Commercial Space Transportation Advisory Committee (COMSTAC)
Systems Working Group Minutes
March 21, 2013, 1:00 – 2:00 pm EST

I. Introduction

a. Livingston Holder, Chairman of COMSTAC's Systems Working Group, opened the call.
b. Randy Repcheck, FAA, reminded everyone this was the 7th telecon, the last one having been two months ago due to the AST Conference. The next and final telecon will be in April.
c. Randy then introduced the today's topic as Medical Guidance for Crew and Space Flight Participants, and introduced the moderators: Dave Gerlach, FAA, and Dr. Melchor Antunano, Director of the Civil Aerospace Medical Institute.
d. Dave Gerlach reiterated that the FAA may not propose regulations covering occupant safety until October 2015.

II. Discussion

a. Objective

i. Dave Gerlach stated today's telecon objective was to explore the industry's medical best practices in human space flight for ensuring that safety critical operations personnel and spaceflight participants are physically capable of performing the necessary tasks for safety of the occupants.
ii. Dave further defined safety critical operations personnel as people that make time sensitive decisions that are essential to ensuring the occupants safety during pre-launch, launch, on orbit, re-entry, landing and post-flight operations.
iii. Dave then cited a June 2012 document, "The Flight Crew Medical Standards and Space Flight Participant Medical Acceptance Guidelines," developed by the Center of Excellence for Commercial Space Transportation (COE-CST), and invited Dr. Melchor Antunano to comment.
iv. Dr. Melchor Antunano first recognized the work of Dr. Richard Jennings, UTMB, and Dr. Jim Vanderploeg. He then described the work as a review of all applicable literature published since 1990 on medical issues in commercial space transportation, as well as input from different people and industry.

b. Medical Certification, specifically for safety critical flight crew members

i. Dave Gerlach began the first topic of Medical Certification by citing regulation 460.5, which currently requires an FAA class two medical certificate.
ii. Mark Campbell, Aerospace Medical Association, first pointed out the only difference between an FAA class one and class two license is that a class one requires an EKG, and is only good for six months, in contrast to a year for a class

two. Second, he stated that various other reports on this topic have suggested moving to an FAA class one certificate.

iii. Randall Clague, XCOR Aerospace, stated that a class two certificate is sufficient, and did not see a significant benefit from a class one.

iv. David Allen, Black Sky, stated a concern about hematology, and certain drugs and drug interactions with zero gravity and G forces, like hypoxia, for why a class one certificate would be a significant safety conscious position within the industry.

v. Dave Gerlach asked him to elaborate, and David said they lack data on neuropsychiatrics affect under altitude G forces, and some statin effects with blood flow and heart rate under G force loading.

vi. Dr. Melchor Antunano clarified that under any FAA class certificate, the applicant is required to disclose any medication that he or she is using. The only difference is how a medical waiver will be given, and that is where the internal criteria of the FAA will differentiate.

vii. David Allen read the COE report, which does not talk about testing for safety critical personnel, and states that disclosure is different from testing.

viii. Dr. Melchor Antunano also responded that the recommendation has always been for companies to use a physician who specializes in aerospace medicine to make decisions based on known effects of medication that any crew member might be one. Though information on medicinal affects in commercial space flight is limited.

ix. Dr. Jim Vanderploeg added that NASA astronauts have flown on medications. And military people on medications have flown under G forces. So it is critical to "centrifuse" people using various profiles for different companies, with both medical illnesses and on multiple medications.

x. Mark Campbell pointed out that limiting the requirement to a FAA class two certificate would potentially have a pilot that is disqualified from flying a commercial airliner but medically certified to fly a space craft.

xi. Randall Clague responded that historical safety records for those two classes of vehicle are different by six quarters of magnitude, and they are not trying to hit that line of safety standards.

c. Medical Screening, between orbital versus sub-orbital

i. Dave Gerlach asked the next question, and Dr. Jim Vanderploeg answered that the difference on an orbital flight is the duration in space with limited access to medical intervention shout it be needed. The risk of an adverse medical event occurring during the orbital portion of a flight, whether that day, a day or several days or several weeks.

ii. Dr. Melchor Antunano added that currently zero G pilots flying parabolic flights use a class one medical certificate, when orbital crew members only require a class

two certificate but face stresses that will be more significant, and will be staying in orbit for some time.

iii. Dr. Tom Weiner in Houston pointed out that the COE guidelines do not discuss the inter-cranial hypertension and visual problems that are still being studied, and pose significant risk.

iv. Randall Clague stated his agreement with Dr. Vanderploeg.

d. Medical Screening, of Spaceflight Participants

i. Dave Gerlach moved to the second topic, and asked if the FAA should recommend medical screening for spaceflight participants, as recommended in the COE guidelines, and whether such a screening is necessary to inform spaceflight participants of their personal medical risk.

