Accelerating Innovation Effectiveness: Model-Facilitated Collaboration by Regulators, Technical Societies, Customers, and Suppliers

28th Annual INCOSE
International Symposium

Delivering Systems in the Age of Globalization

July 7 – 12, 2018
Washington, DC

- **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.

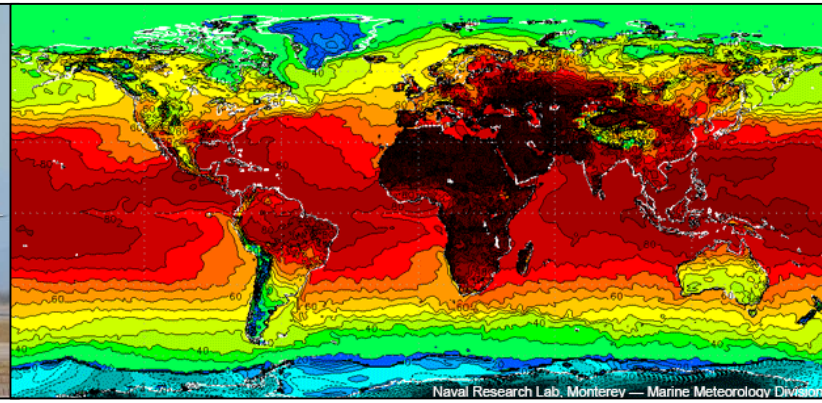
Panel Session Time Line

- Introduction of the session topic and panelists (15 minutes)
- Position discussion from each panelist (90 minutes total)
- Attendee & panel discussion of this subject (15 minutes)

Innovation and Regulation

- Society benefits from innovation across the dimensions of life, including advancements in aviation and ground transport, medicine and health care, production of food, energy, communication, and information systems, distribution of products and services, and other evolving systems.



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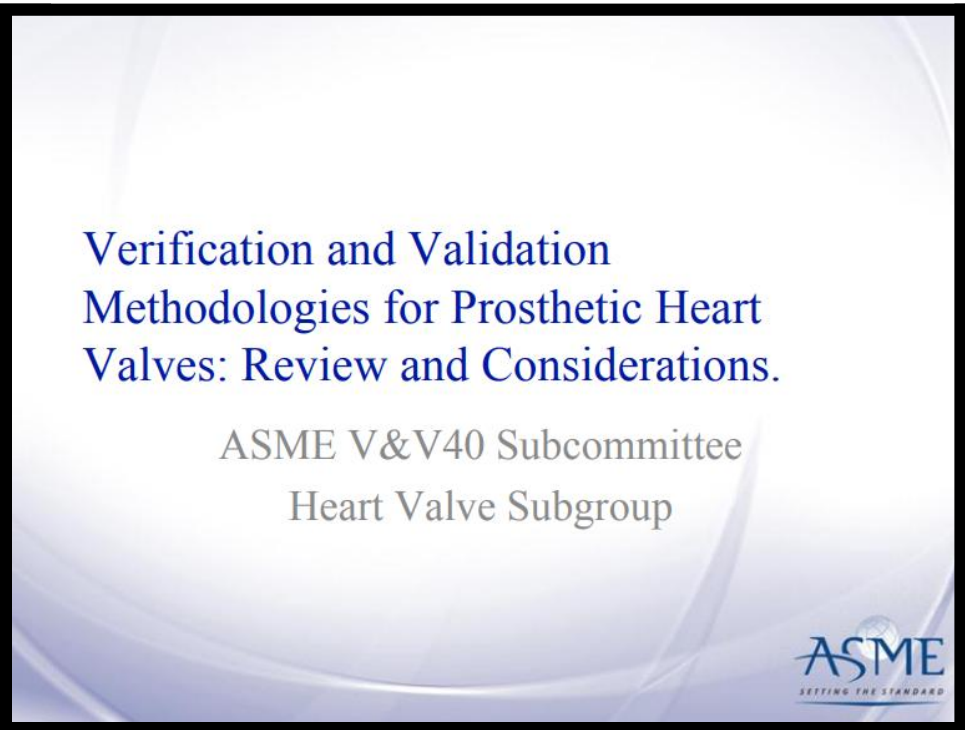

