INCOSE Healthcare Working Group

5th Annual Systems Engineering in Healthcare Conference

May 1-2, 2019
Minneapolis, MN

Transitioning to MBSE
for Medical Device Development

Geoff Cox

Lead Systems Engineer

Stryker Robotics

Presenter Background

- Technical since 1985
- Engineer since 1989
- Systems Engineer by trade since 1995
- Systems Engineer by title since 2003 (Aerospace & Defense)
- Systems Engineer in Medical Devices since 2017
- Passed test for CSEP – waiting for references to respond
- SysML certified to Level 2 (of 4)

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Agenda

- Scope
- Bounding the Problem
- Specific Challenges
- C-Suite Buy In
- Creating The Plan
- Managing Expectations / Controlling Quality
- Arranging the Model
- Creating Infrastructure
- Integration
- Rollout
- Summary
- Q&A

Scope

In Scope

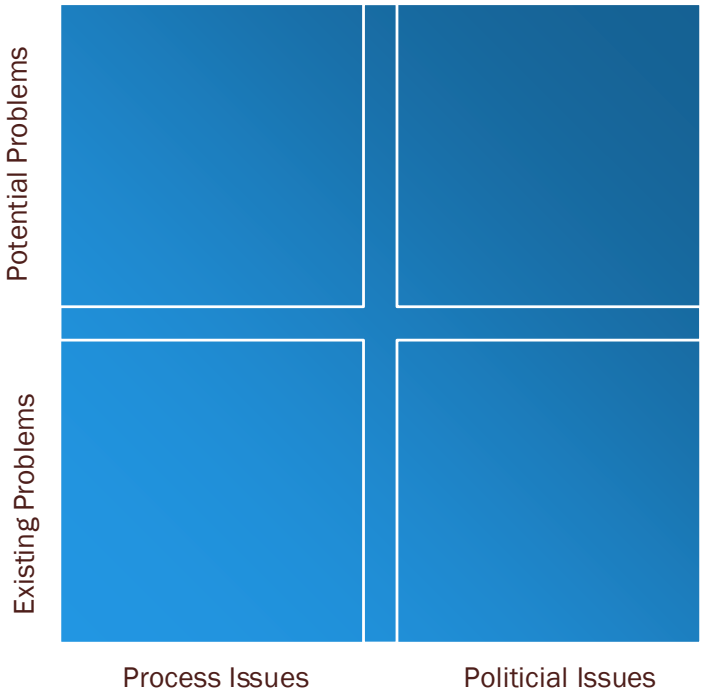
- MBSE
  - OOSEM (*Section 9.4)
  - SysML
- Tool Choice
- Planning
- Political Issues

Out of Scope

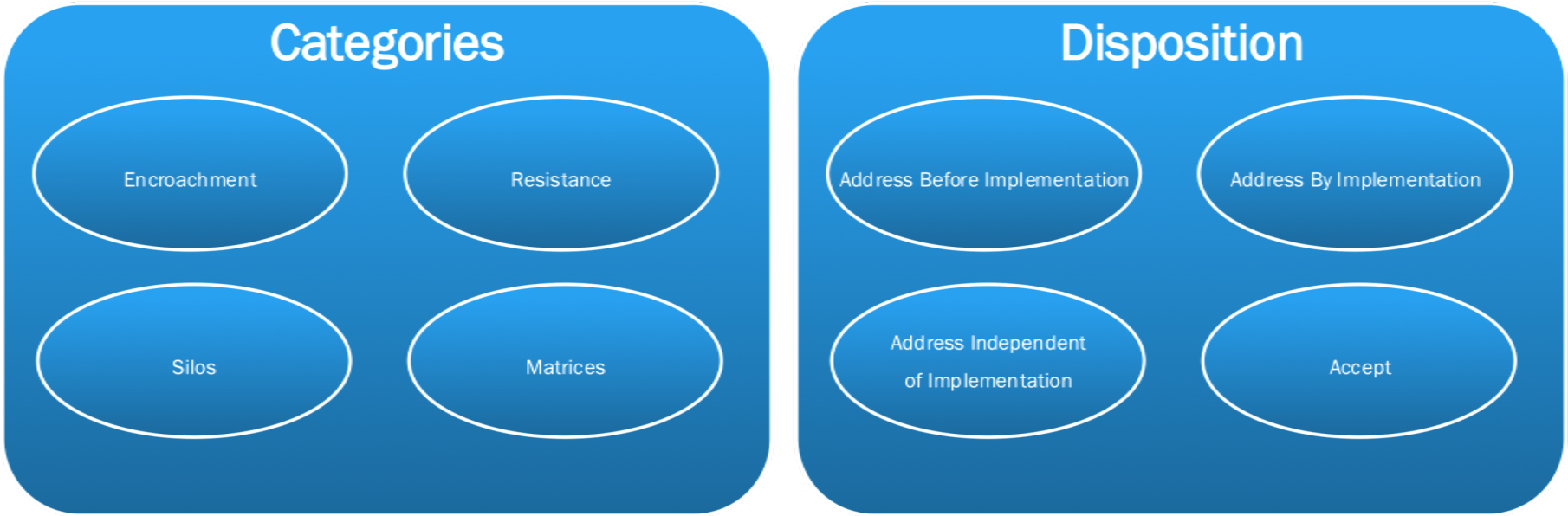
- Function Based SE (*9.3)
- Other modeling languages
- Discussion of specific tools
- Personnel Issues