ii. Dr. Jim Vanderploeg observed that the informed consent requirement is ambiguous as to whether it includes an individual's personal risk related to their medical status. But from an operator's point of view, it seems prudent not to fly someone who has a high risk of an adverse medical event occurring because of their personal medical status.

iii. Randall Clague agreed with Dr. Vanderploeg in part, but stated that it would be better if informed consent meant talking to a participant about all the conditions they might experience and have a problem with, and then the participant got a medical screening and advice personally.

iv. Dr. Richard Jennings noted that the COE report received input form most of the industry, and while there was no unanimous agreement, the recommended guidelines are pretty much a consensus.

e. Limit Spaceflight Participants for Serious Medical Problems

i. Dave Gerlach asked the next question, and Dr. Jim Vanderploeg answered in the negative. Each situation is so highly dependent on what the individual vehicle and flight profile is, making it impossible to set regulations that apply to the industry in general.

ii. Randall Clague agreed that it would be very vehicle and profile dependent, but also operator dependent in terms of ethics. He encouraged every operator to have their own internal set of guidelines and medical guidelines for participants dictating who can and cannot fly. He does not think the FAA should do that.

iii. Randall went on to describe the purpose of informed consent. He hypothesized a spaceflight participant who was getting frailer faster than the vehicle was getting safer. If the participant is unsafe to fly by the time the vehicle is, have they denied the participant his or her life's dream?

f. Medical Screening, between orbital and sub-orbital

i. Dave Gerlach asked the next question, and Dr. Melchor Antunano responded that this was the same issue as dealt with for flight crew members. Magnitudes of stress, extent of microgravity exposure and radiation exposure.
ii. Dr. Richard Jennings added that lack of access to medical care, including daily treatments, while in orbit requires a greater degree of care over sub-orbital.
iii. Randall Clague suggested comparing it to trans-pacific flights, and using trans-packs as a place to start for orbital spaceflight participants.

g. On-Orbit Medical Illnesses

i. Dave Gerlach moved on to the third topic, and asked whether the FAA should recommend a pre-flight quarantine or social isolation period to prevent the occurrence and/or spread of acute infectious diseases among occupants during flight.
ii. Dr. Jim Vanderploeg said that it depends on what the orbital flight is, where you are going and how long you are going to be there. If it is a three person free flyer, then it does not bear the scrutiny of a flight docking with another vehicle, or station. If it goes to the ISS, then NASA and ISA rules apply.
iii. Dr. Melchor Antunano added that other occupants should also be considered, because even if they are the second person to become ill, they may become more critical.
iv. Dr. Vanderploeg also said that down the road, there will be a much broader range of individuals flying, providing opportunity to gather more data before trying to answer this question immediately.
v. Randall Clague agreed, and asked whether NASA had data on how well their rules for quarantine and isolation worked. Dr. Richard Jennings answered that they work fairly well, with only one shuttle flight out of almost one hundred and forty, delayed by illness. It is a matter of limiting contact with the crew for the week before a flight, because most of the things to worry about have a 7-day incubation period.

h. Medical Criteria for Early Termination of Orbital Flight

i. Dave Gerlach asked the next question, and Dr. Jim Vanderploeg answered that first, the response to an emergency should not put at risk the others in the vehicle. Second, where you need to land for access to medical services may delay when you can terminate from orbit.

ii. Dr. Richard Jennings compared this to when airlines call a consulting company to evaluate the best decision, based on the condition of the passenger, the rest of the crew, where you can land and the capabilities available, what kind of medical kit is on board, etc. The FAA should require that each company have a satisfactory approach in place to address the issue with the right expertise.
iii. Randall Clague added that more important to consider is the effect on the uninvolved public.

i. On-Orbit Medical Emergencies

i. Dave Gerlach moved on to the fourth topic, and asked whether there should be medical criteria for early termination of an orbital flight due to an unexpected medical emergency including trauma among the occupants.
ii. Dr. Jim Vanderploeg observed that this question was partially covered in the previous question. Dave Gerlach elaborated whether there should be some injury criteria or type of illness that requires the crew to land the occupants.
iii. Dr. Melchor Antunano contrasted this question with the issue of serious illness that maybe could have been identified prior to flight but was not. This question deals with trauma that occurs during the flight.
iv. Dr. Vanderploeg stated that the same general ground rules apply, including not putting other occupants or the uninvolved public at risk. Sometimes it may be better to stabilize and wait.
v. Dr. Antunano asked what should happen when if the crew, or even the pilot, were the one to suffer an injury.
vi. Dr. Richard Jennings answered that a lot of it would depend on real-time calls. Especially considering limited primary landing sites, and the infrastructure to land and recover participants and crew from limited vehicles. Someone must be severely injured before a vehicle can consider landing in an unplanned location.
vii. Dr. Tom Weiner asked whether the death of a non-essential participant or crew would require early termination. Dr. Jennings responded that it would be an issue of remaining duration and hygiene.
viii. Geoff McCarthy, Aerospace Medicine Association, suggested reframing the issue by contrasting expectations on a commercial airliner with the informed consent of a spaceflight participant. He used the example of a passenger who had died of a heart attack, and a crew member who stayed unstrapped to perform CPR until landing. The crew member would have better served the passengers by staying strapped in safely during landing, but was compelled to avoid liability by attempting an unsuccessful resuscitation. A spaceflight participant who has signed his or her informed consent should not expect the vehicle to de-orbit just because of their death.

