NASA's Human System Risk Assessment Process

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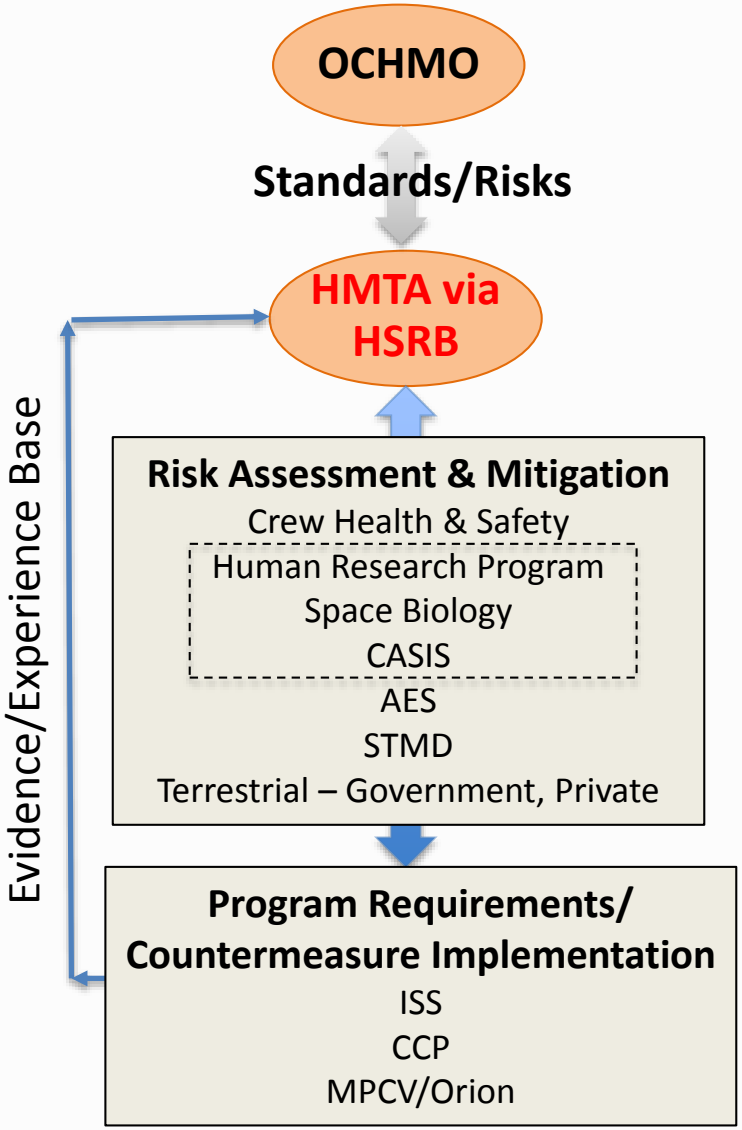
Integrated Human System Risk Management Structure

Policy, Operations, and Research → Human Health/Performance Risk Framework

– **HQ - Office of the Chief Health and Medical Officer (OCHMO) – Health and Medical Authority (HMTA) – Level I**
  - Medical Policy, Health and Performance Standards, and Bioethics
  - Risk Assessment and Mitigation - via the **JSC Chief Medical Officer (JSC CMO)** – **Level II**

