

Commercial Space Transportation Advisory Committee (COMSTAC)



Spring 2022 | Day 2 • AM

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Commercial Space Transportation Advisory Committee (COMSTAC)



**Joel Graham, Staffer
Senate Commerce,
Aviation and Space Subcommittee**

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Break

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Briefing on Space Health Dr. Valerie Jane Gawron, MITRE

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Space Health Update to the Commercial Space Transportation Advisory Committee (COMSTAC)

Valerie J. Gawron PhD

May 4, 2022

Previous COMSTAC

AST Commercial Space
Transportation
Go for launch

Commercial Space Transportation Advisory Committee (COMSTAC)

**September 14, 2020
Public Meeting**

This meeting is livestreamed here:

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Observation/Finding/Recommendation 2

- **Observation:** The SWG reviewed existing commercial space standards published by multiple organizations to determine applicability to the human spaceflight safety framework.
- **Finding:** While industry has contributed significant time and effort to this standards development process, overall development of commercial consensus standards has been a slow process, a phenomenon which is not uncommon in other industries.
- **Recommendation:** FAA retain a systems engineering and technical assistance organization (e.g., MITRE, Aerospace Corporation) as soon as possible to conduct the CSLCA-required independent review on readiness for an evolved commercial human spaceflight safety framework.



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AST Commercial Space Transportation

September 14, 2020 | 24

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CSF/MITRE Workshop to Create a Human Research Program for Spaceflight Participants in the Commercialization of Space

CSF/MITRE Workshop Planning Committee

Name	Affiliation
John Allen, PhD	Program Executive for Crew Health and Safety And the Human Research Program/HEO/NASA)
Michael Altenhofen	Senior Mission Mgr., Dragon Mission, SpaceX
Melchor Antuñano, MD	Director, FAA Civil Aerospace Medical Institute
Sirisha Bandla	Vice President for Governmental Affairs, Virgin Galactic
Jonathan B. Clark, MD	Baylor College of Medicine
Steven Collicott, PhD	Purdue University
Marsh Cuttino, MD	Orbital Medicine, Inc.
Kenneth Davidian, PhD	FAA Office of Commercial Space Transportation, Director of Research
Karina Drees	President, Commercial Spaceflight Federation
Christopher Ferguson; Amanda Ireland	Boeing Company
Valerie Gawron, PhD	MITRE
Jeffrey Jones, MD	Professor, Baylor College of Medicine Center for Space Medicine
Michael Marge, EdD	CSF & MITRE, Co-Chair, Planning Committee
Jaime Mateus, PhD	Medical Researcher, SpaceX
Anil Menon, MD	Medical Director, SpaceX
Phil McAlister	Commercial Space Flight/NASA
Taber MacCallum	Co-CEO, Space Perspective
Tommy Sanford	CSF & Co-Chair, Planning Committee
Christopher Scheibler, MD	Director, Flight and Operational Medicine; Chief, Occupational Medicine; Joint Base Elmendorf Richardson, Department of Defense
Michael Schmidt, PhD	CEO/CSO, Sovaris Aerospace; President, Life Sciences & Biomedical Engineering Branch, Aerospace Medical Association
Victor Schneider, MD	Program Scientist, NASA Headquarters

Subcommittees

■ Suborbital

- Mark Shelhamer (Chair)
- John Allen
- Melchor Antuñano
- Sirisha Bandla
- Jonathan Clark
- Steven Collicott
- Marsh Cuttino
- Michael Marge
- Christopher Scheibler
- Erika Wagner

■ Orbital and Beyond

- Michael A. Schmidt (Chair)
- Michael Altenhofen
- Jonathan Clark
- Marsh Cuttino
- Valerie Gawron
- Jeff Jones
- Anil Menon
- Derek Nusbaum
- Tommy Sanford
- Christopher Scheibler
- Victor Schneider
- Mark Shelhamer
- Emmanuel Urquieta
- Erika Wagner

