INCOSE Healthcare Working Group

4th Annual Systems Engineering in Healthcare Conference

Trusting Models of Controlled Systems

A Model VVUQ White Paper Project

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How Systems Engineering Can Reduce Cost & Improve Quality

19-20 April, 2018
Twin Cities, Minnesota

Abstract

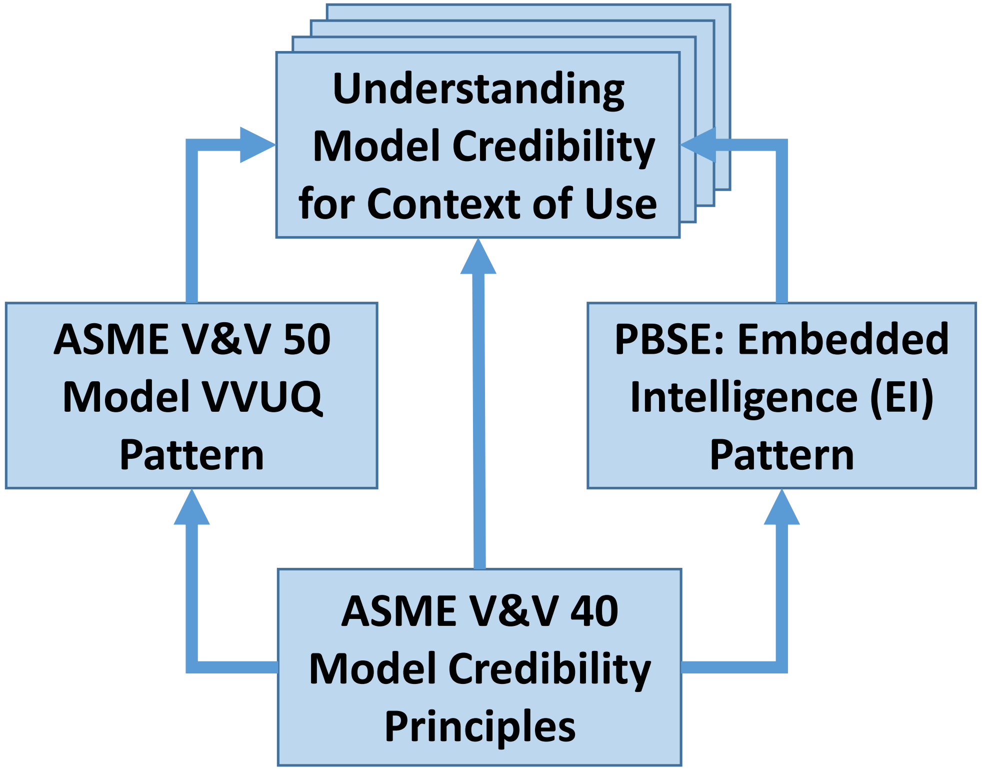
This presentation discusses a white paper being jointly authored during 2018, to illustrate the applications of ASME V&V 40 to medical devices that include embedded control.

There is an historical subject of control systems applied in uncertain situations, but our subject here is uncertainty, risk, and credibility as they apply to the model of the resulting system. What trust should be placed in a model for decision-making about systems with embedded control?

Model VVUQ & MBSE work provides a set of general system principles and assets, and the white paper discussed will summarize how they apply when embedded control is part of the modeled system.

Overall Approach

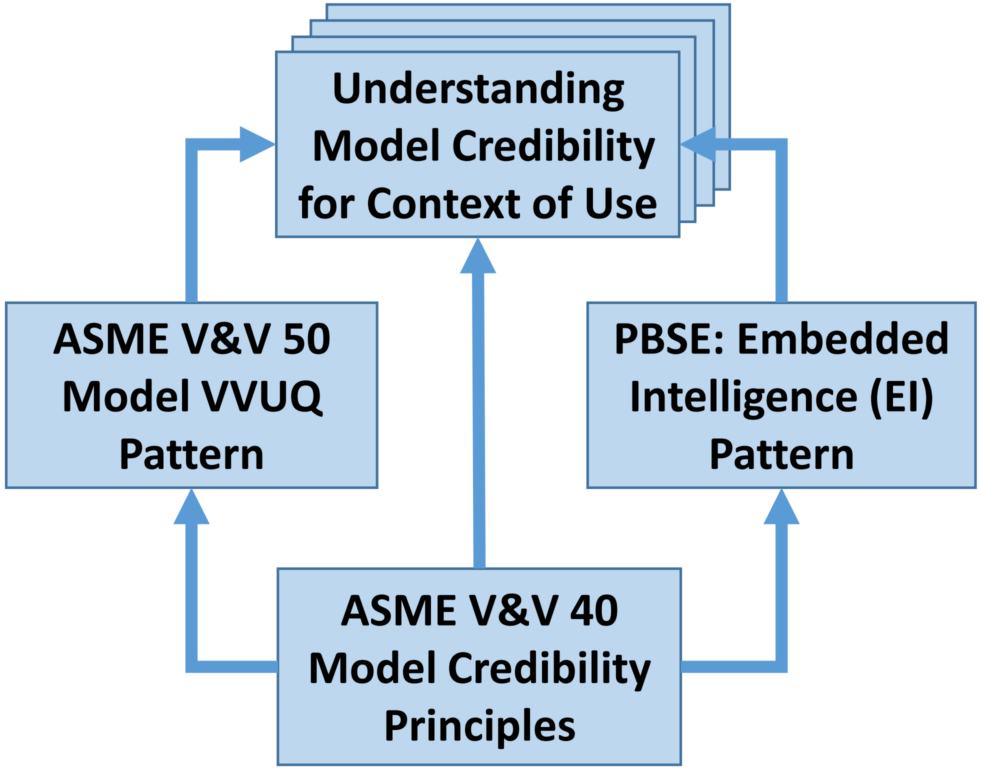
- This talk is about a paper being developed and expanded during the year:
  - This talk summarizes the approach only.
  - It is likely to evolve, as we are at an early stage and authors are still weighing in on issues.
  - Sharing progress publicly as we work through year.
- It begins by using the **V&V 40 Model Credibility Principles** for planning/assessment.
- The **VnV Model VVUQ Pattern** is also used to answer related questions and leverage knowledge.
- The **PBSE EI Pattern** is used to explicate the specialization to cases of embedded control.



  - Resulting understanding of model credibility in a specific Context of Use (CoU) can be applied for devices (discussed), and (later) manufacturing & distributions cases.

Contents

- V&V 40: Model Credibility Principles
- V&V 50: Model VVUQ Pattern
- PBSE Embedded Intelligence Pattern
- Applying the Principles and Assets
- Example
- Additional application domains
- Conclusions
- References
- Supplemental Attachment

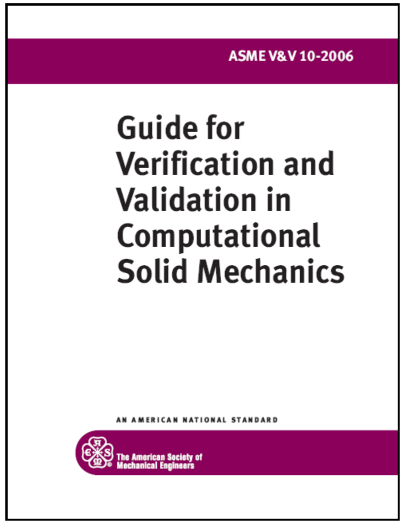


ASME Committee on V&V in CM&S

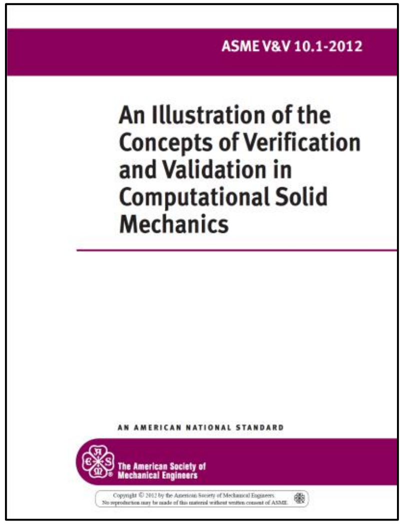
Codes & Standards V&V VERIFICATION AND VALIDATION IN COMPUTATIONAL MODELING AND SIMULATION

