Applications of Systems Engineering to Healthcare

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Medical industry faces many challenges

- Extreme time to market pressures
  - 1st to market usually gains 80% of that market
- Compliance with regulations
  - FDA, IEC, ISO, HIPAA, ICD-10, ACA, etc.
- Defects are VERY costly to handle
  - Want to avoid audit, decrees, warning letters, recalls, etc...
- Most products are developed in a geographically distributed way
  - Need to communicate and define tasks
- Technology is impacting development and delivery
  - IoT, product variants, Mobile Medical Apps, complex deployment models, cloud

Courtesy of Kim Cobb, IBM Rational

Market Driven vs. Contract Driven

GEHC "Extension"

- Customer of "systems engineering" is internal (marketing, product management)
- Requirements, dates, budgets are more 'flexible'…success is judged by the market, not by a single customer

Systems Engineering: *From Needs to Solutions*

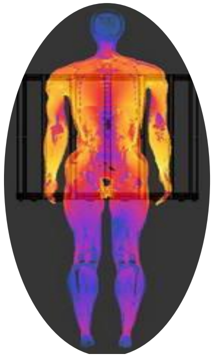
- The product **seamlessly** integrates into the customer’s workflow and systems, **reliably** meets all their needs, and **delights** the customer,
- **robust** delivery of clear **market differentiation (DFSS CTQs)**,
- technical scope/program **work is clearly tied to market impact**,
- technical **risks** are **retired early and robustly**,
- design **decisions** are identified and closed predictably (and **stay closed**),
- designs integrate easily,
- quality problems (when they exist) are **found and resolved early**, and
- **creative ideas** come from everyone and designs are **optimized across organizational boundaries**,
- institutional **knowledge is available to everyone** when and how they need it.

Winning Products happen when **Systems** ~~Engineers~~ **Thinkers** are effective

INCOSE International Council on Systems Engineering Biomedical Healthcare Working group

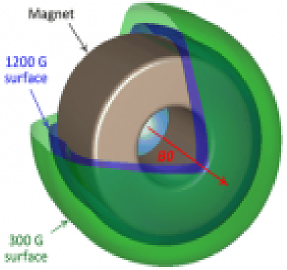
What is Systems Engineering at GEHC?

Image Quality



Safety & Regulatory

Usability



Performance

Reliability

Serviceability

Marketing & Customer Needs

System/Feature Design

V & V
Reli Testing

Manufacturing
Service

Install Base
Support

The Challenge… Energy Conversion & Detection

MR 3T

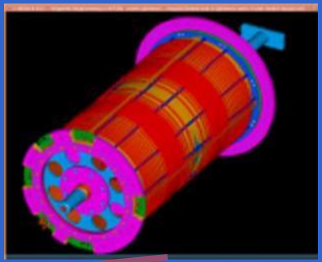
30 MJ

Performix Pro

40 kJ

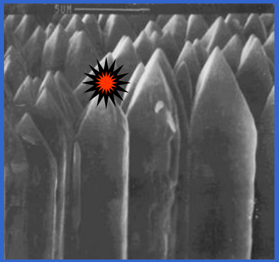
Gradient Coil

1 kJ



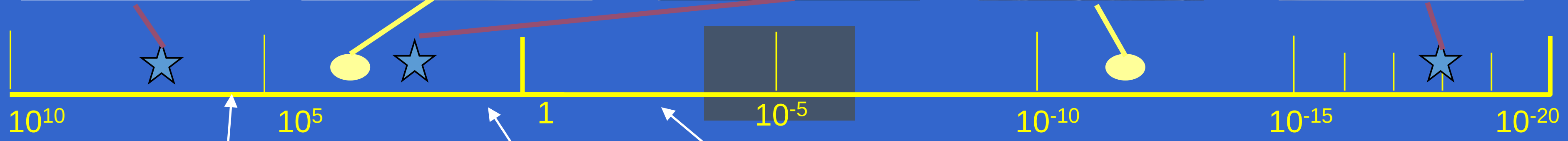
e^- Noise

8 fJ



MR Min Signal

10^{-18} J



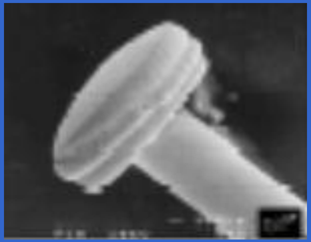
1MJ

Hummer @ 50 mph

400 J

Climbing 1 Step

2 mJ



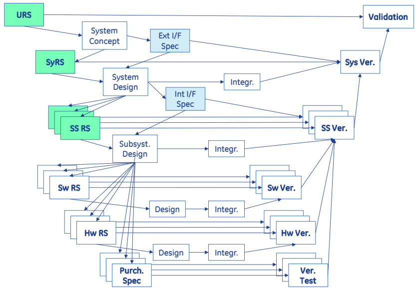
Pin Dropping

How is systems engineering organized?

