MEDICAL HARDWARE FOR THE SPACE ENVIRONMENT:

AN ENGINEERING EXPERIENCE AT THE

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

A Record of Study

by

BARAQUIEL REYNA

Submitted to the Office of Graduate Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

DOCTOR OF ENGINEERING

August 2011

Major Subject: Engineering

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Approved by:

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ABSTRACT

Medical Hardware for the Space Environment: An Engineering Experience at the National Aeronautics and Space Administration. (August 2011)

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Chair of Advisory Committee: Dr. Charles Lessard

The complexity and amount of medical hardware needed by National Aeronautics and Space Administration (NASA) constantly shifts with mission requirements. Early missions such as Mercury, Gemini, and Apollo required minimal, relatively non-complex medical hardware, but as mission lengths have increased from hours to multiple months and mission crew sizes have increased from one to seven, so has the amount and complexity of medical hardware. As such, a need has arisen to develop a methodology by which medical hardware is certified for the space environment in a safe, consistent, and economically viable manner. This record of study documents my experiences certifying medical hardware for the space environment by providing two specific certification examples, a defibrillator, and automated external defibrillator and provides a brief history of the medical hardware used by NASA for its manned space programs.

DEDICATION

This record of study is dedicated to my parents, who made me do my homework every day after school; my wife, who is by my side every day; and my son, who inspires me to be the best that I can be.

ACKNOWLEDGEMENTS

I would like to thank my committee chair, Dr. Charles Lessard, and my committee members, Dr. Johnson-Throop, Dr. Hyman, Dr. Morgan, and Dr. Porter, for their guidance and patience while I completed my studies at Texas A&M.

I would also like to thank my parents, Roel and Rita Reyna, for their encouragement in all my scholastic endeavors and for always serving as role models throughout my life.

Very special thanks to my beautiful wife, Jessica. She is more than my heart and soul; she is my best friend, my partner and my soul mate in this life. Thanks for always being there for me.

NOMENCLATURE

AED	Automated External Defibrillator
ATP	Authorization to Proceed
BPMS	Blood Pressure Monitoring System
CHeCS	Crew Health Care System
CMS	Countermeasures System
COTS	Commercial Off the Shelf
CMRS	Crew Medical Restraint System
CDR	Critical Design Review
DEFIB	HMS Defibrillator
EB	Biomedical Systems Division
ECG	Electrocardiogram
EENT	Ears, Nose, Throat
EHS	Environmental Health System
EIS	End Item Specification
FOD	Foreign Object Debris
GCAR	Government Certification Request
HMS	Health Maintenance System
IAC	Initial Assessment of Criticality
ISS	International Space Station
IV	Intravenous

JSC	Johnson Space Center
MAK	Medical Accessory Kit
NASA	National Aeronautics and Space Administration
OBS	Operational Bioinstrumentation System
PDR	Preliminary Design Review
PDIM	Power/Data Interface Module
RSP	Respiratory Support System
SOMS	Shuttle Orbiter Medical System
SRR	System Requirements Review
SD	Space Medicine Division
SAR	System Acceptance Review
US	United States
USOS	United States On-Orbit Segment

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1. INTRODUCTION

1.1 Internship at the Johnson Space Center

When Alan Shepherd strapped himself into his Freedom 7 spacecraft in the early morning of May 5th, 1961, he carried with him not only the hopes and dreams of a nation, gripped by the fervor of the US/Soviet Space Race and the ushering Cold War, but also a newly developed bio-instrumentation belt made specifically for his upcoming mission to the stars. As his MR-3 Redstone rocket hugged the ground in eager anticipation to be unfettered from the bonds of Earth, mission controllers continuously monitored every aspect of the launch vehicle and spacecraft and, for the first time, the pilot himself. Shepherd's harrowing flight of fifteen minutes and twenty-eight seconds and 232 miles not only narrowed the US/Soviet space race gap, but ushered in a new era of medical hardware operating in the space environment [1].

This Record of study focuses on my experiences working at the Johnson Space Center (JSC), a field center of the National Aeronautics and Space Administration (NASA). At JSC, I worked within two organizations: the Biomedical Systems Division (EB) and the Space Medicine Division (SD). Within each division, I was responsible for certifying medical hardware for the space environment. The hardware varied from non-

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This record of study follows the style and format of *IEEE Transactions on Biomedical Engineering.*

complex hardware such bandages and gauze to more complex hardware such as defibrillators and respirators. This Record of study will outline how I achieved the three objectives outlined in my Final Internship Objective report:

1. Determine the design and certification process that NASA uses on all space flight hardware.

2. Develop project management, time management, and employee management techniques for efficient and timely project completion.

3. Determine how NASA balances the inherent risks of manned space flight with fiscal responsibility.

My principle responsibility during the internship was to oversee a contract workforce of about fifteen to twenty individuals and steward approximately three million dollars annually. The workforce and I were responsible for:

1. Procurement of medical hardware
2. Testing hardware to ensure proper operations
3. Configuration/Packaging of the hardware
4. Sustaining/Maintaining the hardware on-orbit when problems arise
5. Certifying new medical hardware as needed to support the International Space Station Program and the Space Shuttle Program.

My current supervisor at NASA JSC is Dr. Kathy Johnson-Throop, who is a member of my graduate committee.

2. BRIEF HISTORY OF MEDICAL HARDWARE AT NASA

NASA was officially formed with the National Aeronautics and Space Act of 1958. The ACT restructured the fledgling United States space program, which at that point was distributed across multiple federal agencies [1]. The formation of NASA brought all elements of the United States space program under control of one federal agency that could provide clear direction, structure, and organization. In the fall of 1958, NASA announced its first manned space flight program, Mercury.

2.1 Medical Hardware in the Mercury, Gemini and Apollo Program

The Mercury Program started in 1959 and ran through 1963. It had three principle objectives: 1) Orbit a manned spacecraft around the earth; 2) Investigate human beings' ability to function in space; and 3) Safely recover the astronaut and spacecraft. Over the course of two years and six launches of a one-man vehicle all mission objectives were satisfied [2]. Building on the success of the Mercury Program, the Gemini Program hoped to: 1) Send a two-man crew into space for a flight of up to two weeks; 2) Acquire information regarding the Van Allen radiation belts; 3) Demonstrate a controlled landing; 4) Demonstrate rendezvous and docking while in space; and 5) Broaden the agency's understanding of the effects of weightlessness and the medical and psychological impact that a long stay in space might have on astronauts and training. Ten launches from 1963 until 1965 satisfied all mission objectives [3].

Having shown incrementally via Mercury and Gemini the capabilities of the US space program, the Apollo Program wanted to fulfill President Kennedy's dream of landing men on the Moon and returning them to Earth before the end of the 1960's. The Apollo program between 1961 and 1975 consisted of twenty-two unmanned launches intended to qualify the launch vehicle and spacecraft, four manned flights to man-rate the vehicles for lunar exploration, one manned mission that was aborted, and six manned flights to the surface of the moon, most notably the Apollo 11 landing on the moon on July 20th, 1969 [4]. In addition to the moon landing, two other Apollo based missions occurred. The first, Skylab, used re-purposed Apollo Program elements to create the United States' first space station. Three, three-man missions departed for Skylab and each crew lived on the station for 28, 59, and 84 days, respectively [1]. The second Apollo based mission was the Apollo-Soyuz Test Project which demonstrated the first docking of international space elements, namely an American Apollo capsule and a Russian Soyuz space craft [1].

