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**Lyndon B. Johnson Space Center
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Space and Life Sciences Directorate
Office of Bioastronautics

Bioastronautics Critical Path Roadmap (BCPR)

An Approach to Risk Reduction and Management for Human Space Flight: Extending the Boundaries

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Bioastronautics Critical Path Roadmap (BCPR)
An Approach to Risk Reduction and Management
for Human Space Flight: Extending the Boundaries

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Altered pages must be typed and distributed for insertion.			

TABLE OF CONTENTS

TABLE OF CONTENTS

Section **Page**

APPENDICES

LIST OF TABLES

Table **Page**

LIST OF FIGURES

Figure **Page**

ACRONYMS AND ABBREVIATIONS

0-G	Zero Gravity
1-G/1 X G	One Gravity/Earth Gravity
ACICLS	Advanced System Integration and Control for Life Support
ACLS	Advanced Cardiac Life Support
AEMC	Advanced Environmental Monitoring and Control
AEVA	Advanced Extravehicular Activity
AFT	Advanced Food Technology
AG	Artificial Gravity
AHST	Advanced Human Support Technology
AIM	Advanced Integration Matrix
ALS	Advanced Life Support
AMC	Autonomous Medical Care
apoE	apolipoprotein E
ARC	Ames Research Center
ATLS	Advanced Trauma Life Support
BCB	Bioastronautics Program Office Control Board
BCLS	Basic Cardiac Life Support
BCPR	Bioastronautics Critical Path Roadmap
BH&P	Behavioral Health and Performance
BMD	Bone Mineral Density
BPO	Bioastronautics Program Office
BSMT	Bioastronautics Science Management Team
BTLS	Basic Trauma Life Support
CCP	Configuration Control Panel
CDR	Commander
CELSS	Closed Ecological Life Support System
CEV	Crew Explorative Vehicle
CMRS	CO_2 Moisture Removal System
CNS	Central Nervous System
CPCP	Critical Path Control Panel
CPR	Cardiopulmonary Resuscitation
CQ	Critical Question
CR	Change Request
CRL	Countermeasure Readiness Level
DCS	Decompression Sickness
DNA	Deoxyribonucleic Acid
DNR	Do Not Resuscitate
DRM	Design Reference Mission
EBV	Epstein-Barr Virus
ECLS	Environmental Control and Life Support
EMU	Extravehicular Mobility Unit
Env	Environment
EQ	Enabling Question
Ev.	Evidence
EVA	Extravehicular Activity
Fax	Facsimile
G, Gx	Unit Of Measurement For Acceleration Or Gravity; Subscripts X, Y, and Z Indicate Direction Of Force; 1G = Earth Gravity

ACRONYMS AND ABBREVIATIONS

Hab	Habitat
HACCP	Hazard Analysis and Critical Control Point
HHC	Human Health and Countermeasures
HIV	Human Immunodeficiency Virus
HTLV	Human T-cell Leukemia Virus
HZE	High Mass and Energy
IAA	International Academy of Astronautics
IEEE	Institute of Electrical and Electronics Engineers, Inc.
IgE	Immunoglobulin E
IIH	Immunology, Infection & Hematology
IOM	Institute of Medicine
ISRU	In-Situ Resource Utilization
ISS	International Space Station
IV	Intravenous
JSC	Johnson Space Center
KCitrate	Potassium Citrate
LAC	Long Arm Centrifuge
LCVG	Liquid Cooling and Ventilation Garment
LEO	Low Earth Orbit
LET	Linear Energy Transfer
LSA	Lunar Surface Activities
MC	Medical Care
MCC	Mission Control Center
MeV	Megaelectron Volt
MRI	Magnetic Resonance Imaging
N/A	Not Applicable
NAE	National Academy of Engineering
NAS	National Academy of Science
NASA	National Aeronautics And Space Administration
NCRP	National Council on Radiation Protection
NET	No Earlier Than
NLT	No Later Than
NRA	NASA Research Announcement
NRC	National Research Council
NSBRI	National Space Biomedical Research Institute
NTSB	National Transportation and Safety Board
OBPR	Office Of Biological And Physical Research
PCD	Patient Condition Database
PFO	Patent Foramen Ovale
PLSS	Portable Life Support System
PLT	Pilot
psi	Pounds Per Square Inch
RAD	Radiation
RDS	Risk Data Sheet

ACRONYMS AND ABBREVIATIONS

ReMAP	Reprioritization and Maximization Committee
RNA	Ribonucleic Acid
rRNA	Ribosomal RNA
rpm	Revolutions per Minute
RYG	Red, Yellow, Green
SARS	Severe Acute Respiratory Syndrome
SHFE	Space Human Factors Engineering
Si	Silicon
SLS	Spacelab Life Sciences
SLSD	Space and Life Sciences Directorate
SMAC	Space Maximum Allowable Concentration
SMCCB	Space Medicine Configuration Control Board
SMCL	Space Medicine Condition List
SPE	Solar Particle Event
SRC	Short Radius Centrifuge
SRMS	Shuttle Remote Manipulator System
TBD	To Be Determined
TCCS	Trace Contaminant Control System
TGA	Trace Gas Analyzer
TRL	Technological Readiness Level
U/S	Ultrasound
US/U.S.A.	United States/United States of America
UV	Ultraviolet
VPCAR	Vapor Phase Catalytic Ammonia Removal
VPU	Vegetable Production Unit

EXECUTIVE SUMMARY

Bioastronautics is the study and management of the biomedical effects of space flight on humans. It establishes tolerances (operating bands)[1] for humans exposed to the effects of space travel and develops countermeasures to overcome them. Bioastronautics also develops technologies that make human space flight safe and productive. It encompasses research, operations and policies related to human space flight. This document focuses on the research and technology to extend the boundaries of human space flight; it does not address current engineering and operational issues.

The Bioastronautics Critical Path Roadmap (BCPR) is the framework used to identify and assess the risks to crews exposed to the hazardous environments of space. It guides the implementation of research strategies to prevent or reduce those risks. Although the BCPR identifies steps that must be taken to reduce the risks to health and performance that are associated with human space flight, the BCPR is not a "critical path" analysis in the strict engineering sense. The BCPR will evolve to accommodate new information and technology development and will enable NASA to conduct a formal critical path analysis in the future. As a management tool, the BCPR provides information for making informed decisions about research priorities and resource allocation. The outcome-driven nature of the BCPR makes it amenable for assessing the focus, progress and success of the Bioastronautics research and technology program. The BCPR is also a tool for communicating program priorities and progress to the research community and NASA management.

BCPR Objectives

- Identify and assess risks for human space exploration.
- Prioritize research and technology, and communicate those priorities.
- Guide solicitation, selection and development of NASA research (ground and flight) and allocation of resources.
- Assess progress toward reduction and management of risks.
- Define operating bands (acceptable levels of risk).

The key elements of the BCPR include both content and processes. The basic contents of the BCPR are risks, enabling research and technology questions (EQs) and deliverables. Its major processes include risk identification, assessment and management.

Mission requirements set the context for identification and assessment of risks. The development of mission requirements follows an iterative path among the collaborating Program Offices as research, policies and capabilities converge. For purposes of the BCPR, three design reference missions (DRMs) are used to identify and assess risk:

1. A one-year ISS mission
2. A month-long stay on the lunar surface
3. A 30-month journey to Mars and back

1 As defined in the NASA Headquarters Bioastronautics Strategy, "Acceptable levels of risk define the tolerance limits, or desirable operating bands, for the human sub-system."

Risk is the conditional probability of an adverse event occurring, or a system performance-related inefficiency. There are two types of risks for the human element. One represents the human health and medical risks that can arise from exposure to the hazardous conditions of space flight (including microgravity, radiation, vacuum, confinement and others). The other risk type represents the engineering technologies and system performance aspects that provide a safe and habitable environment for the crew to live and work.

EQs represent the issues that must be sufficiently addressed to resolve and retire a risk. Deliverables are the specific end-items, or products, that have been identified as desirable outcomes or solutions to the EQs, and have date-specific expectations associated with them. Deliverables, at a top level, are depicted on the schedules included in the BCPR. Each crosscutting area is represented by a notional schedule (See Appendix C). For planning purposes, two key dates drive Bioastronautics research and technology development: the retirement of the Space Shuttle (and the end of its launch and return capabilities) in 2010, and the end of NASA's commitments to the International Space Station (ISS) in 2016. The BCPR is the integrated product of all of these elements and illustrates the Bioastronautics approach for optimizing human health and performance to enable exploration missions.

Five crosscutting areas integrate the 16 disciplines comprising the BCPR. The crosscutting areas are Human Health and Countermeasures (HH&C), Autonomous Medical Care (AMC), Behavioral Health and Performance (BH&P), Radiation Health, and Advanced Human Support Technologies (AHST). HH&C mainly addresses effective countermeasures for the deleterious effects of space flight. AMC addresses the capability to monitor, diagnose and treat injury or illness during missions, with an emphasis on increasing the use of less Earth-dependent operations. The focus of BH&P is to optimize psychosocial and behavioral functioning and cognitive performance. Radiation Health focuses on setting the requirements for radiation shielding and monitoring, increasing allowable crew time in space and reducing the uncertainties for predicting cancer and other radiation health risks. AHST focuses on efficient solutions for mission-enabling human habitats.

