ASME Perspective on Increasing Collaboration Across Multiple Engineering Societies and Regulatory Authorities

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Overview

- Standards development has historically been a very reactive process.
- More recently, S&C involvement in new technology areas is much earlier (e.g. additive manufacturing, V&V).
- This requires more interaction with industry to develop guidance or Draft Standards for Trial Use early on even as the technology is developing.
- Increased engagement of other engineering societies and regulatory agencies helps focus early efforts and ensure that sharing of guidance documents and best practices throughout the development process fosters acceleration of innovation.
- Complementary activities to standards are being explored.

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V&V 50: Verification and Validation in Computational Modeling of Advanced Manufacturing

Formed 2015-2016

Charter

- To provide procedures for verification, validation, and uncertainty quantification in modeling and computational simulation for advanced manufacturing

Membership:

- Sudarsan Rachuri, *Chair*, DOE
- Mark Benedict, *Vice Chair,* AFRL Mantech
- Marian Heller, *Secretary*, ASME, HellerME@asme.org
- ~40 members in total, 5 subgroups

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V&V 50: V&V Interactions with the Model Life Cycle Working Group

- No standards exists for maintaining model credibility throughout its life cycle.
- Under the ASME V&V 50 subcommittee, a working group on “Verification and Validation Interactions with the Model Life Cycle” is developing generic guidelines and best practices to address this gap.
- 7 members from industry, INCOSE, and government agencies (NIST and AFRL).
- 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.).

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V&V 40: Verification and Validation in Computational Modeling of Medical Devices

Formed 2010-2011

Charter:

- Provide procedures to standardize verification and validation for computational modeling of medical devices

Membership

- T. Morrison, *Chair*, US Food and Drug Administration
- J. Bischoff, *Vice-Chair,* Zimmer Biomet, Inc.
- M. Horner, *Vice Chair*, ANSYS, Inc.
- Ryan Crane, *Secretary*, ASME **Rcrane@asme.org**
- ~46 members in total

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V&V 40: Verification and Validation in Computational Modeling of Medical Devices

Application of V&V for computational modeling of medical devices

- Increased emphasis on modeling to support device evaluation
- Regulated industry with limited ability to clinically validate models
- Use of modeling hindered by lack of V&V guidance and (regulatory) expectations within medical device community

V&V 40 Standard: Anticipated publication of the draft standard *V&V 40 Assessing Credibility of Computational Modeling and Simulation Results through Verification and Validation: Application to Medical Devices*

- The guide does not discuss 'HOW TO' perform V&V (established elsewhere).
- The framework guides the analyst through the risk-informed credibility assessment framework, which helps determine 'HOW MUCH' V&V is necessary to support using a computational model for a context of use.
- **Model risk drives the rigor of the V&V activities**

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Model Based Enterprise Effort

- NIST has been conducting Model-Based Enterprise (MBE) Summits, in which ASME participated April 2017.
  - In conjunction with the 2017 Summit, ASME hosted an MBE Workshop
  - Planning underway for the 9th Summit in 2018
- New Standards Committee in Formation
  - If interested contact Fred Constantino, ConstantinoF@asme.org
  - Inaugural MBE Committee Meeting planned for 2018 NIST MBE Summit
- 50+ interested members from industry, academia, government agencies and societies include:
  - NIST
  - DOD
  - AMT / MT Connect

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Model Based Enterprise Effort

The proposed committee area of concentration would include:

- types of models and their intended uses;
- rules for representing requirements and constraints;
- types of features and data elements for model-based datasets;
- schemas for datasets;
- creating, managing and using product definition and process definition data;
- managing links between product definition and process definition; rules governing data quality;
- managing discrepancies (between existing standards, data format standards, and other standards that affect Model-Based Definition (MBD) and MBE).

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Beyond Standards: Collaborations and Events

- ASME joins Avicenna Alliance
- 5 Technologies
  - Advanced Manufacturing, Robotics, Healthcare, Pressure Technology, Clean Energy
- Healthcare Initiative: AABME CONNECT
  - May 14, 2018 M&S in Healthcare event
  - Co-located with V&V Symposium

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Thank you!

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