Medical equipment for Projects Mercury, Gemini and Apollo (including Apollo-Soyuz) were essentially iterations on the same design and consisted of a Medical Accessory Kit (MAK), a bio-instrumentation belt, thermometer, and a blood pressure monitoring system (BPMS) [5],[6],[7]. The MAK contained bandages, eye and nose drops, and a variety of injectable and tablet medications for emergency situations as seen in Figure 1. The outer structure of the MAK was a Teflon coated Beta cloth layup [6]. Teflon was used to reduce the likelihood of fire propagation. The medications and medical supplies were procured from local pharmacies and medical supply vendors, but

they were removed from their original packaging and uniquely repackaged to ensure compliance to NASA's rigorous flight certification requirements. The bio-instrumentation belt supplied chest movement, and heart action (ECG) and can be seen in Figures 1 and 2. The bio-instrumentation belt was completely design by NASA and complied with all NASA flight certification requirements. The belt consisted of body surface electrodes that picked up small biopotentials that were subsequently amplified by a series of analog amplifiers and circuits [5],[6],[7]. The unit was powered using vehicle/suit power. The thermometer supplied rectal temperatures for early Mercury missions, but was swapped in later missions for an oral thermometer. It consisted of a thermistor and a signal conditioner connected to vehicle/suit power [7]. The BPMS provided blood pressure when initiated by the astronaut. It consisted of an inflatable cuff and microphone to detect Korotkoff sounds [7].

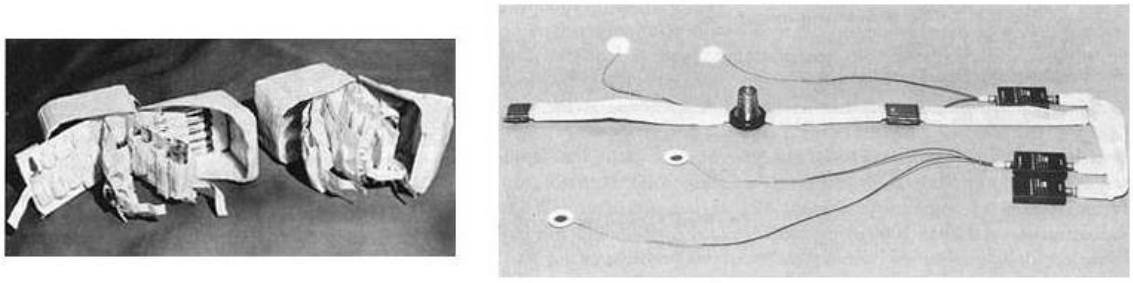

Figure 1. Apollo Medical Accessory Kit and Bioinstrumentation Belt. Source Credit. NASA Special Publication SP-368.

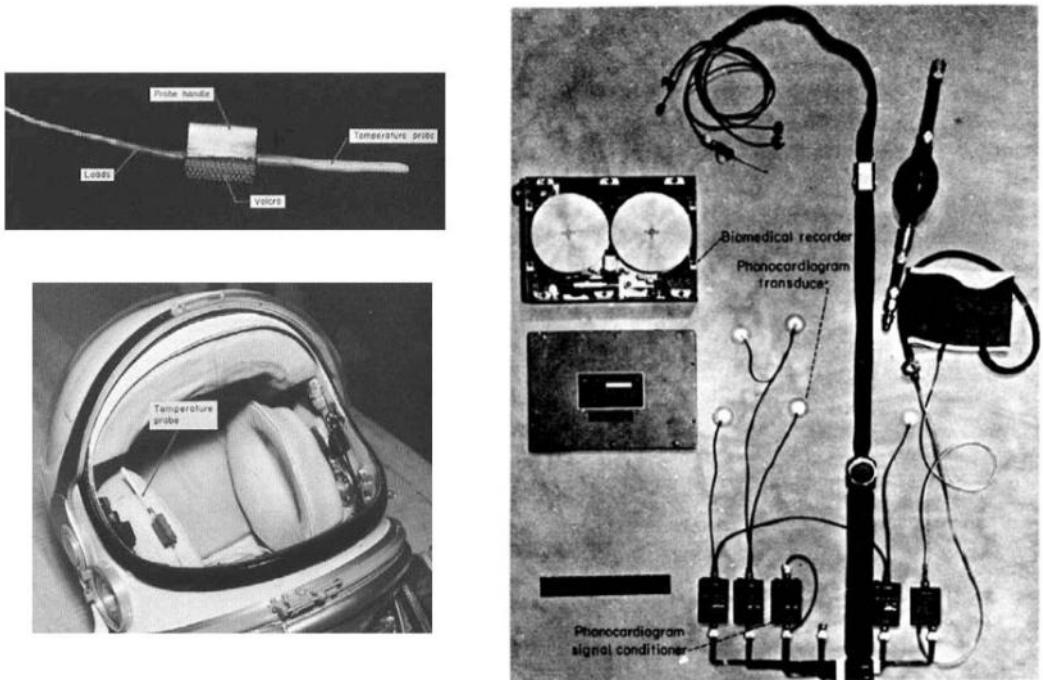

Figure 2. Additional Apollo Medical Hardware. Left, Thermometer Probes. Right, Biomedical Recording System. Source Credit. NASA Special Publications SP-368, SP-4003.

2.2 Medical Hardware in the Space Shuttle Program

The Space Shuttle Program consists of four primary elements: an orbiter spacecraft, two Solid Rocket Boosters, an external tank to house fuel and oxidizer and three Space Shuttle main engines. The shuttle transports cargo and crew into near Earth orbit (100 to 217 nautical miles above the Earth). Design for this re-usable spacecraft started in the early 1970's, but the first launch of a shuttle didn't occur until April 12th, 1981 [1]. Since then over 130 shuttle missions have been launched. The Shuttle

Program differed greatly from the Mercury, Gemini, and Apollo programs as can be seen in Figure 3. Not only was the architecture drastically different, but, more importantly for medical hardware, the crew size increased from a maximum of three to a maximum of seven.

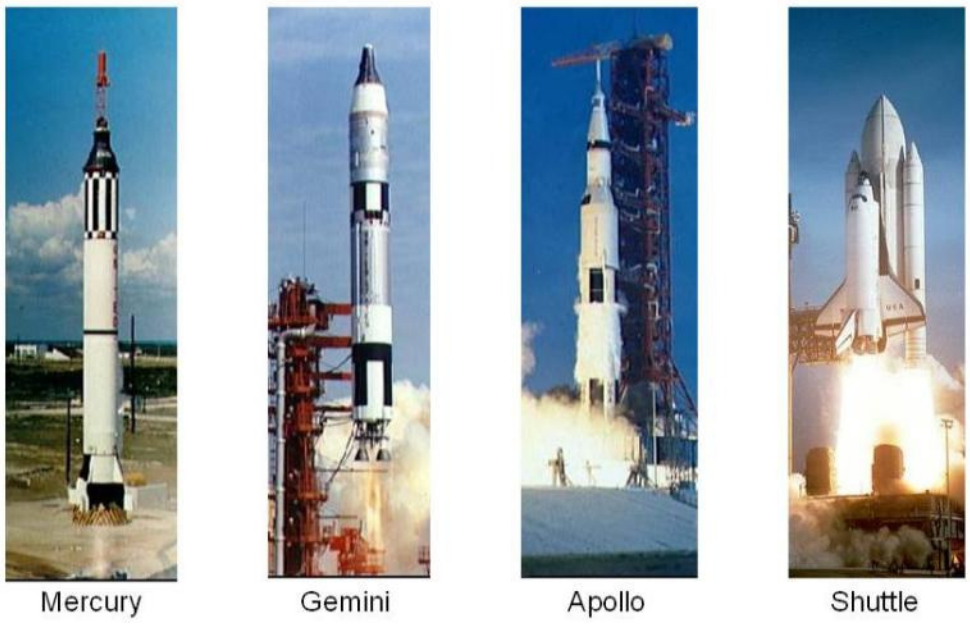

Figure 3. Different Architecture of Launch Vehicles. Source Credit. NASA Images S61-01927, S65-20742, S66-22930, STS51J(S)001.