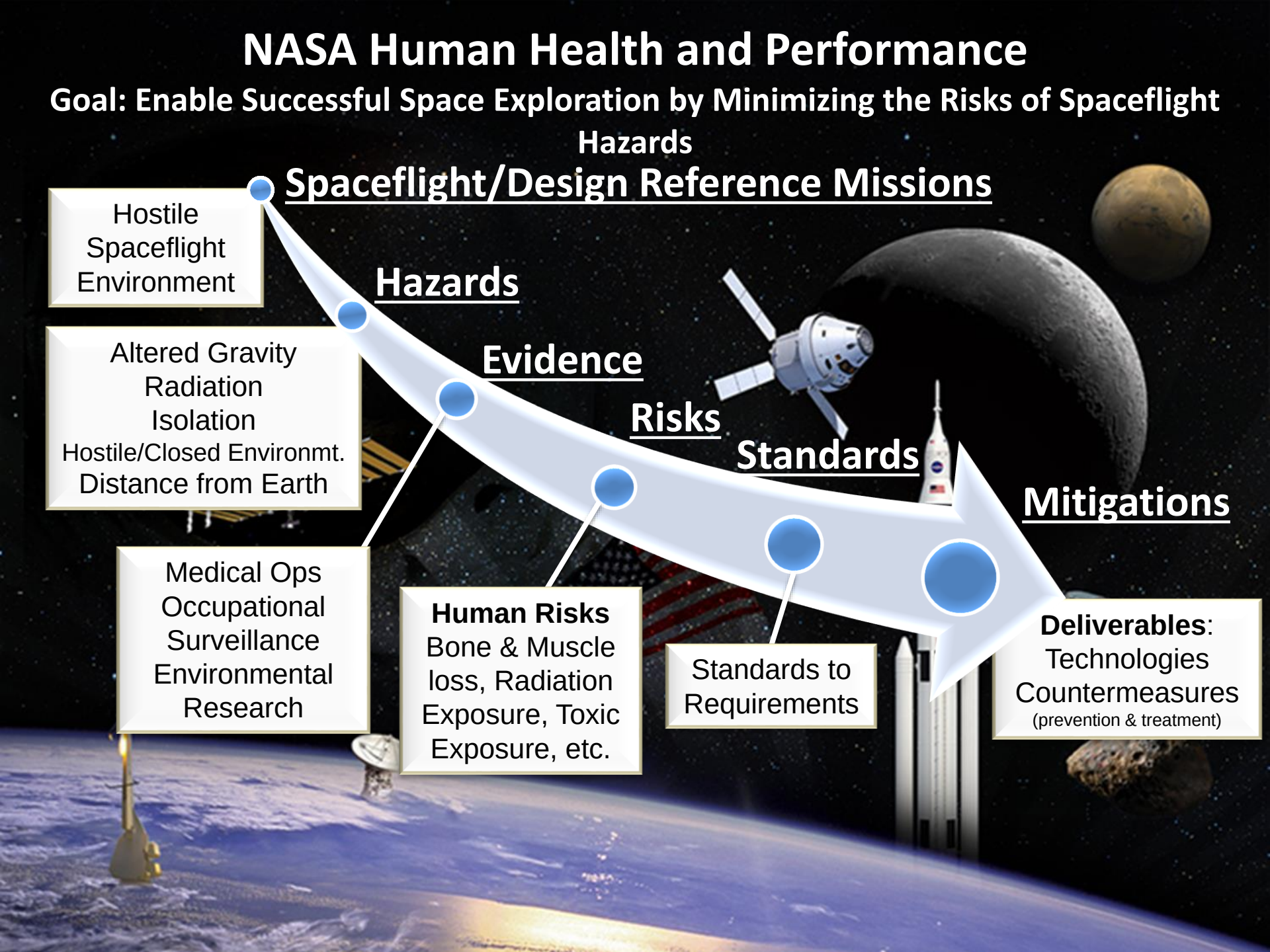
- **Crew Health and Safety (CHS)**
  - Medical Operations & Occupational Health (career health care/post career monitoring)
- **Human Research Program (HRP)**
  - Perform scientific research necessary to understand & reduce health & performance risks for space exploration
- **AES & STMD –** Technology/Protocol Development

– **International Space Station (ISS), Orion, Commercial Crew Programs**
  - Implementation of Medical Operations
    – Medical Requirements, Tests and hardware



NASA Human Health and Performance

Goal: Enable Successful Space Exploration by Minimizing the Risks of Spaceflight Hazards



Design Reference Missions (DRMs) Categories

All of the Human System Risks are evaluated against the following DRMs:

DRM Categories	Mission Duration	Gravity Environment	Radiation Environment	Earth Return
Low Earth Orbit	6 months	Microgravity	LEO - Van Allen	1 day or less
	1 year	Microgravity	LEO - Van Allen	1 day or less
Deep Space Sortie	1 month	Microgravity	Deep Space	< 5 days
Lunar Visit/Habitation	1 year	1/6g	Lunar	5 Days
Deep Space Journey/ Habitation	1 year	Microgravity	Deep Space	Weeks to Months
Planetary Visit/Habitation	3 years	Fractional/ Microgravity	Planetary*	Months

*Planet has no magnetic poles, limited atmosphere

Examples of Missions that would fall into the DRM Categories:

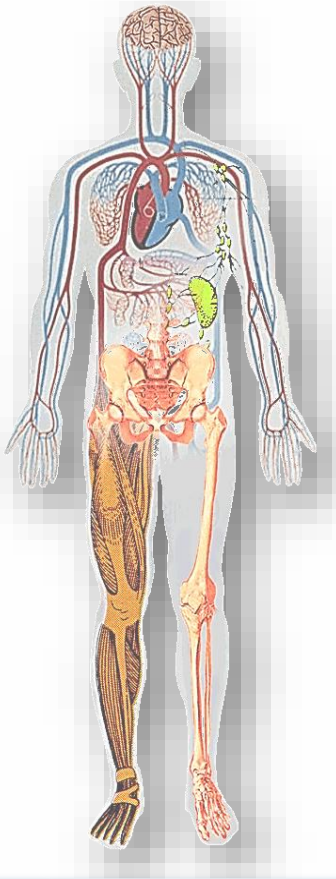
Low Earth Orbit – ISS6, ISS12, Commercial Suborbital, Commercial Visits to ISS, future commercial platforms in LEO
Deep Space Sortie: MPCV test flights, moon fly around or landing, visits to L1/L2, deep space excursion
Lunar Habitation: Staying on the surface more than 30 Days (less than 30 days would be similar)
Deep Space Habitation: L1/L2 Habitation, Asteroid visit, journey to planets
Planetary Habitation: Living on a planetary surface, MARs & extended journey in microgravity to and from

