



# Accelerating Innovation Effectiveness: New Collaboration Roles for Engineering Societies and Regulators



11<sup>th</sup> Annual INCOSE  
Great Lakes Regional Conference

**SUPERIOR SYSTEM SOLUTIONS FOR  
TODAY'S COMPLEX ENVIRONMENTS**

**11 - 14 October 2017  
Twin Cities, Minnesota**

- **Abstract**: Society benefits from innovation across the dimensions of life, including advancements in aviation and ground transportation, medicine and health care, production of food, energy, communication, and information systems, distribution of products and services, and other evolving systems. In many of these areas, society also depends upon effective regulation to protect us from undue risks involving safety, credibility, and other aspects.
- Sometimes we hear questions of whether the systems of regulation are effective in their balance of reward and risk to society. Not so well known are the collaborative efforts by regulators and technical professional societies (ASME, INCOSE, others) to advance new frameworks in which the expectations of regulators and innovators are recognized on behalf of the society both serve.
- This panel will discuss some contemporary efforts, beyond traditional standards-making of earlier generations, including the perspectives of engineering societies, regulators, and enterprises. The discussion will include consideration of how computational models are changing this environment, and ask questions about the implications for future innovation, and the practical issues of sharing regulatory and industry models and patterns. Part of a continuing conversation intended to engage more of our communities in these efforts.



## Panel Session Time Line (90 minute session)

- Introduction of the session topic and panelists (15 minutes)
- Initial position from each panelist (40 minutes total—10 per panelist)
- Attendee & panel discussion of this subject (35 minutes)

# Innovation and Regulation

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## Verification and Validation Methodologies for Prosthetic Heart Valves: Review and Considerations.

ASME V&V40 Subcommittee  
Heart Valve Subgroup



## Reporting of Computational Modeling Studies in Medical Device Submissions

### Guidance for Industry and Food and Drug Administration Staff

Document issued on: September 21, 2016.

The draft of this document was issued on January 17, 2014.

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U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Office of Science and Engineering Laboratories

# Innovation and Regulation

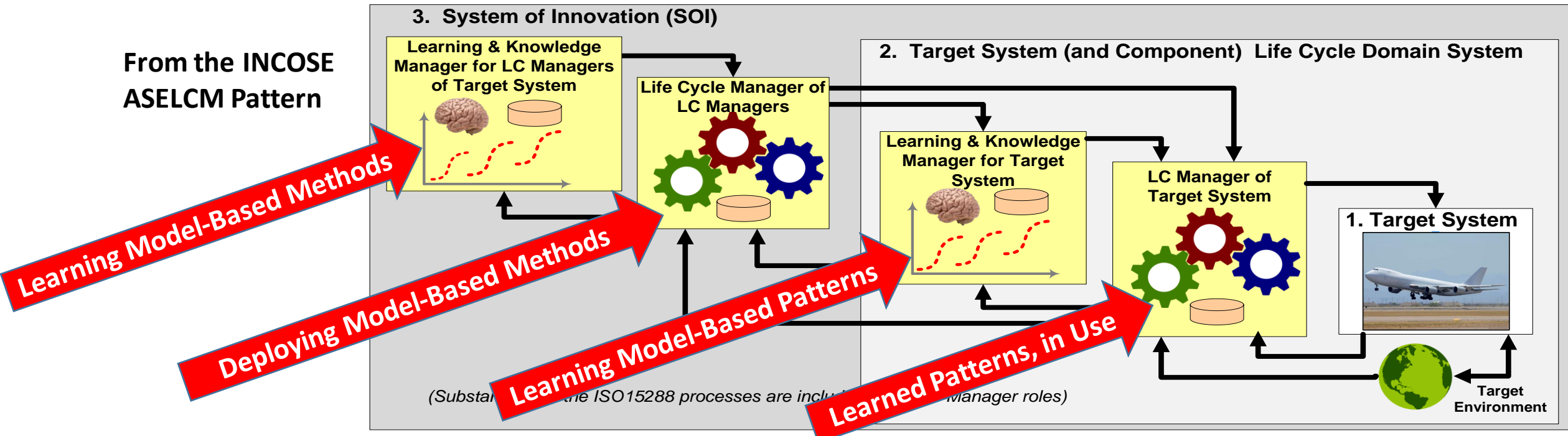
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# Innovation and Regulation

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

- The language of its “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:



# 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., SAE, IEEE)
- Other technical societies and 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)
  - INCOSE International Symposium 2018 (Washington, DC)
  - INCOSE Great Lakes Regional Conference 2018 (IN)
- Indiana private sector aero/medical team standing up a Virtual Verification Institute (V4I), with ASME collaboration from outset



## More than “regulated” domains

- This discussion potentially applies to more than “agency regulated” domains; for example:
  - Defense: In the US, the role of the DoD, NDIA, and suppliers, in defense systems innovation;
  - Educational Policy Domain, innovation, and accreditation
  - Government Policy Domain, innovation, implementation
  - Other domains

# Panelists--Introduction

- GLRC-11 is the first in a series of public panels on this subject at 2017-2018 INCOSE conferences, including INCOSE GLRC for 2017 (MN), INCOSE IS2018 (DC), and INCOSE GLRC for 2018 (IN).
- At the first (GLRC11) panel, engineering society leaders will introduce the conversation, and at the second (IS2018 in DC), they will be joined by regulators. For the GLRC11 panel, those participating are:
  - Moderator: Bill Schindel, Chair of INCOSE MBSE Patterns WG
  - **ASME**: Marian Heller, ASME Initiatives Standards & Certification (NYC)
  - **INCOSE**: Garry Roedler, President-Elect, INCOSE Parent Society
  - **SAE**: Logen Johnson, PE, SAE Aerospace Standards Engineering, SAE International (Washington, DC)
  - **AIAA**: Kristen Gerzina, Chair of Twin Cities AIAA Chapter (MN)



## Panelists: Marian Heller, ASME Initiatives Standards & Certification

- Marian Heller is a mechanical engineer and staff secretary for two of ASME's V&V (verification and validation) standards development committees: V&V 20 Verification and Validation in Computational Fluid Dynamics and Heat Transfer; and V&V 50 Verification and Validation of Computational Modeling for Advanced Manufacturing. Marian serves as Business Development Manager of Healthcare at ASME, exploring ways for ASME to provide greater support to the bioengineering and healthcare industries and increase the positive impact of mechanical engineers. She is also a facilitator, supporting ASME's roadmapping and gap analysis workshops.





## Panelists: Garry Roedler, INCOSE President-Elect

- Garry Roedler is President-Elect of INCOSE, and is Lockheed Martin Fellow and Engineering Outreach Program Manager. He has over thirty years of experience across a variety of leadership roles in programs and systems engineering business functions. Garry is an INCOSE ESEP and INCOSE Fellow, has held significant leadership roles across many other technical and standards organizations, including NDIA, IEEE, and ISO/IEC, and has been recognized a number of times with awards and honors for his leadership contributions to these societies, Lockheed Martin, and to the US Department of Defense.



## Panelists: Logen Johnson, SAE International, Aerospace Standards

- Logen Johnson is an Aerospace Standards Engineer with SAE International base out of Washington, DC. In this role, Logen is responsible for supporting standards development operations for SAE's aerospace standards program. This includes working with the US and global aerospace community on new standards development as well as global strategy and outreach for SAE. Prior to joining SAE, Logen worked with other standard organizations in DC and he holds a BS degree from Wentworth Institute of Technology in Electromechanical Engineering.



## Panelists: Kristen Gerzina, Chair, AIAA Twin Cities

- Kristen Gerzina has been the local chair of the Twin Cities AIAA (American Institute of Aeronautics and Astronautics) since 2011. She is also the Deputy Director, Finance, for the AIAA Region V, and was recently accepted onto the AIAA Applied Aerodynamics Technical Committee.
- Kristen is a Principle Aerospace Engineer with Orbital ATK Armament Systems located in Plymouth, MN and has been with Orbital ATK and in the aerospace and defense industry for over 12 years.

## Panel Moderator: Bill Schindel



- Bill Schindel is a member of the ASME standards team writing guidelines for verification, validation, and uncertainty quantification (VVUQ) essential to regulatory submissions across aviation, medical devices, and other domains. Also a member of INCOSE, Bill chairs the MBSE Patterns Working Group of the INCOSE/OMG MBSE Initiative. He is president of ICTT System Sciences, and has practiced systems engineering for over thirty years, across multiple industry domains. Bill serves as president of the INCOSE Crossroads of America Chapter, is an INCOSE Fellow and Certified Systems Engineering Professional, and a member of AIAA and ASEE.





