



Subject: NASA Health and Medical Technical Authority (HMTA) Implementation

Responsible Office: Office of the Chief Health & Medical Officer

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Preface

P.1 PURPOSE

This NASA Interim Directive (NID) describes the roles, responsibilities, and procedural requirements for implementing the Health and Medical Technical Authority (HMTA) to protect the health and lives of all Agency personnel from hazards associated with aeronautics or human spaceflight missions and associated testing and training.

P.2 APPLICABILITY

- a. This directive is applicable to NASA Headquarters and NASA Centers, including Component Facilities and Technical and Service Support Centers.
- b. Applicability of this directive to the Jet Propulsion Laboratory, a Federally Funded Research and Development Center, is being assessed by NASA. This applicability statement will be updated when that assessment is completed.
- c. This directive is applicable to all human spaceflight and aeronautics activities using NASA resources where NASA vehicles are the destination or NASA contract language directs the applicability.
- d. This directive is applicable to other contractors, international and private flight crews, recipients of grants or cooperative agreements, or parties to other agreements only to the extent specified in their contracts, grants, or cooperative agreements, or where a NASA vehicle is the destination.
- e. This directive is applicable to internationally and commercially provided crewed space systems, as defined in NPR 8705.2, Human-Rating Requirements for Space Systems, where the requirements are applicable as flowed from programs or projects, and are documented in distinct separate agreements, such as joint or multilateral agreements.
- f. This directive is applicable to Research and Technology Development programs involving NASA flight crews.
- g. This directive applies to certain NASA-unique spaceflight and ground activities, risks, or exposures for which federal or industry occupational health standards do not exist. NASA requirements for these items are described in NPR 1800.1, NASA Occupational Health Program Procedures.
- h. In this directive, all mandatory actions (i.e., requirements) are denoted by statements containing the term “shall.” The term “may” denotes a discretionary privilege or permission, “can” denotes statements of possibility or capability, “should” denotes a good practice and is recommended, but not required, “will” denotes expected outcome, and “are/is” denotes descriptive material.
- i. In this directive, all document citations are assumed to be the latest version unless otherwise noted.

P.3 AUTHORITY

- a. National Aeronautics and Space Act, 51 U.S.C. § 20113(a).

- b. NPD 1000.0, NASA Governance and Strategic Management Handbook.
- c. NPD 1000.3, The NASA Organization.
- d. NPD 8900.1, Medical Operations Responsibilities in Support of Human Space Flight Programs.
- e. NPD 8900.5, NASA Health and Medical Policy for Human Space Exploration.

P.4 APPLICABLE DOCUMENTS AND FORMS

- a. The Privacy Act of 1974, as amended, 5 U.S.C. § 552a
- b. NPR 1800.1, NASA Occupational Health Program Procedures.
- c. NPR 7120.5, NASA Space Flight Program and Project Management Requirements.
- d. NPR 7900.3, Aircraft Operations Management.
- e. NPR 8705.2, Human Rating Requirements for Spaceflight Programs
- f. NPR 8900.1, NASA Health and Medical Requirements for Human Space Exploration
- g. NID 8705.153, Safety and Mission Assurance (SMA) Audits, Reviews, and Assessments
- h. NASA-STD-3001, NASA Space Flight Human-System Standards.
- i. NASA/SP-2022-9501, NASA Space Flight Program and Project Management Handbook.
- j. OCHMO-STD-100.1, NASA Spaceflight Medical Selection, Recertification and Mission Evaluation Standards.
- k. OCHMO-STD-1880.1, NASA Aviation Medical Certification Standards.
- l. M-QA-2021-025, Revision Process for NASA Space Flight Human-System Standards and Human Integration Design Handbooks.

P.5 MEASUREMENT/VERIFICATION

The Chief Health and Medical Officer (CHMO), through Agency authority and the HMTA, will measure and verify compliance with this directive by:

- a. Monitoring the development, approval, and execution of NASA Center HMTA Implementation Plans.
- b. Monitoring the development, approval, and execution of program and project requirements derived from NASA-STD-3001.
- c. Assessing requests for relief to applicable requirements derived from HMTA standards.

P.6 CANCELLATION

NPR 7120.11A, NASA Health and Medical Technical Authority (HMTA) Implementation, dated September 08, 2020.

Chapter 1. Introduction

1.1 HMTA Overview

1.1.1 As described in NPD 1000.0, NASA Governance and Strategic Management Handbook, the NASA management system incorporates a robust system of checks and balances between the Programmatic and Institutional Authorities as an important element supporting the achievement of mission success. Figure 1-1, adapted from NASA/SP-2022-9501, NASA Space Flight Program and Project Management Handbook, illustrates the NASA authority structure originating with the Office of the Administrator.

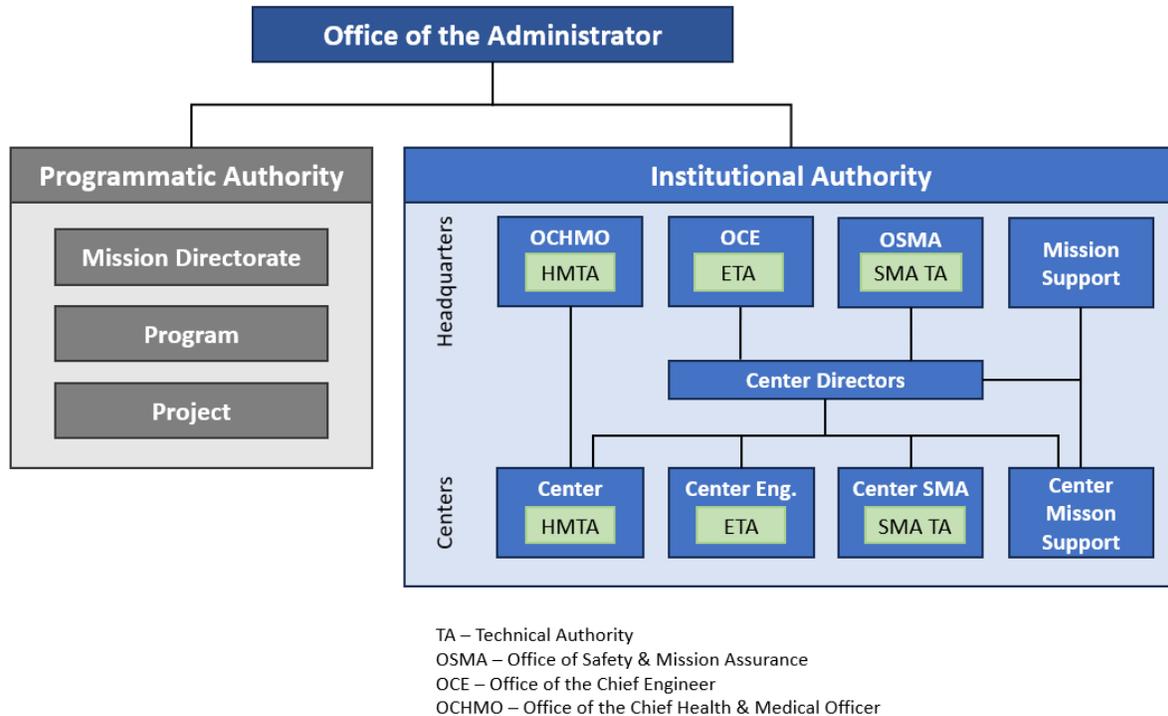


Figure 1-1. NASA Delegation Authority Structure

1.1.2 The CHMO serves as the Agency HMTA in accordance with NPD 1000.3, The NASA Organization. As the office of primary responsibility, the Office of the Chief Health and Medical Officer (OCHMO) implements the HMTA function to ensure health, medical, and human performance policy, requirements, and standards are addressed in program and project activities to protect the health and lives of astronauts, aviation flight crews, other occupants of flight vehicles, and ground personnel from hazards associated with performing human spaceflight and aeronautics missions and associated testing and training. Unlike the Technical Authorities (TAs) for Engineering (ETA) and Safety and Mission Assurance (SMA TA), that delegate TA responsibilities to Center Directors, HMTA responsibilities are not delegated to Center Directors. As shown above in Figure 1-1, HMTA instead flows from CHMO (Level 1) to Center CMOs (Level 2), each of whom is a physician overseeing the respective levels of HMTA responsibility.