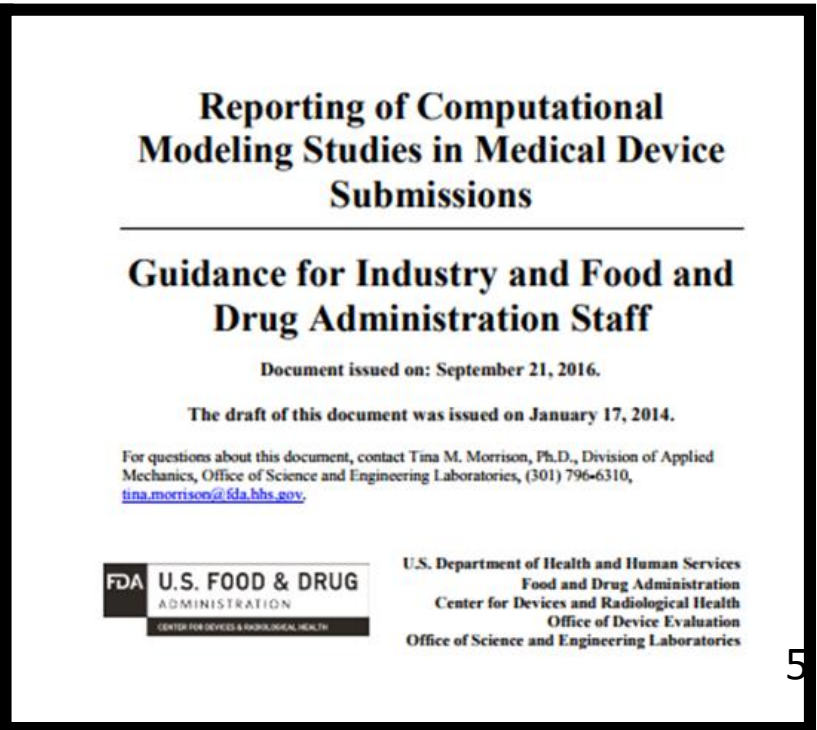

Innovation and Regulation

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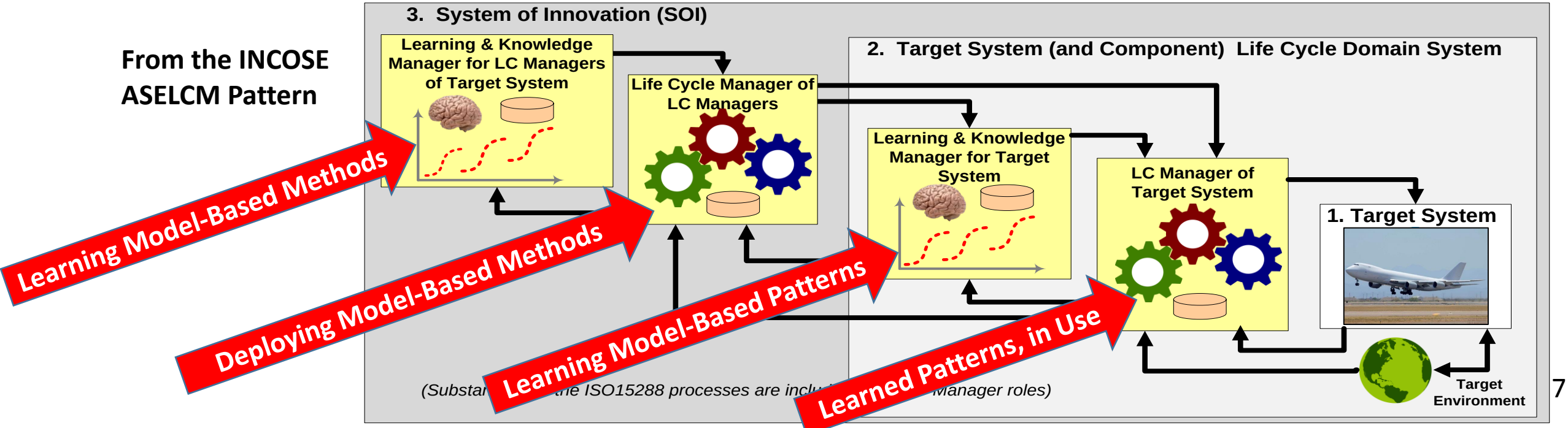
Innovation and Regulation

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.

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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)
- Other technical societies and trade groups discussing this interest (e.g., AIAA)
- Public forum discussion and panel interests for:
  - 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 applies to more than "agency regulated" domains; e.g.:
  - 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

- Series of public panels on this subject at 2017-2018 INCOSE conferences: INCOSE GLRC for 2017 (MN), INCOSE IS2018 (DC), and INCOSE GLRC for 2018 (IN).
- At the first (GLRC11) panel, engineering society leaders introduced the conversation, and at this second (IS2018 in DC), they are joined by the regulatory perspective. For the IS2018 panel, those participating are:
  - **Moderator**: Bill Schindel, Chair of INCOSE MBSE Patterns Working Group
  - **FDA**: Dr. Tina Morrison, Deputy Director, Division of Applied Mechanics, FDA Office of Science and Engineering Laboratories (DC)
  - **FAA**: Dr. Joseph Pellettiere, FAA Chief Scientific and Technical Advisor for Crash Dynamics
  - **ASME**: Marian Heller, ASME Initiatives Standards & Certification (NYC)
  - **INCOSE**: Troy Peterson, AD for Model Based Transformation
  - **NAVAIR**: Steven A. Donaldson, Head, NAVAIR Aeromechanics Engineering Division
  - **SAE**: Logen Johnson, PE, SAE Aerospace Standards Engineering, SAE International (DC)

Panelists: Dr. Tina Morrison, Deputy Director, Division of Applied Mechanics, FDA Office of Science and Engineering Laboratories

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Dr. Tina Morrison is the chair of the new FDA-wide working group on Modelling and Simulation (M&S), in the Office of the Chief Scientist. She has been serving as the Regulatory Advisor of M&S for the Center for Devices and Radiological Health (CDRH) since 2012. In that capacity, she leads the Regulatory Review of Computational Modelling working group, which has developed guidance documents on the use of M&S in the regulatory evaluation of medical devices [1]. She dedicates much of her energy towards advancing regulatory science with M&S because she believes the future of medical device design and evaluation, and thus enhanced patient care, lies with computation and enhanced visualization [2]. She serves as Chair of the ASME V&V Standards Committee on Verification and Validation of Computational Modelling, the Subcommittee V&V40 for Medical Devices, where she is leading the development of a strategy to assess the credibility of computational models [3]. She is also working with a team at CDRH to implement this strategy into the review of submissions that leverage M&S [4]. For seven years, she was a scientific reviewer on a variety of medical device submissions in Cardiovascular Devices. She is the Deputy Director of the Division of Applied Mechanics in FDA's Office of Science and Engineering Laboratories. She is a mechanical engineer who received her PhD in Theoretical and Applied Mechanics from Cornell University in 2006.

Panelists: Dr. Joseph Pellettiere, FAA Chief Scientific and Technical Advisor for Crash Dynamics, Federal Aviation Administration

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Dr. Joseph Pellettiere supports the development of occupant injury criteria as they apply to Aerospace systems and the application of these criteria to the certification of aircraft structure, seats, and cabin interiors. He has been heavily involved in the development of processes and procedures of analysis methods within the certification process with the ultimate goal of seat certification by analysis. Dr. Pellettiere has also supported transport, rotorcraft and small airplane certification programs. Current focal projects include the investigation of full scale test methods and analytical techniques to support system level crash worthiness for both metallic and composite aircraft.

