

Exploration Medical Capability (ExMC), Human Research Program

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

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Acronyms and Abbreviations

AIAA	American Institute of Aeronautics and Astronautics
AMCL	Accepted Medical Condition List
CB	Control Board
CHP	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
HSE&I	Human Systems Engineering & Integration
HTMA	Health and Medical Technical Authority
HTML	Hypertext Markup Language
ICES	International Conference on Environmental Systems
IEEE	Institute of Electrical and Electronics Engineers
IMM	Integrated Medical Model
IMPACT	Informing Mission Planning via Analysis of Complex Tradespaces
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. Background

Upon the completion of the Medical System Foundation for Level of Care IV Short-Duration Lunar Orbit Foundation (“Short Duration Foundation”) in FY20, Exploration Medical Capability (ExMC) Systems Engineering (SE) team began development of the Medical System Foundation for Level of Care IV Long-Duration Lunar Orbit and Lunar Surface (“Long Duration Foundation”) in FY21. This Long Duration Foundation extended the scope of the Short Duration Foundation by including lunar surface operations and the habitats/vehicles associated with it. Ultimately, the Long Duration Foundation represents a medical system recommended for crew medical care on spaceflight missions in lunar orbit and on the lunar surface of durations up to 9 months or 275 days and designated as Level of Care IV, as defined in NASA-STD-3001 Volume 1, Rev A [1] and Volume 2, Rev B [2] and as interpreted by ExMC within NASA/TM-2017-219290 (Interpretation of NASA-STD-3001 Levels of Care for Exploration Medical System Development) [3].

The Long Duration Foundation identifies medical conditions of interest, the concept of operations, and system requirements for a Level of Care IV lunar orbit and lunar surface 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 Long Duration 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 the Long Duration 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.

1.1. Deliverables

The FY22 deliverable of the Long Duration Foundation to the Human Research Program (HRP) ExMC Element consists of:

An HTML Report, accessible by anyone with NASA NDC credentials, of the system model that represents the Level of Care IV Medical System concept of operations, system context and requirements, with rationale and traces to clinical conditions, capabilities, and medical resources, as provided by Informing Mission Planning via Analysis of Complex Tradespaces (IMPACT)-Medical Database (Medical System Foundation for Level of Care IV Long-Duration Lunar Orbit and Lunar Surface Operations).

1.2. Project Team Members

The ExMC SE team is composed of systems engineers from a variety of engineering and science backgrounds (e.g., systems, bio/biomedical, aerospace, mechanical, and human factors). The ExMC Clinical Science Team (CST) is composed of pharmacists, nurses, and physicians of various specialties (e.g., emergency medicine, internal medicine, family practice medicine, physical medicine and rehabilitation, 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 Long Duration Foundation deliverable below:

- Medical system foundation model
- Concept of Operations
- Medical system context
- HTML report of modeled Foundation content
- Clinical capabilities
- Requirements

2. Process

2.1. Systems Engineering Principles and Process

The ExMC SE team, in conjunction with the ExMC CST, developed the Long Duration Foundation by following the guidance of the following documents:

- NPR 7123.1B– NASA Systems Engineering Processes and Requirements [4]
- SP-2016-6105 Rev2 – NASA Systems Engineering Handbook [5]
- Expanded Guidance for NASA Systems Engineering – Volume 1 and 2 [6,7]
- JPR 7120.3B – Program/Project Management and Systems Engineering [8]
- NASA/TM-2017-219290 Interpretation of NASA-STD-3001 Levels of Care for Exploration Medical System Development

Each product is described in the sub-sections below and each went through a vetting process, as defined in this document and in Table 3-1.

The SE team structured its efforts based on typical early design phase activities (pre-phase A) [4,5]. The SE team focused on generating an initial subset of medical system functional requirements (“System requirements” in Figure 2-1).