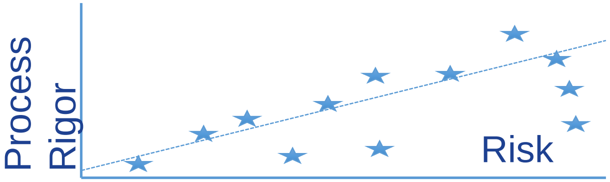
Common Program Milestones

Program kickoff
Requirements Freeze
Design Freeze
Verification complete
Pilot production
General Release

Common System Lifecycle



Differing Risk Profile



Locations all over the world: organized by product line (and segment)

Size of the organization: Lots of Systems Engineers; but SE team sizes vary from <10 to 100+.

Scale of programs: <10 engineers to many hundreds. Less than a year to 3+ years, with basic technology developed over a decade.

Organization: Product Centralized (SE General Manager) to decentralized (no SE managers)

Systems Strategies

Back to the Basics

Focus on the Customer – Usability and Reliability

Scope Management

Decision Management

Technical Risk Management

Active Integration

Focus on the Customer: Usability and Reliability

Design for Usability

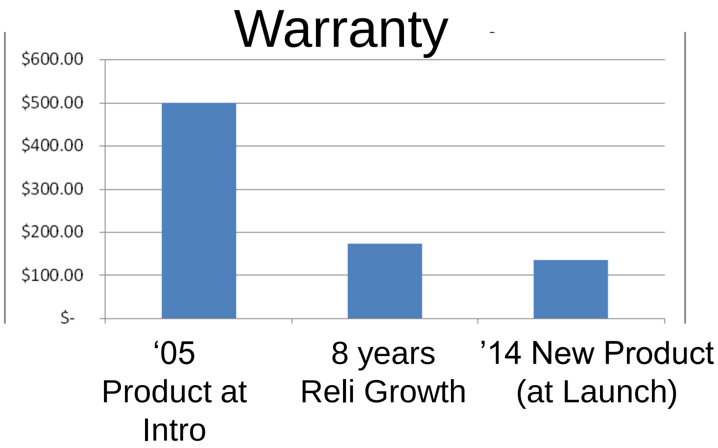
Usability “Work Instruction” (compliance to FDA regulation)

Focus on formative & summative testing, “expected user abuses”

Usability CoE (central resources for coaching, best practices and reviews)

Global Design Team (professional experts in the five user experience disciplines)

Design for Reliability



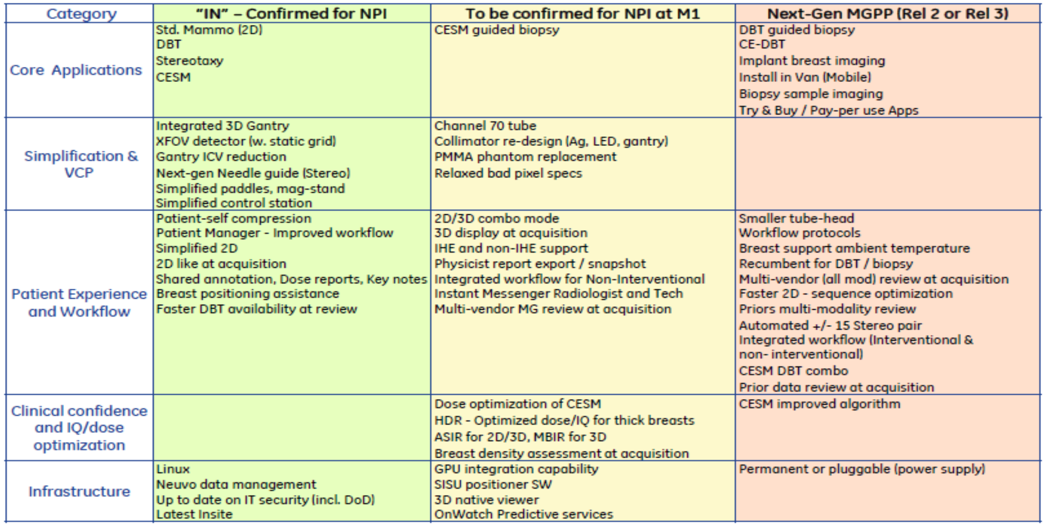
Formal 10 step reliability process

Formal reliability practitioner certification

Improved field data access and analytics

Central support (coaches, design tools, test equipment)