BCPR Processes

All BCPR risks were identified through discipline team deliberations and included review of recent research results and previous advisory committee reports. The discipline teams also provided detailed information about each of the risks on data sheets that included risk descriptions, justifications, current and projected countermeasures, readiness levels and interrelationships with other risks. The Risk Data Sheets (RDS) serve as the database for the BCPR.

Risk assessment was based on a process involving first, deliberations among the discipline teams rating their specific risks for each of the three BCPR DRMs; and second, the Bioastronautics Science Management Team (BSMT), deliberation and consensus for rating the relative importance among the entire set of risks for each of the three BCPR DRMs. The ratings for the human health risks were derived from an analysis of the likelihood of the occurrence of the risk, the severity of its consequence should it occur, and the risk mitigation status. System performance/efficiency risks were assessed using criteria reflecting system performance capabilities for increased efficiency.

The BSMT used a red/yellow/green graphic to communicate the relative priorities across all 50 risks. All risks were assessed for nominal missions and operations. It should be noted that off-nominal, contingency situations would increase the seriousness of each risk.

Managing Risk

Management of all BCPR risks depends on development, selection and implementation of effective and efficient mitigation strategies. Effective management of Bioastronautics risks requires greater use of a project management approach. Project management imposes discipline on research activities and focuses on schedules and deliverables while maintaining quality and cost control. Project management teams foster valued integration and commitment from the participating experts and stakeholders. Project management teams also contribute to the development and use of effective metrics to assess current status, measure progress in reducing risk and answering the EQs.

BCPR management involves the individuals who develop it and those who provide oversight of its management and implementation. The content of the BCPR is developed through deliberative processes involving the discipline teams with their designated leads. The management of the BCPR spans the three collaborating program offices as specified in the Bioastronautics Strategy (January 2003). Program Offices solicit and fund the research and technology development activities. The BSMT currently has oversight of the BCPR. The Critical Path Control Panel (CPCP) will be reconstituted and re-engaged in 2004 to maintain the BCPR baseline document and the companion Website. The field centers contribute to the resolution of the EQs through the development of the BCPR deliverables.

Conclusions

The following conclusions were derived from the Bioastronautics Critical Path Roadmap (BCPR) refinement activity:

1. Given the short lead times remaining for design, verification and delivery of experimental and countermeasure hardware, the physiological countermeasure development activities must now concentrate more on what is currently known than on what remains to be learned.
2. The Bioastronautics research and technology program must fully adopt and promulgate an outcome-oriented approach to fulfill its near-term commitments to the success of human space flight missions over the next few decades.
3. The most serious risks for a Mars mission are (a) addressing the requirements for AMC capabilities; (b) providing radiation health protection; (c) maintaining BH&P; (d) bone loss-related issues; and (e) AHST. For the moon the most serious risks are environmental technologies, remote medical care and radiation. While a one-year stay on the ISS presents a generally lower risk than the other two missions, the ISS is an important platform for reducing the risks for Mars missions.

4. It is imperative that a new paradigm be adopted for Bioastronautics that further integrates flight and ground activities and optimizes flight resources. Project methodology forces forward thinking, integrated planning and planning for contingencies.
5. For these projects to succeed, appropriate sites for ground testing and integration must be available.
6. An important element of risk management is the use of metrics to assess progress. Effective measures of success must be defined with a clear definition of the goal, and must be used by project teams and management to assess progress made in risk reduction and improved efficiency.
7. Participation of the key stakeholders in the deliberation process is integral for risk reduction and management. Since the ultimate beneficiaries of Bioastronautics are the astronauts and the flight surgeons that support them, it is essential that they participate in the continued evolution of the BCPR, especially in setting priorities.
8. Integration at all levels of Bioastronautics: intramural and extramural biomedical researchers, technology developers, flight surgeons, astronauts and various levels of management at the NASA HQ and the field centers is essential for the success of Bioastronautics and the BCPR. Integration ensures that critical elements are not ignored and appropriate resources are applied to the most important areas of risk reduction.

1.0 INTRODUCTION

Bioastronautics is the study of biological and medical effects of space flight on human systems. It establishes limits, defined as safe and acceptable operating bands of tolerance, to the space environment for the human element. Bioastronautics also develops technologies that make human space flight safe and productive. It then develops risk mitigation strategies or countermeasures, targeted at the thresholds of tolerance to maintain crew capabilities and function during and after exposure to the hazardous conditions of space flight (i.e., reduced-gravity, radiation and isolation in a highly confined and enclosed environment for prolonged durations). This information is important to providing the requirements for building human-centered space transportation vehicles and lunar/planetary habitats. Ensuring the health, safety and performance of those exposed to the harsh environment of space requires a research and technology portfolio that spans clinical, basic and applied research and technology development activities, as well as the operational and policy issues related to human space flight.

The Bioastronautics Critical Path Roadmap (BCPR) was established to be the framework for focusing and prioritizing research and technology solutions that ensure human health, safety and performance. The BCPR is an outcome-driven approach to deliver the products to prevent, reduce or eliminate the identified risks that potentially limit human space flight today and enable the era of exploration. The BCPR is not a “critical path” analysis in the strict engineering sense. The BCPR will evolve to accommodate new information and technology development and will enable a formal critical path analysis in the future.

2.0 HISTORY

The BCPR was initiated in 1997 by the Johnson Space Center (JSC) Space and Life Sciences Directorate (SLSD). In 1998, the National Space Biomedical Research Institute (NSBRI) and other members of the external community began to participate. The BCPR began as an iterative approach by discipline experts to identify, review and prioritize the most critical risks confronting human space flight missions. These risks were based on a challenging scenario, a human expedition to Mars. The identification of risks and associated critical research issues were derived using a deliberative process among discipline experts who drew upon recent published research results as well as various advisory committee reports (NASA Advisory Council, 1992; National Academy of Sciences (NAS) 1987, 1998; National Research Council (NRC) 1993; National Academy of Engineering (NAE) 1997, NASA Countermeasure Task Force, 1997; National Council on Radiation Protection (NCRP) 1989, 1997, 2000).

2.1 Risk Assessment

Risk assessment was based on the relative ranking by the discipline experts of a risk within a discipline. A set of criteria was used to estimate the likelihood of an event and the severity of the consequence(s) of a risk as well as its risk mitigation status. In another deliberative process, a separate panel of experts categorized the relative importance of risks across all disciplines, using the experts' assessment and ranking. The basis for managing the risks was developed over several years and included:

- Establishing a configuration control process;
- Developing and publishing of the Bioastronautics Strategy (January 2003);
- Adopting and testing several risk assessment and communication tools;
- Developing NASA Research Announcements (NRAs) and task selection procedures based on the BCPR; and
- Developing a Web-based tool for communicating critical risks and questions.

2.2 Bioastronautics Critical Path Roadmap Baseline Document

The Critical Path Control Panel (CPCP) officially established the baseline version of the Bioastronautics Critical Path Roadmap (BCPR) in 2000; a total of 55 risks and 250 Enabling Questions (EQs) were documented (BCPR Baseline Document Rev D, http://critcalpath.jsc.nasa.gov/). The designated discipline team leads (defined in the CPCP Charter found in Appendix F) submitted specific change requests based on new knowledge of risks and countermeasures, and these were reviewed and dispositioned by the CPCP. Corresponding updates to the baseline document and to the companion Website were implemented. Several subsequent NRA cycles reflected the priorities identified in the BCPR and helped to focus on those investigator-initiated tasks determined to be relevant and congruent with BCPR risk mitigation deliverables. Analyses of program gaps and strengths were undertaken to assist the decision-making process for selection and resource allocation. In 2002, NASA began an effort to prioritize research for the International Space Station (ISS). The Research Maximization and Prioritization Task Force (ReMAP) reviewed the BCPR approach and products, including a matrix for communicating risk priority (i.e., the 5X5 "Boston Matrix" representing a risk's likelihood and consequence by its placement in an stoplight chart), and utilized such items in their deliberations of the ISS research priorities for the Office of Biological and Physical Research (OBPR).

2.3 Bioastronautics Strategy

The Bioastronautics Strategy was developed and signed in January 2003 by the three collaborating Program Offices - the Office of the Chief Health and Medical Officer, the OBPR and the Office of Space Flight. The strategy established the goals and objectives for Bioastronautics based on the risk reduction framework of the BCPR. NASA's Strategic Plan was released in March 2003 and emphasized the role of Bioastronautics in understanding and controlling the human health risks as it set the goal of extending the boundaries and duration of human space flight. In October 2003, the OBPR Enterprise Strategy was published and the BCPR outcome-driven risk reduction and management framework served as the basis for several of the organizing questions found in the Enterprise Strategy. In addition, the NASA Space Flight Enterprise, published in November 2003, emphasized the collaborative nature between addressing its Crew Health and Safety Program priorities and OBPR's research strategy for effective and efficient risk mitigation solutions.

