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BIOMEDICAL MONITORING AND COUNTERMEASURES FACILITY

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ABSTRACT

The Space Station Freedom Program (SSFP) represents the transition within the US Space program from the "heroic" era of space flight (characterized most vividly by the Mercury and Apollo programs) to an epoch characterized by routine access to the space environment. In this new era, the unique characteristics of the microgravity environment will enable new types of research activities, primarily in the life sciences, materials science, and biotechnology fields.

In addition to its role as a "microgravity science laboratory," Space Station Freedom (SSF) constitutes the operational platform on which the knowledge and skills needed to continue our exploration of space will be acquired. In the area of spacecraft operations, these skills include the ability to assemble, operate, and maintain large structures in space. In the area of crew operations, the potentially harmful effects of extended exposure to microgravity must be understood in order to keep the crew mission capable. To achieve this goal, the complex process of physiological deconditioning must be monitored, and countermeasures utilized as needed to keep the individual crew members within acceptable physiological limits.

The countermeasures program under development for the SSF Program is titled the Biomedical Monitoring and Countermeasures (BMAC) program. As implied by the name, this activity has two primary products, a biomedical monitoring element and a countermeasures development effort. The program is a critical path element in the overall SSF Program, and should be considered an essential element of operations on board the space station.

It is readily apparent that the capability to both protect and optimize the health and performance of the human operators onboard SSF will be a critical element in the overall success of the SSFP. Previous experience within the Russian space program has demonstrated that the time required for countermeasures on extended missions can become a monumental operational burden. Therefore, one of the primary objectives of the countermeasures development activity will be to design and implement countermeasures which are significantly more effective than the existing generation. Other primary objectives include the following:

- To set health and human performance standards for all mission phases.
- To determine critical issues that affect performance or return to flight status.
- To develop and implement monitoring systems to follow health and performance status.
- To understand risk, and balance the resource costs of countermeasures vs. the benefit gained.

Program Overview

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A Fact

EITHER SINGLY OR IN COMBINATION, THESE HUMAN RESPONSES ARE DIRECT LIMITATIONS TO MANNED SPACE FLIGHT MISSIONS

- Bone density is reduced
- Muscle strength and mass are reduced
- Neurological changes affect gait, stability, and cardiovascular function on return to a gravity environment
- Would healing appears to be impared
- Body fluid volume and blood volume, including both plasma volume and red blood cells, are reduced
- Orthostatic intolerance and exercise capacity loss is manifested on re-exposure to gravity
- Space motion sickness is experiened during the first week of space flight by about half of the crewmembers
- Cardiac arrhythmias have been seen during extravehicular activity and other mission phases
- Immunity is impaired after prolonged space flight
- Absorption of medications is impaired
- Hormone blood levels and function are altered
- Interpersonal conflicts, irritability and fatigue are increased on long duration space flight missions

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Mission Needs Statement

- NASA plans to continue to fly humans in space
- First, NASA must be sure in so doing that it does not subject humans to a level of risk that is not understood and acknowledged to be appropriate for NASA's overall mission
- Second, NASA must be sure in so doing that human participants are capable of providing the level of activity and performance required to assure mission success

NASA has a need to conduct a continuing program of biomedical monitoring and countermeasure development to assure that space flight involving humans does not contain unknown or unmitigated risks at a level that would harm participating crewmembers or cause mission success to be impacted

BMAC - Biomedical Monitoring and Countermeasures is that program

Background

- Space Medicine as a speciality is in the early stages of discipline development
  - We (including the Russian experience) do not understand the full extent of human risk associated with space flight or the means to mitigate that risk to acceptable levels (more details later in briefing)
- Increasing mission durations (and complexity) carry progressively higher risk levels
- CHeCS (Crew Health Care System) as a stand-alone capability was not intended to accomplish the goals and objectives of BMAC
- BMAC provides the essential medical data base in support of current and future programs (including SEI)
- If human space flight is to successfully extend beyond 16 days, this is a "must do" and not a "could do" program
  - We assume that there will be a continuous progression of the human presence in space

Specific Mission of BMAC

Assure the **health, well-being, and performance** of humans during space operations through a process of diligent monitoring of human adaptation and performance and application of countermeasures

- Health
  - Maintain crewmembers below a clinical horizon
  - Provide information to the clinical health care program so that clinical and long-term health issues are integrated
- Well-being
  - Assure optimal crew performance by maintaining a positive quality of life
  - Monitoring and countermeasures must be efficiently integrated into the operational environment
- Performance
  - Humans must be able to perform in space and on return to earth according to the requirements of each mission