Two Day Virtual Workshop – Day 1 Morning

Day 1: Tuesday, May 11, 2021 - EST		
Time	Topic	Speaker
10:00	Welcome	Dr. Michael Marge, MITRE Workshop Co-chair Tommy Sanford, CSF Workshop Co-chair
10:05	Opening Remarks	Karina Drees, President CSF Dr. Kerry Buckley, Vice President, MITRE Air Force Center
10:20	Plenary Speaker: Health Challenges—Astronauts Compared to Commercial Spaceflight Participants	Dr. Michael Barratt, NASA Astronaut and Physician (Invited)
10:50	Moderated Q&A	Dr. Michael Marge
11:00	Break	
11:15	Commercial Capabilities and Plans: Suborbital/Orbital and Beyond Panel Discussion	Karina Drees, Moderator Dr. Erika Wagner, Blue Origin Sirisha Bandla, Virgin Galactic Dr. Anil Manon, SpaceX Dr. Jaime Mateus, SpaceX Chris Ferguson, Boeing Christian Maender, Axiom Space
11:45	Moderated Q&A	Karina Drees
12:00	Lunch	

Two Day Virtual Workshop – Day 1 Afternoon

12:30	Current Government Efforts: Suborbital/Orbital and Beyond Panel Discussion	Dr. Melchor J. Antuñano FAA Director, Civil Aerospace Medical Institute (CAMI), Moderator Dr. Kenneth Davidian, FAA Dr. Leith States, HHS Dr. John Allen, NASA TBA, DOC
1:00	Moderated Q&A	Dr. Melchor J. Antunano
1:15	Challenges & Opportunities to Develop a Human Research Program for Spaceflights Participants in Suborbital Flight	Dr. Mark Shelhamer, Professor, The Johns Hopkins University, School of Medicine
1:45	Moderated Q&A	Dr. Marsh Cuttino, Orbital Medicine
2:00	Challenges & Opportunities to Develop a Human Research Program for Spaceflight Participants in Orbital and Beyond in Space Flight and Habitation	Dr. Michael Schmidt, CEO/CSO Sovaris Aerospace
2:30	Moderated Q&A	Dr. Leith States
2:45	Break	
3:00	Plenary Session: Protection and Safety of Private and Proprietary Information—Challenges and Solutions	Dr. Valerie Gawron, MITRE Dr. Sybil A. Klaus, MITRE Dr. Kathy Jenkins, Boston Children's Hospital
3:30	Moderated Q&A	Dr. Kenneth Davidian
3:45	Suborbital and Orbital and Beyond Human Research Agenda Working Groups—Question 1: <ul style="list-style-type: none"> ▪ Working Group A: Research Agenda for Suborbital ▪ Working Group B: Research Agenda for Orbital and Beyond 	Dr. Michael Marge For Suborbital Working Group: Dr. Erika Wagner, Blue Origin, Moderator <ul style="list-style-type: none"> ▪ Dr. Marsh Cuttino, Orbital Medicine ▪ Dr. Tarah Castleberry, Virgin Galactic For Orbital and Beyond Working Group: Dr. Victor Schneider, NASA, Moderator <ul style="list-style-type: none"> ▪ Dr. Menon, SpaceX ▪ Dr. Chris Scheibler, DOD
4:30	Closing Remarks/Adjournment	Dr. Michael Marge

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Two Day Virtual Workshop – Day 2 Morning