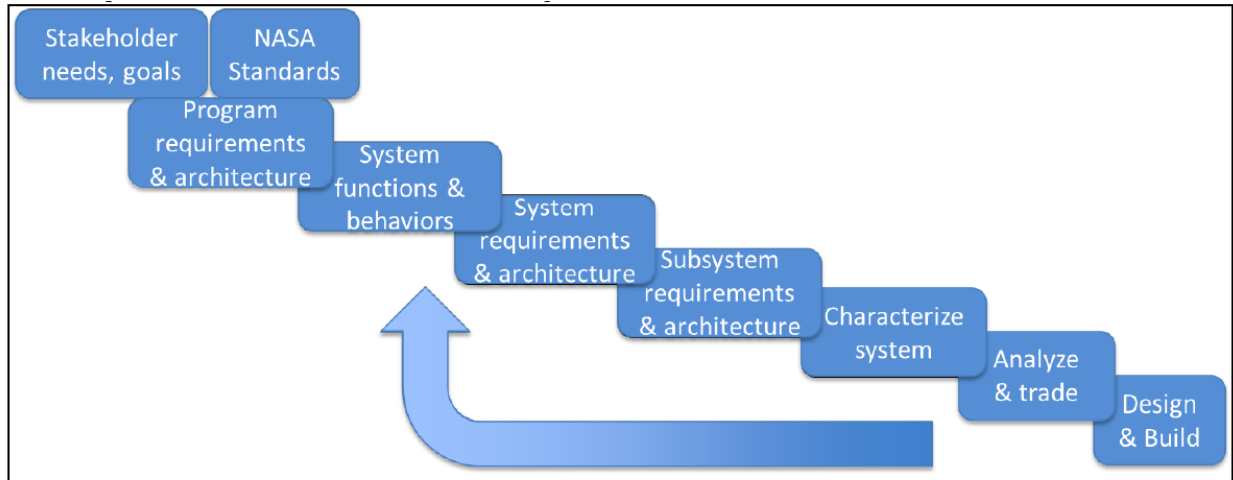


Figure 2-1 ExMC Systems Engineering Team Process for Exploration Medical System Early Development

Additional detail on the requirements development work is shown in Figure 2-2. More information on requirement development can be found in the SE team’s 2019 Institute of Electrical and Electronics Engineers (IEEE) Aerospace Conference paper [9].

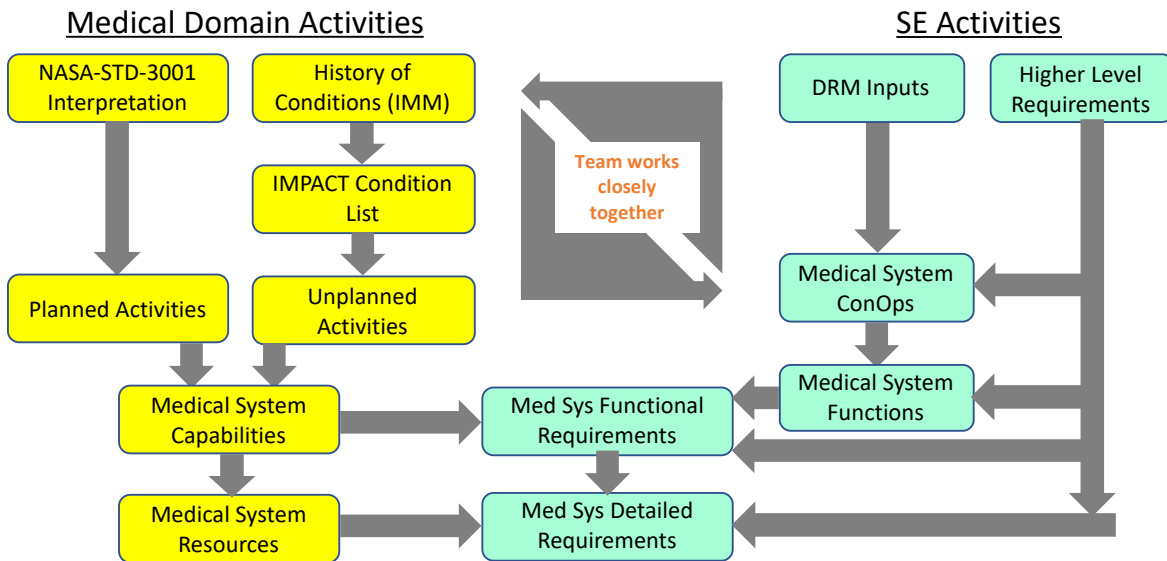


Figure 2-2 Medical System Requirements Development Process

2.2. 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 [4,5,9,10,11]. 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 [12].