ASME V&V Standards Committee

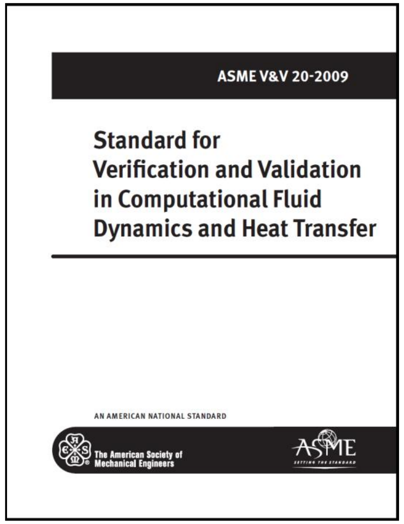
- **Provide procedures for assessing and quantifying the accuracy and credibility of computational modeling and simulation**



ASME V&V 10



ASME V&V 10.1



ASME V&V 20

V&V Standards Committee in Computational Modeling and Simulation

- **V&V 10** - Verification and Validation in Computational Solid Mechanics
- **V&V 20** - Verification and Validation in Computational Fluid Dynamics and Heat Transfer
- **V&V 30** - Verification and Validation in Computational Simulation of Nuclear System Thermal Fluids Behavior
- **V&V 40** - Verification and Validation in Computational Modeling of Medical Devices
- **V&V 50** - Verification and Validation of Computational Modeling for Advanced Manufacturing

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ASME V&V 40

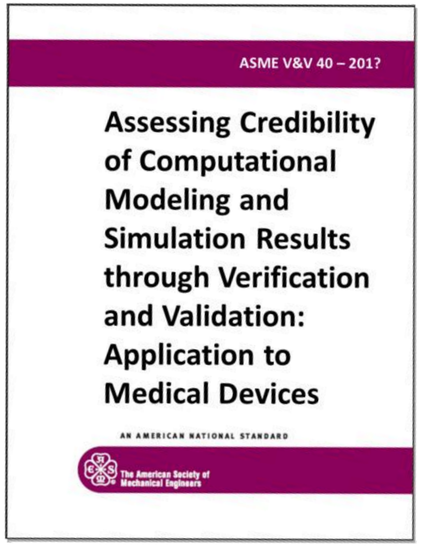
Codes & Standards — V&V 40 VERIFICATION AND VALIDATION IN COMPUTATIONAL MODELING OF MEDICAL DEVICES

ASME V&V 40 Charter

- Provide procedures to standardize verification and validation for computational modeling of medical devices
- Charter approved in January 2011

Motivating factors

- Regulated industry with limited ability to validate clinically
- Increased emphasis on modeling to support device safety and/or efficacy
- Use of modeling hindered by lack of V&V guidance and expectations within medical device community


ASME V&V 40 – 201?
Assessing Credibility of Computational Modeling and Simulation Results through Verification and Validation: Application to Medical Devices
AN AMERICAN NATIONAL STANDARD
The American Society of Mechanical Engineers

ASME V&V 40
(planned for June 2018 pub.)

V&V Standards Committee in Computational Modeling and Simulation

- **V&V 10** - Verification and Validation in Computational Solid Mechanics
- **V&V 20** - Verification and Validation in Computational Fluid Dynamics and Heat Transfer
- **V&V 30** - Verification and Validation in Computational Simulation of Nuclear System Thermal Fluids Behavior
- **V&V 40** - Verification and Validation in Computational Modeling of Medical Devices
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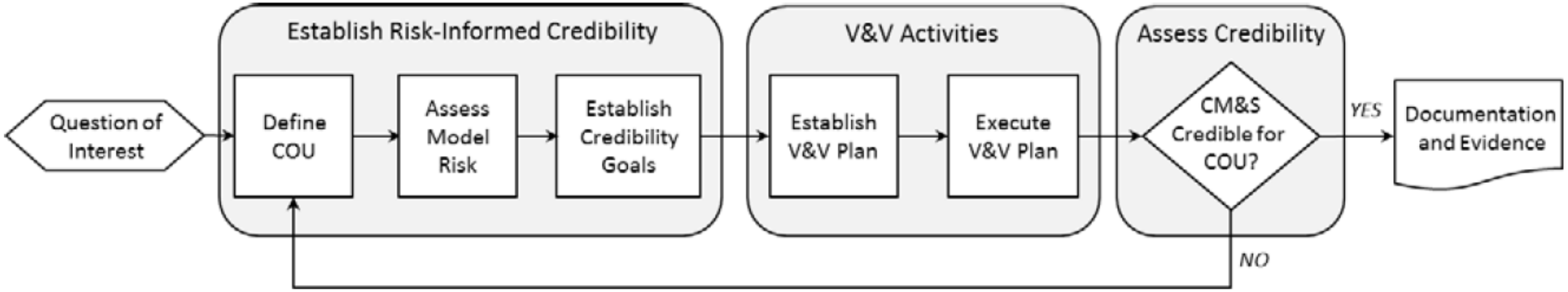
ASME V&V 40 - Model Credibility Principles

RISK-INFORMED CREDIBILITY ASSESSMENT FRAMEWORK



The V&V40 guide outlines a process for making risk-informed determinations as to whether CM&S is credible for decision-making for a specified context of use.

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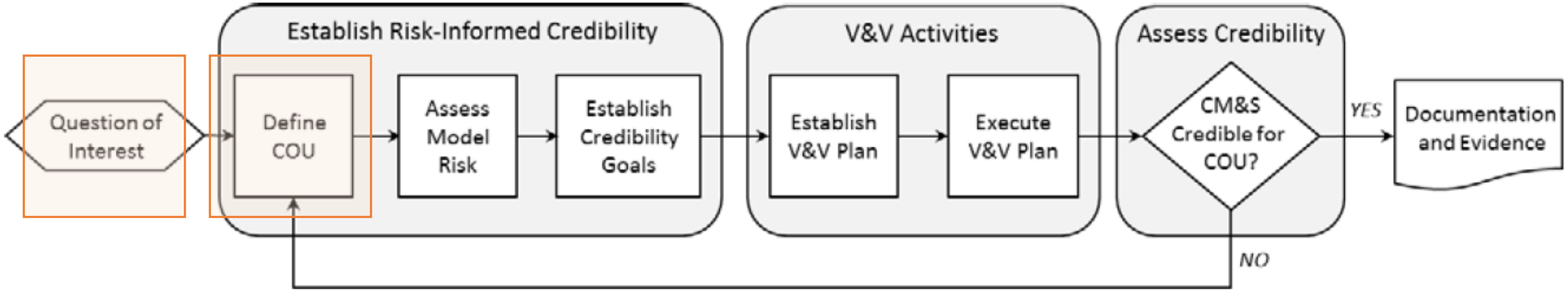
Question of Interest and Context of Use



The **question of interest** describes the specific question, decision or concern that is being addressed.

Context of use defines the specific role and scope of the computational model used to inform that decision.