1.1.3 OCHMO provides key support individuals at appropriate program and project organizational levels, who have a formally delegated TA role traceable to the Administrator, and these roles are funded independent from the Programmatic Authority. These individuals promote open communication, disposition requests for relief to established institutional and programmatic requirements, provide independent oversight of programs and projects, and collaborate as needed with the other agency Technical Authorities, in ETA and SMA TA, to support safety and mission success.

1.2 HMTA Mission

The mission of the HMTA is to provide the human health, safety, and performance capabilities necessary to carry out NASA programs through development, tailoring, and execution of OCHMO policies, standards, and program requirements. Specifically, HMTA:

- a. Supports NASA's Institutional Authority principles of independent oversight by providing the delegated decisional authority at appropriate levels within Mission Directorates and their programs and projects, including authorizing and decision-making boards and Agency management councils.
- b. Provides subject matter expert (SME) availability and risk management methods at all levels of the Agency to assure development and implementation of requirements to prevent and mitigate adverse human health, safety, and performance outcomes.

1.3 HMTA Scope

The HMTA is applied from program inception through operations. Specifically, HMTA:

- a. Facilitates the sharing of expertise, deriving solutions and identifying acceptable compromise through collaboration instead of simply monitoring compliance.
- b. Serves as an effective part of NASA's system of checks and balances.
- c. Develops and maintains NASA health, medical, and human performance policy and standards for NASA programs and projects.
- d. Provides standards applicability to programs and advises in the derivation of program requirements from standards prior to concurrence on the technical baseline.
- e. Dispositions requests for relief from NASA occupational, health, medical, and human performance policy, requirements, and standards.
- f. Provides an avenue for personnel to elevate issues within the HMTA escalation path, or through other single- or multiple-authority (e.g., Programmatic Authority, Technical Authority) escalation paths, in accordance with the NASA Formal Dissent process established in NPR 7120.5, NASA Space Flight Program and Project Management Requirements.
- g. Develops a disciplined systematic approach to identifying, analyzing, and controlling health, medical, and human performance risks that affect the human during flight and ground operations.
- h. Assesses requirements and evidence to approve formal human rating certification.
- i. Engages in Certification of Flight Readiness (CoFR) reviews to declare vehicles ready to fly.

- j. Conducts the Transition to Operations (TtO) process for NASA-sponsored health, medical, or human performance research or technology development products and deliverables.
- k. Engages in procurement at the start of activities and maintains involvement for its duration.
- l. Establishes decisional venues for counsel and decision-making related to health, medical, and human performance technical issues.
- m. Maintains open communication between all levels of the technical authority.
- n. Provides training for HMTA personnel.
- o. Concurs on the medical certification of NASA crewmembers.

Chapter 2. HMTA Execution

2.1 HMTA Delegated Authority

2.1.1 The CHMO, to support NASA's Institutional Authority principles of independent oversight/insight of programs and projects, delegates specific levels of decisional authority to selected individuals to achieve health and medical insight at the Mission Directorate, Center, Program, and Project levels. All delegations are formal and traceable to the Administrator. Each delegation is documented in a memorandum.

2.1.2 The HMTA delegated authority comprises:

- a. Level 1 (L1) – CHMO and Mission Directorate Chief Health and Performance Officers (CHPOs).
- b. Level 2 (L2) – Designated NASA Chief Medical Officers (CMOs) and Program CHPOs.

2.2 HMTA Delegation Paths

2.2.1 The CHMO delegates technical authority directly to some Center CMOs, who are NASA civil service physicians, as decisional integrators. This flow between physicians from L1 to L2 within HMTA recognizes that while the HMTA content is not entirely medical in nature, there is significant direct medical practice content present in the HMTA scope, which requires decisional flow from physician to physician (See Figure 2-1).

2.2.2 The Johnson Space Center (JSC) CMO, who has delegated human spaceflight technical authority from the CHMO, delegates that technical authority directly to the Program CHPOs, who serve as the direct working interface to NASA's programs and projects, and are not required to be physicians. References to CMOs and CHPOs in this directive explicitly describe responsibilities within their delegated technical authority.

Note: No current aeronautics programs require the appointment of a Program CHPO; only human spaceflight programs have assigned L2 CHPO responsibilities.

2.2.3 The CHMO shall serve as the direct working interface to NASA Mission Directorates. The CHMO may delegate technical authority to Mission Directorate CHPOs.

2.2.4 The CHMO shall concur on the following appointments:

- a. Center Directors' appointment of CMOs.
- b. JSC CMO's appointments of Program CHPOs.

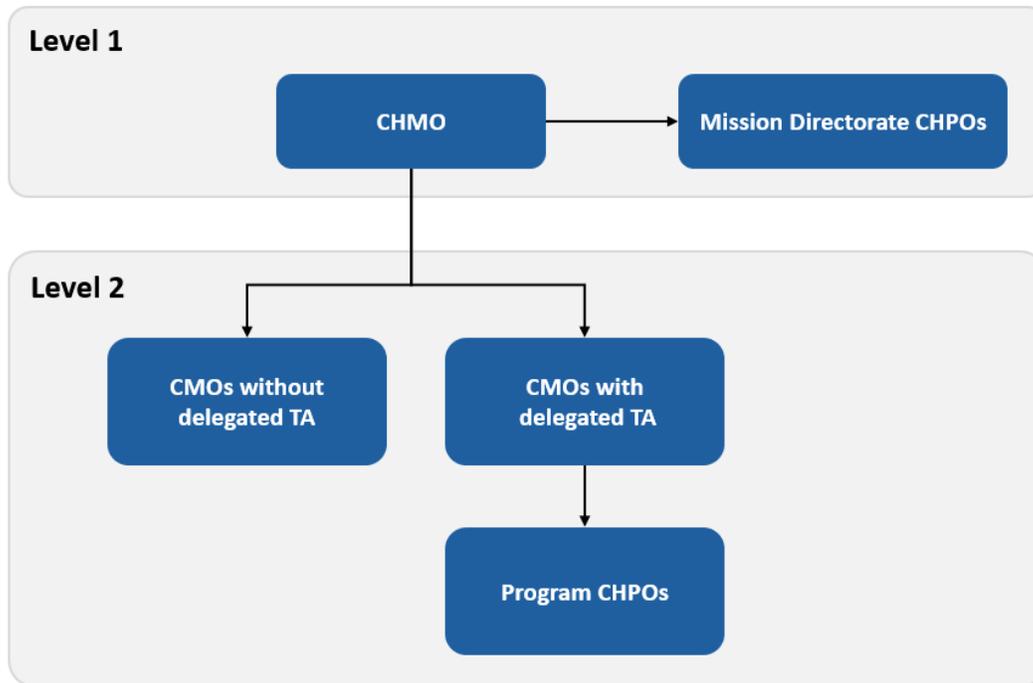


Figure 2-1. HMTA Delegations and Scope of Authority

2.3 HMTA Decisional Authority

2.3.1 The CHMO serves as the L1 HMTA decisional authority for all NASA health and medical matters in all environments and reserves L2 decisional authority for all NASA activities without a jurisdiction.

2.3.2 To promote effective utilization of Agency expertise, consistent assessment of technical issues, and avoid duplication of resources or decisional venues used for the formulation of HMTA decisions, the CHMO has designated CMOs at specific NASA Centers as the HMTA L2 decisional authority for their jurisdiction:

- a. The JSC CMO serves as the L2 HMTA decisional authority for human spaceflight activities.
- b. The Armstrong Flight Research Center (AFRC) CMO serves as the L2 HMTA decisional authority for aeronautics activities.

