

# “Medical Safety Considerations for Passengers on Short-Duration Commercial Orbital Space Flights”

## *International Academy of Astronautics Study Group*

### **Chairs:**

Melchor J. Antuñano, M.D. (USA)  
Rupert Gerzer, M.D. (Germany)

### **Secretary:**

Thais Russomano, M.D. (Brazil)

### **Other Members:**

Denise Baisden, M.D. (USA)  
Volker Damann, M.D. (Germany)  
Jeffrey Davis M.D. (USA)  
Gary Gray, M.D. (Canada)  
Anatoli Grigoriev, M.D. (Russia)  
Helmut Hinghofer-Szalkay, M.D. (Austria)  
Stephan Hobe, Ph.D. (Germany)  
Gerda Horneck, Ph.D. (Germany)  
Petra Illig, M.D. (USA)  
Richard Jennings, M.D. (USA)  
Smith Johnston, M.D. (USA)  
Nick Kanas, M.D. (USA)  
Chrysoula Kourtidou-Papadeli, M.D. (Greece)  
Inessa Kozlovskaya, M.D. (Russia)  
Jancy McPhee, Ph.D. (USA)  
William Paloski, Ph.D. (USA)  
Guillermo Salazar M.D. (USA)  
Victor Schneider, M.D. (USA)  
Paul Stoner M.D. (USA)  
James Vanderploeg, M.D. (USA)  
Joan Vernikos Ph.D. (USA-Greece)  
Ronald White, Ph.D. (USA)  
Richard Williams, M.D. (USA)

## **ABSTRACT**

This report identifies and prioritizes medical screening considerations in order to preserve the health and promote the safety of paying passengers who intend to participate in short-duration flights (up to 4 weeks) onboard commercial orbital space vehicles. This includes the identification of pre-existing medical conditions that could be aggravated or exacerbated by exposure to the environmental and operational risk factors encountered during launch, inflight and landing. Such risk factors include: acceleration, barometric pressure,

microgravity, ionizing radiation, non-ionizing radiation, noise, vibration, temperature and humidity, cabin air, and behavioral and communications issues. Because of the wide variety of possible approaches that can be used to design and operate manned commercial orbital space vehicles, it is very difficult to make unequivocal recommendations on specific medical conditions that would not be compatible with ensuring safety during orbital space flight. However, space flight is associated with a number of physiological and psychological changes that may cause and/or aggravate certain medical conditions and could adversely impact a passenger's health and safety including significant deformities (congenital or acquired) of the musculoskeletal system, diseases, illnesses, injuries, infections, tumors, treatments (pharmacological, surgical, prosthetic, or other), or other physiological or pathological or psychiatric conditions that: 1) may result in an inflight medical emergency, 2) may result in an inflight death, 3) may compromise the health and safety of other passengers or space vehicle occupants, 4) may interfere with the proper use (don and doff) and operation of personal protective equipment, 5) may interfere with emergency procedures (including evacuation), or 6) may compromise the safety of the flight. This report outlines recommendations on the medical history assessment, physical examination and medical tests of prospective orbital space passengers, as well as the recommended disposition of those passengers who have medical conditions that may preclude their participation in space flight. Other issues discussed include pre-flight, inflight and post-flight medical considerations. The first commercial orbital space vehicles will have very limited or even absent medical intervention capabilities onboard, and it will be very difficult (if not impossible) to quickly divert an orbital space flight in order to obtain more advanced medical care for passengers on the ground. Therefore, prospective passengers with significant medical conditions will have to be evaluated very carefully before allowing them to participate in orbital space flight. Finally, this report provides a detailed overview of medical liability issues of other legal aspects applicable to manned commercial orbital space flights.

## ***OBJECTIVE***

To identify and prioritize medical screening considerations in order to preserve the health and promote the safety of paying passengers who intend to participate in short-duration flights (**up to 4 weeks**) onboard commercial **orbital** space vehicles. This report is intended to provide general **medical** guidance to the operators of orbital manned commercial space vehicles for the medical assessment of prospective passengers. **More specifically, this report is intended for medical personnel employed by commercial space vehicle operators.** Physicians supported by other appropriate health professionals who are trained and experienced in the concepts of aerospace medicine should perform the medical assessments of all prospective space passengers. In view of the wide variety of possible approaches that can be used to design and operate **orbital** manned commercial space vehicles in the foreseeable future, the IAA medical safety considerations are generic in scope and are based on current analysis of physiological and pathological changes that may occur as a result of human exposure to operational and environmental risk factors present during **orbital** space flight.

## ***SIGNIFICANT DEVELOPMENTS IN MANNED COMMERCIAL SPACE TRANSPORTATION (sub-orbital and orbital)***

Although this report specifically addresses the medical safety considerations for prospective passengers in orbital space flights, it is relevant to provide a brief background on recent accomplishments and ongoing developments involving commercial sub-orbital and orbital space flights. The emerging commercial industry on sub-orbital human space transportation represents a stepping stone towards making space flight a reality for the “general public”. Furthermore, the success or failure in establishing commercial sub-orbital space flight services available to the general public could have a significant impact (positive or negative) on the future business success of the entire manned space flight industry (sub-orbital and orbital).

### **MANNED SUB-ORBITAL SPACE FLIGHT DEVELOPMENTS**

After many years of hopes, speculation, skepticism, and competition, the sub-orbital vehicle “SpaceShipOne” won the coveted \$10 million “Ansari X Prize” by becoming the first private reusable launch vehicle (RLV) to successfully fly above 328,000 feet (62 miles or 100 kilometers), twice within two weeks, while carrying one civilian astronaut and the equivalent weight of two additional occupants. SpaceShipOne built by Burt Rutan’s Scaled Composites, owned by Microsoft co-founder Paul G. Allen through his company Mojave Aerospace Ventures, was flown to a record altitude of 367,442 ft (69.7 miles or 112.3 km) by test pilot Brian Binnie on October 4, 2004. This prize-winning flight occurred exactly 47 years after the launch of the Russian Satellite “Sputnik” and exceeded the previous altitude record (354,200 feet) set by pilot Joe Walker onboard an X-15 on August 22, 1963. Upon landing, Brian Binnie received his commercial astronaut wings from the Federal Aviation Administration (FAA) Administrator Marion Blakey and officially became the 434<sup>th</sup> human to fly into space. However, it is important to recognize that the 433<sup>rd</sup> human to become an official astronaut was Mike Melvill who, on June 21, 2004, set the world-record for the first private sub-orbital flight (328,491 feet) onboard SpaceShipOne. Melvill flew once again on September 29, 2004, to complete the first of the two official sub-orbital flights (337,500 feet) required to win the “Ansari X Prize.” Melvill and Binnie became the pioneers of the next phase in the exploration and exploitation of space - “Private Manned Space Flight”.

Sir Richard Branson (founder of Virgin Atlantic Airways) has established the first commercial spaceline named “Virgin Galactic”. He licensed the technology owned by Allen’s Mojave Aerospace Ventures, and signed a contract with Burt Rutan’s Scaled Composites to build a larger version of SpaceShipOne capable of carrying 6 passengers on a 2-hour sub-orbital flight (including 3-4 minutes of microgravity). **Several “SpaceShipTwo” vehicles are being built by Scaled Composites.** So far, about 250 people from 30 countries have signed in to fly as passengers with Virgin Galactic **and the first 100 (Founders) are currently undergoing medical evaluations and training in preparation for a tentative sub-orbital flight in 2010.**

There are several other private companies involved in the development of manned sub-orbital commercial space vehicles including Armadillo Aerospace, BensonSpace, Blue Origin, Bristol Aerospace, Canadian Arrow, EADS Astrium, Myasishchev, PlanetSpace, Rocketplane, Starchaser Industries, TGV Rockets and Xcor. In addition, several companies are developing orbital commercial space vehicles including BensonSpace, Energir Kliper, Excalibur Almaz, PlanetSpace, Shenzhou, Soyuz, SpaceX, and Transformational Space.

According to a 2006 "Survey on Public Space Travel" produced by Futron/Zogby, the sub-orbital space tourism market is expected to produce \$650 million in revenues per year by 2021 (13,000 space flight participants per year). The Futron Corporation, is a company that forecasts space-related markets.

**A comprehensive discussion of all advanced aerospace technologies that could facilitate access to space is beyond the scope of this report. However, a highly promising technological development that has the potential of revolutionizing human access to space involves the ongoing development of advanced scramjet aerospace vehicles. For example,** the X-43A unmanned research vehicle successfully flew at an altitude of 110,000 feet above the Pacific Ocean and set a flight record by reaching a speed of Mach 9.8 (about 7,000 mph). The X-43A scramjet demonstrator was mated to a modified Pegasus booster rocket that was air launched from NASA's B52-B at an altitude of 47,000 feet. Following separation, the booster carried the X-43A to 110,000 feet, where it detached and ignited its scramjet engine for approximately 10 seconds. It is predicted that scramjets will reach speeds of Mach 15 and higher. These engines have the advantage over rockets in that they extract oxygen from the surrounding atmosphere instead of having to carry liquid-oxygen tanks onboard the vehicle. This successful X-43A flight was a significant milestone in the development of scramjet technology that has the potential to offer an alternative to rocket propulsion, and that may enable cheaper and safer supersonic flights in the future. Scramjet vehicles could represent the next revolutionary step **(rather than evolutionary)** in manned commercial aerospace transportation.

## **GOVERNMENT OVERSIGHT OF SUB-ORBITAL COMMERCIAL SPACE FLIGHTS**

At the present time, the U.S. is the only country that has established licensing requirements for manned commercial space operations. The U.S. Commercial Space Launch Amendments Act of 2004 (H.R. 5382) laid out the definition of a sub-orbital space passenger vehicle, clarified the process for licensing such vehicles, and allowed paying passengers to fly into space at their own risk. This Act authorizes the FAA to issue permits allowing commercial space vehicle operators to carry paying passengers into space. The Act requires passengers to be fully informed **in writing** about all of the potential risks of participating in space flights. **An operator must inform each passenger about the risks of the launch and reentry, including the safety record of the launch or reentry vehicle type. For each flight, the operator must disclose each known hazard and risk that could result in a serious injury, death, disability, or total or partial loss of physical and mental function. An operator must also inform each passenger that the U.S. Government has not certified the launch vehicle and any reentry vehicle as safe for carrying crew or passengers.** By allowing passengers to fly at their own risk, this Act was intended to limit the operators' liability for passenger safety, thus giving this emerging industry an opportunity to succeed. The FAA will have to wait eight years after enactment of the new Act to begin issuing regulations to protect the safety of space passengers. In the meantime, the FAA may restrict space vehicle design features or operating practices only if they have resulted in a serious or fatal injury to passengers or crew (accident), or caused an unsafe unplanned event (incident). Equally important in this Act is a section on manned space vehicle experimentation. Under current laws, any commercial experimental space vehicle must comply with the FAA licensing requirements of a fully functional space vehicle before it can be launched. However, under the new Act, as long as there are no paying passengers aboard, the licensing requirements are less stringent (and less costly) in order to facilitate the flight testing/evaluation of new space vehicle concepts. Furthermore, there is no limit on the total number of experimental flights permitted under the new licensing requirements.