2.4 BCPR Refinement

The increased visibility of the BCPR, owing to NASA's various strategic planning activities highlighted the need to refocus, update, and refine the BCPR. Subsequently, Bioastronautics management directed the BCPR staff to implement a process that would update information, and in particular, align the BCPR with three BCPR Design Reference Missions (DRMs): a one-year ISS mission, a lunar outpost and a Mars exploration-type mission. Another significant factor driving the refinement activity was the decision to have the BCPR reviewed by an external committee.

2.5 Revision Process

This version of the BCPR is the result of a concentrated effort. It is important to note that it is the nature of the BCPR to continually evolve to accommodate new knowledge about the risks and their efficacious solutions.

The refinement activity included:

(1) Setting the parameters for the three design reference missions (BCPR DRMs);
(2) Initial review and development of guidance for discipline teams to use in the revision of risks and associated EQs;
(3) Greater emphasis on integration and consolidation, where appropriate;
(4) Development of RDS to consistently capture the risk-identifying information;
(5) Provision for a more systematic update of individual areas such as the Advanced Human Support Technology (AHST) and Autonomous Medical Care (AMC) risks;
(6) Greater participation of the stakeholders in the risk assessment process;
(7) Development of an improved methodology for risk assessment and prioritization; and
(8) Preparation of materials for management decision-making and external review purposes.

The guidance for discipline teams in revising the BCPR included instructions to streamline risks and EQs where possible, ensure consistency in the statements of risks and questions, develop new questions unique to the risk and representing measurable and answerable issues to eliminate questions that were already answered.

2.5.1 Bioastronautics Science Management Team

The Bioastronautics Science Management Team (BSMT), composed of individuals representing all Bioastronautics stakeholders - the Office of Space Flight, OBPR and the Office of Health and Medical Systems at NASA HQ and JSC SLSD, Space Medicine & Health Care Systems Office (JSC-SD), the Habitability and Environmental Factors Office (JSC-SF), the Human Adaptation and Countermeasures Office (JSC-SK) and the National Space Biomedical Research Institute (NSBRI) at JSC, was established to provide oversight to the BCPR revision process.

Table 2-1 shows the primary roles and responsibilities of those entities involved in BCPR revision. A steering committee of three individuals from the BSMT, known as the sub-BSMT, was also established to implement the revision process through direct interactions with the discipline teams. Results were documented and communicated to management. At the conclusion of the external review of the BCPR by a joint committee representing the Institute of Medicine, the National Academy of Sciences (NAS) and the National Academy of Engineering (NAE), the BCPR revision activities will be culminated.

Table 2-1 Roles and Responsibilities for BSMT Revision Activity

Function	Responsibility
Sub-BSMT Steering Committee	• Management of the process • Preparation of materials for revision of risks and EQs • Development of risk assessment and rating guidelines • Facilitation of workshops • Conference representation • Interfacing with discipline teams • Preparation of materials for external review • Communication with management regarding BCPR revision progress and results
BSMT	• Process Oversight • Setting/Control of BCPR DRMs • Review and analysis of risks and EQs • Development of risk assessment criteria • Assessment of risk rating • Participation at workshops and conferences
Discipline Teams	• Update risks and EQs relative to the BCPR DRMs • Assessment of risk likelihood and consequences • Completion of all information on risk data sheets • Participation in teleconferences, workshops and conferences

3.0 BCPR GOALS AND OBJECTIVES

The Bioastronautics Strategy identifies three goals: reduce and manage risk; increase risk reduction efficiency and return benefits to Earth. The OBPR Enterprise Strategy is to ensure human survival in space, and that humans retain function and remain healthy and safe during and after long-duration missions in and beyond low Earth orbit (LEO). The Space Flight Enterprise strategy for crew health and safety focuses on managing the adverse health and performance risks of the crew through collaboration with the OBPR. The goal of the BCPR is to enable, support and facilitate those ends.

The BCPR is a systematic approach to prevent, eliminate or reduce the known risks to crew health, safety and performance during and after long-duration human space flight. As a management tool, the BCPR is used to inform the decision-making process. Its objectives are to:

- Identify and assess risk for human space exploration.
- Prioritize research and technology, and communicate those priorities.
- Guide solicitation, selection and development of NASA research (ground and flight) and allocation of resources.
- Assess progress toward reduction and management of risks.
- Define acceptable levels of risk.

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4.0 KEY ELEMENTS OF THE BCPR

The key elements of the BPCR and their inter-relations are shown in the process flowchart in Figure 4-1, and are described in the following section.

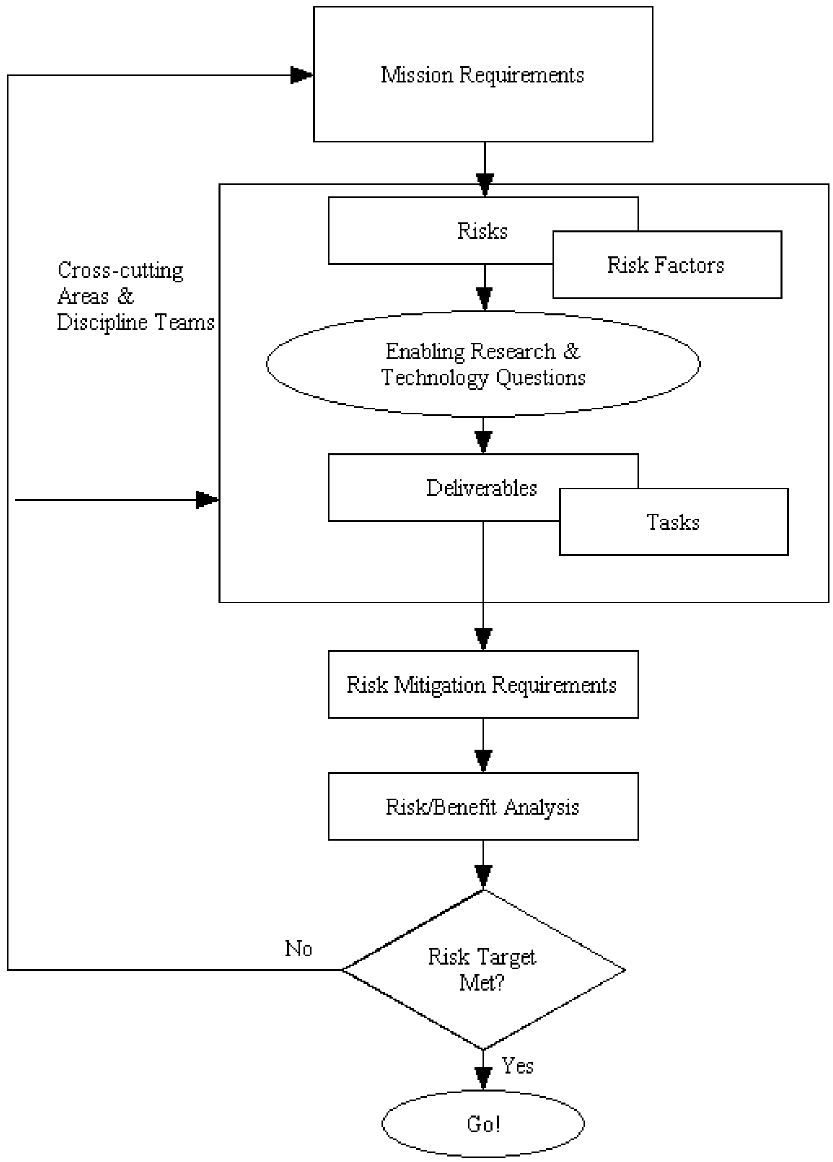

Figure 4-1 BCPR Flow Chart

4.1 Setting BCPR DRM Requirements

Mission requirements set the context for determining risks and their priorities and for establishing acceptable levels of risk. The process for developing mission requirements and the accompanying scenarios is iterated among several Program Offices, including the Office of Space Flight, the Office of the Chief Health and Medical Officer and OBPR. It is a responsibility of Bioastronautics to provide the Program Offices with timely information regarding mitigation requirements, thus ensuring adequate human capabilities and functioning. The most important top-level requirement for Bioastronautics is to execute the mission successfully and return the crew safely to Earth with no unacceptable long-term consequences. This version of the BCPR has been expanded to include three BCPR DRMs. These BCPR DRMs, as described in Table 4-1, are examples of missions illustrating the boundaries of extended mission duration and distance.

Table 4-1 Design Reference Missions (as of January 15, 2004)

Parameters	**DRM**		
	ISS (1-yr)	**Moon (30-d)**	**Mars (30-m)**
Crew Size	2+	4-6	6
Launch Date	2005?	NET 2015, NLT 2020	NET 2025-2030
Mission Duration	12 Months	10-44 Days	30 Months
Outbound Transit	2 Days	3-7 Days	4-6 Months
On-Site Duration	12 Months	4-30-days	18 Months
Return Transit	2 Days	3-7	4-6 Months
Communication lag time	0 +	1.3 Seconds+	3-20 Minutes+
G-Transition (Note 1)	2	4	4
Hypogravity	0-G	1/6-G for up to 30 days	1/3-G for up to 18 mos.
Internal Environment	-14.7 psi	TBD	TBD
EVA	0-4 per mission	2-3 week; 4-15/person	2-3/week; 180/person

4.2 Risk Identification

The discipline teams identified the important biomedical and human health and system performance/efficiency risks during and after space flight missions. For purposes of the BCPR, *a risk* was defined as the conditional probability of an adverse event from exposure to the space flight environment; a *risk factor* is a predisposing condition that contributes to an adverse outcome. Intervening at the level of the risk factor can change the outcome (i.e., the likelihood or severity of risk consequences).