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: Steven A. Donaldson, NAVAIR Aeromechanics Engineering Division Head

- Steven Donaldson currently serves as the Head of the Aeromechanics Engineering Division at the Naval Air Systems Command. This national engineering division is comprised of approximately 160 personnel responsible for delivering aeromechanical engineering products and services for all acquisition and sustainment engineering activities for Naval Aviation. He is responsible for the planning, direction, and execution of the Research and Engineering efforts related to the development and sustainment of Naval Aviation assets across the technical disciplines within the division including Applied Aerodynamics, Stability & Control, Aircraft Performance, Flight Controls, Store Separation, and Flight Vehicle Modeling and Simulation.
- Mr. Donaldson currently serves on the Board of Directors for the Department of Defense (DoD) High Performance Computing Modernization Program Computer Research and Engineering Acquisition Tools and Environments (CREATE) Air Vehicles Project whose charter is to develop and deploy computational engineering tools that address the needs of the air vehicle acquisition programs across the DoD.

Panelists: Troy Peterson
INCOSE AD for Model-Based Transformation

- Troy Peterson is a Vice President and Fellow with System Strategy, Inc. (SSI) where he is providing consulting services to help clients conceptualize and design for the deep interdependencies inherent in today's cyber-physical systems. Before joining SSI, Troy was Booz Allen's Chief Systems Engineer and a Booz Allen Fellow. Prior to this Troy worked at Ford Motor Company and as an entrepreneur operating a design and management consulting business.
- Troy is INCOSE's Assistant Director for Transformational within INCOSE and is the champion for accelerating the transformation of systems engineering to a model based discipline. Troy is also co-chair of the MBSE Patterns WG and Past President of the INCOSE Michigan Chapter.
- Troy has led several large projects in the delivery of complex systems and has instituted several methodologies to speed innovation. His experience spans commercial, government and academic environments across all product lifecycle phases. He has been appointed to several boards to improve engineering education and application. Troy is also a frequent speaker at leading engineering conferences.
- Troy received his BS ME from MSU, his MS in TechMgmt from RPI and an advanced graduate certificate in Systems Design and Management from MIT. He also holds INCOSE CSEP, PMI PMP and ASQ SSBB certifications

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.

ICTT System Sciences®
Understand your systems.

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.

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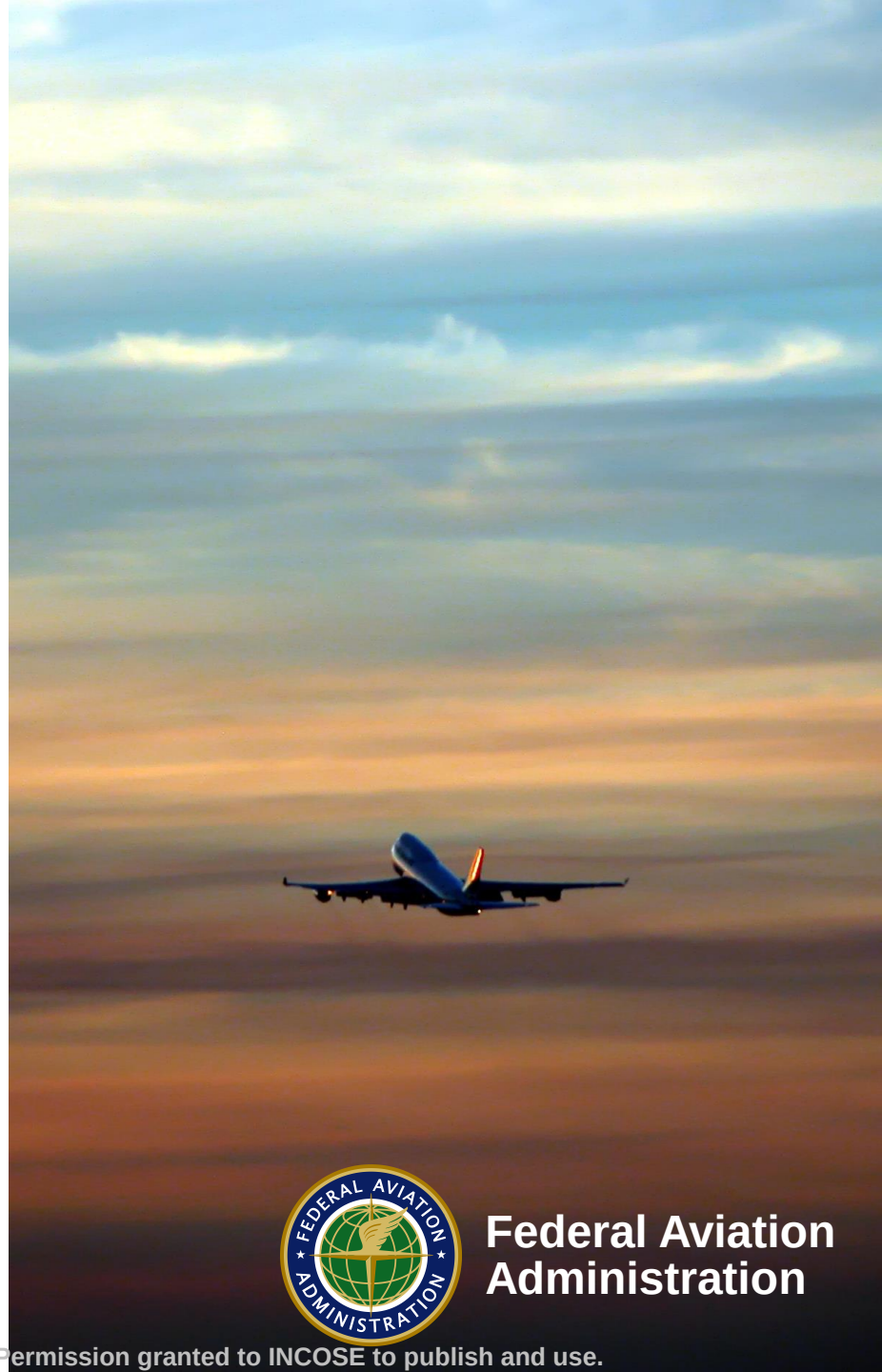
Accelerating Innovation Effectiveness: Model-Facilitated Collaboration by Regulators, Technical Societies, Customers, and Suppliers

Federal Aviation Administration



Presented to: INCOSE International Symposium

By: Joseph Pellettiere, Chief Scientific and Technical Advisor for Crash Dynamics, FAA

Date: July 2018

Disclaimer

- **Certification approvals are based on federal regulations, official FAA policy, and certification engineers – not research opinions**

Certification of Aircraft Articles

- **How do you certify an article?**
  - Demonstrate compliance with the applicable regulations
  - Sometimes in a single step and can be part of certification at aircraft level
  - Oftentimes, articles approved to an industry standard, then compliance to the applicable regulation is later demonstrated
    - Technical Standard Order (TSO)
  - Generally, compliance is through physical testing!