## **MANNED ORBITAL SPACE FLIGHT DEVELOPMENTS**

A joint commercial venture between Space Adventures, the Russian Aviation and Space Agency (Rosaviakosmos), and Rocket Space Corporation Energia (RSC Energia) has made it possible for paying passengers to fly aboard Soyuz TMA launch vehicles to the International Space Station (ISS). To date, there have been five high-profile customers to participate in orbital flights: Dennis Tito (April 2001), Mark Shuttleworth (April 2002), Greg Olsen (October 2005), Anousheh Ansari (September 2006), and Charles Simony (April 2007). At the present time, this successful commercial space venture represents the only means for the general public to experience the thrill and adventure of orbital space flight. Space Adventures has announced plans for additional orbital flights and circumlunar flights for an estimated fee of \$100 million, and **has tentative plans for a first tourist EVA from the ISS. Richard Garriott (son of former NASA astronaut Owen Garriott) is one of several passengers who have expressed interest in performing an EVA for an additional multi-million dollar fee.**

Robert Bigelow (founder of Bigelow Aerospace) announced his decision to sponsor a \$50 million "America's Space Prize" competition to build and fly a private spacecraft capable of carrying no less than 5 people into orbit. Such a vehicle will make it possible to transport space passengers to the private orbital station that he is currently developing based on NASA's inflatable space habitat technology. Bigelow Aerospace launched to low orbit a 1/3 scale "Genesis I" module in July 12, 2006, that was carrying Madagascar Cockroaches and Mexican Jumping Beans. A larger "Genesis II" module was launched in late July 2007 carrying cockroaches and scorpions. If everything goes according to Bigelow's testing plans, a full-size "Sundance" module could be launched in early 2010, and be ready for visitors by 2012.

Despite these incredible aerospace technological achievements and the ongoing efforts to continue facilitating the development of manned commercial space flight operations, the emerging commercial space transportation and tourism industries (sub-orbital and orbital) will also have to address a number of risk factors in order to promote the health and safety of future passengers. An emphasis on occupant safety will also help decrease the companies' potential liability in case of an incident or accident.

### ***MEDICAL REPORTS RELEVANT TO THE SAFETY OF FUTURE PASSENGERS IN MANNED COMMERCIAL ORBITAL SPACE FLIGHTS***

Several reports have been published regarding the subject of medical guidelines for participants in commercial space flights. In 1999, the Aerospace Medical Association (AsMA) approved a resolution urging that appropriate agencies develop relevant U.S. Federal policies, procedures, guidelines, and regulations to ensure the health and safety of human crewmembers and passengers involved in manned commercial space flights. On November 20, 2000, AsMA convened a task force to develop a position paper on "Medical Guidelines for Space Passengers". Two sets of guidelines were published in the "Aviation, Space and Environmental Medicine" journal in the October 2001 and November 2002 issues (Ref <sup>3,4</sup>). **The AsMA medical guidelines for passengers participating in orbital space flights consist of several lists of disqualifying medical conditions for flights of 1 to 7 days based on several assumptions including: 1) The space vehicle would only accommodate 4-6 passengers, 2) The cabin would be pressurized to sea level with an 80% nitrogen and 20% oxygen gas-mixture, 3) Inflight acceleration profile would range between 2**

**and 4.5 +Gz or Gx depending upon the vehicle design, 4) There would be different emergency egress procedures depending upon the vehicle design.**

On February 11, 2005, the FAA Office of Aerospace Medicine released a report on “Recommended Guidelines for Medical Screening of Commercial Space Passengers” during the 8th FAA Commercial Space Transportation Forecast Conference (Ref <sup>1</sup>). This report had actually been completed in March 31, 2003, and was the culmination of a team effort that started in July of 1998. This report was one element of the FAA Office of Commercial Space Transportation’s “Guidance for Commercial Sub-orbital Reusable Launch Vehicle Operations with Space Flight Participants.” **The FAA medical guidelines for passengers participating in orbital space flights includes the recommended medical history questionnaire, physical examination parameters and laboratory testing based on the following assumptions: 1) An inflight cabin environment not exceeding 8,000 ft (10.91 psi) cabin pressure, 2) Passengers would not be required to wear a pressurized suit, 3) Passengers would be expected to perform an emergency evacuation without assistance and would not compromise the safety of other occupants, 4) Vehicle acceleration profile would not exceed +4Gz (-2Gz), ±4Gx and ±1Gy, and 5) Passengers would not be required to use an anti-G suit. These guidelines included a section on medical conditions that may contraindicate passenger participation in space flight and another section on the recommended disposition of prospective space passengers who have such medical conditions.**

The International Space Station (ISS) medical program has been developed by the five partner space agencies in the U.S., Russia, Europe, Canada and Japan. Medical standards have been developed as one aspect of the medical program and one specific set of standards addresses paying passengers called Space Flight Participants (SFP). These SFP standards permit flights up to 30 days in length.

**A detailed comparison of the similarities and differences among the above-mentioned medical guidelines and standards is beyond the scope of this report. However, the traditional philosophy behind government space-agency medical standards has been to ensure operational safety by excluding a large number of medical conditions, to avoid any negative impact on mission success due to medical conditions, to limit the potential risk of medical events occurring during flight, and to enable long-term medical clearances in support of astronaut career longevity. On the other hand, the philosophy behind the medical guidelines recommended by AsMA and FAA is to maximize the number of potential space passengers by limiting the number of truly disqualifying medical conditions, to accept limited mission impact without compromising safety, to accept some risk of medical events occurring during flight, and to focus on one-time medical clearances for one-flight passengers.**

**The IAA “Medical Safety Considerations for Passengers on Short-Duration Commercial Orbital Space Flights” differ from previously published medical guidelines and standards for orbital space passengers in several ways: 1) The identification of medical conditions that could be adversely impacted by space flight is based on the most relevant operational and environmental factors that represent actual risks to the occupants of commercial space vehicles. Some of these factors will vary depending upon the space vehicle design and flight profile, 2) The only operational assumption is that passengers will be capable of performing an emergency evacuation without assistance (unless a special accommodation can be made for an individual with a disability or condition that interferes with an emergency evacuation) and will not compromise the safety of other occupants (crew members or passengers), 3) This approach provides flexibility to accommodate different levels of medical fitness for orbital flight based on differing flight profiles resulting from different approaches to space-vehicle design, and 4) This approach is not based on making assumptions about the flight envelope**

of space vehicles. The different approach used to develop this report represents a more practical method to provide guidance to medical personnel employed by commercial space vehicle operators to make decisions about passenger fitness for flight depending upon the specific operational characteristics of various space vehicle designs.

Since the beginnings of manned space exploration, relatively healthy professional astronauts have been selected to participate in space flights, and, from a medical fitness point of view, they should not be considered a representative sample of the general population. However, even among these professional astronauts who have been subject to very thorough initial medical selection tests and to subsequent medical screening and monitoring evaluation procedures, some have experienced a variety of ground and inflight medical events (**in most cases minor**). For example, a study of 607 astronauts and payload specialists (521 men and 86 women) involved in 106 Space Shuttle missions (STS-1 through STS-108) between April 1981 and December 2001 covering over 5,496 flight days (4,673 days for men and 823 days for women) indicated that 98.1 % of men and 94.2% of women reported 2,207 separate medical events or symptoms during flight (1,882 events in men and 325 events in women). Reported medical events or symptoms included space adaptation syndrome (39.6%), nervous system and sensory organs (16.7%), digestive system (9.2%), injuries and trauma (8.8%), musculoskeletal system and connective tissue (8.2%), skin and subcutaneous tissue (8%), respiratory system (4.5%), behavioral signs and symptoms (1.8%), infectious diseases (1.3%), genitourinary system (1.5%), circulatory system (0.3%), and endocrine, nutritional, metabolic and immunity disorders (0.1%). There were 194 events due to injury, including 14 fatalities (**Ref <sup>9</sup> – Chapter 30, Pages 708-710**).

Orbital space flight exposes individuals to an environment that is **potentially** far more hazardous than what is experienced by passengers who fly onboard current airline transports. In orbital flights, **some** pre-existing medical conditions **could** be aggravated or exacerbated by exposure to the environmental and operational risk factors encountered during launch, inflight and landing (**Table 1**).

Acceleration
Barometric Pressure
Microgravity
Ionizing Radiation
Non-Ionizing Radiation
Noise
Vibration
Temperature and Humidity
Cabin Air
Behavioral

*Table 1. Operational and Environmental Risk Factors in Orbital Space Flights.*

# **MEDICAL IMPLICATIONS OF OPERATIONAL AND ENVIRONMENTAL RISK FACTORS IN ORBITAL SPACE FLIGHTS**

## **ACCELERATION**

Significant medical concerns exist with the application of sustained gravito-inertial forces (Gs) to the human body as a consequence of space vehicle acceleration. In general, the acceleration envelope recommended for an aerospace vehicle carrying passengers should not exceed  $+4G_z$  ( $-2G_z$ ),  $\pm 4G_x$  and  $\pm 1G_y$  (Ref <sup>1</sup>). Neurologic, cardiovascular and musculoskeletal problems are the primary health concerns associated with in-flight acceleration exposure, with head-to-foot (“eyeballs down” or  $+G_z$ ) acceleration causing the most harm. However, exposure to  $+G_z$  can also have an impact on pulmonary function and alter ventilation/perfusion ratios resulting in hypoxemia, airway closure, and atelectasis. To avoid the potential for compromising cardiovascular and neurological function, acceleration forces are preferably applied in the front-to-back ( $+G_x$ ) direction (eyeballs in). An individual is more tolerant to  $+G_x$  acceleration, and with the heart and brain located at approximately the same level within the acceleration field there is less risk for acceleration-induced loss of consciousness (G-LOC). Acceleration stress is known to be dysrhythmogenic (i.e. causing changes in cardiac rate, rhythm, and conduction). Higher and longer exposures to acceleration could potentially increase the frequency of dysrhythmias. As long as the head, neck and spine are stabilized before the acceleration exposure and remain so until the exposure is completed, the potential for musculoskeletal injury is markedly reduced. An individual’s tolerance to  $+G_z$  acceleration is dependent on the individual’s anatomic and physiologic characteristics and the nature of the acceleration profile. The maximum  $+G_z$  level, exposure duration and the rate of onset of the  $+G_z$  are important determinants of the risk of neurological compromise, cardiac rhythm disturbances and musculoskeletal (especially neck) injury. Onset-rates greater than 0.1G/second are considered rapid since they exceed the ability of the cardiovascular system to fully respond to preserve adequate central nervous system blood flow. Rapid-onset rates of 1.0G/second and greater can result in G-LOC without visual warning symptoms. Conservative relaxed, unprotected tolerance of completely healthy humans to  $+G_z$  acceleration is considered approximately  $+3G_z$  (normal range 3.1 to 4.0) for rapid-onset profiles and increases to approximately  $+3.5G_z$  (normal range 3.7 to 5.6) with gradual-onset profiles. Individuals with compromised cardiovascular anatomy or function may have reduced tolerances. Care should be exercised with rapid-onset profiles to  $+3G_z$  or more, sustained for 5 seconds or longer.

For a more comprehensive review of reference information on human exposure limits to acceleration it is recommended to consult “NASA Bioastronautics Data Book” (Ref <sup>8</sup> – [Chapter 4, Pages 149-190](#)), “Fundamentals of Aerospace Medicine” (Ref <sup>9</sup> - [Chapter 4, Pages 86-98](#)), and “[Human Space Flight Mission Analysis and Design](#)” (Ref <sup>9</sup> - [Chapter 5, Pages 115-116](#)).