2.3.3 These decisional authorities at JSC, AFRC, and Headquarters ensure HMTA personnel have access to qualified human system discipline expertise needed for the formulation of HMTA program and project positions, issue resolution, and adjudication of requests from relief from HMTA standards or program or project level requirements within their jurisdiction.

2.3.4 Program CHPOs may exercise decisional authority within their program or project for health, medical, and human performance issues that they determine to be risk-neutral or have a reduction in risk to NASA, NASA programs, projects, partners, personnel, or the public. Program CHPOs shall inform the JSC CMO and CHMO or their designee of these decisions in a

timely manner commensurate with risk and Program context. This “decide and inform” philosophy is vital for an effective implementation of the HMTA.

2.3.5 CMOs with delegated TA may exercise L2 HMTA decisional authority within their jurisdiction for health, medical, and human performance issues that they determine to be risk-neutral or have a reduction in risk to NASA, NASA programs, projects, personnel, and the public.

2.4 HMTA Implementation Plans

2.4.1 The HMTA is implemented through the application of resources and processes documented in this directive and Center HMTA Implementation Plans. Center HMTA Implementation Plans describe the effective execution of HMTA at each Center.

2.4.2 The Center Director ensures programs and projects residing at their Centers comply with established occupational health, medical, and human performance policy, requirements, and standards through the processes specified in this directive and the Center HMTA Implementation Plan.

2.4.3 CMOs at Centers conducting HMTA activities shall develop HMTA Implementation Plans for their Center and obtain approval from the Center Director and concurrence from the CHMO.

2.4.4 The Center CMO shall include the following content in the Center HMTA Implementation Plan:

- a. Description of organizational structure and staffing of program and project support.
- b. Description of the level of delegation of HMTA to the CMO.
- c. Description of responsibilities and scope of delegated authority of Program CHPOs and other interfaces with programs or projects.
- d. Description of HMTA support roles without delegated authority and their respective responsibilities.
- e. Description of process for recommending improvements to health, medical, environmental, habitability, and human factors standards and requirements.
- f. Description of process for maintenance of a requirements traceability matrix.
- g. Description of process for requirements management and adjudication of requests for relief.
- h. Description of process for the development and baseline of flight rules.
- i. Description of process for management of formal dissents.
- j. If at a Center with a CMO who has delegated TA, description of a Risk-Based Decision-Making process for management of HMTA issues for programs and projects under their jurisdiction.
- k. If not at a Center with a CMO who has delegated TA, description of the process for management of HMTA issues, as applicable.
- l. Description of L2 boards responsible for HMTA technical issue integration and coordination at the Center level.
- m. Description of expected communication practices within HMTA at the Center, with other Centers, and with L1.

- n. Descriptions of training plans for HMTA personnel.
- o. Description of procedures for airworthiness request and approval requirements, as applicable, at Centers that conduct aeronautics activities.

2.4.5 CMOs and Program CHPOs shall exercise HMTA as described in this directive and their Center HMTA Implementation Plan.

Note: For the purposes of this document, the term “HMTA” hereinafter may refer to the HMTA function, organization, or to the appropriate NASA official (e.g., for ‘shall’ statements) who is formally delegated the Technical Authority, depending on the context.

2.4.6 The HMTA processes and procedures in the following section will be implemented in accordance with the ethical principles and responsibilities identified in NPR 8900.1, NASA Health and Medical Requirements for Human Space Exploration.

2.5 HMTA Management

2.5.1 The CHMO may appoint an HMTA Manager who does not have delegated technical authority.

2.5.2 The appointed HMTA Manager shall:

- a. Provide organizational HMTA leadership at the Agency level spanning across NASA Centers and Programs.
- b. Conduct resource planning and management for HMTA across the Agency.
- c. Coordinate HMTA staffing and assignments.
- d. Engage with internal and external stakeholders at all levels for HMTA integration.
- e. Assess and report on HMTA organizational performance and strategies.

Chapter 3. HMTA Procedural Requirements

3.1 NASA Health and Medical Standards

3.1.1 NASA health, medical, and human performance standards for human spaceflight are established according to the process presented in M-QA-2021-025, Revision Process for NASA Space Flight Human-System Standards and Human Integration Design Handbooks. These standards are developed in accordance with the ethical principles and responsibilities identified in NPR 8900.1. These standards apply to all NASA human spaceflight programs, and those using NASA resources, as mandated in contractual specifications.

3.1.2 Health, medical, and human performance standards for human spaceflight are documented as follows:

a. NASA-STD-3001 Vol. 1 standards cover the main physiologic parameters associated with the health and successful operation of the human system. They are not all-encompassing but do address those areas where the human system has shown vulnerability in response to adaptation or exposure to applicable mission environments. These standards include appropriate levels of medical care, permissible exposure limits, fitness-for-duty criteria, and permissible outcome limits as a means of defining successful operating criteria for the human system.

b. NASA-STD-3001 Vol. 2 addresses habitability and environmental health, focuses on human physical and cognitive capabilities and limitations and defines standards for spacecraft vehicles, habitats, suits, hardware, software, ground processing, facilities, payloads, and software systems with which the crew interfaces during space operations.

c. OCHMO-STD-100.1, NASA Spaceflight Medical Selection, Recertification, and Mission Evaluation Standards, provides medical requirements and clinical procedures designed to ensure the health, safety, mission performance, and longevity of career NASA astronauts. It also provides medical requirements and clinical procedures for mission specific medical evaluations required for NASA Suborbital Research Specialists and applicable Private Astronauts.

3.1.3 Health, medical, and human performance standards are implemented to ensure the space system (inclusive of the vehicle and its subsystems/hardware, ground systems, and supporting infrastructure) can provide the following systems and capabilities:

a. Medical services (e.g., diagnostic and treatment systems) to support all phases of a mission.

b. Health maintenance, preventive, performance, and countermeasure systems.

c. Protected medical and family support communications consistent with privacy requirements and the Privacy Act of 1974, as amended, 5 U.S.C. § 552a.

d. A healthy and safe environment (e.g., water, air, nutrition, waste systems).

e. Emergency support, rescue, and return to Earth.

3.1.4 NASA aviation health, medical, and human performance standards are documented in OCHMO-STD-1880.1, NASA Aviation Medical Certification Standards, which provides details on the criteria and administrative procedures for the medical certification of NASA aviation flight personnel. These standards apply to NASA aviation across the Agency to ensure that aviation medical certification practices will be implemented consistently in all locations. Additional requirements for crew and occupant safety, airworthiness, and maintenance for NASA aircraft are established in NPR 7900.3, Aircraft Operations Management.

3.2 Program Requirements Life Cycle

3.2.1 Program Requirements Derivation

3.2.1.1 CMOs with delegated TA represent the HMTA L2 function and convey respective institutional requirements established by law, NASA policy, or other external or internal authority to program and project managers.

3.2.1.2 HMTA supports program and project managers in the formulation of health, medical, and human performance system design requirements that comply with NASA-STD-3001.

3.2.1.3 Program CHPOs, in collaboration with other HMTA personnel such as the JSC CMO and SMEs, shall assess a proposed program or project architecture and their Concept of Operations for HMTA standards applicability, non-applicability, and potential HMTA standards relief (see Figure 3-1).

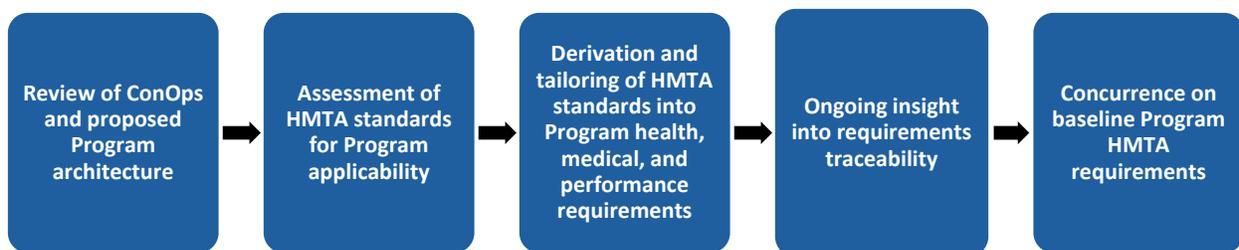


Figure 3-1. HMTA Program Requirements Derivation

3.2.1.4 Following the applicability assessment, Program CHPOs shall advise program and project managers in the development, review, and concurrence of program level health, medical, and human performance requirements. These requirements are first instantiations of HMTA standards allocated to systems and subsystems of a proposed architecture.