Hazards of Spaceflight

Hazards Drive Human Spaceflight Risks

Altered Gravity - Physiological Changes

Balance Disorders
Fluid Shifts
Cardiovascular Deconditioning
Muscle Atrophy
Bone Loss



Distance from Earth

Drives the need for additional "autonomous" medical care capacity – cannot come home for treatment

Space Radiation

Acute In-flight effects
Long term cancer risk

Hostile/ Closed Environment

Vehicle Design
Environmental – CO_2 Levels, Toxic Exposures, Water, Food
Decreased Immune Function

Isolation & Confinement

Behavioral aspect of isolation
Sleep disorders

HMTA Human System Risk Assessment

Evidence is gathered from in-flight medical and research operations, spaceflight analogs, terrestrial analogs, and/or animal data. Data must be correlated from NASA medical (LSAH), research (LSDA), environmental & terrestrial data bases.

NASA/HMTA Human Risks Evidence Base

Medical Data (mandatory)

Medical data generally does not require informed consent and may only be used for:

- ❑ Medical care by clinician
- ❑ Occupational Surveillance

Environmental & Operational Data

Data gathered to understand the occupational environment, such as:

- CO_2 levels, acoustic, landing loads, radiations levels, mission operations

Research Data (voluntary)

- Research data requires informed consent by the subject & the data.
- Ground analogs
- Includes animal research

Terrestrial Data

Related terrestrial incidence, treatment and research

¾ of Risk Evidence from Operational Medical/Environmental/ Occupational Surveillance Programs

+

¼ of Risk Evidence from Research Programs (Focus on Human System Risks understanding and countermeasure development)

Correlation of data by subject matter experts & physicians.

Generation of Metrics to assess Human System Risks

Summary of Human Risks of Spaceflight
Grouped by Hazards – 30 Human Risks

Altered Gravity Field
1. Spaceflight-Induced Intracranial Hypertension/Vision Alterations
2. Renal Stone Formation
3. Impaired Control of Spacecraft/Associated Systems and Decreased Mobility Due to Vestibular/Sensorimotor Alterations Associated with Space Flight
4. Bone Fracture due to spaceflight Induced changes to bone
5. Impaired Performance Due to Reduced Muscle Mass, Strength & Endurance
6. Reduced Physical Performance Capabilities Due to Reduced Aerobic Capacity
7. Adverse Health Effects Due to Host-Microorganism Interactions
8. Urinary Retention
9. Orthostatic Intolerance During Re-Exposure to Gravity
10. Cardiac Rhythm Problems
11. Space Adaptation Back Pain

Concerns
1. Clinically Relevant Unpredicted Effects of Meds
2. Intervertebral Disc Damage upon & immediately after re-exposure to Gravity