Certification of Aircraft Articles

- **If regulation/policy states testing *OR* analysis, applicant can use analytical modeling without a deviation**
- **Example: Advisory Circular 20-146 provides guidance for seats on:**
  - How to validate the computer model
  - Under what conditions the model may be used in support of original certification and design changes
  - If proposing to model vs. test, supply data proving model represents testing conditions/environment
- **FAA considering development of general M&S guidance**

Certification by Analysis

- **AC 20-146a**
  - Completed FAA comments
  - Completed Public comments – awaiting tech writer/legal review
- **New master AC**
  - Include AC 20-146a, but make generally applicable
- **ASME V&V 10**
  - Overarching validation document
- **SAE ARP 5765B**
  - Working on expanding
- **LSDYNA Aerospace Working Group**
  - Data sharing resolved, activities moving forward
- **Industry Processes**
  - Reviewing proposals and working to implement

FAA AC 20-146

- **Methodology for Dynamic Seat Certification by Analysis**
- **Provides high-level guidance on the validation of seat models**
- **Defines the conditions under which computer modeling can be used in support of certification**
- **Applicants using for case analysis**
- **AC 20-146a Revision**
  - Completed public comments
  - In Queue for tech writer and legal review before release

SAE ARP 5765

SAE International

Objectives

ARP5765: Analytical Methods for Aircraft Seat Design and Evaluation

The primary objectives are to provide

- Quantitative method to measure and evaluate the degree of correlation between a model and a physical test
- Best modeling practices to improve the accuracy and predictability of seat analyses

Participants

•Technical Specialist from

•Seat Suppliers
- Weber / Zodiac
- IPECO
- Recaro/Adient
- Sicma
- B/E Aerospace
- Contour

•A/C Manufacturers
- Airbus
- Cessna
- Embraer
- Boeing
- Gulfstream

•Software
- FTSS
- TASS
- ESI
- Altair

Regulatory
- FAA
- EASA

Academic
- NIAR
- VT

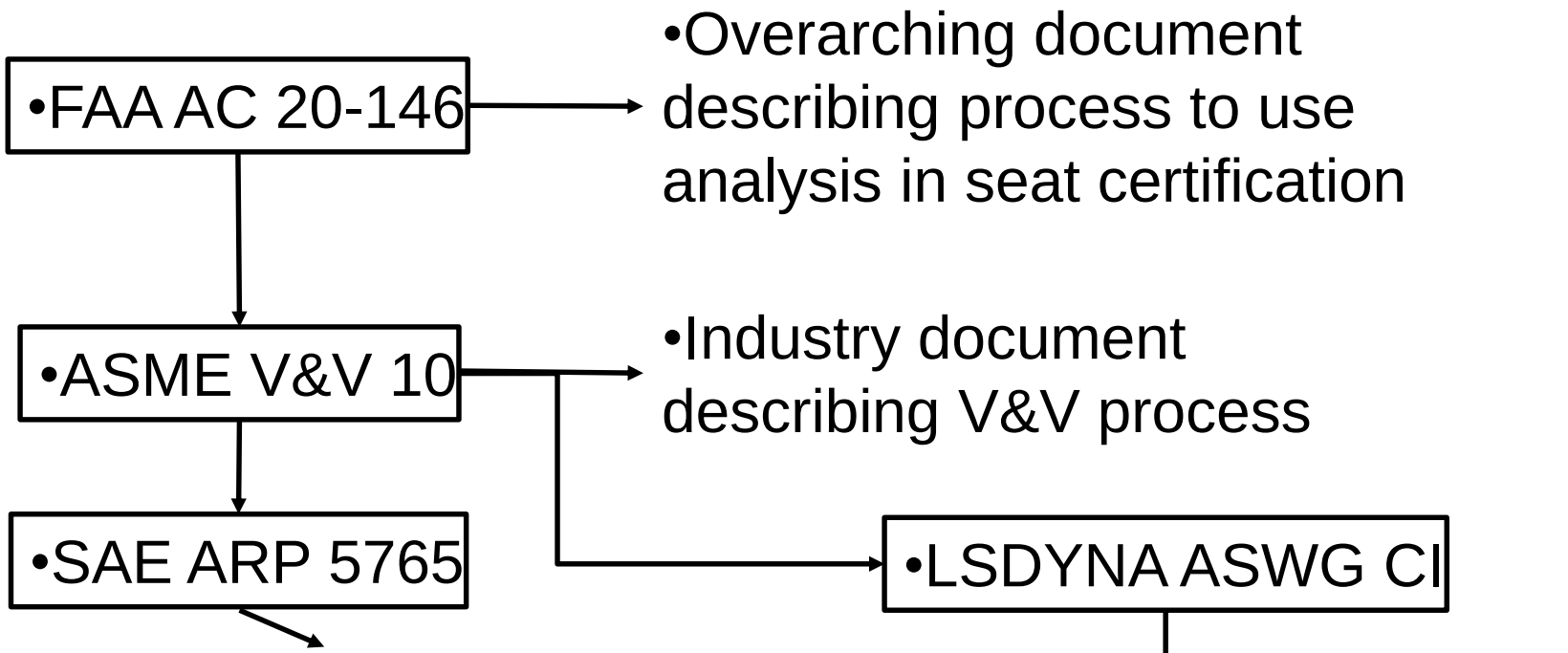
ASME V&V 10

- **ASME committee focused on writing consensus standards on verification and validation (ANSI approved)**
- **Membership includes multiple national laboratories (LLNL, LANL, SNL), DoD, FAA, GM, Boeing, non-profits (SWRI), universities, and consultants**
- **2 documents published, 2 under development**