Additionally, the standard mission length was approximately two weeks. To account for the greater mission length and crew size, the compliment of medical hardware grew. The medical hardware on the shuttle housed within the Shuttle Orbiter Medical System (SOMS). SOMS consists of eleven subpacks, each with a specific function. Figures 4, 5, and 6 shows some of SOMS hardware. The Airway Subpack

contains emergency airway management equipment to maintain an open airway. The Drug Subpack contains oral, topical and injectable medications to treat nominal and off-nominal medical conditions. The EENT Subpack contains general diagnostic and therapeutic items used to treat eyes, ears, nose, and throat (EENT) problems. The Intravenous (IV) Administration Subpack contains the equipment required to deliver IV medications and/or fluids to an ill or injured crewmember and is used in conjunction with the Saline Supply subpack, which contains four 500ml bags of saline. The Trauma Subpack contains items necessary for treating in-flight medical emergencies such as laceration closure and urinary catheterization. The Sharps subpack is provided for disposal of injectable medication cartridges, needles, and other sharp items. Patient and rescuer restraints are also provided and used to restrain an ill crewmember and the rescuer. The Operational Bioinstrumentation System (OBS) subpack provides the ability to downlink Electrocardiogram (ECG) signals for ground monitoring. The TONO-PEN subpack provides hardware to measure intraocular pressure in the eye. Finally, the Medical Accessory Kit (MAK) is provided to be a storage location for all crewmember personal medications, daily vitamins, and other commonly used, medically related crew items.

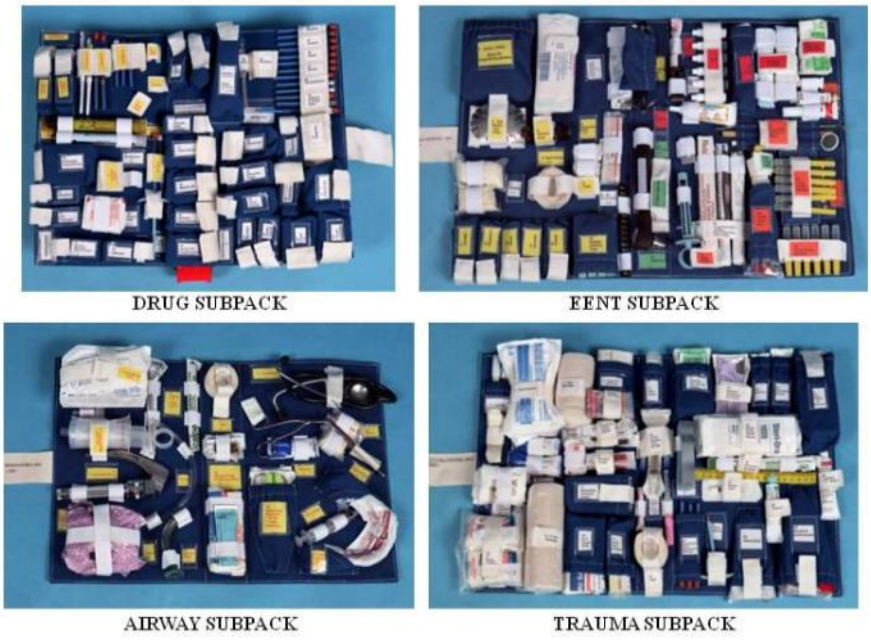

Figure 4. Examples of SOMS Subpacks.

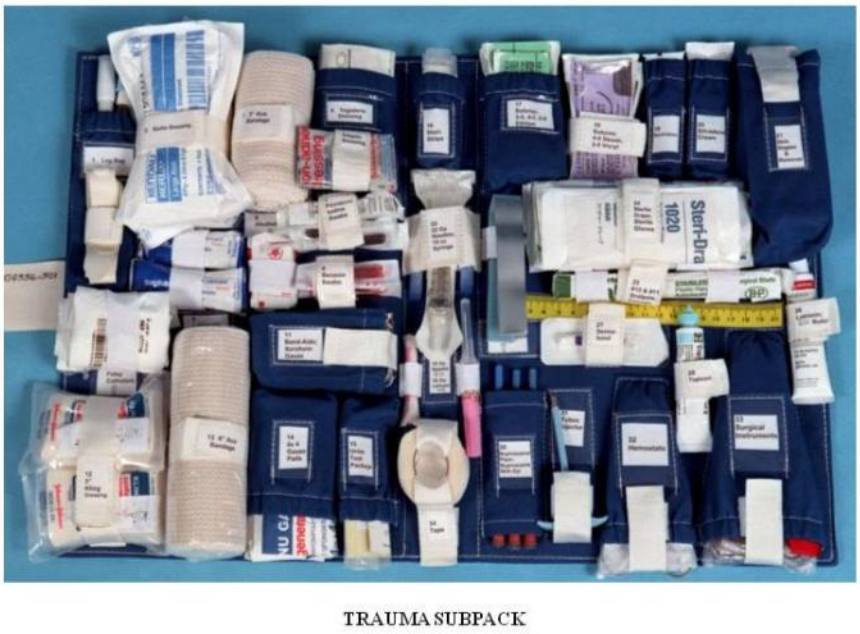

Figure 5. Close In View of Trauma Subpack.

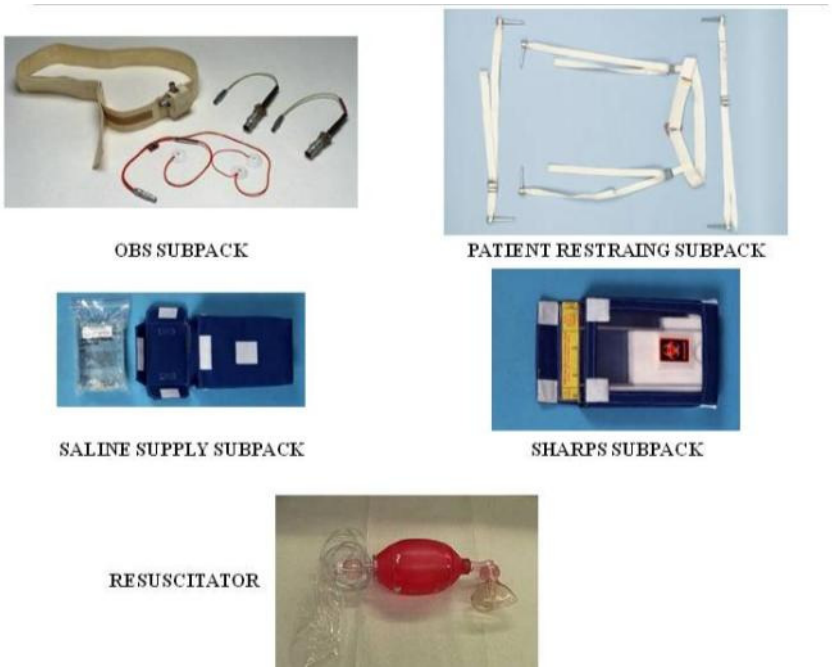

Figure 6. Additional Examples of SOMS Subpacks.

SOMS hardware represents an evolution in thinking at NASA. The fire retardant material used to package the medical kits was switched to Nomex and NASA began to use more and more commercial off the shelf (COTS) products. No longer was NASA designing and manufacturing medical hardware, but rather beginning to rely on a more robust commercial medical hardware market.

2.3 Medical Hardware in the International Space Station Program

The Space Station program began approximately twenty-six years ago in 1984. Originally named Freedom, the space station went through many design evolutions until 1993 when the station was redesigned and Russia was added as an international partner.

The first space station elements were launched in 1998, but full-time human habitation did not begin until November of 2000. Since then, the International Space Station has been continuously manned and operated.