Risks were derived from the deliberations of experts representing the various disciplines involved in Bioastronautics. Sixteen discipline teams are represented in the BCPR and are organized by five crosscutting areas essential for ensuring the health and safety of the crew: Human Health and Countermeasures (HH&C), Radiation Health, Behavior Health and Performance (BH&P), Advanced Human Support Technology (AHST) and Autonomous Medical Care (AMC). Table 4-2 illustrates the crosscutting areas and the associated disciplines and gives a brief description of each area.

Table 4-2 BCPR Discipline Teams and Crosscutting Areas

Discipline Teams	Crosscutting Areas
• Bone Loss • Muscle Alterations & Atrophy • Neurovestibular Adaptation • Cardiovascular Alterations • Immunology, Infection & Hematology • Environmental Effects	Human Health and Countermeasures (HH&C): *Focuses on understanding, characterizing, and counteracting the whole body's adaptation to microgravity, enabling healthy astronauts to accomplish mission objectives and return to normal life following a mission.*
• Radiation Health	Radiation Health: *Defines the research strategy, sets radiation shielding and monitoring requirements, thereby increasing allowable crew time in space, and reducing uncertainty for cancer and other radiation risks.*
• Psychosocial Adaptation • Sleep & Circadian Rhythm Problems • Neurobehavioral Problems – Cognitive Abilities	Behavioral Health and Performance (BH&P): *Focuses on maintaining the psychosocial and psycho-physiological functions of the crew throughout space flight missions and providing an optimal set of countermeasures.*
• Clinical capabilities	Autonomous Medical Care (AMC): *The capability to provide medical care during a mission with little or no real-time support from Earth. Crew medical officers or other crewmembers provide routine or emergency medical care using available resources. The local resources in an autonomous system augment and support the caregiver. Additionally, part of creating an autonomous medical care system includes preventing or reducing the likelihood of conditions before a mission starts, thus reducing the capabilities and consumables needed in the medical system.*
• Advanced Food Technology (AFT) • Advanced Life Support (ALS) • Advanced Environmental Monitoring & Control (AEMC) • Advanced Extravehicular Activity (AEVA) • Space Human Factors Engineering (SHFE) • Advanced Integration Matrix (AIM)	Advanced Human Support Technologies (AHST): *Focuses on developing efficient, reliable and autonomous technologies and systems to support human habitation in spacecraft and planetary dwellings. These technologies include: food and life support systems, environmental monitoring and control systems, EVA technologies, and human factors solutions through integrated testing in appropriate facilities*

4.2.1 Risk Data Sheets

A Risk Data Sheet (RDS) was developed to record all relevant BCPR risk identification information (see Appendix B) including risk title, description, risk factors, current and projected countermeasures with readiness levels, risk assessment for each BCPR DRM, justification, EQs and priorities and important references. Teleconferences were held between the sub-BSMT and discipline team leads to inform them of the revision activity and instruct them on the specific information to be prepared. Leads were asked to work with their team members in completing RDS forms. The RDS serve as the database for the BCPR.

4.3 Identification of EQs

A set of EQs was identified and prioritized by each discipline team on the basis of their relative importance for each reference mission (based on a "1-5," priority ranking of relative importance). The EQs encompass the key research and technology issues that must be sufficiently addressed to mitigate and retire the risk. Discipline teams originally identified these questions by reviewing previous reports from NASA advisory committees and results from NASA's Bioastronautics research program. The discipline teams updated the questions during the revision process, based on instructions from the BSMT to ensure consistent questions (i.e., that questions should be answerable, specific and measurable), streamlining questions to eliminate redundancies, developing new questions as appropriate and eliminating existing questions that may have been answered. Categories for the types of questions were developed for program assessment purposes and are specific to their crosscutting areas, although some overlap exists (see Table 4-3). Appendix E lists all of the EQs for each risk in the crosscutting areas with their associated priorities and categories.

Table 4-3 Enabling Questions Categories

Human Health and Countermeasures Behavioral Health & Performance Radiation Health	Risk Assessment & Acceptability
	Mechanisms and Processes
	Countermeasure Strategies
	Medical Diagnosis & Treatment
Autonomous Medical Care	Prevention (selection and countermeasures)
	Monitoring
	Diagnosis
	Treatment
	Informatics (crosscutting)
Advanced Human Support Technologies	Research Requirements/Specifications
	Design Tools
	Technologies
	Operations and Training

4.4 Defining Deliverables

BCPR deliverables are the end-items or products that have been identified as desirable outcomes or solutions to the EQs and have date-specific expectations associated with them. Deliverables include (but are not limited to) risk characterization and assessment; countermeasure protocols, strategies, or procedures for risk reduction; technology development, requirements specification and design; crew selection and training; and scientific knowledge.

Table 4-4 lists examples of the different types of deliverables. Appendix C shows the proposed schedules of deliverables for the five crosscutting areas at a top level.

Table 4-4 Examples of BCPR Deliverables

(1)	Risk characterization and assessment
	Monitoring (physiological, behavioral, environmental)
	Modeling
(2)	Scientific knowledge
	Mechanisms
	Processes
	Modeling
(3)	Requirements
	Pharmacological
	Nutritional/dietary
	Exercise regimes and fitness levels
	Stress reduction strategies
	Radiation dose limits
(4)	Medical capabilities
	Diagnosis and treatment
	Post-landing rehabilitation
(5)	Crew screening and selection criteria
	Physiological, genetic, psychological
	Individual and group
(6)	Crew training (pre-, in-, and post-flight)
	Expert systems
(7)	Design specifications
	Artificial gravity
	Habitation (lighting, noise, hygiene, food galley, etc.)
(8)	Design Tools
	Mission Design Tools Systems Design Tools
(9)	Mission operations
	Monitoring (physiological, behavioral, environmental) Human Operational Methods/Tools

4.5 Assessing Readiness Levels

Readiness refers to the level of maturity of the countermeasure or technology being addressed by the task or project. Two methods are used to determine readiness, one for countermeasures and one for technology deliverables as shown in Table 4-4. The readiness levels are used for several purposes: to gauge risk mitigation status, assess progress used to evaluate current program tasks and rate risks.

Table 4-5 Countermeasures Readiness Level (CRL)/Technology Readiness Level (TRL)

<table>
<tr><th>TRL Definition</th><th>TRL/CRL Score</th><th>CRL Definition</th><th colspan="2">CRL category</th></tr>
<tr><td>Basic principles observed</td><td>1</td><td>Phenomenon observed and reported. Problem defined.</td><td rowspan="3">Basic research</td><td rowspan="2"></td></tr>
<tr><td>Technology concept and/or application formulated</td><td>2</td><td>Hypothesis formed, preliminary studies to define parameters. Demonstrate feasibility.</td></tr>
<tr><td>Analytical and experimental critical function/proof-of-concept</td><td>3</td><td>Validated hypothesis. Understanding of scientific processes underlying problem.</td><td rowspan="3">Research to prove feasibility</td></tr>
<tr><td>Component and/or breadboard validation in lab</td><td>4</td><td>Formulation of countermeasures concept based on understanding of phenomenon.</td><td rowspan="4">Countermeasure development</td></tr>
<tr><td>Component and/or breadboard in relevant environment</td><td>5</td><td>Proof of concept testing and initial demonstration of feasibility and efficacy.</td></tr>
<tr><td>System/subsystem model or prototype demonstration in relevant environment</td><td>6</td><td>Laboratory/clinical testing of potential countermeasure in subjects to demonstrate efficacy of concept.</td><td></td></tr>
<tr><td>Subsystem prototype in a space environment</td><td>7</td><td>Evaluation with human subjects in controlled laboratory simulating operational space flight environment.</td><td rowspan="2">Countermeasure demonstration</td></tr>
<tr><td>System completed and flight qualified through demonstration</td><td>8</td><td>Validation with human subjects in actual operational space flight to demonstrate efficacy and operational feasibility.</td><td></td></tr>
<tr><td>System flight proven through mission operations</td><td>9</td><td>Countermeasure fully flight-tested and ready for implementation.</td><td colspan="2">Countermeasure operations</td></tr>
</table>

4.6 Defining Risk Mitigation Requirements

A risk mitigation requirement is a requirement imposed on an operational system by a BCPR deliverable after its efficacy has been tested and validated in space flight or in some cases sufficiently demonstrated and proven on the ground. It is Bioastronautics' responsibility to provide this information in a timely manner to the collaborating Program Offices for crew health and safety policy decisions and iteration of mission requirements.

