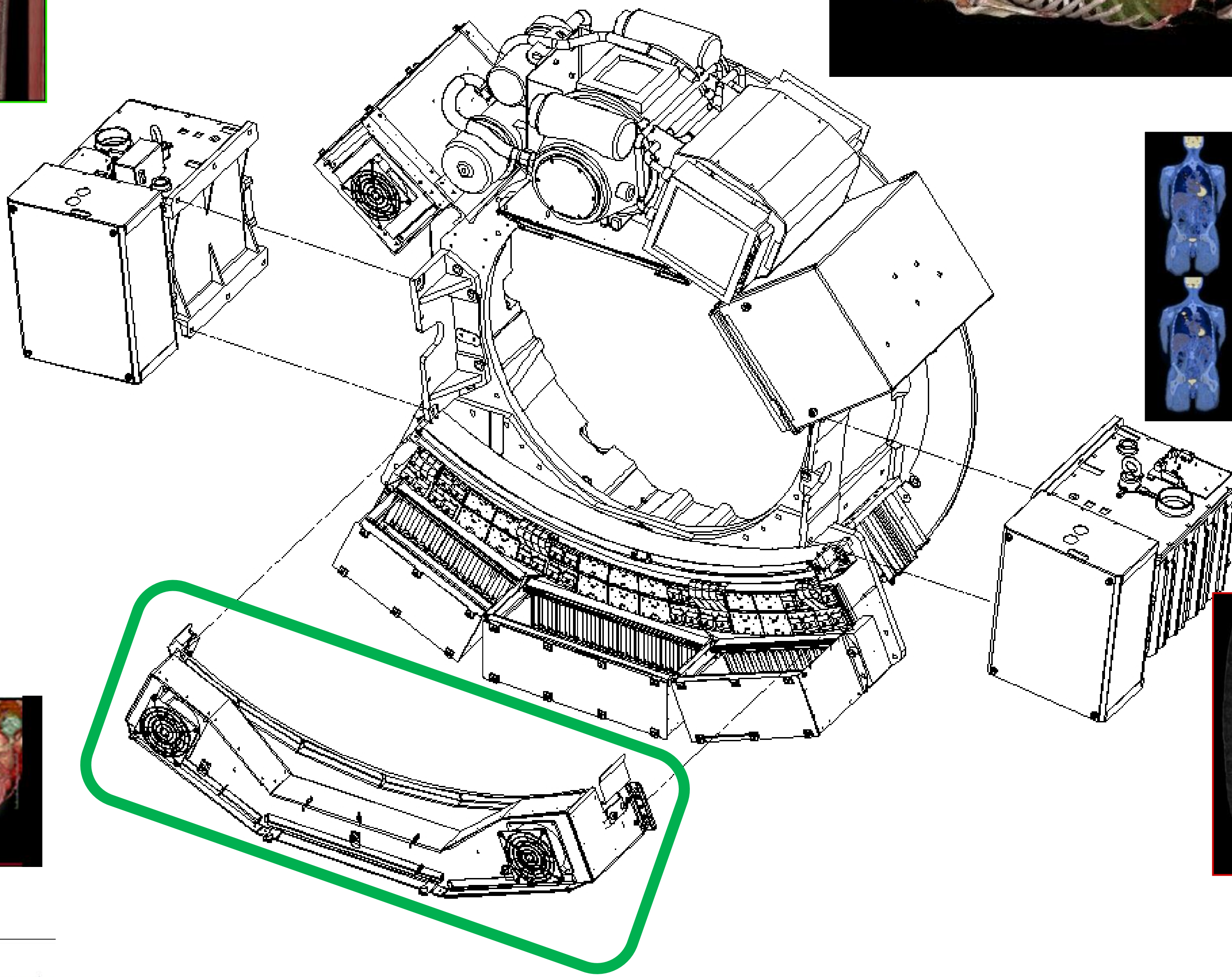
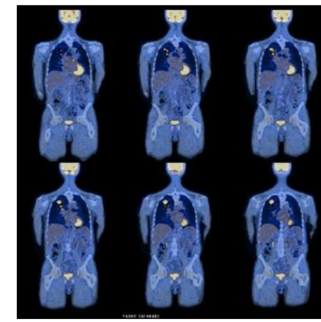
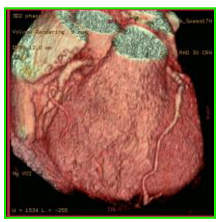
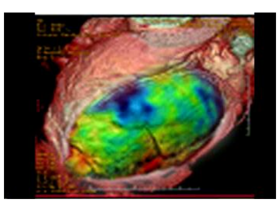
# What is a CT Detector?









