NASA/TM-20205010009



Medical System Foundation for Level of Care IV Short-Duration Lunar Orbit: Context, Process, and Project History

Human Research Program Exploration Medical Capability Element

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December 2020

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Available from:

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ACRONYMS AND ABBREVIATIONS

AIAA	American Institute of Aeronautics and Astronautics
AMCL	Accepted Medical Condition List
СВ	Crew Office
СНР	Crew Health and Performance
ConOps	Concept of Operations
CST	Clinical and Science Team
DRM	Design Reference Mission
ExMC	Exploration Medical Capability
ExMCCB	Exploration Medical Capability Control Board
FY	Fiscal Year
HRP	Human Research Program
HRPCB	Human Research Program Control Board
HTML	Hypertext Markup Language
ICES	International Conference on Environmental Systems
IEEE	Institute of Electrical and Electronics Engineers
JSC	Johnson Space Center
KSA	Knowledge, Skills, and Ability
MBSE	Model-Based Systems Engineering
MEL	Master Equipment List
MIAMI	Model-Based Systems Engineering Infusion And Modernization Initiative
MOG	Medical Operations Group
OMB	Office of Management and Budget
SD	Human Health and Performance Directorate
SD3	Space and Medical Operations Division
SE	Systems Engineering
SMOCB	Space Medicine Operations Control Board
SysML	Systems Modeling Language

1.0 BACKGROUND

The Level of Care IV Short-Duration Lunar Orbit Medical System Foundation (hereon referred to as the "Foundation"), represents a medical system recommended for crew medical care on spaceflight missions in lunar orbit of durations up to 42 days and designated as Level of Care IV, as defined in NASA-STD-3001 Volume 1 [1] and Volume 2 [2] and as interpreted by Exploration Medical Capability (ExMC) within "Interpretation of NASA-STD-3001 Levels of Care for Exploration Medical System Development" [3].

This Foundation identifies medical conditions of interest, the concept of operations, and system requirements for a Level of Care IV lunar orbit spaceflight medical system. It provides a starting point for new medical system development efforts to understand potential medical system needs for a Level of Care IV system. The Foundation exists in a model-based systems format and utilizes rationale statements and traces to clinical or engineering sources or other parent requirements and standards to justify the need for each requirement and why the ExMC team thought these were credible requirements. It also shows how the requirements were developed so that future teams can repeat the process in a systematic way.

The use of this Foundation by system stakeholders, such as engineers, clinicians, and managers, facilitates communication regarding the needs of a medical system and provides content that can be tailored to specific missions.

The Fiscal Year (FY) 2020 (FY20) deliverable of the Foundation to the Human Research Program (HRP) Exploration Medical Capability (ExMC) Element consists of:

- 1) A Concept of Operations (ConOps) for a Level of Care IV Medical System for a short-duration lunar orbital mission (HRP 48012 Baseline) [4];
- An Accepted Medical Condition List (AMCL) that documents relevant medical conditions of interest for a Level of Care IV lunar orbital mission (AMCL Ratio Calculations_CisLunar v0) [5]; and
- A Hypertext Markup Language (HTML) Report of the system model that represents the Level of Care IV Medical System architecture and requirements, with rationale and traces to clinical capabilities and example medical resources (Medical System Foundation for Level of Care IV Short-Duration Lunar Orbit v1.0) [6].

1.1 Systems Engineering Principles

The ExMC Systems Engineering (SE) team, in conjunction with the ExMC Clinical and Science Team (CST), developed the Foundation by following the guidance of the following NASA documents:

- NPR 7123.1B- NASA Systems Engineering Processes and Requirements [7]
- SP-2016-6105 Rev2 NASA Systems Engineering Handbook [8]
- Expanded Guidance for NASA Systems Engineering Volume 1 and 2 [9,10]
- JPR 7120.3B Program/Project Management and Systems Engineering [11]

The SE team is composed of systems engineers from a variety of engineering and science backgrounds (i.e., systems, bio/biomedical, aerospace, mechanical, and human factors). The CST is composed of pharmacists, nurses, and physicians of various specialties (i.e., emergency medicine, internal medicine, family practice medicine, physical medicine and rehabilitation, and aerospace medicine) and provides clinical expertise and a spaceflight medicine knowledge base. The teams used systematic and repeatable processes to develop the more detailed components of the Foundation deliverable below:

- Medical system foundation model
- ConOps
- AMCL
- Clinical capabilities
- Medical system architecture
- Requirements
- Medical resources
- HTML report of modeled Foundation content

Each product is described in the subsections below and each went through a vetting process, as defined in this document and in the Appendix.

