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INCOSE
International Council on Systems Engineering

Agile Health Care Systems and Comfort Zones: Are We Thinking Broadly Enough?

INCOSE Agile Health Care Systems Conference
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 V1.2.4

Abstract

- The most widely-familiar paradigm associated with “agile” approaches refers to (1) the development process, for systems or sub-systems that are (2) software-oriented.
- INCOSE in general, and the INCOSE Agile Health Care Systems Conference in particular, have already examined the notion that agility in development is not a practice limited to software technology.
- In this talk, we will pursue this further, looking beyond system development to the rest of the system life cycle, and how agility applies there as well, in the context of the health care domain. During the 2016 Agile Heath Care Systems Conference, participants in a break-out session identified a set of “bigger picture” targets for agility in the overall Health Care domain, which we’ll also look into further in this session.
- If your agility comfort zone is limited to daily scrums for software development, this session is meant to stimulate discomfort and expanded horizons.

Contents

- Current Agility Landscape
- The INCOSE ASELCM Pattern Discovery Project
- The INCOSE Model-Based Transformation
- The ASME Model VVUQ Project
- Agility, Information Debt, Learning, Models
- Vision for a Collaboration
- Is Your Agility Agile? -- Ideas for Action
- Discussion

- References

State of Practice versus State of the Art

This INCOSE Conference includes great reports on agile implementation, of which those involved can be justifiably proud.

(1) One purpose INCOSE serves is to advance the state of practice:

- by *propagating best practices* to more performers, lifting the overall practice by communicating current good practice.

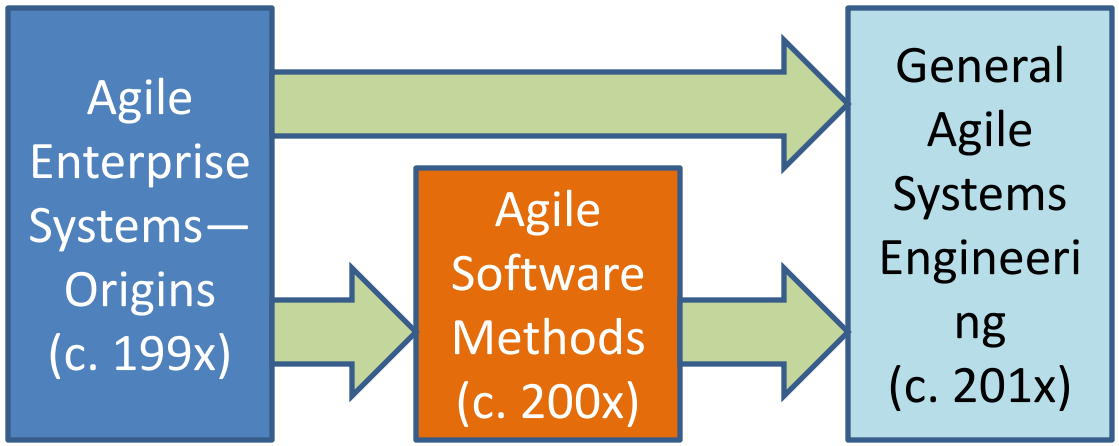
(2) In addition, INCOSE also serves by examining the advancing front of the state of the art:

- by asking what advances are possible, needed, or implied, *beyond well-known practice*.

This session is about (2)—including convergence of some related streams.

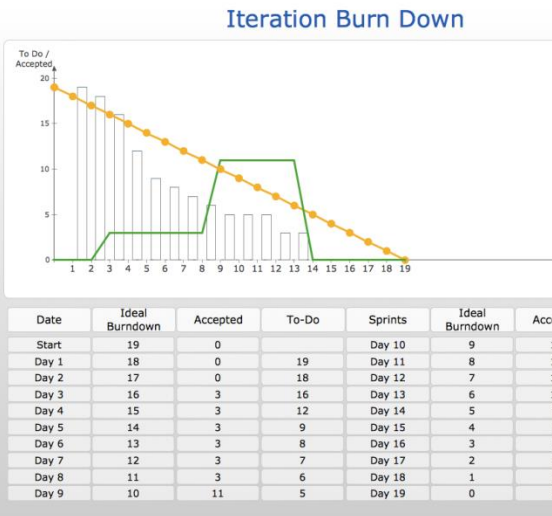
What are Agile Systems? Why do they matter?

Longer history than just Agile Software Development Methods :



- For history and background, see Dove and LaBarge, 2014
- Agile software methods, by far better known, are related.
- General Agile Systems Engineering is the related broader subject of the INCOSE ASELCM Project.
- **Problem space**: *Challenges of uncertainty and rates of change in environment, stakeholders, competition, technologies, capacities, capabilities. Not just "going faster".*

Current Agility Landscape



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Start	19	0		Day 10	9	
Day 1	18	0	19	Day 11	8	
Day 2	17	0	18	Day 12	7	
Day 3	16	3	16	Day 13	6	
Day 4	15	3	12	Day 14	5	
Day 5	14	3	9	Day 15	4	
Day 6	13	3	8	Day 16	3	
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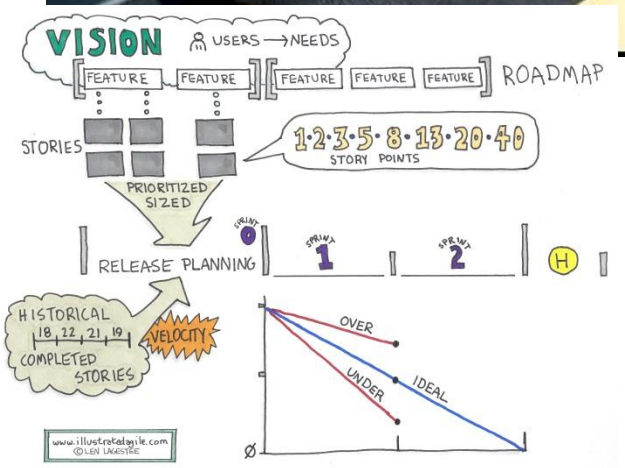
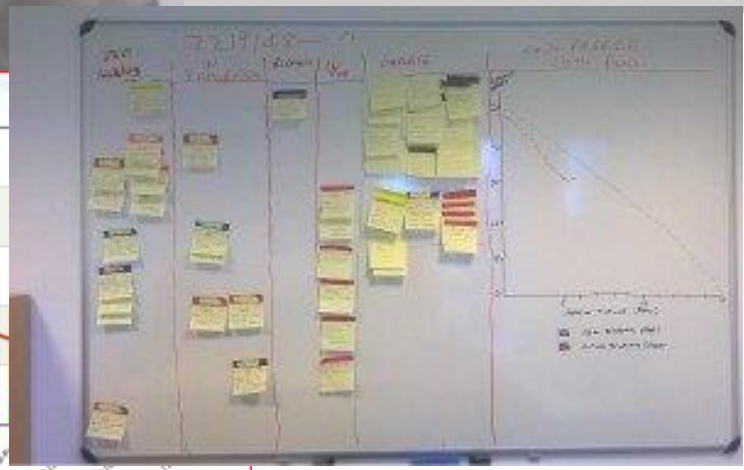
Day 8	11	3	6	Day 18	1	
Day 9	10	11	5	Day 19	0	





Current Agility Landscape

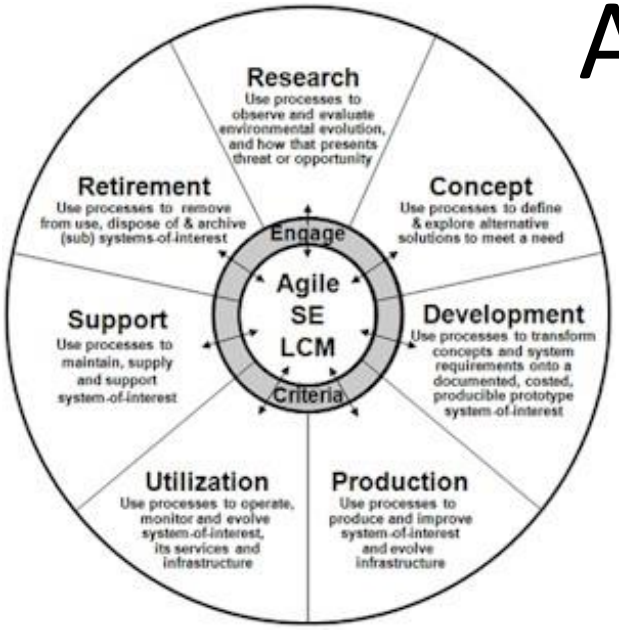
- Great interest in Agile Methods:
  - Or you would not be at this conference
- Best known: Agile methods for software development:
  - But it actually sprang from agile methods in production, c. 1991
  - Growing interest in use for development of general systems
  - Most sessions at this conference reflect that interest, experience
  - We might say that agile methods are defined, practiced, and at the "diffusion" stage, propagating across industry.
- But, notice that all the above are especially thought of as concerned with agility in development
- What about the rest of the system life cycle? . . . .