Three connected MBSE tools from Dassault Systemes’s Catia platform were used to create and share the Medical System Foundation Model: MagicDraw™ 19.0 SP3, Teamwork Cloud and Cameo Collaborator. MagicDraw™ was used to create a visual representation of the system using the SysML modeling language. Teamwork Cloud was used to provide a central repository to store the model data so that all project members have access to and can manipulate the same information. Cameo Collaborator was used to publish simplified versions or reports of the model which were stored in the Teamwork Cloud repository. Anyone with NASA NDC credentials can view these reports without the MagicDraw™ tool by connecting to Teamwork Cloud’s web application via an internet browser.

When developing a model, a variety of model attributes are created to uniquely express the content of interest. The Medical System Foundation Model contains the following model attributes:

- Concept of operations
- Activity diagrams
- System Context
- Functional decomposition
- Requirements
- Requirement rationale
- Requirements traceability
- Medical conditions
- Medical capabilities
- Medical resources
- Medical system interfaces
- Glossary
- Abbreviations
- Meta-model
- Traceability tables
- Instance tables with associated values
- Content diagrams for user-specific views of model data

2.3. Agile Methodology

Continuous evaluation of the Foundation throughout its development is essential to accommodate the various aspects of the system as they are integrated into the model. As parts of the system model are built, limitations of already existing parts of the model and the need for new functionality are identified. Frequent requirement changes in the model are expected and are a feature of agile development, a process through which changing project requirements can be responded to more efficiently.

The ability to implement this process is partly dependent on stakeholder availability. Non-Systems Engineering system stakeholders (e.g., the clinicians and management), who provide source information for the ConOps, distribute their time across many projects and tasks and often face competing milestone and deliverable timelines, which are tracked via a waterfall project management approach. The integrated schedule lists tasks granularly and in a prescribed order. This approach allows program managers to best estimate work completion and resource requirements, a necessity when integrating multiple teams.

The Systems Engineering team, however, needed the flexibility to perform work as people with the experience or expertise became available. In addition, if Systems Engineers completed tasks in less time than budgeted, they needed a mechanism to begin another task. This mechanism was accomplished by identifying tasks that were captured as cards on a Microsoft Teams Planner Board that aligned with the integrated schedule. Details of this process are captured by Cohen, et al. [13].

3. Systems Engineering Content

3.1. ConOps

The SE team initiated the Long Duration 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]. In addition, communications with Artemis EVA and environmental experts provided assistance into developing the assumptions for the various phases of the mission.

With guidance from CST, the SE team generated a set of representative medical scenarios, which served as short narratives of anticipated medical activities for long-duration lunar orbital and surface 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., just-in-time training), a highlighted functionality list, assumptions, a narrative text, and an activity diagram (i.e., a flow chart 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 [10]. The resulting ConOps content was

stored within the model by formatting the ConOps document into MagicDraw™ diagrams, text editors, and tables. Additional process details for developing the ConOps may be found in ref [13].

3.2. Functional Decomposition

In preparation for functional decomposition, the ExMC SE's identified the preliminary set of key top-level system functions, which represent the key system features from the point of view of the customer or product owner. Based on these identified high-level functions, representative medical scenarios were then created and captured as use cases in the SysML model. The system behaviors, as depicted in the ConOps scenarios, were modeled in SysML as activities. Prior to performing the functional decomposition, systems engineers harmonized the activity names on the activity diagrams as necessary to ensure that all scenario activity diagrams use the same activities for the same behavior(s).

The functional decomposition was performed through thematic analysis of the ConOps scenario activities to identify the system functions and sub-functions. The six-phase approach outlined in Braun and Clarke [14] serves as a basis for analysis (as described in more detail in [15]), ensuring that all activities are mapped to a function. If orphan functions are identified, analysis should be performed to ensure the function is properly traced to an activity or re-evaluated as valuable to the system design. As a result, activity diagrams were generated that maintained traceability of the derived functions from the ConOps activities.

3.3. Medical System Context

The medical system will interact with other subsystems within the Crew Health and Performance (CHP) System as well as subsystems outside of the CHP System. These interactions are captured in a SysML block definition diagram that identifies the interfaces of possible subsystems external to the medical system and served as a basis for the interface requirements.

3.4. 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 4.1 – Vehicle subsystem subsystem requirements (e.g. data system): The Data System shall...