ASME V&V 10-2006

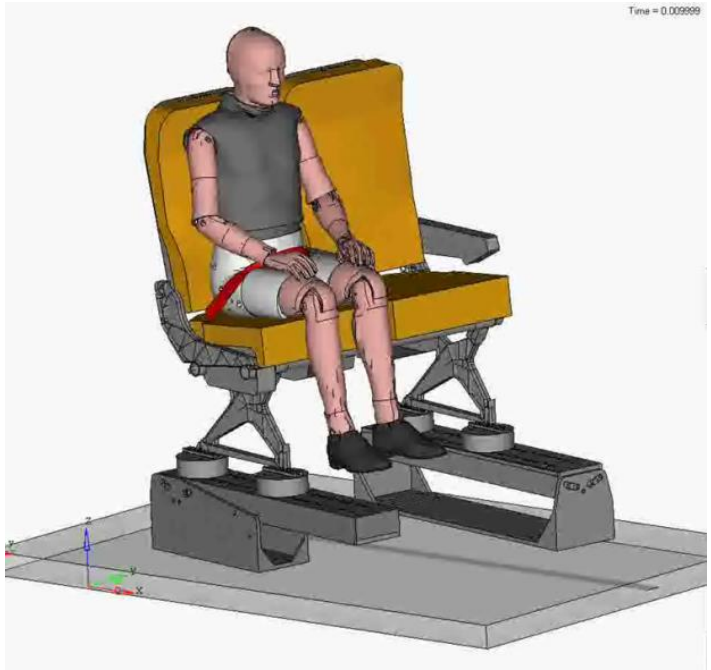
- Guide for Verification and Validation in Computational Solid Mechanics
- High level document that provides a framework for implementing verification and validation of computational models for complex systems in solid mechanics
- Provides a common language and process definition
- ASME V&V 10.1-2012: An Illustration of the Concepts of Verification and Validation in Computational Solid Mechanics

M&S Guidance - Process



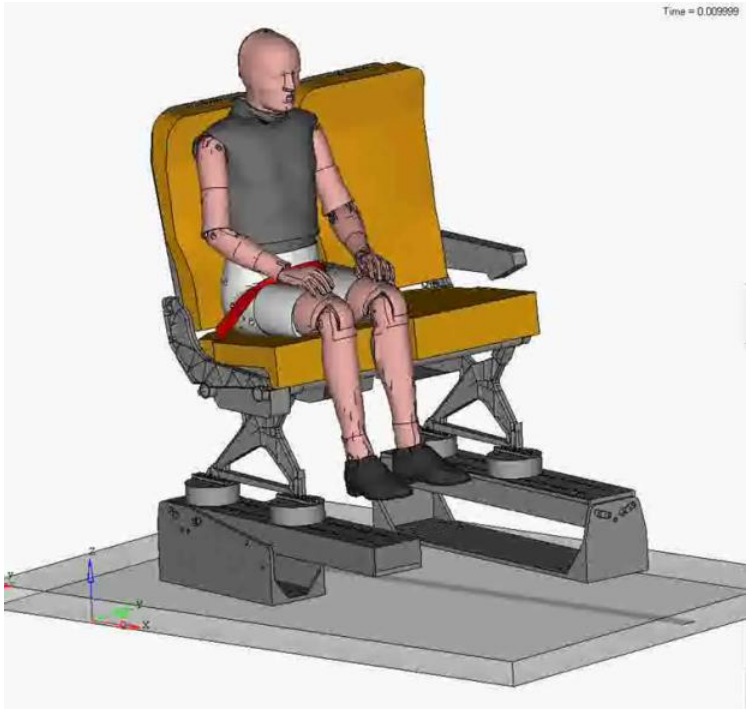
Outreach

- **Dynamic Impact Analytical Methods training course**
  - Training for AC 20-146 and SAE ARP 5765; Combined training with other disciplines
    - Birdstrike/Engine/Structures
    - Goal to work on master AC
- **FAA working with academia and NASA to expand publically available information**
  - Most industry work is proprietary



Outreach

- **Participation in Technical Societies**
  - ASME
  - SAE International
  - ASTM
- **Suppliers**
  - LSTC LS-Dyna Aerospace Working Group
  - Humanetics – v-ATD models
- **Industry Support**
  - Review of process proposals



Questions?

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

Marian Heller
Business Development Manager, Healthcare
ASME
HellerME@asme.org

ASME
SETTING THE STANDARD

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.

ASME
SETTING THE STANDARD

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

ASME
SETTING THE STANDARD

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.).

ASME
SETTING THE STANDARD

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

ASME
SETTING THE STANDARD

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**

ASME
SETTING THE STANDARD

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!