The ISS represents a drastic departure from previous NASA missions. The average ISS mission length is 6 months with a crew size of six at any one time. The Crew Health Care System (CHeCS) is responsible for maintaining the health of the crew while on station. It is divided into three sub-systems 1) Environmental Health System, 2) Countermeasures System, and 3) Health Maintenance System. The Environmental Health System (EHS) monitors the environment of the ISS to ensure that it is compatible for human life. EHS hardware measures radiation level, air quality, water quality, and microbial growth. The Countermeasures System (CMS) provides a variety of exercise equipment such as a treadmill, cycle ergometer, and resistive exercise devices to combat the deleterious effects of microgravity on the human body. The Health Maintenance System (HMS) provides hardware to diagnose and treat an ill or injured crewmember. HMS hardware ranges from diagnostic hardware like a blood pressure monitor, thermometer and pulse oximeter to treatment hardware ranging from bandages, to ventilators and automated external defibrillators. The HMS is divided into the following hardware and can be seen in Figure 7 and Figure 8.

Automated External Defibrillator - The Automated External Defibrillator provides defibrillation capability and ECG monitoring for a crewmember that has experienced a cardiac event.

Crew Medical Restraint System – The Crew Medical Restraint System provides a platform to stabilize, transport, and support defibrillation for an injured crewmember while in microgravity.

HMS Medical Kits – The Convenience Medication Pack contains the non-contingency medications for afflictions deemed to be frequent and which require oral, injectable, or topical administration. The Oral Medication Pack contains the contingency medications for afflictions deemed to be infrequent and require oral administration. The Topical and Injectable Medication Pack contains the contingency medications for afflictions deemed to be infrequent and require injectable or topical administration. The Medical Supply Pack contains the items which will be used for medication administration (catheters, syringes, cotton swabs, etc.) and supplemental items which will be used in conjunction with hardware from other kits to aid in diagnosis or treatment (bandages, gauze, wipes, etc.). The Minor Treatment Pack contains the items which will be used to treat minor wounds (sutures, surgical tools, etc.) as well as the hardware for dental procedures (dental tools, dental mirror, etc.) and urinary retention (urinary catheters, hand-held mirror, etc). The Medical Diagnostic Pack contains the electronic items which will be used in the diagnosis of medical afflictions as well as to perform regular health status checkups (stethoscope, blood pressure device, ophthalmoscope, etc.). The IV Supply Pack contains the items which will be used for IV administration (IV fluids, catheters, tubing, etc). The Physician's Equipment Pack contains auxiliary items which may be used to supplement

medical diagnosis and treatment (otoscope, intubation hardware and tubing, etc.)

The Emergency Medical Treatment Pack contains the emergency medications and items which will be used to sustain life in the event of a life threatening incident.

ISS Medical Accessory Kit – The ISS Medical Accessory Kit provides additional storage for a crewmember's personal medical items.

Respiratory Support Pack – The Respiratory Support pack provides manual and automatic ventilation and low flow O2 to an injured crewman that needs invasive or non-invasive oxygen support.

HMS hardware represents a blend NASA designed medical hardware; vendor modified medical hardware, and pure COTS. It represents a continuing evolution in NASA's position regarding medical hardware towards one of greater and greater use of COTS.

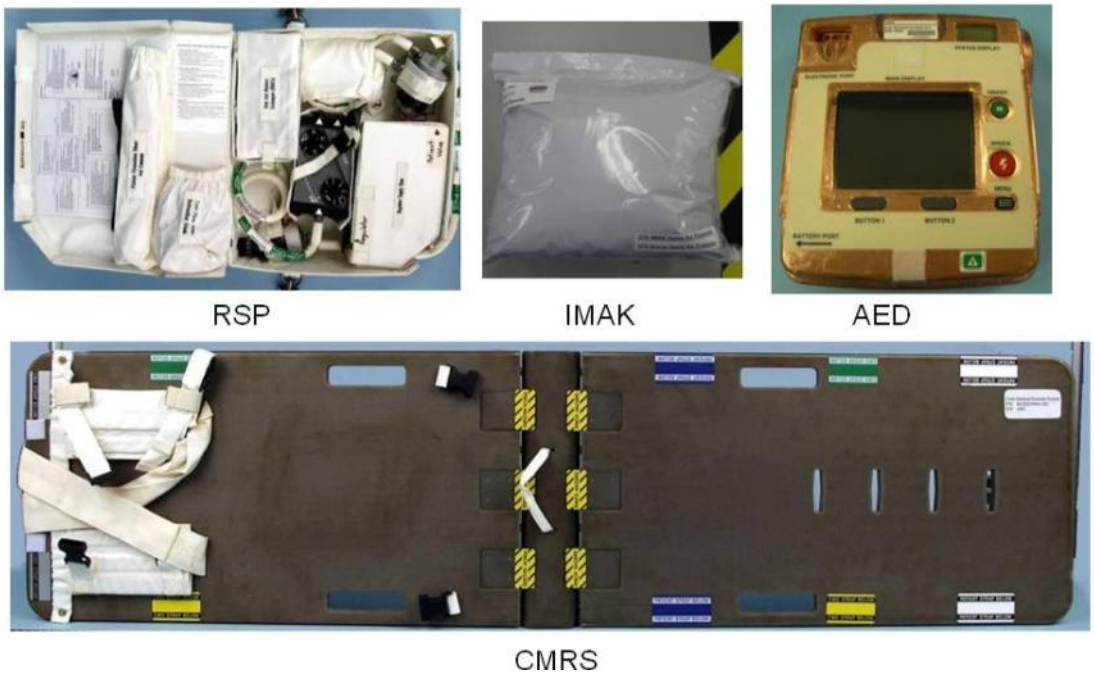

Figure 7. HMS Hardware.

Figure 8. Additional HMS Hardware.

3. NASA DESIGN AND CERTIFICATION PROCESS

NASA follows standard System Engineering practices when developing flight hardware. The process begins with a concept of operations. The concept of operations outlines how the hardware will be operated and is used to generate a functional decomposition for the system. The functional decomposition is a list of functions that the hardware is intended to perform. The functions are then converted into unique functional requirements, which are added to interface requirements to generate a requirements specification for the hardware. The hardware will then be designed based on those requirements. A qualification test article is produced based on the design and tested to ensure the design satisfies all requirements and provides the functions identified by the sponsor. Once the design has been tested, verified, and validated, the unit moves into system operation and maintenance. Each organization within NASA creates work instructions by which the System Engineering process is implemented. Typically, an organization employs a multi-phased design review process to govern projects under its control and allocates System Engineering products to life cycle phases as can be seen in Figure 9.

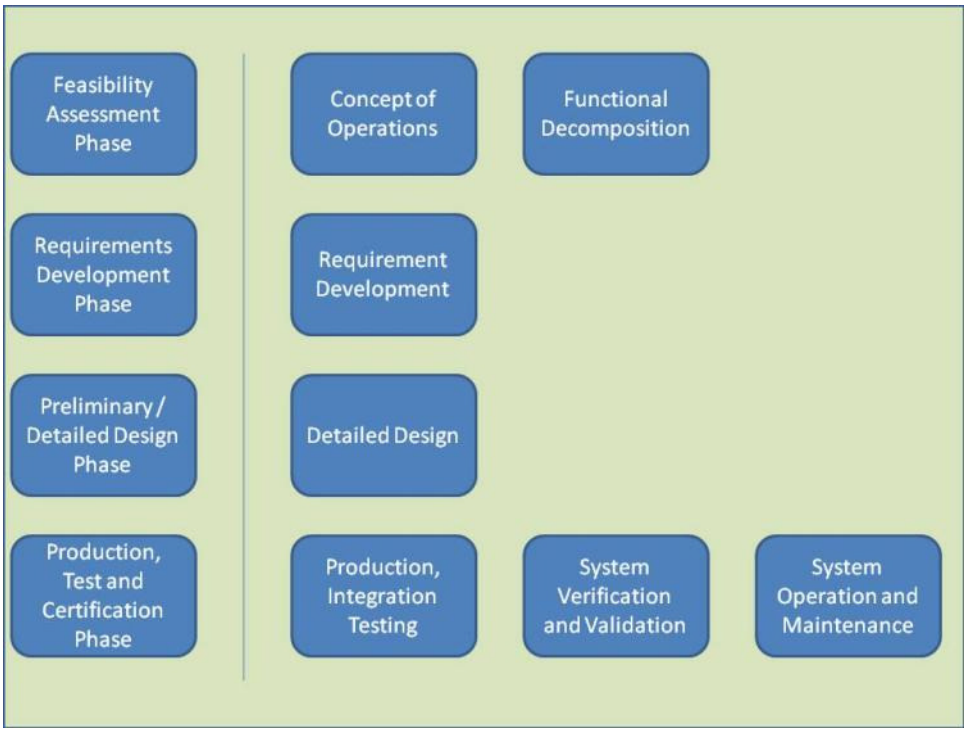

Figure 9. Allocation of System Engineering Phases to Life Cycle Phases.