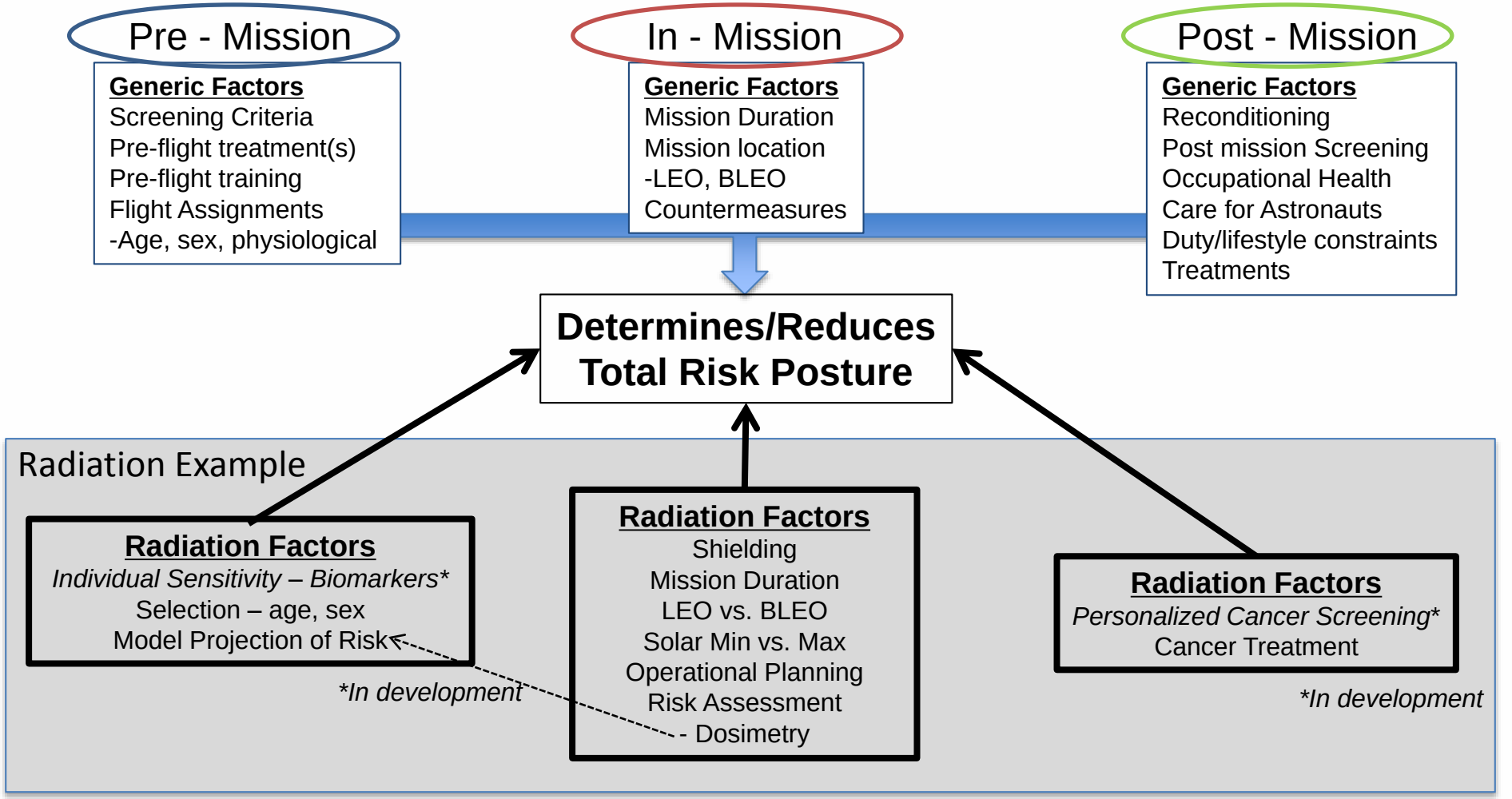
Radiation
1. Space Radiation Exposure on Human Health (cancer, cardio and CNS)

Distance from Earth
1. Adverse Health Outcomes & Decrements in Performance due to inflight Medical Conditions
2. Ineffective or Toxic Medications due to Long Term Storage

Isolation
1. Adverse Cognitive or Behavioral Conditions & Psychiatric Disorders
2. Performance & Behavioral health Decrements Due to Inadequate Cooperation, Coordination, Communication, & Psychosocial Adaptation within a Team

Hostile/Closed Environment-Spacecraft Design
1. Acute and Chronic Carbon Dioxide Exposure
2. Performance decrement and crew illness due to inadequate food and nutrition
3. Reduced Crew Performance and of Injury Due to Inadequate Human-System Interaction Design (HSID)
4. Injury from Dynamic Loads
5. Injury and Compromised Performance due to EVA Operations
6. Adverse Health & Performance Effects of Celestial Dust Exposure
7. Adverse Health Event Due to Altered Immune Response
8. Reduced Crew Health and Performance Due to Hypobaric Hypoxia
9. Performance Decrements & Adverse Health Outcomes Resulting from Sleep Loss, Circadian Desynchronization, & Work Overload
10. Decompression Sickness
11. Toxic Exposure
12. Hearing Loss Related to Spaceflight
13. Injury from Sunlight Exposure
14. Crew Health Due to Electrical Shock

Factors that Influence Human Risk – by Mission Phase



HMTA considers pre, in and post mission factors/countermeasures to evaluate risks and ensure crew health.

Sample Risk – Human System Risk Board (HSRB)

Assessment Performed for all 30 Risks

Risk Title: Risk of Impaired Performance Due to Reduced Muscle Mass, Strength & Endurance*

Risk Statement: Given that exposure to a microgravity environment causes skeletal muscles to undergo reduced mass, strength, and endurance, there is a possibility that mission task performance would be impaired or tasks could not be performed.