Day 2: Wednesday, May 12, 2021 - EST		
Time	Topic	Speaker
10:00	Plenary Session Goals and Objectives for Day 2	Dr. Michael Marge
10:05	Suborbital and Orbital and Beyond Human Research Agenda Working Groups—Question 2 <ul style="list-style-type: none"> ▪ Working Group A: Research Agenda for Suborbital ▪ Working Group B: Research Agenda for Orbital and Beyond 	For Suborbital Working Group, Dr. Erika Wagner, Blue Origin, Moderator <ul style="list-style-type: none"> ▪ Dr. Rebecca Blue (Invited) ▪ Dr. Erik Antonsen, Baylor College of Medicine For Orbital and Beyond Working Group, Victor Dr. Schneider, NASA <ul style="list-style-type: none"> ▪ Dr. Emmanuel Urquieta, TRISH ▪ Dr. Jonathan B. Clark, Baylor College of Medicine
10:45	Break	
11:15	Working Group Summary Reports <ul style="list-style-type: none"> ▪ Suborbital: Dr. Erika Wagner ▪ Orbital and Beyond: Dr. Victor Schneider 	Karina Drees
11:45	Moderated Q&A	Dr. Valerie Gawron
12:15	Recommendations and Next Steps	Dr. Michael Marge, Moderator Dr. Kenneth Davidian Karina Drees Dr. Leith States Benjamin Neumann, NASA Dr. Valerie Gawron
1:00	Adjourn	

Contributing Organizations

- Axiom Space, Inc.
- Baylor College of Medicine
- Boston Children's Hospital
- Blue Origin
- Civil Aerospace Medical Institute
- Commercial Spaceflight Federation
- Department of Commerce
- Department of Defense
- Department of Health and Human Services
- Federal Aviation Administration
- National Aeronautics and Space Administration
- Orbital Medicine, Inc.
- Sovaris Aerospace, LLC
- SpaceX
- The Boeing Company
- The Johns Hopkins University School of Medicine
- The MITRE Corporation
- Translational Research Institute for Space Health
- Virgin Galactic

Roll Out of CSF/MITRE Workshop Summary Report

- Tuesday November 16, 2021
 - 1:00 pm Introduction Tommy Sanford & Michael Marge Ed.D. Consultant for MITRE
 - 1:10 pm Welcomes by Karina Drees (CSF) and Kerry Buckley, Ph.D (MITRE)
 - 1:20 pm Panel 1: Space Industry Perspectives Moderator: Bruce Morris (Sierra Space)
 - Sirisha Bandla, Virgin Galactic
 - Erika Wagner, Ph.D., Blue Origin
 - Jamie Mateus, Ph.D., SpaceX
 - Christian Maender, Axiom Space
 - 1:40 Panel 2: Federal Government Perspectives Moderator: Linda Fischetti (MITRE)
 - Victor Schneider, M.D., NASA
 - Melchor Antuñano, M.D., M.S., FAA
 - Leith States, M.D., M.P.H., Office of the Assistant Secretary for Health/HHS

Roll Out of CSF/MITRE Workshop Summary Report

- 1:55 Panel 3: Researcher Perspectives Moderator: Michael Marge, Ed.D.
- Discuss Inspiration4 and EXPAND Dorit Donoviel, Ph. D. (TRISH)
- Priority to Create a Database:
 - Valerie Gawron, Ph.D. and Sybil Russell, M.D. (MITRE)
- Priority Human Research Projects
 - Mark Shelhamer, Ph.D. (Johns Hopkins School of Medicine)
- 2:25 Closing Remarks: Tommy Sanford (CSF) and Michael Marge, Ed.D. (Consultant to MITRE)
- 2:30 Roll-Out Adjourns

[CSF/MITRE Workshop Created a Human Research Program for Spaceflight Participants in the Commercialization of Space | The MITRE Corporation](#)

Research Areas

- Suborbital
 - Space Motion Sickness
 - Sleep Deprivation
 - Anxiety
 - Stress
 - Disabilities
 - Preexisting Health Conditions
 - Acceleration Forces
 - Microgravity
 - Cardiovascular Response
 - Effect on Spine
- Orbital
 - Physiological Effects
 - Psychological Impacts
 - Space Encountered Radiation
 - Distance from Earth Phenomenon
 - Isolation
 - Acceleration during Launch and Landing
 - Preflight Training
 - Disabilities
 - Preexisting Health Conditions

Establish a Public-Private Partnership to Safeguard Data, Support Analysis, and Share Anonymized Findings

