Human System Risk Management for Space Flight

This brief abstract reviews the development of the current day approach to human system risk management for space flight and the development of the critical components of this process over the past few years. The human system risk management process now provides a comprehensive assessment of each human system risk by design reference mission (DRM) and is evaluated not only for mission success but also for long-term health impacts for the astronauts.

The discipline of bioastronautics is the study of the biological and medical effects of space flight on humans. In 1997, the Space Life Sciences Directorate (SLSD) initiated the Bioastronautics Roadmap (Roadmap) as the "Critical Path Roadmap", and in 1998 participation in the roadmap was expanded to include the National Space Biomedical Research Institute (NSBRI) and the external community. A total of 55 risks and 250 questions were identified and prioritized and in 2000, the Roadmap was baselined and put under configuration control. The Roadmap took into account several major advisory committee reviews including the Institute of Medicine (IOM) "*Safe Passage: Astronaut care for Exploration Missions"*, 2001. Subsequently, three collaborating organizations at NASA HQ (Chief Health and Medical Officer, Office of Space Flight and Office of Biological & Physical Research), published the Bioastronautics Strategy in 2003, that identified the human as a "critical subsystem of space flight" and noted that *"tolerance limits and safe operating bands must be established"* to enable human space flight. These offices also requested a review by the IOM of the Roadmap and that review was published in October 2005 as *"A Risk Reduction Strategy for Human Exploration of Space: A Review of NASA's Bioastronautics Roadmap",* that noted several strengths and weaknesses of the Roadmap and made several recommendations.

In parallel with the development of the Roadmap, the Office of the Chief Health and Medical Officer (OCHMO) began a process in 2004 of evaluating the tolerance limits and safe operating bands called for in the Bioastronautics Strategy. Over the next several years, the concept of the "operating bands" were turned into Space Flight Human System Standards (SFHSS), developed by the technical resources of the SLSD at the NASA Johnson Space Center (JSC). These standards were developed and reviewed at the SLSD and then presented to the OCHMO for acceptance. The first set of standards was published in 2007 as the NASA-STD-3001, Volume 1, Crew Health that elaborated standards for several physiological areas such as cardiovascular, musculoskeletal, radiation exposure and nutrition. Volume 2, Human Factors, Habitability and Human Health was published in 2011, along with development guidance in the Human Integration Design Handbook (HIDH). Taken together, the SFHSS Volumes 1 and 2, and the HIDH replaced the NASA-STD-3000 with new standards and revisions of the older document.

Three other changes were also taking place that facilitated the development of the human system risk management approach. In 2005, the life sciences research and development portfolio underwent a comprehensive review through the Exploration

Systems Architecture Study (ESAS) that resulted in the reformulation of the Bioastronautics Program into Human Research Program (HRP) that was focused on appropriate mitigation results for high priority human health risks. The baseline HRP budget was established in August 2005. In addition, the OCHMO formulated the Health and Medical Technical Authority (HMTA) in 2006 that established the position of the Chief Medical Officer (CMO) at the NASA JSC along with other key technical disciplines , and the OCHMO became the responsible office for the SFHSS as noted above. The final change was the establishment in 2008 of the Human System Risk Board (HSRB), chaired by the CMO with representation from the HRP, SLSD management and technical experts. The HSRB then began to review all human system risks, established a comprehensive risk management and configuration management plan and data sharing policy. These major developments of standards, the HRP, the HMTA and a forum for review of human system risks (HSRB) facilitated the integration of human research, medical operations, systems engineering and many other disciplines in the comprehensive review of human system risks.

The HSRB began a comprehensive review of all potential inflight medical conditions and events and over the course of several reviews consolidated the number of human system risks to 30 where the greatest emphasis is placed for investing program dollars for risk mitigation. The HSRB considers all available evidence from human research, medical operations and occupational surveillance in assessing the risks for appropriate mitigation and future work. All applicable DRMs (low earth orbit 6 and 12 months, deep space sortie for 30 days and 1 year, a one year lunar mission, and a planetary mission for 3 years) are considered as human system risks are modified by the hazards associated with space flight such as microgravity, exposure to radiation, distance from the earth, isolation and a closed environment. Each risk has a summary assessment representing the state of knowledge/evidence base for that risk, the available risk mitigations, traceability to the SFHSS and program requirements, and future work required. These data then can drive coordinated budgets across the HRP, the International Space Station, Crew Health and Safety and Advanced Exploration System budgets.

These risk assessments were completed for 6 DRMs in December of 2014 and serve as the baseline for which subsequent research and technology development and crew health care portfolios can be assessed. The HSRB will review each risk at least annually and especially when new information is available that must be considered for effective risk mitigation. The current status of each risk can be reported to program management for operations, budget reviews and general oversight of the human system risk management program.