*The following are some medical conditions that could be adversely impacted by exposure to acceleration:*

- ◆ *Cardiovascular pathologies such as congenital heart diseases, valvular heart diseases, cardiomyopathies, pericarditis, myocarditis, endocarditis, ischemic heart diseases, dysrhythmias, aortic aneurysm, peripheral vascular diseases, uncontrolled hypertension, or autonomic neuropathy associated with hypotension.*
- ◆ *Cerebrovascular diseases such as stroke, transient ischemic attack (TIA), intracranial bleed, intracranial aneurysm, AV malformations, cavernous angiomas.*
- ◆ *Cerebral tumors.*
- ◆ *Loss of consciousness of unknown origin or recurrent syncope.*

- ◆ *Musculoskeletal disorders such as symptomatic cervical arthritis, recent spinal injury, severe osteoporosis, spondylolysis, spondylolisthesis, herniated nucleus pulposus, non-healed displaced fractures, non-reduced dislocations of large joints.*
- ◆ *Ophthalmologic disorders such as retinal detachment, hemorrhages or other retinal vascular problems.*
- ◆ *Individuals with high degrees of myopia (<-6 diopters) may be at increased risk of retinal detachment*
- ◆ *Severe chronic dizziness, positional vertigo, motion sickness, or other vestibular/orientation problems of any cause.*
- ◆ *Recent intra-cranial, intra-thoracic or intra-abdominal trauma.*
- ◆ *Acute or chronic hemorrhagic states of any cause.*
- ◆ *Chronic symptomatic hernias.*
- ◆ *Draining fistulas.*
- ◆ *Pregnancy.*
- ◆ *Recent significant health problems or recovery from surgery*

## **BAROMETRIC PRESSURE**

Cabin pressure may vary depending upon the design of the space vehicle. In the NASA Space Shuttle program, the cabin pressure is typically maintained at a sea level pressure of 14.7 psi. This allows for essentially a shirt-sleeved environment. In preparation for extravehicular activity, the cabin pressure is lowered to 10.2 psi. This is equivalent to approximately a 10,000 feet cabin altitude; however, the partial pressure of oxygen is increased to be equivalent to an 8,000 feet cabin altitude. Ear and sinus blocks are possible with changes in cabin pressure. Depending upon the design of the space vehicle, lower pressures may exist in the cabin possibly requiring the use of a pressure suit. This requirement for a pressure suit may present a problem to individuals with certain medical conditions and/or disabilities. The partial pressure of oxygen may also vary depending upon the vehicle design. For example, airline transport aircraft are designed to maintain a cabin altitude of up to 8,000 feet while flying at their maximum operational altitude. This altitude can present a problem to individuals with certain cardiac or pulmonary conditions. Lower partial pressures of oxygen (higher cabin altitude equivalent) can pose greater problems for some individuals and supplementary oxygen might be required.

Space vehicles operate at such high altitudes that there is a potential risk for an inflight decompression (rapid or explosive) to very low or even absent atmospheric pressures. Such an exposure could result in decompression sickness (DCS) or even death (due to hypoxia or ebullism) among occupants. Similar risks exist during extravehicular activities (EVA) with the use of EVA suits. Individuals who have experienced a previous incident of DCS may have an increased risk of experiencing a subsequent incident if exposed to an inflight decompression. Other DCS predisposing factors **during EVA** include: increasing age, obesity, recent injuries, alcohol consumption, exposure to high barometric pressure differentials, exposure to high rates of pressure change, longer duration of exposure to pressure changes, repetitive exposures to pressure changes, and exposure to low ambient temperatures. **The onset of any signs or symptoms of space motion sickness should preclude passenger participation in EVA for the next few days. Therefore, due the reported higher incidence of space motion sickness during the first few days of space flight, passengers should abstain from participating in EVA during the first 5 days after launch.**

For a more comprehensive review of reference information on human exposure limits to changes in barometric pressure it is recommended to consult "NASA Bioastronautics Data Book" (Ref <sup>8</sup> –

**Chapter 1, Pages 1-34), “Fundamentals of Aerospace Medicine” (Ref <sup>9</sup> - Chapter 3, Pages 46-82), and “Human Space Flight Mission Analysis and Design” (Ref <sup>9</sup> - Chapter 17, Pages 543-544).**

*The following are some medical conditions that could be adversely impacted by exposure to decreased barometric pressure and/or hypoxia:*

- ◆ *ENT disorders that may interfere with normal ventilation of paranasal sinuses or the middle ear, allergic rhinitis, severe adenoid hypertrophy, severe otitis media, severe otitis externa, recurrent bleeding from the nasopharynx.*
- ◆ *Pulmonary disorders such as pulmonary vascular disease, pneumothorax, pulmonary fibrosis, active asthma, emphysema, pulmonary blebs and bullae, chronic obstructive pulmonary disease (COPD), pulmonary infectious diseases, bronchitis.*
- ◆ *Cardiovascular pathologies such as congenital heart diseases, valvular heart diseases, cardiomyopathies, pericarditis, myocarditis, endocarditis, ischemic heart diseases, dysrhythmias.*
- ◆ *Cerebrovascular diseases such as stroke, transient ischemic attack, intracranial bleed.*
- ◆ *Seizures, convulsions, epilepsy.*
- ◆ *Acute or chronic hemorrhagic states of any cause.*
- ◆ *Anemia, hemoglobinopathies, hemolytic disorders, blood dyscrasias.*
- ◆ *Recent intra-cranial, intra-thoracic or intra-abdominal trauma or surgery.*
- ◆ *Colostomies, ileostomies.*

## **MICROGRAVITY**

In general, the physiological changes resulting from exposure to microgravity depend upon the total duration of the exposure, and can vary in magnitude from individual to individual.

**Cardiovascular Effects** - In microgravity, body fluids shift toward the head because of the lack of gravity that, in 1G, keeps a balanced distribution of fluid in the abdomen, pelvis and lower extremities. This fluid shift manifests itself in the typical facial puffiness seen in astronauts and the frequent reports of nasal congestion and headache. The body senses that it is overloaded with fluid and responds by a rapid extravasation that leads to a rapid decrease of plasma volume between 10-15%. In addition, thirst and fluid intake also decrease. While these adaptive changes do not cause a problem, and are actually beneficial during microgravity exposure, on return to a +1G environment, they result in orthostatic intolerance. While these changes are still incompletely understood, it is thought that lower norepinephrine levels and decreased vascular responsiveness to norepinephrine in those affected play an important role in the development of orthostatic intolerance.

Other changes include a decrease in heart rate and diastolic pressure at rest as well as a decrease in the diurnal variation of these parameters; however during exercise the heart rate increases more than with similar work on Earth. Among Space Shuttle astronauts, an increase in central venous pressure (CVP) is initially seen while lying on their backs in preparation for launch. This is followed by a decrease in CVP in microgravity to below normal levels. Left ventricular end diastolic volume initially increases in microgravity then gradually decreases over several days to below baseline levels.

The following cardiac rhythm disturbances have been noted in space flight (**mostly during EVA**): premature atrial and ventricular contractions (PACs and PVCs), atrial bigeminy, ventricular bigeminy and short runs of ventricular tachycardia. In the absence of underlying heart disease there is no evidence that microgravity causes cardiac rhythm disturbances. **However, spaceflight may expose individuals to a variety of stresses including exercise, electrolyte imbalance, psychological stress, and sleep loss that may cause cardiac rhythm disturbances. This not likely to be a**

**significant problem for a healthy passenger, but the potential impact on an individual with pre-existing heart disease is unknown.**

**Neurovestibular** - Microgravity exposure results in space motion sickness (SMS) in about 70% of astronauts flying for the first time. It is thought that a sensory conflict between visual and vestibular stimuli may be a leading cause of SMS. Susceptibility to SMS cannot be predicted by susceptibility to ground-based motion sickness. Symptoms typically occur within the first 24 hours and resolve within 48-72 hours as adaptation occurs. Some individuals have continued to experience SMS symptoms throughout the mission. Symptoms include stomach awareness, malaise, loss of appetite, nausea, and vomiting. Prophylactic use of anti-motion sickness medications may be considered.

On return to the +1G environment, a re-adaptation process occurs. This varies in severity and manifests itself as difficulty turning corners, difficulty walking a straight line, illusions of movement of self or surroundings, nystagmus, nausea, vomiting. Typically, re-adaptation occurs fairly quickly; however, severe cases may take days to weeks to resolve. The duration of the recovery is affected by the duration of the exposure to microgravity or prior vestibular dysfunction. Longer duration missions in general require a longer re-adaptation period. Anecdotally, it is noted that those astronauts that continue to move their heads or walk around despite symptoms tend to readapt quicker than those who lie flat not moving. NASA flight surgeons have found that treating the nausea symptoms in severe cases with IM promethazine allows these individuals to be able to get up and walk around thereby speeding their re-adaptation to a +1 G environment.

**Musculoskeletal** - In microgravity, muscles no longer have to work against the force of gravity. As a result of this unloading of the antigravity muscles, a decrease in muscle mass and strength is seen along with neuromuscular changes including a decrease in the fatigue resistance of muscles and decreased neuromuscular efficiency. These changes are seen on short duration flights and become more pronounced with increased flight length. **This is not likely to be a significant problem for a healthy passenger, but the potential impact on an individual with pre-existing neuromuscular pathology is unknown.** Recovery time post-flight also increases proportionally with increased flight duration.

A common inflight medical complaint is that of back pain during space flight and then again on returning to Earth. About seventy-five percent of Space Shuttle crewmembers experience some degree of back pain. This is thought to possibly result from stretching of spinal ligaments and tendons with the unloading of gravity or possibly due to muscle use in fighting the natural microgravity posture.

Mechanical unloading of the skeletal system is also seen in microgravity resulting in changes in bone structure. While the amount of bone loss on short duration flights may not be clinically significant, bone loss from long duration flights can be significant. The rate of bone loss is approximately 1-2% mass loss per month in the lower body (spine, hip and legs). **This not likely to be a problem for a healthy passenger, but it could be troublesome for an individual with pre-existing moderate to severe osteoporosis where such a condition could become aggravated.** Recovery after space flight takes longer than mission duration.

**Hematological** - A decrease in red blood cell (RBC) mass is typically seen post-flight. This is thought to occur because as plasma volume decreases inflight, hemoglobin concentration increases causing a decrease in erythropoietin. Destruction of recently formed RBCs then occurs to reduce the level to that appropriate for microgravity. On return to Earth, as the body restores plasma volume that was lost inflight, a decrease in hemoglobin concentration occurs and an increase in erythropoietin is seen. This "space flight anemia" tends to generally be very mild and is not significant after short

duration flights. **This not likely to be a problem for a healthy passenger but it could be troublesome for an individual with pre-existing anemia.**

**Renal and Gastrointestinal** - A decrease in urine volume is seen in space flight probably due to decreased fluid intake and vomiting associated with SMS. Urinary calcium levels also increase during flight as calcium is reabsorbed from the bone. An increase in urinary phosphate and uric acid is also seen. This increase in urinary calcium, phosphate, uric acid, and decrease in urine volume can lead to supersaturation of the urine and an increased risk for the formation of renal stones. Another factor in renal stone risk is hypocitriuria.

A decrease in gastrointestinal motility is seen during space flight as well as a delay in gastric emptying. These changes may affect the absorption of nutrients and medications. Therefore, during the first 3 days of Space Shuttle operations it is preferred to use parenteral medications (such as IM promethazine) instead of oral medications. **There is insufficient knowledge regarding the metabolism and effectiveness of medications used in microgravity.** Constipation is a fairly common complaint during space flight. This is likely due to a variety of factors including decreased fluid intake, eating low fiber foods, decreased gastrointestinal motility, lack of privacy, reduced exercise, etc.