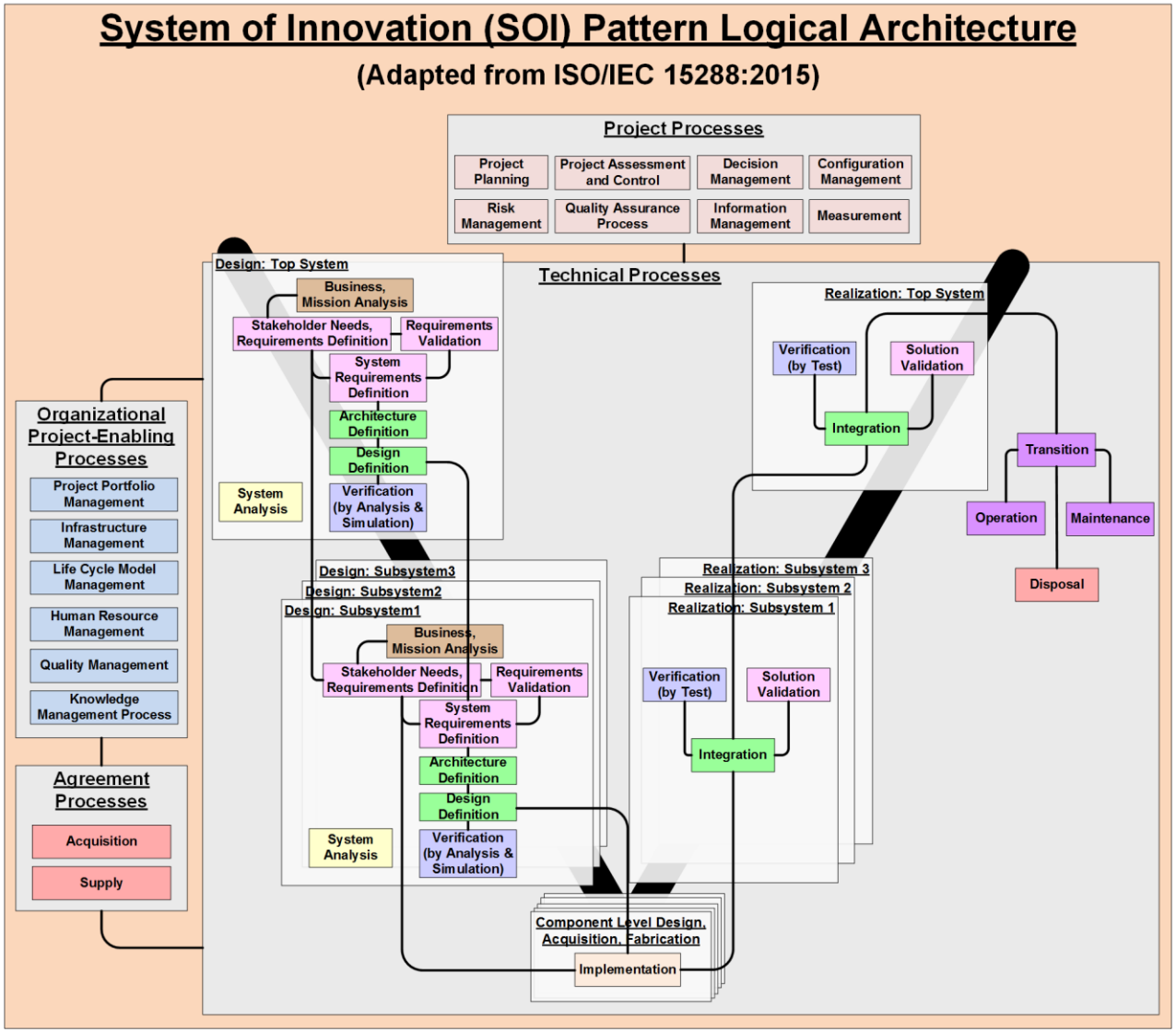
Current Agility Landscape

- The name of this conference reflects a wide belief that agile methods are about development.
- If we think of agile methods by "how to do them", then they do seem to be rooted in development.
- But, if we think of agile methods by "why we do them", we see they may apply to other life cycle stages.
- Example: Agility of the Health Care Delivery System; at this conference, a session on the Virtual ER.

From Schindel and Dove, 2017

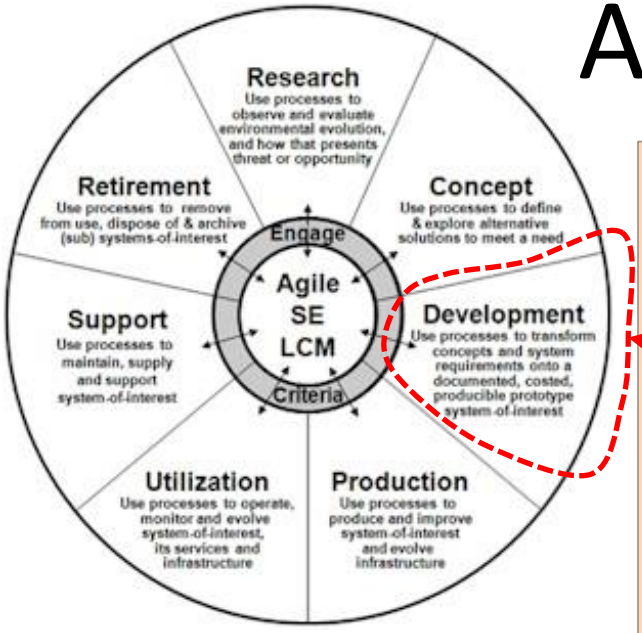
Agility Across the Life Cycle

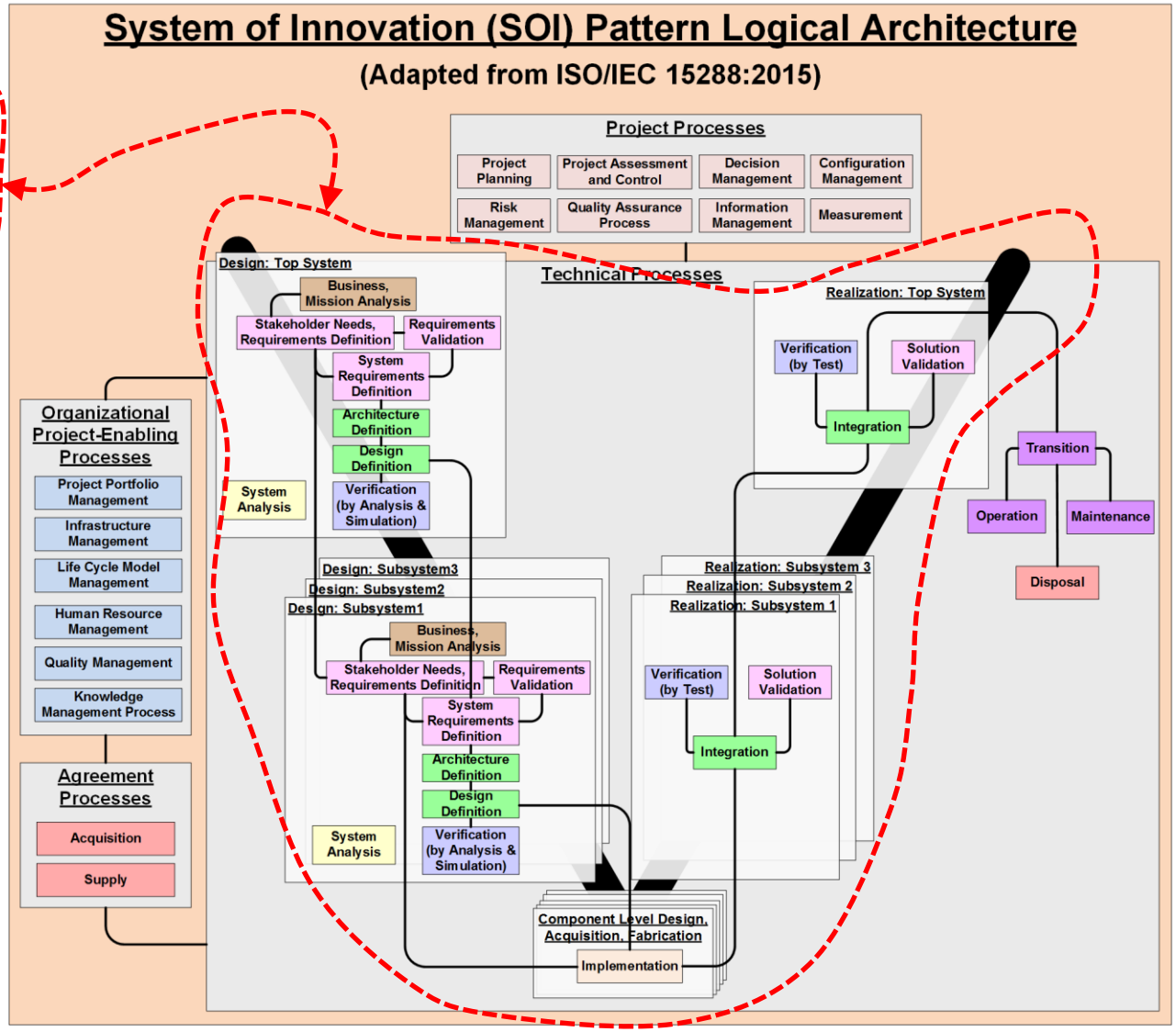




From Schindel and Dove, 2017

Agility Across the Life Cycle





Current Agility Landscape: Additional Evolution

- Perceived conflicts between agile development versus traditional acquisition contracting and regulation are slowly resolving.
- Fail Fast Literature and Recover Early methods, literature.
- The Lean Business Startup and Minimum Viable Product (MVP)
- AIAA Aviation 2017 CASE session in June: Agile and Incremental Development of Complex Aero Systems