# CT Detectors – Mechanical Challenges

**Human Hair**
0.0035 inch
0.0869 mm

Micron

Human Hair

**Watson Collimator**

**Collimator CTQs: Microns!**
- Radial Alignment
- Cell Segmentation
- Collimator to XRay Converter Alignment

**1000 Plates - 1 meter Arc**

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**Plate Sorting & Stuffing**

**Painstaking Preparation**
**Manual Assy**

**Gluing**

**“Arthroscopic Assembly”**

***Stresses over 10 Year Life…***

- **Rotations**: 20 million @ 0.35sec
- **Start/Stop**: 300k cycles…. 972 days Accel./Decel. (0-20Gs)
- **Thermal Cycles**: 4,000 transitions from 15C to 65C
- **Airflow**: 3 Billion Cubic Ft Air, 6kg of dust

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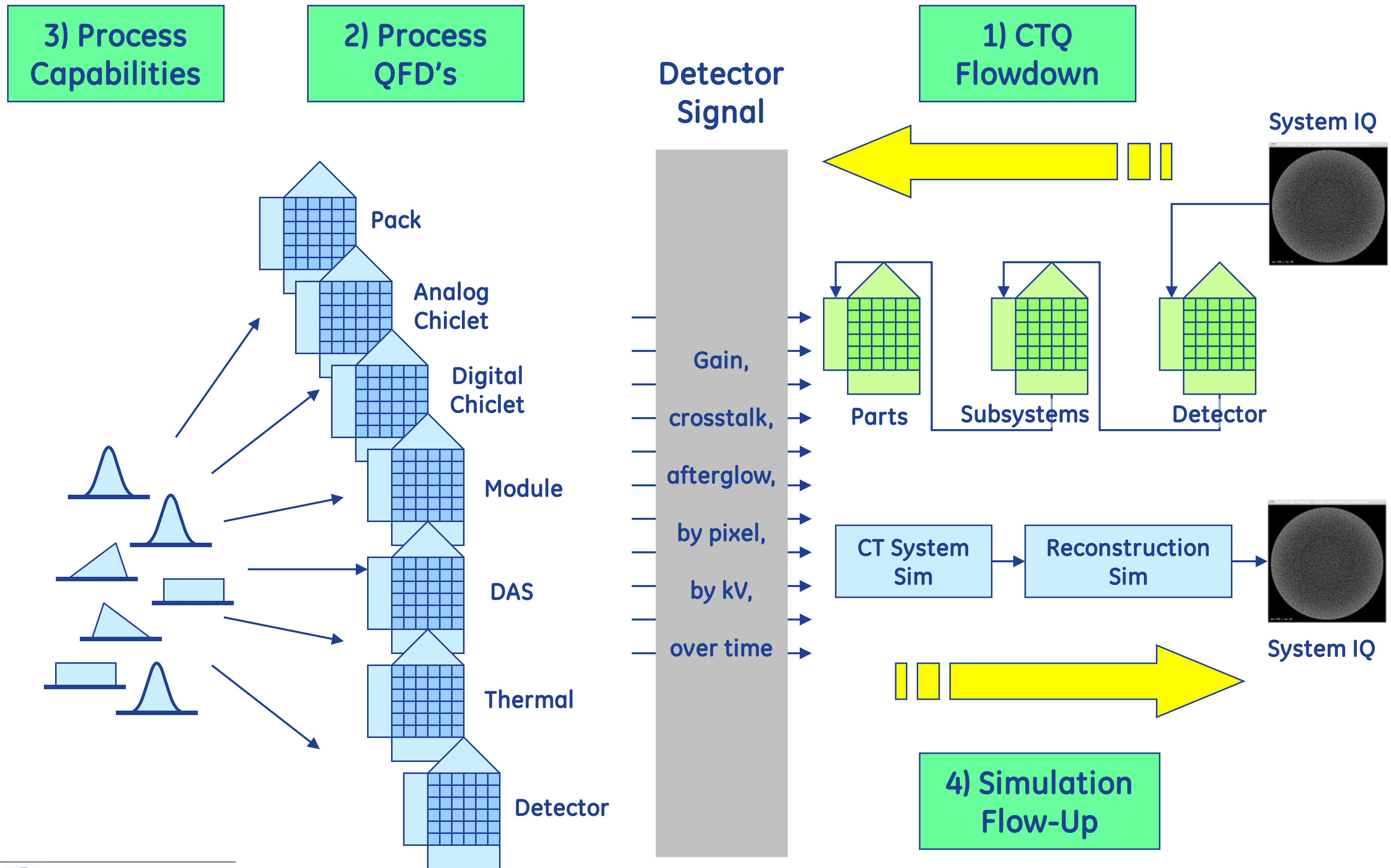
# Framework for CT Detector Simulation





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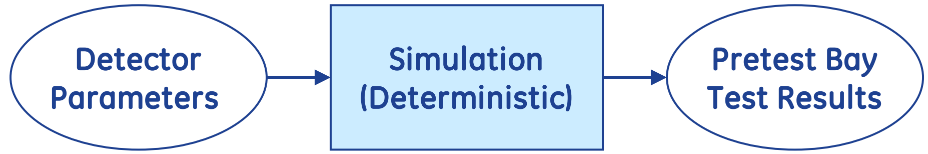
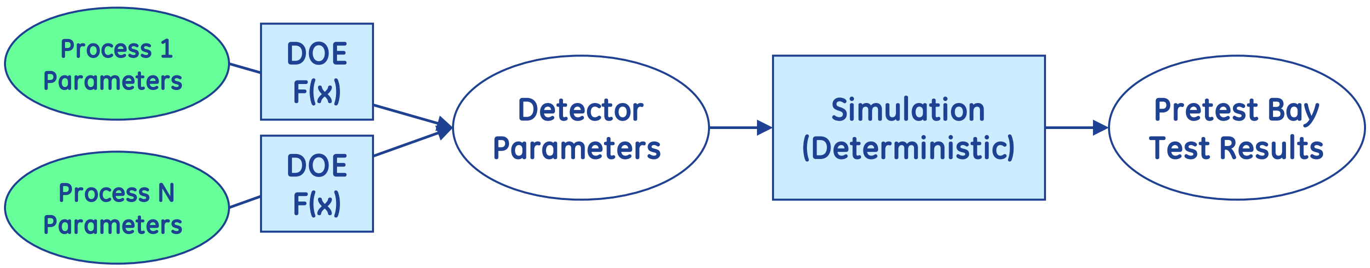
# Strategy

