A composite image of space. The top left shows the Earth's horizon with white clouds and blue sky. The top right shows the Moon in a dark sky. In the center, a small orange planet (Mars) is visible. The bottom half of the image is a dark, starry space.

The Office of the Chief Health and Medical Officer as an Independent Technical Authority

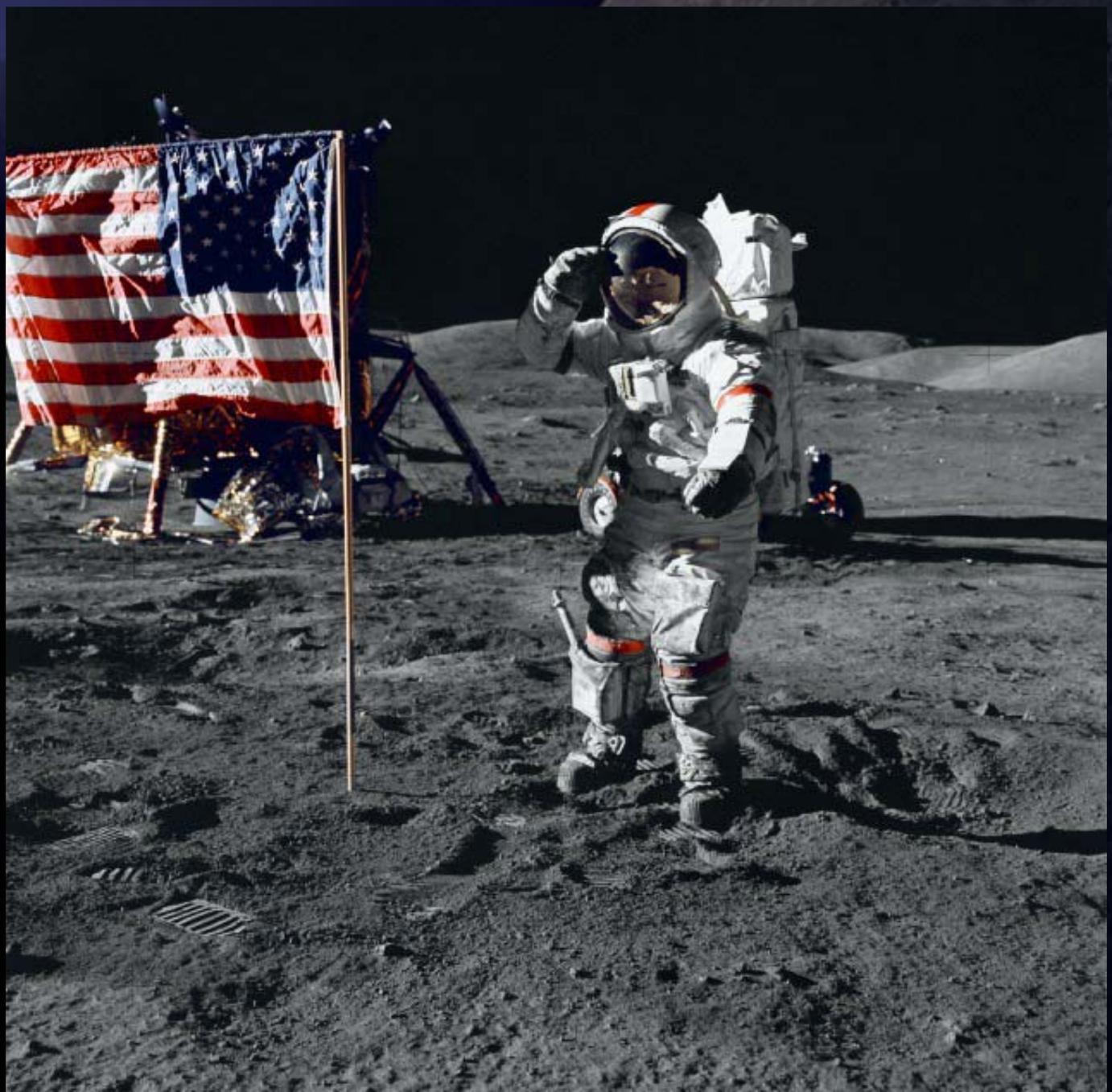
**Richard Williams, MD
NASA Chief Health and Medical Officer**





“Today I announce a new plan to explore space and extend a human presence across our solar system”

***President George W. Bush
January 14, 2004***





Technical Authority Definition

- ◆ **Technical Authority is the authority, responsibility, and accountability to establish, approve, and maintain technical requirements, processes, and policy**
- ◆ **NASA is establishing the Technical Authority as a direct response to CAIB Recommendation 7.5-1**

Technical Authority owns the decision on what is technically acceptable in matters involving safe and reliable operations in both engineering and health/medical related areas.