Within the Space Medicine Division (SD), the governing work instruction is SA-WI-014, Project Management of Flight Hardware Developments. SA-WI-014 provides hardware developers the general framework for the project management of a hardware development project [8]. Figure 10 identifies the typical life cycle phases and control gates as called out within SA-WI-014. Control gates provide the formal mechanism by which development efforts are promoted to the next life cycle phase.

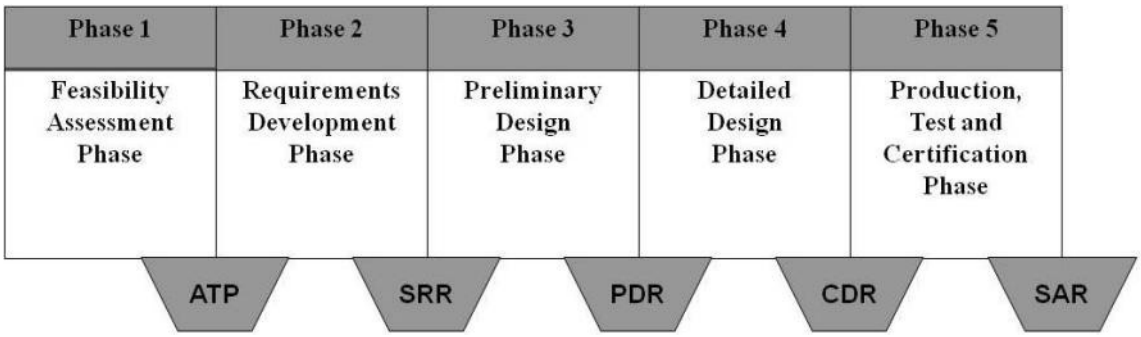

Figure 10. Life Cycle Phases within SA-WI-014.

3.1 Feasibility Assessment Life Cycle Phase

The Feasibility Assessment Life Cycle phase affords NASA the opportunity to ensure a project is structured for success. This phase creates an operational concept under which the hardware will be operated. Early efforts focus on documenting the expectations between the Customer/Sponsor of the effort and the Hardware Provider in terms of technical, resource, schedule, cost, and operational considerations. Later efforts focus on solidifying the methodology for development, the assignment of roles and responsibilities, the number and type of products to be delivered and the baseline of internal and contract agreements to allow for appropriate execution. This work is later documented within a feasibility assessment. The control gate of this phase is an Authorization to Proceed (ATP) given by the Customer/Sponsor to the Hardware Provider. Table 1 summarizes the products generated during this phase.

TABLE 1.
Feasibility Assessment Phase Products

Feasibility Phase Products	Purpose
Change Request	Documents request for hardware
Feasibility Assessment	Documents the assessment for successful project completion
Project Management Plan	Documents agreements by stakeholders on how the project will be managed
Technical Work Plan	Documents any significant technical assumptions for successful project completion
Operational Concept	Documents how the hardware will be operated

TABLE 2.
Requirement Phase Products

Requirement Phase Products	**Purpose**
Requirements Specification	Documents applicable requirements for the hardware
Interface Control Documents	Documents any interfaces between the hardware and an external element
Software Development Plan	Documents the plan for and software that needs to be developed
Configuration Management Plan	Documents the plan to manage the configuration of the hardware
Work Breakdown Structure	Documents the individual work elements that make up the project schedule
Project Schedule	Documents the order in which the WBS will be executed

TABLE 3
Preliminary Design Phase Products

Prelim Design Phase Products	**Purpose**
Preliminary End Item Specification	Documents any additional requirements that may need to be levied to the hardware
Preliminary Software Requirements Specification	Documents any additional requirements that may need to be levied to the software
Preliminary Software Design Document	Documents the manner in which software will be designed
Preliminary Verification and Validation Plan	Documents the verifications for all requirements
Preliminary Engineering Drawings	Documents the design of the hardware
Preliminary Safety Data Package	Documents the hazards and controls associated with the hardware
Preliminary Engineering Analyses	Documents any analyses (e.g. thermal, battery, stress, etc) associated with the hardware
Preliminary Test Plan	Documents the manner in which the hardware will be tested
Preliminary Training Plan and Materials	Documents the manner in which the hardware will be trained

3.2 Requirements Definition Life Cycle Phase

The Requirements Definition Life Cycle Phase provides for the definition, review and approval of developmental requirements. This process is iterative in nature and considers numerous design disciplines such as performance, interface, safety, quality, acoustics, human factors, reliability, and transportability. This life cycle phase will identify all necessary and sufficient requirements to ensure success and establish a baseline for the design effort. During this phase the Initial Assessment of Criticality (IAC) is created that formally establishes the criticality of the project. Criticality is determined by impacts to mission success and human injury if the hardware fails. Projects of higher criticality have more impacts to mission success and human injury and thus typically receive additional scrutiny. The control gate of this phase is System Requirements Review (SRR) that invites stakeholder to agree on a common set of requirements for the hardware. Table 2 documents the products that are typically generated during this phase.

3.3 Preliminary Design Life Cycle Phase

The Preliminary Design phase established the early design that will meet the requirements baselined in the Requirements Development phase. Preliminary design has been characterized at about ten-percent completion of engineering drawings and design documentation. During preliminary design, the safety data package is developed

that identifies all potential hazards and causes of hazards in the preliminary design. The safety data package is reviewed a Phase I safety review to consider alternatives that may reduce or eliminate the hazard and at the minimum control the hazard. The development team also identifies failure modes and conducts effects analyses. The control gate of this phase is the Preliminary Design Review (PDR) that invites stakeholders to agree on the fundamental direction the design. Table 3 documents the products typically generated during this phase.

3.4 Detailed Design Life Cycle Phase

The purpose of the Detailed Design phase is to iterate the design solution presented at PDR to a final or near final design. The design solution must be supported by engineering drawings, development test results, verification pathways and design analyses and typically represents at least 90 percent design complete. The safety review process continues with the Phase II Safety Review which considers the controls implemented in the design and the veracity of the verification approach. The development team updates failure modes and effects analyses. The control gate of this phase is the Critical Design Review (CDR) that invites stakeholders to agree on the final hardware design. Table 4 documents the products generated during this phase.

TABLE 4.

