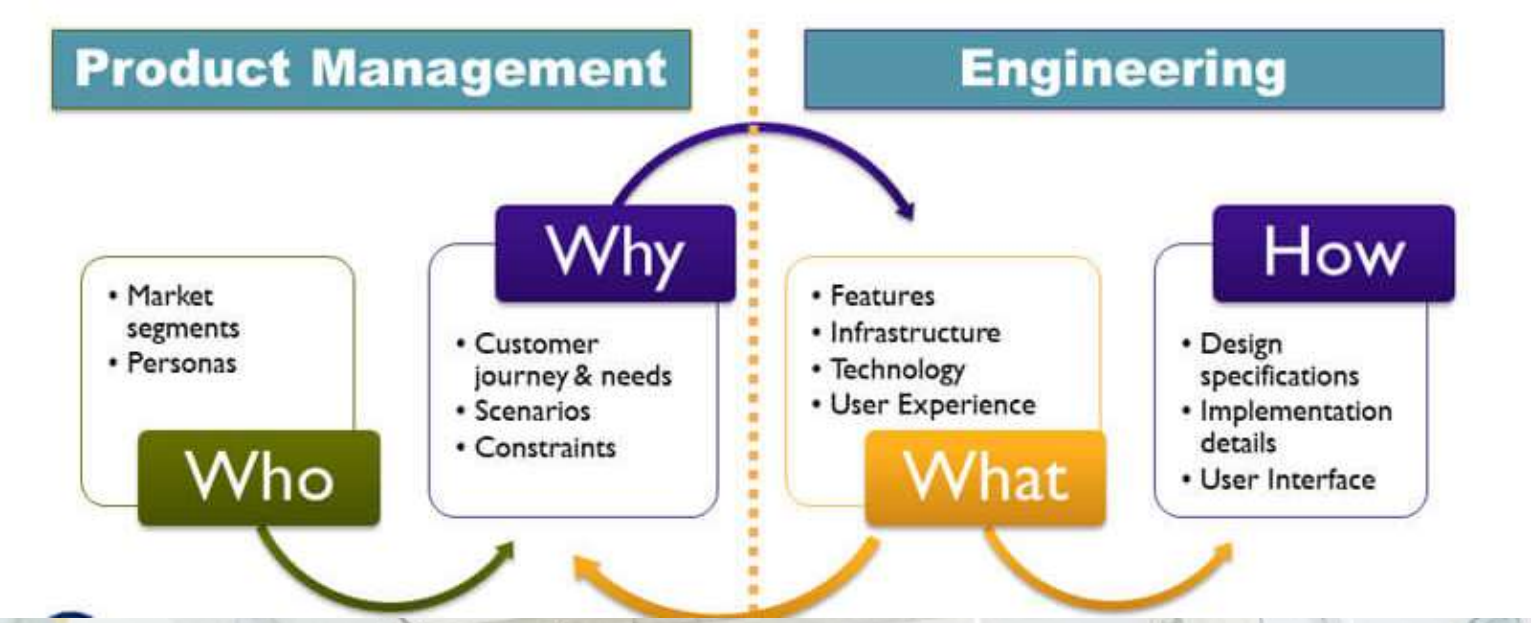
Elektronikos sistemų testavimas

Produkto reikalavimų dokumentas PRD.

Specifikacijos.

Reikalavimų testavimas.



EST

PRD sudarymo taisyklės

1. Ensure each requirement is specific

2. Define requirements in measurable terms

3. Use imperatives such as “shall” or “must” properly and consistently

4. Enforce consistency of terminology and prohibit industry or company jargon

5. Prohibit passive voice

6. Avoid duplicate or contradictory requirements

7. Keep risk in mind

8. Perform cross-functional design reviews to assess your requirements before implementation

9. Maintain an audit trail of requirements improvements for your ISO 13485 Compliant Quality Management System (QMS)

10. Revisit your requirements

1. ENSURE EACH REQUIREMENT IS SPECIFIC

Broad requirements are weak and difficult to verify. One way to make sure that your requirements are specific is to eliminate the use of inherently weak words such as user-friendly, reliable, capable, etc. These words are vague and do not tell the user what is being measured (see Tip #2). Your medical device requirements specifications should be able to stand-alone without supplementary information to explain what “user-friendly” or other broad terms mean.