Primary Hazard: μ-gravity | **Secondary Hazard:** Closed Environment (spacecraft design), radiation

Countermeasur

Contributing Factors: Mission Design, Microgravity, Cardiovascular Changes, Diet, Hydration, Radiation, Closed Environment

Risk title and statement are generated. Primary hazard (only one) and then secondary hazards (can be multiple) are determined. Any contributing factors are listed.

State of Knowledge: Fitness for duty standard; maintain 80 shall be within normal values for age & sex of the astronaut popu (see metric). No capability for direct strength measurements on environment unquantifiable, but considered to be contributing cardiovas vestibular/sensorimotor alterations associated with space flight (referenc

…ss is also tightly coupled with

DRM Categories	Mission Duration	LxC OPS	Risk Disposition	LxC LTH	Risk Disposit
Low Earth Orbit	6 Months	1 x 4	Accepted/ Optimize	3 x 1	Accepted
	1 Year	1 x 4	Accepted/ Optimize	3 x 1	Accepted
Deep Space Sortie	1 Month	1 x 4	Accepted/ Optimize	3 x 1	Accepted
Lunar Visit/ Habitation	1 Year	1 x 4	Accepted/ Optimize	3 x 1	Accepted
Deep Space Journey/Hab	1 Year	1 x 4	Accepted/ Optimize	3 x 1	Accepted
Planetary	3 Years	1 x 4/ 3 x 3^	Requires Mitigation	3 x 2	Requires Mitigation

…Drivers: The assumption is that "ISS-like" countermeasures will be available for all future exploration DRMs. **OPS Likelihood: ALL DRMs:** Activities with the highest impact are emergency egress & rescue of an incapacitated crew member. Probability of these occurrences is ≤ 0.1%. Additionally, (^) **Planetary:** Surface EVA (freq./type) would also be impacted and the probability is ≥1% due to transit duration effect on muscle strength/endurance. **Ops Consequence, All DRMs:** Death if unable to emergency egress or rescue an incapacitated crew member. In addition, (^) **Planetary:** Significant Reduction of Performance (shorter duration EVA, less strenuous activities) for surface operations.

- **LTH Likelihood: All DRMs** : ~25% of crew do NOT maintain 80% of preflight values during a 6 month ISS mission with CEVIS, ARED & T2. **LTH Consequence: All DRMs ex. Planetary:** Crew return to baseline within 3 months with limited intervention. **Planetary:** Anticipate taking longer to return to baseline - 1 year recovery.

Risk Disposition Rationale: **For all missions except Planetary**, the risk is accepted but optimization of countermeasure is desired (particularly inflight exercise hardware). **For Planetary:** Mitigation is required to provide effective countermeasures with less mass and volume.

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Sample Risk – Human System Risk Board (HSRB)

Assessment Performed for all 30 Risks

Risk Title: Risk of Impaired Performance Due to Reduced Muscle Mass, Strength & Endurance*

Risk Statement: Given that exposure to a microgravity environment causes skeletal muscles to undergo reduced mass, strength, and endurance, there is a possibility that mission task performance would be impaired or tasks could not be performed.

Primary Hazard: μ-gravity

Secondary Hazard: Closed Environment (spacecraft design), radiation

Contributing Factors: Mission Design, Microgravity, Cardiovascular Changes, Diet, Hydration, Radiation, Closed Environment

Countermeasure: ***Prevention:*** Pre-flight training, inflight exercise, diet, aerobic & resistive hardware. ***Treatment:*** Post flight reconditioning

State of Knowledge: Fitness for duty standard; maintain 80% of baseline muscle strength. Pre-flight standard: Pre-flight muscle strength & function shall be within normal values for age & sex of the astronaut population. Ample data from shuttle and ISS document pre & post flight strength assessment (see metric). No capability for direct strength measurements on ISS. Limited in flight time course of change in muscle strength. Impact of radiation environment unquantifiable, but considered to be contributing cardiovascular factor (reference radiation risk). Capability for emergency egress is also tightly coupled with vestibular/sensorimotor alterations associated with space flight (reference sensorimotor risk)

DRM Categories	Mission Duration	LxC OPS	Risk Disposition	LxC LTH	Risk Disposition
Low Earth Orbit	6 Months	1 x 4	Accepted/ Optimize	3 x 1	Accepted
	1 Year	1 x 4	Accepted/ Optimize	3 x 1	Ac
Deep Space Sortie	1 Month	1 x 4	Accepted/ Optimize	3 x 1	Acce
Lunar Visit/ Habitation	1 Year	1 x 4	Accepted/ Optimize	3 x 1	Accep
Deep Space Journey/Hab	1 Year	1 x 4	Accepted/ Optimize	3 x 1	Accepted
Planetary	3 Years	1 x 4/ 3 x 3^	Requires Mitigation	3 x 2	Requires Mitigation

➢**L x C Drivers:** The assumption is that "ISS-like" counterm… available for all future exploration DRMs. OPS … with the highest impact … member … shorter … do NOT maintain 80% of preflight … mission with CEVIS, ARED & T2. **LTH Consequence:** … ex. **Planetary:** Crew return to baseline within 3 months with limited intervention. **Planetary:** Anticipate taking longer to return to baseline - 1 year recovery.