The Long Duration 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 Long Duration Foundation are described in Table 3-1:

Table 3-1 Long Duration Foundation Requirements

Requirement Type	Description
NASA Standards	These 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	These are Level 2 and 3 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 requirements. 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	These are Level 4 requirements 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) [10]. 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	These 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) [16]. 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	These represent medical needs that are allocated to other systems based on the proposed system context 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.
Historical requirements	Aid 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 the Long Duration Foundation delivery. The ISS Medical Kit Project Requirements and Verification Document [17] and the ISS Medical Operations Requirements Document [18] 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.
Representative Level 4.1 Requirements	Project requirements that fall between Level 4 and Level 5 requirements. For example, a project may document Level 4.1 requirements that capture the specific functionality of a vehicle subsystem, such as an integrated data system or clinical decision support system. These requirements do not have end item specifications that are identified by Level 5 requirements; rather they provide the capabilities such a system shall maintain.

3.5. Requirements Tracing

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, 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 [9].

3.6. CST Review

After the ExMC Requirements Team completed their drafts of requirements and traces, they were provided to the ExMC CST for clinical review. This review was important to capture the medical viewpoint and ensure the requirements reflected the appropriate clinical content. Furthermore, the CST provided medical conditions, capabilities, and resources via an export from Medical Database. Also, the CST provided the tracing between requirements and medical capabilities that were maintained by the Foundation model. Additional details on clinical content are detailed in Section 4.

3.7. Requirements Management

The requirements were configuration managed in Excel through their development by the ExMC SE Requirements Team. Once all requirements and traces were completed, the requirements were imported to Cradle, a requirements management tool created by 3SL, which became the source of truth for the MBSE model going forward. These requirements were exported as a .csv file that was imported to MagicDraw™ that provided the update to the foundation MBSE model. Each time the requirements completed a review (e.g., SE team, ExMCCB), the requirements were updated in Cradle where comments could be captured and changes saved for historical purposes.

3.8. Model Review

Model reviews (e.g., ExMC SE Team, ExMC CB), including the requirements, were performed in Teamwork Cloud. The Teamwork Cloud software tool provided reviewers the platform to make comments directly to the model using annotations to highlight specific text or aspects of a figure that was in question. Each time the model was prepared for review, the updated requirements were imported to MagicDraw™ from Cradle via a .csv file. When the model completed preparation for review, the model was published from MagicDraw™, using Cameo Collaborator, to Teamwork Cloud for the review.

4. Clinical Content

4.1. Medical Condition List

While the Short Duration Foundation included an Accepted Medical Condition List (AMCL) provided by the Clinical & Science Team, the Long Duration Foundation relied on the medical condition list developed and stored within the Medical Database tool, which also stores the traces of conditions to the capabilities and resources required to diagnose and treat those conditions. This change was based on the rationale that an accepted medical condition list is unique to the parameters of a specific design reference mission. Given that the Long Duration Foundation has a generic mission profile, the development of an AMCL would be neither practical nor appropriate. Instead, the users of data contained within the Long Duration Foundation would be responsible for tailoring that data per the needs of their design reference mission. All clinical content, including medical conditions, clinical capabilities, and clinical resources presented in the Long Duration Foundation was provided by data files (CSV) exported from the Medical Database.

4.2. Clinical Capabilities

The CST used the medical conditions to derive the medical system capabilities that would be required for the mission (Figure 2-2), such as wound repair, laboratory analysis, medical imaging, periodic physical exams, and private medical conferences. For details on the methods of collecting the data used to derive the capabilities list, please refer to the Evidence Library Methods Paper (HRP-48036 Rev A) [19]. 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, pharmaceuticals, and the knowledge, skills, and abilities (KSA) needed to prevent, diagnose, treat, and provide long-term management of conditions and perform the planned activities. While 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 [9].

The capabilities list presented in the Long Duration Foundation was exported from the Medical Database tool as an Excel file, which was both imported into MagicDraw™ to generate the capabilities table included in the Foundation model and also used by the CST for the tracing of capabilities to requirements. For this purpose, the CST was divided into 3 groups of 3-4 individuals who met to map the 700+ clinical capabilities to the 80 functional requirements of the CHP Habitat Medical System. Each CST team first re-ordered the functional requirements into a system that is more intuitive to the typical clinical workflow of patient care; then, the requirement to each applicable capability was mapped in reverse. This permitted the teams to identify both redundant and orphan requirements or capabilities and denote the need for revisions to address these deficiencies. The mapping was then transcribed to display the functional requirements traced to all the associated capabilities. The Excel file of these traces was then imported into the Cradle requirements management tool and then exported into MagicDraw™.