“The device must be user-friendly” – This is a weak requirement that leaves many questions unanswered. How is “user-friendly” defined? Who are the users? Is this talking about the user-interface, ergonomics, or other features that the user interacts with?

Instead, this requirement should be broken down into a series of small, objective requirements.

2. DEFINE REQUIREMENTS IN MEASURABLE TERMS

When writing a medical device essential requirements checklist, it is important to keep in mind that you must be able to demonstrate how the requirement is met. If you cannot quickly come up with an objective way to show that the requirement has been met, it probably needs to be rewritten. Requirements should be written so that they contain a clearly measurable objective. A person unfamiliar with the product or process should be able to come in and verify requirements are met through a review of documentation.

Remember, if it isn't documented then it didn't happen!

3. USE IMPERATIVES SUCH AS “SHALL” OR “MUST” PROPERLY AND CONSISTENTLY

Anyone that works in the Quality or Regulatory side of medical device is well-versed in reading standards and regulatory requirements like ISO …. closely for shall and should statements. Your requirements document should not require a close reading to determine intent.

"The device must interface with common accessories." – This reads as non-negotiable, it **MUST** interface

"The device **SHOULD** interface with common accessories." – This reads an optional or nice to have feature

4. ENFORCE CONSISTENCY OF TERMINOLOGY AND PROHIBIT INDUSTRY OR COMPANY JARGON

Sticking with consistent terminology makes it easier to search through requirements quickly and minimizes the risk of incorrect interpretation. It may be helpful to include a definitions or glossary section to the requirements document if conflicting terminology is a consistent concern or the requirements document will be used by personnel that may be downstream in the process and use different terminology.

This also includes consistently referring to acronyms or abbreviations. Acronyms are only useful when they are standardized and understood by all document users. Your device requirements specification needs to be easily understood by all personnel that may work with it.

5. PROHIBIT PASSIVE VOICE

Requirements are living documents for a product that needs to actively meet the general safety and performance requirements continuously. The requirement statements should be written in a consistent voice that reflects the active nature of the requirement.

The device must be tested at a consistent flow rate of 5L/min for 30 minutes.
This suggests that this flow rate is an upper limit test and only needs to happen once.
The device must be able to withstand a consistent flow rate of 5L/min for 30 minutes
This is better, but still sounds like an upper limit that the device won't necessarily hit.

The device must withstand a consistent flow rate of 5L/min for 30 minutes.

This is clear and concise. Every unit of the device must withstand the flow rate.

6. AVOID DUPLICATE OR CONTRADICTORY REQUIREMENTS

Requirements for regulatory agencies often overlap completely or significantly. It is important to decide on a strategy for addressing this issue early on when developing requirements. Will you list the requirement under a section for each regulator or will you lump all regulatory requirements into one section to avoid duplication? Further, regulatory requirements and functional or material requirements may overlap as well.

Depending on the structure of your template it may be easier to list the requirement as both a functional and a regulatory requirement or list all applicable regulations as a source of the requirement.

7. KEEP RISK IN MIND

Assessing risk continues to be a focus for regulatory agencies. The latest revision of ISO ….. expanded risk assessment to the entire quality. Working on risk assessment in conjunction with requirements is one way of mitigating risk before it getting further down the development pipeline.

Is there a process that is user-dependent and high-risk? Can a requirement be written to mitigate that risk through design?

8. PERFORM CROSS-FUNCTIONAL DESIGN REVIEWS TO ASSESS YOUR REQUIREMENTS BEFORE IMPLEMENTATION

The requirements document should be reviewed within your Design Controls process and the review documented accordingly. The design review requirements outlined in ISO …….. require that personnel involved in the design stage attend the design review. Since the requirement document will be covering overall requirements there should be representatives present from all potentially affected departments. Getting input from a cross-functional team can minimize hiccups down the line when requirements are being reviewed by areas that may not have seen the requirements document before.

9. MAINTAIN AN AUDIT TRAIL OF REQUIREMENTS IMPROVEMENTS FOR YOUR ISO …. COMPLIANT QUALITY MANAGEMENT SYSTEM (QMS)

As the project advances through development it is likely that new requirements will be added and existing requirements will be improved upon. A change control system should be in place to capture these changes. An audit trail should be maintained for all changes to requirements to ensure that the methods and reason for the changes are available for regulatory inspection.

Documenting clear reasons for the requirement change can be helpful later in the development process and can potentially reduce iterations in the development process.