The SE team structured its efforts based on typical early design phase activities (pre-phase A) [7,8]. The SE team focused on generating an initial subset of medical system functional requirements ("System requirements" in Figure 1).



Figure 1. ExMC Systems Engineering Team Process for Exploration Medical System Early Development

Additional detail on the requirements development work is shown in Figure 2. More information on requirement development can be found in the SE team's 2019 Institute of Electrical and Electronics Engineers (IEEE) Aerospace Conference paper [12].



Figure 2. Medical System Requirements Development Process

1.2 Model-Based Systems Engineering

In addition to the typical systems engineering processes described above, the SE team also embraced a Model-Based Systems Engineering (MBSE) approach, which uses modeling software to visually represent a system. MBSE facilitates the development of engineering activities by having a single source of information for all project actions and decisions throughout the project life cycle. MBSE provides an alternative to the more traditional document-based approach to engineering. Diverging from the document-based approach has the potential to be more efficient through avoidance of maintaining disparate documentation that runs the risk of becoming obsolete or inconsistent with evolving project goals. MBSE also improves shared understanding of system needs with stakeholders [7, 8, 12, 13, 14]. As NASA continues to embrace MBSE, the NASA MBSE Strategy Group, a part of the community of practice called MBSE Infusion And Modernization Initiative (MIAMI), is providing a 20-year vision and strategic plan to enable the implementation of the "state of the art" in systems engineering, which will rely heavily on the MBSE discipline [15].

1.3 Medical System Foundation Model

MBSE tools include modeling software that uses a systems modeling language, SysML, to communicate the visual representation of the system. ExMC used the NoMagic's MagicDraw[™] 18.5 software for the Medical System Foundation Model that models many of the components of the Foundation and is housed on a NASA server for accessibility and security across the team. Although the ConOps and AMCL documents are partially modeled, the scenario activity diagrams from the ConOps and list of conditions from the AMCL are fully modeled. The fully modeled Foundation components include the clinical capabilities and the requirements. When developing a model, ExMC creates a variety of model

attributes to uniquely express the content of interest. The Medical System Foundation Model contains the following model attributes:

- Activity diagrams
- System architecture
- Functional decomposition
- Requirements
- Requirement rationale
- Requirements traceability
- Medical conditions
- Medical capabilities

- Medical resources
- Medical system interfaces
- Glossary
- Abbreviations
- Meta-model
- Traceability tables
- Matrices
- Lists with associated attributes
- HTML Report content diagram

2.0 MEDICAL SYSTEM FOUNDATION

2.1 Concept of Operations

The SE team initiated the Foundation development process by creating a ConOps [4] in which the team identified stakeholder needs, system goals, mission constraints, and the vision for medical care philosophy, which is based on NASA's health and performance standards, NASA-STD-3001, Vol 1 and 2 [1,2] and ExMC's "Interpretation of NASA-STD-3001 Levels of Care for Exploration Medical System Development" [3]. The SE team and CST then worked together to author a set of representative medical scenarios, which served as short narratives of anticipated medical activities for short-duration lunar orbit missions involving the crew, onboard equipment and tools, and ground personnel. The scenarios provided unique use cases that outlined areas of stakeholder concerns and highlighted potential needs the system must fulfill. Each scenario consisted of a context description (e.g., dental exam), a highlighted functionality list, assumptions, a narrative text, and an activity diagram (i.e., a flowchart built in the model to visually represent the scenario and to aid the engineers in identifying the medical system activities that may be required of the system). Each scenario was intended to demonstrate a unique set of functions and, collectively, the scenarios represented a wide range of possible medical capabilities and provided a high-level operational description of the system [13].

ExMC used the resulting ConOps document, "Recommendation for a Medical System Concept of Operations for Gateway Missions (HRP-48012)" [4], as the basis of this Level of Care IV Medical System Foundation. Even though this document has Gateway in the title, it is not an official Gateway Program medical system ConOps. This ConOps was written prior to the formation of the Gateway Program and was developed as a recommended starting point for missions designated as Level of Care IV, such as Gateway.