Detailed Design Life Cycle Phase

Detailed Design Phase Products	Purpose
Final End Item Specification	Documents any additional requirements that may need to be levied to the hardware
Final Software Requirements Specification	Documents any additional requirements that may need to be levied to the software
Final Software Design Document	Documents the manner in which software will be designed
Final Verification and Validation Plan	Documents the verifications for all requirements
Final Engineering Drawings	Documents the design of the hardware
Final Safety Data Package	Documents the hazards and controls associated with the hardware
Final Engineering Analyses	Documents any analyses (e.g. thermal, battery, stress, etc) associated with the hardware
Final Test Plan	Documents the manner in which the hardware will be tested
Final Training Plan and Procedures	Documents the manner in which the hardware will be trained

TABLE 5.
Production/Test/Certification Life Cycle Products

Production/Test/Cert Phase Products	Purpose
Certification Data Package	Collection of any documents used to certify the hardware
Verification and Validation Plan	Documents the verifications for all requirements
Version Description Document	Documents the version history of any software
Acceptance Data Package	Collection of any documents used to produce the hardware
Safety Data Package	Documents the hazards and controls associated with the hardware
Sustaining Engineering Plan	Documents any post-certification maintenance needed for the hardware

3.5 Production, Test and Certification Life Cycle Phase

The Production, Test and Certification phase completes the design and performs all actions needed to document the design presented during CDR. Once the design has been fully documented, qualification hardware is fabricated to the design and tested to ensure the hardware operates in accordance with customer expectations. When the qualification hardware has met all functional and interface requirements the project creates a Government Certification Approval Request (GCAR) that certifies that the hardware has meet all performance and interface requirements. Once the GCAR is complete, acceptance hardware is fabricated and tested in a manner similar to the qualification hardware. The hardware is prepared for shipment and then delivered to be integrated into the vehicle. The control gate of this phase is the System Acceptance Review (SAR) that invites stakeholders to agree that the hardware has met all performance and interface requirements and is ready to transition to full-time operations. Table 5 documents the products generated during this phase.

The conclusion of the SAR represents the end of the hardware design life cycle, but represents the beginning of the hardware being used for operations. After SAR, the hardware has a team of engineers that provides Sustaining Engineering in the event of any problems.

4. DEVELOP PROJECT MANAGEMENT SKILLSET

4.1 Defibrillator Project Management

The International Space Station (ISS) System Specification and the United States On-Orbit Segment (USOS) specification require preventative, diagnostic, and therapeutic medical equipment available on the ISS to monitor, treat, and maintain the health of the crew. Based on the terrestrial standard of care, the NASA medical community requires a defibrillator on the ISS to reduce or mitigate the effects of a cardiac event on Station. My first assignment as a NASA employee was to provide project engineering support for the HMS Defibrillator (Defib) repair project.
The HMS Defib, as shown in Figure 11, consisted of three principle parts:

1) A Modified Commerical Off the Shelf (mCOTS) Zoll PD1400 defibrillator that monitored the heart's electrical activity and rate, and treated abnormal heart rhythms via defibrillation and electrical pacing.

2) A government designed Power/Data Interface Module (PDIM) that provided power management for battery charging and operating voltage, and data management for command and data handling for health/status data and an ECG signal.

3) A variety of interface cables that linked the HMS Defib to the ISS and the HMS Defib to the patient.

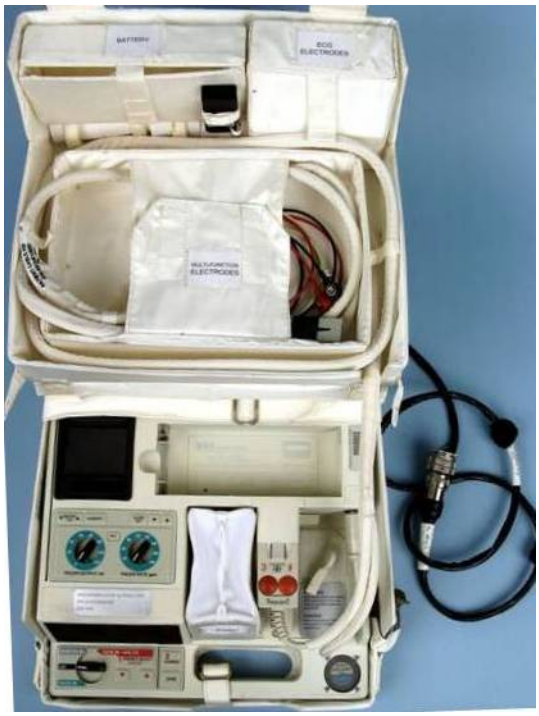

Figure 11. HMS Defibrillator.

The HMS Defib project was originally certified for flight in the late 1990's and launched to the ISS in 2001. Approximately two years later in February of 2003, ground controllers noticed that ECG data being downlinked from the Defib appeared very noisy and that current draws from the battery wandered significantly. This led ground controllers to believe that there was a problem with HMS Defib. A Tiger team, a team of specialists in a particular field brought together to work on a specific task, was formed to look into the anomalies and their investigation yielded a combination of firmware and hardware problems. In August of 2004, a team was formed to solve the firmware and hardware problems, but a contract change delayed the start of the project until June of 2005 which coincided with my start date at NASA. My management felt that my

background in Biomedical Engineering would be beneficial to the project so I was assigned as a project engineer. My initial responsibilities were to

1) Generate an End Item Specification that documents the capabilities of the entire system,

2) Develop a hardware test plan to ensure that the hardware is operating correctly, and

3) Develop a software test plan to ensure that the hardware is able to send and receive commands and data appropriately.

I was partnered with a contractor for each of these products. We were given approximately eight months to generate these products. At first glance, the task appeared quite daunting, but fortunately I did not have to start from scratch. I was able to begin with products generated during the initial flight certification from the late 1990's. Since I had no familiarity with the system, I decided to start the project by getting familiar with non-flight hardware in the lab. Unfortunately the lab had not yet been outfitted, so I spent the first two months at NASA obtaining soldering stations, ESD stations, power supplies, function generators, oscilloscopes, multimeters, and a variety of other standard lab equipment required to outfit an electronics lab. Once the lab had been outfitted, I started familiarizing myself with every operation of the Defib. I referenced vendor provided manuals, NASA provided certification documents and developed a working knowledge of the operations of the mCOTS defib and the PDIM. Armed with this information, my contractor team and I started to update the End Item Specification to match the capabilities of the system. This was my first lesson that real

live differs greatly from what is taught in books. In my engineering coursework, End Item Specifications were always created before the hardware had been manufactured and served as the "design-to" document, but in this situation, the End Item Specification (EIS) was being updated to match the current capabilities of the hardware, which had been updated over the course of the years in a very ad-hoc manner. In essence, the design had been implemented, but not fully documented. It took about two months to fully update the EIS. Upon completion of the EIS, functional test plans could be created to verify that all of the EIS requirements were successfully met. The creation of the hardware and software test plans took approximately two months. The documents were provided back to the project manager about a month before the original due date in December of 2005. These documents were part of the System Design Review that took place during January of 2006. A System Design Review (SDR) is a combination of a preliminary design review (PDR) and a critical design review (CDR) and is intended for projects where the design complexity is low to moderate. Since the HMS Defib repair project was simply repairing a variety of design components, it was decided that two separate reviews, a PDR and CDR, were not needed. The System Design Review was a meeting that lasted one entire day. The following was presented:

1) Requirements for the project
2) Design/Drawing changes
3) Test Plans
4) Safety Documentation

5) Design Analysis Reports for Stress, Thermal, EEE Parts, Materials, Toxicity, and Battery

The design review lasted approximately one month and the majority of my time was spent answering questions related to the products that I was responsible for generating. Upon completion of the SDR, the project was given authority to begin design modifications on flight hardware. The spring of 2006 was spent coordinating with technicians to ensure that the design changes were being implemented appropriately. In May of 2006, the HMS Defib repair project manager was assigned to another project and I was asked to assume the role of project manager. I felt extremely under prepared for this role, but the team (approximately 15 individuals) was very efficient and I had tremendous support at all levels. As a project manager, I began to receive cost information for the first time. The project, however, had essentially an open checkbook, since the principle driver for the project was not cost, but meeting an August 2006 shuttle launch date.