4.3. Clinical Resources

Lastly, the resources included in the Master Equipment List (MEL) are those that were imported from Medical Database and have no link to requirements. The process on how resource data was collected is outlined in the Medical ID document (IMPACT-PRO-0027) [20].

5. Reports

5.1. NASA-Internal Web Report

A read-only report generated by Cameo Collaborator was hosted on a Teamwork Cloud server. This report provided a model that is viewable within a web browser and expands the visibility of model content for stakeholders without requiring MagicDraw™ credentials [Medical System Foundation for Level of Care IV Long-Duration Lunar Orbit and Lunar Surface Operations. Representing the content described above, the web-facing report of the model is designed to enable communication, to organize

content in a way that makes it easy for the user to find information, and to guide the user through the SE process taken to derive the requirements. During reviews, reviewers of the NASA-internal web report can use the web interface to leave comments directly linked to model elements and diagrams that can later be dispositioned by the Medical System Foundation project team.

The Cameo Collaborator report uses a variety of visualizations, similar to those contained in the MagicDraw™ model, such as flow-chart diagrams, tables, lists, links, and text that show that the Long Duration 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 Foundation 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.

5.2. Public Facing Web Report

The NASA-internal web report is available only to users with access to NASA's internal networks. To show the system model to a larger audience, a web report is generated using MagicDraw's™ Web Publisher 2.0 tool and hosted on the Human Research Program's public facing website. The objectives and presentation of the public facing web report are the same as the NASA-internal web report. However, users of the public facing web report are unable to leave comments and instead are asked to contact ExMC by a dedicated email address provided in the report.

6. Vetting, Verification, and Validation

Products that are managed and delivered to the ExMC Element by the SE team are considered "SE products", while those that are managed and delivered by the CST are considered "CST products."

All SE and CST products that are included in the model were reviewed by both teams before being considered complete. In planning the review for the Long Duration 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 Long Duration 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 NASA vetting – review by members of the SE team and the CST, with review by representatives from the JSC Space and Medical Operations Division (SD3) and the Crew Office (CB) as available. Prior to the ExMCCB, the model was presented to NASA Office of the Chief Health and

Medical Officer (OCHMO) representatives, Health and Medical Technical Authority (HTMA) representatives, and the JSC Human Systems Engineering & Integration (HSE&I) CB.

- ExMC vetting – review by the ExMC Control Board (ExMCCB). The ExMCCB process can be found on the ExMC SharePoint Site:
<https://hrp.sp.jsc.nasa.gov/exmc/ExMCInternalTeamWebsite/SitePages/Configuration%20Management.aspx>
- External to ExMC vetting –because the Medical Foundation is the first of its kind for long duration lunar orbit and surface missions intended to 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 Long Duration Foundation (see Reference section).

The development and vetting timeline for the products that make up the Long Duration Foundation products are specified in Section 7.

7. History

The Medical System Foundation for Level of Care IV Long-Duration Lunar Orbit and Lunar Surface was developed by the ExMC Systems Engineering and Clinical and Science Teams in FY21-FY22 (for the federal government). This Long Duration Foundation effort was based on the framework and processes used in the preceding model for the Short Duration Foundation [21]. The primary differences between the two Foundations are the incorporation of the ConOps content into the model, the establishment of scenarios and clinical conditions based on the longer duration, and additional operational environments considered in the Long Duration Foundation.

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

Concept of Operations	FY21	<ul style="list-style-type: none"> • Drafted (development team: SE and CST) • Internal vetting: SE and CST review
	FY22	<ul style="list-style-type: none"> • ExMCCB vetting of ConOps (SA-04372) <ul style="list-style-type: none"> ○ Mandatory reviewers: ExMC Element Manager, Element Scientist, Center Leads
Capabilities	FY21	<ul style="list-style-type: none"> • Drafted capabilities list mapped to conditions (CST product) • Addition of conditions to resources • Refined capabilities to conditions and capabilities to resources
	FY22	<ul style="list-style-type: none"> • Internal vetting: CST review of clinical content

