David R. Francisco⁽¹⁾, Sarah D. Childress⁽²⁾

⁽¹⁾ NASA Headquarters – Office of the Chief Health and Medical Officer, 2101 E NASA Parkway, Houston, Texas, USA 77058, Email: <u>david.r.francisco@nasa.gov</u>

⁽²⁾ NASA Headquarters – Office of the Chief Health and Medical Officer; & JES Tech., 2450 NASA Parkway, Houston, Texas, USA 77058 Email: <u>sarah.d.childress@nasa.gov</u>

1. ABSTRACT

This paper describes NASA's Agency-level Space Flight Human System Standards and technical briefs that prescribe technical requirements for crew selection, medical operations, and vehicle design that enables human space flight missions by minimizing health risks to astronauts, providing vehicle design parameters that maintain astronaut safety and enable the performance of both flight and ground crews. NASA human space flight standards provide knowledge, guidelines, thresholds, and limits for crew medical selection, the successful design and operation of human rated spacecrafts, and missions. These standards cover many topics including medical and behavioral care in space, limits to protect health outcomes, launch and landing accelerations limits, extravehicular suit design, radiation exposure, monitoring, and shielding, environmental parameters (oxygen concentration, carbon dioxide levels), food and nutrition requirements, microbial control, net habitable volume. acoustic limits, maximum allowable concentrations of compounds, autonomy, task analysis, maintainability, and usability of vehicle systems.

2. HAZARDS OF SPACE FLIGHT

Space travel is inherently risky to human health, and astronauts face a myriad of physiological and psychological impacts during space flight missions. NASA summarize the five primary hazards of space flight [1] as the following:

- 1. Radiation Exposure: Crew exposure to the space radiation environment may pose health risks including the risk of neoplasm, damage to the central nervous system, altered cognitive functioning, reduced motor functioning, and acute behavioral changes.
- 2. Hostile/Closed Environment: Spacefaring humans must depend on an enclosed vehicle to survive, which involves inherent risks due to engineering (i.e., oxygen, pressure, temperature, noise, lighting, carbon dioxide levels, etc.). The habitability of the spacecraft is imperative for astronaut health and safety.
- 3. Isolation and Confinement: Crewmembers live and work within a small, enclosed environment with other crewmembers for extended periods of time during space flight. Even with careful

selection of crewmembers and extensive training, interpersonal and behavioral health issues within the crew are expected. Workload considerations, circadian desynchronization and sleep disturbances, and lack of communication with Earth all play a role in potential performance decrements, negative health outcomes, and potentially loss of mission objectives.

- 4. Distance from Earth: As the future of space travel moves towards longer-duration missions beyond lower-Earth Orbit to the Lunar surface and Mars, distance from Earth will become one of the biggest obstacles of safe and productive human space flight. Lack of resupply vehicles, communication delays, potential medical emergencies, and equipment failures are just some of the obstacles that astronauts will face during future space flight missions.
- 5. Altered Gravity Environment: The experience of astronauts transitioning from one gravitational field to another introduces a host of considerations for crew health, safety, and performance. Future missions will involve several changes in the gravity environment, thus operational parameters must implement all strategies available to mitigate these decrements as much as possible.

When combined, these five hazards of space flight create a complicated landscape and impact the ability to support the health, safety, and optimal performance of space flight crews. Additionally, as mission duration lengths increase with a greater focus on deep space exploration, these hazards become even more significant to address in order to support the future of space travel. Thus, NASA seeks to mitigate the risk as much as possible through the selection of healthy and capable crew members, and the engineering of space flight vehicles that integrate human health and performance into the design.