* INCOSE Systems Engineering Handbook – Fourth Edition

Bounding the Problem Space



Existing Problems



Specific Challenges

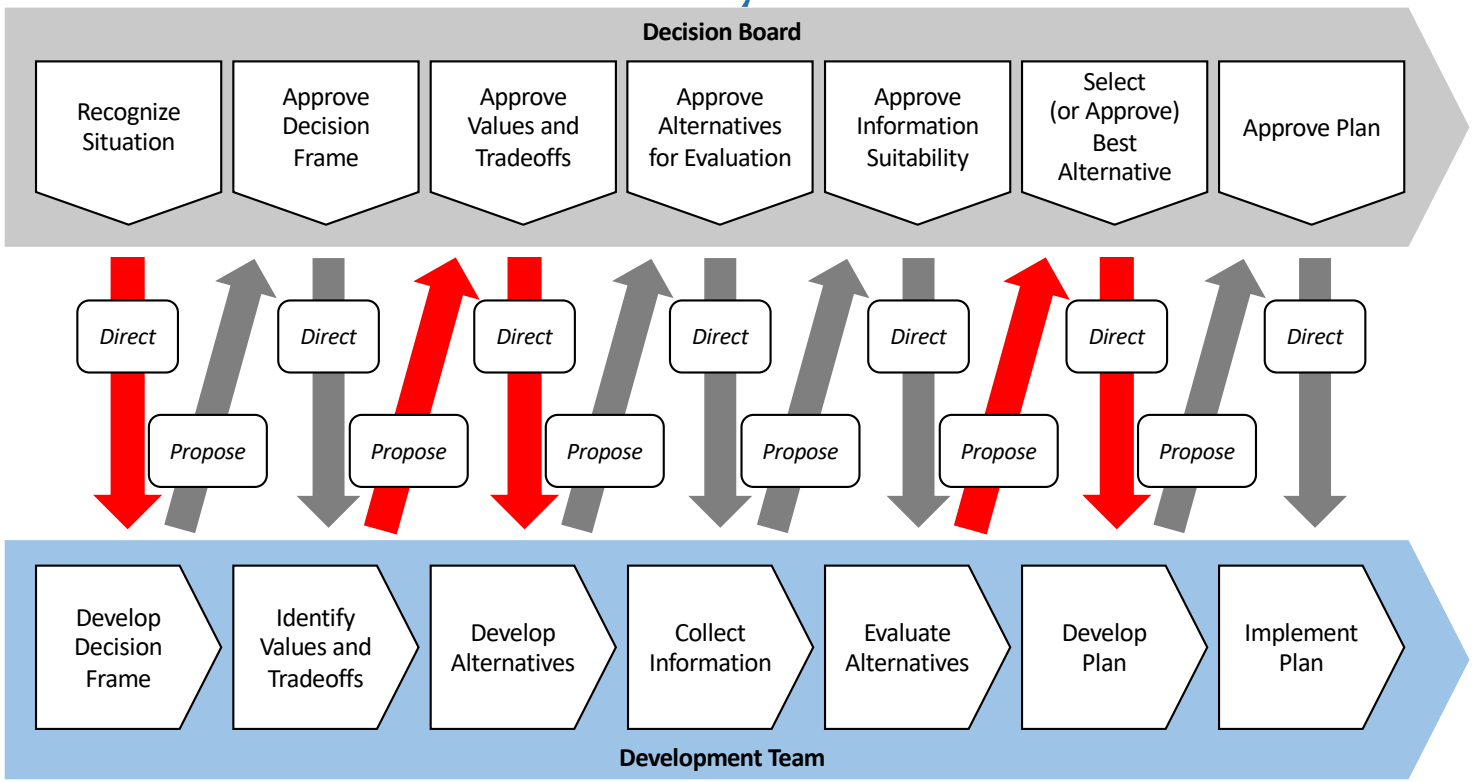
Process/Technical

- SE relatively new to the Medical Device Industry
- Level of Embedment
  - Multiple Levels
  - Multiple SW Methods
- Version Control

Political

- FDA / Other Regulatory Agencies
- QA-centric Companies/Processes
- Sales-centric Companies/Processes