**Pharmacological** - Microgravity produces physiological changes that may influence the pharmacodynamics and pharmacokinetics of medications, alcohol, and drugs. For example, blood and bodily fluids shift to the upper part of the body; gastric emptying, intestinal absorption, and renal excretion rates are reduced; and the first pass effect in the liver may be decreased. How these changes interact to affect specific medications and drugs is **still** unclear. **All of these changes may be relevant to those individuals who are required to take medications regularly due to pre-existing medical conditions, and who must continue their use during space flight.** Regarding alcohol consumption, until more information on its effects in microgravity is gathered, abstinence is the safest course for space vehicle occupants.

For a more comprehensive review of reference information on human physiological changes during exposure to microgravity it is recommended to consult "Fundamentals of Aerospace Medicine" (**Ref <sup>9</sup> - Chapter 24, Pages 516-529**), "Space Physiology and Medicine" (Ref <sup>10</sup> – **Section IV, Pages 139-222**), and "Space Physiology" (Ref <sup>11</sup> – **Chapters 1-9, Pages 4-205**).

*The following are some medical conditions that could be adversely impacted by exposure to microgravity:*

- ◆ *Cardiovascular pathologies such as congenital heart diseases, valvular heart diseases, cardiomyopathies, pericarditis, myocarditis, endocarditis, ischemic heart diseases, dysrhythmias, aortic aneurysm, peripheral vascular diseases, uncontrolled chronic hypertension.*
- ◆ *Cerebrovascular diseases such as stroke, transient ischemic attack (TIA), intracranial bleed, intracranial aneurysm.*
- ◆ *Recent intra-cranial, intra-thoracic or intra-abdominal trauma or surgery.*
- ◆ *Ophthalmologic diseases such as pathologic nystagmus, glaucoma, diplopia, ocular hypertension, papilledema.*
- ◆ *Endocrine disorders such as diabetes insipidus, hypothyroidism, Addison's disease, hyperparathyroidism, and diabetes mellitus.*
- ◆ *Severe chronic dizziness, positional vertigo, motion sickness, or other vestibular/orientation problems of any cause.*
- ◆ *Musculoskeletal disorders such as progressive or severe atrophy of the muscles, myasthenia gravis, muscular dystrophy, severe osteoporosis.*

- ◆ *Spinal disorders such as disk disease.*
- ◆ *Renal disorders such as a history of urinary calculus.*
- ◆ *Gallbladder disorders such as gallstones.*
- ◆ *Anemia, hemoglobinopathies, hemolytic disorders, blood dyscrasias.*
- ◆ *Acute or chronic hemorrhagic states of any cause.*
- ◆ *Severe chronic infections of any cause.*
- ◆ *Gastrointestinal disorders such as symptomatic or bleeding hemorrhoids, constipation, gastrointestinal obstruction, symptomatic diverticulosis or diverticulitis, symptomatic esophageal reflux, gastritis, esophageal varices or bleeds.*
- ◆ *Pulmonary disorders such as emphysema or chronic obstructive pulmonary disease.*

## IONIZING RADIATION

**Ionizing radiation has enough energy to collide with atomic nuclei inside human cells and cause genetic damage that can lead to cellular death or dangerous mutations.** The main sources of ionizing radiation in space are: 1) galactic cosmic radiation, 2) solar radiation that includes solar wind/solar cosmic radiation, solar flares, and solar particle event radiation, and 3) geomagnetically trapped radiation.

Galactic cosmic radiation (**GCR**) is predominantly particle radiation that originates outside **the solar system and** contains high-energy subatomic particles such as hydrogen nuclei protons (~87%), helium nuclei alpha particles (~12%), and heavy nuclei **such as iron and lithium** (~1%). **Such high-energy particles can penetrate through thick solid matter (meters) including a space vehicle fuselage. The amount of GCR reaching earth decreases during periods of increased solar activity.** People on the ground are somewhat protected by the geomagnetic fields that surround the earth and partially block these particles from reaching the earth's surface. However, space vehicle occupants have a higher risk of exposure to these particles during orbital space flight **outside low earth orbit (LEO).**

**The main component of solar wind or solar cosmic radiation (SCR) is proton-electron plasma ejected from the surface of the sun at very high velocities that varies in magnitude according to the sun's 11-year activity cycle. During the solar max periods, SCR represents the main source of radiation exposure during space flight.**

**Solar flares are magnetic disturbances on the sun's surface generating electromagnetic radiation and high-energy protons that result in solar particle events (SPEs). SPE events are very difficult to predict and could expose unprotected space vehicle occupants (flying outside LEO) to a lethal dose of radiation. The only defense is to seek shelter immediately whenever space-based radiation detectors show a sudden increase in solar electromagnetic radiation that occurs during a solar flare, which provides indirect evidence that a SPE may be happening.**

**Earth's geomagnetic fields encircle the entire planet and are thicker at the equator and thin over the poles. Commonly known as Van Allen Belts, these fields contain trapped protons, heavy ions and electrons that are responsible for the Auroras. This magnetically trapped high-energy particles can expose space-vehicle occupants to significant levels of radiation.** The degree of radiation exposure during space flight is dependent on altitude and inclination. Radiation exposure is greater the higher the inclination. At lower inclinations, 90% of the radiation dose is due to passes through the South Atlantic Anomaly. At higher inclinations, only 50% of the

radiation dose is due to passes through the South Atlantic Anomaly. At the same inclination, a higher altitude flight would provide greater radiation exposure than a lower altitude flight.

During Gemini, Apollo-Soyuz, or Space Shuttle (<400km) flights, the radiation dosage ranged from 0.6-1.5 mSv/day. For passengers who would likely not fly frequently and whose flights would be expected to be of short duration solar radiation exposure would typically not be significant. Most medical conditions would not likely be affected by this amount of exposure. Pregnancy, however, would certainly be of concern. Radiation exposure during pregnancy can have significant adverse effects on the developing fetus. The U.S. National Council on Radiation Protection recommends that the total radiation dose received by a pregnant woman not exceed 5 mSv during the entire pregnancy, while the International Commission on Radiological Protection (ICRP) recommends at total dose not to exceed 2 mSv.

For a more comprehensive review of reference information on the effects of human exposure to ionizing radiation during space flight it is recommended to consult “NASA Bioastronautics Data Book” (Ref <sup>8</sup> – **Chapter 9, Pages 417-454**), “Fundamentals of Aerospace Medicine” (Ref <sup>9</sup> - **Chapter 8, Pages 221-235, and Chapter 10, Pages 253-255**), and “**Human Space Flight Mission Analysis and Design**” (Ref <sup>9</sup> - **Chapter 3, Pages 65-73**).

*The following are some medical conditions that could be adversely impacted by exposure to solar and galactic cosmic radiation:*

- ◆ *Pregnancy.*
- ◆ *Cataracts.*

## **NON-IONIZING RADIATION**

**Non-ionizing radiation covers the electromagnetic spectrum from near-ultraviolet, visible light, infrared, radiofrequency, microwave to extremely low frequency.** The main natural sources of non-ionizing radiation include continuous solar emission of ultraviolet light and radiofrequency radiation, solar flare events, electromagnetic radiation from sources outside the solar system, and magnetic fields from the sun and planets. Man-made sources include communications equipment (receivers, antennas, radio transmitters, radar transmitters, microwave transmitters), lasers **and high intensity optical sources**, lamps (UV, visible, IR), electronic equipment, power-conditioning and distribution equipment. The main effect of human exposure to non-ionizing radiation is the heating of tissues that may result in pain, cataracts, gastric ulcers, blood changes, agitation, drowsiness, weakness, headaches, decreased endurance, etc. Photosensitizing agents such as sulfonamides, chlorothiazides, and tetracyclines can decrease skin tolerance to UV light exposure. **Some windows used in a space station or a space vehicle are made of Quartz to allow special experiments and can allow UVB and UVC to pass through when the respective window is “active” and unprotected. Special care should be taken when space passengers are present to avoid serious sunburns after only short exposure times, as it has occurred to some individuals in the past.**

For a more comprehensive review of reference information on the effects of human exposure to non-ionizing radiation it is recommended to consult “Fundamentals of Aerospace Medicine” (Ref <sup>9</sup> - **Chapter 10, Page 253, and Chapter 11, Pages 280-281**) and Ref <sup>13</sup> - **Chapter 11, Page 292, and Chapter 29, Pages 638-640**).

*The following are some medical conditions that could be adversely impacted by exposure to non-ionizing radiation:*

- ◆ *Pregnancy.*
- ◆ *Cataracts.*
- ◆ *Gastrointestinal bleeding disorders.*
- ◆ *Skin injury and/or skin cancer.*
- ◆ *Implanted medical devices such as pacemakers and cardiac defibrillators.*

## **NOISE**

The term “noise” refers to a sound, especially one that lacks agreeable musical quality, is noticeably unpleasant, or is too loud. In other words, noise is any unwanted or annoying sound. The interior of a space vehicle can be a very noisy environment. Noise is produced by rocket propulsion systems, thrusters, hydraulic and electrical actuators, cabin air conditioning and pressurization systems, cockpit advisory and alert systems, communications equipment, motors, fans, pumps, transformers, oscillators, etc. Noise can also be caused by the aerodynamic interaction between ambient air (boundary layer) and the surface of the space vehicle during the atmospheric portion of the flight.

High-intensity noise exposure may cause hearing impairment or deafness, fatigue, irritability, startle responses, sudden awakening, poor sleep quality, loss of appetite, headache, vertigo, nausea, and may impair concentration and memory. Loud noise can interfere with or mask normal speech, making it difficult to understand verbal communication. Noise is a distraction and can increase the number of errors in any given task. Tasks that require vigilance, concentration, calculations, and making judgments about time can be adversely affected by chronic exposure (>8 h/day) to loud noise higher than 90 dBA. Ear discomfort may occur during exposure to a 120 dBA noise, ear pain at 135 dBA, and eardrum rupture at 155 dBA. Although chronic exposure to noise levels higher than 90dB can cause deafness, permanent hearing impairment would not be expected after a short duration space flight.

For a more comprehensive review of reference information on the effects of human exposure to noise it is recommended to consult “NASA Bioastronautics Data Book” (Ref <sup>8</sup> – [Chapter 15, Pages 693-750](#)), “Fundamentals of Aerospace Medicine” (Ref <sup>9</sup> - [Chapter 5, Pages 123-141](#)), and “[Human Space Flight Mission Analysis and Design](#)” (Ref <sup>9</sup> - [Chapter 5, Pages 116-118](#)).

*The following are some medical conditions that could be adversely impacted by exposure to high-intensity noise:*

- ◆ *Pre-existing hearing loss.*
- ◆ *Acoustic trauma.*
- ◆ *Anxiety.*
- ◆ *Sleep disorders.*

## **VIBRATION**

Vibration exposure usually occurs during the launch and atmospheric entry phases of a space flight, or while using the thrusters. Other sources of inflight vibration include motors, pumps, and other mechanical equipment. Vibration is transmitted throughout the entire body. Common effects of human exposure to vibration include impaired vision, impaired fine psychomotor coordination, impaired speech, impaired pulmonary ventilation, fatigue, internal organ discomfort or pain, and back pain. Exposure to high magnitudes of continuous vibration can cause body injury.

For a more comprehensive review of reference information on the effects of human exposure to vibration it is recommended to consult “NASA Bioastronautics Data Book” (Ref <sup>8</sup> – [Chapter 7, Pages 297-348](#)), “Fundamentals of Aerospace Medicine” (Ref <sup>9</sup> - [Chapter 5, Pages 110-123](#)), and “Human Space Flight Mission Analysis and Design” (Ref <sup>9</sup> - [Chapter 5, Pages 118-120](#)).