Technical Authority Principles*

1. Resides in an individual, not an organization,
2. Clear and unambiguous,
3. Independent of the Program Manager,
4. Credible (based on knowledge, experience, resources, personnel pipeline), and
5. Visible and accepted as valid, i.e. has influence and prestige.

* Each separately necessary, but not sufficient in isolation.



The CAIB and Technical Authority



“The practices noted here suggest that **responsibility and authority for decisions involving technical requirements and safety should rest with an independent technical authority.**”

“Organizations that successfully operate high-risk technologies have a major characteristic in common: they place a premium on safety and reliability by structuring their programs so that **technical and safety engineering organizations own the process of determining, maintaining, and waiving technical requirements with a voice that is equal to yet independent of Program Managers, who are governed by cost, schedule and mission-accomplishment goals.**”

“The Naval Reactors Program, SUBSAFE program and the Aerospace Corporation are examples of **organizations that have invested in redundant technical authorities and processes to become highly reliable.**”

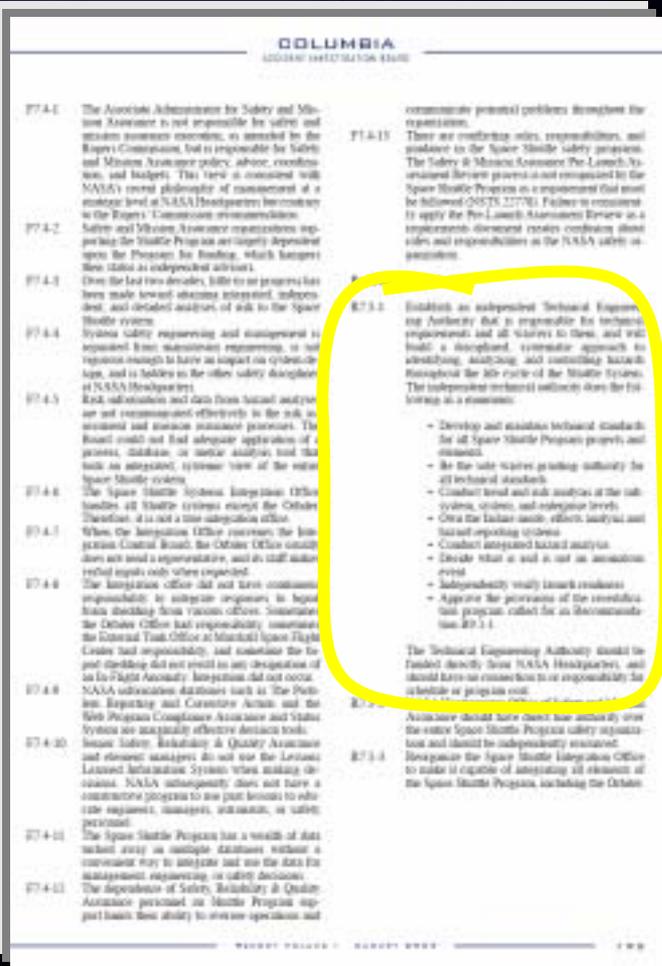
*Excerpted from:
CAIB Report Volume 1, Chapter 7.3*



CAIB Recommendation 7.5-1

R7.5-1: Establish an independent Technical Engineering Authority that is responsible for technical requirements and all waivers to them, and will build a disciplined, systematic approach to identifying, analyzing and controlling hazards throughout the life cycle of the Shuttle System. The independent technical authority does the following as a minimum.

- **Develop and maintain technical standards for all Space Shuttle Program projects and elements**
- **Be the sole waiver-granting authority for all technical standards**
- **Conduct trend and risk analysis at the sub-system, system, and enterprise levels**
- **Own the failure mode, effects analysis and hazard reporting systems**
- **Conduct integrated hazard analysis**
- **Decide what is and is not an anomalous event**
- **Independently verify launch readiness**
- **Approve the provisions of the recertification program called for in Recommendation R9.1-1.**



*Excerpted from:
Recommendations,
CAIB Report Volume 1, Chapter 7.6*

The Technical Engineering Authority should be funded directly from NASA Headquarters, and should have no connection to or responsibility for schedule or program cost.