BMAC Goals

- To understand and maintain crew health and performance on missions 16 days and longer
- To provide systems and procedures which minimize the time required to return to flight status

Agency Goals

- It is NASA's policy when humans travel in space
  - Medical risk is reduced to an acceptable minimum level
  - They are provided medical care and support to enable them to accomplish the goals of the mission
- Recent Presidential directives have provided a major challange to that policy
  - "establishing a permanent human presence in space"
  - This requires a level of effort and priority above that needed for current short duration flights (16 days or less)
- Advisory groups have been unaminous in their support for a vigorous human life science program
  - Robbins, Augustine, Stafford, AMAC

BMAC Program Review

BMAC Objectives

- To set health and human performance standards for all mission phases
- To determine critical issues that affect performance or return to flight status
- To develop and implement monitoring systems to follow health and performance status
- To develop, implement, and validate countermeasures that mitigate the negative biomedical consequences of mission 16 days and longer
- To understand risk, and balance the resource costs of countermeasures vs. the benefit gained

Typical Programmatic Questions Addressed by BMAC

- What are the optimal biomedical monitoring scenarios and schedules?
- Are there physiological, biochemical, or behavioral changes that limit mission duration?
- Do these changes limit the number of missions an individual can fly?
- How can crew productivity be optimized on flights of increasing duration & mission complexity?
- What countermeasures are needed? When?
- Is there an optimum mission length?
- How can the operational impacts from monitoring & countermasures application be minimized
- Are there crew selection criteria related to observed changes that need to be implemented?
- What major program/mission design considerations should be considered during early planning and development

Primary Deliverables

- Risk levels associated with un-mitigated human adaptation to and operation in the space flight environment
- Evaluation of the impact of these human risks on mission performance and success
- A set of operational countermeasures that reduce unacceptable human risks to acceptable levels
- Biomedical monitoring equipment, procedures, data analysis techniques, and selection criteria that provide individualized risk status during all mission phases
- Human-machine inerfaces and habitability requirements
- A set of recommendations for mission planning and operations that integrate the knowledge of individual human risk and the resultant impact on mission risk
  - With sufficient advance that the information can "enable" the design of future manned programs and missions

Level I Requirements/Program Discipline Areas

- BMAC shall be organized around 5 discipline areas
  - Neurosensory
  - Cardiovascular/Pulmonary
  - Musculoskeletal
  - Regulatory Physiolgy
  - Behavior and Performance
- Critical issues shall be defined within these categories
- Monitoring capabilities shall be defined within these categories
- Risk assessment studies shall be defined within these categories
- Countermeasures shall be defined within these categories

Level I Requirements/Investigative Approaches

- Detailed investigative approaches shall be developed which includes three main functions for understanding risk
  - Operational Biomedical Monitoring (during all feasible scheduled operational activities)
  - Functional Monitoring - standardized, periodic testing of all body system categories in order to detect and monitor adaptative trends
  - Risk Assessment Studies - test protocols designed to evaluate specific risk issues
- A robust process shall be established which integrates the information from these three activities and along with any clinical health information provides an overall health status assessment capability

Operational Monitoring

- Monitoring during all operational activities in which human responses provides essential information associated with risk assessment - specific monitoring depends on mission design
  - EVA
  - During utilization of verified countermeasures
  - Launch
  - Landing/recovery
- Basic physiological and performance measurements
  - Heart rate
  - EKG/EMG
  - Blood pressure
  - Respiration rate
  - Body temperature/skin temperature
  - Motion
  - Doppler blood flow
  - Performance parameters
- Specific monitoring tailored to operational activity
- Monitoring activities must not increase risk of accomplishing the operational activity

Functional Monitoring

- Periodic functional tests conducted on each crewmember through the application of standardized stress and other tests
  - Determine status of all body systems
- Determine the time course and magnitude of adaptation
  - Efficacy of applied countermeasures
  - Determine what changes in countermeasure procedures should be implemented
- Attempt will be made to develop an optimized test set which will not require major changes during the course of the BMAC program
- Baseline measurement set
- Provides the major input for a long-term standardized data base of human responses to space flight
- Monitoring Schedule
  - Weekly (2 hours per crewman)
  - Bi-weekly (3 hours per crewman)

Functional Monitoring - Cont'd

- Specific test protocol TBD but considerations include
  - Single level known workload aerobic exercise test
  - Focused muscle strength test
  - Single level LBNP test
  - Selected pulmonary function tests
  - Sleep monitoring
  - Selected blood and urine tests
  - Selected neurosensory tests
  - Selected anthropomentric tests
  - Selected behavioral and performance measurements
- Approach is to look at end-point parameters which indicate overall system status
- Contingency measurement/evaluation systems available to "follow-up" on any anomalous responses