The design changes had been implemented in the flight hardware, but all of the hardware needed to be tested to ensure proper operation. The first item to be functionally tested was the PDIM using the test plan that I created. Minor changes needed to be made to the test plan to capture the post SDR design of the PDIM. The PDIM was then subjected to a random vibration workmanship screen to ensure that the hardware was fabricated correctly. Once the PDIM had been tested, it was mated with the mCOTS defib and the entire assembly was put through a variety of environmental tests that included power quality, electromagnetic emissions and susceptibility, thermal

cycling, and pressure cycling to ensure that the hardware will operate correctly in the ISS environment. Prior to each environmental test, a pre-test functional was performed to ensure that the hardware operated correctly going into the test and was followed by a post-test functional to ensure that the hardware operated after the environmental test. The final test was an integrated test that simulated the hardware was on the ISS and being commanded and controlled from Mission Control. The testing program lasted 3 months from May to July and was highly accelerated. A typical testing program of similar complexity and testing requirements would have required 9 to 12 months. My responsibility during the testing program was to coordinate with the testing facilities for test time and to ensure that the hardware arrived at the testing facility at the pre-coordinated time. The last part of the project was to finalize all of the documentation and get the appropriate signatures on all of the documents. I was surprised at how long this took. The documents had been reviewed multiple times by all the stakeholders, but the signature process still took at least a month. All of the stakeholders needed to be reminded of agreements that were made during the design process and walked through all of the requirements. The hardware passed all environmental and functional tests and the requirements and verifications were approved by all of the stakeholders. The hardware delivered to the Kennedy Space Center and launched into space on Atlantis, STS 115, on September 9th, 2006. It was functionally tested eight days later and passed all tests. The HMS Defib operated for two years on the ISS until August 2008 when it was replaced with an Automated External Defibrillator. In September 2008, the HMS Defib was placed into Jules Verne, the European Space Agency's Automated Transfer

Vehicle. Jules Verne undocked with the ISS later that same month and was directed on a trajectory that caused it to burn up harmlessly in the atmosphere over an uninhabited area of the Pacific Ocean.

4.2 Automated External Defibrillator Project Management

The HMS Defib satisfied all Medical Operations requirements, but the hardware itself was procured in 1995 and while still in good condition, would not last the life of the station program. In October of 2006, Medical Operations approached EB to perform a feasibility assessment of COTS Automated External Defibrillators (AEDs) for use with the Space Shuttle Program and the International Space Station Program. The goal was to select a COTS AED unit that would 1) satisfy both medical requirements and space flight certification requirements and 2) not require significant hardware modifications. I was given the responsibility to serve as the project manager for this project. The feasibility assessment conformed to the NASA design process to as large extent as possible, but the project did tailor the process to fit the design complexity of the hardware. As the project manager, I was responsible for developing and directing the team, developing milestones and incorporating them into a schedule, reporting progress, and identifying any financial/technical/schedule risk.

My first responsibility was to generate a list of significant milestones in which to attempt to scope the project. I divided the feasibility assessment into five different phases:

Phase 1: Coordinate with Space Life Sciences to baseline medical requirements/capabilities and combine with already known space flight certification requirements to generate a requirements document.

Phase 2: Review publicly available vendor data to determine compliance to requirements and begin the process of down selecting to one AED.

Phase 3: Contact vendors to request additional non-public information to determine compliance to requirements and further down select to one AED.

Phase 4: Perform supplemental hardware testing (Offgas, EMI/EMC, Ionizing Radiation, human factors) to down select to one AED.

Phase 5: Final AED recommendation and feasibility assessment debrief.

Now that the scope of the work had been defined at a very high level, I worked with my management to generate a new task order with the Bioastronautics Contract (BC) to allocate resources to the activity. The initial schedule allocated approximately 85K to the project over an eleven month period and three people were assigned to the activity on a half-time basis. I set up a weekly team meeting to go report progress and problems. During our first meetings, an operation concept was generated on how the hardware would be used in the space environment. The concept was returned to the customer (Medical Operations) for concurrence. Upon receiving operational concept concurrence, the team decomposed the operational concept into a list of functions. Each function was then used to generate a list of functional requirements. The functional requirements were scrubbed numerous times and returned to the customer for concurrence. Numerous rounds of iteration occurred until there was a final agreed upon set of functional

requirements. In addition to the development of functional requirements, I was focused on working with requirement owners to develop a subset of space flight certification requirements for COTS hardware. The majority of space flight certification requirements are design type requirements, but COTS hardware has already been designed, so certifying COTS for space is really just about making sure that the hardware is safe to be operated in space. In addition to minimizing the number of space flight certification requirements, I was also obtaining concurrence on using vendor provided data to verify those requirements. Up until this point, NASA did not rely heavily on vendor information, but rather chose to perform independent assessments to verify the authenticity of vendor claims. The team recognized that if vendor information could be used to satisfy space flight certification requirements then the cost of the project could be significantly reduced. Next, the team surveyed the market to determine the number of AEDs on the commercial market. Of the 19 AEDs on the market, all satisfied the functional requirements. Using publicly available product literature, the AEDs were rated by what extent they complied with existing NASA space flight certification requirements. For example, NASA requires a non-operational temperature range from -50c to 85C. No vendor met the requirement completely, but some vendors had larger ranges than others. Using public information, we were able to down select from 19 to 5 AEDs that most complete met NASA certification requirements. Next, we generated a vendor questionnaire and submitted it to all vendors requesting additional proprietary information and used it further discriminate between AEDs. Using this process, we were able to down select from 19 to 3 AEDs. We procured these AEDs and

began a variety of NASA specific tests including an Offgas test, electromagnetic emissions and susceptibility, radiation susceptibility, and human factors testing. From all of the product literature and hardware testing, one device was chosen to proceed to flight certification, the Medtronic LifePak 1000. The feasibility phase was completed in April of 2007.

In July of 2007, I drafted a Change Request (CR) to the ISS program to authorize the certification of the LifePak 1000 for the ISS. The CR was a significant departure from the standard NASA way of certifying hardware. Instead of listing pages and pages of requirements, the CR simply asked that a variety of NASA experts concur that the hardware is safe to be operated on the ISS. This approach was met with a variety of reactions. Most realized that the intent of the flight certification requirements were being met and did not have a technical argument about the methodology for flight certification, but certain organizations felt that the proposed process did not adequately trace requirements from the ISS operating requirements down to the AED. I then spent the next six months coordinating with stakeholders to generate a minimum set of requirements that would satisfy any requirement traceability concerns. Now that the requirements had been defined, the project was officially authorized to certify the LifePak 1000 for the ISS. The bulk of the certification work had been accomplished during the feasibility phase, so the principle work to certify the hardware was to generate safety documentation and to test a unit for flight. During this process, I oversaw a contractor team of about seven individuals. The team was responsible for producing the following documentation:

1. Test plans
2. Pre-delivery plans
3. Safety documentation
4. Verification documents

The hardware was delivered to the ISS on a Russian Progress vehicle in May of 2008 and was successfully operated for the first time in June of 2008. The hardware has been in operation on the ISS continually since the initial launch. Every 30 days the hardware is checked out to ensure that it is operating appropriately.

The experience gained during these two projects afforded me the opportunity to participate in the creation of a new work instruction, SA-WI-014, Project Management of Flight Hardware Developments. This work instruction, as mentioned in section 3, is the governing document by which the Space Life Sciences Directorate performs project management for hardware development activities. I was part of a small team of approximately 5 individuals chartered to review this work instruction. Previously, the directorate did not have a unified system for performing project management and relied on individual project managers. The intent of SA-WI-014 was to codify a common process for performing project management over the entire directorate. My portion of the document focused primarily on the tailoring of the process for COTS hardware. Other Project Management work instructions used by other directorates were very rigid and written for highly complex design projects. COTS hardware, because it is already designed, does not require as much rigor from a project management perspective, so we tailored the process to incorporate a section that discusses flight hardware developments

of low design complexity. This provides a useful template that encourages project managers to use a more streamlined approach when managing hardware developments. This process for managing COTS hardware was then used as a springboard to generate an entirely new process by which the International Space Station Program certifies COTS hardware. The new process, that I helped create, reduced the number of requirements for a COTS project by approximately 75 percent which significantly reduced the cost for certifying COTS hardware.