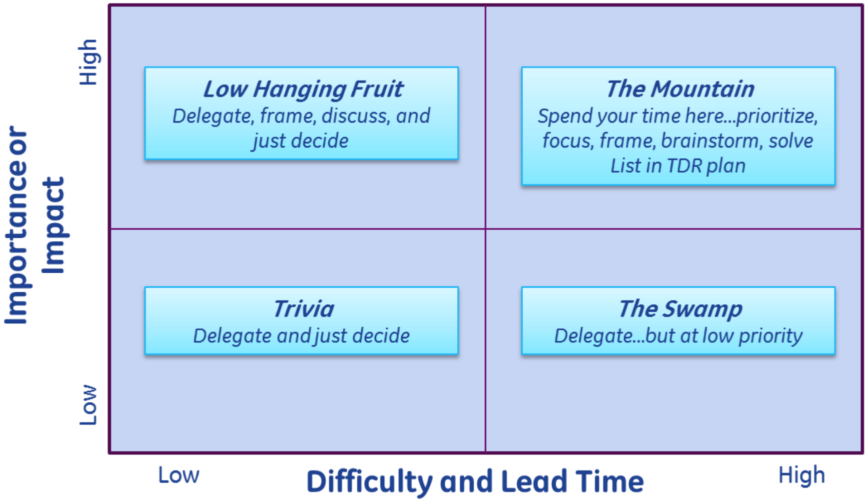
Scope Management



Category	"IN" – Confirmed for NPI	To be confirmed for NPI at M1	Next-Gen MGPP (Rel 2 or Rel 3)
Core Applications	Std. Mammo (2D) DBT Stereotaxy CESM	CESM guided biopsy	DBT guided biopsy CE-DBT Implant breast imaging Install in Van (Mobile) Biopsy sample imaging Try & Buy / Pay-per use Apps
Simplification & VCP	Integrated 3D Gantry XFOV detector (w. static grid) Gantry ICV reduction Next-gen Needle guide (Stereo) Simplified paddles, mag-stand Simplified control station	Channel 70 tube Collimator re-design (Ag, LED, gantry) PMMA phantom replacement Relaxed bad pixel specs	
Patient Experience and Workflow	Patient-self compression Patient Manager - Improved workflow Simplified 2D 2D like at acquisition Shared annotation, Dose reports, Key notes Breast positioning assistance Faster DBT availability at review	2D/3D combo mode 3D display at acquisition IHE and non-IHE support Physicist report export / snapshot Integrated workflow for Non-Interventional Instant Messenger Radiologist and Tech Multi-vendor MG review at acquisition	Smaller tube-head Workflow protocols Breast support ambient temperature Recumbent for DBT / biopsy Multi-vendor (all mod) review at acquisition Faster 2D - sequence optimization Priors multi-modality review Automated +/- 15 Stereo pair Integrated workflow (Interventional & non- interventional) CESM DBT combo Prior data review at acquisition
Clinical confidence and IQ/dose optimization		Dose optimization of CESM HDR - Optimized dose/IQ for thick breasts ASIR for 2D/3D, MBIR for 3D Breast density assessment at acquisition	CESM improved algorithm
Infrastructure	Linux Neuvo data management Up to date on IT security (incl. DoD) Latest Insite	GPU integration capability SISU positioner SW 3D native viewer OnWatch Predictive services	Permanent or pluggable (power supply)

- The Scope Ensures the **Clinical, Customer, and Business** aspects of the program
  - Start by **managing 'features'**, more than specific requirements…tie priorities to the business case
  - Includes **required, stretch, and dropped functions**
  - Covers **all cross-functional business expectations** (service, MFG, regulatory…)
  - Includes both quality goals, and engineering constraints (platforms, standards)
- Future challenges: Better integration of the systems engineer with the market strategy; improved integration of Agile and Fastworks approaches

Decision Management



High

Importance or Impact

Low

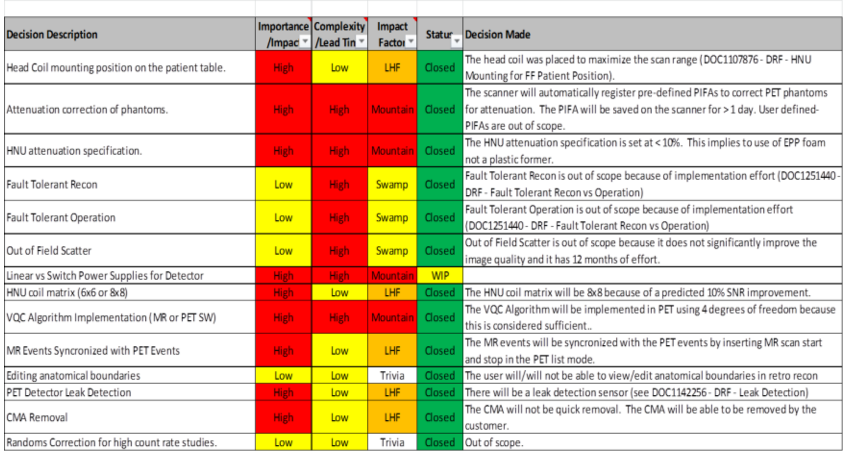
Low Hanging Fruit
Delegate, frame, discuss, and just decide

The Mountain
Spend your time here…prioritize, focus, frame, brainstorm, solve
List in TDR plan