A subsequent draft ConOps for a crew health and performance (CHP) system was also developed. This document enhances some of the clinical concepts and system architecture that originated in the medical system ConOps [16]. This CHP ConOps defines the CHP system in relation to the vehicle system and identifies subsystems, of which the medical system is included. The Medical System Foundation subsequently identifies the medical systems as part of the broader crew health and performance system

based on the draft CHP ConOps. Due to the redirection of HRP work, this ConOps did not undergo any review and is not part of the deliverable other than for reference. Please contact the ExMC SE Lead for additional information.

2.2 Accepted Medical Condition List

The CST further defined clinical needs that align with the vision outlined in the ConOps and identify planned and unplanned clinical activities for consideration (Figure 2). Planned activities are those that are expected to occur during spaceflight to promote the health and performance of the crew, such as routine physical exams. Unplanned activities are medical conditions (e.g., illnesses or injuries) that occur during a mission and require medical evaluation, diagnosis, monitoring, treatment, or long-term management (such as rehabilitation and recovery) that has to be implemented by the crew. It is understood that, for exploration missions, NASA will not be able to provide exhaustive clinical capabilities to manage all the potential medical conditions that could occur in-flight due to resource and technology constraints. As such, an established list of expected or predictable medical conditions is referenced when planning for medical system design [12]. Thus, the team utilized a process to develop an evidence-based consensus position on what medical conditions planners should prioritize for vehicle and mission design. The resulting products were the AMCL for a cis-lunar mission that aligned with a Level of Care IV medical care designation and a white paper documenting the process taken [5,17].

2.3 Clinical Capabilities

The CST used the AMCL conditions and list of planned activities to derive the medical system capabilities, which would be required for the mission (Figure 2), such as wound repair, laboratory analysis, medical imaging, periodic physical exams, and private medical conferences. The teams then used these capabilities to derive the associated medical system resources required to support them. These resources (e.g., bandages, an ultrasound device, acetaminophen, and sonography experience) represent the consumables, devices, and pharmaceuticals, as well as the knowledge, skills, and abilities (KSAs) needed to prevent, diagnose, treat, and provide long-term management of conditions and perform the planned activities. Although KSAs are important for understanding the full scope of spaceflight clinical needs, ExMC has not yet developed a complete list of KSAs or a process to fully define them. Additional information on this clinical content can be found in the team's publication in the 2019 IEEE Aerospace Conference proceedings [12].

2.4 Medical System Architecture

A system architecture defines the underlying structure and relationships of the vehicle systems and subsystems that provide for the implementation of the requirements. As requirements are written, the architecture is refined, including defining lower levels of detail and eventually including relationships to system resources [7].

A medical system architecture was developed based on the needs, goals, and behaviors of the medical system as defined in the ConOps and in the context of the overarching crew health and performance (CHP) system and associated subsystems (i.e., medical, wellness, environmental monitoring, task

performance support, data) and vehicle flight systems (e.g., structures, maintenance and repair, and trash management) with which the medical system will interact. For example, defining the required medical need of vacuum for medical suction is important for understanding the necessary medical system support from the vehicle structures systems. Another example is that defining the required medical needs of exercise for musculoskeletal rehabilitation drives support from the wellness system. The medical system support needed from the structures and wellness vehicle systems drives the allocation of requirements to those systems. The system architecture was ultimately built within the model and visually represented through a diagram (the medical system architecture diagram) and corresponding system architecture definitions.

2.5 Requirements

System requirements represent the functional and non-functional system needs and are driven by the content documented in the ConOps (e.g., medical system architecture and scenarios), clinical capabilities, NASA standards, NASA historical documents, and parent system requirements. Requirements are the language that exploration programs speak that translate needs into actions, transforming "stakeholder expectations into unique, quantitative, and measurable technical requirements expressed as "shall" statements that can be used for defining a design solution" [8]. Requirements are defined by "levels" (i.e., Levels 1-5), which can vary per program/project. A hierarchy was defined for the Medical System, as follows:

- Level 1 Agency-level requirements (NASA Standards are included in this)
- Level 2 Program-level requirements: The Program shall...
- Level 3 Vehicle system-level requirements (e.g., vehicle habitats): The Habitat shall...
- Level 4 Vehicle subsystem-level requirements (e.g., medical system): The Medical System shall...
- Level 5 End item requirements (e.g., medical resource): The (x medical resource) shall...