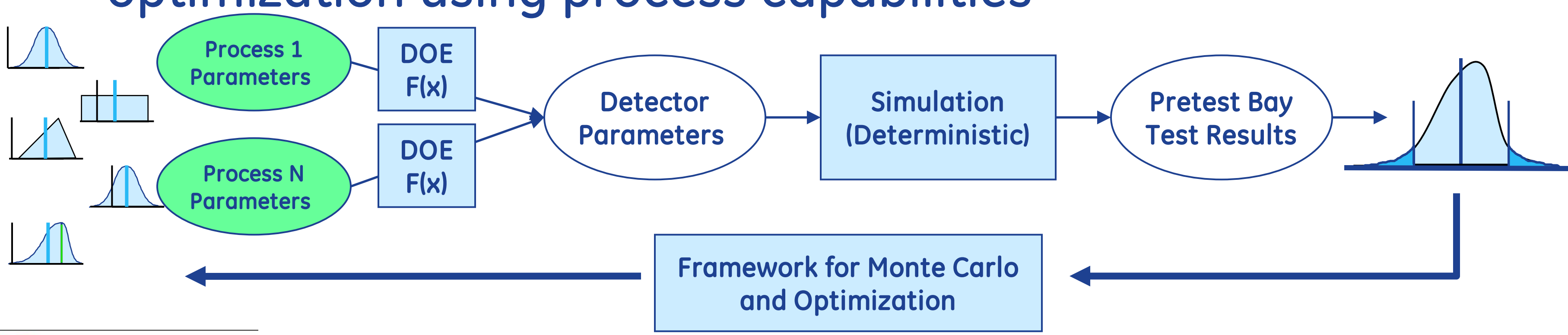
1. Assemble Detector Simulation Engine



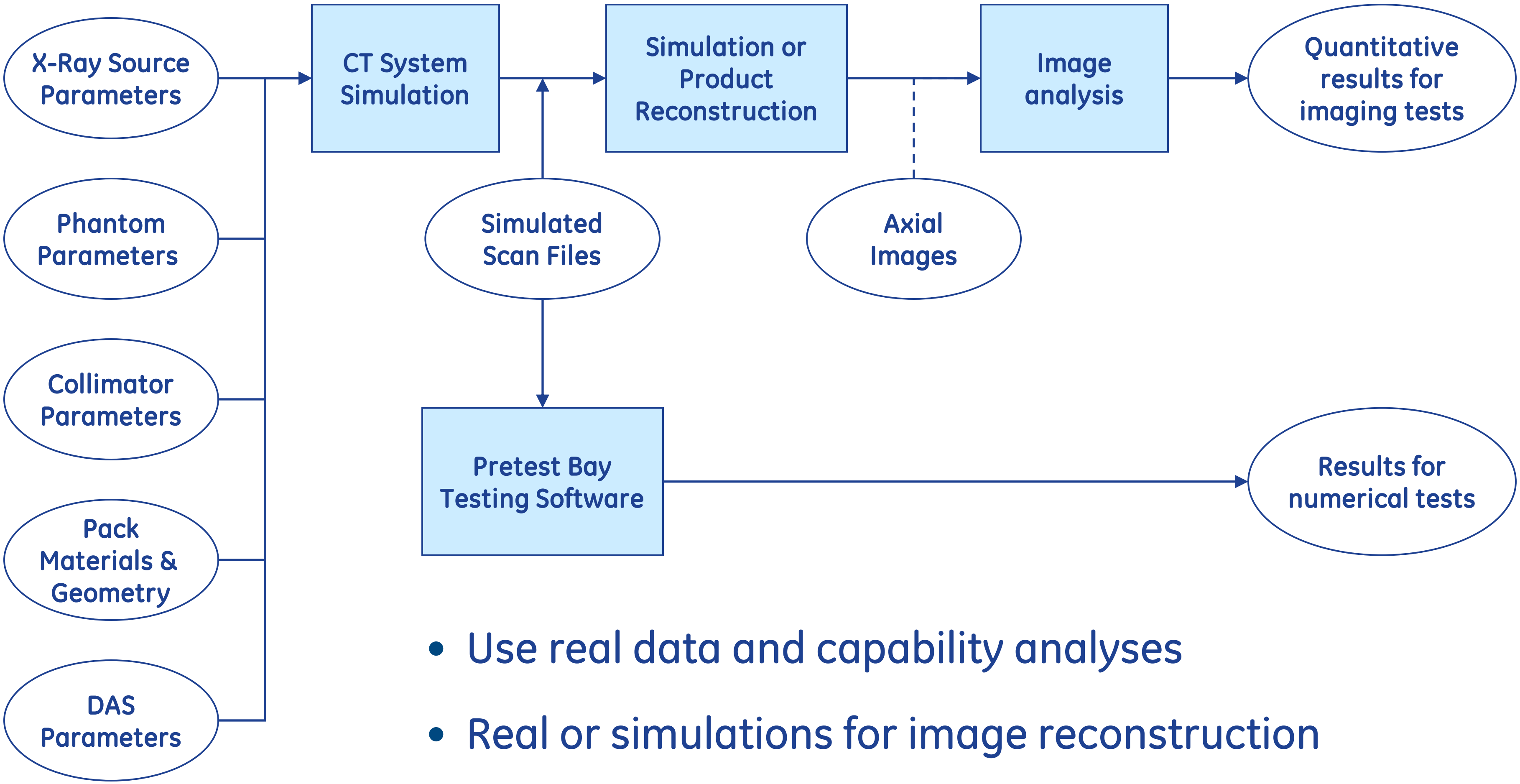

2. Pursue process DOE’s on high-priority CTQ’s




3. Implement Statistical Simulation: Perform yield prediction, optimization using process capabilities

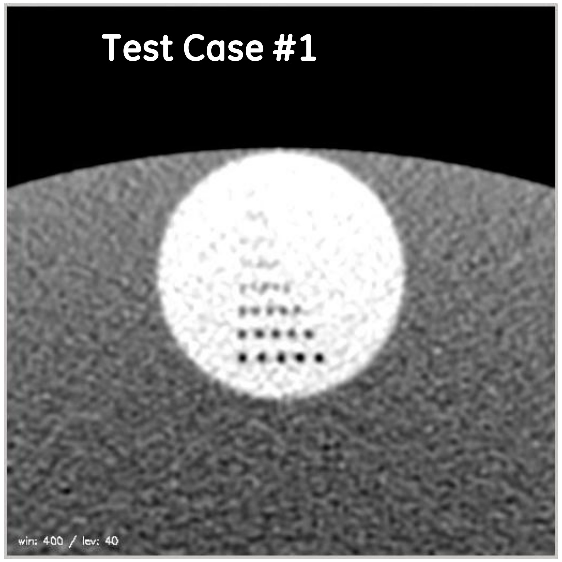


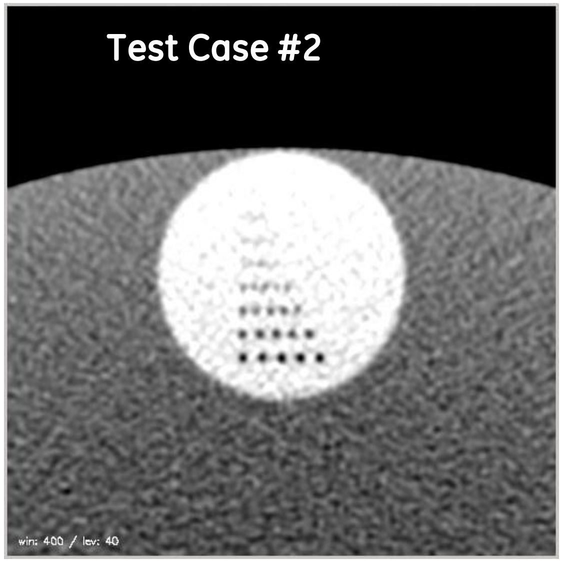
# Detector Simulation Engine

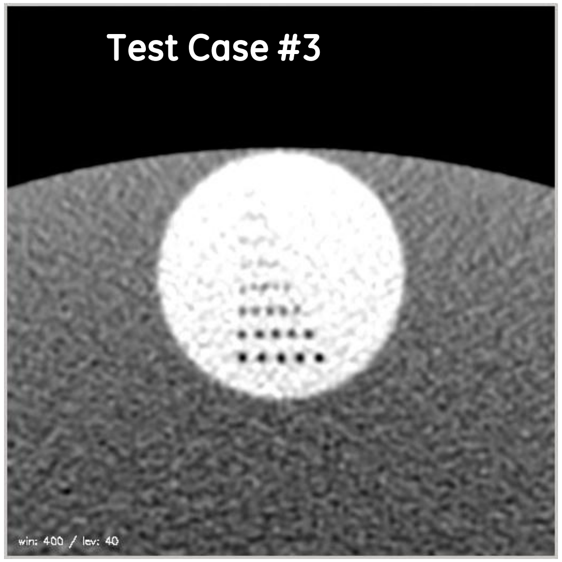


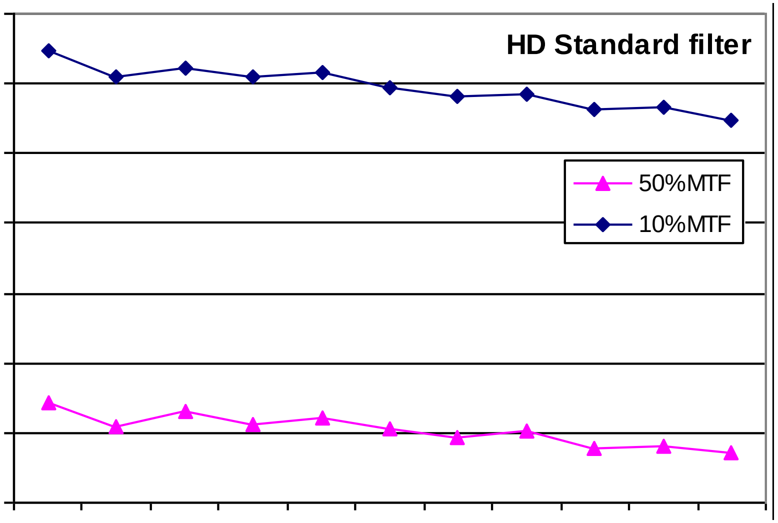