Trivia
Delegate and just decide

The Swamp
Delegate…but at low priority

Low **Difficulty and Lead Time** High

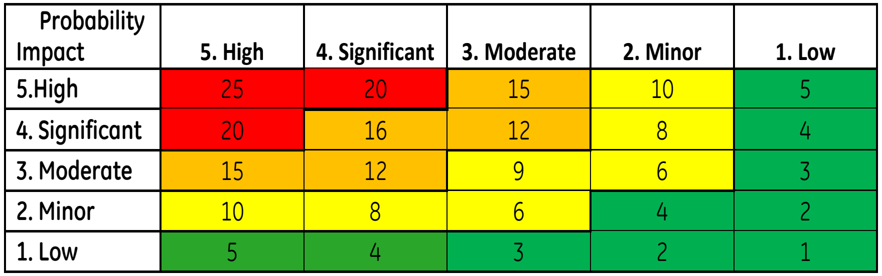


Decision Description	Importance /Impac	Complexity /Lead Tin	Impact Facto	Statu	Decision Made
Head Coil mounting position on the patient table.	High	Low	LHF	Closed	The head coil was placed to maximize the scan range (DOC1107876 - DRF - HNU Mounting for FF Patient Position).
Attenuation correction of phantoms.	High	High	Mountain	Closed	The scanner will automatically register pre-defined PIFAs to correct PET phantoms for attenuation. The PIFA will be saved on the scanner for > 1 day. User defined-PIFAs are out of scope.
HNU attenuation specification.	High	High	Mountain	Closed	The HNU attenuation specification is set at < 10%. This implies to use of EPP foam not a plastic former.
Fault Tolerant Recon	Low	High	Swamp	Closed	Fault Tolerant Recon is out of scope because of implementation effort (DOC1251440 - DRF - Fault Tolerant Recon vs Operation)
Fault Tolerant Operation	Low	High	Swamp	Closed	Fault Tolerant Operation is out of scope because of implementation effort (DOC1251440 - DRF - Fault Tolerant Recon vs Operation)
Out of Field Scatter	Low	High	Swamp	Closed	Out of Field Scatter is out of scope because it does not significantly improve the image quality and it has 12 months of effort.
Linear vs Switch Power Supplies for Detector	High	High	Mountain	WIP	
HNU coil matrix (6x6 or 8x8)	High	Low	LHF	Closed	The HNU coil matrix will be 8x8 because of a predicted 10% SNR improvement.
VQC Algorithm Implementation (MR or PET SW)	High	High	Mountain	Closed	The VQC Algorithm will be implemented in PET using 4 degrees of freedom because this is considered sufficient..
MR Events Syncronized with PET Events	High	Low	LHF	Closed	The MR events will be syncronized with the PET events by inserting MR scan start and stop in the PET list mode.
Editing anatomical boundaries	Low	Low	Trivia	Closed	The user will/will not be able to view/edit anatomical boundaries in retro recon
PET Detector Leak Detection	High	Low	LHF	Closed	There will be a leak detection sensor (see DOC1142256 - DRF - Leak Detection)
CMA Removal	High	Low	LHF	Closed	The CMA will not be quick removal. The CMA will be able to be removed by the customer.
Randoms Correction for high count rate studies.	Low	Low	Trivia	Closed	Out of scope.

- **The critical decisions are listed…**
  - Any decision gating team productivity is listed…the team agrees to the list and prioritization
  - The **decisions listed are truly decisions**, not just topics (there are options to choose between with decision criteria which guide the downselection)
- The proper level of attention is applied to each decision
  - **Complex, important decisions** have a decision plan which includes **stakeholder analysis and pre-briefings** to ensure consensus and decision buyin
  - Simple tracker (excel) to ensure **focus and execution** and **publicly record decisions**

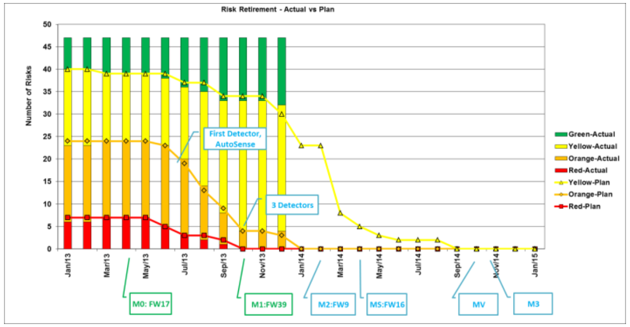
Technical Risk Management

Assess Risk Classes



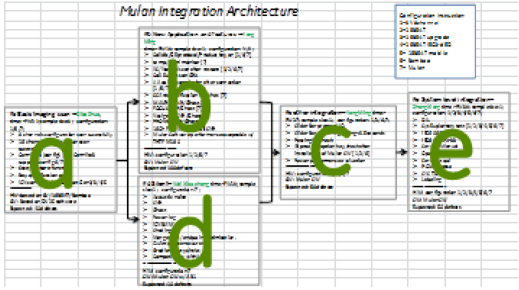
Probability Impact	5. High	4. Significant	3. Moderate	2. Minor	1. Low
5.High	25	20	15	10	5
4. Significant	20	16	12	8	4
3. Moderate	15	12	9	6	3
2. Minor	10	8	6	4	2
1. Low	5	4	3	2	1

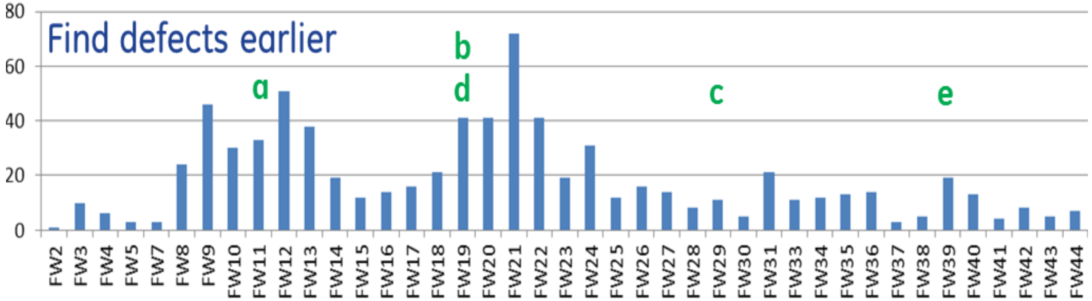
Annotated Risk Waterfall



- The Technical Risk Management Plan covers all cross-functional scope
- Focus on risk classes, not a “score”; Simple criteria on risk classes tied to business checkpoints
- Guidelines (objective criteria) for assessing probability and impact
- Technical risks have an appropriate level of senior technical ownership & review
- There are clear completion (feasibility) criteria for each technical risk, with incremental steps (reviews, tests, repeatability, customer testing, …) tied to program plans…with contingency plans as appropriate
- Future: make the risk classes ‘asymmetric’…more focus on impact (black swans)