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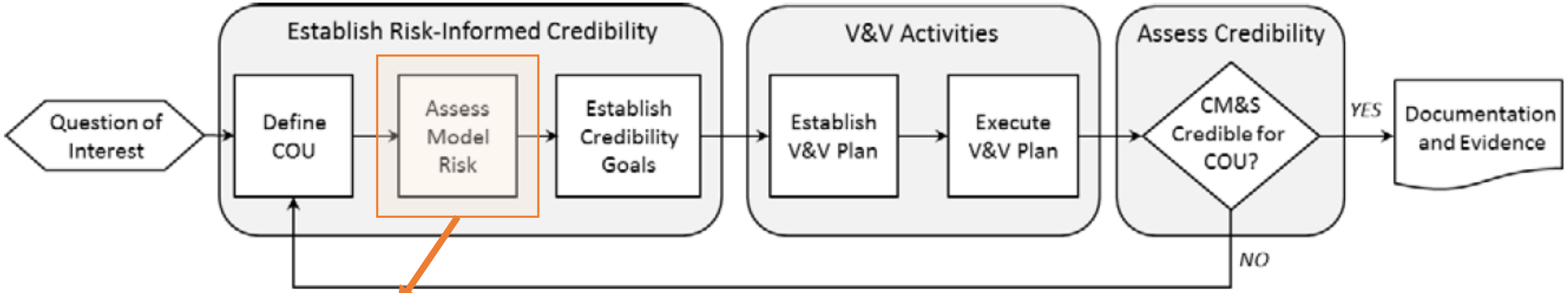
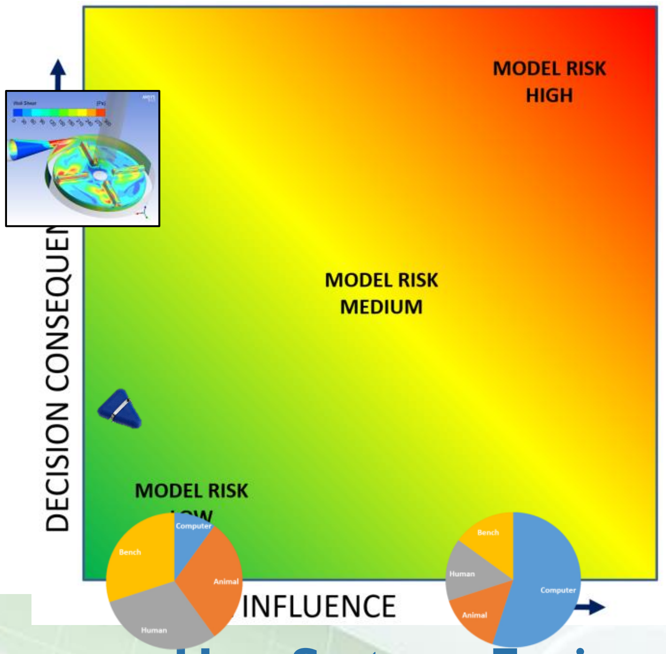
Risk Assessment





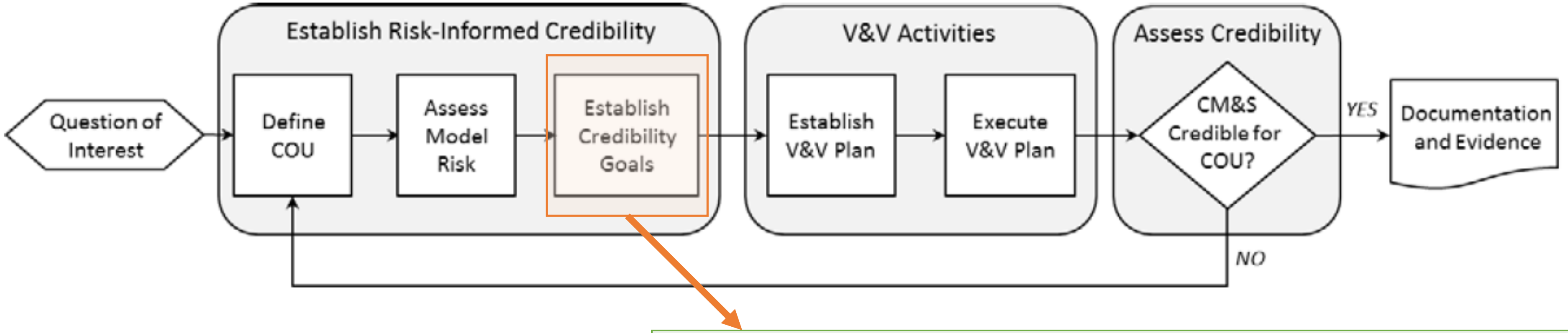
Model risk is the possibility that the model may lead to a false/incorrect conclusion about device performance, resulting in adverse outcomes.

- **Model influence** is the contribution of the computational model to the decision relative to other available evidence.

- **Decision consequence** is the significance of an adverse outcome resulting from an incorrect decision.

* Blood pump image courtesy Mark Goodin, SimuTech Group

Credibility Factors



Credibility Factors															
Verification					Validation									Applicability	
Code		Solution			Model				Comparator			Output Assessment			
Software Quality Assurance	Numerical Algorithm Verification	Discretization Error	Use Error	Numerical Solver Error	System Configuration	System Properties	Boundary Conditions	Governing Equations	Sample Characterization	Control Over Test Conditions	Measurement Uncertainty	Equivalency of input and output types	Rigor of Output Comparison	Relevance of the Quantities of Interest	Applicability to the Context of Use

Model credibility refers to the trust in the predictive capability of the computational model for the COU.

Trust can be established through the collection of V&V evidence and by demonstrating the applicability of the V&V activities to support the use of the CM for the COU.

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Examples/Illustrations

- Examples highlight specific aspects of the risk-informed credibility assessment framework.
- The examples should not be considered “industry-approved” or “regulatory-approved.”

Example 2: Context of Use
Medical device: a new posterior stabilized total knee arthroplasty assembly

Context of Use: Finite element analysis (FEA) will be used to determine if the locking mechanism has sufficient strength to prevent lift-off of the new device. Specifically, the model predi
of liftoff of the tibial component under a variety of loads. The tibial component liftoff is e
exclusively using the computational model. All device configurations will be simulated.
device exists to compare with the computed results. No bench testing will be performed
particular device. However, these FEA techniques have been employed for other produ

Example 3: Model risk
Medical device: centrifugal blood pump for circulatory support

Context of Use: Use computational fluid dynamics identify the key pump features whose dimensional variation could potentially lead to increased hemolysis; those features will be directly assessed with testing. Results will be compared against a predicate device.

CM&S influence: based on the classification scheme below, the model influence is medium because testing will be used to confirm some of the results.

Decision consequence: An incorrect decision to alter the key pump feature’s dimensional tolerances
na hemoglobin levels during clinical use if hemolysis occurs. Patient injury
e immediate intervention of the clinician to monitor patient hemoglobin levels
mp. Therefore, the decision consequence is HIGH.

ed to be Medium-High. This result is directly used to determine the validation
r “Rigor of Output Comparison,” see Example 4.

		Consequence		
		Low	Medium	High
Influence	Low	1	2	3
	Medium	2	3	4
	High	3	4	5

Example 4: Rigor of Output Comparison
Medical device: centrifugal blood pump for circulatory support

From Example 3, model risk was determined to be Medium-High. This result is directly used to determine the validation assessment criteria for “Rigor of Output Comparison”:

Within the scheme presented, the assessment levels for CM&S validation are as follows:
1. Visual comparison concludes good agreement.
2. Comparison by simply measuring the differences between computational results and experimental data. Differences are less than 20%.
3. Comparison by simply measuring the differences between computational results and experimental data. Differences are less than 10%.
4. Comparison with uncertainty captured and incorporated from the comparator or computational model. Differences are less than 5%, including consideration of some uncertainty, but statistical distributions for further uncertainty quantification are unknown.
5. Comparison with uncertainties captured and incorporated from both the comparator and the computational model, including comparison error. Differences are less than 5%, and statistical distributions are known for rigorous treatment of uncertainty.

Based on a Medium-High model risk for the blood pump, the validation activities should Level 4, demonstrating model accuracy to within 5 with uncertainty captured.