- Use real data and capability analyses
- Real or simulations for image reconstruction
- Ability to quickly compare data to test theories

# Can we optimize resolution?



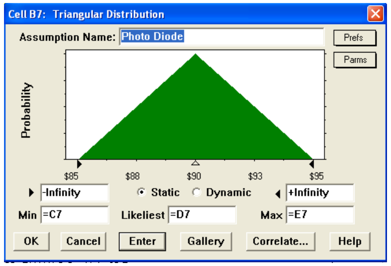



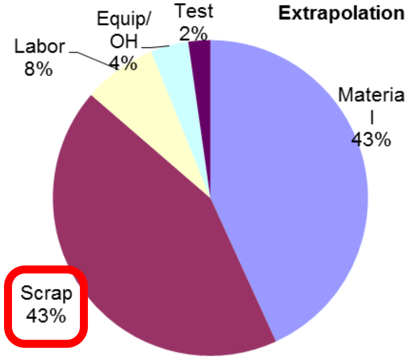



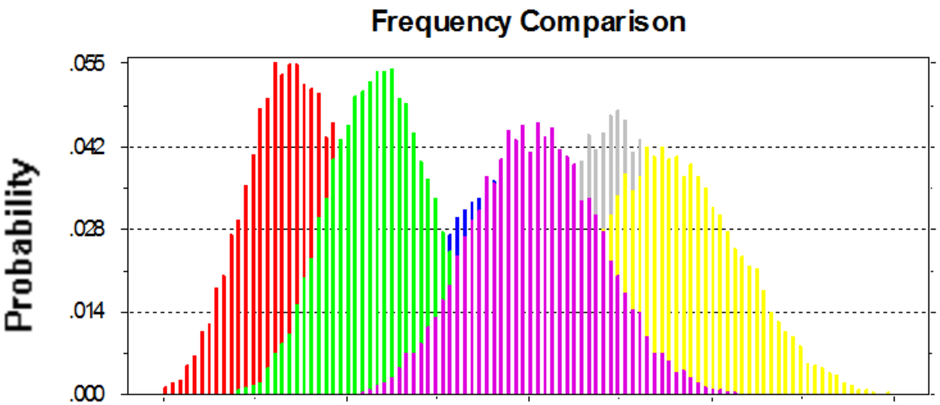




Use of simulations allowed us to optimize the design and manufacturing process with no noticeable impact on customers