*The following are some medical conditions that could be adversely impacted by exposure to vibration:*

- ◆ *Musculoskeletal disorders such as symptomatic cervical arthritis, recent spinal injury, severe osteoporosis, spondylolysis, spondylolisthesis, herniated nucleus pulposus, non-healed displaced fractures, non-reduced dislocations of large joints.*
- ◆ *Ophthalmologic disorders such as retinal detachment, hemorrhages.*
- ◆ *Recent intra-cranial, intra-thoracic or intra-abdominal trauma.*
- ◆ *Implanted medical devices such as pacemakers, cerebrovascular shunts.*

## **TEMPERATURE AND HUMIDITY**

The lack of an atmosphere in space exposes space vehicles to extremely cold and hot ambient temperatures that vary depending upon the effective surface area of the vehicle that is directly exposed to radiant heat coming from the sun. In addition, a space vehicle is exposed to high levels of aerodynamic heat produced during the atmospheric entry. These temperature extremes represent a potential hazard for all vehicle occupants, who must rely on the proper operation of the cabin heating, air circulation, and cooling systems. These systems must maintain the right balance between air temperature, air velocity, barometric pressure, and humidity.

Comfort and health have a critical impact on human performance in space. The perception of comfort is highly influenced by ambient temperature, humidity, and airflow conditions. Other factors that have an impact on comfort include metabolic generation of heat during exercise and the type of clothing worn by the occupants. The human body exchanges thermal energy with the surrounding environment through radiation, convection, evaporation, and conduction. Microgravity interferes with convective thermal exchange.

Cabin temperature and humidity may vary depending on vehicle design. In the Space Shuttle program, the cabin temperature is typically in the middle to upper 70°F range with a relative humidity in the range of 30-40%. The dry atmosphere can lead to eye irritation, nosebleeds and skin dryness and irritation. Depending on the commercial space vehicle design, cooler cabin temperatures might be experienced requiring the use of personal protective garments.

Inappropriate control or a malfunction of the cabin heating, air circulation, and/or cooling systems could result in an uncomfortable cabin environment that affects cognitive and psychomotor performance. In a worst-case scenario, problems with these systems could expose occupants to extreme temperatures that could predispose to or result in heat or cold illnesses. Heat illnesses include heat stroke, heat hyperpyrexia, heat syncope, heat exhaustion, heat cramps, heat edema, transient heat fatigue, and chronic heat fatigue. Cold illnesses include hypothermia, frostnip, and frostbite. The same potential hazards apply to individuals performing activities in EVA suits.

For a more comprehensive review of reference information on the effects of human exposure to changes in temperature and humidity it is recommended to consult “NASA Bioastronautics Data Book” (Ref <sup>8</sup> – [Chapter 3, Pages 65-148](#)), “Fundamentals of Aerospace Medicine” (Ref <sup>9</sup> - [Chapter 7, Pages 206-220](#)), and “Human Space Flight Mission Analysis and Design” (Ref <sup>9</sup> - [Chapter 17, Page 544](#)).

*The following are some medical conditions that could be adversely impacted by exposure to heat stress:*

- ◆ *Pre-flight dehydration.*
- ◆ *Uncontrolled chronic hypotension or hypertension.*
- ◆ *Severe sweat gland abnormalities.*
- ◆ *Previous severe heat illnesses predispose to subsequent incidents.*
- ◆ *Peripheral vascular diseases including recurrent thrombosis.*
- ◆ *Decreased heat tolerance due to use of medications such as anticholinergics, phenothiazines, tricyclic antidepressants, MAO inhibitors, amphetamines, diuretics.*
- ◆ *Decreased heat tolerance due to endocrine disorders such as hypothyroidism.*
- ◆ *Skin allergies.*
- ◆ *Impaired sweating due to spinal cord injuries or autonomic neuropathy .*

*The following are some medical conditions that could be adversely impacted by exposure to cold stress:*

- ◆ *Previous severe cold injuries predispose to subsequent incidents.*
- ◆ *Uncontrolled hypertension or hypotension.*
- ◆ *Peripheral microvascular diseases, such as Reynaud's Disease.*

## **CABIN AIR**

In the sealed cabin environment of a space vehicle there are several potential risks including the presence of biological, chemical and particulate contaminants. Carbon dioxide released by all occupants during exhalation could accumulate and become a breathing hazard especially during sleep due to lack of convective air circulation. Breathing 100% oxygen (instead of a gas mixture) at sea level pressure for prolonged periods of time could cause reduced vital capacity (Lorraine Smith Effect), respiratory disturbances, heart problems, blindness, and loss of consciousness. Odors are known to cause symptoms such as nausea, nasal congestion, coughing, headaches and irritability. The most common sources of odor onboard a space vehicle are sweat, food, and organic waste.

For a more comprehensive review of reference information on the effects of human exposure to a variety of cabin air factors it is recommended to consult "NASA Bioastronautics Data Book" (Ref <sup>8</sup> – [Chapter 10, Pages 455-488](#)), "Fundamentals of Aerospace Medicine" (Ref <sup>9</sup> - [Chapter 24, Pages 532, 536 and 537](#)), "Fundamentals of Space Medicine" (Ref <sup>14</sup> – [Chapter 7, Page 302](#)), and "[Human Space Flight Mission Analysis and Design](#)" (Ref <sup>9</sup> - [Chapter 17, Pages 545-546](#)).

## **BEHAVIORAL:**

Psychological, psycho-physiological, and interpersonal stressors related to isolation and confinement can have a definite impact on individual behavior and performance. Space flight brings with it certain psychological stressors including being in a confined space, the lack of privacy and risk of injury or death. These stressors become more significant during longer duration flights and in missions involving heterogeneous groups comprised of people from different national and cultural backgrounds. The resulting on-board stress can impact negatively on the ability of individuals to respond efficiently to operational emergencies and to communicate effectively with people in mission control.

*The following are some medical conditions that may be of concern and require further evaluation:*

- ◆ *Psychiatric problems, such as personality disorders, adjustment and psychosomatic reactions, anxiety disorders and phobias (e.g., fear of flying, fear of closed spaces), severe depression, acute psychotic reactions, bipolar disorder, suicidality, and asthenization (a syndrome of low energy, fatigue, and irritability reported to occur in space by Russian psychologists and flight surgeons).*
- ◆ *Nicotine addiction.*
- ◆ *A history of recent or current alcohol and drug abuse can lead to craving or withdrawal effects during the early days of the mission.*
- ◆ *Disruptions in sleep, circadian rhythmicity, and cognitive performance.*

*NOTE: No behavioral issues would be expected during space flights lasting one day or less in any person except among those already identified as having active psychiatric pathology.*

The ability to communicate and understand instructions during flight, particularly emergency instructions is very important to ensure the safety of a space flight.

*The following are some medical conditions that may be of concern and require further evaluation:*

- ◆ *Ophthalmologic disorders that interfere with vision.*
- ◆ *ENT disorders such as deafness, tinnitus that interferes with hearing/communication, disorders that interfere with speech.*
- ◆ *Neurological disorders such as Alzheimer's, dementia, Huntington's chorea.*

## **RECOMMENDED MEDICAL HISTORY ASSESSMENT OF PROSPECTIVE ORBITAL SPACE PASSENGERS**

Prospective space passengers should be required to provide their medical history (including family history), emphasizing those medical conditions that could be adversely impacted by exposure to the operational and environmental risk factors of orbital space flight.

In addition, they should provide information about the following:

- Use of implanted pacemaker or defibrillator.
- Tuberculosis, hepatitis, AIDS, or other serious infectious disorders.
- Use of medications (over-the-counter or prescription), alcohol and other drugs.
- History of psychiatric and/or psychological problems, based on the most current DSM, ICD or other classification systems
- Occupational exposure to ionizing radiation
- Date of last menstrual period, current pregnancy, recent post-partum (less than 6 weeks), or recent spontaneous or voluntary termination of pregnancy.
- Recent significant trauma.
- History of surgery and/or any implanted medical devices.
- Recent significant illness.
- Recent admission to a hospital.
- Current medical conditions requiring treatment.

- Any rejection for life or health insurance. Including medical military discharge or medical disability
- Any medical practitioners seen in the last 3 years and reason for visit.

## ***RECOMMENDED PHYSICAL EXAMINATION OF PROSPECTIVE ORBITAL SPACE PASSENGERS***

Prospective space passengers should undergo a general physical examination including:

- Vital signs (heart rate, respiratory rate, temperature, blood pressure).
- Head, face, neck, and scalp.
- Nose, sinuses, mouth, throat, ears (including eardrum integrity and function, Eustachian tube function).
- Eyes
- Lungs and chest.
- Heart.
- Peripheral vascular system.
- Abdomen and viscera.
- Genitourinary system.
- Rectal, pelvic, and breast examination (only if indicated by medical history).
- Upper and lower extremities.
- Spine.
- General neurological evaluation.
- General psychiatric evaluation including a mental status examination.

## ***RECOMMENDED MEDICAL TESTS FOR PROSPECTIVE ORBITAL SPACE PASSENGERS***

Prospective space passengers should complete the following medical tests:

- Routine hematology.
- Clinical chemistry (serum).
- Urinalysis.
- Resting electrocardiogram.
- Chest X-ray (PA & lateral).
- Corrected visual acuity.
- Tonometry
- Audiogram.
- Pulmonary function testing and/or metacholine provocation test (if clinically indicated).

## ***MEDICAL CONDITIONS THAT MAY PRECLUDE PASSENGER PARTICIPATION IN COMMERCIAL ORBITAL SPACE FLIGHTS***

In general, medical conditions that may preclude passenger participation in commercial orbital space flights include: Any significant deformities (congenital or acquired) of the musculoskeletal system, diseases, illnesses, injuries, infections, tumors, treatments (pharmacological, surgical, prosthetic, or other), or other physiological or pathological or psychiatric conditions that: 1) may result in an inflight medical emergency, 2) may result in an inflight death, 3) may compromise the health and safety of other passengers or space vehicle occupants, 4) may interfere with the proper use (don and doff) and operation of personal protective equipment, 5) may interfere with emergency procedures (including evacuation), or 6) may compromise the safety of the flight. Any significant medical condition that results in an unexpected inflight medical emergency represents a potential risk to the safety of the flight.

## ***RECOMMENDED DISPOSITION OF PROSPECTIVE PASSENGERS WHO HAVE MEDICAL CONDITIONS THAT MAY PRECLUDE THEIR PARTICIPATION IN COMMERCIAL ORBITAL SPACE FLIGHTS***

Prospective space passengers who have significant medical conditions that may preclude their participation in orbital space flights could be given a special medical clearance, on a case-by-case basis, by a physician employed and/or contracted by the commercial space vehicle operator. Such a physician should be trained and/or experienced in aerospace medicine. Ultimately, the granting of such a special medical clearance should be based solely on the best available medical and physiologic information, and the clinical judgment of the consulting aerospace medicine specialist(s).