3.2.1.5 Program CHPOs shall maintain appropriate insight to requirements traceability to ensure program and project compliance with HMTA standards.

3.2.1.6 To obtain concurrence from the CHMO of baseline health, medical, and human performance requirements for a program or project, Program CHPOs shall provide the following evidence:

- a. An applicability assessment highlighting areas of interest and potentially increased risk related to standards applicability.
- b. Rationale for non-applicable standards.
- c. First instantiation of requirements for each applicable standard.
- d. Verification statements for the requirements.

3.2.1.7 The HMTA shall provide concurrence on the program level technical baseline of health, medical, and human performance requirements.

3.2.2 Adjudication of Requests for Relief from Program Requirements

3.2.2.1 The HMTA may grant or deny relief from program requirements in the technical baseline that were derived from HMTA standards. Relief may be granted by approving a deviation or waiver request submitted by a program per the requirements tailoring process described in NPR 7120.5 and the guidance given in NASA/SP-2022-9501 (see Figure 3-2).

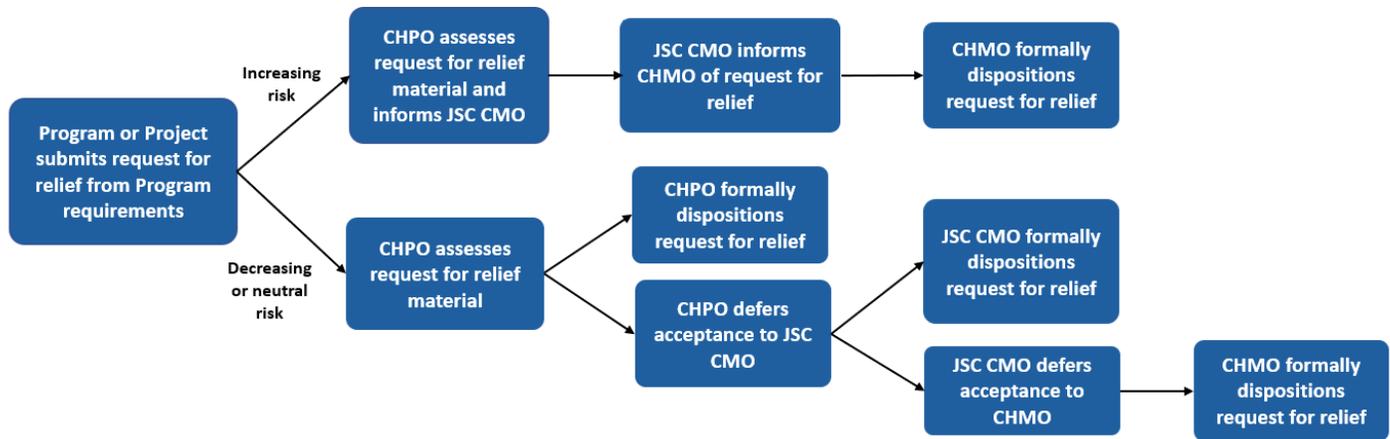


Figure 3-2. HMTA Flow for Adjudication of Requests for Relief

3.2.2.2 Program CHPOs shall review requests for relief from program requirements that they determine to be risk-neutral or have a reduction in risk. They may adjudicate these requests for relief or defer them to the JSC CMO for adjudication.

3.2.2.3 The JSC CMO may adjudicate deferred requests for relief from Program CHPOs that are determined to be risk-neutral or have a reduction in risk, or defer them to the CHMO for adjudication at L1.

3.2.3 Program Requirements Closure

3.2.3.1 The Program CHPO shall track the closure of program requirements derived from HMTA standards.

3.2.3.2 The Program CHPO shall provide concurrence on the closure of a requirement when the program demonstrates verification evidence.

3.2.3.3 The CHMO shall certify program and project compliance with NASA health, medical, and human performance requirements through established Agency processes at life cycle milestones.

3.2.3.4 As part of the requirement verification process, the Exemption Determination Research Officer (EDRO) shall determine whether a planned test involving NASA personnel (human-in-the-loop testing) requires review by the NASA Institutional Review Board (IRB) as human research or is exempt from that process.

3.3 Formal Dissents

3.3.1 Formal Dissents Overview

3.3.1.1 NASA supports and promotes open discussion of issues that can improve safety and mission success throughout the Agency, including alternative and divergent views. To empower team members with the ability to provide their best input during a decision, diverse views are to be fostered and respected without any suppression or retribution. In assessing a decision or action, an individual member has three choices: agree, disagree but be willing to fully support the decision, or disagree and raise a Formal Dissent. For disagreements rising to the level of importance that warrant a specific review and decision by higher-level management, NASA has formalized the Formal Dissent process applicable to human spaceflight and aeronautics.

3.3.1.2 A Formal Dissent is a substantive disagreement with a decision or action that an individual judges is of sufficient importance that it warrants a timely review and decision by higher-level management, and the individual specifically requests that the dissent be recorded and resolved by the Agency Formal Dissent process. The decision on whether the issue in question is of the significance that warrants the use of the Formal Dissent process is the responsibility and personal decision of the dissenting individual.

3.3.2 Handling Formal Dissents

3.3.2.1 All NASA civil service and contract personnel have a fundamental responsibility to express their views to the appropriate decision maker in a timely manner. Unresolved health, medical, and human performance issues within a program or project team should be quickly elevated to achieve timely resolution at the appropriate level.

3.3.2.2 Formal Dissents adjudicated within the HMTA will be addressed using the process set forth in NPR 7120.5 and the guidance given in NASA/SP-2022-9501. Formal Dissents are resolved by elevation through conversations between successively higher levels of the involved.

3.3.2.3 Program CHPOs, CMOs with delegated TA, and the CHMO shall engage the NASA Formal Dissent process, where necessary, and provide personnel with an avenue to elevate issues within HMTA or through other single- or multiple-authority (e.g., Programmatic Authority, Technical Authority) escalation paths.

3.3.2.4 CMOs with delegated TA shall hear appeals of HMTA decisions when they cannot be resolved at the program or project level.

3.3.2.5 The CHMO shall hear appeals of HMTA decisions when they cannot be resolved at HMTA L2.

3.3.2.6 The NASA Administrator may hear appeals of HMTA decisions when they cannot be resolved at HMTA L1.

3.4 Risk Management and Acceptance

3.4.1 Assessing Risk

3.4.1.1 Individuals with delegated HMTA, or designees, who are assessing risks associated with requests for relief or CoFR exceptions should ensure the following evidence is documented and considered:

- a. Rationale for the waiver, deviation, or CoFR exception.
- b. Risk assessment characterizing whether the request for a waiver, deviation, or CoFR exception results in a change in risk.
- c. Reference to all material that provides justification supporting acceptance, including programmatic cost and schedule information.
- d. List of defined risk mitigation actions/plan, including dates or development milestones for bringing the program to compliance or mitigation steps closure.
- e. List of all appropriate NASA organizations and SMEs involved in the review of the request for relief.
- f. List of all concerns with the request that were expressed during the identification process.
- g. Name and role of the NASA management official accepting the risk and implementing the request for relief or the CoFR exception.