# Modeling Process Critical to Quality (CTQ) Parameters v Cost





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# Why Build a Cost Model Early?

Design Architecture / Early choices lock in most of cost (detailed design decisions have less impact – “80/20” rule)

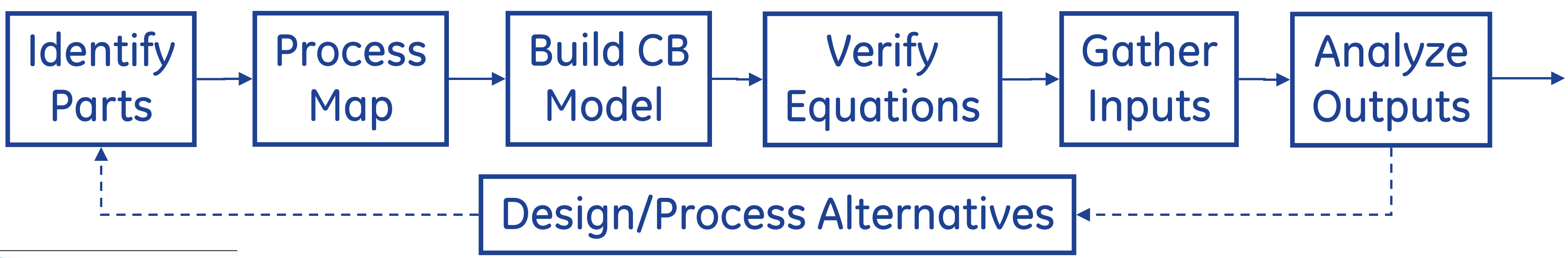
In face of early uncertainty still be able to quantify cost between design alternatives and cost impact of process alternatives

Drive “cost risk” retirement (reduce uncertainty, focus on big ticket items)