Technical Authority is...

- independent of programmatic authority
 - organizationally & financially
- **executed in support of programs and projects** to provide
 - adequate checks and balances to ensure safety and reliability,
 - engineering and technical requirements,
 - a disciplined, formal process, standardized across the Agency, for technical requirements and decision making, and
- organic to programs/projects
- centralized
- individualized
- dependent on a balance of power

Technical Authority is the
“technical conscience”.



Who is the Technical Authority?

- ◆ The mandatory NASA Procedural Requirement (NPR)1000.3A, issued July 30, 2004 to define the transformed NASA, in section 4.10.2.8 states:

“ The Chief Engineer is responsible for: Serving as the Agency Independent Technical Authority, delegating this authority through the issuance of warrants.”

The NASA Chief Engineer is the Technical Authority responsible **for all NASA technical requirements affecting safe and reliable operations.**

The NASA Chief Health and Medical Officer is the Technical Authority responsible **for all health and medical matters.**



Office of the Chief Health and Medical Officer

Health and Medical Policy

Aerospace Medicine

Occupational Health

Independent Technical Authority for Health and Medical Matters

Oversight of Health Care Delivery

Provide Health/Medical Policy Direction

Assurance of Health Professional Competency

Bioethics, Research Subject Protection

Human and Animal

Review/Approval of Health Related Research

Deliverables

Review/Approval Health/Medical Related Requirements

Owner of Health/Medical Related Standards



Medical Boards in Support of NASA Health Care

- ◆ **Medical Policy Board (HQ)**
 - CHMO chairs
 - Medical policy for space medicine, atmospheric flight, and occupational health
 - CHMO has permanent medical waiver authority
 - Reviews/approves crew health and medical standards
 - Review of health and medical issues with recommendations to the Mission Directorate AA's and other NASA leaders
 - Reviews (internally and externally) health and bioethical related issues
- ◆ **Aerospace Medicine Board (JSC)**
 - Clinical board
 - Temporary waiver authority
 - Develops crew health and medical standards



Health and Medical Technical Requirements

Rationale:

In order to guide and focus all efforts to protect the health of the NASA workforce, including space-faring crews, medical qualification standards, exposure standards and fitness for duty standards will be established and maintained under the direction of the Chief Health and Medical Officer (CHMO).



Health and Medical Technical Requirements

- **Crew Medical Qualification Standards**
- **Exposure Control Standards**
- **Fitness for Duty Standards**
- **Standards serve as *de facto* declaration of acceptable risk**
- **Standards serve as basis for biomedical research requirements and health related systems requirements**



Health and Medical Technical Requirements

Purpose

To promote the development of countermeasures, interventions, and procedures to ameliorate and prevent the deleterious health and performance effects of space flight and to protect the NASA workforce in all environments.



Health and Medical Standard Setting

Scope

- All standards will be based on the best available scientific and clinical evidence.
 - ❖ research findings
 - ❖ lessons learned from previous space missions
 - ❖ analogue environments
 - ❖ current standards of medical practices
 - ❖ risk management data
 - ❖ expert recommendations



Health and Medical Standard Setting

- **Space faring crew health related standards will address all mission phases and target physiologic, and behavioral and performance systems at risk from exposure to the characteristics of the space environment.**
- **Standards will be periodically and regularly reviewed, and may be updated as new evidence emerges.**



Health and Medical Standard Setting

Background

- **Medical standard setting process modeled on that used by the United States Occupational Safety and Health Administration (OSHA).**
- **NASA's medical standard setting process will use performance standards to set exposure/outcome limits and/or fitness for duty criteria for dangerous or noxious physical and chemical entities, and for the liabilities of isolation and confinement.**
- **The adequacy of subsequent products or deliverables to effectively address the standards will be assessed using an appropriate review mechanism.**
 - ❖ **engineering design reviews**
 - ❖ **established OCHMO Transition to Medical Practice process**
 - ❖ **independent technical evaluations.**



Health and Medical Standard Setting

Types of Standards

- **Fitness for duty standards, and other criteria and limits as appropriate**
 - ❖ **Fitness for duty standards consist of a minimum measurable capability or capacity for a given physiological or behavioral parameter that allows successful performance of all required duties.**
- **Permissible Exposure/Outcome Limits (POL)**
 - **POLs delineate an acceptable maximum decrement or change in a physiological or behavioral parameter, as the result of exposure to the space environment, or a quantifiable limit of exposure to a space flight factor over a given length of time (e.g. life time radiation exposure).**