C-Suite Buy-In

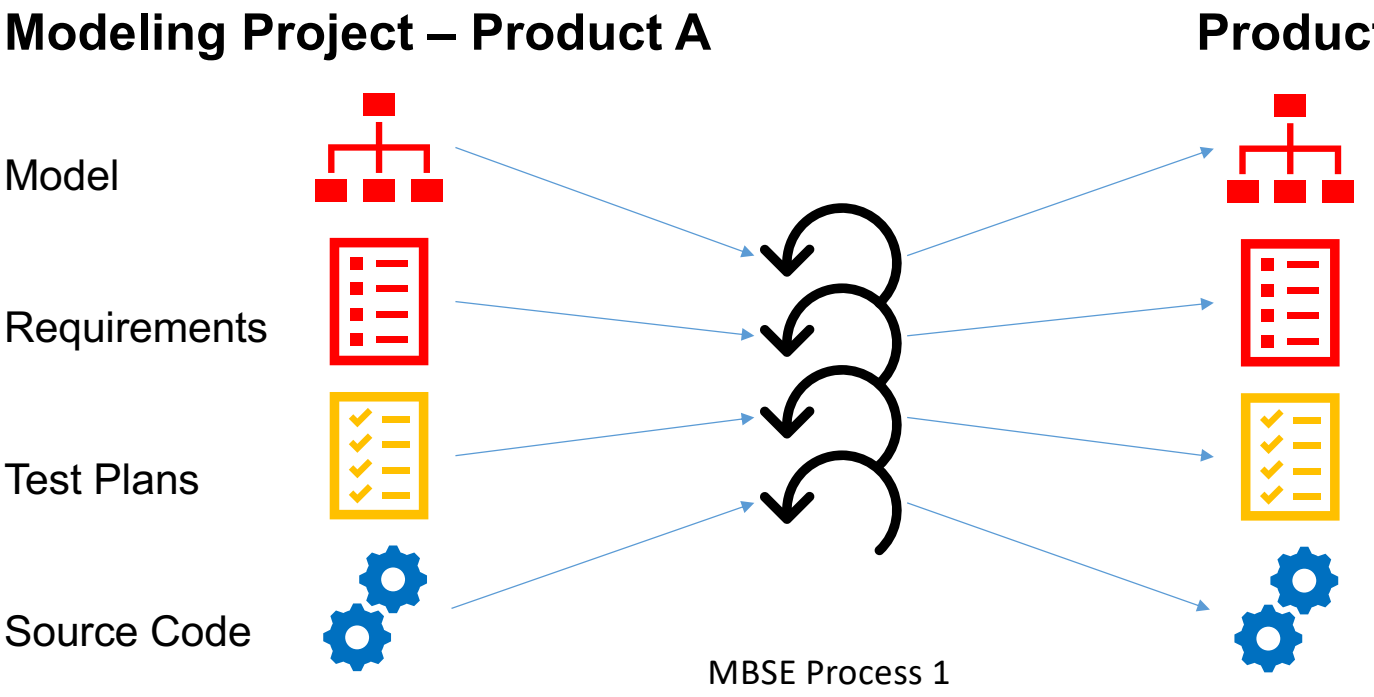


Decision Quality: Value Creation from Better Business Decisions – Spetzler et al

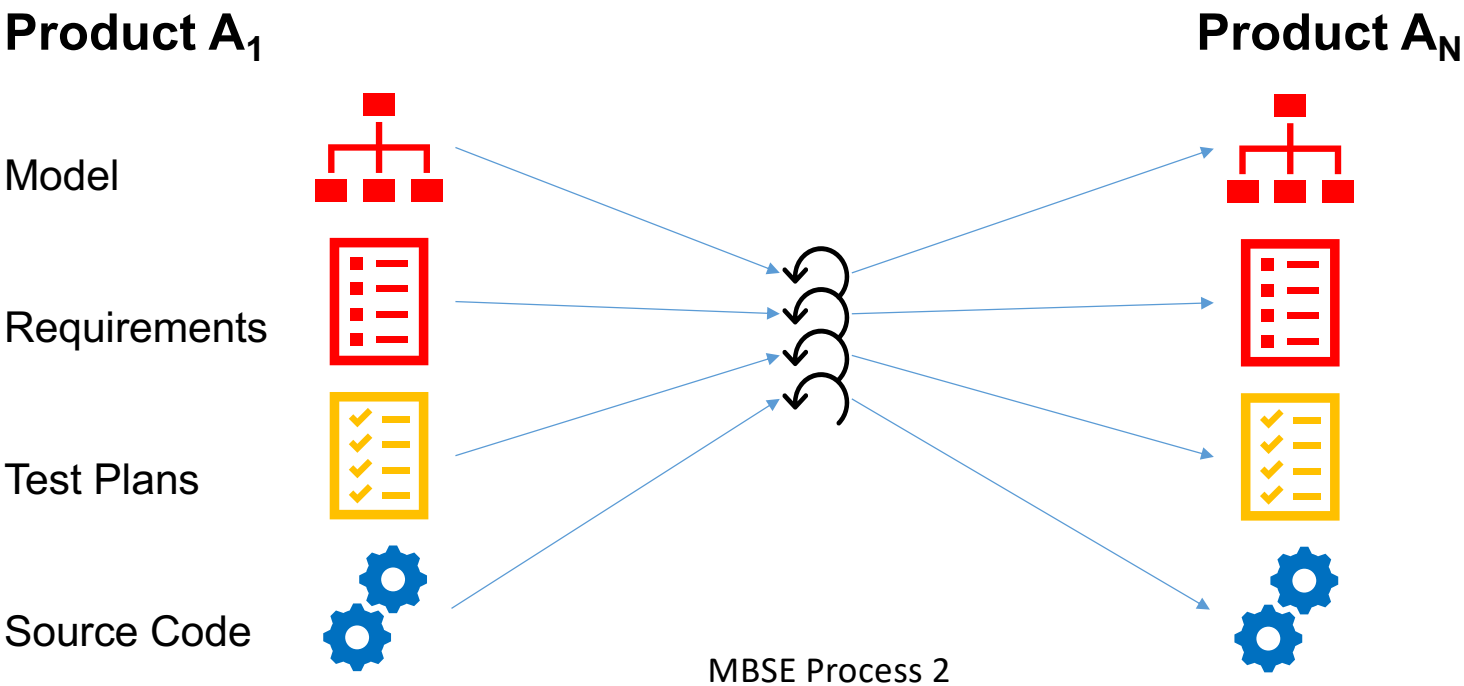
Creating the Plan

- Start with ONE project/product
- Have a SEPARATE project (with a PM) for:
  - Creation of original model
  - Creation of requirements
  - Establishing MBSE process
- Process should say what, not how
- Consider using/establishing PE role as well
- Incorporate PLE into the plan

Creating the Plan – Original Effort



Creating the Plan – Future Development



Managing Expectations / Controlling Quality

Process/Technical

- Library Use
  - Understand Elements of Definition/Usage
  - Don't Overdo It
- Train Method/Language/Tool
- Recruit from other industries?