Based on the specific nature of the medical condition, a prospective passenger could be temporarily prohibited from participation in orbital space flight until the medical condition is resolved, or until it can be effectively brought under medical control and such a condition is no longer likely to: 1) result in an inflight medical emergency, 2) result in an inflight death, 3) compromise the health and safety of the passenger or other space vehicle occupants, 4) interfere with the proper use (don and doff) and operation of personal protective equipment, 5) interfere with emergency procedures (including evacuation), or 6) compromise the safety of the flight. The requirement for the use of personal protective equipment and the ability to perform an emergency evacuation may mean that passengers with certain disabilities or medical conditions may not be able to fly, **unless a special accommodation can be made for an individual with such a disability or condition.**

Some medical conditions may be cleared for short-duration orbital flight following medical assessments in simulated space flight environments including the use of a zero-G aircraft, a sub-orbital space vehicle, a high performance aircraft, a hypobaric (altitude) chamber, or a human centrifuge. Furthermore, using a flexible common-sense approach that applies aerospace medicine knowledge and experience-based medical risk analysis, it may be possible to permit special medical accommodations for prospective passengers who have certain pathologies (including disabilities). For example, Professor Stephen Hawking, who suffers advanced amyotrophic lateral sclerosis with significant mobility impairment, was able to safely participate in a zero-G flight (Ref <sup>12</sup>). In order to do so, he was accompanied by his own medical team (including an aerospace medicine specialist) who were involved in providing inflight medical support as needed. The aeromedical preparation for this unique flight included: 1) a training flight carrying a healthy volunteer on the day before Professor

Hawking's flight, 2) the use of non-invasive biomedical monitoring equipment for blood pressure, heart rate, electrocardiography, respiratory rate, oxygen saturation (SaO<sub>2</sub>) and carbon dioxide (PcapCO<sub>2</sub>), and 3) a practical simulation of possible inflight medical emergencies. This zero-G flight demonstrated that it may be feasible to allow selected individuals with severe disabilities (or other pathologies) to participate in short-duration orbital space flights, but this may require a comprehensive preflight aeromedical preparation, appropriate inflight biomedical monitoring (including medical equipment and supplies), and it may even require a special flight dedicated to carry such an individual with real-time support provided by a medical team to ensure his/her health and safety. However, this could be a complex operational scenario due to the dynamic characteristics of a space flight profile, the limited and confined occupable space onboard a commercial space vehicle, and the practical limitations in modifying a flight plan after launch.

Finally, there may be some prospective passengers suffering terminal medical conditions who may wish to participate in a commercial space flight (sub-orbital or orbital) before they pass away. Therefore, commercial space vehicle operators will have to decide whether or not such individuals will be allowed to participate in a space flight. This will be a very difficult decision to make due to a number of significant ethical and legal implications.

## ***OTHER SAFETY RECOMMENDATIONS***

Prospective passengers should be briefed on all of the potential hazards to their health and safety during orbital space flight, including the hazards of exposure to operational and environmental risk factors and to possible psychological stressors.

Because of the potential hazards of space flight, it is recommended that a female of child-bearing age be offered a pregnancy test. Space vehicle operators may wish to consider excluding pregnant women from participating in orbital space flights.

No conclusive data exist concerning the potential adverse physiologic and pathologic effects of space flight on infants or young children. For this reason, space vehicle operators may wish to establish a minimum age for passengers participating in orbital space flights.

Additional performance and safety evaluations of prospective passengers may be considered, such as training in a human centrifuge (based on the G-profile of the actual flight), a high performance aircraft, a hypobaric (altitude) chamber, and a parabolic (zero-G) flight in preparation for orbital space flight. These training activities could help identify certain medical conditions that prospective passengers may not voluntarily disclose in their medical history.

## ***PRE-FLIGHT MEDICAL INTERVIEW, PHYSICAL EXAMINATION AND HEALTH STABILIZATION OF PROSPECTIVE SPACE PASSENGERS***

Confining relatively untrained individuals (not professional astronauts) inside a small space vehicle, with limited possibilities of emergency egress, makes it obvious that some sort of pre-flight preparation and/or control is necessary in order to minimize potential concerns pertaining to the health and safety of all space vehicle occupants during flight.

Within one week of the actual departure of a commercial orbital space flight, all passengers should be subjected to an abbreviated medical interview and physical examination as part of a pre-flight passenger health stabilization period established by the space vehicle operator. The purpose of this pre-flight medical screening is to ensure that passengers have not developed significant acute medical conditions or exacerbations of chronic medical conditions after having received their original medical clearances from the operator. This includes identifying infectious illnesses that could affect other passengers and/or crew members. Such a pre-flight medical screening should include vital signs and a brief medical history and physical examination concentrating on the following: eye, ear, nose, throat, cardiopulmonary, gastrointestinal tract, musculoskeletal, and neurological systems. A brief mental health status assessment should also be obtained.

Strict inspection and control of allowable personal items is recommended in order to prevent undesirable passenger behaviors such as the inflight use of non-reported medications (over-the-counter or prescription) as well as unauthorized alcohol consumption and/or drugs use. This could be accomplished by having approved personal kits and standard hygiene items supplied to the passengers by the space vehicle operators. Furthermore, the use of approved flight garments and personal protective equipment provided by the operators would further limit the carrying of unauthorized items by passengers. Currently, the FAA Office of Commercial Space Transportation requires operators to implement security requirements to prevent any space flight participant from jeopardizing the safety of the occupants or the public. A passenger may not bring on board any explosives, firearms, knives or other weapons. It is therefore imperative that the operator have some control over the pre-boarding activities of all passengers.

## ***INFLIGHT MEDICAL CONSIDERATIONS***

It is reasonable to expect limited onboard medical intervention capabilities during short-duration commercial orbital space flights. Certain medical conditions may appear or worsen during space flight and represent a significant problem due to: 1) limited medical intervention capabilities onboard, 2) restricted access to medical care because of the remote location, and 3) the fact that return-to-earth may be stressful or take a considerable amount of time even after declaring a medical emergency. Passengers may not be able to take required oral medications secondary to Space Motion Sickness. Additionally cabin space may be very limited such that a sick person's position could not be changed nor could another individual be in a convenient position to help especially during return to Earth and landing. Unlike airliners that can divert to another airport in case of a medical emergency, return to earth from an orbital space flight is not as simple. There may be limited landing sites capable of handling the space vehicle and the de-orbit burn must occur at the proper time to ensure appropriate re-entry and the safety of the flight. In the Space Shuttle program, preparation for an unplanned or emergency de-orbit to a primary landing site may take up to 24 hours. Therefore, the effective medical screening of passengers will be of critical importance to prevent and/or minimize the occurrence of severe medical emergencies during flight. However, it is highly recommended to carry an emergency medical kit onboard that should include an automated external defibrillator (AED) and airways equipment. At this point in time, it is not known if space vehicle operators will utilize a space flight attendant and, if so, whether the attendant receives training on cardiopulmonary resuscitation (CPR) and basic life support (BLS) to provide basic emergency medical assistance during flight. Without a flight attendant, inflight medical care may not be available unless flight crews and/or passengers receive CPR and BLS training for self-care or for the care of other space vehicle occupants. The most likely medical problems to occur during short-duration orbital space flights involve the nervous system and sensory organs (including space adaptation

syndrome), digestive system, injuries and trauma, musculoskeletal system and connective tissue, and skin and subcutaneous tissue.

As mentioned previously in this report, it is possible to consider a scenario where a disabled or diseased passenger wishes to pay for additional seats (or even an entire flight) to fly with his/her full medical team and the required medical equipment and supplies. Although feasible, this would be a logistically complex and operationally difficult flight to accomplish.

**Commercial space vehicle operators may decide to implement a process for non-invasive biomedical monitoring (during the launch, the entire flight and the immediate post-landing period) of some passengers who were granted medical waivers to participate in short-duration orbital space flights. The implementation of such a biomedical monitoring process represents an additional tool that could be used to support the decisions made by the operator's medical staff to grant waivers to some passengers with more complex medical conditions. Another benefit of conducting biomedical monitoring would be to provide space vehicle operators with additional medical data that could be used for continual improvement of health risk management techniques applicable to the medical evaluation and granting of medical waivers to future prospective passengers. Some of the basic physiological parameters that could be monitored may include body temperature, heart rate, ambulatory electrocardiography, blood pressure, respiratory rate, transcutaneous arterial oxygen saturation (PSaO<sub>2</sub>) and carbon dioxide partial pressure (PaCO<sub>2</sub>). Any monitoring equipment used for this purpose should be fully portable, light and compact, self-powered, capable of automated data collection/sampling and data storage capability, non-invasive, minimally intrusive on the wearer, and should not interfere with or be affected by the space vehicle electrical equipment/systems.**

Other inflight health issues to be addressed by commercial space vehicle operators include nutrition, hydration, personal hygiene, sleeping, and physical fitness.

## ***POST-FLIGHT MEDICAL CONSIDERATIONS***

The most likely post-flight passenger medical issues to be expected involve the nervous system and sensory organs (including motion sickness and postural instability), digestive system, injuries or trauma occurred during flight, musculoskeletal system and connective tissues, skin and subcutaneous tissues, and post-landing orthostatic intolerance. Passengers should be instructed on the early identification and proper medical handling of delayed symptoms if they occur. Post-flight care may be required if prophylactic medication is administered during flight. A period of post-flight monitoring and/or rehabilitation may be required before a full "return to duty" is permitted, including the operation of any machinery such as driving a car or flying an aircraft.

Passenger medical debriefs post-flight are highly recommended, not only for collection of critical medical data, but also for the resolution and/or follow up of any health issues resulting from space flight. A practical tool to facilitate and standardize these post-flight debriefs would be a medical questionnaire to be completed by all passengers. Because the manned commercial space flight industry is in its embryonic stage, all medical information collected on orbital space passengers (particularly those who fly with medical waivers) **could be used to establish company-owned space passenger medical databases. Such databases could support the development of outcome-based medical information support systems for continual improvement of health risk management techniques applicable to the medical evaluation and granting of medical waivers**

**to future prospective passengers.** The database **could** include the results of the initial medical evaluation of passengers, any additional findings during the pre-flight medical evaluations, the results of the inflight biomedical monitoring (**if any**), as well as any post-flight medical issues. All medical information collected and compiled into a **company** database **could** be de-identified (**if legally required**) in order to fully protect the individual medical-legal privacy rights of all passengers.

## **REFERENCES**

1. Antuñano, M.J, Baisden, D.L., Davis, J., Hastings, J.D., Jennings, R., Jones, D., Jordan, J.L., Mohler, S.R., Ruehle, C., Salazar, G.J., Silberman, W.S., Scarpa, P., Tilton, F.E., and Whinnery, J.E. "Guidance for Medical Screening of Commercial Aerospace Passengers" Federal Aviation Administration, Office of Aerospace Medicine, Washington, D.C. 2006. Technical Report No. DOT-FAA-AM-06-1
2. Futron Corporation. "Space Tourism Market Study: Orbital space travel & destinations with suborbital space travel" October 2002. Futron Corporation, 7315 Wisconsin Avenue, Suite 900W, Bethesda, MD 20814.
3. Rayman, R.B., Antuñano, M.J., Barker, C.O., Church, T.G., Garber, M.A., Hastings, J.D., Illig, P.A., Landry, R.R., McMeekin, R.R., Northrup, S.E., Rapmund, G., Ruehle, C., Ruiz, R.T., Saenger, A., and Schneider, V.S. "Medical Guidelines for Space Passengers" *Aviat. Space. Environ. Med.* 2001;72(10):948-950.
4. Rayman, R.B., Antuñano, M.J., Garber, M.A., Hastings, J.D., Illig, P.A., Jordan, J.L., Landry, R.R., McMeekin, R.R., Northrup, S.E., Ruehle, C., Saenger, A., and Schneider, V.S. "Medical Guidelines for Space Passengers – II" *Aviat. Space. Environ. Med.* 2002;73(11):1132-1134.
5. NASA Man System Integration Standards, NASA-STD-3000. July 1995.
6. Kanas, N. and Manzey, D. *Space Psychology and Psychiatry* (2<sup>nd</sup> Edition). Microcosm Press, El Segundo (California) & Springer Publications, Dordrecht (The Netherlands), 2008.
7. Kanas, N., Sandal, G., Ritsher, J.B., Manzey, D., Gushin, V.I., et al. *Psychology and Culture During Long-Duration Space Missions. Final Report, Study Group on Psychology and Culture During Long-Duration Space Missions, International Academy of Astronautics, 2006.*
8. NASA Bioastronautics Data Book, NASA SP-3006. Second Edition. U.S. Government Printing Office, Scientific and Technical Information Office 1973.
9. *Fundamentals of Aerospace Medicine* (4<sup>th</sup> Edition). Edited by Jeffrey R. Davis, Robert Johnson, Jan Stepaneck and Jennifer A. Fogarty. Lippincott Williams & Wilkins. 2008.
10. *Space Physiology and Medicine* (2<sup>nd</sup> Edition). Edited by Arnauld E. Nicogossian, Carolyn Leach Huntoon, and Sam L. Pool. Philadelphia: Lea & Febiger. 1989.
11. *Space Physiology*. Edited by Jay C. Buckey Jr. New York: Oxford University Press. 2006.
12. Mackenzie I, Viirre E, Vanderploeg J.M., et al. ZeroG in a patient with advanced amyotrophic lateral sclerosis. *Lancet* 2007;370(9587):566.