Marian Heller

ASME

HellerME@asme.org

28th Annual INCOSE international symposium

Washington, DC, USA
July 7 - 12, 2018

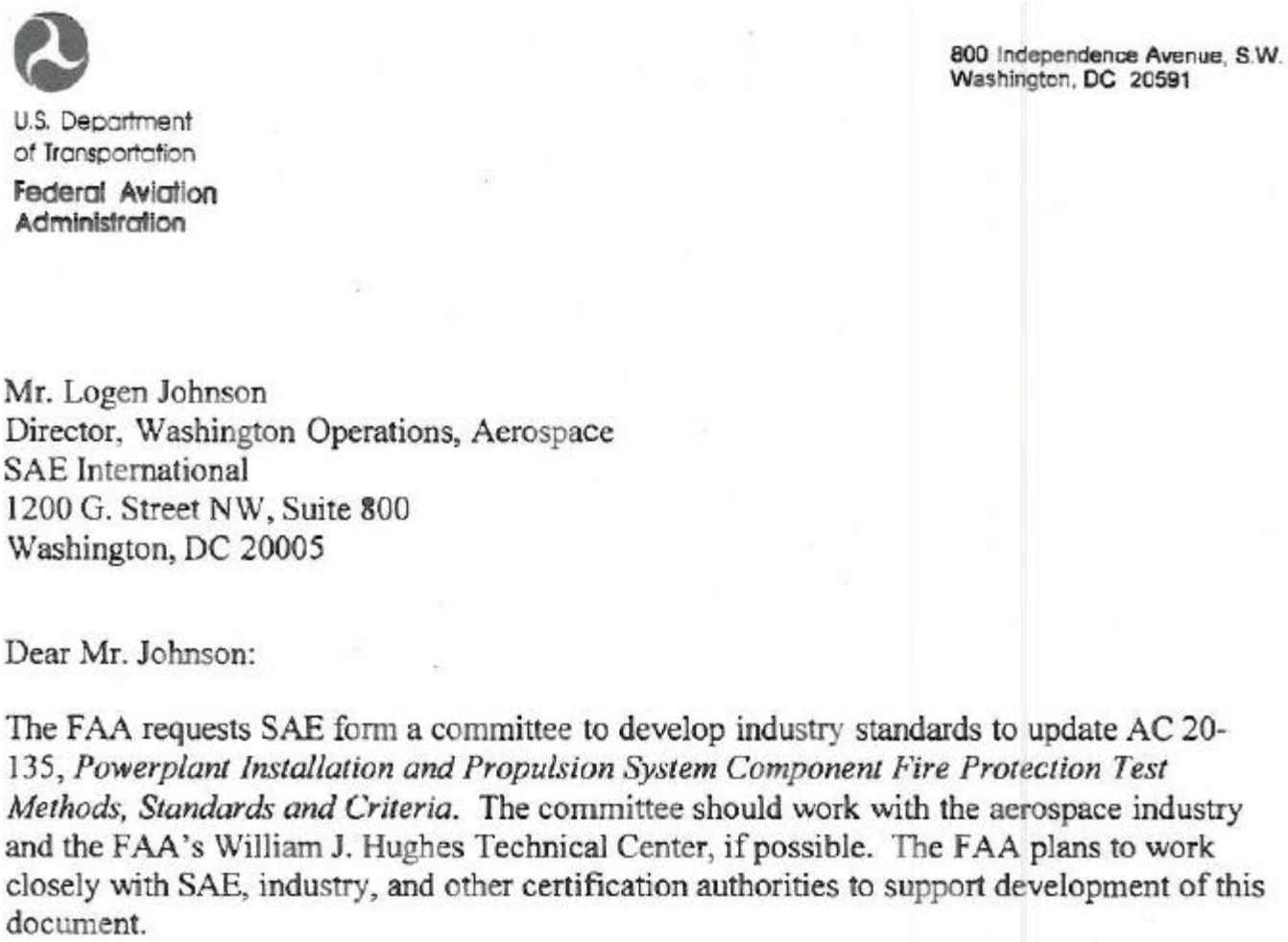
Model-Facilitated Collaboration by Regulators, Technical Societies, Customers, and Suppliers

Accelerating Innovation Effectiveness

www.incose.org/symp2018

COLLABORATION WITH REGULATORS

- SAE INTERNATIONAL SUPPORTS THE FAA THROUGH A STANDARDS TASKING REQUEST PROCESS



U.S. Department
of Transportation
Federal Aviation
Administration

800 Independence Avenue, S.W.
Washington, DC 20591

Mr. Logen Johnson
Director, Washington Operations, Aerospace
SAE International
1200 G. Street NW, Suite 800
Washington, DC 20005

Dear Mr. Johnson:

The FAA requests SAE form a committee to develop industry standards to update AC 20-135, *Powerplant Installation and Propulsion System Component Fire Protection Test Methods, Standards and Criteria*. The committee should work with the aerospace industry and the FAA's William J. Hughes Technical Center, if possible. The FAA plans to work closely with SAE, industry, and other certification authorities to support development of this document.

SAE Integrated Vehicle Health Management

- FAA and EASA supported activity

- The SAE HM-1 Integrated Vehicle Health Management committee addresses the integration of health management systems at both the platform and fleet levels and provide technical standardization to support, guide and advance the realization of Integrated Vehicle Health Management – through common definitions, parameters and taxonomy

SAE IVHM

- *This Aer*ARP6904 Data Interoperability for IVHM
- ARP6887 Verification & Validation of Integrated Vehicle Health Management Systems and Software
- JA6268 Design & Run-Time Information Exchange for Health-Ready Components
  - *The intent is to provide an IVHM system that can robustly report the degradation of a given component before it reaches the point where it goes outside its operational performance envelope by providing sufficient advance notice to deal with the issue.*