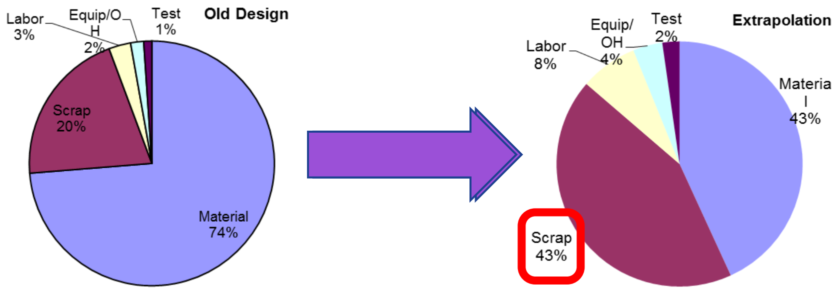
# Model Development Process Steps

1) ID Main product components
2) Create process flow map
3) Create Empty Cost Model in Crystal Ball (CB)
4) Verify Model Equations
5) Gather Inputs
6) Generate & Analyze outputs

Discussion/ Brainstorm

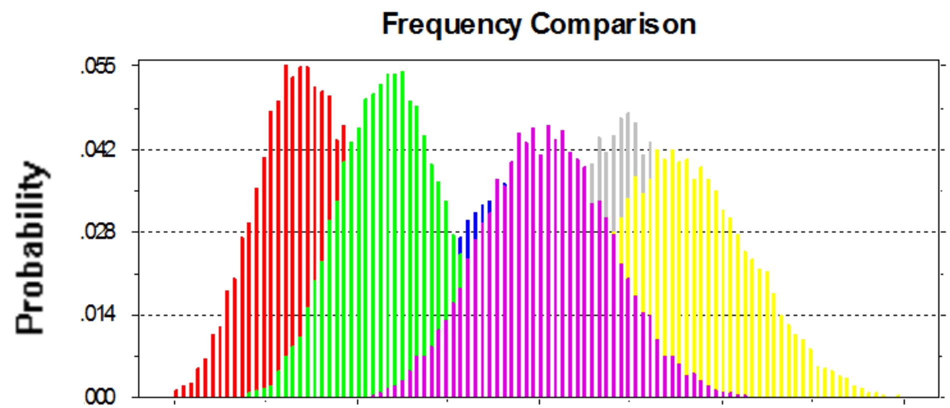


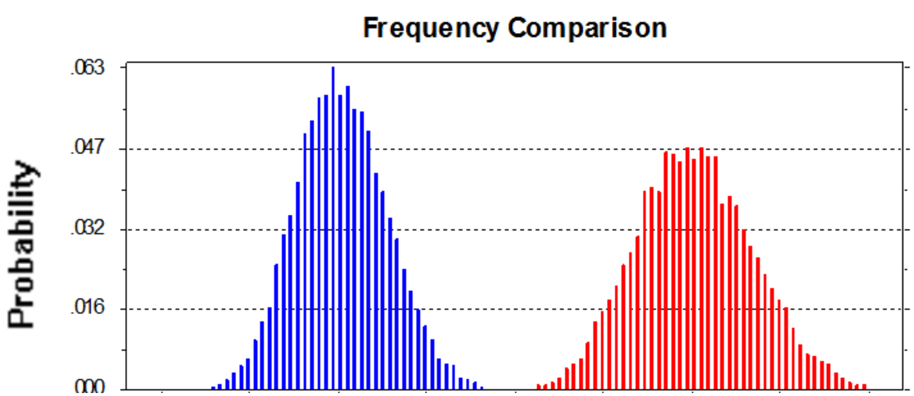
# Case Study – CT Detector "Module"




One Year Prior to Program Start (M0):
Simple scale up from prior architecture blows up scrap cost
EMBARK ON ALTERNATE PATH

Nine Months Prior to M0:
Input into Pugh Matrix for selecting between product architecture alternatives




Seven Months Prior to M0:
Deciding factor in "detailed" architecture decision

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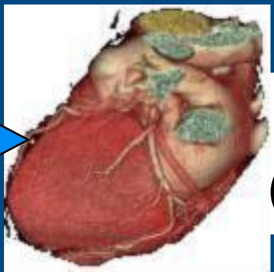
# X-Ray Sources…