## Pre-Conference Summaries

- The following are pre-conference summaries submitted by each Society Panelist, for three questions.
- These may be supplemented by other opening slide presentations or statements by the panelists.

### **1: Please summarize your organization's support or position on the subject of collaboration across engineering societies and with regulatory authorities for purposes of advancing frameworks for enhanced innovation on behalf of society:**

- *INCOSE is a systems engineering professional society, so we are uniquely interested in the overall systemic outcomes that result from the work by our engineering colleagues in mechanical, electrical, chemical, software, and other engineering disciplines, creating the products and services vital to our society, in transportation, defense, health care, communications, energy, and other fields. Just as inter-disciplinary collaboration is essential to the individual engineering projects we perform, so also is collaboration of our professional societies essential to advancement in methods of innovation in public systems, as illustrated in regulated domains such as aerospace, automotive, medical devices and pharmaceuticals, advanced manufacturing, and other domains. Balanced protection of the public trust along with “fast enough” accelerating innovation to meet the needs and expectations of society in targeted areas is a key issue for working together as regulators and technical societies.*

### **2. Do you have either current/historical examples or future plans for activities of this kind?**

- *INCOSE has an historical track record of productive liaison with other professional societies and other types of standards-making bodies. In the specific subject of this panel, we have joined with our colleagues in ASME over the last two years to work together on model-based guidelines and standards that include work joined with regulators at FAA and FDA. INCOSE has brought systems emphasis to this, working with our ASME colleagues' own deep knowledge of more specialized computational models, toward guidelines on the verification, validation, and uncertainty quantification (VVUQ) of those models. Our INCOSE technical working groups contribute technically, but INCOSE leadership wants to express support and encouragement here to our colleagues in the other engineering societies for collaboration in this space. Just as in our enterprise projects, leadership commitment to effective collaboration is essential—technical expertise alone is not enough to assure that collaboration. Progress in virtual verification requires commitment to working together effectively.*

### **3. What actions would help address challenges to progress in this space?**

- *The whole notion of trusted models for use in decision-making and innovation is relatively new and unfamiliar to most businesses, but growth in complexity and criticality of systems makes this subject critical to future innovation progress. So, conducting public joint projects to demonstrate the related ideas is important, and we are doing that in our current collaboration. We will also be holding versions of this panel at the INCOSE IS2018 meeting in Washington, DC, where we will be joined by regulators participating in this work. We want to encourage members from across INCOSE, ASME, SAE, AIAA, and other professional societies to participate in this work together.*



## Pre-conference summary: ASME

### **1. Please summarize your organization's support or position on the subject of collaboration across engineering societies and with regulatory authorities for purposes of advancing frameworks for enhanced innovation on behalf of society:**

- *ASME strongly supports collaboration, which supports ASME's mission and is one of our key strategic actions. Through collaboration with peer engineering societies, ASME can enhance its impact, create greater scale, and address cross-discipline engineering challenges. ASME has a long history of collaboration with other engineering societies and with regulatory authorities around the development of standards. Current challenges are enormously complex, far beyond the ability of any single organization to significantly impact them. They demand collaboration on a much wider scale.*

## **2. Do you have either historical examples or future plans for activities of this kind?**

- *ASME's engages actively with regulators (e.g., NRC, DOT, FDA) in our standards development activities, including participation of regulatory members on standards development committees, such as ASME's well-known Boiler Code and V&V standards committees, and adoption of our standards into regulations. We are participating in the America Makes & ANSI Additive Manufacturing Standardization Collaborative (AMSC). ASME has collaborated with other engineering societies on many levels and occasions, including events such as E-Week and National Nanotechnology Day, technical conferences, joint memberships, joint position statements on technology policy, and major initiatives such as Engineering for Change.*
- *ASME also collaborates with other engineering societies through our government relations and public policy initiatives. ASME participates in several coalitions and convenes the annual Engineering Public Policy Symposium, in collaboration with engineering society leaders from 44 engineering organizations representing more than two million engineers.*
- *Future activities include the addition of collaborating partners in the newly formed Alliance of Advanced Biomedical Engineering (AABME), and participation in collaborative initiatives such as ASSESS and the Avicenna Alliance.*

### **3. What actions would help address challenges to progress in this space?**

- *Jointly organized conferences on innovation, perhaps with individual conferences focused on particular challenges; innovation as a theme of E-week; an innovation portal formed and supported by engineering societies. Research into other domains (e.g. non-technical) where there is greater success bringing disparate organizations together, for learning effective best practices.*