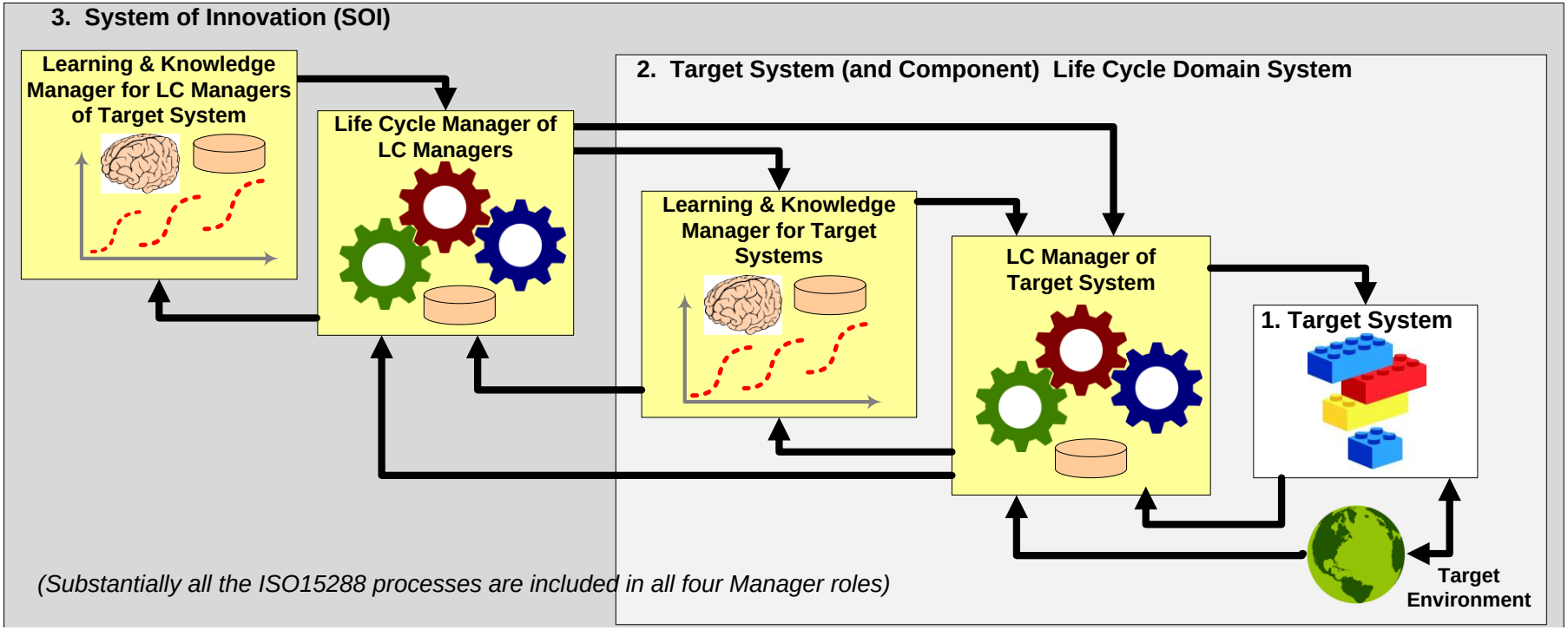
Converging Streams: Three Initiatives in Engineering Professional Societies

1. The INCOSE ASELCM Pattern Discovery Project
2. The INCOSE Model-Based Transformation
3. The ASME Model VVUQ Project

1. The INCOSE Agile Systems Engineering Life Cycle Management (ASELCM) Pattern Discovery Project

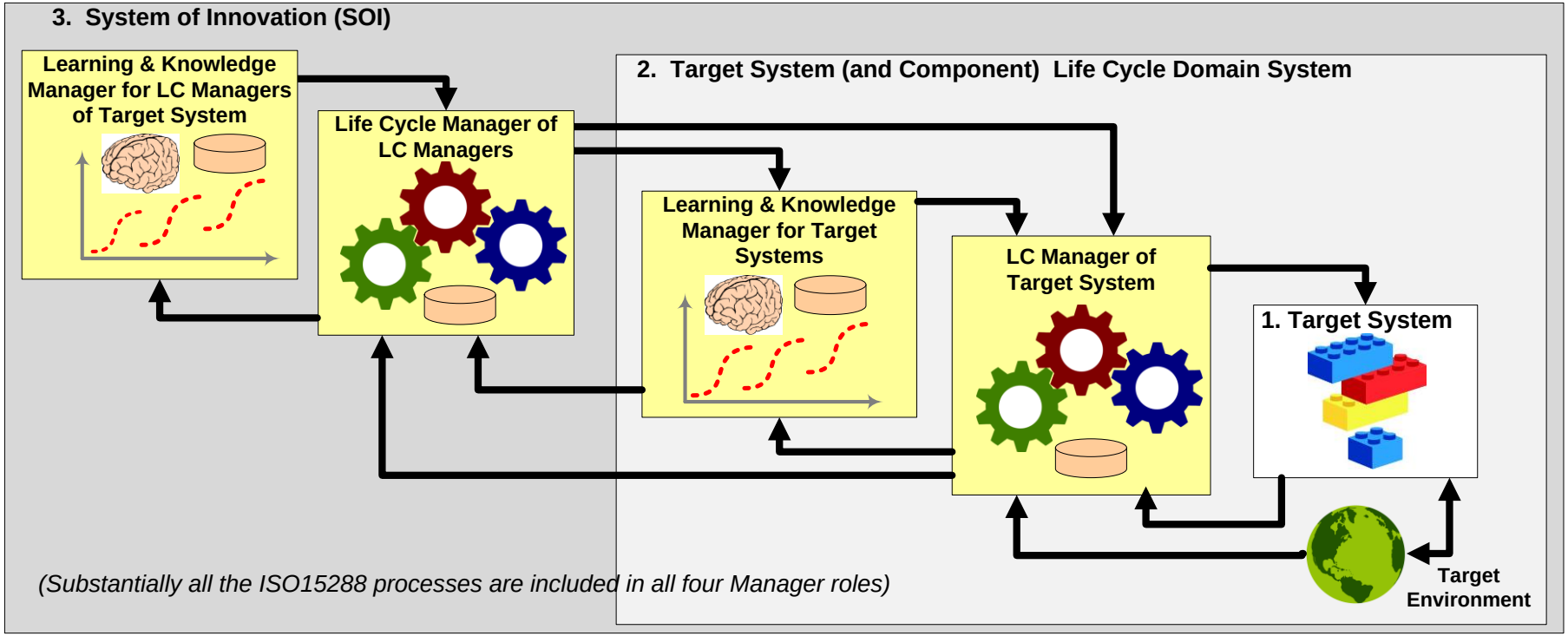
- The INCOSE parent society is sponsoring the Agile Systems Engineering Life Cycle Model (ASELCM) Discovery Project, based on a series of workshop clinics being held at host example discovery sites:
  - INCOSE Agile SE and MBSE Patterns Working Groups
- This project, underway, will provide INCOSE inputs to a future version of ISO 15288, to improve explicit understanding of principles and practices of agility as applicable to systems engineering across different domains.
- The Agile SE Life Cycle Management Pattern, an S*Pattern, is one of the deliverables of this project.