Active Integration





95% confidence at each integration step that **we are done**…

”ready for release”

- **Verification is an ongoing process** throughout design & development.
  - Strategic plan for minimal rework and regression testing
  - **Each integration step is tested as though it were ready to ship**, with cross-functional involvement where appropriate**.**
  - Defects are fixed promptly when found, so there is only a **small backlog of planned fixes.**
- **The goal of testing is to find problems.**
  - A variety of methods and tools are used for performing verification throughout the program, not just testing of the final implementation. (Challenging testing, usability testing, reliability)
- **Future Challenge**: better integration with Agile philosophy, and better integration with use case testing and function verification…not just requirements traceability

Examples of Design Thinking

Challenge: Pediatric Sedation Rates

Imaging exams are scary to children.

They often require no movement, thus children are sedated

That is expensive, dangerous, and time consuming

Solutions ($$M of development):

- Make the exams faster
- Silent MR
- Motion correction algorithms

How hard is it to see from the perspective of others?

http://www.kidsmathgamesonline.com/pictures/illusions/saxophoneorwoman.html
https://www.flickr.com/photos/31721843@N07/2968290717

Solution: Adventure Series

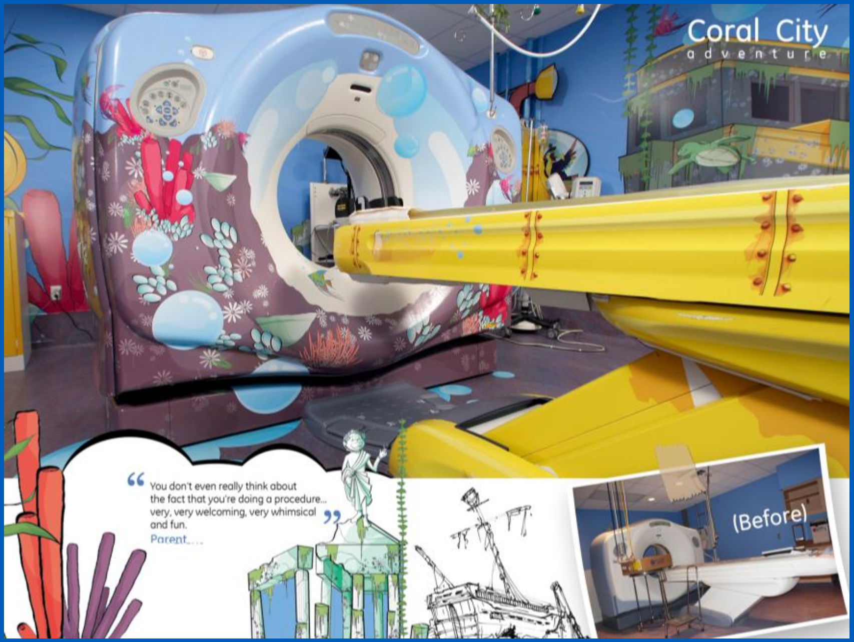
Make the exam an adventure (a journey) for the patient

Solution:

- Story for the technicians
- Coloring book for the patient
- Paint (for the room and system)

Outcomes:

- 80% lower sedation rates
- "Can I come back tomorrow?"



"You don't even really think about the fact that you're doing a procedure... very, very welcoming, very whimsical and fun."
Parent....

Can you truly identify the "customer's" pain point and think of non-traditional solutions?

http://www.kidsmathgamesonline.com/pictures/illusions/saxophoneorwoman.html
https://www.flickr.com/photos/31721843@N07/2968290717

Challenge: Mammography Compression

Mammography is looking for small pathology (microns) with lots of overlapping tissue (cms)

Breast is compressed with a paddle

Pain leads to fewer exams (lower compliance)

Solutions ($$M of development):
- Faster exams (less compression time)
- Tomosynthesis/dual energy (less compression needed)

What is “truly” the problem?

http://www.kidsmathgamesonline.com/pictures/illusions/saxophoneorwoman.html
https://www.flickr.com/photos/31721843@N07/2968290717

Solution: Patient Assisted Compression

Being out of control → fear

Fear → tension, discomfort, pain

Solution:

- Patient control (patient assisted compression)

Outcomes:

- Higher Compression levels
- Better positioning
- Lower discomfort

Can you think of examples in your product teams?

http://www.kidsmathgamesonline.com/pictures/illusions/saxophoneorwoman.html
https://www.flickr.com/photos/31721843@N07/2968290717