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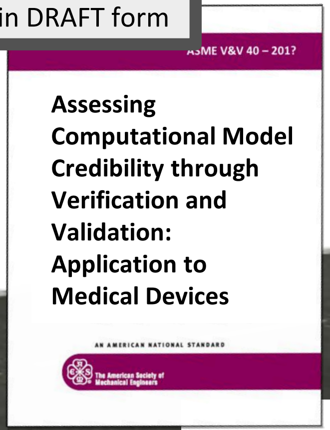
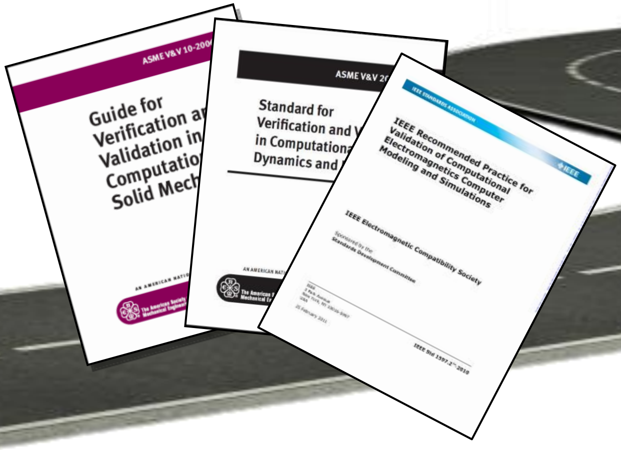
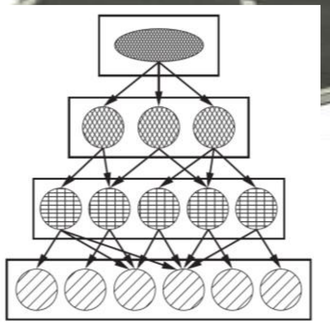
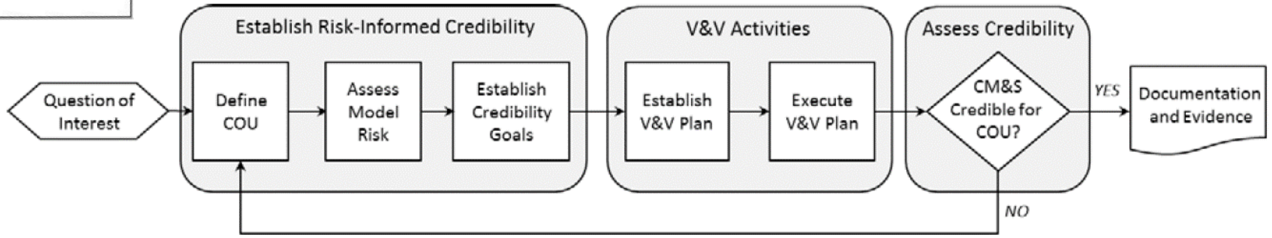
Regulatory Pathway for CM&S

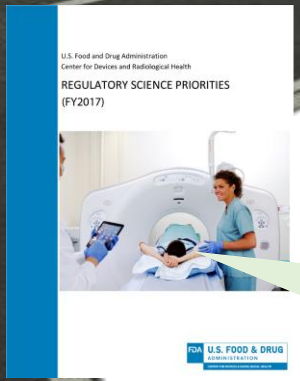
currently in DRAFT form











"Develop computational modeling technologies to support regulatory decision-making"

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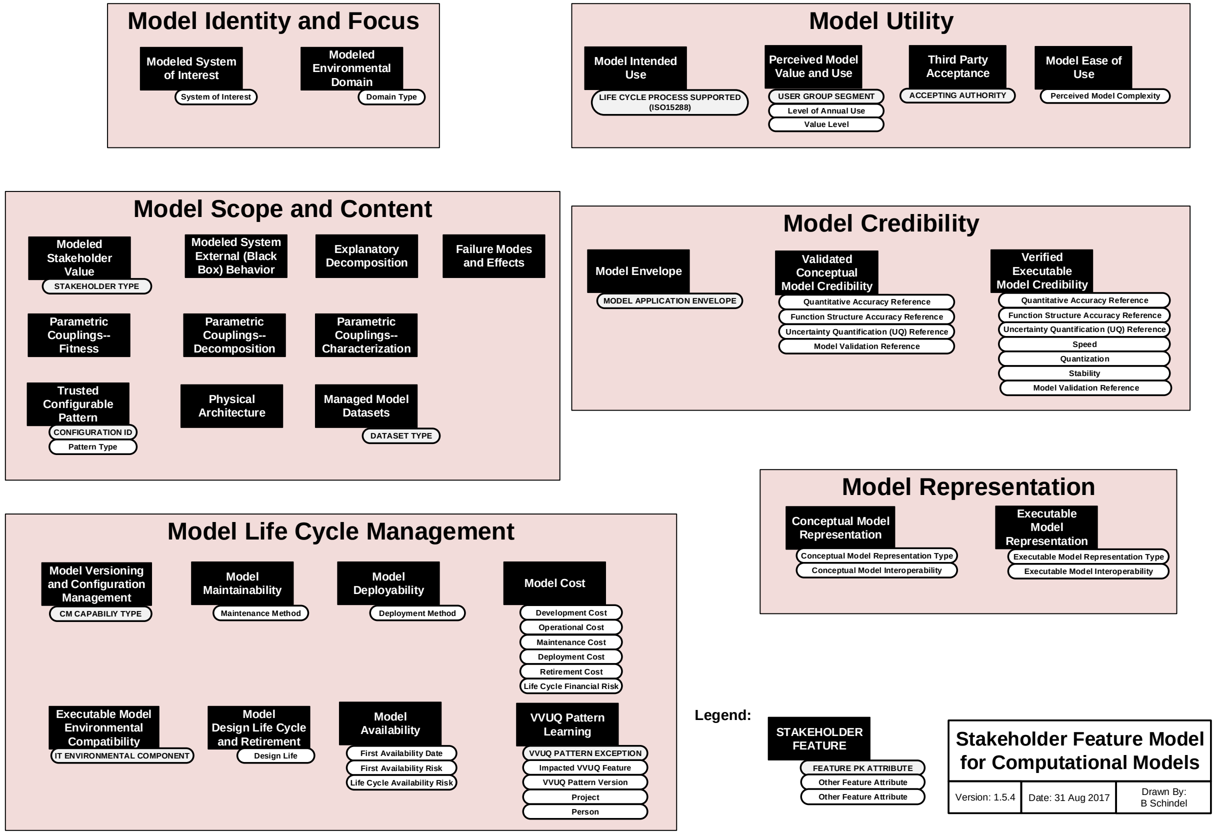
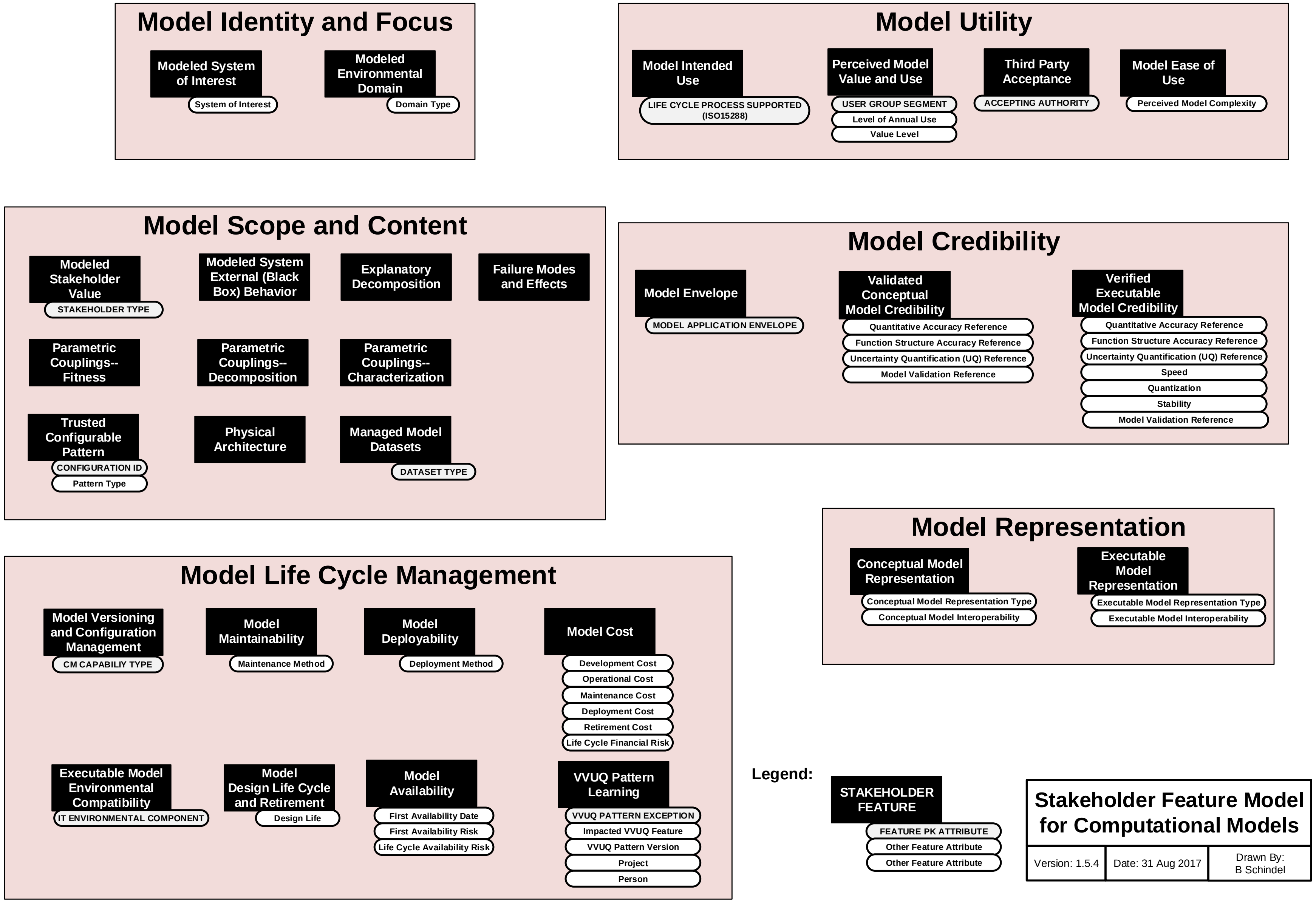
The V&V 50 Model VVUQ Pattern