1. The INCOSE ASELCM Pattern Discovery Project: ASELCM Pattern Iconic View



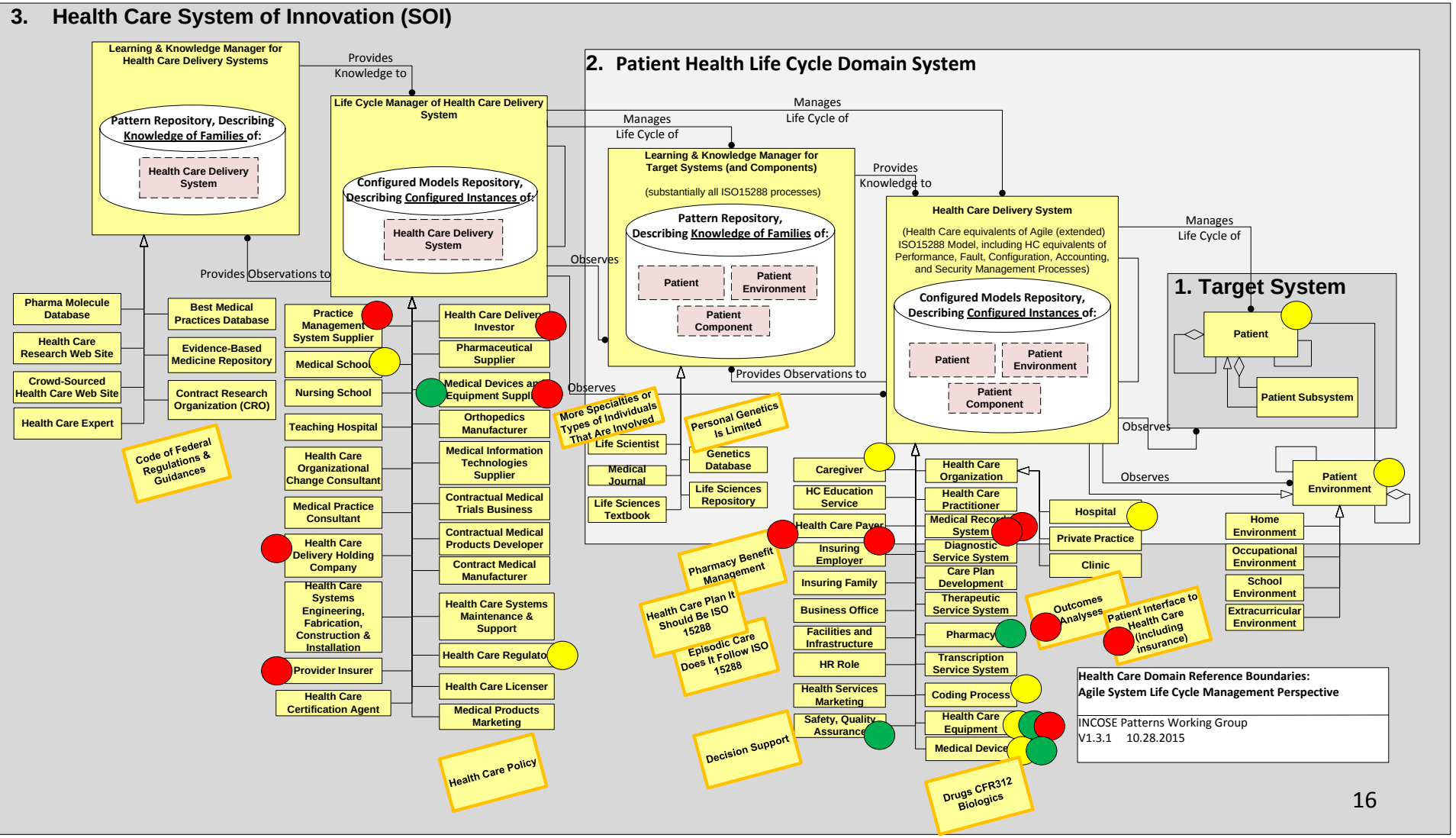
- System 1: Target system of interest, to be engineered or improved.
- System 2: The environment of (interacting with) S1, including all the life cycle management systems of S1, including learning about S1.
- System 3: The life cycle management systems for S2, including learning about S2.

1. The INCOSE ASELCM Pattern Discovery Project: ASELCM Pattern Iconic View

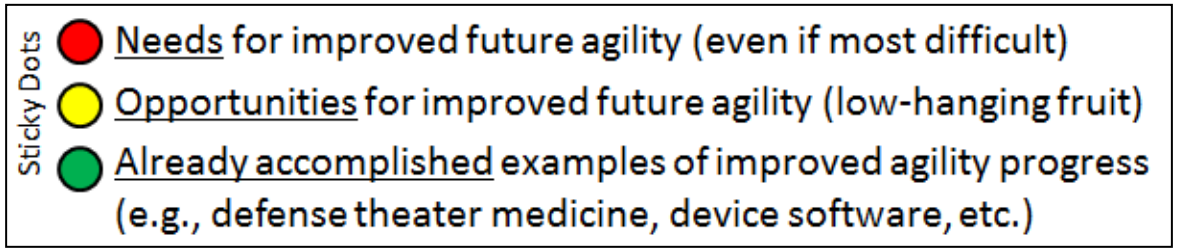


- System 3 asks us: Is your (System 2) agility agile? Is there any reason to consider why it might need to be?

ASELCM Systems of Interest, Health Care Domain: Output from INCOSE 2016 Agile Health Care Systems Conference break out group



Systems of Interest: Output from INCOSE 2016 Agile Health Care Systems Conference break out group



Red:

- Patient Interface to Health Care (Including Insurance)
- Medical Devices and Equipment Supplier
- Health Care Delivery Investor
- Health Care Payer
- Provider Insurer
- Insuring Employer
- Practice Management System Supplier
- Health Care Delivery Holding Company
- Medical Record System
- Health Care Equipment
- Outcomes Analysis

Yellow:

- Caregiver
- Medical School
- Hospital
- Coding Process
- Health Care Equipment
- Medical Devices

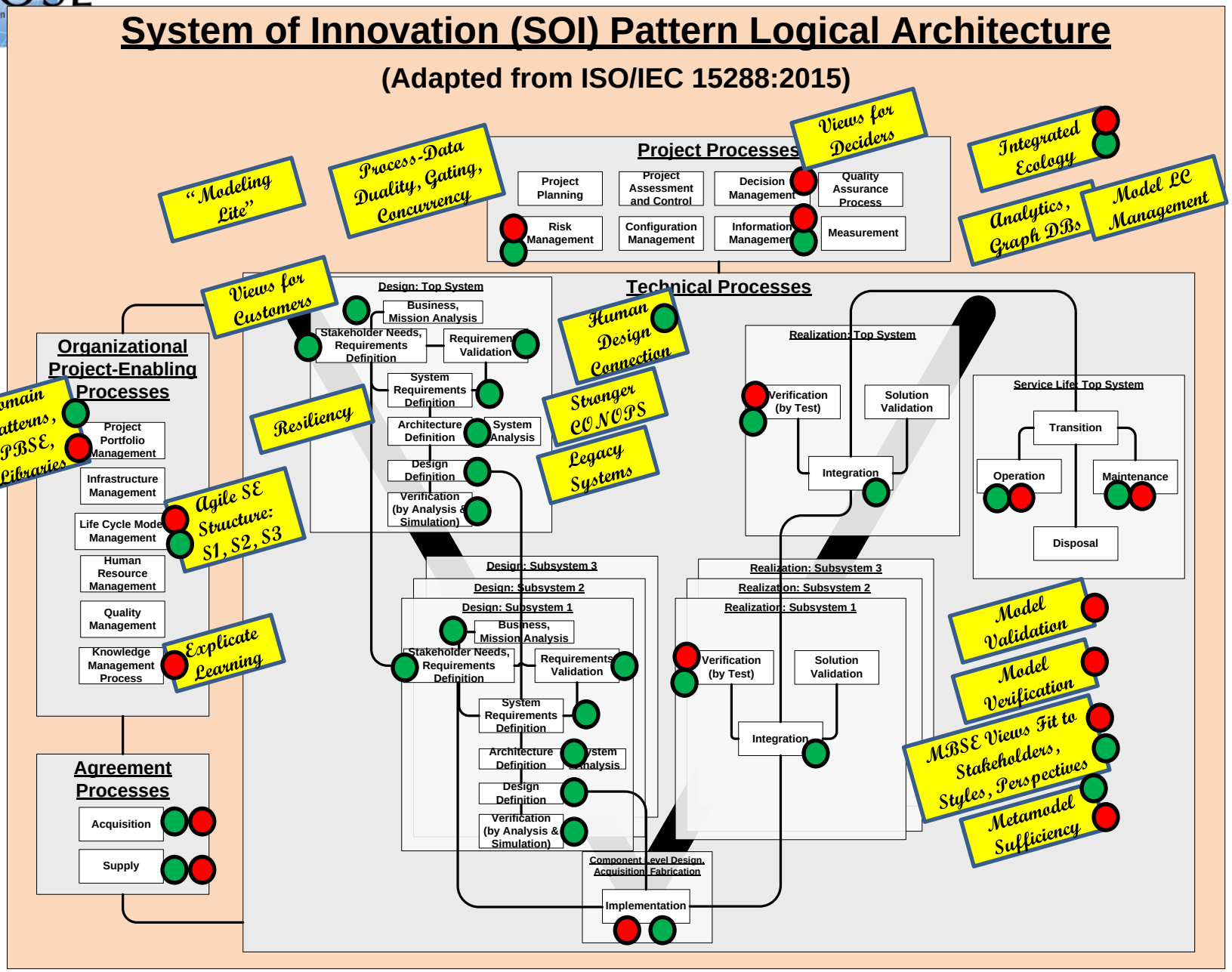
Green:

- Medical Devices and Equipment Supplier
- Safety, Quality Assurance
- Pharmacy
- Health Care Equipment
- Medical Devices

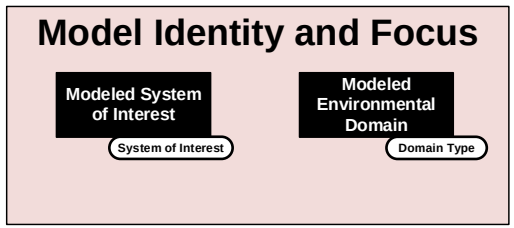
2. The INCOSE Model-Based Transformation