Advisory Committee

- Chaired by CSF
- Melchor Antunano MD FAA
- Sirisha Bandla Virgin Galactic
- Rich Boling Techshot
- Dorit Donoviel PhD TRISH
- Valerie Gawron PhD MITRE
- Mike Gold JD Redwire Space
- Michael Lapidus SpaceX
- Michael Lapidus SpaceX
- Christian Maender Axiom Space
- Bruce Morris Sierra Nevada
- Michael Schmidt PhD Sovaris Aerospace
- Victor Schneider MD NASA
- Leith States MD HHS
- Erika Wagner PhD Blue Origin

Valerie J. Gawron Ph.D.

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Commercial Space Transportation Advisory Committee (COMSTAC)



**ASTM Standards Development
Andrew Nelson, Vice Chair,
ASTM Committee**

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ASTM INTERNATIONAL
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ASTM Committee F47 on Commercial Spaceflight

Progress / Update Presentation to
FAA's Commercial Space Transportation Advisory Committee (COMSTAC)
May 4th, 2022

Andrew Nelson, Vice Chairman

•www.astm.org

U.S. Legal and Policy Framework



National Technology Transfer and Advancement Act of 1995 (NTTAA)

- Requires federal government agencies to use standards developed by voluntary consensus standards organization, when possible
- Encourages federal government agencies to participate in standards development organizations

“...all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies,and shall, ...participate with such bodies in the development of technical standards.”

OMB Circular No. A-119

- Reinforces goals of the National Technology Transfer and Advancement Act
- Discourages federal agencies from using government-unique standards
- Clarifies that agency representatives can participate, vote, and even lead activities

“A voluntary consensus standards body is defined by the following attributes: (i) Openness. (ii) Balance of interest. (iii) Due process. (vi) An appeals process. (v) Consensus”

Committee F47 on Commercial Spaceflight

- Formed in 2016 with support/interest from CSF and industry
- More than 110+ members
- Eight (8) sub-committees (with growth plans)
- Six (6) published standards (10-12 in pipeline)
- Full committee meets twice/year in-person
- Executive Committee meets monthly
- Task groups (mostly) hold weekly to bi-weekly meetings to develop standards

Current (New) Structure

F47.01 Occupant Safety
F47.02 **Reserved**
F47.03 Launch & Reentry Vehicles
F47.04 Spaceports
F47.05 Cross-Cutting
F47.90 Executive Committee
F47.91 Terminology
F47.92 Standards Roadmapping
F47.93 Liaison
F47.TBD Future Concepts
F47.TBD Satellites/On-orbit Veh.



Committee F47 Priorities

- Goal -- safe launch, reentry and missions with data driven shared best practices for learned improvements and innovation
- Coordinate with FAA on spaceflight regulations, Advisory Circulars and commercial standards that can serve as alternative means of compliance
- Develop and promulgate commercial human spaceflight (HSF) safety standards and other standards that will enable the commercialization of LEO & Beyond
- Share best practices and consensus guides with industry, academia, other standards organizations, Congress, and the Executive Branch and its departments / entities such as NASA, DOC, DOS and DOD

ASTM F47 – Stakeholders / Members



Broad Representation

- Vehicle operators and parts manufacturers
- Regulators / Other USG users & advisory groups
- National Air Space (NAS) users
- Spaceport operators
- Medical professionals
- Other interested stakeholders





F47 Standards Development Phases

Phase 1

Start-up, Learn, Recruit,
Respond to User Pull, Coordinate

- Learn “ASTM Way”
- Organize the Committee & Sub-committees
- Identify Early Standards to Produce (“User Pull”)
- Coordinate with Admin., Industry/Orgs, other SDOs
- Recruit SMEs

Phase 2

Accelerate, Grow, Address HSF &
“End of Learning Period”