3. NASA OCHMO TECHNICAL REQUIREMENTS

The OCHMO-STD-1001.A document, NASA Space Flight Medical Selection, Recertification and Mission Evaluation Standards, establishes the medical requirements to select and recertify NASA crew members and private astronauts that visit NASA vehicles along with the medical evaluations for specific missions [2]. The NASA Space Flight Human-System Standard (NASA-STD-3001) consists of two volumes of technical requirements: NASA-STD-3001 Volume 1: Crew Health addresses the requirements needed to support astronaut health, enable performance, and provide medical care; NASA-STD-3001 Volume 2: Human Factors, Habitability, and Environmental Health addresses human-integrated vehicle system design and operational requirements that will maintain astronaut safety and promote human performance [3]. These standards are managed by a team within NASA's Office of the Chief Health and Medical Officer (OCHMO), who continuously works with national and international subject matter experts and space flight programs to provide the applicable technical requirements and implementation documentation to effectively enable the development of new programs. Through partnerships across the space flight industry, these technical requirements are constantly evolving to enable successful implementation of NASA programs and the commercialization of human space flight. These criteria and requirements set by NASA OCHMO establish a cohort of crew members who are healthy and meet the physical and medical requirements to successfully perform a given space flight mission, and space flight vehicles that are designed to protect the astronauts from space flight hazards while meeting requirements for human usability and performance. Together, these requirements lead to the successful completion of space flight missions.

3.1 Astronaut Selection and Recertification Standard

The NASA OCHMO-STD-100.1A document provides the uniform requirements for processes, procedures, practices, and methods that have been endorsed as standard for NASA programs and projects, including requirements for selection and annual recertification of NASA astronauts. The medical standard for NASA astronaut selection and recertification is designed to ensure the health, safety, and longevity of career NASA The standards reflect the medical astronauts. requirements to successfully complete specific mission tasks and the multifaceted training and performance required. These include, but are not limited to, flying in high performance aircrafts, extreme environment analogues exposure to hypobaric and hyperbaric conditions., exposure to unique environments (i.e., microgravity), and conducting specialized operations (e.g., extra-vehicular activities (EVA), robotic arm operations).

Additionally, OCHMO-STD-100.1A provides the medical requirements, clinical procedures, and evaluation criteria for the following:

- (a) Mission specific medical evaluation requirements for NASA Astronauts assigned to missions, oriented toward the assurance of crew health and safety, as well as functional competence in the space flight environment.
- (b) Medical Evaluations for Private Astronauts: Private astronauts are crewmembers who are not a U.S. Government Astronaut, or an International Partner (IP) Astronaut. They undergo a comprehensive medical evaluation as part of their mission selection.
- (c) Medical Evaluations for NASA Suborbital Research Specialists, which provides medical testing requirements for NASA Suborbital Research Specialists (NSRS). NSRS are defined as an individual who is employed by NASA or contracted by NASA to conduct research, technology testing, training, or other activities onboard a suborbital vehicle. This excludes those individuals who are the commercially employed crew of the suborbital vehicle.

Health risk assessment is a complex and dynamic process, and the medical requirements and screening procedures account for the fact that the risk for a medical event is based on mission parameters such as vehicle design, duration, environment, location (low-Earth orbit, below low-Earth orbit, etc.), time to return to definitive medical care, and individual needs. This NASA Medical Standard retains the flexibility for incorporation of new clinical procedures as a part of the health evaluation process in a preventive, diagnostic, or treatment capacity. Although these requirements address medical conditions and the effects of space flight as presently known, it is fully intended that as knowledge accumulates, this NASA Medical Standard will be revised as appropriate. Any requirement invalidated by new medical information may be appended by the Aerospace Medicine Board (AMB) with Chief Health and Medical Officer (CHMO) approval. See OCHMO-TB-034 Crew Selection and Recertification [3] for additional information on NASA's process for implementing OCHMO-STD-100.1A in the selection and recertification of astronauts.