Health and Medical Standard Setting

Prospective medical standards for space exploration:

- **A Permissible Exposure/Outcome Limit for microgravity induced bone atrophy**
- **A Permissible Exposure/Outcome Limit for muscle mass and strength loss**
- **A Permissible Exposure Limit for space flight radiation exposure, both in Low Earth Orbit and beyond**
- **Fitness for duty standards for cardiovascular fitness, that will evaluate the ability of crew members to perform all required duties during all phases of a mission**
- **Fitness for duty standards for neurosensory and motor functioning, that will allow crew members to perform all required duties during all phases of a mission**
- **Individual and group, behavioral health standards for crew selection, composition and performance**



Health and Medical Standard Setting

Process

- **Decision to initiate a medical standard (OCHMO/Medical Policy Board[MPB])**
- **Drafting the standard (internal group, e.g. OCHMO, MPB, augmented by experts, with ops community involvement)**
- **Review (external group, e.g. IOM)**
- **Revision (internal group, e.g. OCHMO, MPB, augmented by experts, with ops community involvement)**
- **Solicit comments from affected parties (astronaut office; Exploration and Operations mission directorates)**
- **Analysis of policy implications (OCHMO)**
- **Final standard published (MPB through appropriate NASA document)**
- **Ongoing review (review every 5 years or sooner)**



Technical Warrants

- ◆ **The Chief Engineer, NASA Technical Authority for Engineering, will issue warrants including:**
 - **Discipline Technical Warrants**
 - Establish, approve and maintain technical requirements (i.e. specifications, standards, processes, procedures) for their assigned technical discipline.
 - **Systems Warrant Holders**
 - Establish, approve and maintain the technical requirements for the system integration of a total vehicle or program system. These Warrant Holders will utilize Warrant Holders in particular technical areas and disciplines, as required and appropriate.



Technical Warrant Holder

◆ Responsibilities

- Establishing and maintaining technical requirements,
- Approving changes and/or variances to technical requirements,
- Maintaining individual technical expertise,
- Ensuring products capable of safe and reliable operations,
- Making unbiased, independent technical decisions,
- Using sound technical rationale, and
- Being accountable for technical decisions.

◆ Independence

- Organizationally, will not report to program or project managers,
- Are not dependent on Program funding, and
- Have a direct line to the Agency's Technical Authority via the Warrant, without going through Programs.



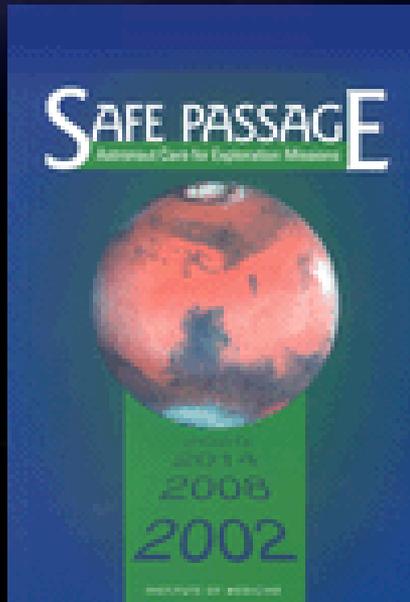
Relationship to Programs

- ◆ In order to ensure **safe** and reliable operations/missions:
 - Program/ Project Managers (PMs) will comply with the technical requirements and decisions issued by Technical Warrant Holders (TWHs).
 - The TWH will provide PMs and other NASA users with technical requirements as well as ranges of technically acceptable alternatives with risk and value assessments where appropriate.
 - PMs will insure TWH has real time access to all technical information from programs.
 - TWH will issue technical resolution of changes and/ or variances in a timely manner.



Anticipated CHMO ITA Impact

- ◆ Provide health/medical policy direction
- ◆ Focus health and medical technical requirements
 - Foundation for all health protective efforts
- ◆ Elevate health and medical technical standards to maximize health protective effect
- ◆ Enhance cognizance of health and medical technical requirements at all levels
- ◆ Help focus NASA biomedical research efforts



“NASA should develop and use an occupational health model for the collection and analysis of astronaut health data, giving priority to the creation and maintenance of a safe work environment.”

***“Safe Passage”
Institute of Medicine, 2001***