- Respond to the “End of the Learning Period” Challenge
- Engage Deeply w/FAA-AST, NASA, & Industry on HSF
- Eval FAA HSF Recommended Practices, NASA Crew Reqts, & Map to Needed Standards
- Congressional Coordination

Phase 3+

Expand, Means of Compliance,
Enable LEO Commercialization

- Re-organize to meet more new challenges & needs
- Industry-proposed Means of Compliance (e.g., Part 450)
- Enable sustainable LEO & beyond operations:
 - Rules of road, active debris removal, end of life/disposal
 - SSA/STC & Space Operations
 - Habitats, exploration, resource utilization related standards

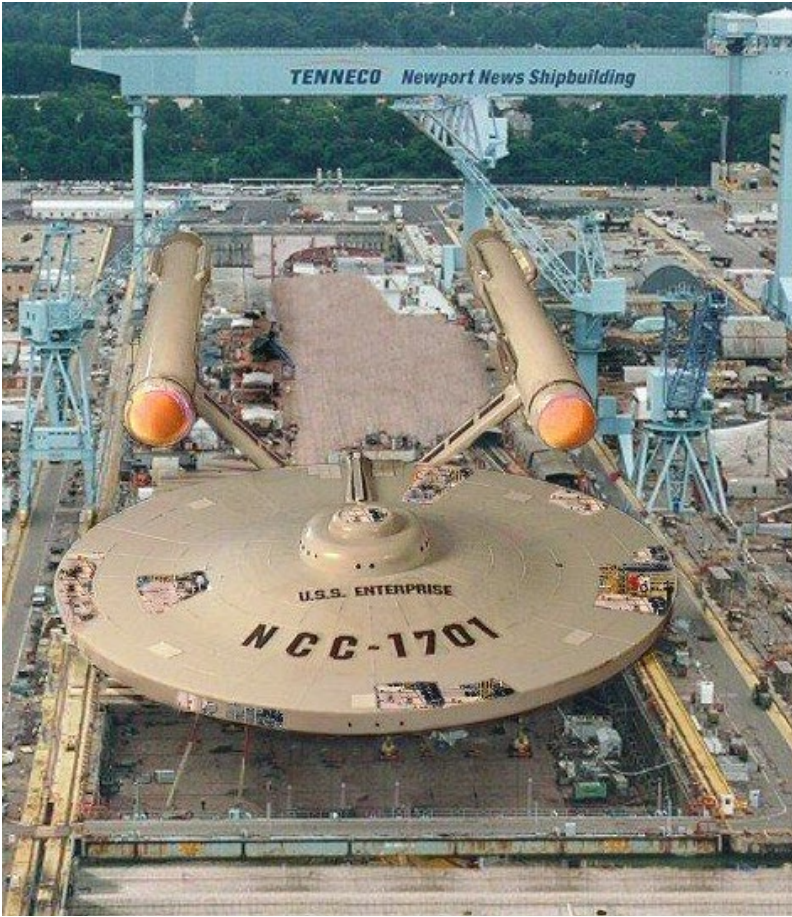
Published Standards (Primarily Phase 1)



Published Standards (Abbreviated Names)

- F3344 Storage, Use, and Handling of Liquid Rocket Propellants
- F3377 Terminology for Commercial Spaceflight
- F3479 Failure Tolerance for Occupant Safety of Suborbital Vehicles
- F3514 Space Data Exchange to Integrate Space Ops into NAS
- F3520 Training/Qual of Safety-Critical Space Ops Personnel
- F3550 Classifying Safety-Related Events

Standards Under Construction (Phase 1&2)



Standards Under Construction (Abbreviated Names)

- WK 61254 Spacecraft Vehicle Classification Types
- WK 70011 Crew Safety
- WK 76298 Software/Systems Verification for Space Vehicles
- WK 74019 Space Flight Safety Critical Systems Qualification
- WK 74068 Spaceport Standardization & Classification
- WK 76057 Suborbital Spaceflight Participant Medical Qual. (Orbital next)
- WK 73835 Spaceflight Participant Safety / Training
- WK 77620 Design of Suborbital Space Vehicles (Orbital next)
- **NEW** Human Factors in Human Spaceflight Vehicles

Recent & Upcoming Meetings



- In person meetings twice a year (pending pandemics)
 - April 8, 2022 - Friday after the Space Symposium
 - And ... witnessed MLA's launch aboard the Ax-1 Mission
 - Upcoming: Fall 2022; coordinated with CSF Board Meeting in Washington, D.C.