3.4.1.2 Program CHPOs and the JSC CMO may adjudicate waivers, deviations, or CoFR exceptions that are determined to be risk-neutral or have a reduction in risk. The CHMO shall adjudicate the request if any of the following criteria apply:

- a. Existing risk posture increases because of the changes.
- b. High consequence events related to the following areas with associated waivers, deviations, or CoFR exceptions:
 - (1) Crew survival;
 - (2) Life support;
 - (3) Abort capability;
 - (4) Launch/landing;
 - (5) Docking/berthing;
 - (6) Extravehicular activities (EVA);
 - (7) Crew recovery.
- c. Other exceptions the CHMO has identified and communicated to the JSC and AFRC CMOs.

3.4.2 HMTA Issues

3.4.2.1 HMTA issues relate to the potential for adverse effects on an individual's well-being, physical condition, or medical status, arising from exposure to mission-specific hazardous events. Evaluating and managing HMTA issues involves identifying potential threats, assessing their probability and severity, and implementing mitigation strategies with the goal of safeguarding the health and medical integrity of individuals and populations involved in the mission.

3.4.2.2 CMOs with delegated TA and Program CHPOs shall elevate HMTA issues that represent an increase in risk to the CHMO for a decision.

3.4.2.3 The CHMO shall be the final decisional authority on HMTA decisions that represent an increase in overall risk posture for NASA, NASA programs, projects, partners, personnel, and the public.

3.4.3 Human System Risks

3.4.3.1 Human system risks pertain to program-agnostic or mission-agnostic challenges that affect the human system in any spaceflight context (i.e., environmental exposures, crew performance issues, biomedical stressors and susceptibilities, or the ability to provide medical care).

3.4.3.2 The Human System Risk Manager shall manage human system risks in accordance with the Human System Risk Board (HSRB) Management Plan.

3.4.3.3 The Human System Risk Manager shall elevate human system risk decisions, recommendations, or positions to the CHMO for concurrence.

3.4.4 Program and Project Risks

3.4.4.1 Program and project risks include cost, schedule, and technical risks and those that affect the human as a system.

3.4.4.2 Program CHPOs shall maintain cognizance of crew health and medical risks for their assigned program.

3.4.4.3 CMOs with delegated TA shall develop and document a Risk-Based Decision-Making process for the management of health, medical, and human performance issues for programs and projects within their jurisdiction.

3.5 Human Rating

3.5.1 NPR 8705.2 describes human rating as follows:

a. “A human-rated system accommodates human needs, effectively utilizes human capabilities, controls hazards, manages safety risks associated with human spaceflight, and provides, to the maximum extent practical, the capability to safely recover the crew from hazardous situations. Human-rating is not and should not be construed as certification for any activities other than carefully managed missions where safety risks are evaluated and determined to be acceptable for human spaceflight.

b. Human rating must be an integral part of all program activities throughout the life cycle of the system including, but not limited to, design and development; test and verification; program management and control; flight readiness certification; mission operations; sustaining engineering; and maintenance, upgrades, disposal, and ground processing.”

3.5.2 Program CHPOs shall assess the human rating certification evidence for progress towards requirements compliance throughout the program life cycle.

3.5.3 The JSC CMO or their designee shall assess the compliance of human rating certification per the relevant certification requirements.

3.5.4 The JSC CMO or their designee shall communicate human rating certification compliance findings to the CHMO.

3.5.5 After being provided with sufficient compliance evidence, the CHMO shall provide concurrence to approve formal human rating certification.

3.5.6 For NASA aircraft, the AFRC CMO for aeronautics shall work with relevant Center management to identify the appropriate airworthiness review process for experimental, research, and operational configurations and nonstandard ground or flight operations for all aircraft contracted or operated by that Center.

3.6 Certification of Flight Readiness (CoFR)

3.6.1 Certification of Flight Readiness (CoFR) is declaring readiness of spacecraft to fly and is comprised of a series of reviews culminating in a signed 'Certification of Flight Readiness.' HMTA actively engages in CoFR milestone reviews when the nature of the mission is within the HMTA scope.

3.6.1.1 Program CHPOs shall coordinate with the CHMO prior to CoFR reviews to establish a communication plan for previews and recommendations on items representing substantive HMTA risk for the upcoming flight.

3.6.2 Technical Authority CoFR Milestones

3.6.2.1 The Safety and Mission Success Review (SMSR), as described in NID 8705.153, Safety and Mission Assurance (SMA) Audits, Reviews, and Assessments, ensures the Agency TAs are properly informed of all substantive risks before making a critical decision about readiness to proceed to the Agency Flight Readiness Review (FRR). A similar review, called the Technical Authority Mission Review (TAMR), may also be performed in lieu of or in addition to the SMSR. When both reviews are conducted, the TAMR precedes the SMSR. TA review packages should focus on open risks and new anomalies or issues rather than everything presented at earlier reviews.

3.6.2.2 The Program CHPO shall present an independent assessment of HMTA readiness for the upcoming flight, including special topics, to the TAMR and SMSR boards.

3.6.3 Agency CoFR Milestones

3.6.3.1 The Program Flight Readiness Review (FRR) sets the risk acceptance for the mission, certifies compliance with the Program CoFR plan, gains concurrence from stakeholders, and polls for readiness of all in-line functions.

3.6.3.2 The Program CHPO shall present an independent assessment of HMTA readiness to the Program FRR board and is polled for an L2 HMTA response.

3.6.3.3 The CHMO shall provide an HMTA recommendation to the responsible mission director concerning residual risk and the advisability of proceeding to Agency Flight Readiness Review (FRR).

3.6.3.4 The Agency FRR evaluates the readiness of the Program and all supporting systems for a safe and successful launch, flight, and mission. A formal agency leadership readiness poll to "GO" certifies that the integrated Agency is ready to proceed with flight and the mission.

3.6.3.5 The CHMO shall evaluate and present to the Associate Administrator a recommendation for "GO" or "NO-GO" as the L1 HMTA response.

3.6.3.6 The Launch Readiness Review/Mission Management Team (LRR/MMT) evaluates the readiness of the Program and all supporting systems for launch. At the launch site, the review

updates the mission status, closes out actions from the Agency FRR with explicit focus on CoFR exceptions, authorizes approval to proceed into launch countdown, and formally and functionally hands over the mission, vehicle, and crew to the operations team (the MMT).

3.6.4 MMT Representation. The JSC CMO or their designee shall serve as the HMTA representative to the MMT.

3.6.5 NASA Aircraft. In addition to being certified as airworthy through a Center airworthiness process, all NASA aircraft are cleared through separate flight readiness reviews in accordance with NPR 7900.3.

3.6.6 CoFR Exceptions

3.6.6.1 In preparation for the Program FRR and Agency FRR, HMTA evaluates the identified non-standard open work for each endorsement criterion. Non-standard open work is work that is outside of the nominal planned process as defined in the certifying organization's endorsements. Non-standard open work includes work that is not typically done by HMTA and standard work that has become late or delinquent (deviated from its nominally scheduled timeframe for completion). Non-standard open work is usually driven by new constraints, processes, or operations.

3.6.6.2 When the criteria for an endorsement cannot be met, HMTA may generate a CoFR exception at any milestone in the CoFR flow and assign a corresponding action to the appropriate HMTA representative. Program CHPOs should address and resolve CoFR exceptions in accordance with their Program's documented CoFR process.

3.6.6.3 For any CoFR exceptions generated by a Program CHPO, the Program CHPO shall provide background and rationale to the CHMO as an informational briefing, or for an L1 decision as necessary, prior to the Agency FRR.

3.6.6.4 The HMTA shall include all initiated CoFR exceptions in the HMTA readiness assessment presented at the FRR to be dispositioned by the FRR Chair. Each CoFR exception will indicate the specific endorsement statement(s) that cannot be met.

3.6.6.5 All CoFR exceptions will be dispositioned prior to flight. Exceptions are applicable only against the mission for which they are generated. Effectivity for multiple-mission exceptions will be considered on a case-by-case basis. Closure occurs when the FRR Chair:

- a. Approves the completion of identified actions which results in no longer having a CoFR exception; or
- b. Accepts the risk associated with a CoFR exception.