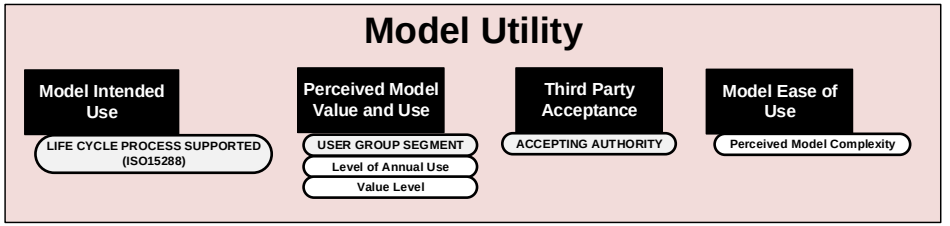
- The INCOSE parent society Board of Directors made it a strategic objective to support the transformation of SE to a model-based discipline.
- An Assistant Director (Troy Peterson) for this Transformation was appointed, and a plan of actions and deliverables adopted.
  - http://www.incose.org/about/strategicobjectives/transformation
- Among the products: The MBE Transformation Roadmap, a planning and assessment instrument for progress in model-based methods.
- Initial minimal product version was shown and piloted at Agile Health Care Systems 2016, at Energy Tech 2016, at IW2017 MBSE Workshop, and at IW 2017 CAB meeting,
- Initial Model Stakeholder Features being piloted in INCOSE support for the ASME Model VVUQ project.
- What does it mean to become a model-based discipline?
  - The Stakeholder Features of Models, and how they support the overall discipline
- An SE view: Model-based ISO15288 processes and life cycle stages
  - ISO15288 is not agile incompatible and is not waterfall

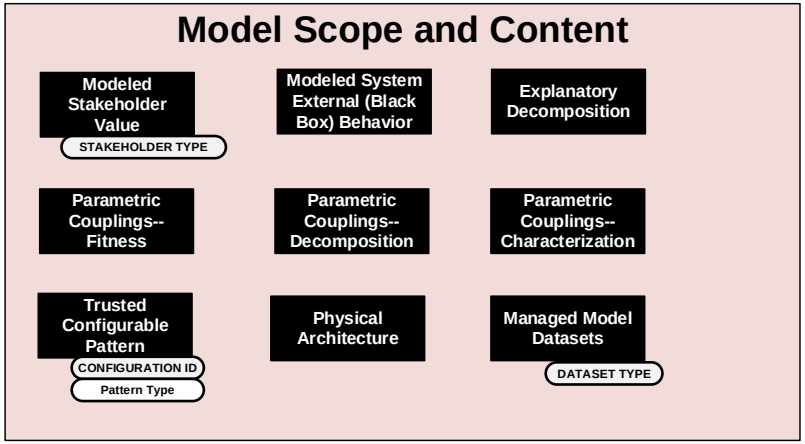
2. The INCOSE Model-Based Transformation: Energy Tech 2016 Feedback on MBSE in ISO15288

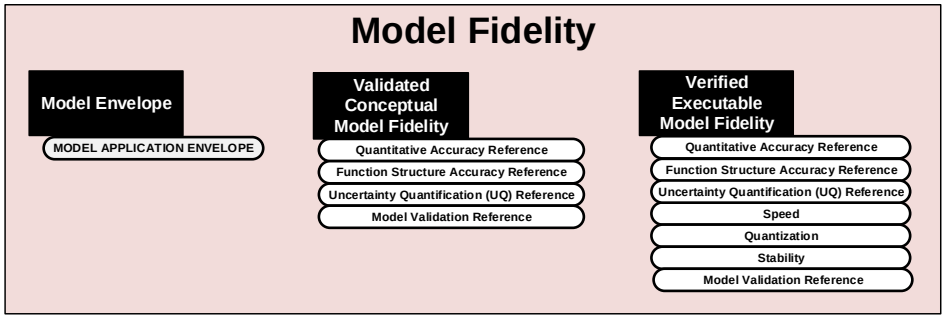


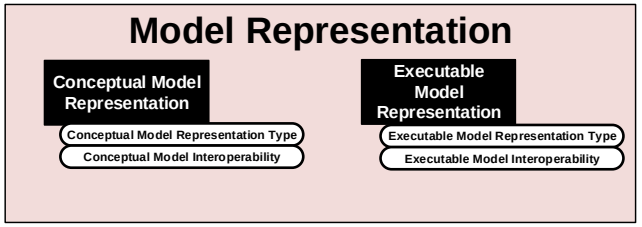
2. The INCOSE Model-Based Transformation: Model Stakeholder Features

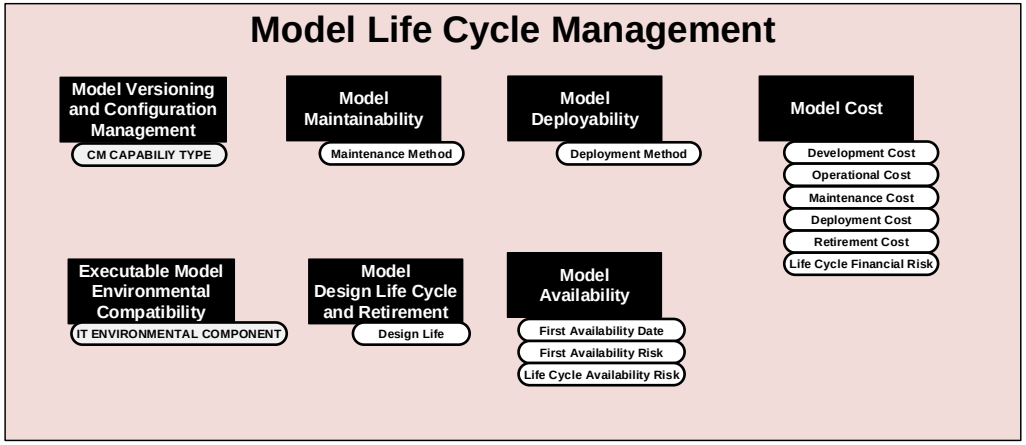












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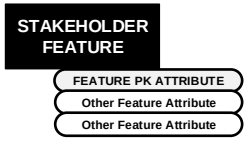
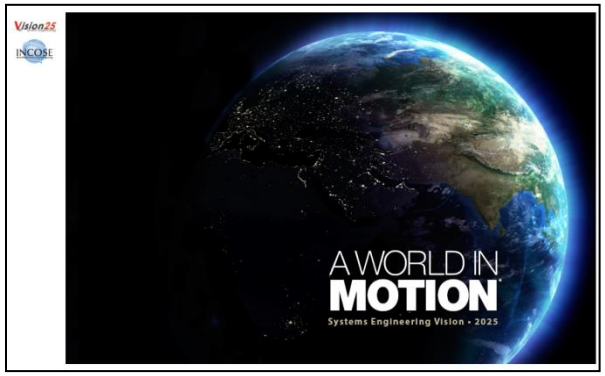
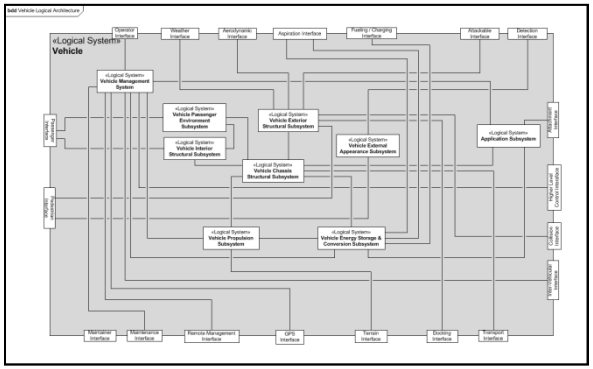


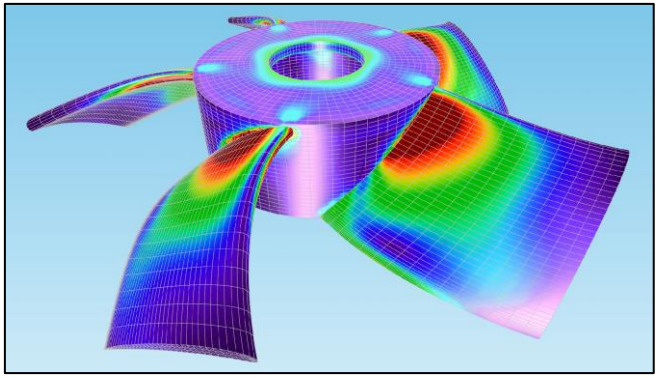
Stakeholder Feature Model for Computational Models

Version: 1.4.15	Date: 30 Apr 2017	Drawn By: B Schindel

3. The ASME Model VVUQ Project





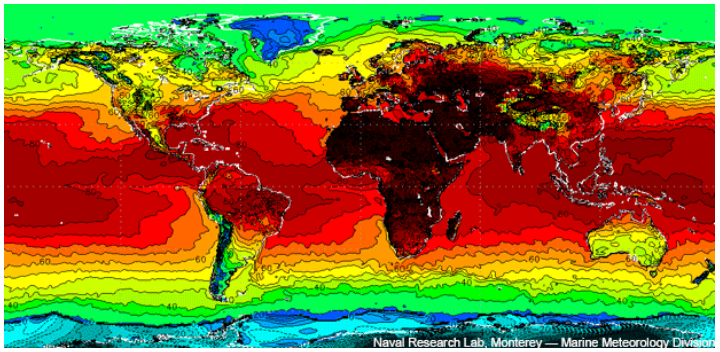


The INCOSE systems community has shown growing enthusiasm for “engineering with models” of all sorts:

- Historical tradition of math-physics engineering models
- A World in Motion: INCOSE Vision 2025
- Growth of the INCOSE IW MBSE Workshop
- Growth in systems engineers in modeling classes
- INCOSE Board of Directors’ objective to accelerate transformation of SE to a model-based discipline
- Joint INCOSE activities with NAFEMS

If we expect to use models to support critical decisions, then we are placing *increased trust in models*:

- Critical financial, other business decisions
- Human life safety
- Societal impacts
- Extending human capability



- This project is about efforts to characterize and manage the structure of that trust (confidence in models):
  - The Validation, Verification, and Uncertainty Quantification (VVUQ) *of the models themselves*.