Conclusion

Good Systems Engineering is Compliant Engineering

21CFR820.30	ISO/IEC/IEEE 15288:2015	INCOSE SE Handbook
(b) Design and development planning	6.3.1 Project Planning Process	5.1 Project Planning Process
(c) Design input.	6.4.2 Stakeholder needs and requirements definition process 6.4.3 Systems requirements definition process	4.2 Stakeholder needs and requirements definition process 4.3 Systems requirements definition process
(d) Design output	6.4.5 Design definition process 6.4.7 Implementation process	4.5 Design definition process 4.7 Implementation process
(e) Design review	6.3.2 Project Assessment and Control process	5.2 Project Assessment and Control process
(f) Design verification	6.4.9 Verification Process	4.9 Verification Process
(g) Design validation	6.4.11 Validation Process	4.11 Validation Process
(h) Design transfer	6.4.10 Transition Process	4.10 Transition Process
(i) Design changes	6.3.5 Configuration Management Process 6.4.13 Maintenance Process	5.5 Configuration Management Process 4.13 Maintenance Process
(j) Design history file	6.2.6 Knowledge Management Process	5.6 Information Management Process

SE Effectiveness Survey – SEI Study on Value of SE

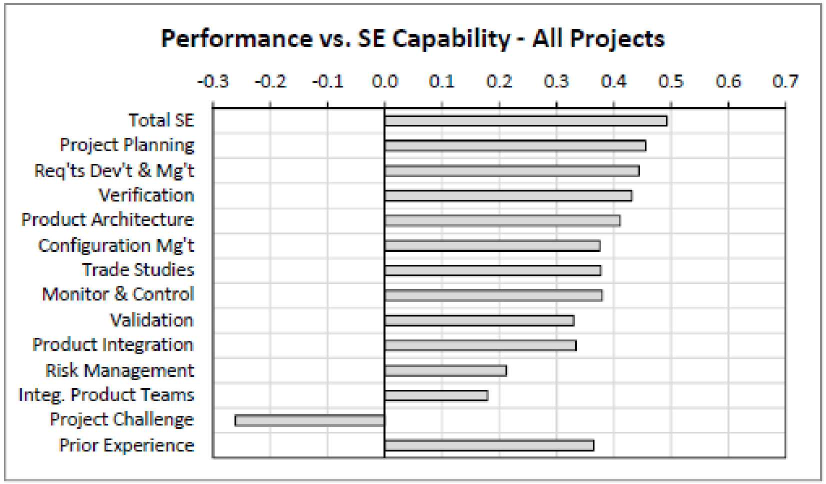


Figure 2: Project Performance vs. SE Capabilities and Drivers

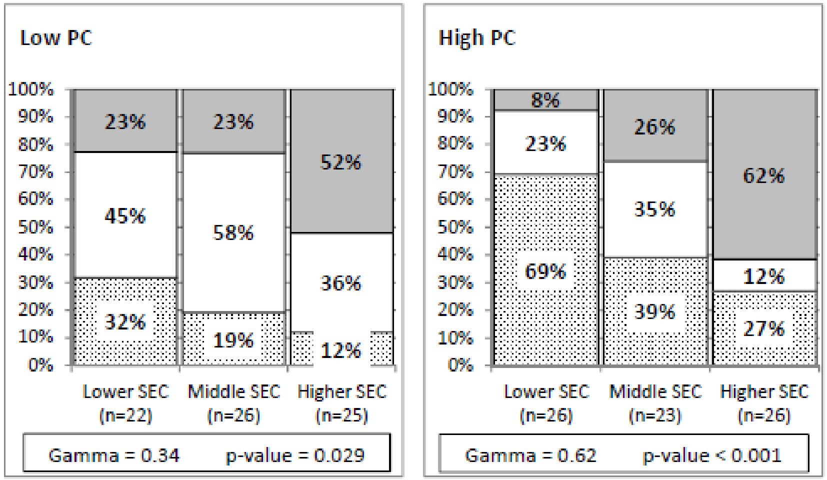


Figure 19: SEC-Total vs. Perf Controlled by *PC*

Systems Engineering Artifacts Correlate with Project Success

- Effort applied to create does not correlate with success

Correlation is stronger with more challenging projects

- Easier projects don't require much rigor; on 1/3 most challenging projects, ↑8x success

Conclusions

- Focus on the basics (but at world class performance levels) generates high returns
- “Market Driven” business means focusing on competitive value creation and use cases more than “requirements”
- Internal forces can drive as much scope creep as a customer
- Ideal state seems to be a hybrid of Agile/Fastworks and “more traditional” systems approach

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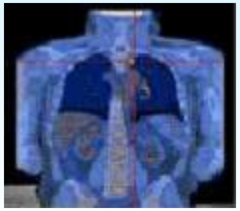
Questions?