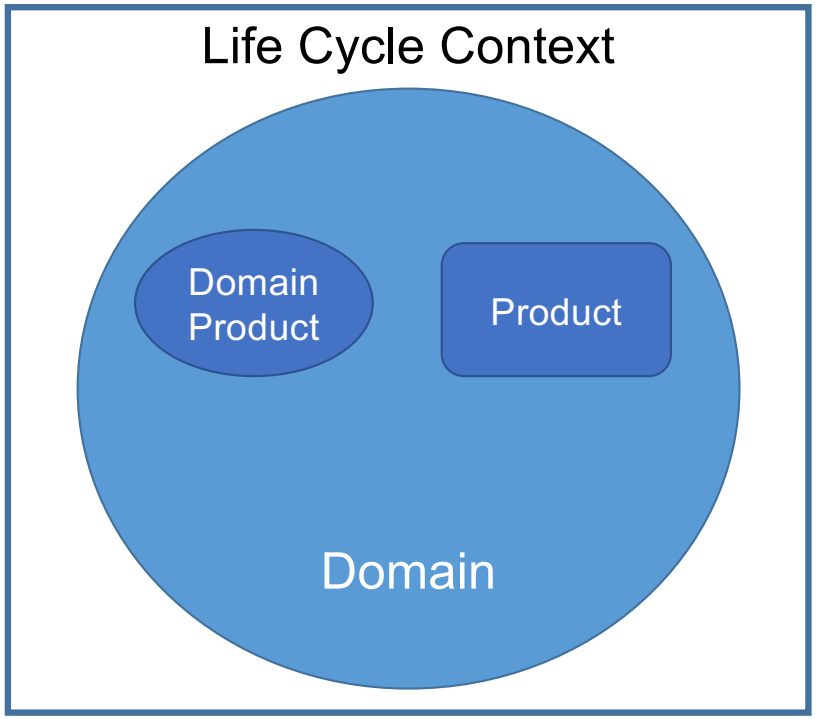
Political

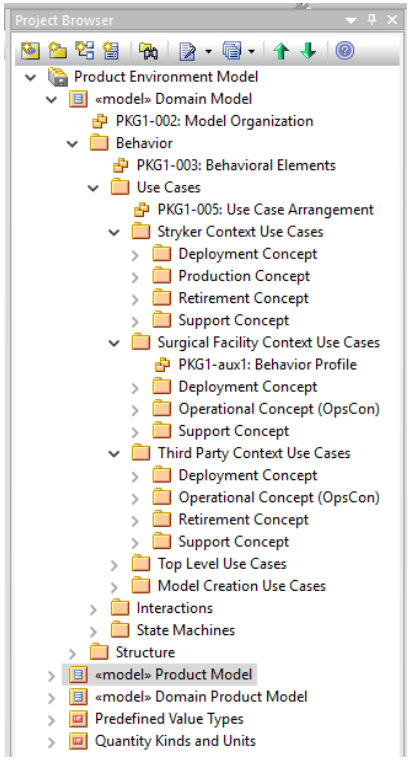
- Intelligent Rollout
- Early Wins
- In-Person Meetings

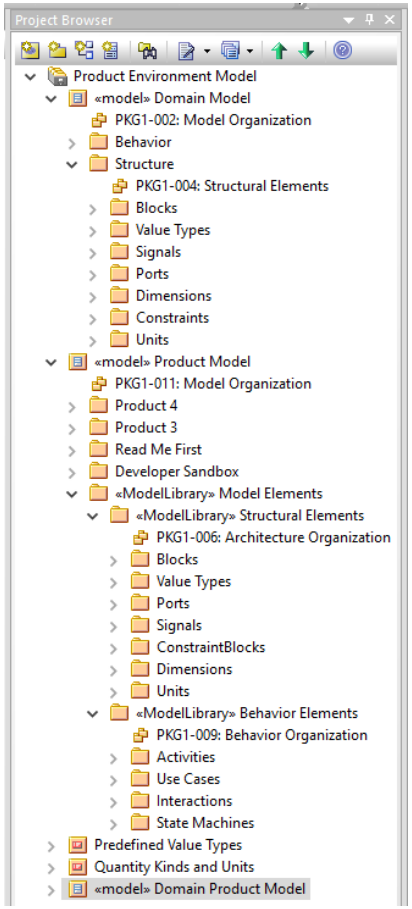
Managing Expectations / Controlling Quality