5.0 Risks and Enabling Questions

This section presents summary information for the enabling questions and descriptions of the risks. While an informal assessment indicates that progress has been made to answer some of the questions in the original BCPR, a complete formal analysis (which is beyond the scope of this document) remains to be done to determine what questions have been sufficiently or partially answered, and how that contributes to retiring or mitigating a risk. The three BCPR DRMs present a total of 50 risks with 444 EQs for ISS, 484 EQs for the moon and 486 EQs for Mars, as shown in Table 5-1.

Table 5-1 Number of Risks and EQs for Each Discipline and Crosscutting Area

Crosscutting Area	**Discipline**	**Total No. Risks**	**Total No. EQs**		
			ISS	**Lunar**	**Mars**
Advanced Human Support Technology (AHST)	Advanced Life Support (ALS)	5	30	58	58
	Advanced Environmental Monitoring & Control (AEMC)	5	25	25	25
	Space Human Factors Engineering (SHFE)	2	19	20	20
	Advanced Extravehicular Activity (AEVA)	1	4	14	14
	Advanced Food Technology (AFT)	1	12	16	16
	AHST	1	7	7	7
	Totals	*15*	*97*	*140*	*140*
Radiation Health	Radiation Health	5	39	39	39
	Totals	*5*	*39*	*39*	*39*
Behavioral Health & Performance (BH&P)	Behavior & Performance	3	20	20	20
	Space Human Factors (Cognitive)	1	13	15	15
	Totals	*4*	*33*	*35*	*35*
Autonomous Medical Care (AMC)	Clinical	8	75	72	72
	Totals	*8*	*75*	*72*	*72*
Human Health and Countermeasures (HH&C)	Bone	4	30	30	30
	Cardio	2	25	25	25
	Muscle	2	42	42	42
	Neuro	3	45	40	42
	Immunology, Infection & Hematology (IIH)	5	30	30	30
	Environmental Health	1	11	14	14
	Nutrition	1	12	12	12
	Totals	*18*	*200*	*198*	*200*
	Totals	*50*	*444*	*484*	*486*

The specific risks and their descriptions for each of the disciplines as shown in Tables 6-3 through 6-9 are organized by the five crosscutting areas.

Table 5-2 Crosscutting Area: Human Health and Countermeasures (HH&C)

Risk No.	Discipline	Risk Title	Risk Description *(Brief)*
1	Bone	Accelerated Bone Loss and Fracture Risk	Failure to recover bone lost during mission coupled with age-related bone loss can lead to osteoporotic fractures at a younger age. Important for long duration missions for crew health and for designing rehabilitation strategies.
2	Bone	Impaired Fracture Healing	Bone fractures incurred during and immediately after long duration space flight can be expected to require a prolonged period for healing, and the bone may be incompletely restored, owing to the changes in bone metabolism associated with space flight.
3	Bone	Injury to Joints and Intervertebral Structures	Fascia, tendon and ligament overuse or traumatic injury, joint dysfunction upon return to normal/partial gravity. Hypogravity changes to intervertebral discs may increase risk of rupture, with attendant back pain, possible neurological complications.
4	Bone	Renal Stone Formation	Urine calcium concentration is increased due to increased bone resorption during hypogravity and to decreased urine volume during periods of dehydration.
5	Cardio	Occurrence of Serious Cardiovascular Dysrhythmias	Cardiac dysrhythmias pose a potentially lethal risk during long-duration space flight. Cardiac dysrhythmias may also cause hypotension and syncope. Cause is unknown.
6	Cardio	Diminished Cardiac and Vascular Function	Short-duration space flight has been associated with a decrease in cardiac mass. Long-duration space flight may result in greater decrease in cardiac mass and additional alterations that may diminish cardiac function, aggravate underlying cardiovascular disease (e.g., arterial atherosclerosis) leading to myocardial infarction, stroke or heart rhythm disturbances that could be irreversible.
7	Env Health	Define Acceptable Limits for Trace Contaminants in Air and Water	Lack of information needed to set requirements for air and water quality. This includes inadequate information about: 1) sources of contaminants; 2) identification of potential contaminants; and 3) bases for setting acceptability limits for individual contaminants and combinations of contaminants.
8	IIH	Immunodeficiency / Infection	It is possible that space flight may suppress immune function, a newly designated form of secondary immunodeficiency disease. Secondary immunodeficiency causes an unusual number of infections, with greater severity and duration. Secondary immunodeficiency leads to reactivation of latent virus infections with organisms that lay dormant until immune resistance is lowered and virus replication begins.
9	IIH	Virus-Induced Lymphomas and Leukemia's	This risk occurs in humans who are immunosuppressed and develop latent virus reactivation. Since the astronauts all carry many latent viruses in their bodies because of universal exposure, it is possible that if their immune resistance is lowered to a critical level, they may be subject to B-cell lymphomas and T-cell leukemias.
10	IIH	Anemia, Blood Replacement & Marrow Failure	There is loss of plasma and red blood cells due to exposure to microgravity and a here is a decrease of RBCM of 15% in the first week in space (2 units of blood). This can lead to problems with spaceflight anemia, or hemorrhage.

11	IIH	Altered Host-Microbial Interactions	The balance between human host and microbes found on Earth may be altered in space because of responses associated with microgravity, stress, radiation, or other space flight factors
12	IIH	Allergies and Autoimmune Diseases	Genetic inheritance and environmental insults are the two factors that trigger development of allergic and autoimmune diseases. Failure of immunologic tolerance due to malfunction of regulatory immune mechanisms leads to immune-mediated diseases in life. Space flight conditions have been shown to upset immune regulation and produce immunologic disease in experimental systems.
13	Muscle	Skeletal Muscle Atrophy Resulting in Reduced Strength and Endurance	Given that deficits in sensory-motor regulation of muscle-force generation capacity and movement skill occur in space flight, this deficiency could result in an inability or reduced ability/fidelity in performing mission-directed physical activities (especially when the system becomes loaded), as well as cause a proneness for muscle/connective tissue (muscle fiber; fiber-tendon; tendon-bone interfaces) damage and soreness, further exacerbating intrinsic muscle performance capacity.
14	Muscle	Increased Susceptibility to Muscle Damage	Given that muscle fiber atrophy and corresponding contractile protein phenotype shifts occur in response to space flight, this deficiency could result in an inability or reduced ability/fidelity in performing mission-directed physical activities, as well as cause a proneness for muscle/connective tissue damage and soreness further exacerbating one's performance.
15	Neuro	Vertigo, Spatial Disorientation and Perceptual Illusions	When astronauts transition between gravitational environments, head movements and/or vehicle maneuvering can cause spatial disorientation, perceptual illusions and/or vertigo. Should any of these occur in flight deck crewmembers during critical entry or landing phases it could lead to loss of vehicle. In-flight spatial disorientation can cause operational difficulties during docking and remote manipulation of payloads that can (and has) caused dangerous collisions, while in-flight frame-of-reference illusions, direction vertigo, or navigation problems could cause reaching errors, spatial memory failures, difficulty locating emergency egress routes and/or fear of falling during EVA (height vertigo). While rotational artificial gravity (AG) has great potential as a bone, muscle, cardiovascular and vestibular countermeasure, head movements out of the plane of rotation will produce illusory spinning sensations about an axis orthogonal to the head motion, which may lead to spatial disorientation.
16	Neuro	Impaired Movement Coordination Following G-transitions	When astronauts adapt to 0-G transition to an Earth, Moon, or Martian gravitational environment, balance, locomotion and eye-head coordination are transiently disrupted. Some symptoms may be masked by sensory substitution, only to emerge unexpectedly in response to changing sensory affordance contexts. Muscle atrophy and orthostatic hypotension may also contribute to post-flight balance and locomotion impairment. Some long-duration crewmembers have been unable to egress the spacecraft unassisted in 1-G, so affected crew are at an increased risk of emergency at or soon after landing. There are large individual differences, but recovery of normal abilities requires several days to weeks. Recovery time increases as the 0-G exposure time increases. Lower extremity coordination is often the slowest to return.

			Post-flight rehabilitation currently employs only traditional methods and may not be optimal. Sensory-motor changes on long-duration flights increases the potential risk of post-landing falls and bone fractures and delays safe return to normal daily activities (running, driving and flying).
17	Neuro	Motion Sickness	Motion sickness symptoms frequently occur in crewmembers during and after G-transitions. Symptoms include nausea, stomach awareness, gastrointestinal stasis, anorexia, dehydration and less overt but operationally significant symptoms such as “space stupids,” irritability, profound fatigue (“sopite” syndrome) and changes in sleep-wake cycle. Motion sickness symptoms decrease crew work capacity, vigilance and motivation, impair short-term memory and increase the likelihood of cognitive error. Although only 10-20% of Shuttle crews vomit, 75% experience symptoms for the first 2-4 days in 0-G and many experience similar symptoms for hours to days after landing. Several crewmembers have remained symptomatic during flight for up to two weeks. Current anti-motion sickness drugs are only partially effective. Though they appear to reduce symptoms and delay onset, they have significant side effects that prevent regular prophylactic use. While rotational AG has great potential as a bone, muscle, cardiovascular and vestibular countermeasure, head movements out of the plane of rotation may lead to motion sickness. How provocative the AG stimulus is at levels between 0 and 1-G and how rapidly and completely humans can adapt is largely unknown and cannot be fully determined in ground laboratories. If motion sickness drives an EVA crewmember to vomit in the extant extravehicular mobility unit (EMU), a complete shutdown of the primary and secondary oxygen supplies could occur, leaving only a few minutes of residual oxygen in the suit, creating a serious emergency. Vomit on the faceplate could also block vision. Even if the crewmember survives, vomit is biologically active, so the EMU cannot be reused and must be returned to the ground for refurbishment..
18	Nutrition	Inadequate Nutritional Requirements	Without scientifically supported nutritional requirements, a food system cannot be developed to support astronaut health. Nutritional requirements for space include fluids, macronutrients, micronutrients and compounds or elements that may be essential and may include compounds that may be required to optimize health status such as lipids, energy distribution (e.g., % calories from carbohydrate), fiber, and non-nutritive factors such as various phytochemicals, etc. Requirements must take into account any changes in the sensory system that might influence taste and smell influence intake, and the role of countermeasure-induced alterations on nutrient requirements.