3. The ASME Model VVUQ Project

- The INCOSE systems community has a strong tradition of using the terms Verification and Validation to refer to System of Interest being engineered.
- Returning to industry efforts to characterize and manage trust in models, we find that these same two terms and ideas appear again:
  - but pointed to a different target;
  - This framework is what caused the speaker, a year earlier, to join the related ASME effort;
  - Observation: There is some lack of awareness, on both the INCOSE (Systems V&V) and ASME (Model V&V) sides of the respective other side of the practice;
  - it is important to keep the related ideas clear . . .

3. The ASME Model VVUQ Project

V&V of *Models*,
Per Emerging ASME Model V&V Standards

Does the Model adequately describe what it is intended to describe?

Model Validation

Model validated?

Model

Model verified?

Model Verification

Does the Model implementation adequately represent what the Model says?

Describes Some Aspect of

V&V of *Systems*,
Per ISO 15288 & INCOSE Handbook

Do the System Requirements describe what stakeholders need?

System Validation

Requirements validated?

System of Interest

Design verified?

System Verification

Does the System Design define a solution meeting the System Requirements?

Don't forget: A model (on the left) may be used for system verification or validation (on the right!)

3. The ASME Model VVUQ Project

- At ASME Model V&V Symposium earlier this month: Met with regulators who serve directly on, and even chair, model V&V standards committees
- Especially important: Coming to agreement on how evidence can effectively be provided to regulators (Model VVUQ)
- These agreements can be effectively encoded as System Patterns for the respective domain systems (medical devices, pharmaceuticals, aircraft, automobiles, etc.)

Agility, Information Debt, Learning, Models

- Agile methods have a key focus on Learning:
  - The most explicit form of this is learning by (the individuals on) the Development Team—especially human learning about what is key to delivered product value
- Agile teams also track Technical Debt in the drive toward delivery:
  - In the ASELCM Project, we learned about another type of "debt".
- Information Debt: The remaining amount of deliverable information still needed to support the System of Interest through its life cycle.
  - Depending on your point of view, Information Debt might be thought of as a subset of Technical Debt.
- The Agile Manifesto reminds us that it is possible to err on the side of too much bureaucracy, paperwork, or formal documents:
  - *"We value . . . Working software over comprehensive documentation."*
- Is there also a converse error?
- Information Debt asks that we understand and agree on what deliverable information is ultimately valued—not just by the Development team--without inflating it beyond the minimum.

Agility, Information Debt, Learning, Models

- In many enterprises, recording "lessons learned" is viewed as good practice:
  - At least, at the end of a project.
  - Often, in the form of a report or memorandum to file
- Likewise, "Knowledge Management" efforts are seen, focusing on encoding what is deemed important for future work by others.
- Measuring effectiveness of such practices:
  - Instead of how often the data is referred to, how about . . .
  - how frequently related future work that could be impacted is effectively impacted, versus repeating similar work or problem consequences.

Lessons Learned?

Lessons Learned Report

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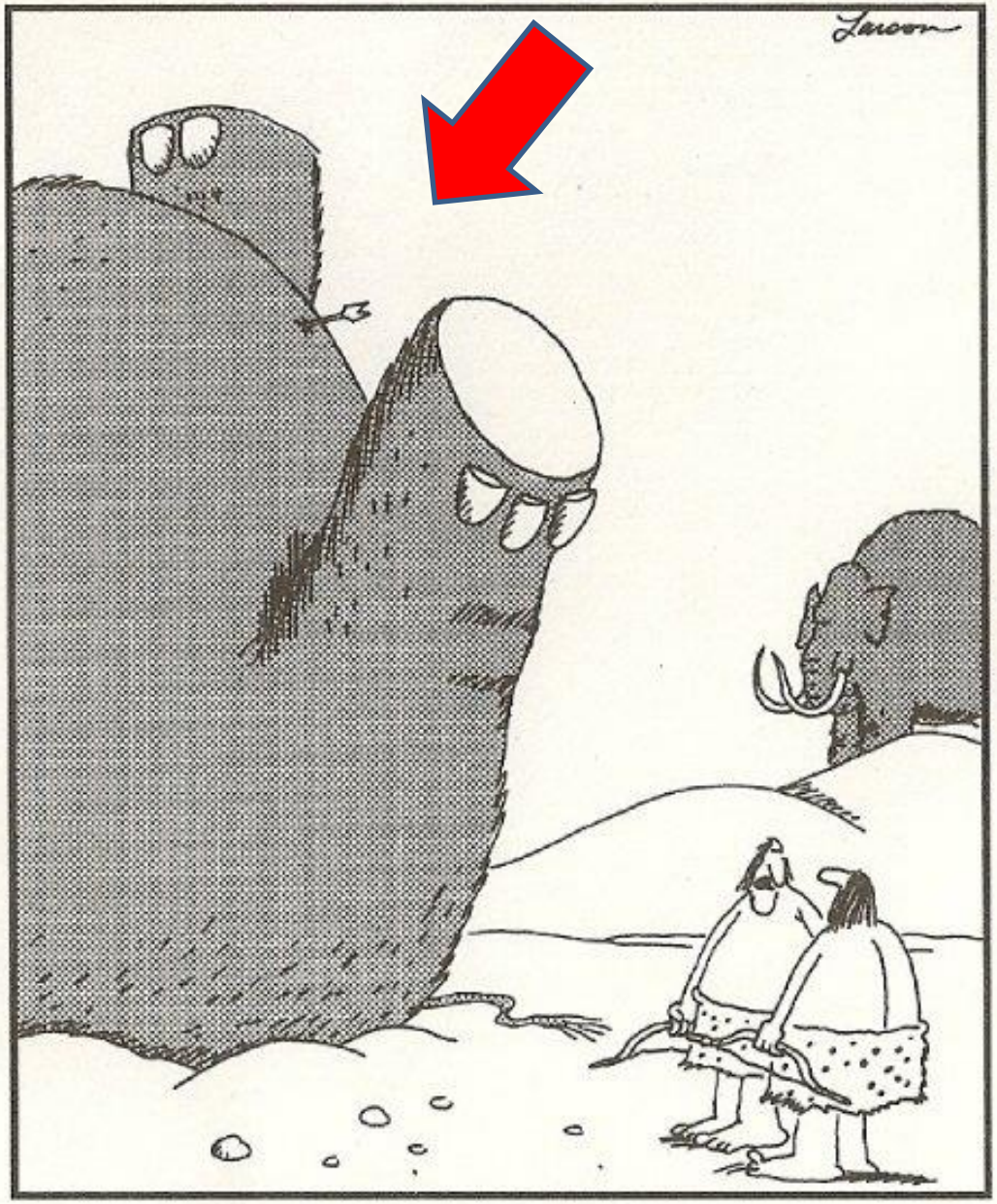

"We should write that spot down."

Lessons Effectively Learned?