The Foundation focused on the Level 4 functional medical system requirements, as these are the most critical to the clinical needs for the system. The requirements captured in the Foundation include Level 1 NASA Standards, representative Level 2 and 3 requirements (also termed "parent" requirements"), Level 4 functional, representative non-functional, representative interface medical system requirements, and representative Level 5 requirements. Additionally, it includes historical requirements that aided in the development of these medical system requirements by ensuring that previous medical systems were considered and analyzed for relevancy. Representative requirements were written to ensure that those requirements and mapping to them allowed for the development of a full medical system model; however, complete sets of these representative requirements were not the focus of this Foundation delivery.

NASA Standards represent Level 1 Agency Level requirements. For the Medical System Foundation, NASA Space Flight Human-System Standard Vol 1 and 2 (NASA-STD-3001, Vol 1 and 2) [1], [2] was imported into the model to ensure that the medical system requirements could be traced to the medical standard for all NASA Programs. *Representative parent requirements* are requirements that the SE team drafted to simulate sets of Level 2 and 3 system requirements from which the medical system requirements (Level 4) would flow, per the standard systems engineering process. Specifically, the SE team developed representative sets of Program requirements and Habitat vehicle system requirements to serve as parents to the medical system. These requirements were written prior to the formation of the Gateway Program and were developed as representative parent requirements for missions designated as Level of Care IV, such as Gateway. This hierarchy demonstrates how each of the requirements relate to others and provides a trace to requirements that are levied on the medical system.

Functional requirements are those that the system must implement to satisfy the clinical needs and are a part of the Level 4 requirement set. Functional requirement development started with identifying system functions through a functional decomposition of the ConOps content for the technical, human, and operational aspects of the medical system. A function typically starts with a verb and describes what the system does (e.g., "Inform decisions on crew health actions" or "prompt crew").

Initial functional decomposition content was documented in an Excel spreadsheet and subsequently moved to the model. Using SysML, the medical system functions and sub-functions were traced in the model and a functional diagram was developed for visualization of the information and relationships. Additional information on this process can be found in a paper developed for the 2020 International Conference on Environmental Systems (ICES) [13]. The SE team was then able to transform the functions into a set of functional requirements with requirement rationale. The requirements were initially written and reviewed in an Excel spreadsheet and imported into the SysML model. The requirements were then traced to the identified system functions.

Representative non-functional requirements specify product quality and quality in use pertaining to the technical and operational aspects of the system (e.g., effectiveness to achieve specific goals of the system, and performance efficiency in the use of time and resources in a given clinical activity) [18]. These Level 4 representative non-functional requirements were also imported into the model. Examples of non-functional requirements categories included: human risk (not to exceed the stated threshold of the ExMC-defined medical risk metrics such as of loss of crew life), performance (to provide interoperability with other vehicle systems), maintainability (to be able to replace damaged resources), reliability (to have an operational lifecycle estimate for the duration of crewed activities), security (to have authentication of users), physical constraints (to comply with applicable requirements for vehicle interfaces), and resource allocation (to minimize mass, volume, power, and data).

Representative interface requirements represent medical needs that are allocated to other systems based on the proposed system architecture and are also part of the Level 4 requirement set. For example, the medical system needs to provide medical suction as a medical capability to maintain the crew's health. The resulting requirement of providing vacuum will not remain a medical system requirement because it is assumed that the vehicle structures system will already have vacuum capability. Therefore, these requirements were allocated to the structures system and will remain integrated with the medical system and tracked as a medical system interface requirement.

Using the model, traces were made from these representative interfaced systems to medical system capabilities to maintain traceability to the medical information behind the requirements. The model was also used to create an example of how interface points that interact with the medical system can be visualized using an interface diagram.

Representative Level 5 requirements, which are at the resource level (e.g., medical suction device), were developed external to the SE team and they did not follow the same systems engineering process as the medical system requirements. However, they were included in the model to show that a full system includes the design solution and that those requirements must also relate back to the higher-level medical system requirements [13]. These Level 5 requirements were also imported into the model and traced appropriately.