Table 5-3 Crosscutting Area: Autonomous Medical Care

Risk No.	Discipline	Risk Title	Risk Description *(Brief)*
19	Clinical	Monitoring & Prevention	Monitoring and Prevention (Health Tracking, Prophylaxis & Disease Prevention). The primary means to reduce the risk of life and/or mission-threatening medical conditions is to prevent those conditions from happening. The second most effective means to reduce such risk is to monitor for medical conditions so as to catch them at an early stage to treat.
20	Clinical	Major Illness & Trauma	Major Illness & Trauma (Diagnosis, Management, CPR, BCLS, ACLS, BTLS, ATLS, DCS, Toxic Exposure-Detection and Management, Surgical Management, Medical Waste Management). There is a risk of major illness that increases with length of mission. There is always a risk of trauma, which can vary according to activities (e.g. construction, vehicle driving, etc.) Lack of capability to treat these major illnesses and injuries poses a threat to life and mission.
21	Clinical	Pharmacology of Space Medicine Delivery	Pharmacology of Space Medication Delivery (Space flight Physiology Effects – Pharmacodynamics/Pharmocokinetics, Drug Stowage/Utilization/Replenishment, Drug Use Optimization), . If issues relating to pharmaceutical stowage, generation, effectiveness, and administration methods are not solved then we may be unable to treat some medical conditions during flight, resulting in a threat to both life and mission.
22	Clinical	Ambulatory Care	Ambulatory Care (Minor Illness-Diagnosis, Management; Minor Trauma – Management) The risk of not being able to diagnose and treat minor illnesses and minor trauma can lead to more significant conditions that may threaten limb, life and mission.
23	Clinical	Return to Gravity/Rehabilitation	Return to Gravity/Rehabilitation. Possibility of deconditioning during space flight to another gravitational body entails the need for rehabilitation once a crewmember returns to gravity. Otherwise the crewmember may not be able to function as needed.
24	Clinical	Insufficient Data/Information/Knowledge Management & Communication Capability	Insufficient Data/Information/Knowledge Management & Communication Capability. The risk of not being able to get the right data/information/knowledge to the right place at the right time.
25	Clinical	Skill Determination and Training	Skill determination and Training. Risk of not having crewmembers with the right medical skills and training to perform the medical procedures needed. Assumption: For Mars, there will be at least one physician, assisted by non-physician space medical care providers.
26	Clinical	Palliative, Mortem, and Post-Mortem Medical Activities	Palliative, Mortem and Post-Mortem Medical Activities. As the length of mission and distance from Earth increase, the likelihood that a crewmember will become so ill or injured that he/she cannot survive increases.

Table 5-4 Crosscutting Area: Behavioral Health and Performance (BH&P)

Risk No.	Discipline	Risk Title	Risk Description *(Brief)*
27	BH&P	Human Performance Failure Due to Poor Psychosocial Adaptation	Human performance failure due to problems associated with adapting to the space environment; poor interpersonal relationships and/or group dynamics; inadequate team cohesiveness; and poor pre-mission preparation.
28	BH&P	Human Performance Failure Due to Neurobehavioral Problems	Human performance failure during missions due to such conditions as depression, anxiety, trauma or other neuropsychiatric, cognitive problems
29	BH&P	Mismatch Between Crew Cognitive Capabilities and Task Demands	Human performance failure due to inadequate accommodation of human cognitive limitations and capabilities. If human cognitive performance capabilities are surpassed due to inadequate design of tools, interfaces, tasks or information support systems, mission failure or decreased effectiveness or efficiency may result. Identifying, locating, processing or evaluating information to make decisions and perform critical tasks in short time-frames in nominal and emergency situations, with limited crew size, relying on strictly local resources is extremely subject to human error.
30	BH&P	Human Performance Failure Due to Sleep Loss and Circadian Rhythm Problems	Human performance failure due to disruption of circadian phase, amplitude, period or entrainment and/or human performance failure due to acute or chronic degradation of sleep quality or quantity

Table 5-5 Crosscutting Area: Radiation Health

Risk No.	Discipline	Risk Title	Risk Description *(Brief)*
31	Rad	Carcinogenesis	Unacceptable levels of increased cancer morbidity or mortality risk in astronauts caused by occupational radiation exposure or the combined effects of radiation and other space flight factors. These risks would be expressed following the mission (late).
32	Rad	Acute and Late CNS Risks	Damage to the central nervous system (CNS) leading to unacceptable levels of risk for changes in motor function and behavior, or neurological disorders caused by occupational radiation exposure or the combined effects of radiation and other space flight factors. These risks can be manifested during an extended mission (acute), or following return to Earth (late).
33	Rad	Other Degenerative Tissue Risks	Unacceptable levels of morbidity or mortality risks for degenerative tissue diseases (non-cancer or non-CNS) such as cardiac, circulatory or digestive diseases or cataracts caused by occupational radiation exposure or the combined effects of radiation and other space flight factors.
34	Rad	Heredity, Fertility and Sterility Risks	Unacceptable levels of increased hereditary, fertility, or sterility risk caused by occupational radiation exposure or the combined effects of radiation and other space flight factors. These decrements can be following return to Earth (late), or in the progeny of astronauts (for hereditary risks).
35	Rad	Acute Radiation Syndromes	Any increased risk of clinically significant acute radiation syndromes caused by occupational radiation exposure or the combined effects of radiation and other space flight factors. These decrements can be manifested during an extended mission (acute), or following return to Earth (late)

Table 5-6 Crosscutting Area: Advanced Human Support Technology (AHST)

Risk No.	Discipline	Risk Title	Risk Description *(Brief)*
36	AEMC	Monitor Air Quality	Lack of timely information about the buildup of chemicals, pre-combustion reaction products, malfunction of life support equipment, or other events (e.g., accidental release from an experiment) can lead to delayed response by crew or by automated equipment resulting in a hazard to the crew.
37	AEMC	Monitor External Environment	Failure to detect hazards external to the habitat can lead to lack of remedial action and poses a hazard to the crew.
38	AEMC	Monitor Water Quality	Lack of timely information about the build-up of chemicals or microbial growth in the crew water supply, or elsewhere in the water reclamation system, can lead to a delayed response by the crew or the automated response equipment posing a hazard to the crew.
39	AEMC	Monitor Surfaces, Food and Soil	Lack of timely information, or failure to detect the presence of harmful chemicals or microbial growth on surfaces, food supplies or soil required for plant growth can pose a crew health hazard.
40	AEMC	Provide Integrated Autonomous Control of	Lack of stable, reliable, efficient process control for the life support system.

		Life Support Systems	
41	AEVA	Provide Space Suits and Portable Life Support Systems	Inability to provide a robust EVA system that provides the life support resources, mobility and ancillary support, including robotics interactions and airlock design, to perform defined mission EVA tasks.
42	AFT	Maintain Food Quantity and Quality	If the food system is inadequate for the mission, then crew nutritional requirements may not be met and crew health and performance will suffer. An inadequate food system is one that is unsafe provides food that fails to meet nutritional requirements or is unacceptable from a sensory standpoint.
43	ALS	Maintain Acceptable Atmosphere	Inability to control atmosphere concentration CO_2, O_2 and trace contaminants in habitable areas (excessive airborne chemical pollutants e.g., formaldehyde, ethylene glycol, freon from leaks, fires, etc.) including microbial contaminants (microbial degradation of biological wastes).
44	ALS	Maintain Thermal Balance in Habitable Areas	Inability to acquire, transport and reject waste heat from life support systems reliably and efficiently with minimum power, mass and volume. Capability is crucial to enabling extended human exploration of space.
45	ALS	Manage Waste	Inability to adequately process solid wastes reliably with minimum power, mass, volume and consumables can harm to crew health and safety. Inadequate waste management can also lead to contamination of planetary surfaces or significant increases in mission costs in terms of system mass, power, volume and consumables.
46	ALS	Provide and Maintain Bio-regenerative Life Support Systems	Inability (with minimal or no re-supply) to provide adequate fresh food products, assimilate carbon dioxide, produce oxygen and recycle solid and liquid wastes at the levels of performance required for a specified mission due to lack of bio-regenerative subsystems integrated with other physical and chemical life support systems.
47	ALS	Provide and Recover Potable Water	If there is an inability to provide and recover potable water from human-generated wastewaters, then a potable water shortage may exist. Lack of potable water is a risk to crew health.
48	AHST	Inadequate Mission Resources for the Human System	Lack of low mass, low power, low consumable, highly reliable, low maintenance solutions to human support systems can lead to excessive mission costs.
49	SHFE	Mismatch between Crew Physical Capabilities and Task Demands	Human performance failure due to habitats, work environments, workplaces, equipment, protective clothing, tools and tasks, not designed to accommodate human physical limitations, including changes in crew capabilities resulting from mission and task duration factors, leading to loss of mission, crew injury or illness or reduced effectiveness or efficiency in nominal or predictable emergency situations.
50	SHFE	Misassignment of Responsibilities within Multi-agent Systems	If multi-agent systems, including ground support, crewmembers and intelligent devices are designed and assigned functions and responsibilities without due regard to human capabilities and limitations, mission degradation or failure will result. Various combinations of agents are required to accomplish mission objectives.