## **1. Please summarize your organization's support or position on the subject of collaboration across engineering societies and with regulatory authorities for purposes of advancing frameworks for enhanced innovation on behalf of society:**

- *SAE International has a long, successful and ongoing legacy of leading mobility sector collaborative standards development and lifetime learning amongst various engineering societies, enterprise, and regulators around the world. Both in SAE's ground vehicle and Aerospace standards programs there is shared committee membership amongst engineering societies and a continuous push for increased awareness and participation from global interested parties. A notable example of support for collaboration amongst many stakeholders is SAE's Aerospace Council which is the most active global governance structure in standards to date (with seats for up to 30 stakeholder representatives, it includes OEMs, MROs, Government Agencies, Regulatory bodies, and academia from around the world). This provides significant standards reach into the industry around the world. More than half the members are from organizations outside of the US and more than half of their meetings are outside of the US.*
- *Furthermore, the involvement of government agencies is integral to SAE standards. FAA, EASA and DoD are all represented on the SAE Aerospace Council, with the UK MoD and ICAO also playing a strong role in the SAE standards program.*

## **2. Do you have either historical examples or future plans for activities of this kind?**

- *Within SAE, the AE-7M Aerospace Model Based Engineering committee is creating standards for aircraft electrical power systems modeling, simulation, validation and verifications methods.*
- *SAE's G-33 Configuration Management committee prepares positions on government policies, practices, specifications, and standards dealing with technical data, drawing practices, and configuration management practices. It promotes understanding of configuration and data management principles, and develops standards. The committee provides innovative solutions and educational services through workshops and related publications.*
- *SAE's Integrated Vehicle Health Monitoring (IVHM) steering group and Health monitoring (HM-1) standards committee are working on standards related to system level data collection for the purpose of predictive maintenance, predictive analysis, and prognostics.*
- *The 2017 SAE Aerospace Standards Summit included a panel session on MBSE led by INCOSE President Alan Harding. Panel included INCOSE, UK MoD, UTAS, and Airbus*
- *SAE staff participate on a number of standards committees outside SAE with the intent of pursuing harmonized standards development and avoiding duplication of efforts. One example is a SAE participation in an ANSI UAS collaborative workshop and well as a similar ANSI effort for Additive Manufacturing.*
- *SAE regularly presents at, attends, sponsors, and hosts industry wide events to listen, learn and inform others about collaborate efforts in a technical area.*



## Pre-conference summary: SAE

*Examples of SAE collaborating with regulators and government agencies:*

- SAE has proven experience in transitioning government standards to industry standards and was chosen to take on and maintain the largest number of Mil-Specs (around 1,500) during Mil-Spec Reform between 1997-2004*
- 3,400 SAE standards have been adopted by US DoD for procurement processes, and over 400 SAE standards are referenced in FAA regulatory documents – almost 150 in the case of the European Aviation Safety Agency and 34 at the ICAO global level.*
- SAE receives requests from ICAO, FAA, DoD and EASA to create specific standards with the expectation and trust that the open consensus standards development process will take place around a global table*
- SAE created the Defense Automotive Technologies Consortium (DATC) with the objective of providing members from private industry, not-for-profit and academia opportunities to develop and transition advanced automotive technologies to all branches of military and government agencies.*

## Pre-conference summary: SAE

*Examples of SAE's reputation on the global arena include:*

- Signed MOU with NATO*
- Invited participant in ICAO's Standards Roundtable*
- Large presence in Asia with offices in London, Paris, Brussel and Shanghai and affiliates in India and Brazil.*
- Connections with aerospace industry associations in USA, France, Europe, UK, Russia and Brazil*
- Representation from technical experts and leaders residing in over 50 countries*
- Invited seat at the table with USTR providing standards policy guidance during trade negotiations (e.g., the US-EU TransAtlantic Trade Investment Partnership)*

### **3. What actions would help address challenges to progress in this space?**

- *Digital technology is here and playing an ever more important role in Industry. Many organizations are focusing on technologies that enable a broad range of opportunities, including digital twin, the Internet of Things and big data analytics to drive productivity, quality and cost improvements throughout the product lifecycle. SAE's Digital Systems Steering Group will help to alleviate disparate digital activities by coordinating industry consensus standard development within SAE, supporting industry cohesion and certification. The Steering Group's activity will be critical in shaping a digitally integrated approach to design, manufacturing, operations and maintenance in the mobility sector through consensus standards and other materials.*