3.7 Transition to Operations (TtO)

3.7.1. The HMTA TtO process is designed to assess the safety, effectiveness, and operational readiness of products under consideration to become part of operations to support human spaceflight.

3.7.2 The CHMO delegates authority to the JSC CMO to conduct the HMTA TtO process.

3.7.3 The JSC CMO shall outline the TtO process in the HMTA Implementation Plan including, at a minimum, the process to assess the following:

- a. Compliance with applicable requirements.
- b. Work instructions or standards for the operational application.
- c. Transition strategy with schedule and funding for implementation.
- d. Feasibility for use in the intended operation.
- e. Rationale or benefit of implementation.

3.7.4 The JSC CMO or delegate shall present outcomes of the HMTA TtO process to the CHMO as an informational briefing. The briefing will include at a minimum:

- a. An overview of the assessment process including the submitting organization.
- b. The personnel involved in the review.
- c. The proposed operational application and the transition plan.
- d. The outcome of the assessment including the JSC CMO's determination of Approve, Reject, or Defer with rationale including the benefit of implementation.

3.7.5 The CHMO may request that additional review(s) be conducted at any point during the HMTA TtO process.

3.8 Procurement Activities

3.8.1 The NASA Office of Procurement executes innovative, effective, and efficient acquisition business solutions to optimize capabilities and operations that enable NASA's missions. To mitigate risk and minimize costs to the Agency, HMTA engages with procurement at the start of activities and maintains involvement for its duration.

3.8.2 As the primary HMTA interface to programs, the Program CHPO, or an HMTA representative assigned by the CHPO, shall participate in key procurement activities and milestones, including generation of the Request for Information (RFI), Request For Proposal (RFP) or other competitive procedures, and the Source Evaluation Board (SEB).

3.8.3 The Program CHPO, or an HMTA representative assigned by the CHPO, shall engage in adjudication activities to ensure health, medical, and human performance requirements are levied appropriately on contracted providers.

3.8.4 The Program CHPO shall concur with the baselined health, medical, and human performance requirements levied on the contracted providers.

3.8.5 The Program CHPO shall regularly communicate pertinent procurement information to the JSC CMO and CHMO.

3.9 HMTA Decisional Venues

3.9.1 Level 1 control boards provide a place for Headquarters-level counsel and decision-making to be applied to technical issues related to human health and performance. Additional details on scope and authority of the boards and forums listed may be found in their respective charters.

a. The Chief Health and Medical Officer (CHMO) Management Board (CMB) is a L1 multidisciplinary leadership board to provide advice and counsel and make recommendations for consideration by the CHMO relating to maintaining and improving all aspects of the Agency's health and medical capability and technical authority. When technical issue resolution is not achieved at a Level 2 board, or the issue represents an increase in Agency risk posture, items may be presented to the CHMO for a L1 decision at the CMB.

b. The International Space Station (ISS) Multilateral Medical Policy Board (MMPB) is the L1 decisional authority for the development and establishment of space medicine policies related to crew health on the ISS. Developed in a collegial and mutually beneficial environment by representatives of the ISS partner space agencies of Canada, Europe, Japan, Russia, and the United States, the MMPB oversees the maintenance of crew health and habitability on ISS through an integrated medical support system.

c. The Artemis Medical Policy Board (AMPB) is the L1 medical decisional authority for Gateway and Artemis vehicles, crews, and missions. Based on the successful principles of the MMPB, the AMPB serves as the ultimate authority for the medical policies and strategies that guide all crew health issues related to human spaceflight under the Gateway and Artemis Programs.

d. The Aerospace Medicine Board (AMB) is the L1 clinical and implementation body for addressing crew medical certification. The AMB addresses establishment of, or modification of, health and medical policies and standards, and oversees surveillance of crew health including evaluating and recommending approval or disapproval of waivers related to medical standards for atmospheric and space flight. Private medical information and data are managed as described in NPR 8900.1.

3.9.2 Level 2 control boards provide a place for Center-level integration, discussion, and resolution of technical issues related to human health and performance. Additional details on scope and authority of L2 boards and forums may be found in their respective charters and in Center HMTA Implementation Plans. Center HMTA Implementation Plans will provide detailed descriptions of boards responsible for coordination at the Center level.

3.9.3 The JSC CMO and Program CHPOs shall serve as members of program or project control boards, change boards, and organizational review boards, as appropriate.

3.10 HMTA Training

3.10.1 OCHMO shall provide training for HMTA personnel supporting human spaceflight and aeronautics and make materials available to internal and external collaborators to enable understanding the purpose of HMTA and familiarity with organizational processes and best practices.

3.10.2 All personnel with HMTA responsibilities shall complete the OCHMO-provided HMTA training within six months of beginning their role.

Appendix A. Definitions

Acceptance. Agreement by the appropriate NASA management official to the change in the level of risk to programs, hardware, and personnel and taking the responsibility for the potential outcome of any increase in risk.

Adjudication. The process of review, concurrence, and approval of a request for relief from an Agency-wide HMTA standard. The process includes the approval or disapproval of the request by the CHMO (or delegated approval authority) and acceptance or rejection of the change in risk and acceptance of the new risk level by the appropriate NASA management official. A request is adjudicated when all steps in the process are complete.

Aeronautics. Activities related with the study, design, and manufacturing of air flight capable machines and the techniques of operating aircraft and rockets within the atmosphere.

Approval. Decision by the HMTA that a program or project position, issue resolution, or request for relief from HMTA standards, or program or project level requirement may be implemented after the appropriate NASA management official accepts the risk.

Chief Health and Medical Officer (CHMO). A physician who serves as the principal advisor to the NASA Administrator on health and medical requirements, matters of astronaut health, research subject protection, and matters to ensure the mental and physical health and well-being of the NASA workforce in all environments.

Chief Medical Officer (CMO). A physician assigned by the CHMO to designated NASA Centers who is responsible for overseeing health policy and medical programs at their Center but does not have L2 HMTA decisional authority.

Chief Medical Officer (CMO) with delegated Technical Authority. A CMO who serves as the L2 HMTA decisional authority for all activities under their jurisdiction, i.e., human spaceflight, aeronautics, etc.

Concurrence. A documented agreement by a management official that a proposed course of action associated with a program or project position, issue resolution, request for relief from HMTA standards, or program or project level requirements is acceptable.

Decide and Inform. Philosophy used by HMTA that allows TAs to make independent decisions that are risk-neutral or reduce risk, within their scope of authority, and keep the next higher level of HMTA informed of those decisions.

Delegation. The official process for assigning TA to a named individual and communication of that delegation to the appropriate community.

Deviation. A documented authorization releasing a program or project from meeting a requirement before the requirement is put under configuration control at the level the requirement will be implemented.

Formal Dissent. A disagreement with a decision or action that an individual judges is of sufficient importance that it warrants a timely review and decision by higher-level management, and the individual specifically requests that the dissent be recorded and resolved by the Formal Dissent process.

First Instantiation. The first representation of a standard in program or project-level requirements.

Health. The physiological and psychological well-being of an individual.

Human Performance. The physiological, cognitive, and perceptual capabilities and limitations of crewmembers.

Human System Disciplines. The family of human-related clinical, technical, and scientific disciplines closely associated with the performance capabilities and needs of the human (e.g. clinical medicine, nutrition, toxicology, physical performance, cognitive abilities, human factors, microbiology, and health physics) as captured in NASA-STD-3001, NASA Space Flight Human System Standards, Volumes 1 and 2.

Medical. The prevention, diagnosis, treatment, and long-term management of acute or chronic illness or injury.

Mission Directorate Chief Health and Performance Officer (Mission Directorate CHPO). Personnel delegated by the CHMO to serve as the direct HMTA working interface to mission directorates.

Program Chief Health and Performance Officer (Program CHPO). Personnel delegated by the JSC CMO to serve as the direct HMTA working interface to programs or projects.

Relief. A waiver, deviation, or request for determination of non-applicability to modify or eliminate a stated standard or requirement and usually not meet the full intent and letter as stated.