6.0 RISK ASSESMENT AND RATING RESULTS (STOPLIGHT CHART)

This section describes the methods and results for rating the BCPR risks. It includes the definition of the criteria used to rate the two general types of risks: human health risks and system performance/efficiency risks. The ratings for the human health risks were derived from an analysis of the likelihood of its occurrence, the severity of its consequence should it occur, and the risk mitigation status (for details see Appendix A). Two stoplight charts (human health and system performance/efficiency) are presented showing the results of the ratings. These results are summarized and the conclusions are discussed.

6.1 Risk Assessment and Rating Process

A three-step process was developed to assess and rate the identified risks.

(1) Discipline experts provided the initial risk assessment information.
(2) The BSMT utilized that data as input for conducting the rating of relative risk priority using the red/yellow/green classification.
(3) The third step (to be conducted) is a workshop involving the BSMT, flight surgeons and astronauts. This workshop will develop a consensus rating of the 50 risks, using the red/yellow/green classifications.

6.2 Risk Rating Results

Each of the 50 risks is important and needs to be addressed for human health, safety and performance during and after space flight.

The BSMT adapted the traditional stoplight chart (see Table 6-1) as a communication and decision-making tool for guiding the research and technology program, but not for assessing flight readiness. The red/yellow/green categories used for the various ratings were applied consistently across all 50 risks for each of the three BCPR DRMs.

The results of this rating and the categories for designating the priority status of each risk are shown in Table 6-2 and 6-3.

Table 6-1 Red/Yellow/Green Risk Rating

Risk Rating	Human Health Risks	System Performance/Efficiency Risks
Red	Unacceptable risk of serious adverse health or performance consequences; there is no mitigation strategy that has been validated in space or demonstrated on Earth.	Considerable potential for improvement in mitigation efficiency in many areas; proposed missions may be infeasible without improvements.
Yellow	High risk of serious health or performance consequences; there is no mitigation strategy that has been validated in space.	Considerable potential for improvement in mitigation efficiency in a few areas.
Green	Health and performance consequences are known or suspected, but will not affect mission success due to effective mitigation strategies that have been validated in space.	Minimum or limited potential for improvement in mitigation efficiency

Table 6-2 Rating Bioastronautics Risks: Human Health

Rating	
R	Unacceptable risk of serious adverse health or performance consequences; there is no mitigation strategy that has been validated in space or demonstrated on Earth.
Y	High risk of serious health or performance consequences; there is no mitigation strategy that has been validated in space.
G	Health and performance consequences are known or suspected, but will not affect mission success due to effective mitigation strategies that have been validated in space.
HH&C	Human Health and Countermeasures
AMC	Autonomous Medical Care
RAD	Radiation Health
BH&P	Behavior Health and Performance

Risk Number	Theme	Discipline	Risk Title	ISS (1-yr)	Moon (30-d)	Mars (30-m)
1	HH&C	Bone	Accelerated Bone Loss and Fracture Risk	Y	G	Y
2	HH&C	Bone	Impaired Fracture Healing	G	G	R
3	HH&C	Bone	Injury to Joints and Intervertebral Structures	Y	Y	Y
4	HH&C	Bone	Renal Stone Formation	G	G	G
5	HH&C	Cardio	Occurrence of Serious Cardiovascular Dysrhythmias	Y	Y	Y
6	HH&C	Cardio	Diminished Cardiac and Vascular Function	Y	Y	Y
7	HH&C	Env Health	Define Acceptable Limits for Contaminants in Air and Water	G	Y	R
8	HH&C	IIH	Immunodeficiency / Infection	Y	Y	Y
9	HH&C	IIH	Virus-Induced Lymphomas and Leukemia's	Y	G	Y
10	HH&C	IIH	Anemia, Blood Replacement & Marrow Failure	G	Y	Y
11	HH&C	IIH	Altered Host-Microbial Interactions	G	G	Y
12	HH&C	IIH	Allergies and Autoimmune Diseases	G	G	Y
13	HH&C	Muscle	Skeletal Muscle Atrophy Resulting in Reduced Strength and Endurance	G	G	Y
14	HH&C	Muscle	Increased Susceptibility to Muscle Damage	G	G	Y
15	HH&C	Neuro	Vertigo, Spatial Disorientation and Perceptual Illusions	Y	Y	Y
16	HH&C	Neuro	Impaired Movement Coordination Following G-Transitions	Y	Y	Y
17	HH&C	Neuro	Motion Sickness	G	G	G
18	HH&C	Nutrition	Inadequate Nutritional Requirements	G	G	Y
20	AMC	Clin	Major Illness & Trauma	Y	R	R
21	AMC	Clin	Pharmacology of Space Medicine Delivery	Y	Y	R
22	AMC	Clin	Ambulatory Care	G	G	Y
23	AMC	Clin	Return to Gravity/Rehabilitation	G	Y	R
24	AMC	Clin	Insufficient Data/Information/Knowledge Management & Communication Capability	G	Y	R
25	AMC	Clin	Skill Determination and Training	G	Y	R
26	AMC	Clin	Palliative, Mortem, and Post-Mortem Medical Activities	Y	R	R
27	BH&P	HBP	Human Performance Failure Due to Poor Psychosocial Adaptation	R	Y	R
28	BH&P	HBP	Human Performance Failure Due to Neurobehavioral Problems	R	Y	R
29	BH&P	SHFE	Mismatch between Crew Cognitive Capabilities and Task Demands	Y	Y	R
30	BH&P	HBP	Human Performance Failure Due to Sleep Loss and Circadian Rhythm Problems	G	G	Y
31	RH	Rad	Carcinogenesis	Y	R	R
32	RH	Rad	Acute and Late CNS Risks	Y	Y	R
33	RH	Rad	Other Degenerative Tissue Risks	Y	Y	R
34	RH	Rad	Heredity, Fertility and Sterility Risks	G	G	Y
35	RH	Rad	Acute Radiation Syndromes	G	R	R

Table 6-3 Rating Bioastronautics Risks: System Performance/Efficiency

Rating	
R	Considerable potential for improvement in efficiency in many areas, or proposed missions may be infeasible without improvements.
Y	Considerable potential for improvement in efficiency in a few areas.
G	Minimum or limited potential for improvement in efficiency.

Risk Number	Theme	Discipline	Risk Title	ISS (1-yr)	Moon (30-d)	Mars (30-m)
36	AHST	AEMC	Monitor Air Quality	Y	R	R
37	AHST	AEMC	Monitor External Environment	Y	R	R
38	AHST	AEMC	Monitor Water Quality	Y	R	R
39	AHST	AEMC	Monitor Surfaces Food and Soil	Y	R	R
40	AHST	AEMC	Provide Integrated Autonomous Control of Life Support Systems	G	Y	R
41	AHST	AEVA	Provide Space Suits and Portable Life Support Systems	G	Y	R
42	AHST	AFT	Maintain Food Quantity and Quality	Y	G	R
43	AHST	ALS	Maintain Acceptable Atmosphere	G	Y	R
44	AHST	ALS	Maintain Thermal Balance in Habitable Areas	G	Y	R
45	AHST	ALS	Manage Waste	G	Y	R
46	AHST	ALS	Provide and Maintain Bioregenerative Life Support Systems	G	Y	R
47	AHST	ALS	Provide and Recover Potable Water	G	Y	R
48	AHST	AHST	Inadequate Mission Resources for the Human System	Y	R	R
49	AHST	SHFE	Mismatch between Crew Physical Capabilities and Task Demands	G	Y	R
50	AHST	SHFE	Mis-assignment of Responsibilities within Multi-agent Systems	Y	Y	R

6.3 Summary of Results

While NASA's investment in studying the physiological changes associated with space flight has pointed out the path to minimizing or preventing harmful effects, there is still little data demonstrating that proposed exercise and pharmacological countermeasures are safe and effective in space. It is imperative that putative countermeasures be validated in the operational environment of long duration space flight. Until this is accomplished, physiological risks cannot be retired.