SAE Digital & Data Steering Group

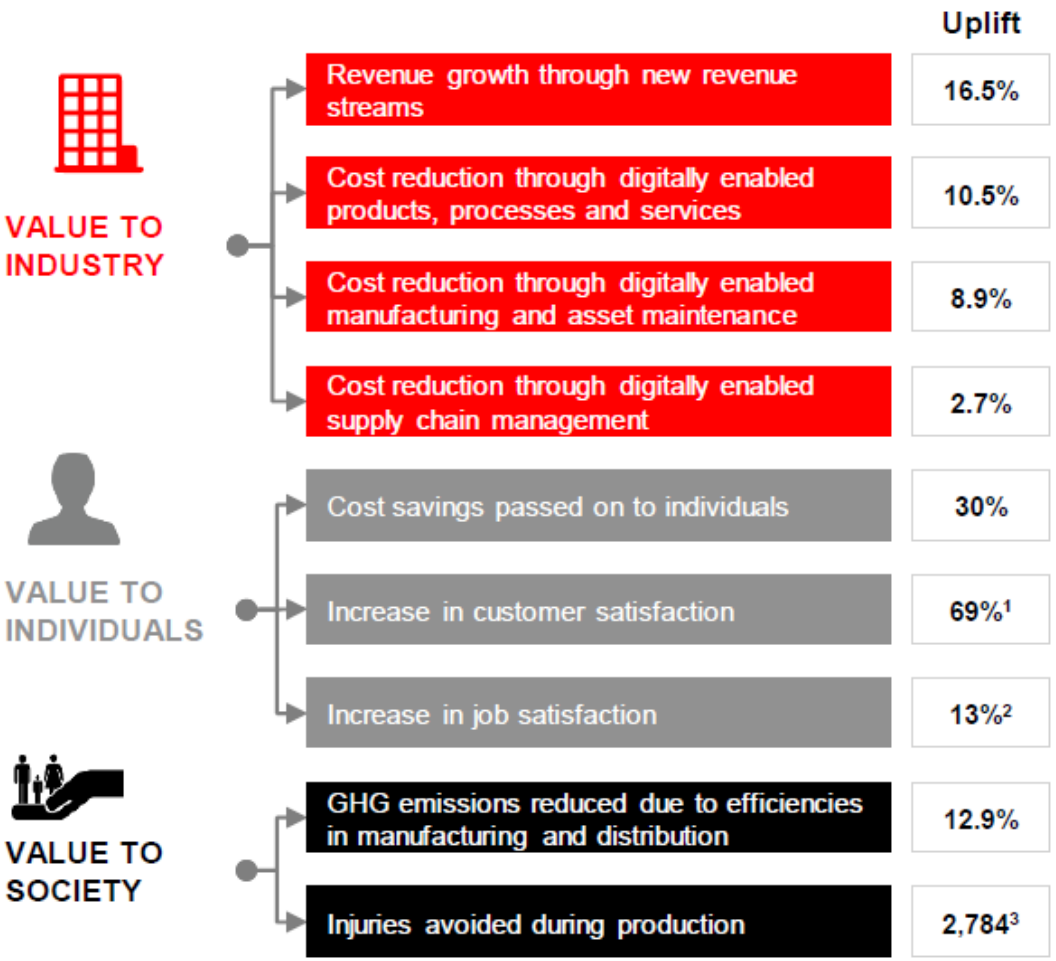
- FAA and EASA supported activity

- The DDSG will strategically identify emerging technologies, and coordinate standardization activities such as data interoperability, ownership, sharing, and security necessary to support D&D technologies at the system, subsystem, and component levels, as well as within the supporting organizational infrastructure.

SAE Digital & Data Steering Group

- A prime area for regulatory involvement is managing the certification phase of Connected Aviation. Essentially, regulators will need to work with airframe manufactures and suppliers to ensure that aircraft, when delivered to operators, meet the standards defined by the regulator.
- For connected aviation to succeed, suppliers and operators alike must partner with regulators to help drive standards. The partnership enables 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 DDSG



Reference: Industrial Digitalisation UK benefits analysis, Accenture Strategy 2017

Connected Devices (IoT)

- Real-time operational prognostics
- Intelligent data and capacity management
- Interoperability (new and legacy systems)

Big Data Analytics

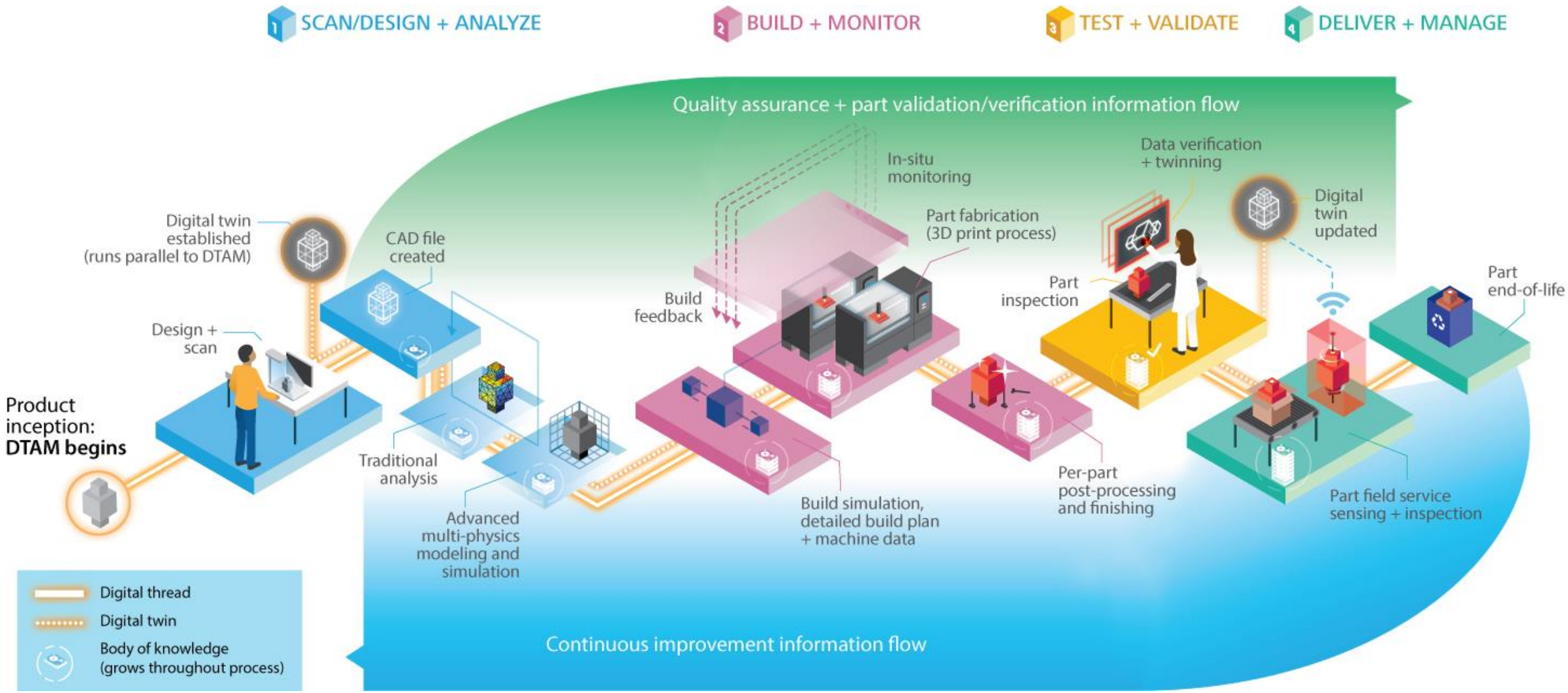
- Mining data - Informing the product life cycle
- Improved product/situational awareness
- Validation and Provence of data