Risk-Based Decision-Making. The process that organizes information about the possibility of various outcomes into an orderly structure that helps decision makers make better informed management choices.

Risk Neutral. Outcomes of programmatic decisions, proposed implementation, pursuit of standards/requirements deviations or waivers that do not increase the health, medical, and human performance risks.

Standards. NASA documents that contain common and repeated use of rules, conditions, guidelines, or characteristics for products, or related processes, production methods and related management system practices.

Subject Matter Expert (SME). A person recognized as an expert in the technical area under review.

Tailoring. The process used to adjust or seek relief from a prescribed requirement to accommodate the needs of a specific task or activity (e.g., program or project). If a revised requirement meets or exceeds the parent standard and has no increase in risk from the original requirement, then it may be accepted and implemented by the appropriate delegated authority; otherwise, a waiver or deviation may be required.

Technical Authority (TA). A part of NASA's checks and balances system that provide independent oversight of programs and projects in support of safety and mission success through the selection of individuals at delegated levels of authority. TA delegations are formal and traceable to the Administrator, and are funded independently of a program or project.

Traceability. The process of mapping original standards and requirements to implementing requirements.

Waiver. A documented authorization releasing a program or project from meeting a requirement after the requirement is put under configuration control at the level the requirement will be implemented.

Appendix B. Acronyms

AFRC	Armstrong Flight Research Center
AMB	Aerospace Medicine Board
AMPB	Artemis Medical Policy Board
CHMO	Chief Health and Medical Officer
CHPO	Chief Health and Performance Officer
CMB	Chief Health and Medical Officer (CHMO) Management Board
CMO	Chief Medical Officer
DRM	Design Reference Mission
CoFR	Certification of Flight Readiness
EDRO	Exemption Determination Research Officer
ESDMD	Exploration Systems Development Mission Directorate
ETA	Engineering Technical Authority
EVA	Extravehicular Activities
FRR	Flight Readiness Review
HMTA	Health and Medical Technical Authority
HSRB	Human Systems Risk Board
IRB	Institutional Review Board
ISS	International Space Station
JPL	Jet Propulsion Laboratory
JSC	Johnson Space Center
KDP	Key Decision Point
L1	Level 1
L2	Level 2
MMPB	Multilateral Medical Policy Board
NID	NASA Interim Directive

NPD	NASA Policy Directive
NPR	NASA Procedural Requirements
NSRS	NASA Suborbital Research Specialists
OCE	Office of the Chief Engineer
OCHMO	Office of the Chief Health and Medical Officer
OSMA	Office of Safety and Mission Assurance
RFI	Request For Information
RFP	Request For Proposal
SEB	Source Evaluation Board
SMA	Safety and Mission Assurance
SMA TA	Safety and Mission Assurance Technical Authority
SME	Subject Matter Expert
SMSR	Safety and Mission Success Review
SOMD	Space Operations Mission Directorate
STD	Standard
TA	Technical Authority
TAMR	Technical Authority Mission Review
TtO	Transition to Operations
U.S.C.	United States Code

Appendix C. References

C.1 NPD 7120.4, NASA Engineering and Program/Project Management Policy.

C.2 NPR 7123.1, NASA Systems Engineering Processes and Requirements.

C.3 NPR 8000.4, Agency Risk Management Procedural Requirements.

C.4 NASA/SP-2016-6105, NASA Systems Engineering Handbook.

Appendix D. Roles and Responsibilities

Role	Responsibilities
Chief Health and Medical Officer (CHMO)	<ul style="list-style-type: none"> a. Implements the HMTA function to ensure health, medical, and human performance policy, requirements, and standards are addressed in program and project activities to protect the health and lives of astronauts, aviation flight crews, and other occupants of flight vehicles, from hazards associated with performing the flight missions and associated testing and training. (1.1.2) b. Concurs on program-level technical baseline of health, medical, and human performance requirements and flight rules. (3.2.1.7) c. Certifies program and project compliance with NASA health, medical, and human performance requirements through established Agency processes at life-cycle milestones. (3.2.3.3) d. Provides final decisional authority for any HMTA position or requests for relief associated with HMTA standards, or program or project requirements that represent change in overall risk posture for NASA, NASA programs, partners, personnel, and the public. (3.4.2.3) e. Designates CMOs at specific NASA Centers as the HMTA L2 decisional authority for their jurisdiction. (2.3.2) f. Concurs on Center Director appointments of NASA civil service physicians as Chief Medical Officers. (2.2.2.1) g. Concurs on Center HMTA Implementation Plans. (2.4.1) h. Concurs on JSC CMO appointments of Program CHPOs as HMTA delegates to programs. (2.2.2.1) i. Serves as the direct working interface to NASA Mission Directorates. (2.2.3) j. Provides training requirements for HMTA personnel. (3.10.1, 3.10.2) k. Engages the NASA Formal Dissent process, where necessary, and provides employees an avenue for elevating issues within the HMTA or through other single- or multiple-authority (e.g., Programmatic Authority, Technical Authority) escalation paths. (3.3.2.3) l. Hears appeals of HMTA decisions when they cannot be resolved at HMTA L2. (3.3.2.5) m. Provides an HMTA recommendation at the SMSR to the responsible mission director concerning residual risk and the advisability of proceeding to Agency FRR. (3.6.3.3) n. Evaluates and presents to the Associate Administrator a recommendation for “GO” or “NO-GO” as the L1 HMTA response at Agency FRR. (3.6.3.5)

Center Director	<ul style="list-style-type: none"> a. Appoints, with CHMO concurrence, their respective Center CMO. (2.2.1.1) b. Approves, with CHMO concurrence, their respective Center HMTA Implementation Plan. (2.4.1) c. Provides necessary assets and capabilities (staffing, procedures, and training) to effectively execute the Center HMTA Implementation Plan. (2.4.1) d. Ensures programs and projects residing at their Center comply with established occupational health, medical, and human performance policy, requirements, and standards through the processes specified in this directive and their Center HMTA Implementation Plan. (2.4.1)
Chief Medical Officer (CMO) with Delegated Technical Authority (TA)	<ul style="list-style-type: none"> a. Develops and publishes, with approval from the Center Director and concurrence from the CHMO, their Center HMTA Implementation Plan. (2.4.2) b. Exercises HMTA as described in this directive and their Center HMTA Implementation Plan. (2.4.3) c. Develops and documents a Risk-Based Decision-Making process for the management of HMTA issues for programs and projects within their jurisdiction. (3.4.4.3) d. Appoints, with concurrence from the CHMO, Program CHPOs as HMTA delegates to programs or projects. (2.2.2.1) e. Establishes HMTA interfaces with assigned programs or projects at their Centers, as described in this directive and their Center HMTA Implementation Plan. (2.2.2) f. Exercises L2 HMTA decisional authority within their jurisdiction for health, medical, and human performance issues that are determined to be risk-neutral or have a reduction in risk to NASA, NASA programs, projects, personnel, and the public. (2.3.5) g. Adjudicates requests for relief determined to be risk-neutral or have a reduction in risk. (3.2.2.3) h. Elevates to the CHMO decisions for health, medical, and human performance issues representing an increase in risk. (3.4.2.2) i. Hears appeals of HMTA decisions when they cannot be resolved at the program or project level. (3.3.2.4) j. Works with the Center to identify the appropriate airworthiness review process for experimental, research, and operational configurations and non-standard ground or flight operations for all aircraft contracted or operated by the Center. (3.5.6) k. Engages the NASA Formal Dissent process, where necessary, and provides employees an avenue for elevating issues within the HMTA or through other single- or multiple-authority (e.g., Programmatic Authority, Technical Authority) escalation paths. (3.3.2.3) l. Serves as the HMTA representative to the MMT. (3.6.4) m. Serves as a member of program or project control change and organizational review boards. (3.9.3)