Right-Size the Team

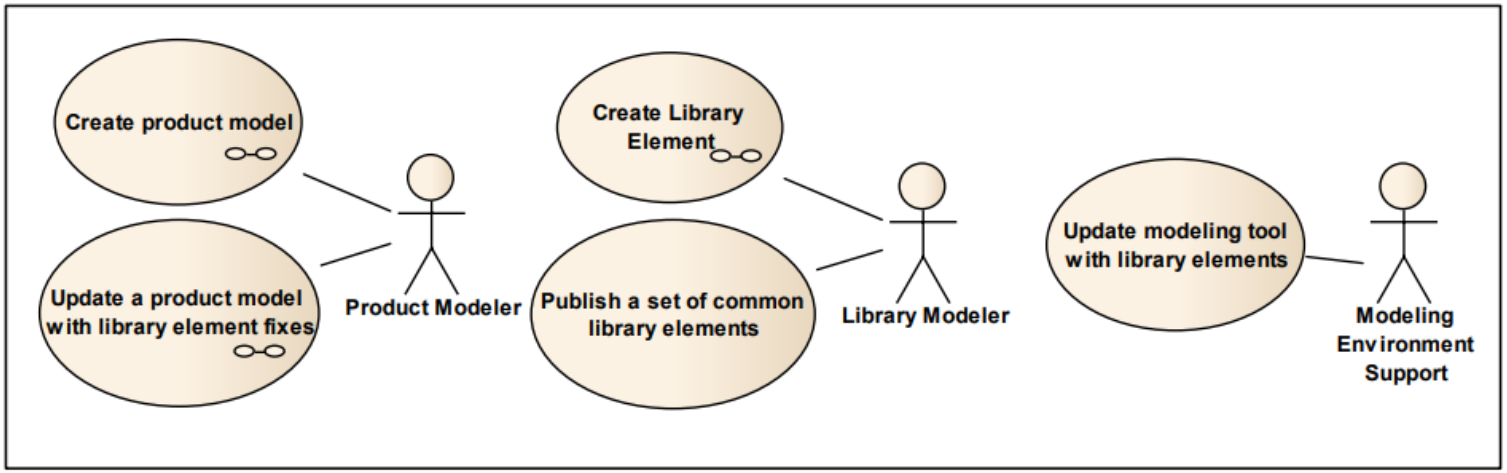
Arranging the Model: An Example







Using Libraries



* Emerging Usability Patterns in the Application of Modeling Libraries – Bjorn Cole, JPL et al

Examples

* Pause for an excursion into an example model, if necessary

Creating the Infrastructure

Model		Requirements ->			
Diagram Number	Diagram Name	ABC CR	EFG CR	XYZ CR	SR
		xxxxxx	xxxxxx	xxxxxx	
		xxxxxx	xxxxxx	xxxxxx	
		xxxxxx	xxxxxx	xxxxxx	
		xxxxxx	xxxxxx	xxxxxx	
		xxxxxx	xxxxxx	xxxxxx	
STM1-001	Surgery	xxxxxx	xxxxxx	xxxxxx	xxxxxx
STM1-002	End of Surgery	xxxxxx	xxxxxx	xxxxxx	xxxxxx
STM1-003	ABC Surgery	xxxxxx			xxxxxx
STM1-004	EFG Surgery		xxxxxx		xxxxxx
STM1-005	Degromificator XYZ Surgery			xxxxxx	xxxxxx
STM1-006	Unobtanium XYZ Surgery			xxxxxx	xxxxxx
STM1-007	Power/Login States	xxxxxx	xxxxxx	xxxxxx	xxxxxx
STM1-008	Intraop Warnings	xxxxxx	xxxxxx	xxxxxx	xxxxxx
STM1-009	Intraop Planning	xxxxxx	xxxxxx	xxxxxx	xxxxxx