Lessons Learned Report

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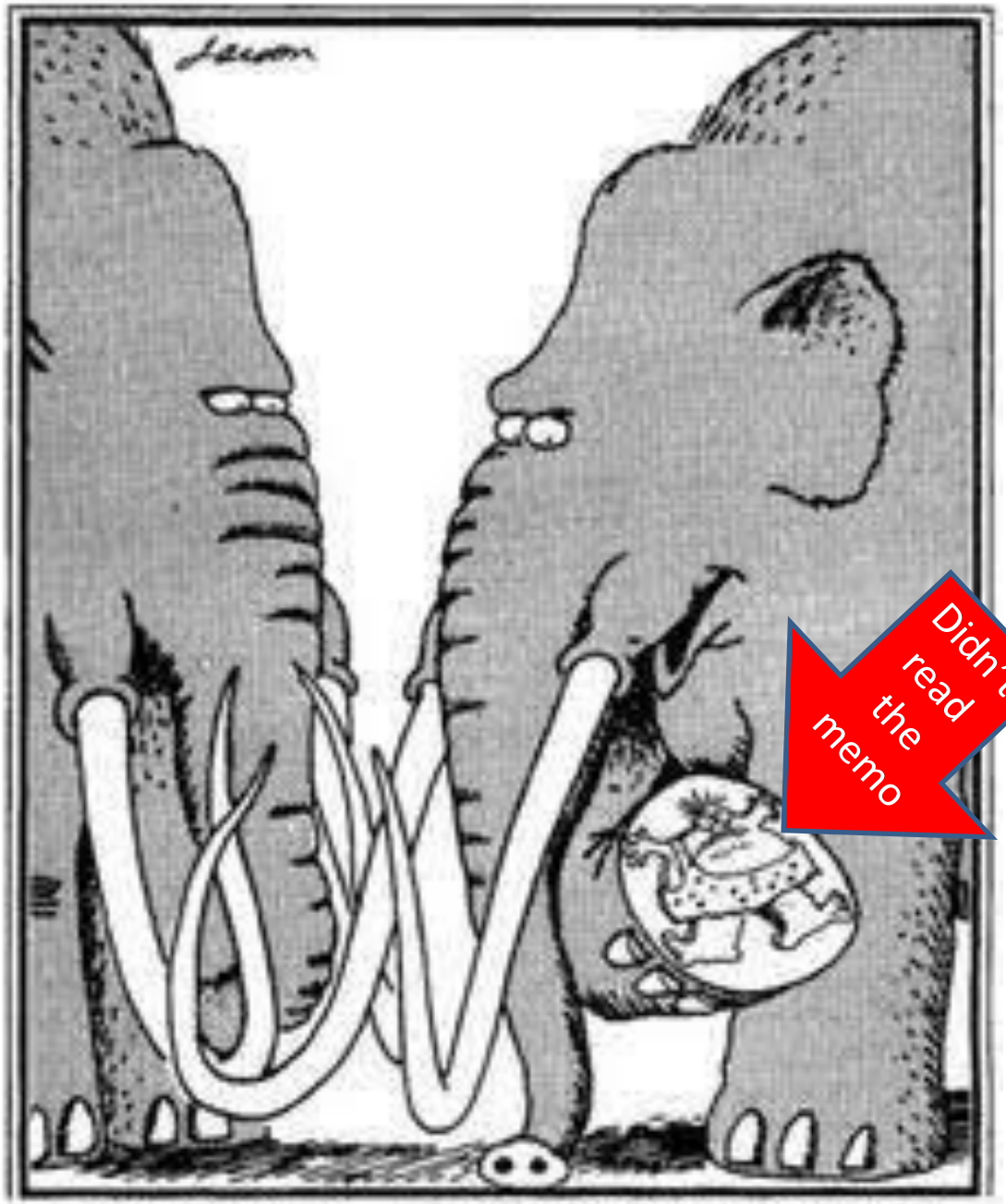


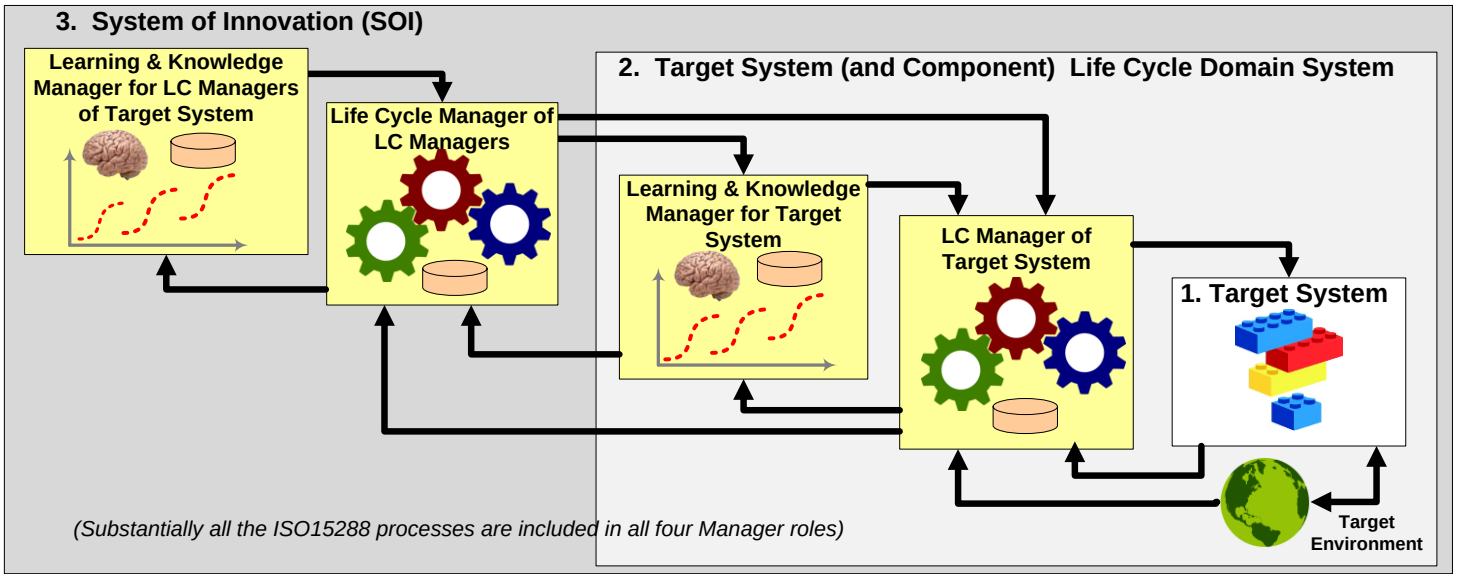
Agility, Information Debt, Learning, Models

- Where are the "lessons learned" encoded? What would cause them to be accessed?
- Compare to biology:
  - "Muscle Memory" builds "motor" learning directly *in line with a future task*, for future unconscious use, *vs*. syllogistic reasoning that may not be remembered fast enough, or at all
  - This is about "effective learning" for future agile use
  - Just having a growing file of "lessons learned", even if text searchable, is not the same as building what we learn directly in line with the path of future related work that will have to access it in order to be executed.
- Just because we label a report "lessons learned" does not mean that those who will need this information in the future will have access to it.

Agility, Information Debt, Learning, Models

We argue that the most dramatically successfully impactful example of extended group-wide learning process, during the last three centuries, is the edifice of the physical sciences:

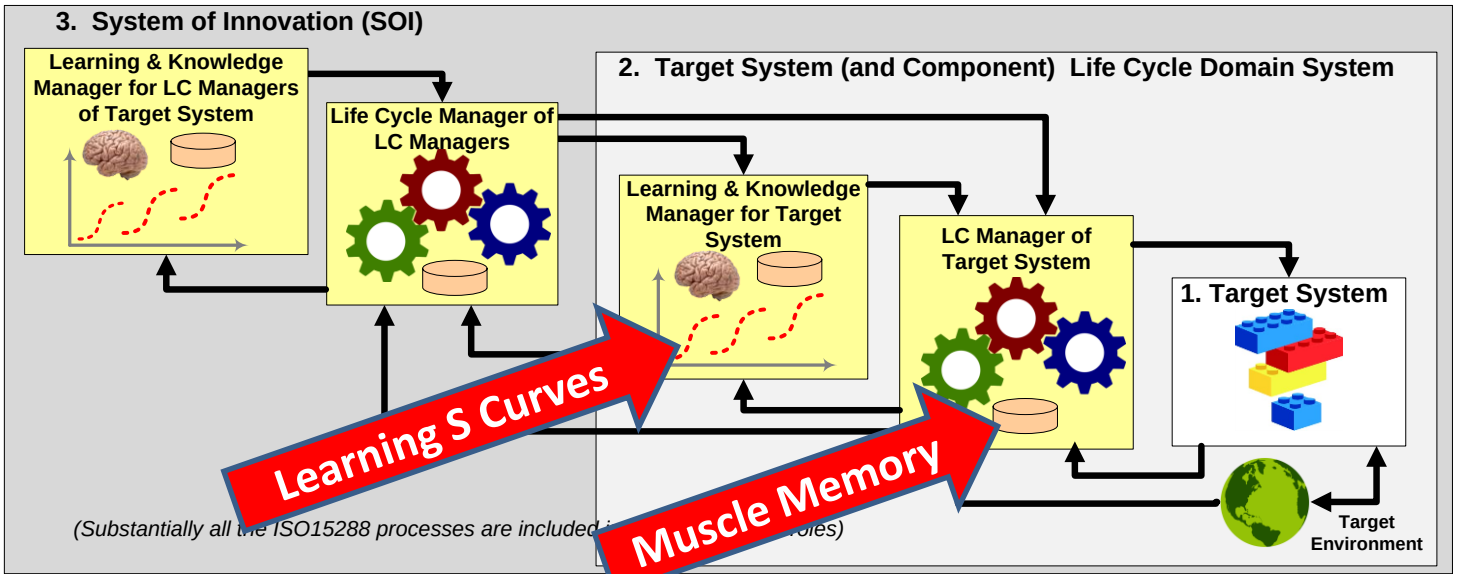
- Notice that the language of the "lessons learned" repository is that of explicit quantitative models;
- Notice that the credibility of these models (whether wrong, close, or right) is Model Validation, Verification, and Uncertainty Quantification (Model VVUQ);
- Described in this way, the System 2 and System 3 portions of ASELCM Pattern are models of Group Learning.