Risk Disposition Rationale: **For all missions except Planetary**, the risk is accepted but optimization of countermeasure is desired (particularly inflight exercise hardware). **For Planetary**: Mitigation is required to provide effective countermeasures with less mass and volume.

State of Knowledge is a summary of the evidence. Detailed evidence is listed in the presentation package of each risk and a summary is added as a metric (see next page).

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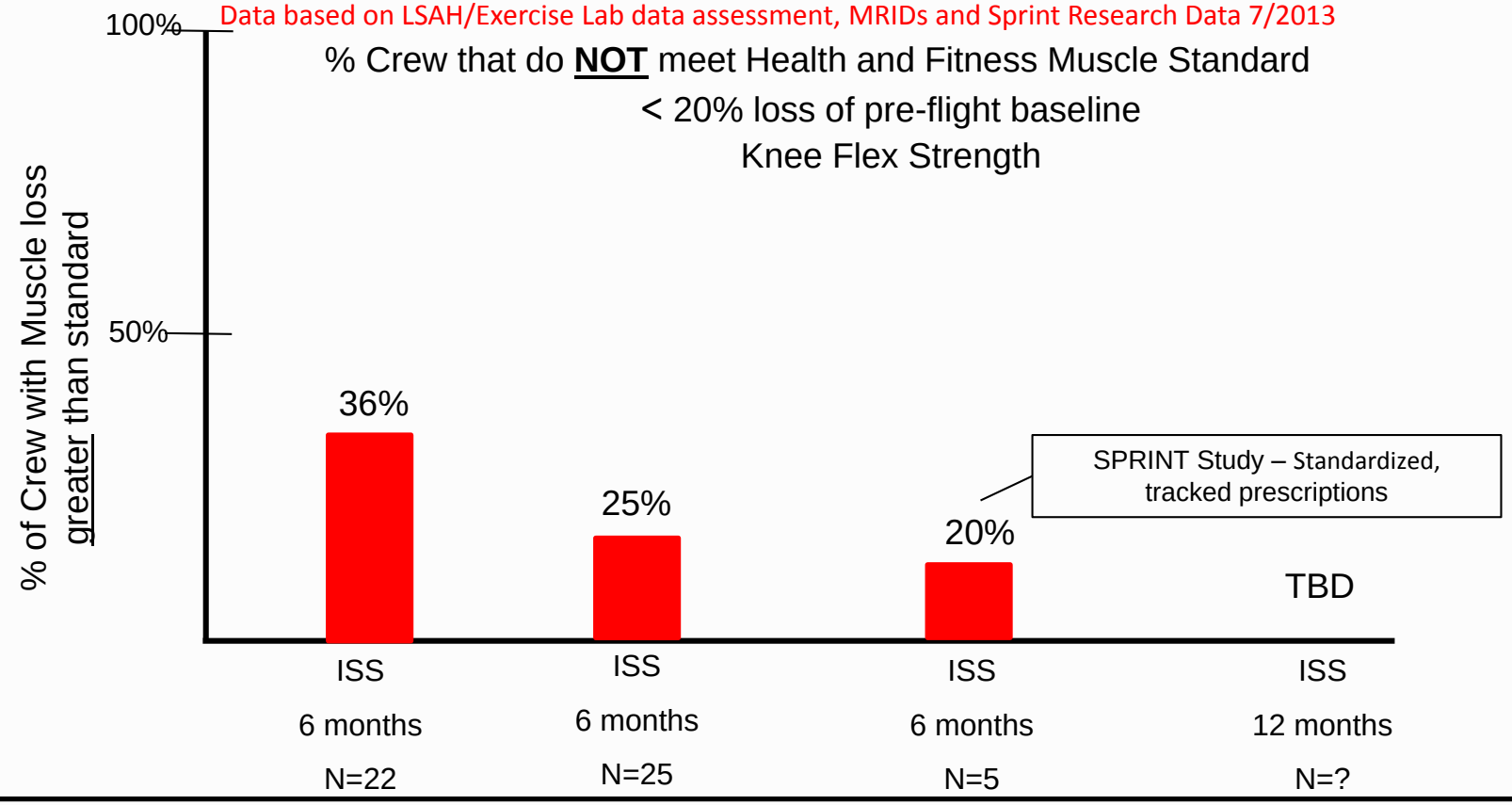
Metric for Risk of Impaired Performance Due to Reduced Muscle Mass, Strength & Endurance