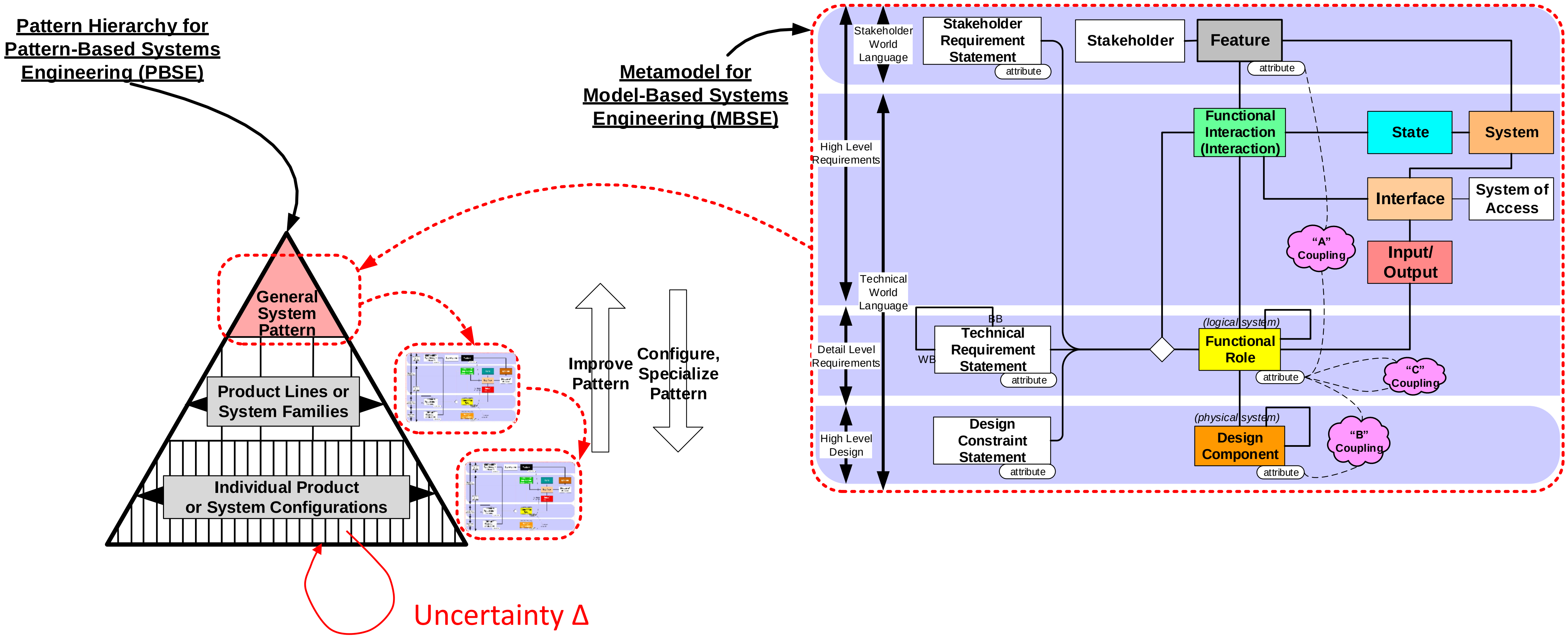
- Itself a model, describes features of a model of interest, for planning, developing, validating, and life cycle management of a model of interest--including key emphasis on the model's VVUQ.
- Being generated in the V&V 50 team and INCOSE.
- Helps structure and capture metadata describing intentions and other aspects of the model of interest—some of which are model-based answers to what V&V 40 asks us for.



Computational Model Feature Groups: 29 Features, in 6 Feature Groups, *Configurable for Specific Models*



Comparing different configurations (model instances) of a generic pattern (e.g., a pattern of a class of medical devices) provides a structured means of analyzing model UQ in light of the UQ of a "nearby" model configuration:



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The V&V 50 Model VVUQ Pattern

- Are "system" models really so different from "computational models"?
- Can/should "system" models be subject to VVUQ as in "computational models"?
- Does the credibility of "system models" matter less than the credibility of "computational models"?
- Read about PIRT (Phenomena Identification and Ranking Table) to realize that confidence in the structure of a "system model" is connected to confidence in the identification and ranking of "phenomena".

SANDIA REPORT
SAND2002-0341
Unlimited Release
Printed March 2002

General Concepts for Experimental Validation of ASCI Code Applications

Timothy G. Trucano, Martin Pilch, and William L. Oberkampf

Prepared by
Sandia National Laboratories
Albuquerque, New Mexico 87185 and Livermore, California 94550

Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company, for the United States Department of Energy under Contract DE-AC04-94AL85000

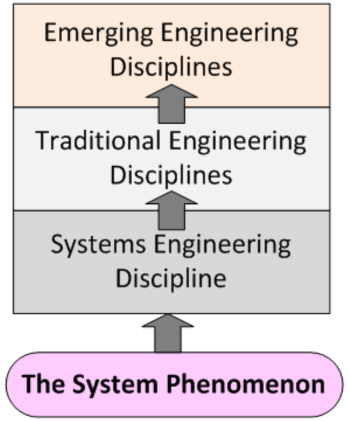
Approved for public release; further dissemination unlimited.