## **1. Please summarize your organization's support or position on the subject of collaboration across engineering societies and with regulatory authorities for purposes of advancing frameworks for enhanced innovation on behalf of society:**

- Our local AIAA section is very supportive of collaboration across engineering societies in order to maximize our collective resources and allow for interaction between members with shared interests. Often, locally, collaboration between societies including AIAA exists for certain activities like technical lectures, or training / professional development where information and lessons learned can be shared. Additionally, societies collaborate or at events that are STEM and Outreach focused and which may expose those societies to authorities in government or regulatory areas. Locally, our AIAA section has a renewed public policy drive to promote policy matters that are of interest to our members in the aerospace industry and which bring these policy matters to the attention of government and regulatory authorities. Locally, we feel it is important to keep government and regulatory agencies informed of the contributions of the local aerospace industry and the issues that are important to this industry, especially in how it relates to society as a whole. As an overall organization, AIAA is supportive of collaboration both with other societies and certainly with government and regulatory agencies. The AIAA organization also promotes the advancement of technology including, technology advancement in how it would pertain to the benefit of society.*

## 2. Do you have either historical examples or future plans for activities of this kind?

- *Our local AIAA section has partnered with the local Institute of Navigation (ION) for the past many years on a technical lecture series to discuss some of the latest technologies in the fields of Guidance, Navigation, and Control, and how it relates to different aspects of the aerospace industry, like UAV's for example. Our local AIAA section, along with the other sections represented on this panel, are a part of the Minnesota Federation of Engineering, Science, and Technical Societies (MFESTS). One of MFESTS main objectives is for collaboration and unity amongst our local technical societies for the purpose of knowledge sharing, resource maximization, increased exposure, and the overall betterment of all its members societies. Our AIAA society has only been a part of MFESTS for about the past four years, but even in this short time our organization has benefited from additional collaboration and invitations to other society functions, an expanded local network, and some great lessons learned. In regards to collaboration with regulatory authorities, our local section has had some collaboration with government representatives in the past. Each year our local section sends representatives to the annual AIAA Congressional Visits Day, which provides AIAA members an opportunity to represent their section and meet with the offices of their section representatives in order to discuss aerospace public policy matters of importance. Our local section works to keep contact with state and national representatives throughout the year. In regards to future activities, as North Dakota is part of our local AIAA section, it is a very real possibility that there could be future collaboration with regulatory authorities as it pertains to the growing UAS/UAV testing in that state, for example. This type of activity has important impacts both the aerospace industry and to society. The national AIAA organization is involved in aspects of UAV/UAS development and testing, and also in the regulations surrounding this industry.*



## 3. What actions would help address challenges to progress in this space? :

- Information exchange and knowledge sharing. Effective communication with other societies and regulatory industries is also very important, but first and foremost the different societies and regulatory industries need to know about each other, their goals and mission, and most importantly, how we can collaborate in a mutually beneficial way. Once the different organizations are aware of one another, the next challenge is simply getting an effective and productive audience with one another. Perhaps this is where collaborative amongst other engineering societies is key. Often times there are overlaps between different societies and the key regulatory agencies. Effective unity and collaboration amongst different engineering societies can help push pertinent technology forward, but in regards to collaboration with regulatory agencies, a stronger ‘united front’ across multiple engineering societies might allow for a better audience and collaborative process with regulatory agencies. Additionally, sometimes there seems to be a disconnect between the local professional societies and their national organizations. Locally, our sections are involved in direct collaborations. At a national level, I know what my organization is involved with, but I don’t necessarily know what resources or contacts are available at that same level in other organizations. It seems that locally, societies could collaborate and are already doing so. However, if societies are interested in collaborating for the purpose driving technological and societal impacts, turning local collaboration, especially with regulatory agencies, into a more national level collaboration seems an uphill battle. A challenge is getting the support and a ‘united’ front amongst collaborating societies at higher levels than just the local level. I know sometimes impact has to be driven from the bottom up. And I know what matters are important to my society as a whole and how that translates into what is done at a local level. But, if collaboration amongst societies and with regulators is key, then this collaboration should be driven in both direction – from the top down and also from the bottom up.*