Digital thread/ Digital twin

- Integration and validation of products and processes through data
- Fundamental to all aspects of aerospace

Virtual Certification

- Consistency of data architecture
- Fidelity of data to achieve virtual certification
- Probabilistic quantification methods


1 SCAN/DESIGN + ANALYZE
2 BUILD + MONITOR
3 TEST + VALIDATE
4 DELIVER + MANAGE
Quality assurance + part validation/verification information flow
Digital twin established (runs parallel to DTAM)
CAD file created
Design + scan
Product inception: DTAM begins
Traditional analysis
Advanced multi-physics modeling and simulation
In-situ monitoring
Build feedback
Part fabrication (3D print process)
Build simulation, detailed build plan + machine data
Data verification + twinning
Part inspection
Per-part post-processing and finishing
Digital twin updated
Part field service sensing + inspection
Part end-of-life
Continuous improvement information flow
Digital thread
Digital twin
Body of knowledge (grows throughout process)

CONCLUSION

While the cooperation is not inherent in the highly competitive aviation industry, the adoption of standards in essential. Connected aviation will likely drive many opportunities for industry to adopt common development practices and policies including:

- Data Formatting
- Application programs interfaces (APIs)
- Cybersecurity standards
- Communication protocols
- Requirements for availability, latency and redundancy
- Data policies
- Network Segregation
- Predictive Maintenance
- Virtual Certification

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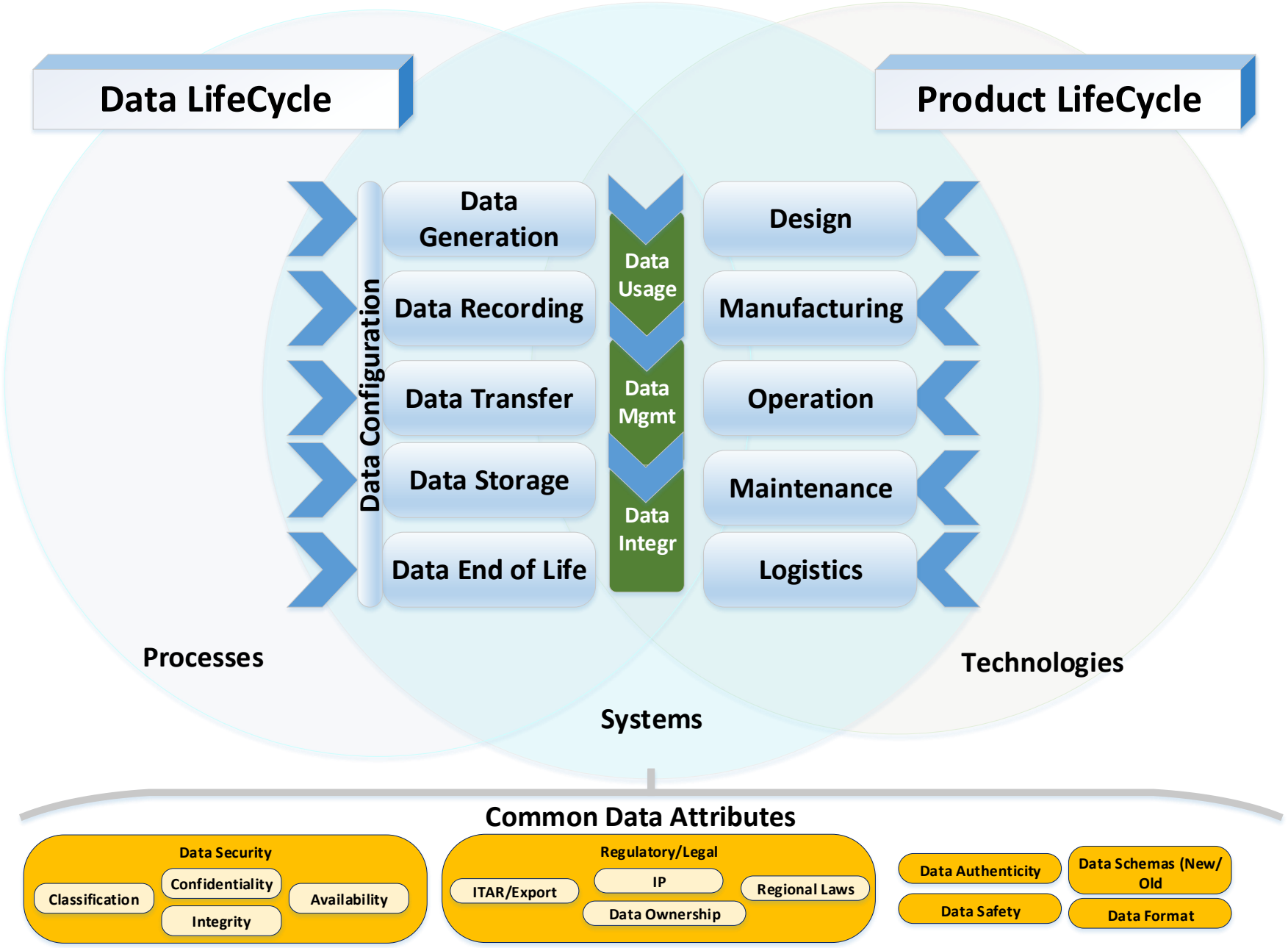
Appendix


Data LifeCycle
Product LifeCycle
Data Configuration
Data Generation
Data Recording
Data Transfer
Data Storage
Data End of Life
Data Usage
Data Mgmt
Data Integr
Design
Manufacturing
Operation
Maintenance
Logistics
Processes
Technologies
Systems
Common Data Attributes
Data Security
Classification
Confidentiality
Integrity
Availability
Regulatory/Legal
ITAR/Export
IP
Data Ownership
Regional Laws
Data Authenticity
Data Safety
Data Schemas (New/ Old
Data Format