3.2 NASA-STD-3001 Volume 1, Crew Health

Volume 1 of NASA-STD-3001 focuses on human physiological functioning and views the human system as an important part of the overall vehicle design process and mission design. It sets the standards for fitness-for-duty, space permissible exposure limits, permissible outcome limits, medical care, medical diagnosis, intervention, treatment and care, and countermeasures. The included technical requirements are established to maintain crew health and performance, contributing to overall mission success and preventing negative long-term health consequences related to spaceflight. In NASA-STD-3001 Volume 1, OCHMO establishes NASA's space flight crew health technical requirements for the pre-mission, in-mission, and post-mission phases of human spaceflight. All technical requirements are based on the best available scientific and clinical evidence, as well as operational experience from Gemini, Apollo, Skylab, Shuttle, Shuttle/Mir (Russian space station), International Space Station (ISS) missions and Commercial Crew Program (CCP). Technical requirements are periodically and regularly reviewed, especially as the concept of operations and mission parameters for a program become defined and may be updated as new evidence emerges. Aerospace medicine is deeply rooted in preventive care in addition to being prepared to respond to known physiological and psychological challenges of space flight, as well as unexpected injury and illnesses that could impact crew members during their career as an astronaut. Volume 1 seeks to address this comprehensive approach through screening, preventive healthcare strategies, medical care, launch and landing contingencies, and post-mission care, reconditioning, and long-term monitoring. As of Revision C published in 2023, NASA-STD-3001 Volume 1 contains 77 technical requirements that are levied against all humanintegrated space flight programs, numbered and indicated by the word 'shall' with accompanying 'rationale', which is explanatory guidance or text indicated in italics. See Tab. 1 below for example technical requirements from NASA-STD-3001, Volume 1, Revision C.

Table 1 – Selected Examples of Technical Requirements from NASA-STD-3001 Volume 1

Section and Title	Shall Statement	Rationale
3.7 In-Mission	[V1 3008] Plans and vehicle(s) shall be	[Rationale: If a return to Earth of a severely ill or injured
Evacuation to	available to transport severely ill or injured	crewmember is possible and is undertaken, coordination
Definitive	crewmember(s) to appropriate Medical Care	with suitable DMCFs in proximity to potential landing
Medical Care	Facilities, including Definitive Medical Care	sites will be made in advance of the crewmember's landing
Facilities	Facilities (DMCF) in the event of a	to ascertain readiness of the facility to accept and
	contingency.	implement immediate medical care. Mobile ground
		resources with the capability to initiate medical care en
		route to the DMCF will be deployed at potential landing
		sites.]
4.8.1 As Low as	[V1 4029] All crewmember radiation	[Rationale: It is important to minimize crewmember health
Reasonably	exposures shall be minimized using the	risk due to radiation exposure by decreasing crewmember
Achievable	ALARA principle.	radiation exposure from all sources using the ALARA
(ALARA)		principle. The ALARA principle is a fundamental guiding
Principle		principle for radiation protection which requires programs
		to minimize radiation exposures below the limits/technical
		requirements within the design constraints of the mission.]

3.3. NASA-STD-3001 Volume 2, Human Factors, Habitability, and Environmental Health

Volume 2 of NASA-STD-3001 focuses on humansystems integration, including human physical and cognitive capabilities and limitations, and defines requirements for spacecrafts (including orbiters, habitats, and suits), internal environments, ground processing, facilities, payloads, and related requirement, hardware, and software systems. These include requirements to the design of systems that directly interface with the flight crew such as environmental support systems, architecture, controls and displays, and operations, as well as requirements for the design of systems that both ground and/or flight crew access during assembly, test, checkout, or troubleshooting procedures supporting ground processing, launch, landing, and recovery operations. The focus is on performance issues during a mission - whether the human and the system can function together within the environment and habitat and accomplish the tasks necessary for mission success.

Combined with NASA-STD-3001 Volume 1, these documents provide Agency-level technical requirements for the development of environments that are suitable for human habitation, certification of human participants, provide the necessary level of medical care, and risk-mitigation strategies against the deleterious effects of space flight. These technical requirements help to ensure mission completion, limit morbidity, and reduce the risk of mortality during space flight missions.

NASA-STD-3001 Volume 2 contains 466 technical requirements as of Revision D published in 2023 that are levied against all human space systems and for each space flight program, and the applicability of these requirements must be determined based on the mission parameters. Individual requirements may then be tailored with appropriate risk assessment. The overall goal is to levy the minimum set of requirements to ensure safety and mission success without overburdening the development process. See Tab. 2 below for example technical requirements from NASA-STD-3001, Volume 2, Revision D.