13. Fundamentals of Aerospace Medicine (3<sup>rd</sup> Edition). Edited by Roy L. DeHart and Jeffrey R. Davis. Lippincott Williams & Wilkins. 2002.
14. Fundamentals of Space Medicine (1<sup>st</sup> Edition). Edited by Gilles Clément. Microcosm Press and Kluwer Academic Publishers. 2003.
15. Human Space Flight Mission Analysis and Design (1<sup>st</sup> Edition). Edited by Wiley J. Larson and Linda K. Pranks. The McGraw-Hill Companies Inc. – Space Technology Series.

# COMMERCIAL SPACE VEHICLE OPERATOR MEDICAL LIABILITY ISSUES AND OTHER LEGAL ASPECTS

## ABSTRACT

Any legal consideration concerning commercial orbital space flights has first to ask which law applies. Partly air law and partly space law can be applicable. In space law we have international as well as national legislation. Any licensing which is required for airplanes as well as space planes needs to be implemented either under the provisions of the Chicago Convention with its Annexes or in accordance with international space law and national space legislation. With regard to liability, international space legislation falls short of granting a claim to passengers against the space flight operator. If one argues that space flight participants are not involved in the general operation of a spacecraft, one could arguably apply the Liability Convention to these passengers. Taking examples, however, from national space legislation we see that e.g. under U.S. law the licensee must inform the space flight participant in writing about the risks of the launch and re-entry including the safety record of the launch/re-entry vehicle type. The space flight participant must provide written certification of compliance with the physical examination. A licensee is required to make a reciprocal waiver of claims with its contractors, subcontractors and customers. Personal insurance in the form of passenger life and passenger liability insurance policies may also help to reduce the risk of medical legal liability. Also importantly, each flight participant under U.S. law has to provide his/her written informed consent for participating in the space flight as well as a written certification of compliance with the physical examination, if such is required. Only competent persons can give informed consent. Thus, the respective flight participants must understand the proposed examination and make an informed decision. With regard to the status of space flight participants, it is up to now unclear what exact status they should possess. For space tourism activities to become a commercial reality there is a need to come up with international legislation for public access to space.

The thorough study of medico-legal aspects of commercial orbital space flights aims to fulfil four objectives:

- Ensuring passenger / flight participant safety
- Advancement of the commercial space flight industry
- Development of the rule of law against medical requirements in a new field of space applications and
- Guaranteeing certainty in medical and legal issues for commercial space flight operators.

This requires a consideration of the following legal issues: (1) the applicable law; (2) jurisdiction, authorisation and licensing; (3) liability for medical risk exposure; and (4) informed consent. This section will discuss these four issues in turn.<sup>1</sup>

## 1. Preliminary Issues: The Applicable Law

A discussion of legal aspects pertaining to the field necessarily requires the consideration of which law applies. Since this study focuses on “Commercial Orbital Space Flights”, it is assumed that international space law and the various national space legislations apply. It is important to note however, that depending on the method of launch, the altitude flown at any given time and the

---

<sup>1</sup> Hobe, S. and Cloppenburg J., “Towards a New Aerospace Convention? – Selected Legal Issues of ‘Space Tourism’”, (2005) Proceedings of the 47<sup>th</sup> Colloquium on the Law of Outer Space pp. 377 – 385; Hobe, S., “Legal Aspects of Space Tourism”, (2007) 85 Nebraska Law Review (forthcoming)

function of the flight, certain aspects of air law may also apply.<sup>2</sup> In such cases, medical liability laws pertaining to aircraft are applicable. This study considers only that part of the flight that is “orbital”, and therefore space law is the applicable law. From this perspective, applicable laws include international space law and national space legislation.

### **1.1. International Space Law**

The written corpus of international space law consists of five basic United Nations (UN) treaties, as well as a host of UN General Assembly resolutions. Of these, documents pertinent to this study are the 1967 Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, including the Moon and other Celestial Bodies (“Outer Space Treaty”), the 1972 Convention on International Liability for Damage Caused by Space Objects (“Liability Convention”) and the 1976 Convention on Registration of Objects Launched into Outer Space (“Registration Convention”).

### **1.2. National Space Legislation**

National legislation provides the method through which international laws may be implemented and enforced, especially on commercial service providers. As such, the applicable national legislation of the relevant State would apply on commercial orbital space flights. The mechanism of such implementation is through the jurisdiction, authorisation and licensing provided for in these national legislations. At the time of writing, there is only one State that has an elaborated legislation relating to medical safety guidelines for passengers on commercial orbital space flights – the United States of America.

## **2. Jurisdiction, Authorisation and Licensing**

Jurisdiction is the authority to make practical binding pronouncements on legal matters and to administer justice within a defined area of responsibility. Jurisdiction is an important legal concept because it determines which authority may exercise its power over an entity, and the extent to which that power may be exercised. States have the general jurisdiction to prescribe applicable national laws and to enforce them. States usually require operators to apply for authorisation and licenses to conduct space activities. These mechanisms of authorisation and licensing allow States to supervise the activity and to ensure that the applicable law is enforced.

Registration of the space flight vehicle and consequently the exercise of quasi-territorial jurisdiction on board is decisive for the determination of the legal régime applicable on board. Under international space law, a space object is to be registered by the “launching State” in accordance with Article II of the Registration Convention. Where more than one State is involved in the launch, an agreement between the parties is required in order to determine which State shall register the launched space object. The State of registry pursuant to Article VIII of the Outer Space Treaty “shall retain jurisdiction and control over such object, and over any personnel hereof, while in outer space”. Thus, subject to certain restrictions in the Outer Space Treaty, the State of registry has jurisdiction over the space flight vehicle, including the application of its national laws.

A space flight vehicle is a space object, requiring authorisation under international and national space law. Participation in commercial space flight has occurred to a very limited extent so far. As such, the

---

<sup>2</sup> The application either of air law or space law depend on whether the flight takes place in airspace or in outer space. There is no clear physical line between airspace and outer space, and the views concerning legal demarcation take different approaches (“functional” vs. “spatial”). It is beyond the scope of this study to consider this debate. A good summary of the various demarcations of outer space (for medical, legal, propulsion, administrative and engineering purposes) can be found in C. Laymance, “Science of Space”, (1993), *Space and Missile Orientation Course*, Vandenberg Air Force Base CA: 30<sup>th</sup> Operations Support Squadron, 1 – 3.

legal environment for the authorisation of such commercial space flight activities, and the medico-legal standards of such flights, is still at a nascent stage.

Article III of the 1972 Liability Convention makes a “launching State” liable for damage caused to persons on board a space object where the damage is due to its fault or the fault of persons for whom it is responsible. Article I(c) defines a “launching State” as a State which launches or procures the launch of a space object, or a State from whose territory or facility a space object is launched. Further to this, Article VI of the 1967 Outer Space Treaty makes States Parties “bear international responsibility” for activities in outer space, even where such activities are carried out by non-governmental entities. Such activities require “authorisation and continuing supervision” by the appropriate State. This obligation is generally fulfilled through a licensing process. It is significant to note however, that these treaties do not require States to adopt safety and certification standards for crew, vehicles or passengers.

It must be noted that a lack of safety regulations could result in international liability under the Liability Convention. Therefore, it is likely that the State of registration of the space vehicle operator, the State of registration of the space flight vehicle, and the State that launches or procures the launch of the space flight vehicle, would have license requirements in domestic legislation that demand adherence to medico-legal requirements for passenger health and safety. Thus far, no rule of customary international law has been developed regarding passenger safety or medico-legal liability in relation to commercial orbital space flights due to a lack of clear practice and the belief that such practice is obligatory.<sup>3</sup> Minimum regulation and general compliance to minimum passenger safety standards appear to be sufficient.<sup>4</sup>

### **3. Liability for Medical Risk Exposure**

Liability is the legal doctrine that makes a person or entity responsible to pay compensation or make reparation for any damage incurred to a victim. Liability includes third party liability and contractual liability. Third party liability provides for compensation where damage is done to the person or property of third parties, and is regulated by principles of international and national space legislation. For example, if a piece of the space vehicle were to break off during launch and injure a third party, international legislation provides for compensation by the launching State of that vehicle to the victim. Contractual liability refers to compensation payable due to the breach or non-fulfilment of terms in a legal agreement. Contractual liability is regulated by the place and forum of law chosen by the contract concluded between the parties concerned. For example, the sale of a ticket for a seat onboard a space vehicle is concluded by a contract between the space flight provider and the flight participant. If either party breaches the terms of the contract, that party would be liable to pay compensation. Such compensation would be regulated by the law of the place of jurisdiction stated in the contract.

Commercial orbital space flight as an industry is at its infancy and understandably risk-adverse in terms of medico-legal liability. Sources where such liability may stem from include international law, national legislation and contract and tort / delict laws at national level. Methods to reduce exposure to such medico-legal liability include contractual waivers of liability and insurance.

#### **3.1. Passenger Liability at International Law**

---

<sup>3</sup> I. Brownlie, *Principles of Public International Law*, (2003), 6<sup>th</sup> ed., p. 4 et seq

<sup>4</sup> R. Jakhu, *FAA Regulation of Crew and Passenger Safety Aboard Reusable Launch Vehicles*, (November 2001), Term Essay 1 (496-491A), (unpublished), p.14

Passengers can potentially raise claims against the space vehicle operator, other passengers, the vehicle manufacturer, and against the relevant launching State(s).

A régime of fault-based liability of the “launching state” is established by the 1972 Liability Convention for damage caused by a space object elsewhere than on the surface of the Earth to a space object of another launching state or to persons or property on board such space object. Under Article VII of the same Convention however, its provisions do not apply to passengers who are nationals of the launching state of the space object or to passengers who are not nationals of that launching state but participating in the operation of its space object.

Arguably, space flight participants are not involved in the general operation of the spacecraft. Thus, it could be argued that the Liability Convention may apply to those passengers. However, space flight remains “inherently risky”<sup>5</sup> and is “far from being routine, or even a mode of transportation per se”<sup>6</sup>. Passengers of a space flight voluntarily put themselves at high risk by participating in a space mission. As such, it has been argued that passengers are not protected by the provisions of the Liability Convention and cannot claim compensation therefrom.<sup>7</sup> This exclusion has been criticised, since the protection of passengers is paramount for the success of the industry.<sup>8</sup> If the Liability Convention is inapplicable, liability may be established according to national laws.