5. BALANCING RISK AND COST AT NASA

Putting humans in space is an expensive endeavor. Physiologically speaking, humans were not evolved to live life in space. There are a myriad of environmental hazards that make human presence in space a challenge including the high radiation environment that increases the risk for cancer and the microgravity environment that causes bone and muscle atrophy. In order to combat these challenges, humans must surround themselves with technology and this technology, unfortunately, is very expensive. As stewards of taxpayer dollars, NASA has the responsibility to ensure that money is spent in a cost-efficient manner. To that end, NASA has instituted a variety of processes to ensure that, to as large an extent as possible, rigor and effort is applied to the projects that would most benefit from additional rigor and effort. This is achieved by a careful balance of criticality and complexity. Table 6 documents the common criticality definitions used by NASA.

TABLE 6.
NASA Criticality Definitions

Criticality	Definition
1	Single failure that could result in loss of life or vehicle.
1R	Redundant hardware item(s), all of which if failed could cause loss of life or vehicle.
1S	A single failure in a safety or hazard monitoring system that could cause the system to fail to detect, combat, or operate when needed and could result in loss of life or vehicle.
2	Single failure that could result in loss of mission
2R	Redundant hardware item(s), all of which if failed, could cause loss of mission
3	All others

Hardware of criticality 1, 1R, 1S, 2, and 2R is called critical hardware while hardware of criticality 3 is called non-critical hardware. Complexity has numerous definitions within NASA, but essentially boils down to 1) complex hardware that has numerous interfaces and requires numerous sub-specialties for design and operation (e.g. life support system, propulsion system) and 2) non-complex hardware that typically has limited interfaces and requires few sub-specialties for design and operation (e.g. iPod, blood pressure monitor). As a general rule, NASA applies additional rigor and effort to projects of greater criticality and complexity, but both the complexity and criticality are reviewed to adjust the rigor applied to the project. A highly complex project with a high criticality, such as a propulsion system, would receive a tremendous amount of support and rigor from the various disciplines that are involved, but a non-complex project with high criticality, such as a cardiac medication, will not receive a tremendous amount of effort because the hardware is so simple. Similarly, a low criticality project with low complexity, such as a mechanical pencil, would receive little rigor, but a low criticality ultrasound machine that is highly complex would receive much more rigor and effort. The balance of complexity and criticality helps NASA ensure that funds are directed to the projects that would be most benefited by additional rigor and effort.

Another manner in which NASA attempts to balance the cost vs risk trade is through the use of Commercial Off the Shelf (COTS) hardware. When NASA purchases a COTS device, it completely bypasses the design and manufacturing process and thus does not incur the expense of designing and manufacturing a particular piece of hardware. The trade, however, is that COTS hardware rarely meets all of NASA's

stringent design and manufacturing requirements which can lead to hardware that is not as safe as NASA designed hardware nor as reliable. Thus, NASA chooses carefully when to use COTS and when to not use COTS. In some cases, it is impossible to use COTS. There are few space shuttle, space suit, or space station manufacturers, so the larger more complex and more critical hardware can only be produced by NASA engineers, but, in other cases, there are a variety of commercial vendors that produce a variety of devices that NASA uses on a daily basis to avoid the design and manufacturing costs. This hardware is typically small, ranging from the size of a laptop computer to an iPod, and does not have significant vehicle interfaces. For this type of hardware, NASA realizes that it should not invest millions and millions of dollars to invent a laptop when there are plenty of laptops available commercially. The cost to NASA, however, is that it may have to accept additional reliability risk and in some cases increased safety risk. For example, NASA recently certified a small portable blood pressure monitor that can be purchased from most medical supply wholesalers for about one hundred dollars. The device is hospital grade equipment, but it does not follow most of NASA's design guidelines for space flight hardware. It does not use radiation hardened processors to increase the likelihood of surviving a radiation event or have conformally coated circuit boards to decrease the likelihood of foreign object debris (FOD) causing and electrical short. As such, the hardware is not as reliable as a NASA designed blood pressure monitor, but if NASA were to design the hardware, it would literally spend a couple million dollars developing a piece of hardware than can be procured for one hundred dollars. The hardware still goes through the safety process

to ensure that it is safe and will not cause harm to the operator or the vehicle, but NASA is willing to accept the fact that the hardware may not work as advertised in space. A great example of NASA's increased use of COTS to decrease the cost of certifying hardware for the space environment is by comparing the HMS Defib which was certified in the late 1990's and repaired in 2006 to the HMS AED which was certified in 2008. I estimate the original certification cost for the HMS Defib to be on the order of two – three million dollars. The HMS Defib Repair Project cost an additional 1.2 million dollars, so over the life of the HMS Defib, over four million dollars was spent on designing, building, and testing the HMS Defib. Please keep in mind that the HMS Defib consisted of COTS defibrillator, so the costs could have been drastically higher if NASA would have designed a defibrillator from scratch. The HMS AED, however, cost NASA a total of about $700K for a savings of over three million dollars.

TABLE 7.
Summary of HMS Defib and HMS AED Projects

	HMS Defib	HMS AED
Length	1995 - 2000, 2005 - 2006	October 2006 - May 2008
Cost	$4,000,000	$700,000
NASA Design Complexity	High	Low
Vendor Design Complexity	High	High
NASA Risk Acceptance	Medium	Low
Training	High Training	Low Training
Capability	High	Low
Mass	High	Low
Volume	High	Low

How did NASA achieve such savings? NASA accepted decreased capability in exchange for eliminating design costs as summarized in Table 7.

The HMS Defib had significantly more capability (i.e.increased ability to deliver shocks at variable levels, ability for pacing, real-time ECG monitoring), but after a careful look at Medical Operation needs, it was determined that these capabilities are "nice to haves" and not true requirements, so Medical Operations was willing to accept a piece of hardware that met all of its requirements, but did not supply capability beyond those requirements. For the HMS Defib and HMS AED, NASA accepted decreased functional capability to achieve a great amount of cost savings. These two projects are a great example of NASA using COTS to carefully balance risk and cost to better steward taxpayer dollars.

6. CONCLUSION

I have had the pleasure of working at NASA for six years. As I reflect on that time, I realize that I have learned a tremendous amount about how NASA certifies medical hardware for the space environment and how NASA balances risk to better spend taxpayer dollars. I have been able put that knowledge into practice as both a project engineer and a project manager and certify literally hundreds of medical devices that are currently orbiting the earth on the International Space Station. As I certify more and more pieces of hardware, I am constantly striving to increase the quality of the products that are generated while decreasing the cost for those projects. In six years, I have been able to decrease the typical certification cost for a simple piece of hardware (e.g. blood pressure monitor, thermometer, pulse oximeter) from approximately $250K to approximately $30K. I have been able to realize these cost savings by satisfying my internship objectives of becoming intimately aware of the hardware certification process and becoming intimately aware of how NASA makes Cost/Risk trades and searching for ways to realize efficiencies in both processes. I strive to only perform those steps that add value to the process and not perform work simply because “it has always been done that way”.

It gives me a great sense of pride and accomplishment that my efforts, however small, are helping an organization that is literally on the cutting edge of technology and inspiring the nation to do great things. As I look to the future, I hope to remain an active part of NASA and to continue to contribute to this great organization.

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