Appendix

GEHC Portfolio

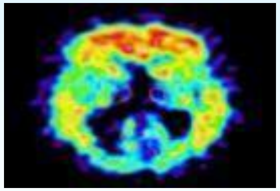
Broad Based Diagnostics

Diagnostic Imaging



- CT, PET/CT
- MR

Medical Diagnostics



- Contrast agents
- Molecular diagnostics

Clinical Systems

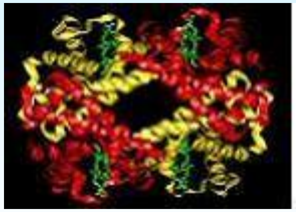
- Ultrasound
- Critical care systems

Information Technology & Services

- Electronic medical records
- Revenue cycle

- Performance solutions
- Multi-vendor services

Life Sciences



- Discovery systems
- Protein separations

Examples of Tailoring

What to look for in customizing

Attribute	Measure	Example Customization
Technical Risk	Hazard Analysis	Rigor of technical reviews Level of functional excellence rigor
Team Experience	Subjective… Local senior engineers	Rigor of technical reviews Level of signoff (level of functional excellence rigor)
Globally Distributed Team	# of sites Max time dif	Rigor and detail in the program communication plan; level of review
Team Size	# of Engineers	Rigor and detail in the program communication plan; level of review
Product Maturity	New technology vs. cost out	Level of ease of use/’quality’ required Documentation rigor Senior engineer allocation

Example of Tailoring the Eng. Process

CT Scanner

~ 1000 System Requirements

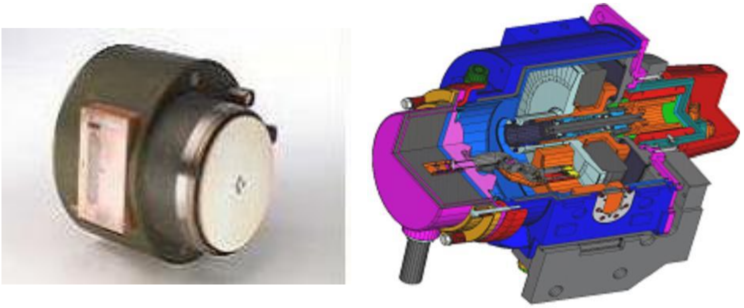
~30 options

~30 process critical parameters

Response

High Traceability, using DOORs and RQM

XRay Tube



~30 Subsystem Requirements

~15 **very** process critical parameters

Response

Design for Six Sigma/Reliability, using Minitab and Reliasoft

Modeling Approaches

Computed Tomography

Moderately complex system with complex behavior

- ~5,000 parts
- ~5M lines of code
- Triple nested control loops
  - Axial, Cradle, mA/kV

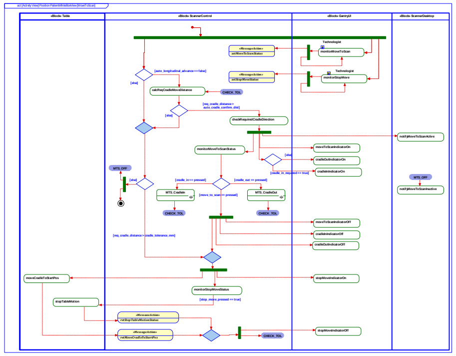
First GEHC project using MBSE

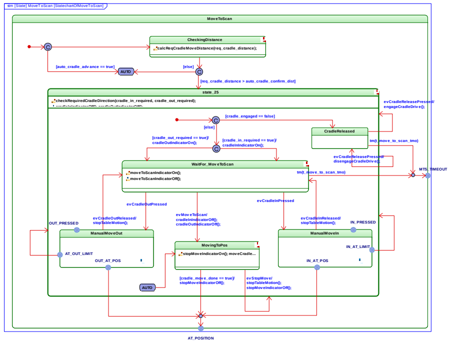
- <10 engineers using the tool
- 3 year process
- Principal engineer leads the effort
- Used several consultants to review and optimize the process
- Focused on a few applications and a few critical components

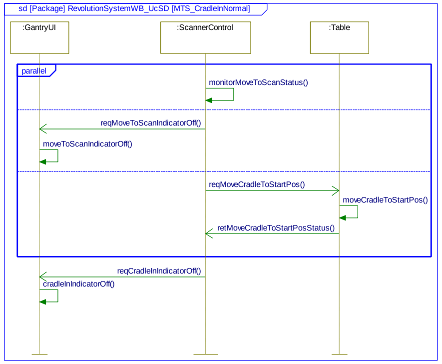
Computed Tomography

MBSE techniques are used to perform behavioral analysis of key system features and functions.

- discover and verify system requirements
- identify and detail subsystem functions and interfaces
- seed FMEA analysis
- develop system test scenarios

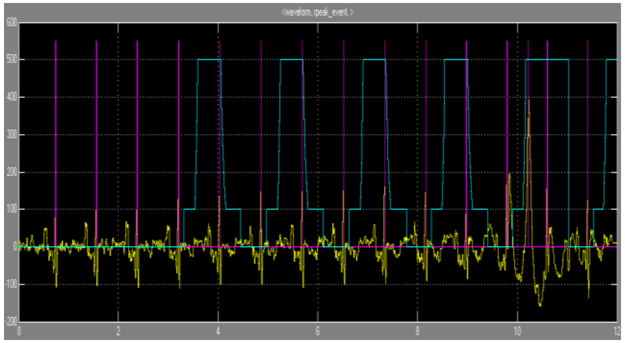






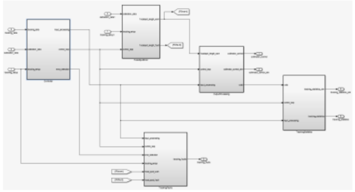
Computed Tomography

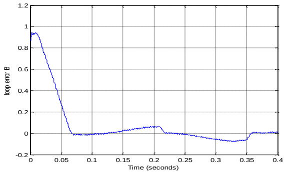
CT Systems is deploying several model based designs directly to software and hardware.