Historical requirements were utilized to aid in the development and analysis of these medical system requirements. The ISS Medical Kit Project Requirements and Verification Document [19] and the ISS Medical Operations Requirements Document [20] were used to help understand how the requirements for the ISS medical system may differ from the requirements for the exploration medical system as well as to identify potential missing requirements. These requirements were also imported into the model and traced appropriately.

Overall, model traces were developed amongst the various types of requirements (i.e., Level 1 NASA standards, Level 2 and 3 parent requirements, Level 4 medical system functional, non-functional, and interface requirements, Level 5 medical resource requirements, and historical requirements) and clinical content (i.e., capabilities, conditions, and resources), as needed for traceability and requirements analysis. Traceability allows medical system requirements to be associated with relevant information as to why the requirement was needed, which provides clear justification for requirements that is vital to aid in negotiations anticipated through the space system maturation process. Visualizations of model traceability were created to aid in effective communication with the team as well as stakeholders [12].

2.6 Medical Resources

Lastly, example resources that satisfy some of the requirements were identified and used to create an example master equipment list (MEL) of a potential resulting system that could be based on the developed requirements and rationale. The associated mass, volume, and power needs for each resource were imported into the model and the CST identified draft resource quantities in order to create the MEL.

2.7 Hypertext Markup Language Report

A read-only HTML report of the model that is viewable within a web browser was provided to expand visibility of model content for stakeholders without requiring MagicDraw[™] credentials [6]. This HTML report provides links to the ConOps, and the AMCL, and contains a representative subset of the content described above. The HTML report is designed to enable communication and is organized in a way that makes it easy for users to find information and guides them through the SE process taken to derive the

requirements. An HTML Report Guide document is also supplied in the HTML report to help navigate the Foundation model.

The HTML report uses a variety of visualizations such as flowchart diagrams, tables, lists, links, and text that show that the Foundation provides a foundational starting point for a medical system that is traced to the relevant sources used to derive the requirements and their rationale. The HTML Report provides a capability to stakeholders such as engineers, clinicians, and managers so they can effectively communicate information about the resulting candidate medical system and the clinical content upon which it is based.

3.0 HISTORY OF DEVELOPMENT AND VETTING

The ExMC Systems Engineering and Clinical and Science Teams developed the Medical System Foundation beginning in FY17. These teams continue to collaborate and refine the products that make up the Foundation. Products that are managed and delivered to the ExMC Element by the SE team are considered "SE products," whereas those that are managed and delivered by the CST are considered "CST products." All products had internal review before being considered complete. In planning the review for the Foundation, the SE team defined the following:

- Vetting review of content
- Verification review of the requirements against the system needs
- Validation review of the system against stakeholder needs

The SE team determined that developing and executing a verification and validation plan at this time was premature, as the Foundation will not be used immediately by an Exploration Program to develop an operational system based on these requirements verbatim. Instead, the Exploration Program would use Foundation requirements as a starting point from which to build their own set of tailored, baselined, verified, and validated requirements.

The vetting took place per the following definitions:

- Internal vetting review by members of the SE team and the CST, with review by representatives from the Johnson Space Center (JSC) Space and Medical Operations Division (SD3) and the Crew Office (CB) as available.
- ExMC vetting review by the ExMC Control Board (ExMCCB). The ExMCCB process can be found on the ExMC SharePoint Site: <u>https://hrp.sp.jsc.nasa.gov/exmc/ExMCInternalTeamWebsite/SitePages/Configuration%</u> <u>20Management.aspx</u>.
- External to ExMC vetting because the Medical Foundation is the first of its kind and will be used by emerging Exploration Programs, it is version controlled and was offered to the Human Research Program as a United States Office of Management and Budget (OMB) milestone. Associated with its delivery, HRP requested a series of informational roadshow presentations to certain groups and boards within NASA JSC Human Health and Performance Directorate (SD): SD3's Medical Operations Group (MOG), SD's Space

Medicine Operations Control Board (SMOCB), and HRP's Human Research Program Control Board (HRPCB).

• External to NASA vetting – several peer-reviewed papers and presentations have been published that document processes and products developed for the Foundation (see Reference section).

The development and vetting timeline for the products that make up the Foundation products are specified in the Appendix.