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Creating the Infrastructure

Diagram Number	Diagram Name	Model	% Complete	Last Modified	Assigned to	References	Found In	Importance	Comments
ACT3-001	xxxxxxxxxxxxxxxxxxx	Product	10				ACT3-013 ACT3-018	Primary	Needs to be redone, but some (a lot?) of the work can be copied to the new diagram.
ACT3-002	xxxxxxxxxxxxxxxxxxx	Product	10				ACT3-012	Primary	Needs to be redone, but some (a lot?) of the work can be copied to the new diagram.
ACT3-003	xxxxxxxxxxxxxxxxxxx	Product	25				ACT2-012	Secondary	
ACT3-004	xxxxxxxxxxxxxxxxxxx	Product	25			ACT2-005	ACT2-012	Secondary	This is not the primary diagram for the Activity (See ACT3-003).
ACT3-005	xxxxxxxxxxxxxxxxxxx	Product	25			ACT2-005	ACT2-012	Secondary	This is not the primary diagram for the Activity (See ACT3-003).
ACT3-006	xxxxxxxxxxxxxxxxxxx	Product	25			ACT2-005	ACT2-012	Secondary	This is not the primary diagram for the Activity (See ACT3-003).
ACT3-007	xxxxxxxxxxxxxxxxxxx	Product	25				ACT2-012	Secondary	This is not the primary diagram for the Activity (See ACT3-003).
ACT3-008	xxxxxxxxxxxxxxxxxxx	Product	25			ACT2-005	ACT2-012	Secondary	This is not the primary diagram for the Activity (See ACT3-003).
ACT3-009	xxxxxxxxxxxxxxxxxxx	Product	100				ACT2-019 ACT2-020 ACT2-021	Primary	Might be deleted in favor of ACT4-004
ACT3-010	xxxxxxxxxxxxxxxxxxx	Product	100				ACT2-019	Secondary	
ACT3-011	xxxxxxxxxxxxxxxxxxx	Product	100					Low	
ACT3-012	xxxxxxxxxxxxxxxxxxx	Product	100			ACT3-002	ACT2-003 ACT2-019 ACT2-020 ACT2-021	Primary	
ACT3-013	xxxxxxxxxxxxxxxxxxx	Product	100			ACT3-001	ACT2-003 ACT2-019 ACT2-020 ACT2-021	Primary	
ACT3-014	xxxxxxxxxxxxxxxxxxx	Product	100				ACT2-020	Primary	
ACT3-015	xxxxxxxxxxxxxxxxxxx	Product	100				ACT2-021	Primary	
ACT3-016	xxxxxxxxxxxxxxxxxxx	Product	0					Secondary	For use in ACT2-030, ACT2-031, and ACT2-032.
ACT3-017	xxxxxxxxxxxxxxxxxxx	Product	0					Secondary	For use in ACT2-030, ACT2-031, and ACT2-032.
ACT3-018	xxxxxxxxxxxxxxxxxxx	Product 3	100			ACT3-001 ACT3-019	ACT1-007	Primary	
ACT3-019	xxxxxxxxxxxxxxxxxxx	Product	50				ACT3-018	Primary	
ACT3-020	xxxxxxxxxxxxxxxxxxx	Product 3	100			ACT3-021 ACT3-022 ACT2-026	ACT1-006	Primary	