Cardiac Acquisition and Emission Modulation

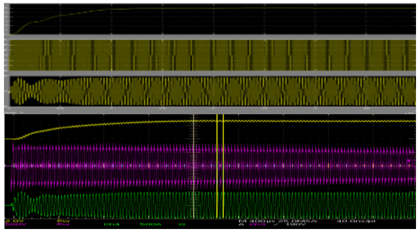
- Feature analysis and simulation performed in SIMULINK
- Auto-generating C++ code





Active X-Ray Beam Position Control

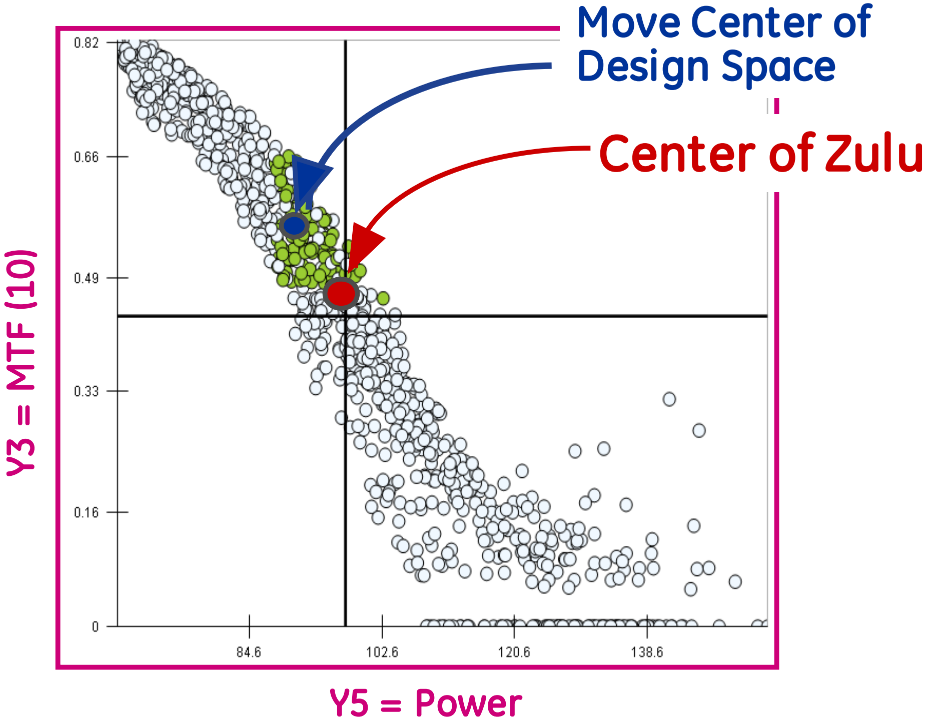
- Control/Plant models designed/analyzed in SIMULINK.
- Auto-generating C++ code

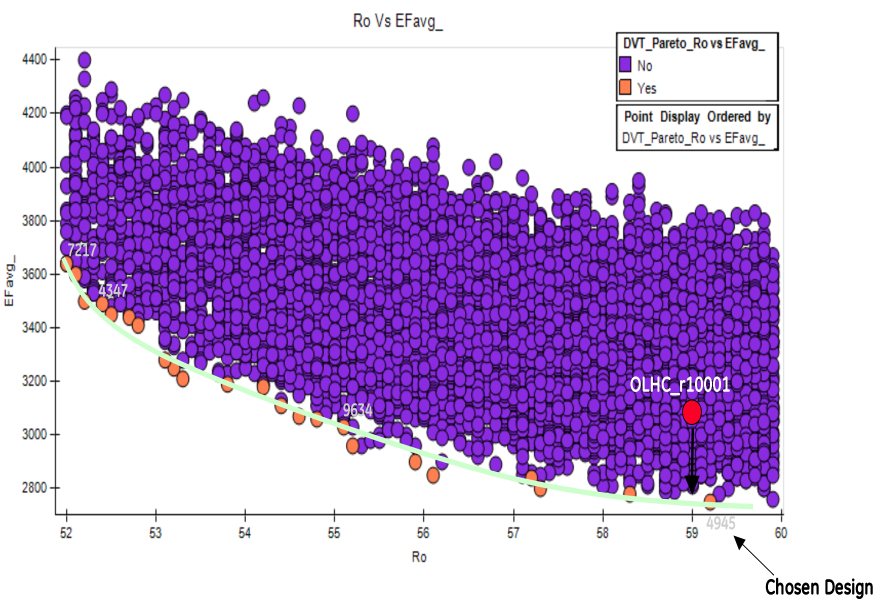


X-Ray Generator KV Control Loop

- Control/Plant models designed/analyzed in SIMULINK.
- Auto-generated vhdl

Robust Design using “Space Filling” computer experiments





Robustness: move design to center of feasible range

Optimality: move design along Pareto Optimal Edge to maximize a third Figure of Merit

Needs: Efficient Simulation, Automated Parameterization, ***Great*** Visualization tools