		<ul style="list-style-type: none"> Imported into model and created trace tables of capabilities to conditions and capabilities to resources
Functional Decomposition	FY21	<ul style="list-style-type: none"> Created functional decomposition (SE product)
		<ul style="list-style-type: none"> Internal vetting: SE review of decomposition
Requirements	FY21	<ul style="list-style-type: none"> Drafted non-functional requirements Internal (SE) review of non-functional requirements
	FY22	<ul style="list-style-type: none"> Drafted interface requirements Drafted functional requirements (development team: SE) Internal vetting: CST and SE review of all requirements
Model Development	FY21	<ul style="list-style-type: none"> Added ConOps content (needs, goals, assumptions, scenarios) Drafted medical system architecture and activity diagrams (as part of the ConOps)
	FY22	<ul style="list-style-type: none"> Added requirements and traces Added clinical content
HTML Report	FY22	<ul style="list-style-type: none"> Internal vetting: SE and CST review of model report ExMC CB vetting of completed Foundation via model report (SA-XXX) <p>External to ExMC vetting:</p> <ul style="list-style-type: none"> SD3, Forum: Medical Operational Group (MOG) Weekly Meeting SD, Forum: Space Medicine Operations Control Board (SMOCB) HRP, Forum: Human Research Program Control Board (HRPCB)
Publications external to NASA	FY22	<ul style="list-style-type: none"> Cohen, J., Kaetzer, M.S., Lumpkins, S., Rubin, D., & McGuire, K. (2022, March) A model-based systems engineering journey to developing a concept of operations (ConOps). <i>2022 IEEE Aerospace Conference</i>.

8. References

1. [NASA. "NASA Space Flight Human-System Standard Volume 1, Change 1, Revision A: Crew Health," NASA-STD-3001 Vol. 1, Feb 2015.](#)
2. [NASA. "NASA Space Flight Human-System Standard Volume 2, Revision A: 2019," NASA-STD-3001 Vol. 2, Rev A Sep 2019.](#)
3. [Hailey, M., Urbina, M., Reyes, D., Antonsen, E. "Interpretation of NASA-STD-3001 Levels of Care for Exploration Medical System Development," NASA/TM-2017-219290, April 2017.](#)
4. [NASA. "NASA Systems Engineering Processes and Requirements," NPR7123.1C, Feb 2020.](#)
5. [NASA. "NASA Systems Engineering Handbook," NASA/SP-2016-6105 Rev 2, 2016.](#)
6. [NASA. Expanded Guidance for NASA Systems Engineering, Volume 1: Systems Engineering Practices, 2016.](#)

7. [NASA. Expanded Guidance for NASA Systems Engineering, Volume 2: Crosscutting Topics, Special Topics, Appendices, 2016.](#)
8. [NASA. Program/Project Management and Systems Engineering, JPR 7120.3B, 2015.](#)
9. [Hanson, A., et al., "A Model-Based Systems Engineering Approach to Exploration Medical System Development", 2019 IEEE Aerospace Conference, Big Sky, MT, USA, 2019, pp. 1-19.](#)
10. 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).
11. [Mindock, J., et al. "Systems Engineering for Space Exploration Medical Capabilities", Proceeding of the AIAA SPACE and Astronautics Forum and Exposition. 2017.](#)
12. [Bajwa, A., et al. "Strategic Perspectives on the Future of Systems Engineering at NASA", NASA/TM-20205002911.](#)
13. Cohen, J., Kaetzer, M.S., Lumpkins, S., Rubin, D., & McGuire, K. (2022, March) A model-based systems engineering journey to developing a concept of operations (ConOps). 2022 *IEEE Aerospace Conference*.
14. Braun, V. and V. Clark, *Using thematic analysis in psychology*. Qualitative research in psychology, 2006. **3**(2): p. 77-101.
15. Hanson, A., et al., *Using a Model-Based Systems Engineering Approach for Exploration Medical System Development*, in *68th International Astronautical Congress 2017*: Adelaide, Australia.
16. ["Systems and Software Engineering - Systems and Software Quality Requirements and Evaluation \(SQuaRE\) - System and Software Quality Model", ISO/IEC 25010:2011.](#)
17. ["Project Requirements and Verification Document: Plan and Report for the ISS Health Maintenance System \(HMS\) Medical Kit Hardware", JSC 65805, March 2011.](#)
18. ["International Space Station Medical Operations Requirements Document", SSP 50260, Rev E, November 2017.](#)
19. [ExMC. "Evidence Library Methods Paper", HRP-48036 Baseline, 2021.](#)
20. ExMC. "Exploration Medical Capability IMPACT Medical Database - MedID Content Development Methods", IMPACT-PRO-0027 Baseline, 2022.
21. [ExMC. "Medical System Foundation for Level of Care IV Short-Duration Lunar Orbit, Version 1.0a, January 2021"](#)