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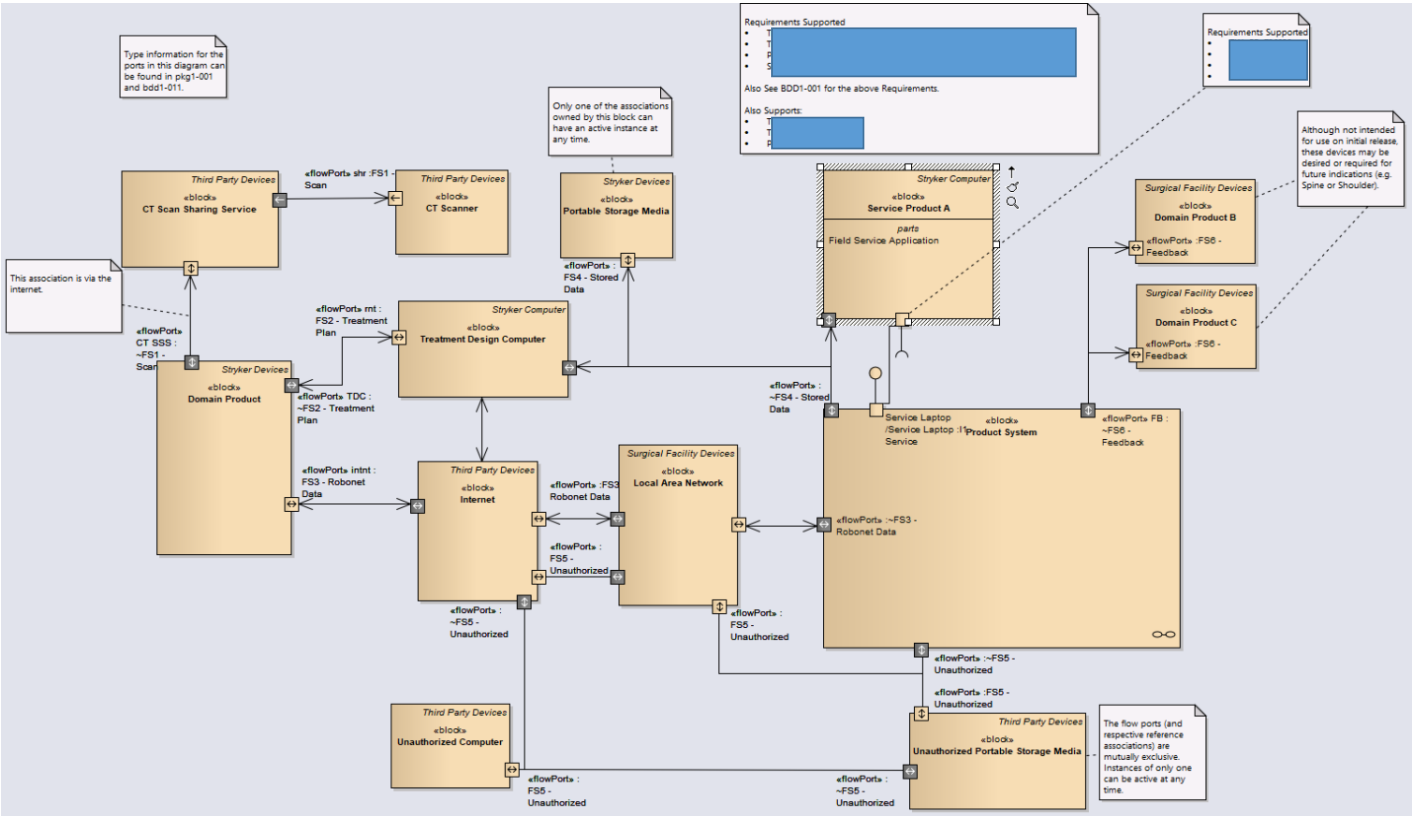
Integration



Rollout

- To each internal customer as needed
  - Systems Engineers and Department Heads or Designees: The Model
    - Show package structure every time you open a diagram until they ask you to refrain from doing so
    - Reviews are not meetings: Meetings capture review findings
    - Keep the Model Elements and Diagrams Simple
  - All Others: Diagrams
    - SysML is intuitive, but they will need help
    - Reviews may be longer
    - Keep Diagrams Simple
- Publish as PDFs (officially)

Summary

- Determine the problem(s) you are trying to solve
  - And those you are not
- Plan, and include PLE in the plan
  - Begin with the end in mind
- Know the method/language/tool
  - In that order

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Q&A

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Thank you for attending!

Share your experiences at #HWGSEC