In the area of BH&P, one of the most challenging issues for exploration missions is the ability to ensure the psychological health and well being of a crew throughout an entire 30-month mission to and from a distant planet such as Mars. Prolonged isolation, confinement and delayed communication are just some of the potential sources of stress that can be detrimental to crew dynamics, compatibility and individual performance. Plans to define both physical and cognitive performance requirements, as well as measures of crew compatibility and individual functioning, need to be undertaken in integrated ground-based facilities.

An important safety concern for long-term space travel is the health effect of space radiation. NASA uses ground-based research facilities to simulate the space radiation environment, and to analyze the biological effects at the molecular and cellular levels. These facilities are used to understand and mitigate the biological effects of space radiation on astronauts, to ensure proper calibration of radiation doses received by astronauts on the ISS, and to develop advanced material concepts for improved radiation shielding for future exploration missions.

Missions of greater duration and distance require human support technologies that are more autonomous, efficient and reliable. The major challenges are developing new technologies to support and protect life during space travel, utilizing resources at the destination point and developing technologies integrated across spacecraft systems, including humans. Such technologies must function under variable gravity conditions, guarantee crew health and safety and enable optimal performance throughout the mission.

6.4 Conclusions

The following conclusions were derived from the BCPR refinement activity:

- Given the short lead-times remaining for design, verification and delivery of experimental and countermeasure hardware, the physiological countermeasure development activities must now concentrate more on what is currently known than on what remains to be learned.
- The Bioastronautics research program must fully adopt and promulgate an outcome-oriented approach to fulfill its near-term commitments to the success of human space flight missions over the next few decades.

- It is imperative that a new paradigm be adopted for Bioastronautics that further integrates flight and ground activities and optimizes flight resources. Project methodology forces forward thinking, integrated planning and contingency planning.
- In order for these projects to succeed, appropriate sites for ground testing and integration must be available.
- An important element of risk management is the use of metrics to assess progress. Effective measures of success must be defined with a clear definition of the goal and be utilized by project teams and management to assess the progress made with regard to risk reduction and improved efficiency.
- Participation of the key stakeholders in the deliberation process is integral for risk reduction and management. Since the ultimate beneficiaries of Bioastronautics are the astronauts and the flight surgeons that support them, it is essential that they participate in the continued evolution of the BCPR, particularly in setting priorities.
- Integration at all levels of Bioastronautics: intramural and extramural biomedical researchers, technology developers, flight surgeons, astronauts and various levels of management at NASA HQ and the field centers, is essential for the success of Bioastronautics. Integration assures that critical elements are not ignored and that appropriate resources are applied to the most important areas of risk reduction.

7.0 MANAGING RISK

7.1 Participants

The management of the BCPR involves the individuals who develop it and those that provide oversight of its management and implementation. The content of the BCPR is developed through deliberative processes involving the discipline teams with their designated leads. The management of the BCPR spans the three collaborating program offices as specified in the Bioastronautics Strategy (January 2003). Program offices solicit and fund the research and technology development activities. The BSMT currently has oversight of the BCPR and the CPCP will be reconstituted and reengaged in 2004 to maintain the document and the companion website. The field centers contribute to the resolution of the EQs through the development of the BCPR deliverables.

7.2 Integration

The previous version of the BCPR was based on a discipline approach to risk identification and assessment and did not emphasize integration among the various research disciplines and organizational collaborating units involved in implementing the BCPR. In this version, considerably more attention has been placed on integration at all levels of Bioastronautics: intramural and extramural biomedical researchers, technology developers, flight surgeons and various levels of management at NASA HQ and the field centers. Since the ultimate beneficiaries of Bioastronautics are the astronauts and the flight surgeons that support them, it is essential that they participate in the development of the BCPR, providing a unique, operational perspective to the risks being addressed. All of these risks have potential for becoming the responsibility of the flight surgeons if the countermeasures do not work as planned, so their clinical insights are extremely important. This integration is essential for Bioastronautics to successfully ensure that critical elements are not ignored and appropriate resources are applied to the most important areas of risk reduction.

A significant step in management and institutional integration was the establishment of the BSMT. This group has provided a forum for the various interested parties to regularly discuss problems and approaches for resolution and to recast the BCPR to meet the Nation's space goals.

A major effort has been made to incorporate the technology-focused efforts in AFT, ALS, AEMC, SHFE and AEVA systems into this document. This required merging different cultures within NASA: approaches, methodologies and management systems. The significant results of this are a strengthening of the integrated BCPR approach and the multi-disciplinary science and engineering team, and the increased breadth and value of products that will be delivered by Bioastronautics to NASA human exploration programs.

In this current iteration, several risks in the previous version were combined into a more general statement; research teams are being encouraged to coordinate efforts and focus more on applications to reduce risk and less on understanding mechanisms.

7.3 Using a Project Approach

Effective management of Bioastronautics risks requires greater use of a project management approach. Project management imposes discipline on research activities and focuses on schedules and deliverables while maintaining quality and cost control. Formerly, in the flight program, insufficient emphasis was placed on development of high levels of readiness for countermeasures and other human support system technologies. This was appropriate for a science-driven open-ended program. With the current limitations of human space flight and emphasis on human exploration, it is imperative that a new paradigm be adopted for Bioastronautics that further integrates flight and ground activities and optimizes flight resources. The obvious approach is to move to an integrated project research and development model. Project management imposes discipline on research activities and helps focus on schedule, budget and products. Project management methodology forces forward thinking, integrated planning and contingency anticipation. Project teams can bring the stakeholders (physicians, scientists, engineers, managers and astronauts) together to assure that progress is being made and to deal with problems. The project teams can be composed of experts from NASA and/or outside the Agency. Project plans will be thoroughly reviewed to ensure that technical details, budget and management approach are appropriate.

To illustrate how project management methodology could be used, a schedule for each of the five crosscutting themes of Bioastronautics were developed, and these thematic schedules were used to make an integrated Bioastronautics schedule. The philosophy behind these schedules is that there is a progression from laboratory research and technology development to the use of terrestrial analogs to simulate the space flight environment, followed by flight demonstrations and operational validation. (See Appendix C).

This analysis showed that although some projects already exist in the Bioastronautics portfolio, no organized efforts exist in behavioral health and performance, pharmacology, exercise countermeasure development, advanced medical technology development and some elements of advanced life support systems. Project teams should be formed in these areas, project plans written and reviewed, resources allocated and then implement the projects.

For these projects to succeed, appropriate sites for ground testing and integration must be available. Such facilities will be necessary to demonstrate that all elements (hardware, software, humans, procedures and operations) coordinate successfully. This is an important issue. Before the ISS was assembled, NASA routinely used ground integration and testing in the development of various missions. In the last decade NASA has resorted to analytical modeling rather than physical demonstration. For Bioastronautics to succeed, facilities are needed for physical integration, including the human system for appropriate durations. AIM will be key to integrating various aspects of human support technologies and behavioral health and performance. This will permit mission simulations in which hardware and procedures can be demonstrated, thereby reducing the risk to flight operations by flying systems that have not been tested. The stringent limitations on flight opportunities in the foreseeable future make it critical to do as much as possible on the ground prior to space flight so that this scarce resource is effectively used.

7.4 Metrics

Another important element of risk management is the use of metrics to assess progress. Effective measures of success must start with a clear definition of the goal. In the technology areas, metrics such as mass, power, volume and self-sufficiency are already available and are being used in project planning and management. In the Radiation Health discipline, an increase of no more than 3% above the background lifetime incidence of fatal cancer was adopted as the target, along with the commitment to keeping the space radiation dose as low as reasonably achievable. Comparable specific targets (or operating bands) are currently not available in other biomedical disciplines. For example, determining how much loss of bone density or muscle strength is acceptable is very difficult. Nevertheless, measurable targets need to be developed by the space medicine community and after appropriate review, used as metrics to assess the effectiveness of space flight countermeasures.

8.0 Forward Work

The current BCPR refinement activity was undertaken in response to the recent strategic planning activities at NASA Headquarters and the announcement of the new NASA vision for space exploration in January 2004. This version of the BCPR incorporates an expanded set of missions, streamlines the content, eliminates redundancies and includes greater representation of AHST and AMC. Additional risks were identified in the human support and medical care areas and HH&C risks were consolidated. In addition, considerably more questions were delineated for addressing and resolving risks. For each of the BCPR DRMs, a total of 50 risks and their EQs were identified and prioritized.

At this time open items include the following:

- Completion of the risk ratings by holding a consensus workshop involving key stakeholders (Bioastronautics management, flight surgeons and astronauts).
- Greater delineation of the deliverables.
- Metrics development to assess progress made toward risk reduction and retirement.
- Reconfiguration of the CPCP.
- Assessment of each risk's level of evidence.
- Development of operating bands (acceptable levels of risk).
- An additional and important step, quantification and assessment of overall relative risk, is currently under development.

8.1 Benefit/Cost Analysis

The selection of effective countermeasures and efficient risk mitigation strategies is closely linked to the safe operating bands or acceptable levels of risk (refer to the Bioastronautics Strategy). Benefit/Cost analysis allows balancing of resources along with potential improvements in risk reduction or mitigation efficiencies.