Risk Assessment Studies

- A basic premise of BMAC is the ability to assess and understand human risk related to adaptation and operations in the space flight environment
  - These risks are not the same same as safety issues being addressed by SR&QA
- As noted previously, there is not currently a sufficiently complete data base to assign risk levels for the known issues (and new issues that may be uncovered)
- It will be necessary to implement specific test protocols or investigations designed to elucidate the necessary risk information
- AMAC Report used as a driving function for investigations
- Risk assessments are different from operational monitoring or functional testing
  - Specific investigative protocols with required number of subjects conducted over an identified number of flights
  - As required to identify specific risk parameters and/or levels
  - May or may not involve assessment of specific countermeasures
  - While exact manifesting of these studies is TBD, current experience has demonstrated a need of 1.5 hours/day/crewmember

Involving the Scientific Community

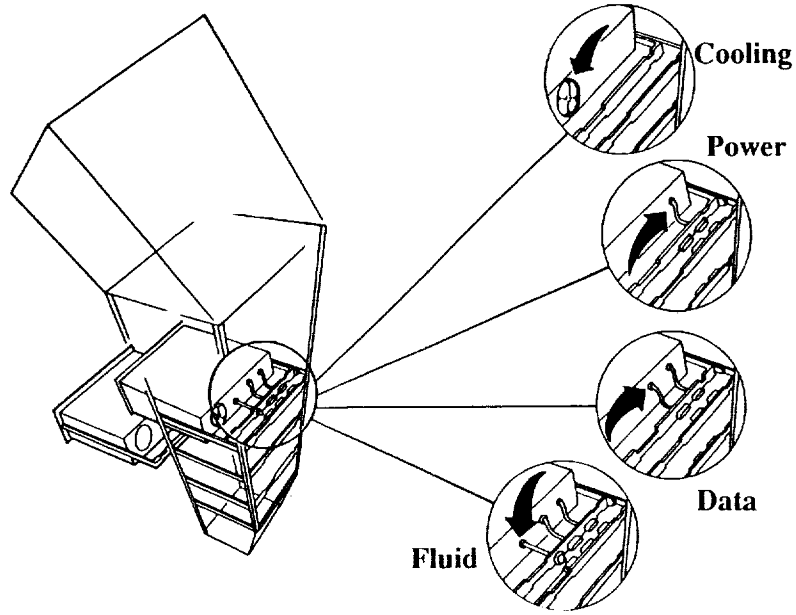
- One of NASA's charters is to provide access to space for conducting research
- The operational medical certification of humans and space flight systems is a NASA *responsbility* which cannot be "transferred"
- However, the breadth and challenges of BMAC will require that the expertise and knowledge of the life science community be utilized and included in the program
- BMAC will provide this colloboration within schedule and budgetary resources
- Two recommended approaches will be detailed later that address this issue
  - Resident Discipline Expert (RSE) Program
  - Focused NASA Research Announcements (NRAs)

Extramural Participation - Flight Opportunities

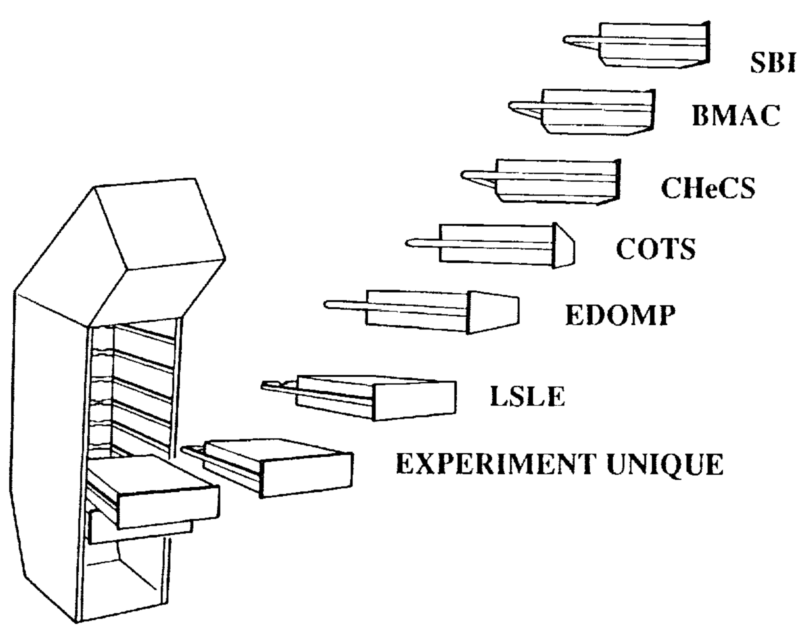
- BMAC traffic model based on 12/91 OSSA plan:
  - 1 double rack launched in 1997 (Phase 1)
  - 1 double rack launched in 1998 (Phase 1)
  - 2 double racks launched in 1999 (Phase 2)
- SSF traffic model provides 3 "utilization flights" (UF - assumed 13 day durations) in 1997, 3 UFs in 1998, and 2 UF in 1999
- Additional 12 "Mission Build" (MB -assumed 7 day duration) flights projected through the same timeframe

