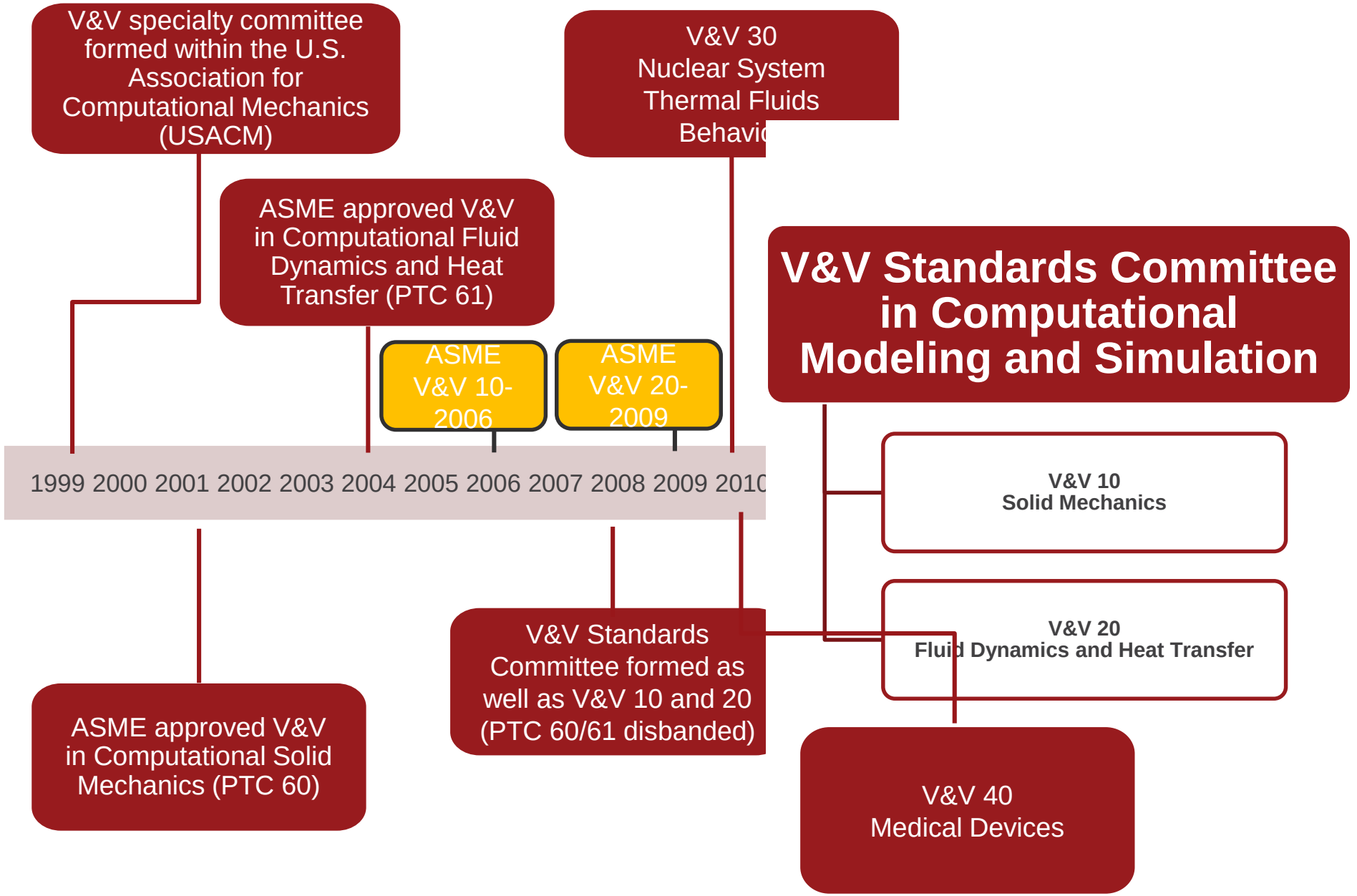
28th Annual INCOSE international symposium
Washington, DC, USA
July 7 - 12, 2018

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

www.incose.org/symp2018

Overview

- ASME – since 1880, a standards development organization, convening stakeholders in technology communities to support innovation and enhance safety.
- Involvement in emerging technology areas is earlier than in the past (e.g. additive manufacturing, V&V).
- Complementary activities to standards are being explored for use early on, even as the technology is developing, e.g. guidance documents or Draft Standards for Trial Use.
- Increased engagement of industry, other engineering societies and regulatory agencies helps focus early efforts and foster acceleration of innovation.


V&V specialty committee formed within the U.S. Association for Computational Mechanics (USACM)
V&V 30 Nuclear System Thermal Fluids Behavi
ASME approved V&V in Computational Fluid Dynamics and Heat Transfer (PTC 61)
ASME V&V 10-2006
ASME V&V 20-2009
V&V Standards Committee in Computational Modeling and Simulation
1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010
V&V 10 Solid Mechanics
V&V 20 Fluid Dynamics and Heat Transfer
ASME approved V&V in Computational Solid Mechanics (PTC 60)
V&V Standards Committee formed as well as V&V 10 and 20 (PTC 60/61 disbanded)
V&V 40 Medical Devices

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

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

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

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
- Fred Constantino, Secretary, ASME, ConstantinoF@asme.org
- ~40 members in total, 5 subgroups

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.).

Model Based Enterprise Effort

- NIST has been conducting Model-Based Enterprise (MBE) Summits, in which ASME participated April 2017 and April 2018.
  - At 2017 Summit, ASME hosted an inaugural brainstorming session
  - At 2018 Summit, ASME conducted a meeting where >40 attendees participated
- Steering group of industry experts to establish a schedule and roadmap for MBE standards committee development.
- If interested contact Fred Constantino, ConstantinoF@asme.org
- 90+ interested members from industry, academia, government agencies and societies include:
  - NIST
  - DOD
  - AMT / MT Connect

Model Based Enterprise Effort

The proposed committee areas 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).

Thank you!

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