ix. Livingston Holder noted there were only 10 minutes left in the call and two more topics to discuss.

j. De-Orbit Capability for medical emergencies; and In-Flight Emergency Medical Care

i. Dave Gerlach asked the next two questions, and Dr. Jim Vanderploeg suggested that the question of In-Flight Emergency Medical Care ties into the planned fifth topic of medical kits. He said that the issue is again vehicle and flight profile dependent. Sometimes the first responsibility of the pilot and crew is to fly the vehicle. There should also not be an expectation of passengers to take care of each other, though airlines sometimes ask for volunteers. But with so much variability, the FAA should not make in-flight medical care provisions by regulation.
ii. Dr. Richard Jennings suggested that emergency de-orbit capability will likely already be there for other emergencies, like a cabin leak or problem with attitude control, and will therefore be available for medical emergencies.

k. On-Orbit Medical Kits

i. Dave Gerlach moved to the next topic, and asked is whether the FAA should recommend an on-orbit medical kit and what type of medical equipment should be on board, like first aid or something more.
ii. Dr. Jim Vanderploeg said the first question is who is going to use the kit. Without someone trained to use advanced equipment, requiring it is worthless.
iii. Geoff McCarthy compared this with trans-Atlantic and trans-Pacific airlines that have a bit more equipment than their crews are trained to use, on the chance that they may have a doctor or paramedic on board.
iv. Dr. Richard Jennings also compared this with long flights and even NASA, where communication made a big difference, so that a non-physician can talk to somebody on the ground. When the Soyuz is out of communication range with Russia, or the Shuttle was on a long duration mission, the available kit is very basic. But on the ISS, it is much bigger. So it depends on the operation, the type of persons on board, and the ability to communicate.
v. Randall Clague and Dr. Tom Weiner agreed.
vi. Dave asked whether medical kits would be different between sub-orbital and orbital flights. Randall responded that having a pilot on a sub-orbital flight stop flying to administer assistance could endanger the short-duration flight. Dr. Vanderploeg agreed.

l. Training for On-Orbit Medical Care

i. Dave Gerlach moved to the last topic, and asked whether the FAA should be recommending specific or minimum training for on-orbit flights.
ii. Randall Clague responded that there are no such trainings yet. Dave changed the question to training for specific kits.
iii. Dr. Jim Vanderploeg responded that on-orbit medical care training should cover self-care sufficient enough to apply their own band-aids, medicine, or wrap up a sprained ankle. Beyond that, it depends on communication with the ground, and who is available to render care without jeopardizing vehicle operations. It goes back to being dependent on the vehicle and flight profile, the specific needs of a given situation.
iv. Pete Fahrenthold, Northrop Grumman, stated that from a liability standpoint, whoever might have potential to render aid had better be trained on that specific kit. Then he asked whether medical treatment should be part of informed consent. For instance, in cases where it's not really feasible for crew to render assistance.
v. Geoff McCarthy noted that emergency medical care is greatly simplified by two things. First, the automatic defibrillator requires no training can serve in place as well as the best cardiologist. Second, there is no longer as great a need for chest tubes for a collapsed lung or endotracheal tubes that are minimally adequate for most situations. All the drama seen on TV is excess in terms of emergency care nowadays.

III. Conclusion

a. Brenda Parker, FAA, reminded everyone to e-mail if they would like to be added to the e-mail list, and the attendance list.
b. Livingston Holder thanked everyone for their participation.

Teleconference Participants:

David Allen (Black Sky Training), Melchor Antunano (Civil Aerospace Medical Institute), Mark Campbell (Aerospace Medical Association), Randall Clague (XCOR Aerospace), Pete Fahrenthold (Northrop Grumman), Livingston Holder, Richard Jennings (UTMB), Geoff McCarthy (Aerospace Medical Association), Jim Vanderploeg, Thomas Wiener (private practice)

Participants from the FAA Office of Commercial Space Transportation (AST) included:

Randy Repcheck, Dave Gerlach, Brenda Parker