Section and Title	Shall Statement	Rationale
6.2.8.3 Lunar Dust Contamination	[V2 6053] The system shall limit the levels of lunar dust particles less than 10 μm in size in the habitable atmosphere below a time- weighted average of 0.3 mg/m ³ during intermittent daily exposure periods that may persist up to 6 months in duration.	[Rationale: This limit was based on detailed peer-reviewed studies completed by the Lunar Atmosphere Dust Toxicity Assessment Group (LADTAG) and is specific to the conditions relevant to the lunar surface, i.e., this requirement would not necessarily be applicable to other missions. The requirement assumes that the exposure period is episodic and is limited to the time before ECLSS can remove the particles from the internal atmosphere (assumed as eight hours post introduction). Although the requirement is being conservatively applied to all inhalable particles (all particles $\leq 10 \ \mu$ m), it is most applicable to dusts in the respirable range ($\leq 2.5 \ \mu$ m) that can deposit more deeply into the lungs. Studies show that the particle size of lunar dust generally falls within a range of 0.02-5 μ m. The ability to meet this requirement will depend upon factors such as the level of lunar dust introduction and ECLSS removal rates. The monitoring of dust is captured in [V2 6153] Celestial Dust Monitoring and Alerting.]
10.6.5 Automation and Robotics Override and Shut- Down Capabilities	[V2 10165] Automated or robotic systems shall provide the human operator the ability to safely override and shut down automated systems or subsystems.	[Rationale: The system is to allow the human operator the ability to override or shut down automated or robotic systems if it is determined that these systems present a risk, or if redirection of activities is needed. The human is to remain in ultimate control of the vehicle at all times throughout a mission. It is essential that the override or shut down capability is performed safely, i.e., avoids inadvertent harm to crew and vehicle.]

Table 2 – Selected Examples of Technical Requirements from NASA-STD-3001 Volume 2

4. NASA PROGRAM REQUIREMENTS

Each individual NASA program that will include human-rated systems must implement NASA-STD-3001 in the development of their specific program requirements. The program is responsible for reviewing the set of standards, identifying the technical requirements that are applicable to their specific program/design reference mission, and tailoring the standards into detailed requirements to be implemented in the program. In addition, the programs must provide verification information which details the program's plan to verify that their requirements are meeting their intent. Example of a tailored 3001 technical requirement to program requirement and its related verification language is provided in Fig.1 below.

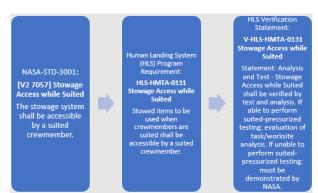


Figure 1. Example NASA-STD-3001 to Program Requirement Flow

5. PROCESS FOR UPDATING NASA-STD-3001

The NASA-STD-3001 documents are reviewed and updated in a continuous cycle in order to keep the technical requirements current and up to date with the latest knowledge and guidance. Potential updates and recommendations for the technical requirements are identified through several different avenues, which include, but are not limited to:

- NASA, national, and international Subject Matter Experts (SMEs) are invaluable resources for ensuring that current technical requirements include relevant and important content for each individual area of interest, utilizing the expertise and experience of the SMEs to provide the best available information to form new and update existing technical requirements. During the development of existing spaceflight programs, many topics are reassessed by SMEs and associated standards are reviewed.
- OCHMO Independent Assessments are working groups and technical interchange meetings with the goal of gathering external SMEs to provide insight to high-priority topics of interest in a rapid-response manner to inform current program development activities. The outcomes of these independent assessments may include updates to the

NASA-STD-3001 documents, OCHMO-STD-100.A document, new development of OCHMO technical briefs (described in the next session), and/or summary reports shared with the appropriate stakeholders. High-priority topics are identified by Chief Health Program Officers (CHPOs), the OCHMO office, or through ongoing work with various commercial and international partners.

- NASA Human Research Program (HRP) is a program dedicated to conducting ongoing space flight research in many facets of human space travel and includes five elements: the International Space Station Medical Projects, Space Radiation, Human Health Countermeasures, Exploration Medical Capability, and Human Factors and Behavioral Performance. The results from HRP's research and findings helps to inform the technical requirements and provide important updates using new and updated knowledge. [7]
- The NASA Human System Risk Board (HSRB) was created as a cross-discipline process to understand the hazards of space flight and gather, assess, and correlate evidence to better predict the probability of an event occurring and the level of consequence the event would have on human health and productivity. The HSRB helps to inform the standards through regular reviews of identified space flight human health risks, which includes an overview of the related technical requirements and potential recommendations to update those technical requirements to address any changes or concerns regarding each specific risk [5-6].