(*) "Non-Standard" indicates customized exercise prescriptions

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Sample Risk – Human System Risk Board (HSRB)

Assessment Performed for all 30 Risks

Projectized Approach to Human System Risk Mgmt

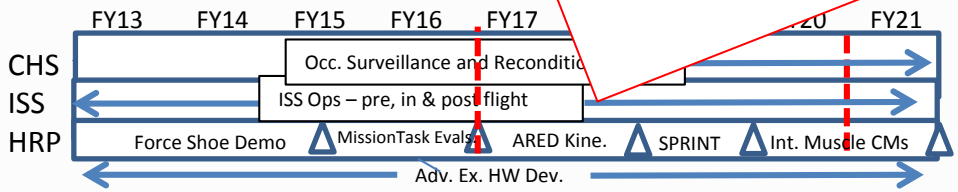
Deliverables Required	Responsible Program/Mechanism	Budget ($M) - FY 2014-2018 Timeline
Knowledge/Research:		
-ARED Kinematics	HRP	$0.5M
-ISS SPRINT	HRP	$3M
-Other Post Task (Activity/Payload)	HRP, NSBRI	$3M
Technology:		
-Portable Load Sensing Evals.	HRP/ISS/EA	$600K/2015
-Adv. Exercise Concept Evals. ISS	HRP	$6.3M
-MPCV Exercise Concept Dev.	HRP	$1.5M
- Adv Exercise Risk Mitigation	*TBD*	*~$7M*
Operational Protocols:		
-ASCR Std - Exercise Prescriptions	ISS/CHS	$4M
-MedB 5.1-3 (Fn Fit., IsoTestingCMS)	ISS	$3.3M
-ISS Ex. HW – Sustaining, Log, Main.	ISS	$27M
Guidelines/Requirements/Standards:		
-Standard Updates	ISS/CHS/HRP	
-Requirements for MPCV	MPCV	

Each risk matures as it follows the **CRM** Process

Note: All tasks costs are shared with the A

**Italics indicates desired work for whi included in totals)*

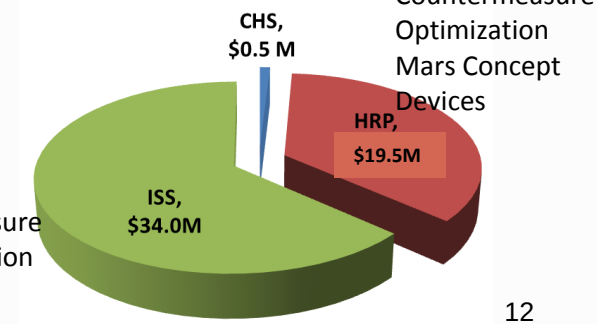
Deliverables required to mitigate the risk are tracked at a high level. Detailed tracking maintained by funding programs.



= Risk Evaluation Assessment

Countermeasure implementation

Total Budget 2014-18 = $54M



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Risks to Standard - Requirement Flow

Risks

- Bone Fracture due to Spaceflight-induced Changes to Bone
- Reduced Physical Performance Capabilities Due to Reduced Aerobic Capacity
- Impaired Performance Due to Reduced Muscle Mass, Strength & Endurance

Risks to Standards

Standard(s)

Space Flight Health Standard
NASA-STD-3001, VOLUME 1, CREW HEALTH
March 2007, In process of update

4.2.8 Permissible Outcome Limit for Muscle Strength Standard
4.2.8.2 Countermeasures shall maintain in-flight skeletal muscle strength at or above 80 % of baseline values.

Space Flight Health Standard
NASA-STD-3001, VOLUME 2, HUMAN FACTORS,...
January 2011

7.4.1 The system **shall** provide countermeasures to meet crew bone, muscle, sensory-motor, and cardiovascular standards defined in NASA-STD-3001, Volume 1.

Standards to Program Requirements

Requirements

ISS	Commercial Crew	MPCV
SSP 50260 International Space Station Medical Operations Requirements Document - MORD	CCT-REQ-1130 ISS Crew Transportation Requirements Document	MPCV Human System Integration Requirements -HSIR
8.5.2.2 CREW PARTICIPATION IN DAILY PHYSICAL EXERCISE ISS crewmembers shall participate in physical exercise, consisting of aerobic, anaerobic and resistive exercise as prescribed by medical specialists.	**N/A – due to limited duration of mission**	**3.5.4.1 Exercise Capability [HS6032]** The system shall provide the capability for aerobic and resistive exercise training for 30 continuous minutes each day per crewmember for missions greater than 8 days.