Sandia National Laboratories

3.2 The Phenomena Identification and Ranking Table (PIRT)

As argued in version 2 of the Sandia V&V planning guidelines (Pilch et al. 2000a), the PIRT is the most important tool in our V&V planning process for translating requirements of the stockpile driver application into requirements on usage of the code, hence specifically on validation activities. The PIRT is particularly important for prioritizing and directing dedicated validation experiment tasks. The intended use of this methodology is thoroughly specified and elaborated in Pilch et al. (2000a) and is not repeated here. However, we do point out that the PIRT is designed to convert the DSW driver application and its associated requirements into specific technical requirements for the code, verification activities, validation activities, and consequent experimental validation requirements. It is the code technical requirements for the driving application that are the proper focus of V&V activities. As a result of a well-executed PIRT process, the validation requirements of the code application are rank ordered in importance. The prioritized PIRT elements directly create the definition and prioritization of the specific validation tasks, especially dedicated validation experiments, which are performed under the validation plan for the code application.

The PIRT is critical for planning validation experiments because it helps establish both *sufficiency* and *efficiency* of the validation activities. To demonstrate *sufficiency*



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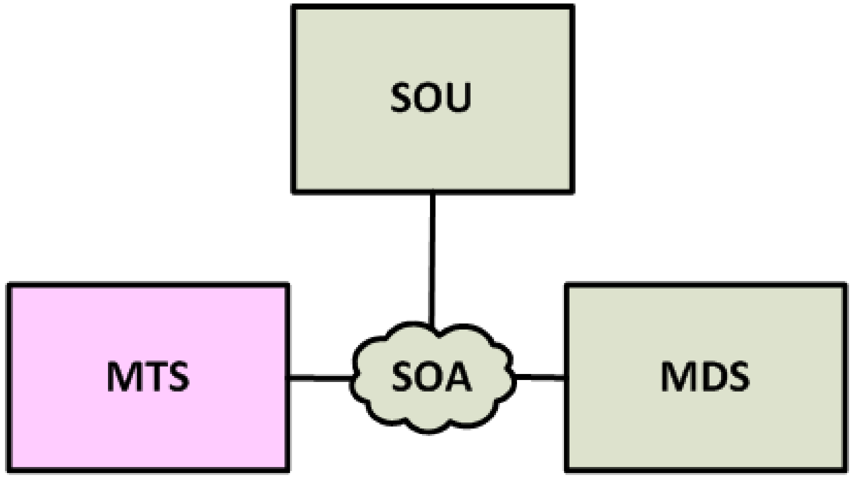
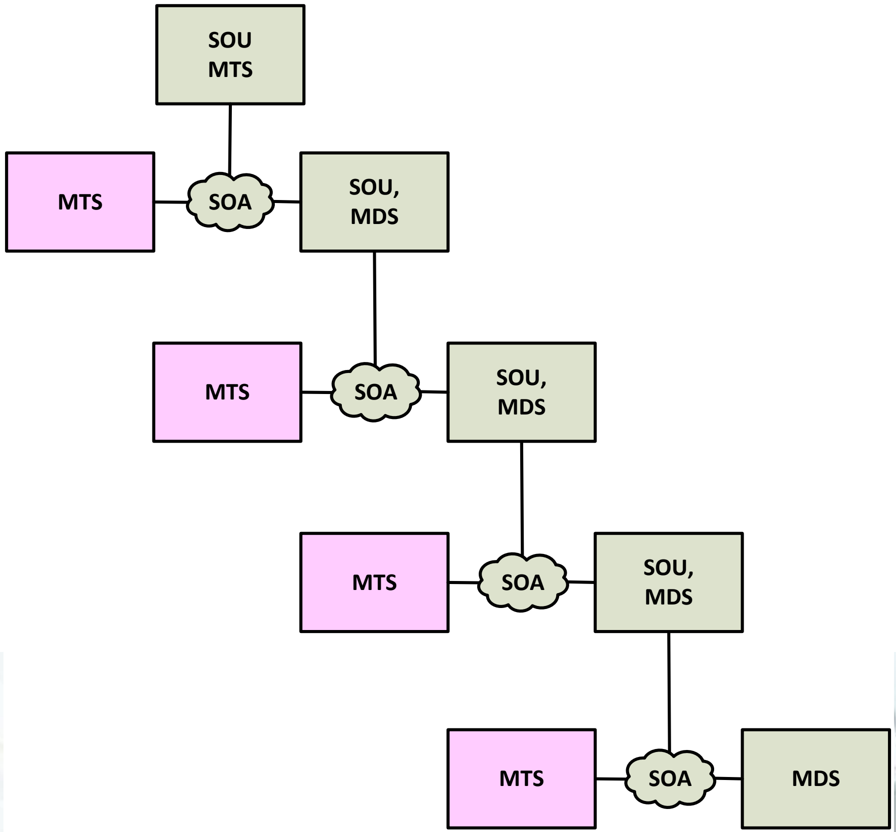
Embedded Intelligence (EI) Pattern

- The EI Pattern is an S*Pattern that describes intelligence in explicit models of evolving systems in the natural and man-made world:
  - Also referred to as the Management System Pattern.
  - Concerned with the emergence of four roles, at multiple levels:





PBSE: Embedded Intelligence (EI) Pattern

- As usual in model VVUQ, we are concerned with multiple sources of uncertainty—model, input data, etc.—and uncertainty propagation.
- In the case of the EI Pattern, this also turns out to be equivalent to (what other domains call) Operational Control Strategy model uncertainty.

Applying the Principles and Assets

- Because of the general form of (1) the V&V 40 principles, (2) the Model VVUQ Pattern, and (3) the Embedded Intelligence Pattern, we can predict the general form of the resulting model VVUQ/credibility problem and the form of analysis for the model of embedded control:
  - It is still necessary to analyze specific cases, but the approach and form can be predicted in advance, reducing effort to generate and communicate it to others.
  - This can reduce the time and effort necessary to address model credibility questions.
  - It is not just a time-saver for the analyst, but also for those with whom the analysis is to be shared, requiring credibility.

Applying the Principles and Assets

- Subsequent updates will include the application of the above approach, principles and assets to the problem.
- For purposes of this meeting, we are interested in your questions and comments about the approach.

Example

- We are likewise planning an example for the paper, from the medical device controls.

Additional application domains: Model scopes and uncertainties about…

- Medical device application domain:
  - Control system, sensors, actuators
  - Controlled device
  - Human physiology and activity
  - Human environment
- Manufacturing domain:
  - Controls, equipment, material, and operational control strategy, model
  - Use in GMP and other production environments (V&V 50 world)
- Distribution domain:
  - Warehouse, transport, and retail control systems, sensors, actuators
  - Controlled equipment and environment
  - Product in distribution

Growth of paper scope over time

Conclusions

- V&V 40, V&V 50, and MBSE Patterns can provide key assets and structured methods for dealing with model uncertainty concerning medical devices with embedded control.
- The white paper being written is to bring a set of complementary but less familiar ideas into both combination and awareness.
- We are still at an early stage in writing the paper, and plan to report on progress at subsequent meetings.

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References

1. "ASME V&V 10-2006: Guide for Verification and Validation in Computational Solid Mechanics", ASME, 2006.
2. "ASME V&V 20-2009: Standard for Verification and Validation in Computational Fluid Dynamics and Heat Transfer", ASME, 2009.
3. Schindel, W., "INCOSE Collaboration In an ASME-Led Standards Activity: Standardizing V&V of Models", INCOSE MBSE Workshop at INCOSE International Workshop, Jacksonville, FL, Jan, 2018, http://www.omgwiki.org/MBSE/lib/exe/fetch.php?media=mbse:patterns:standardizing_v_v_of_models_iw2018_mbse_workshop_report_01.21.2018_v1.2.1.pdf
4. ASME V&V40-20xx draft, "Assessing Credibility of Computational Models through Verification and Validation: Applications to Medical Devices", Draft Nov 2017.
5. Peterson, T., and Schindel, W., "Pattern Based Systems Engineering – Leveraging Model Based Systems Engineering for Cyber-Physical Systems", Proc. of 2014 NDIA Ground Vehicle Systems Engineering and Technology Symposium, Novi, MI, 2014.
6. INCOSE Patterns Working Group, "MBSE Methodology Summary: Pattern-Based Systems Engineering (PBSE), Based On S*MBSE Models", V1.5.5A, retrieve from: http://www.omgwiki.org/MBSE/doku.php?id=mbse:pbse

Thank you.