# References

1. Hightower, Joseph, “Establishing Model Credibility Using Verification and Validation”, INCOSE MBSE Workshop, IW2017, Los Angeles, January, 2017.  
[http://www.omgwiki.org/MBSE/lib/exe/fetch.php?media=mbse:incose\\_mbse\\_iw\\_2017:models\\_and\\_uncertainty\\_in\\_decision\\_making\\_rev\\_a.pptx](http://www.omgwiki.org/MBSE/lib/exe/fetch.php?media=mbse:incose_mbse_iw_2017:models_and_uncertainty_in_decision_making_rev_a.pptx)
2. Schindel, W., “Agile Health Care Systems and Comfort Zones: Are We Thinking Broadly Enough?”, Proc. of INCOSE 2017 Conference on Agile Health Care Systems, Chicago, IL, May, 2017, download from [http://www.omgwiki.org/MBSE/lib/exe/fetch.php?media=mbse:patterns:incose\\_ahcs\\_conf\\_2017\\_--are\\_we\\_thinking\\_broadly\\_enough\\_v1.2.4.pdf](http://www.omgwiki.org/MBSE/lib/exe/fetch.php?media=mbse:patterns:incose_ahcs_conf_2017_--are_we_thinking_broadly_enough_v1.2.4.pdf)
3. Moorcraft, D., “V&V 10: Verification and Validation in Computational Solid Mechanics”, Proc. of ASME V&V Symposium, May, 2017.
4. Morrison, T., “What is needed to bring computational models to the clinic?”, Proc. of ASME V&V Symposium, May, 2017.
5. Morrison, T., “Reporting of Computational Modeling Studies in Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff”, US FDA, September 21, 2016
6. Wizemann, T., ed., “Public Health Effectiveness of the FDA 510(k) Clearance Process: Balancing Patient Safety and Innovation: Workshop Report”, Institute of Medicine of the National Academies, Institute of Medicine. National Academies Press. Washington, DC. 2010. <https://doi.org/10.17226/12960>
7. Makower, J., and Meer, A., “FDA Impact on US Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies”, Medical Device Manufacturers Association (MDMA) Nov, 2010.

# References

8. Assessing the Reliability of Complex Models: Mathematical and Statistical Foundations of Verification, Validation, and Uncertainty Quantification ISBN 978-0-309-25634-6 THE NATIONAL ACADEMIES PRESS, <http://nap.edu/13395>
9. Box, G., and N. Draper. *Empirical Model Building and Response Surfaces*. New York: Wiley, 1987.
10. Beihoff, B., et al, “A World in Motion: INCOSE Vision 2025”, INCOSE.
11. Schindel, W., and Dove, R., “Introduction to the Agile Systems Engineering Life Cycle MBSE Pattern”, in Proc. of INCOSE 2016 International Symposium, 2016.
12. Schindel, W., “Got Phenomena? Science-Based Disciplines for Emerging Systems Challenges”, Proc. of INCOSE IS2017 Symposium, Adelaide, UK, 2017.
13. “ASME V&V 10-2006: Guide for Verification and Validation in Computational Solid Mechanics”, ASME, 2006.
14. “ASME V&V 20-2009: Standard for Verification and Validation in Computational Fluid Dynamics and Heat Transfer”, ASME, 2009.
15. “ASME V&V 10.1-2012: An Illustration of the Concepts of Verification and Validation in Computational Solid Mechanics”, ASME, 2012.
16. AIAA (American Institute for Aeronautics and Astronautics). 1998. *Guide for the Verification and Validation of Computational Fluid Dynamics Simulations*. Reston, Va.: AIAA.

# References

17. *Journal of Verification, Validation, and Uncertainty Quantification*, ASME.  
<https://verification.asmedigitalcollection.asme.org/journal.aspx>
18. INCOSE MBSE Initiative Patterns Working Group web site, at  
<http://www.omgwiki.org/MBSE/doku.php?id=mbse:patterns:patterns>
19. 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>
20. INCOSE web site, systems related standards section: <http://www.incose.org/AboutSE/SEStandards>
21. FDA web site, medical devices section: <https://www.fda.gov/MedicalDevices/default.htm>
22. FAA web site, aircraft certification section:  
[https://www.faa.gov/licenses\\_certificates/aircraft\\_certification/](https://www.faa.gov/licenses_certificates/aircraft_certification/)
23. SAE web site, aerospace standards section: <http://standards.sae.org/aerospace/>
24. AIAA web site, aerospace standards section: <http://www.aiaa.org/standards/>
25. ASME web site, computational models VVUQ section:  
<https://cstools.asme.org/csconnect/CommitteePages.cfm?Committee=100003367>