Recently completed OCHMO Independent Assessments include:

- Exploration Atmosphere Characterization: Provided future testing plans to determine pressurized chamber testing activities to directly support HLS and refine existing 3001 Standards; with a focus on prebreathe duration, flammability risk, hypoxia, and decompression sickness (DCS).
- **Communication Delay:** Completed initial testing for hardware maintenance with a 5-second communication delay to further understand impacts to future mission comms. The outcomes will be used to design future follow-on studies.
- Patent Foramen Ovale (PFO) and Risk of DCS: This assessment assembled a group of internal and external physicians and subject matter experts to review and quantify the potential increased risk associated with the

presence of a PFO during decompression protocols utilized in ground testing and space flight EVAs.

Additional ongoing OCHMO Independent Assessments (as of August 2024) include the following:

- **Venous Thromboembolism (VTE) in Space Flight:** Recently, an asymptomatic, obstructive, left internal jugular vein deep vein thromboembolism (DVT) was identified in a long-duration astronaut during a research ultrasound examination aboard the International Space Station. NASA OCHMO is establishing a working group comprised of internal and external experts to assess the existing screening, in-flight treatments, and countermeasures for VTE during spaceflight.
 - Suited Carbon Dioxide (CO₂) Test Methods: NASA OCHMO is supporting ongoing testing to determine safe levels of inspired CO₂ within spacesuit helmets. Phase I and Phase II testing of suited CO₂ washout has been completed, and various stakeholders have been meeting on a regular basis to discuss the results of the testing and create plans for Phase III. NASA OCHMO is utilizing the participating external experts to review the analysis of the data collected thus far in an effort to produce testing methods that are repeatable, minimize variability, and easily implemented for NASA's commercial providers developing future spacesuits.
 - Acceleration and Dynamic Loads: NASA OCHMO is supporting a reassessment of existing technical requirements for landing loads, due to a concern that landing on the lunar surface will need further risk reduction to prevent minor injuries that may occur during a lunar surface landing that could impair crew ability to perform EVA mission tasks on the surface.
 - Advanced Displays and Controls: NASA OCHMO is currently reviewing questions from partners regarding the implementation of graphical user interface (GUI) standards in relation to advanced displays and controls, including projection displays, XR/VR/AR, etc., and working with internal and external experts to determine if new or updated NASA-STD-3001 technical requirements are needed.

6. REVIEW PROCESS FOR UPDATING NASA-STD-3001

After standards are revised with the latest evidence, NASA OCHMO initiates a rigorous review process. After completing an internal review which includes gathering all relevant evidence, internal SME review, and as appropriate, external SME review, the document is revised and submitted for a comprehensive review. This comprehensive review includes distribution across all of NASA along with distribution to international partners and the general public.

For the last revision of the OCHMO-STD-100.1A document, over YYY comments were received from outside of NASA along with XXX comments within NASA. All of the comments were dispositioned by the NASA OCHMO Standards team. This process entails SME review of every comment and determination on whether the comment is accepted or rejected. For comments that required additional consideration, additional SMEs (internal and/or external) are consulted.

After all comments are dispositioned the document is updated, approved and posted to the public website. This process allows for the broadest collection of ideas and knowledge to ensure the best standards are established while also enabling knowledge sharing.

7. INFORMATION SHARING

The future of NASA and human space flight is undergoing significant changes, with the landscape of space travel and exploration turning towards longerduration missions on the Lunar surface and eventual deep space to Mars. In addition, commercial partners have become the primary contributors to supporting ongoing human space travel and thus it is imperative to consider their role in the future of space flight. The OCHMO Standards Team seeks to provide invaluable resources for the evolving space flight environment, providing both commercial and international partners with the necessary knowledge and guidance to enable safe and effective human space travel. Additionally, lessons learned and feedback from previous programs development activities and operations helps to inform future programs on how to appropriately integrate the 3001 technical requirements to achieve their goals and objectives for overall mission success.