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- Chris Unger christopher.unger@med.ge.com

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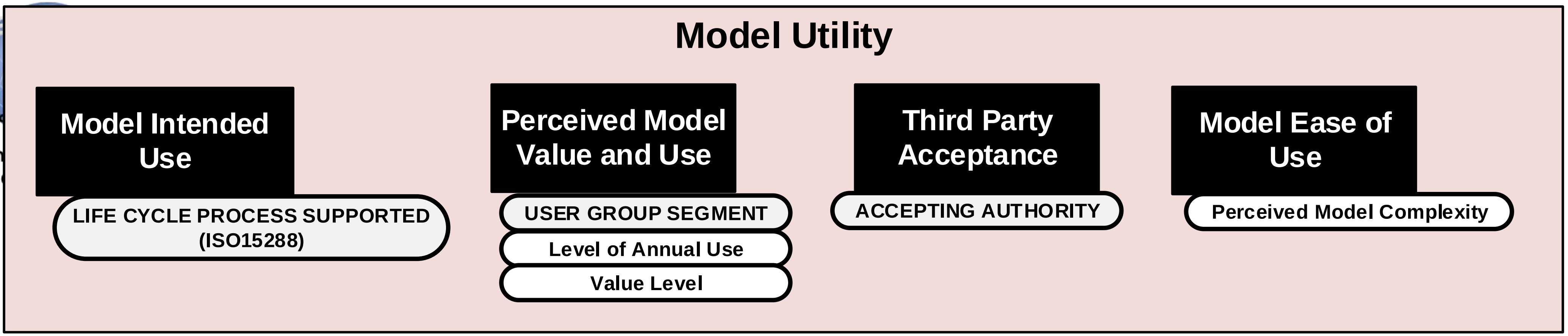
Bob Malins rjmalins@eaglesummittech.com

Supplemental Attachment

- A little more about the Model VVUQ Pattern
- A little more about the Embedded Intelligence Pattern

- For still more, see the References



Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder							Model Type	
					Model User	Model Developer	Model Maintainer	Mdl Deployer-Distributor	Model Use Supporter	Regulatory Authority	Mdl Investor-Owner	Physics Based	Data Driven
Describes the intended use, utility, and value of the model													
Model Utility	Model Intended Use	The intended purpose(s) or use(s) of the model.	Life Cycle Process Supported	The intended life cycle management process to be supported by the model, from the ISO15288 process list. More than one value may be listed.	X					X	X	X	X
	Perceived Model Value and Use	The relative level of value ascribed to the model, by those who use it for its stated purpose.	User Group Segment	The identify of using group segment (multiple)	X					X	X	X	X
			Level of Annual Use	The relative level of annual use by the segment	X					X	X	X	X
			Value Level	The value class associated with the model by that segment	X					X	X	X	X
	Third Party Acceptance	The degree to which the model is accepted as authoritative, by third party regulators, customers, supply chains, and other entities, for its stated purpose.	Accepting Authority	The identity (may be multiple) of regulators, agencies, customers, supply chains, accepting the model	X					X	X	X	X
	Model Ease of Use	The perceived ease with which the model can be used, as experienced by its intended users	Perceived Model Complexity	High, Medium Low	X					X		X	X

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Model Credibility

Model Envelope
- MODEL APPLICATION ENVELOPE

Validated Conceptual Model Credibility
- Quantitative Accuracy Reference
- Function Structure Accuracy Reference
- Uncertainty Quantification (UQ) Reference
- Model Validation Reference

Verified Executable Model Credibility
- Quantitative Accuracy Reference
- Function Structure Accuracy Reference
- Uncertainty Quantification (UQ) Reference
- Speed
- Quantization
- Stability
- Model Validation Reference

Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder: Model User	Model Developer	Model Maintainer	Mdl Deployer	Model Use Supporter	Regulatory Authority	Mdl Investor	Model Type: Physics Based	Data Driven
Describes the credibility of the model													
	Model Envelope	The capability of the model to meet its Model Credibility requirements over a stated range (envelope) of dynamical inputs, outputs, and parameter values.	Model Application Envelope	The range over which the model is intended for use.	X		X			X	X	X	X
	Validated Conceptual Model Credibility	The validated capability of the conceptual portion of the model to represent the System of Interest, with acceptable Credibility.	Quantitative Accuracy Reference	The specification reference describing the quantitative accuracy of the conceptual model compared to the system of interest.	X					X	X	X	X
			Function Structure Accuracy Reference	The specification reference describing the structural (presence or absence of behaviors) accuracy of the conceptual model compared to the system of interest.	X		X			X	X	X	X
			Uncertainty Quantification (UQ) Reference	The specification reference describing the degree of uncertainty of the Credibility of the conceptual model to the system of	X		X			X	X	X	X
			Model Validation Reference	The reference documenting the validation of the conceptual model's Credibility to the system of	X		X			X	X	X	X

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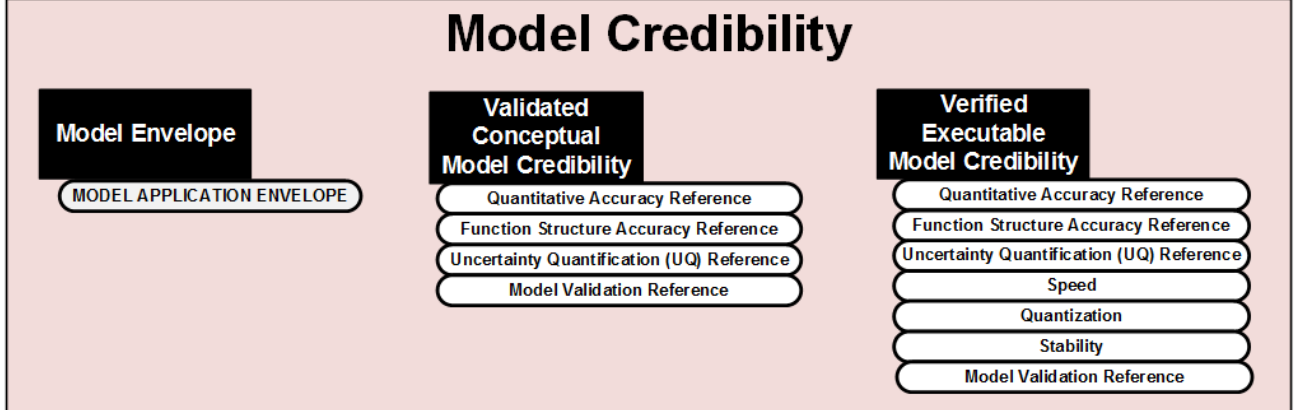

Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder: Model User	Model Developer	Model Maintainer	Mdl Deployer-	Model Use Supporter	Regulatory Authority	Mdl Investor-	Model Type: Physics Based	Data Driven
Model Credibility	Verified Executable Model Credibility	The verified capability of the executable portion of the model to represent the System of Interest, with acceptable Credibility.	Quantitative Accuracy Reference	The specification reference describing the quantitative accuracy of the executable model to the conceptual model.	X		X			X	X	X	X
			Structural Accuracy Reference	The specification reference describing the structural (presence or absence of elements) accuracy of the executable model to the conceptual model.	X		X			X	X	X	X
			Uncertainty Quantification (UQ) Reference	The specification reference describing the degree of uncertainty of the Credibility of the executable model to the conceptual model.	X		X			X		X	X
			Speed	The specification reference describing the execution run time (speed) for the executable model.	X		X			X	X	X	X
			Quantization	The specification reference describing the quantization error of the executabl e model.	X		X			X	X	X	X
			Stability	The specification reference describing the level of stability of the accuracy and uncertainty of the executable model error characteristics.	X		X			X	X	X	X
			Model Validation Reference	The reference documenting the verification of the executable model's Credibility to the conceptual model.	X		X			X	X	X	X