SAMPLING OF ONGOING WORKS ...

- May 9th, 4PM ET – WK 76298 – Software Verification “Tiger Team”
- May 11th, 3PM ET – WK 70011 – Crew Safety – Draft Standard
- May 12th, 11AM ET – F47.90 Executive Committee
- May 13th, 1:30PM ET – F47.93 Liaison SC – ALPA Pres. Capt Joe DePete

Standards From Space – *A FIRST!!!*





ASTM International Staff Contacts

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F47 Vice Chair

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Regulatory Working Group

Tasker #2 Response and Discussion



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Regulatory Working Group Task #2



- FAA requests the COMSTAC review and recommend improvements and changes to Part 440. Specifically, provide recommended language on thresholds used to determine MPL, the cost of a casualty, and what alternatives to insurance would industry recommend for operators



COMSTAC's Recommendations on Maximum Probable Loss (MPL) Requirements



- MPL calculations should not and cannot be based only on the likelihood of damage or casualties but must include the federal government's assurance to the public and to the licensee that regulatory requirements and compliance with regulatory requirements protect against the likelihood of damage or casualties.
- Increase transparency around the process for determining MPLs so that insurance providers can better understand the process for calculating them.
- Examples of questions from insurance providers:
 - Who performs the MPL calculation work?
 - How often are the inputs revised and adjusted?
 - What "cost of casualty" is used, and why?
 - How has social inflation been accounted for?
 - How have increases in labor and materials, particularly in the past two years, been accounted for?
 - How have increased utilization and higher value of facilities (e.g., new launch pads, new processing buildings) been accounted for?
 - How have new launch vehicles, materials, and propellants (e.g., carbon fiber structures, methane, "green" propellants) been accounted for?
 - How have lessons learned been incorporated into the models after accidents and incidents?



COMSTAC's Recommendations on Maximum Probable Loss (MPL) Requirements

COMSTAC

- The FAA contract with a third-party entity with a strong and credible background in risk assessment to evaluate the appropriateness of the current 1 in 10 million MPL threshold to ensure that the Federal Government is not exposed to greater costs than intended and that launch companies are not required to purchase more insurance coverage than necessary. As per the Commercial Space Launch Act.
- Prior to formal rulemaking on MPL thresholds the FAA should:
 - Consult with industry stakeholders as was required for the evaluation of the MPL calculation in Section 102 of the Commercial Space Launch Act (P.L. 114-90)
 - Assess the insurance market for launch and reentry and what it can bear on risk assessments
 - Make a formal notice of inquiry or public consultation to examine potential changes and inform the issuance of a formal notice of proposed rulemaking
 - Engage Congress on the key points in advance of a formal notice of proposed rulemaking to inform them of potential liability exposure to the federal government from revisions to the risk sharing regime.
 - Assess commercial launch infrastructure operations at launch and reentry sites that could impact MPL calculations; and
 - A formal notice of proposed rulemaking
- COMSTAC believes that the 1 in 100,000 threshold for government property is appropriate.



COMSTAC's Recommendations on Cost of Casualty Calculations

COMSTAC

- FAA should work with similar regulatory agencies that produce risk calculations associated with potential injuries and casualties that are commensurate with other risky activities that represent a public good.
- FAA should investigate the utilization of an MPL calculation that takes into account casualties, as well as potential bodily injury, and evaluate the potential risks and costs associated with bodily injury instead of total casualty calculations.