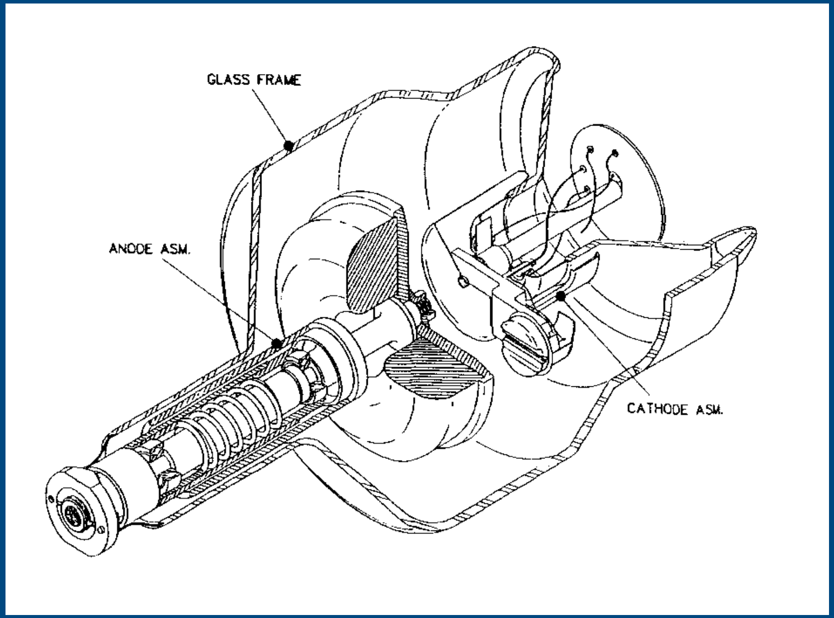
| <= 1991 | 1992 | 1997 | 2000 | 2004 | 2005 |
|---|---|---|---|---|---|
| 24 kW | 48 kW | 60 kW | | 100 kW | |
| 0.7G | 3G | | 5G | 15G | 20G |

***Enabling New Applications Through Technology***




***HTD 5 sec Heart***

***VCT 5 sec Heart***




- Temp: >2500C… Steel Melts at 1500C
- Load : 20Gs… Rocket Launch <10Gs
- 60 km/hr; 2 ton force; 50μ stability
- Voltage: 140,000 volts
- Power: 100kW – Power for 30 Houses into a 5 liter target
- 10,000 RPM… Porsche engine red-lines @ 9500

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# Examples of Computer Experiments + Advanced Visualization



QFD: Translate Customer needs to product reqmts



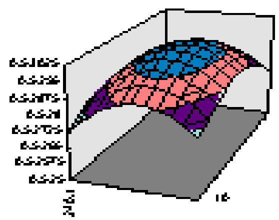

Measurement System Analysis




Reliability Modeling



Scorecards



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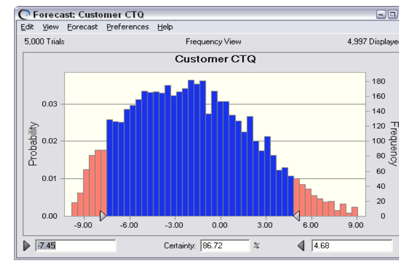
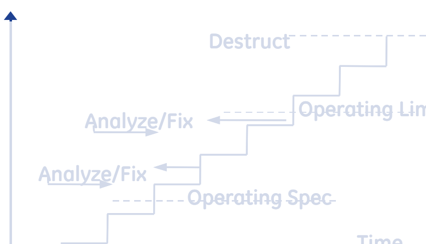


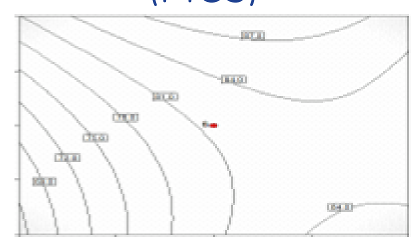

Monte Carlo Simulation (MCS)