4.0 REFERENCES

- 1. <u>NASA. "NASA Space Flight Human-System Standard Volume 1, Change 1, Revision A: Crew</u> <u>Health," NASA-STD-3001 Vol. 1, Feb 2015.</u>
- <u>NASA. "NASA Space Flight Human-System Standard Volume 2, Revision A: 2015," NASA-STD-3001 Vol. 2, Feb 2015.</u>
- 3. <u>Hailey, M., Urbina, M., Reyes, D., Antonsen, E. "Interpretation of NASA-STD-3001 Levels of Care</u> for Exploration Medical System Development," NASA/TM-2017-219290, April 2017.
- 4. <u>ExMC. "Recommendation for a Medical System Concept of Operations for Gateway Mission",</u> <u>HRP 48012 Baseline, 2018.</u>
- 5. <u>ExMC. "Accepted Medical Condition List (AMCL) Pilot Project Cis Lunar DRM", AMCL Ratio</u> <u>Calculations_CisLunar, Version 0, 2019.</u>
- 6. <u>ExMC. "Medical System Foundation for Level of Care IV Short-Duration Lunar Orbit", Version</u> <u>1.0, 2020.)</u>
- 7. NASA. "NASA Systems Engineering Processes and Requirements," NPR7123.1C, Feb 2020.
- 8. NASA. "NASA Systems Engineering Handbook," NASA/SP-2016-6105 Rev 2, 2016.
- 9. <u>NASA. Expanded Guidance for NASA Systems Engineering</u>, <u>Volume 1: Systems Engineering</u> <u>Practices</u>, 2016.
- 10. <u>NASA. Expanded Guidance for NASA Systems Engineering, Volume 2: Crosscutting Topics,</u> <u>Special Topics, Appendices, 2016.</u>
- 11. NASA. Program/Project Management and Systems Engineering, JPR 7120.3B, 2015.
- 12. <u>Hanson, A., et al., "A Model-Based Systems Engineering Approach to Exploration Medical</u> <u>System Development", 2019 IEEE Aerospace Conference, Big Sky, MT, USA, 2019, pp. 1-19.</u>
- McGuire, K., et al., "Using Systems Engineering to Develop an Integrated Crew Health and Performance System to Mitigate Risk for Human Exploration Missions", 2020 ICES 50th International Conference on Environmental Systems. Lisbon, Portugal, 2020 (draft, conf was cancelled for 2020).
- 14. <u>Mindock, J., et al. "Systems Engineering for Space Exploration Medical Capabilities", Proceeding</u> of the AIAA SPACE and Astronautics Forum and Exposition. 2017.
- 15. <u>Bajwa, A., et al. "Strategic Perspectives on the Future of Systems Engineering at NASA",</u> <u>NASA/TM-20205002911.</u>
- 16. <u>In-Work. "Crew Health and Performance System Concept of Operations for Gateway Missions"</u>, <u>2018: NASA Human Research Program Exploration Medical Capability Element.</u>
- 17. <u>Blue, R., et al., "Development of an Accepted Medical Condition List for Exploration Medical</u> Capability Scoping", NASA/TM-2019-220299, July 2019.
- 18. <u>"Systems and Software Engineering Systems and Software Quality Requirements and</u> Evaluation (SQuaRE) - System and Software Quality Model", ISO/IEC 25010:2011.
- 19. <u>"Project Requirements and Verification Document: Plan and Report for the ISS Health</u> <u>Maintenance System (HMS) Medical Kit Hardware</u>", JSC 65805, March 2011.
- 20. <u>"International Space Station Medical Operations Requirements Document", SSP 50260, Rev E,</u> November 2017.

5.0 APPENDIX: TIMELINE OF HISTORY OF DEVELOPMENT AND VETTING

The following depicts the development and vetting timeline for each product specified:

- 1. Accepted Medical Condition List (AMCL)
 - a. FY18: Drafted (CST product)
 - b. FY19: ExMCCB vetting of AMCL (SA-01117)
 - i. Mandatory Reviewers: ExMC Element Manager, Deputy Element Manager, Element Scientist, JSC Center Lead
- 2. Concept of Operations (ConOps) for Level of Care IV: Short-Duration Lunar Orbit
 - a. FY18: Drafted (development team: SE and 2 CST clinicians)
 - b. FY18: Internal vetting: SE and CST review (6 CST clinicians)
 - c. FY19: ExMCCB vetting of ConOps (SA-01821)
 - i. Mandatory reviewers: ExMC Element Manager, Element Scientist, JSC Center Lead
 - ii. Optional reviewers: Deputy Element Manager, Center Leads
- 3. Clinical Capabilities
 - a. FY18: Drafted capabilities list mapped to conditions (CST product)
 - b. FY18: Imported into model and created matrices of capabilities to conditions and capabilities to resources
 - c. FY19: Iterated on capabilities to conditions and capabilities to resources
 - d. FY20: Refined capabilities to conditions and capabilities to resources
 - e. FY20: Addition of conditions to resources
 - f. FY20: Internal vetting: CST review of clinical content (4 CST clinicians)
 - g. FY20: Created resource quantity list
- 4. Requirements
 - a. FY18: Created functional decomposition (SE product)
 - b. FY18: Drafted functional requirements (development team: SE and 3 CST clinicians)
 - c. FY19: Internal vetting: CST review of functional requirements (5 CST clinicians)
 - d. FY19: ExMCCB vetting of functional requirements (SA-01402)
 - i. Mandatory reviewers: ExMC Leadership, Center Leads, SA Export Control Rep
 - ii. Optional Reviewers: ExMC Scheduler, Financial Analyst, SE Project Planning Lead
 - e. FY19: External to ExMC vetting due to OMB milestone designation
 - i. SD3, Forum: Medical Operational Group (MOG) Weekly Meeting
 - ii. SD, Forum: Space Medicine Operations Control Board (SMOCB)
 - iii. HRP, Forum: Human Research Program Control Board (HRPCB)
 - f. FY19: Drafted data system requirements that pertain to the Medical System
 - g. FY19: Internal vetting: SE and CST review of data system requirements (3 CST clinicians)

- h. FY19: ExMCCB vetting of data system functional requirements (SA-01821)
 - i. Mandatory reviewers: ExMC Leadership, SE Lead
 - ii. Optional Reviewers: Center Leads, SA Export Control Rep
- i. FY19: Drafted interface requirements
- j. FY20: Drafted performance requirements
- k. FY20: Internal vetting: SE and CST review of all requirements (3 CST clinicians)
- I. FY20: Performed SE requirements analysis
- 6. Crew Health and Performance Medical System Model (SE product)
 - a. FY18: Drafted medical system architecture and activity diagrams (as part of the ConOps)
 - b. FY19: Updated system architecture
 - c. FY19: Updated activity diagrams
 - d. FY19: Created interface diagram
 - e. FY19: Preliminary work on relationship maps (for both the condition, capabilities, and resource traces as well as requirements traces)
 - f. FY19: Preliminary work on HTML views
 - g. FY20: Updated relationship maps
 - h. FY20: Created requirement tracing visualizations (i.e., traces and matrices)
 - i. FY20: Created master equipment list
- 7. Completed Foundation via HTML Report
 - a. FY20: Drafted HTML report of model artifacts (SE product)
 - b. FY20: Internal vetting: SE review of model artifacts
 - c. FY20: Internal vetting: SE and CST review of HTML Report (3 CST clinicians)
 - i. Additional reviewers included SD and CB reps
 - d. FY20: ExMCCB vetting of completed Foundation via HTML Report (SA-02900)
 - i. Mandatory reviewers: ExMC Leadership, Center Leads, SE Lead
 - e. FY20: External to ExMC vetting
 - i. SD3, Forum: Medical Operational Group (MOG) Weekly Meeting
 - ii. SD, Forum: Space Medicine Operations Control Board (SMOCB)
 - iii. HRP, Forum: Human Research Program Control Board (HRPCB)
- 8. Publications external to NASA
 - a. FY17: "Systems Engineering for Space Exploration Medical Capabilities" in proceedings of the 2017 American Institute of Aeronautics and Astronautics (AIAA) SPACE and Astronautics Forum and Exposition [8]
 - FY19: "A Model-Based Systems Engineering Approach to Exploration Medical System Development" in proceedings of the 2019 Institute of Electrical and Electronics Engineers (IEEE) Aerospace Conference [6]
 - c. FY20:" Using Systems Engineering to Develop an Integrated Crew Health and Performance System to Mitigate Risk for Human Exploration Missions" drafted for the 2020 International Conference on Environmental Systems (ICES) [7]