COMSTAC's Recommendations on Cost of Casualty Calculations

COMSTAC

- **When pursuing a formal rulemaking on the cost of casualty calculation, the FAA should consider in its evaluation prior to the formal rulemaking the following factors:**
 - Consult with industry stakeholders as was required for the evaluation of the MPL calculation in Section 102 of the Commercial Space Launch Competitiveness Act (P.L. 114-90)
 - A formal assessment of the insurance market for launch and reentry liability insurance, and what limits of liability the market can provide;
 - A formal notice of inquiry, or public consultation, to examine potential changes and inform the issuance of a formal notice of proposed rulemaking;
 - Engage with Congress, both committees of jurisdiction and the appropriations committees, on the key points in advance of the issuance of the formal notice of proposed rulemaking, including range of potential liability exposure to the federal government from any revisions to the risk-sharing regime; and
 - A formal notice of proposed rulemaking.



Commercial Space Transportation Advisory Committee (COMSTAC)



Regulatory Working Group

Tasker #5 Response and Discussion



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Regulatory Working Group Task #5



Given that not all of Part 450: Streamlining of Launch and Reentry Licensing Requirements' Advisory Circulars have been completed, what is the recommended priority for completion?

Also, are there others that should be developed to assist the industry in compliance with Part 450?



Proposed Advisory Circulars (ACs)



AC 450.3-1 Scope of License

AC 450.161-1 Control of Hazard Areas

AC 450.167-1 Tracking

AC 450-119-1 Malfunction Trajectory Analysis

AC 450.110-1 Physical Containment as a Hazard Control Strategy

AC 450.31-1 Applying for FAA Determination on Policy or Payload Reviews

AC 450.123-1 Population Exposure

AC 450.169-1 Collision Avoidance Analysis

AC 450.139-1 Toxic Hazards Analysis and Thresholds

AC 413.5-1 Pre-Application Process

AC 450.133-1 Airspace and Waterborne Vessel Hazard Areas

AC 450.131-1 Probability of Failure

AC 450.137-1 Distance Focusing Overpressure Risk Analysis

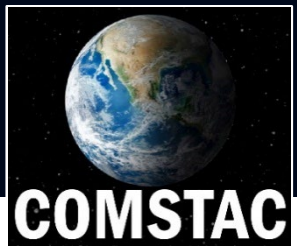
AC (TBD) Hybrid Launch Systems

AC 450.143-1 Safety Critical Systems

AC 450.113-1 Flight Safety Analysis: Levels of Rigor



Recommended AC Order of Priority



1	AC 450.3-1 Scope of License	9	AC 450.133-1 Airspace and Waterborne Vessel Hazard Areas
2	AC 450.131-1 Probability of Failure	10	AC 450.119-1 Malfunction Trajectory Analysis
3	AC 450.113-1 Flight Safety Analysis: Levels of Rigor	11	AC (TBD) Hybrid Launch Systems
4	AC 450.137-1 Distance Focusing Overpressure Risk Analysis	12	AC 450.110-1 Physical Containment as a Hazard Control Strategy
5	AC 450.143-1 Safety Critical Systems	13	AC 450.139-1 Toxic Hazards Analysis and Thresholds
6	AC 450.129-1 Population Exposure	14	AC 450.169-1 Collision Avoidance Analysis
7	AC 413.5-1 Pre-Application Process	15	AC 450.167-1 Tracking
8	AC 450.31-1 Applying for FAA Determination on Policy or Payload Reviews	16	AC 450.161-1 Control of Hazard Areas



Additional Recommendations



An advisory circular is needed to identify how legacy operators (those who have licenses under 417, 431, etc.) can smoothly and easily transition to Part 450. As these vehicles are already verified and validated, and have flown humans under their licenses, there should be minimal additional work needed to transition current legacy operators into Part 450.

Some new operators may find it challenging to operate under the new rule without a full understanding of all advisory circulars and therefore, less sensitive to the order of priority and more interested in seeing all advisory circulars completed.



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**Break –
Return at 12:30**

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