Human Risks Disposition for all DRMs

4/22/2015	In Mission Risk - Operations						Post Mission Risk - Long Term Health					
Human System Risks 04/22/15	Low Earth Orbit	Low Earth Orbit	Deep Space Sortie	Lunar Visit/Habitation	Deep Space Journey/Habitation	Planetary	Low Earth Orbit	Low Earth Orbit	Deep Space Sortie	Lunar Visit/Habitation	Deep Space Journey/ Habitation	Planetary
	6 Months	12 Months	30 Days	1 year	1 Year	3 years	6 Months	12 Months	30 Days	1 year	1 Year	3 years
VIIP	A	A	A	A	RM	RM	A	A	A	A	RM	RM
Renal Stone Formation	A	A	A	A	RM	RM	RM	RM	RM	RM	RM	RM
Inadequate food and nutrition	A	A	A	A	A	RM	A	A	A	A	A	RM
Risk of Space Radiation Exposure	A	A	A	A	A	TBD	A	A	A	RM	RM	RM
Medications Long Term Storage	A	A	A	A	A	RM	A	A	A	A	A	RM
Acute and Chronic Carbon Dioxide	A	A	A	A	RM	RM	A	A	A	A	A	A
Inflight Medical Conditions	A	A	A	RM	RM	RM	A	A	A	RM	RM	RM
Cognitive or Behavioral Conditions	A	RM	A	RM	RM	RM	A	A	A	A	A	RM
Risk of Bone Fracture	A	A	A	A	A	RM	A	A	A	A	A	A
Human-System Interaction Design	A	A	A	RM	RM	RM	A	A	A	A	A	A
Team Performance Decreme[illegible]	A			A	R	RM	A	A	A	A	A	A
Cardiac Rhythm Problems- U[illegible] Review	A			A	M	RM	A			A	A	A
Reduced Muscle Mass, Stre[illegible]th	A			A	A	RM	A			A	A	RM
Reduced Aerobic Capacity	A	A	A	A	A	RM	A	A	A	A	A	RM
Sensorimotor Alterations	A	A	A	RM	RM	RM	A	A	A	A	A	RM
Injury from Dynamic Loads	A	A	RM	RM	RM	RM	A	A	RM	RM	RM	RM
Sleep Loss	A	A	A	A	RM	RM	A	A	A	A	RM	RM
Altered Immune Response	A	A	A	A	A	RM	A	A	A	A	A	RM
Celestial Dust Exposure	N/A	N/A	TBD	A	TBD	TBD	N/A	N/A	TBD	A	TBD	TBD
Host-Microorganism Interactions	A	A	A	A	A	RM	A	A	A	A	A	RM
Injury due to EVA Operations	A	A	A	RM	A	RM	A	A	A	RM	A	RM
Decompression Sickness	A	A	RM	A	RM	A	A	A	A	RM	A	RM
Toxic Exposure	A	A	A	A	A	A	A	A	A	A	A	A
Hypobaric Hypoxia	RM	RM	A	RM	RM	RM	RM	RM	A	RM	RM	RM
Space Adaptation Back Pain	A	A	A	A	A	A	N/A	N/A	N/A	N/A	N/A	N/A
Urinary Retention	A	A	A	A	A	A	A	A	A	A	A	A
Hearing Loss Related to Spaceflight	A	A	A	A	A	A	A	A	A	A	A	A
Orthostatic Intolerance	A	A	A	A	A	A	A	A	A	A	A	A
Injury from Sunlight Exposure	A	A	A	A	A	A	A	A	A	A	A	A
Risk of electrical shock	A	A	A	A	A	A	A	A	A	A	A	A

A – Accepted RM- Requires Mitigation

Green – low/very low consequence Yellow – low to medium consequence Red – high consequence

Summary

- **Human Health/Performance Risk Framework –** Level I (Policy) & Level II (Operations & Research)
- **Risk Assessments for Space Exploration are based on DRM Categories** as actual DRMs are not available (conceptual) – These categories were designed to envelope the different DRMs
- **5 hazards of Spaceflight engender the 30 identified HS risks**
- **All factors that influence human risk pre/in/post-flight are evaluated together to ensure crew health**
- **Systematic development of individual risk crew summaries** with risk statements, hazards, state of knowledge, metrics, LxC ratings, deliverables, etc. **evolve via the Continuous Risk Management (CRM) process**
- **The individual risk plans are "Projectized"** via high-level budget pie charts and high-level schedules via Gantt charts
- **Portfolio Management approach** will take advantage of **risk dispositions and common elements identified** within individual risks **to develop priorities and broad range mitigation strategies**

Thank you!

Backup