<p>Program Chief Health and Performance Officer (CHPO)</p>	<ul style="list-style-type: none"> a. Serves, as delegated by the JSC CMO, as the direct HMTA program delegate and working interface to NASA’s programs and projects. (2.2.2) b. Exercises HMTA, within the assigned program, as described in this directive and their Center HMTA Implementation Plan. (2.4.3) c. Serves as a member of program or project control boards, change boards, and internal review boards. (3.9.3) d. Assesses their program or project architecture and related Concept of Operations for HMTA standards applicability, non-applicability, and potential HMTA standards relief. (3.2.1.3) e. Advises program and project managers in the development, review, and concurrence of program level health and medical requirements. (3.2.1.4) f. Maintains insight to requirements traceability to ensure program and project compliance to HMTA technical requirements. (3.2.1.6) g. Reviews requests for relief from program requirements that are determined to be risk-neutral or have a reduction in risk. (3.2.2.2) h. Informs the JSC CMO or their designee prior to providing programs or projects with an HMTA decision. (2.3.4) i. Tracks the closure of program requirements derived from HMTA standards. (3.2.3.1) j. Concurs on the closure of a requirement when the program demonstrates evidence of verification or proof of compliance with the requirement criteria. (3.2.3.2) k. Engages the NASA Formal Dissent process, where necessary, and provide employees with an avenue to elevate issues within HMTA or through other single- or multiple-authority (e.g., Programmatic Authority, Technical Authority) escalation paths. (3.3.2.3) l. Assesses the human rating certification evidence for progress towards requirements compliance throughout the program life cycle. (3.5.2) m. Presents an assessment of items representing substantive HMTA risk to the CHMO prior to the TAMR and SMSR. (3.6.2.2) n. Presents an independent assessment of HMTA readiness for upcoming flights, including special topics, to the Program FRR board. (3.6.3.2) o. Participates in key procurement activities and milestones. (3.8.2) p. Engages in adjudication activities to ensure health and medical requirements are levied appropriately on the contracted provider. (3.8.3) q. Concurs on the baselined health and medical requirements levied on contracted providers. (3.8.4) r. Communicates pertinent procurement information to the CMO and CHMO. (3.8.5)
<p>Human Systems Risk Manager</p>	<ul style="list-style-type: none"> a. Manages human system risks in accordance with the Human Systems Risk Board Management Plan. (3.4.3.2) b. Elevates human system risk decisions, recommendations, or positions requiring Level 1 concurrence to the CHMO. (3.4.3.3)

Exemption Determination Research Officer (EDRO)	a. Determines whether a planned test involving NASA personnel (human-in-the-loop testing) requires review by the JSC Institutional Review Board as human research or is exempt from that process. (3.2.3.4)
HMTA Manager	<ul style="list-style-type: none"> a. Provides organizational HMTA leadership at the Agency level spanning across NASA Centers and Programs. (2.5.1 a) b. Conducts resource planning and management for HMTA across the Agency. (2.5.1 b) c. Coordinates HMTA staffing and assignments. (2.5.1 c) d. Engages with internal and external stakeholders at all levels for HMTA integration. (2.5.1 d) e. Assesses and reports on HMTA organizational performance and strategies. (2.5.1 e)

Appendix E. Process for Evaluating an Operational Exception to Health, Medical, and Performance Standards

E.1 General Operational Exceptions

E.1.1 An operational exception should only be considered when it is known that a health, medical, or human performance standard cannot be met and the risk to the crew reaches a level which requires a more thorough review, including the consideration of ethical and policy factors. The appropriate HMTA official will make this determination.

E.1.2 An exception to a health, medical, and human performance standard will be considered an operational exception under the authority of the NASA Administrator.

E.1.3 The evaluation of the operational exception to a health, medical, and human performance standard is based on a three-level decision framework that examines:

- a. Decisions about allowing risk to astronaut health and safety beyond that permitted by health/medical standards.
- b. Decisions about undertaking specific missions.
- c. Decisions concerning individual astronaut participation and crew composition.

E.2 Mission-Specific Operational Exceptions

E.2.1 Determining the need for an operational exception to a health, medical, and human performance standard that cannot be met for all crewmembers during a proposed human space flight mission should originate early in the Program/Project development.

E.2.2 The Mission Directorate Associate Administrator(s) responsible for human spaceflight will:

- a. Include the CHMO in Design Reference Mission (DRM) discussions and program/project pre-formulation activities to assess the need for an operational exception to a health, medical, and human performance standard.
- b. In consultation with the CHMO, determine the program/project Key Decision Point (KDP) by which evaluation of the operational exception (including approval by the NASA Administrator) will be finalized before requesting the operational exception.
- c. Document the identification and evaluation of the operational exception in appropriate Risk Management processes.

E.2.3 When it is known that a health, medical, and human performance standard cannot be met for all crewmembers during a proposed human space flight mission, evaluation of an operational exception to that standard for the mission can be considered per the following process:

- a. HMTA (i.e., CHMO and JSC CMO) will conduct a health/medical risk assessment for the proposed mission and will provide the impact to the mission (e.g., loss of crew/loss of mission) by not meeting the health, medical, and human performance standard, along with any impact to crewmember long-term health (post-mission health).
- b. The CHMO risk assessment will be reviewed through the established risk management process of the HSRB and the HMTA and provided to Mission Directorates.

- c. The CHMO will provide recommendations to mitigate the human health and performance impacts of the operational exception.
- d. The Mission Directorate will combine the CHMO assessment with the operational, engineering, and safety analyses conducted by the Mission Directorate and the Office of the Chief Engineer (OCE) and the Office of Safety and Mission Assurance (OSMA) Technical Authorities to develop the overall mission risk assessment.
- e. Prior to the Program/Project KDP, presentation of the mission's risk posture, including the operational exception, will be made to NASA senior management through the established reporting mechanisms (i.e., Agency Program Management Council).
- f. The NASA Administrator, in consultation with senior management, will make the final determination to accept the operational exception to the health, medical, and human performance standard for the mission. In making this decision, factors to be considered include:
 - (1) The overall risk assessment for the mission.
 - (2) A balancing of the overall risk with the ethical principles and responsibilities identified in NPR 8900.1.
 - (3) Other characteristics of the mission (e.g., national priorities, time urgency, expected benefit, mission design to meet objectives compared to other alternatives).

E.2.4 If the operational exception to a health, medical, and human performance standard is approved, HMTA personnel ensure that the relevant ethical responsibilities and principles are met (e.g., informed decision, provision of appropriate medical monitoring, and health care) and the actions to meet them will be identified and implemented by the appropriate Agency organizations.

E.3 Individual-Specific Operational Exceptions

E.3.1 When, because of operational or programmatic necessity, the operational community intends to offer a flight assignment to an individual crewmember under circumstances where a crew health, medical, and human performance standard cannot be met for the crewmember, an operational exception to that standard for the individual may be evaluated per the following process:

- a. The crew selection authority will develop a rationale and justification for the request to except the health, medical, and human performance standard, which may include:
 - (1) Operational factors;
 - (2) Programmatic factors; and/or
 - (3) Consideration and possible balancing of competing ethical principles and responsibilities (e.g., avoid harm vs. fairness and equality of opportunity).
- b. The AMB will assess the risk of the health, medical, and human performance standard being exceeded for the individual and provide the assessment to the HMTA, who will then provide a risk analysis on exceeding the standard to the crew selection authority and the individual.
- c. Based on the original proposal and the HMTA assessment, the crew selection authority, in consultation with Agency senior management and other relevant stakeholders (e.g., Astronaut Office) will make a determination regarding crew assignments. The final decision as to whether

an operational exception to a health/medical standard will be granted for an individual crew-member will be made by the NASA Administrator.

d. An individual assigned to a mission in this situation will fly under an operational exception per the authority of the NASA Administrator.

E.3.2 Flight assignments under these conditions should only be made with full assurance by the Agency that the appropriate ethical responsibilities will be met, including:

- a. The crewmember fully understands and accepts the risks involved;
- b. Assurance that all feasible means of exposure control will be implemented; and
- c. Assurance that all feasible attempts to monitor long-term health effects will be made.