The OCHMO Human Spaceflight and Aviation Standards publicly accessible website [8] houses a wealth of information and guidelines on supporting safe human space flight. In addition to the NASA-STD-3001 and OCHMO-STD-100.1A documents, the website contains reference libraries covering the topics of Decompression Sickness Prebreathe, Vehicle Acceleration Limits, and Food and Nutrition in Space; and summary documents that discuss details of Spaceflight Mishaps Investigation and Parastronaut considerations. The Human Integration Design Handbook (HIDH), also posted to the website, is a companion document to NASA-STD-3001 Volume 2 and is a compendium of human space flight history, lessons learned, and design information for a wide variety of disciplines, providing background information on the rationale for human-system design standards.

The OCHMO Technical Briefs and Medical Technical Briefs are a primary tool available on the website that is utilized by the OCHMO Standards Team that are developed for certain topics to offer technical data, background, and application notes to aid with the interpretation of standards for the development of hardware, systems, and vehicles, as well as human needs and limitations. These technical briefs integrate content from multiple Standards and provide quick, informative resources to reference when working with NASA-STD-3001. As of August 2024, there are 47 technical briefs published on the OCHMO Standards website. Topics covered by the technical briefs include human physiology and behavioral health, vehicle systems, medical care, and space flight mishaps. The OCHMO Standards Team continuously updates and adds additional technical briefs as topics of interest arise through conversations with programs, commercial, and international partners. Some recent topics published to the website includes Crew Survivability [9], Spaceflight Associated Neuro-ocular Syndrome (SANS) [10], and Microbiology in Space [11].



Figure 2. Example Technical Briefs from the OCHMO Human Spaceflight and Aviation Standards website

Lastly, the OCHMO Standards website provides a Contact Us form for anyone with questions, comments, or in need of further guidance on the Human Health and Spaceflight Standards to submit an inquiry directly to the OCHMO Standards. With these combined efforts of providing the necessary knowledge, historical experiences, and recommendations for future space exploration, the OCHMO Standards Team hopes to support the continuation of safe and successful human space flight missions for many years to come.

8. REFERENCES

- Whiting, M., and Abadie, L. 5 Hazards of Human Spaceflight. NASA Human Research Program. (2019). Retrieved from: <u>https://www.nasa.gov/hrp/5-hazards-of-human-spaceflight</u>
- 2. Aerospace Medical Certification Standard. Retrieved from: <u>https://www.nasa.gov/ochmo/aerospace-medical-</u> certification-standard/
- 3. Human Spaceflight & Aviation Standards. Retrieved from: <u>https://www.nasa.gov/ochmo/human-spaceflight-and-aviation-standards/</u>
- 4. OCHMO-TB-032 Crew Selection and Recertification. Retrieved from: <u>https://www.nasa.gov/ochmo/hsa-standards/ochmo-technical-briefs/#medical-care</u>
- 5. Romero, E., and Francisco, D. The NASA human system risk mitigation process for space exploration. *Acta Astronautica* 175, 606-615 (2020).
- 6. NASA Human System Risk Board. Retrieved from: <u>https://www.nasa.gov/directorates/esdmd/hhp/huma</u> <u>n-system-risk-board/</u>
- 7. NASA Human Research Program (HRP). Retrieved from: <u>https://www.nasa.gov/hrp/</u>
- NASA Office of the Chief Health & Medical Officer Human Spaceflight and Aviation Standards. Retrieved from: <u>https://www.nasa.gov/ochmo/hsastandards/</u>
- 9. OCHMO-TB-047: Crew Survivability. Retrieved from: <u>https://www.nasa.gov/wpcontent/uploads/2024/07/ochmo-tb-047-crew-</u> survivability.pdf?emrc=386004?emrc=386004
- 10. OCHMO-MTB-001: Spaceflight Associated Neuroocular Syndrome (SANS). Retrieved from: <u>https://www.nasa.gov/wp-</u> <u>content/uploads/2024/02/ochmo-mtb-001-</u> <u>sans.pdf?emrc=48bd95?emrc=48bd95</u>
- 11. OCHMO-TB-046: Microbiology in Space Overview. Retrieved from: <u>https://www.nasa.gov/wp-</u> <u>content/uploads/2024/05/microbiology-in-space-</u> <u>overview.pdf?emrc=418cec?emrc=418cec</u>