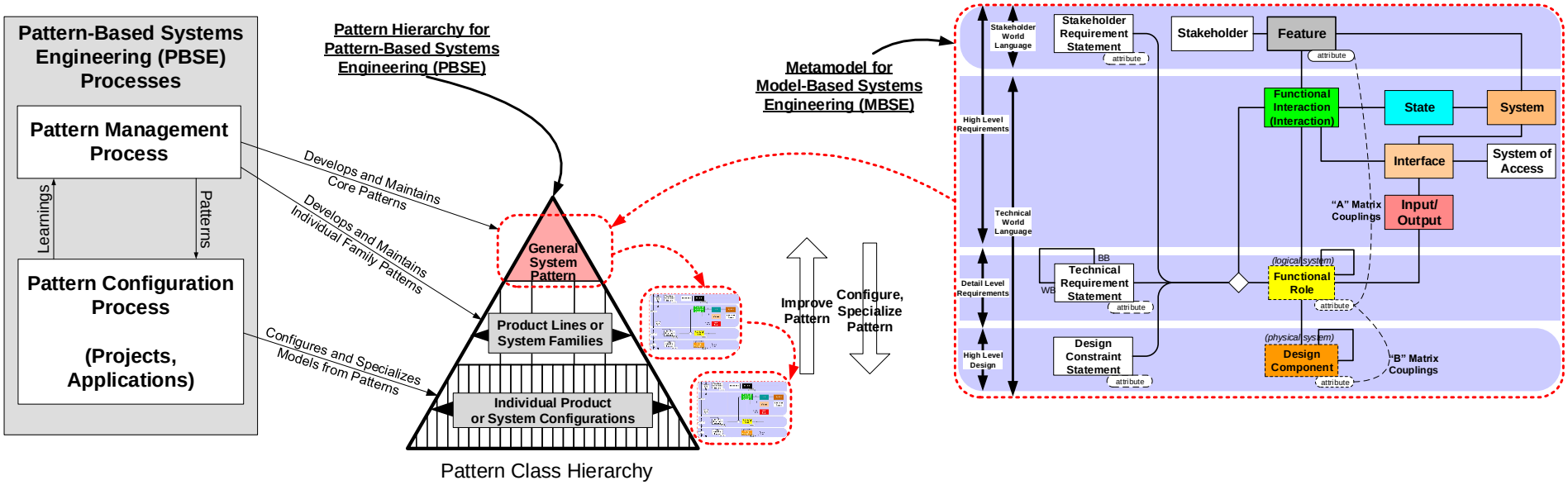
Agility, Information Debt, Learning, Models

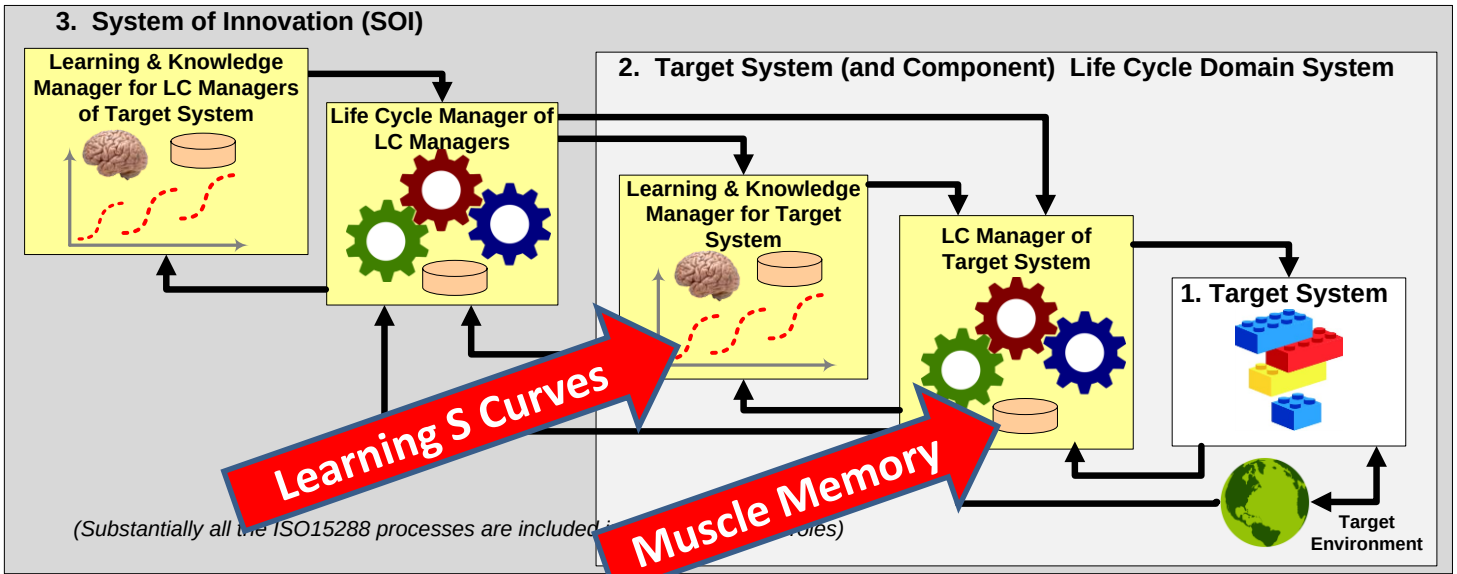
We argue that the most dramatically successfully impactful example of extended group-wide learning process, during the last three centuries, is the edifice of the physical sciences:

- Notice that the language of the "lessons learned" repository is that of explicit quantitative models—specifically, recurring patterns expressed as general models;
- The credibility of these models (whether wrong, close, or right) is expressed via Model Validation, Verification, and Uncertainty Quantification (Model VVUQ);
- Described in this way, the System 2 and System 3 portions of ASELCM Pattern are models of Group Learning as well its effective ("muscle memory") application:



That is exactly what Pattern-Based Systems Engineering (PBSE), a form of Model-Based Systems Engineering (MBSE) is about:





Vision for a Collaboration

- **The Setting**: Innovation, particularly in regulated domains
- **The Need**: Streamline the innovation cycle while still achieving regulatory goals
- **The Domains**: Aerospace, medicine, electrical grids, automotive, others
- **The Opportunity**: Enhanced trust shared models that society and regulatory authorities can trust during interaction with enterprises and researchers, streamlining joint processes
- **Achieved Example**: Automotive virtual crash testing
- **Engineering Professional Societies**: These System 3 entities occupy a special place in this ecosystem, by virtue of their ethical commitment, combined with technical expertise:
  - Not the same position as the enterprises, or trade groups;
  - Not the same position as the regulators;
  - Not the same position as the academic research community;
  - But a potentially catalytic collaborator with them all, to accelerate the advancement of this vision to reality.

Vision for a Collaboration

- **ASME's Model VVUQ Leadership Position**: Attracted participation by INCOSE beginning in 2016, in connection with:
  - ASME's goals and leading position in V&V of Computational Models
  - INCOSE's transformation of SE to a Model-Based Discipline
- Special role played by MBSE Patterns (re-usable, configurable models) in this transformation, and in the tradition of the physical sciences (shared, validated general models, configurable)
- Other engineering professional societies discussing this interest (e.g., IEEE)
- Other trade groups discussing this interest (e.g., AIAA)
- Public forum discussion and panel interests for:
  - INCOSE Agile Health Care Systems Conference 2017 (IL)
  - INCOSE Great Lakes Regional Conference 2017 (MN) and 2018 (IN)
  - AIAA Aviation 2017 (CO)
  - IEEE/NASA/INCOSE Energy Tech 2017 (OH)
- Indiana private sector aero/medical team standing up a Virtual Verification Institute (V4I), with ASME collaboration from outset

Is Your Agility Agile?
Four Ideas for Action . . . .

1. **System of Interest**: Consider agility for the medical systems life cycle stages besides Development, and systems of interest beyond health care products and information systems (e.g., care delivery, supply chains, manufacturing systems, distribution, marketing).
2. **Impactful Learning**: Consider more effective architecture for persistent impactful Lessons Learned, model-based in-line process muscle memory, and a formal System 3 for your organization.
3. **Maps vs. Itineraries**: To understand what future agility is possible, separate understanding of what flows through the process pipes (System Models) from the plumbing (life cycle management work Processes).
4. **Industry Collaborations**: Engineering society consortia that can advance and share system patterns of mutual interest to regulators, suppliers, and society, INCOSE Patterns Working Group, related conferences and panels.

Discussion

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Agile Health Care Systems and Comfort Zones: Are We Thinking Broadly Enough?

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Speaker

William D. (Bill) Schindel chairs the Model-Based Systems Engineering Patterns Working Group of the INCOSE/OMG MBSE Initiative. An ASME member, he is part of the ASME VV50 standards team's effort to establish guides and standards for model verification, validation, and uncertainty quantification. Schindel is president of ICTT System Sciences, and has practiced systems engineering for over thirty years, across multiple industry domains. He earned the B.S. and M.S. degrees in mathematics, and is an INCOSE Fellow and Certified Systems Engineering Professional.