### **3.2. Passenger Liability at National Law**

At present there is no international legislation that regulates passenger liability. National legislation however, may be used as a source for formulating international legal rules, especially where such legislation is adopted by States whose interests are specially affected by the particular issue at hand. In this regard, the United States of America has established the most sophisticated national space legislation. The regulation of reusable launch vehicles (RLV) by the Federal Aviation Administration (FAA) was governed by the 1998 Commercial Space Launch Act (Title 49 of the US Code, Chapter 701) and the Final Rule of the Commercial Space Transportation Reusable Launch Vehicle and Reentry Licensing Regulations.<sup>9</sup>

In 2004, the United States enacted the Commercial Space Launch Amendment Act (“CSLAA” – amending Chapter 701 of Title 49 U.S.C.), with the objective “to encourage the development of a commercial space flight industry”.<sup>10</sup> The Act defines “space flight participants” as “individual[s], who [are] not crew, carried within a launch vehicle or re-entry vehicle”, providing for additional licence requirements “for a launch vehicle carrying a human being for compensation”.

On 11 February 2005 the FAA published the Draft Guidelines for Commercial Sub-orbital Reusable Launch Vehicle Operations with Space Flight Participants.<sup>11</sup> On 29 December 2005 it released a notice of proposed regulations on “Human Space Flight Requirements for Crew and

---

<sup>5</sup> Federal Register, December 29, 2005, Vol. 70, No. 249, p. 77269.

<sup>6</sup> M. S. Kelly, Northrop-Grumman/Xon Tech, Statement to the Commercial Space Launch Activities Act of 2003, H.R. 3245, 108th Cong. (5 Nov. 2003).

<sup>7</sup> P. Malanczuk, Haftung, in: K.-H. Böckstiegel (ed.), Handbuch des Weltraumrechts, Köln et al. 1991, p. 755 (791); E. Wins, Weltraumhaftung im Völkerrecht, Berlin 2000, pp. 126 et seq.

<sup>8</sup> R. Jakhu/ R. Bhattacharya, Legal Aspects of Space Tourism, 45 Proc. Colloq. L. Outer Space 2002, p. 112 (129).

<sup>9</sup> For an account of the RLV Regulatory Regime according to the CSLA and the Final Rules, see C. T. Ryabinkin, Let there be Flight: It's Time to Reform the Regulation of Commercial Space Travel, 69 J. Air L. & Com. 101.

<sup>10</sup> 49 U.S.C. 70105a(c). On the objectives of the CSLAA, see S. H. Bromberg, Public Space Travel - 2005: A Legal Odyssey into the Current Regulatory Environment for United States Space Adventurers Pioneering the Final Frontier, 70 J. Air L. & Com. 639, 658 et seq.

<sup>11</sup> In the following referred to as FAA Draft Guidelines.

Space Flight Participants”.<sup>12</sup> The final regulations were issued on December 15, 2006, and became effective on February 13, 2007.<sup>13</sup>

Under the CSLAA a licence is required for the launch of a launch vehicle or the operation of a launch site or reentry site, or for the reentry of a reentry vehicle, either in the United States or by a US citizen. The licence requirements are set out in 49 U.S.C. 70105(b). For launch vehicles carrying a human being for compensation or hire, additional licence requirements necessary to protect the health and safety of crew or space flight participants may be prescribed, but only by means of final regulations.

According to 49 U.S.C. 70105(b)(5)(A), the licensee must inform the space flight participant in writing about the risks of the launch and re-entry, including the safety record of the launch/re-entry vehicle type. Moreover, the space vehicle operator must disclose that participation in space flight may result in death, serious injury, or total or partial loss of physical or mental function. The space flight participant must be given an opportunity to ask questions orally before flight. On the basis of this information, each space flight participant has to provide written informed consent to participate in the launch and re-entry. The written consent must state that the space flight participant understands the risk and takes the flight voluntarily. Moreover, the written consent must identify the specific launch vehicle and be signed and dated by the space flight participant.

The space flight participant must also provide written certification of compliance with the physical examination, if so required. However, the FAA in its final rules does not require that a space flight participant undergo a physical examination.<sup>14</sup> The FAA Draft Guidelines do however recommend that space flight participants obtain an evaluation of their medical history to determine whether a physical examination might be appropriate.<sup>15</sup> The memorandum “Guidance for Medical Screening of Commercial Aerospace Flight Participants” of 31 March 2003 provides guidance for the medical assessment.

### **3.3. Liability of the Space Vehicle Operator to the Passenger under Tort / Delict and Contract Law**

The applicable law in the context of tort / delict and contractual liability for acts committed on board the space flight vehicle is determined in accordance with the law of the state of registration of the space vehicle after take-off or launch and before landing. Passenger liability can be established by contract or delict/tort if the applicable national law so provides.

Contracts should contain a choice-of-law provision. With respect to tort / delicts, in many jurisdictions such claims are subject to the *lex loci delicti* rule, the law of the “place of the wrong” being applicable. Therefore in claims of tort / delict, *lex loci* should be judged in accordance with the law of the state of registration of the space object while in outer space or on the ground in that state or on the territory of undetermined sovereignty. The *lex loci delicti* rule has been criticised in its application to outer space, since outer space is not subject to national appropriation and therefore not subject to national law. Other criteria proposed in the determination of the applicable law include contractual stipulation, law of the plaintiff or defendant, or law of the forum.

### **3.4. Waivers of Liability**

---

<sup>12</sup> Federal Register, December 29, 2005, Vol. 70, No. 249, p. 77262 *et seq.*

<sup>13</sup> 14 CFR Parts 401, 415, 431, 435, 440 and 460, Human Space Flight Requirements for Crew and Space Flight Participants; Final Rule, December 15, 2006, p. 75627.

<sup>14</sup> 14 CFR Parts 401, 415, 431, 435, 440 and 460, Human Space Flight Requirements for Crew and Space Flight Participants; Final Rule, December 15, 2006, p. 75626.

<sup>15</sup> Sec. 8 FAA Draft Guidelines.

Under 49 U.S.C. 70112(b)(1) of the 2004 CSLAA, the licensee is required to make a reciprocal waiver of claims with its contractors, subcontractors and customers. While the FAA final rule makes it clear that a space flight participant is not a customer, the space vehicle operator is not prevented by the CSLAA from making a waiver of liability part of the agreement with a space flight participant except in cases of gross negligence. This is in line with section 7 (a.)(7) of the FAA Draft Guidelines, which provide that the written informed consent to be signed by the space flight participant should not relieve the RLV operator of responsibility for gross negligence.

Additionally, 49 U.S.C. 70112(b)(2) requires that among others, licensees and space flight participants are to make a reciprocal waiver of claims with the US Government under which each party agrees to be responsible for property damage or loss it sustains, or for personal injury to, death of, property damage or loss sustained by its own employees or by space flight participants, if the damage results from an activity under the licence. Such waiver of claims only applies to any amount exceeding the insurance or to an amount exceeding USD\$ 100,000,000. Further, the space flight participant must hold harmless and indemnify the US Government and its agencies, servants, agents, subsidiaries, employees and assignees from and against liability, loss or damage arising out of claims brought by anyone for property damage or bodily injury, including death, resulting from licensed or permitted activities.

Legislative tendency seems to indicate that in order to stimulate space tourism industry, the parties' freedom of contract is upheld to the greatest extent possible. In this context it is also important to note that, while space flight remains inherently risky, the informed space tourists are voluntarily putting themselves at such high risk. Therefore, contractual waivers of liability, including in case of death of a space flight participant, would be recommended.

### **3.5. Insurance**

Another mechanism to reduce the risks of medico-legal liability is insurance in the form of passenger life and passenger liability insurance policies. A life insurance policy is a contract in terms of which the insurer undertakes to pay a certain sum of money on the death of the insured.<sup>16</sup> Russian authorities apparently required the two space tourists *Tito* and *Shuttleworth* to obtain life insurance, which were made available by the Russian insurance companies *Avicos* and *Megaruss*.<sup>17</sup> An insurance market is thus already developing. Passenger liability insurance protects the space vehicle operator against its legal liability to passengers. Insurers undertake to pay on behalf of the insured entity all sums which the insured shall become legally liable to pay as damages.

## **4. Informed Consent**

As mentioned above, each space flight participant has to provide his/her written informed consent to participate in the space flight as well as written certification of compliance with the physical examination, if such is required. If the physical examination is to be undertaken by a medical practitioner, whether associated with the commercial space flight company or otherwise, informed consent must be obtained from the participant for such an examination.

---

<sup>16</sup> R. D. Margo, *Aviation Insurance*, 3rd ed., London et al. 2000, § 18.01, p. 307.

<sup>17</sup> [http://www.space.com/missionlaunches/shuttleworth\\_insurance\\_020208.html](http://www.space.com/missionlaunches/shuttleworth_insurance_020208.html) (date accessed: 12.11.2003); L. J. Smith/K.-U. Hörll, *Legal Parameters of Space Tourism*, IAC-03-IISL-1.109, p. 7; W. Kowal, *Legal Prerequisites*, Astrium/EADS Working Paper, Bremen 2002 (unpublished), p. 31.

Some legal jurisdictions (most notably the common law jurisdictions) recognise that non-consensual touch of a person constitutes battery. Placing a person in fear of being touched without consent constitutes an assault. Informed consent is consent granted by the participant based on knowledge of the nature of the procedure to be performed, and its associated risks, benefits and alternatives. Consent is insufficient if it is given based on inadequate or incomplete information or explanation.

The medical practitioner who will perform the examination should be responsible for providing information about the examination and answering any questions that may arise. The “reasonable practitioner” standard is generally accepted as the degree of disclosure required. This requires that the medical practitioner disclose information that most practitioners would disclose in similar circumstances. Such information includes the probable outcomes, any possible complications or temporary discomfort, any possible permanent results, reasonably foreseeable risks and alternative procedures.<sup>18</sup>

Only a competent person can give informed consent. Competence in this context means the ability to understand the proposed examination and make an informed decision. Competent persons generally mean mentally competent adults over age 18. In the case of space flight, emancipated minors cannot give such informed consent, and parents or legal guardians are also incompetent to give consent on behalf of minors.

Given that a possible result of the physical examination is the certification that the participant may not be fit to take part in the orbital space flight, it is extremely important to ensure that the consent obtained for the examination is informed and written. Informed consent is a process and must be clearly documented. Consent forms for the physical examination must be completed and signed by the participant. These forms should use language that the participant can reasonably understand. Interpreters must be provided where necessary. No abbreviations should be used and the form should include the procedure, risks, benefits and alternatives to the examination.

A participant may revoke consent to the physical examination at any time, either verbally or in writing. The examination may not be performed once the participant revokes consent. If the patient revokes consent during an examination, the procedure must be terminated as soon as reasonably possible. It is possible to counsel a participant to allay any possible fear; however coercion or duress should never be used to prevent a revocation of consent.<sup>19</sup>

## References

1. Hobe, S. and Cloppenburg J., “Towards a New Aerospace Convention? – Selected Legal Issues of ‘Space Tourism’”, (2005) Proceedings of the 47<sup>th</sup> Colloquium on the Law of Outer Space pp. 377 – 385
2. Hobe, S., “Legal Aspects of Space Tourism”, (2007) 85 Nebraska Law Review (forthcoming)

---

<sup>18</sup> Fay A. Rozovsky, *Consent to Treatment: A Practical Guide*, Boston 1984

<sup>19</sup> University HealthSystem Consortium, *Medical-Legal Survival: A Risk Management Guide for Physicians*, 2000, pp. 55 – 65