Standard Interface Rack - Concept

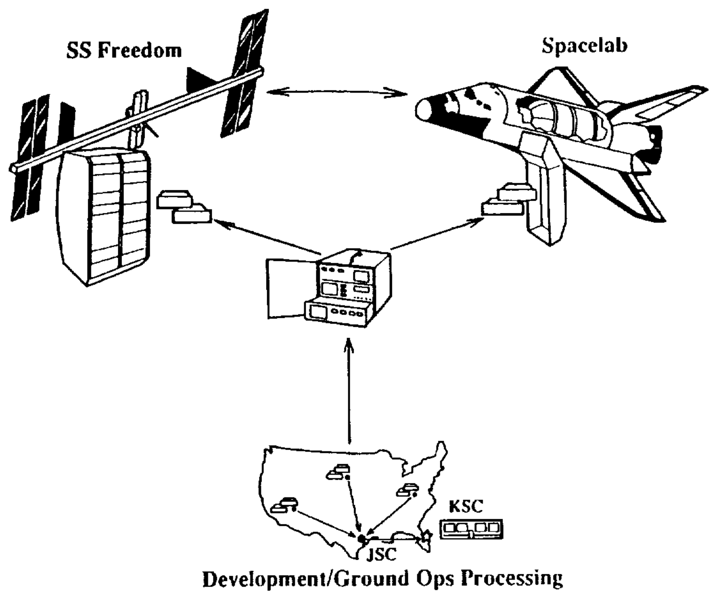
Hardware to Rack Standard Interfaces



Standard Interface Rack - Applications



Standard Interface Rack - Utilization



Deliverables - End-Items/Rack 1

Rack Mounted

Activity Monitor (has stowed component)
Automatic blood pressure system (ABPS)
Body temperature - core
Computer system, experiment control
Data recorder, 12 channel
Echocardiograph/doppler blood flow
Gastrointestinal pH capsule system
Physiological bio-potential recorder-12 lead
Pulmonary analysis system - mass spec
Pulse oximeter
Pulse pressure measurement device
Refrigerator/freezer
Specimen labelling device

Stowed

Ambulatory blood pressure monitor (ABPM)
Bar code reader
Biowaste ID tag generator
Blood centrifuge
Blood collection systems
CMI multi-test hypersensitivity system
pH sensitive strips in fluid handling tools
Fluid handling tools and system
Electrode impedance meter
Hematrocit centrifuge
Lower body negative pressure (LBNP)
Physiological monitor (Vitalog)
Stress and strain devices
Holter monitor
Temperature measurement kit
Urine sample device
Voice recorder

Other Location

Dynamometer, isometric-isokinetic
Ergometer, dual cycle
In-suit doppler bubble detector

Deliverables - End-Items/Rack 2

Rack Mounted

Auditory evaluation system
Biopotential Acquisition system
Breath hydrogen analyzer (microlyzer)
Carotid sinus baroreceptor stimulator
CO delivery/measurement system
Glovebox (GFE)

Stowed

Eye & head movement detection system
Gustatory & olfactory threshold tester
Physiological monitoring system (PMS)
Proprioceptive tester
Pulmonary analysis system - K2
Saliva collection unit
Spirometer
Three-D linear accelerometers (translation)
Video/data collection system

Deliverables - End-Items/Rack 3

Rack Mounted

Anthropometric measurement system
Body position detection system
Incentive field recording system S/W
Mass measurement - whole body
Microbial analyzer
Microscope system
Motion analysis system
Musculoskeletal overload trainer
Small mass measurement device
Visual sensory evaluation
Visual stimulator

Stowed

Macro-zoom lens
Middeck posture platform
Phantom head/torso
Sample prep device

Deliverables - End-Items/Rack 4

<u>Rack Mounted</u>

Cognitive performance tester
Electromagnetic stimulator
Rotating chair system
Virtual reality system

<u>Stowed</u>

Muscle bioopsy kit