Accelerated Life Tests



Failure Modes & Effects Analysis

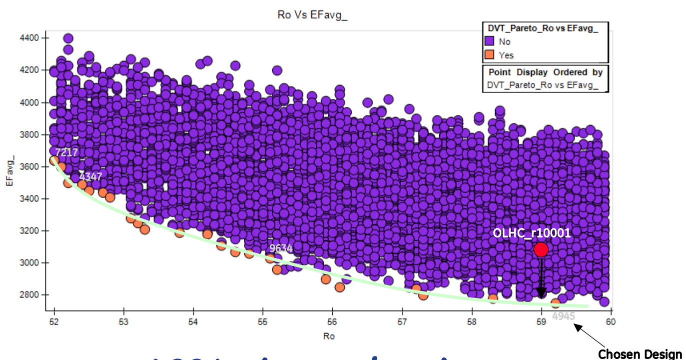


Optimization

# Simulation Results and Benefits

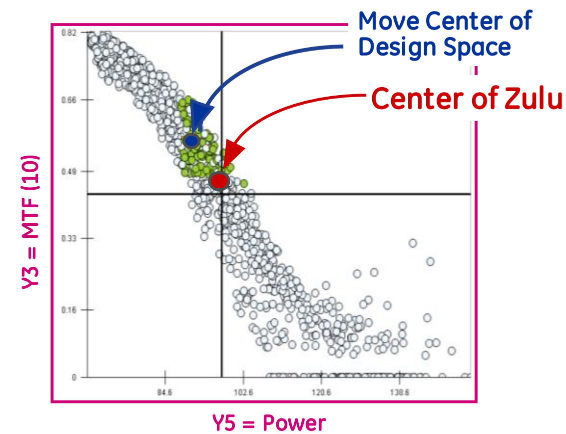
## HV Insulator Optimization

10,000 pts centered around first 16 pts
Only feasible points shown




*40% size reduction*

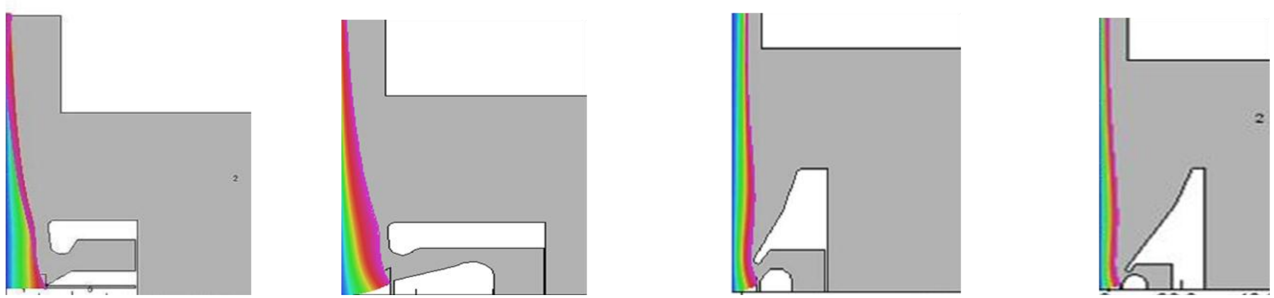
## Power / Resolution Optimization




*Greater Robustness*

## Electron Optics Optimization

Textbook → MCS → Engineer → Engineer+ MCS



***Engineering insight still a valuable part of the process!***

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# Simulation Five Golden Rules

Validated models

Good engineering knowledge

Vision

Linked Hierarchical Models

Visualization tools


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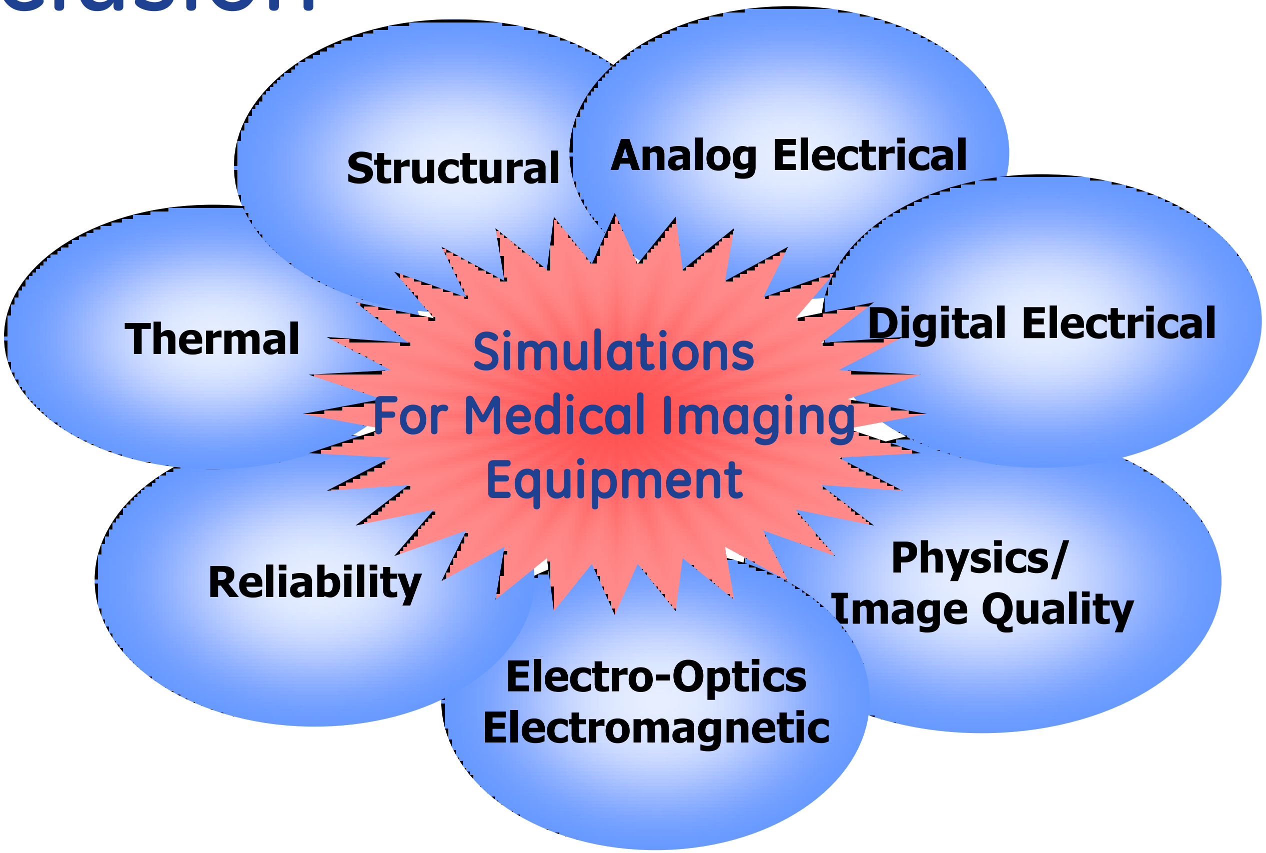
# Conclusion




Challenging specs: Micron Tolerance, Quantum Noise Levels, 10's of G-Forces
$10^{25}$ Variation in Scales (eg. Energy)
Continued Cost Containment Pressures from Governments
Worldwide Competition Drives Time to Market