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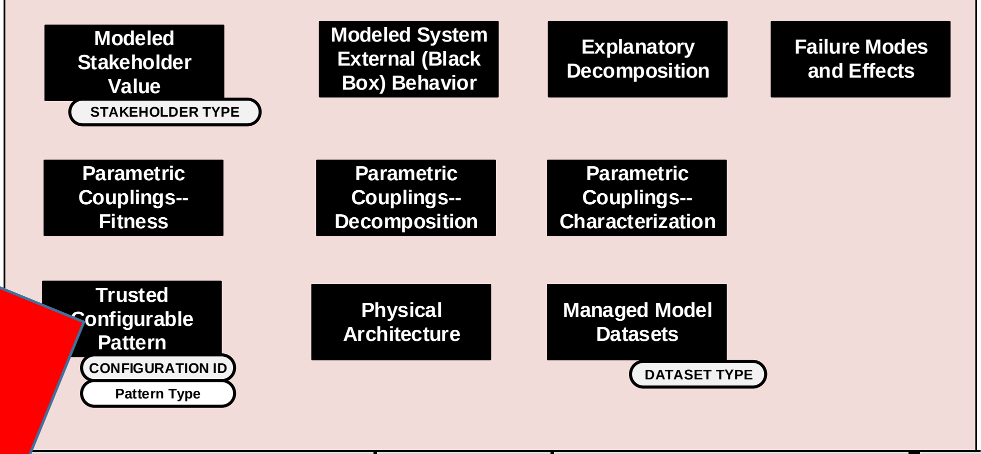
Model Scope and Content

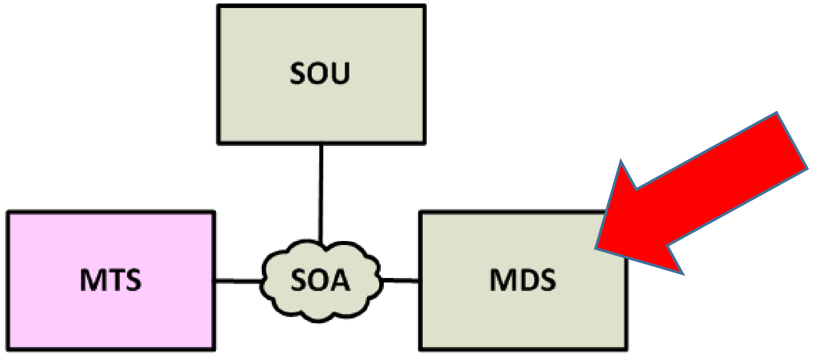


Of special importance to the economics of trust and VVUQ

	[illegible]ame	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder							Model Type	
					Model User	Model Developer	Model Maintainer	Mdl Deployer-Distributor	Model Use Supporter	Regulatory Authority	Mdl Investor-Owner	Physics Based	Data Driven
Describes the scope of content of the model													
	Parametric Couplings--Fitness	The capability of the model to represent quantitative (parametric) couplings between stakeholder-valued measures of effectiveness and objective external black box behavior performance measures.			X					X		X	X
	Parametric Couplings--Decomposition	The capability of the model to represent quantitative (parametric) couplings between objective external black box behavior variables and objective internal white box behavior variables.			X					X		X	X
	Parametric Couplings--Characterization	The capability of the model to represent quantitative (parametric) couplings between objective behavior variables and physical identity (material of construction, part or model number).			X					X		X	
	Managed Model Datasets	The capability of the model to include managed datasets for use as inputs, parametric characterizations, or outputs	Dataset Type	The type(s) of data sets (may be multiple)	X		X			X		X	X
	Trusted Configurable Pattern	The capability of the model to serve as a configurable pattern, representing different modeled system configurations across a common domain, spreading the cost of establishing trusted model frameworks across a community of applications and configurations.	Configuration ID	A specific system of interest configuration within the family that the pattern framework can represent.	X		X			X	X	X	X
			Pattern ID	The identifier of the trusted configurable pattern.	X		X			X	X	X	X

Embedded Intelligence (EI) Pattern

INCOSE Healthcare Working Group
4th Annual Systems Engineering in Healthcare Conference



- Managed System (MDS): Any system behavior whose performance, configuration, faults, security, or accounting are to be managed--referred to as System Management Functional Areas (SMFAs) or in ISO terminology fault, configuration, accounting, performance, security (FCAPS). (*performance = classical controls*)
- These are the roles played by the so-called “physical systems” in a cyber-physical system, providing physical services such as energy conversion, transport, transformation, or otherwise.

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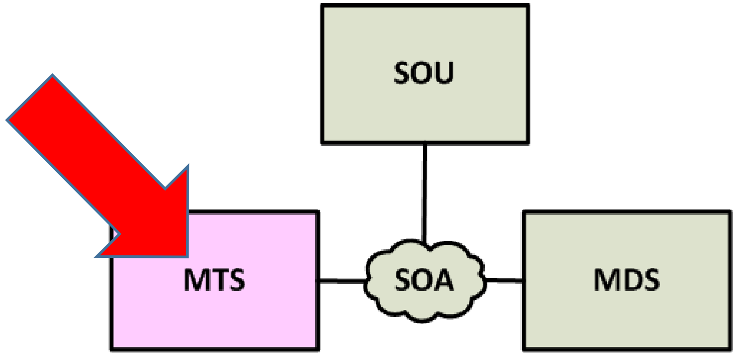
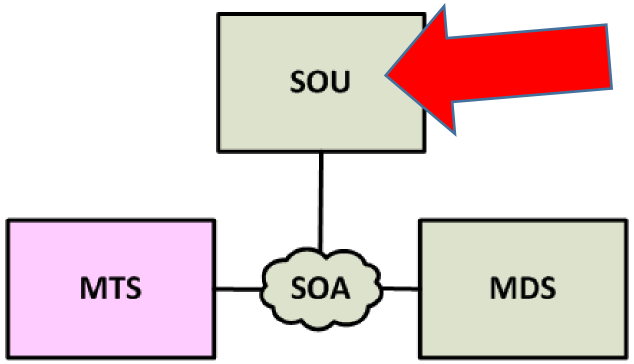
Embedded Intelligence (EI) Pattern



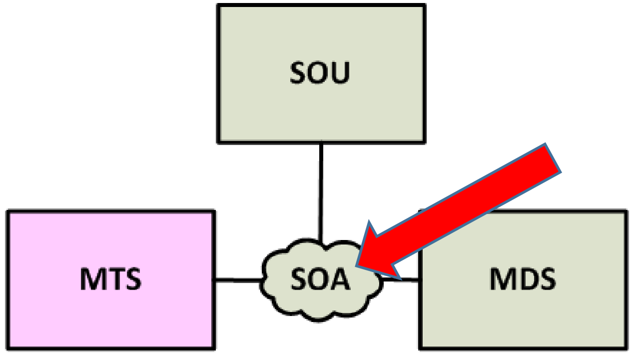
- Management System (MTS): The roles of performing management (active or passive) of any of the SMFAs of the managed system.
- These are so-called “cyber” roles in a cyber-physical system, and may be played by automation technology, human beings, or hybrids thereof, to accomplish regulatory or other management purposes.

Embedded Intelligence (EI) Pattern



- System of Users (SOU): The roles played by a system which consumes the services of an managed system and/or management system, including human system users or other service-consuming systems at higher levels.

Embedded Intelligence (EI) Pattern



- System of Access (SOA): The roles providing a means of interaction between the other EI roles.
- Engineered sensors, actuators, the Internet, and human-machine interfaces have contributed greatly to the emergence of the “Internet of Things”..