10. REVISIT YOUR REQUIREMENTS

Once the device hits the market the requirements work is not done, especially as regulatory bodies put increasing scrutiny on clinical follow-up and risk assessment. Your device requirements are subject to change. As new information about the device is acquired through clinical trials, post-market clinical follow-up, through user experiences, and other pathways, the requirements will need to change.

This may not mean changing your requirements document for the current version of your device, but it may mean creating a new, draft medical device requirements specification that reflects this new information. This may later be used to develop a new version of the device or an alternative device to meet customer needs.

10. NASA PRD Pavyzdys

Stakeholder Expectations Definition

The Stakeholder Expectations Definition Process is the initial process within the SE engine that establishes the foundation from which the system is designed and the product is realized. The main purpose of this process is to identify who the stakeholders are and how they intend to use the product. This is usually accomplished through use-case scenarios (sometimes referred to as Design Reference Missions [DRMs]) and the ConOps.

10. NASA PRD Pavyzdys

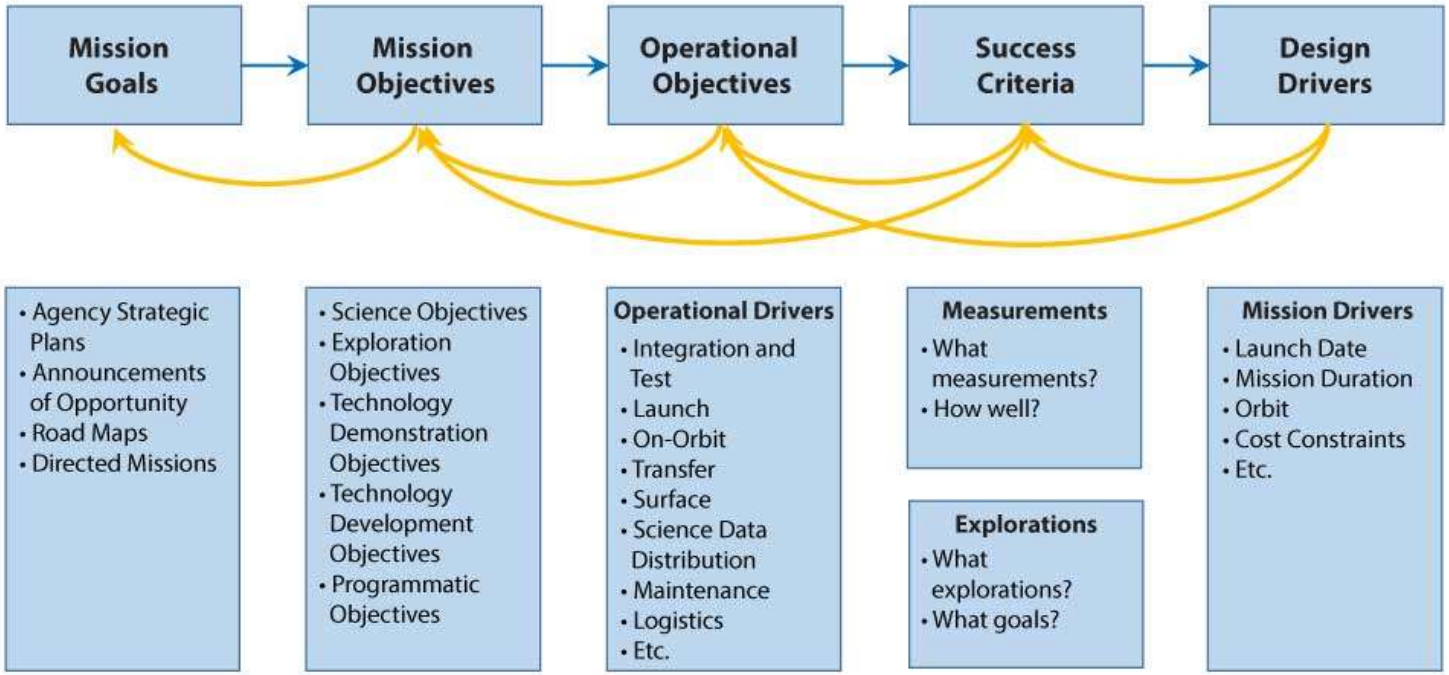


FIGURE 4.1-2 Information Flow for Stakeholder Expectations

10. NASA PRD Pavyzdys

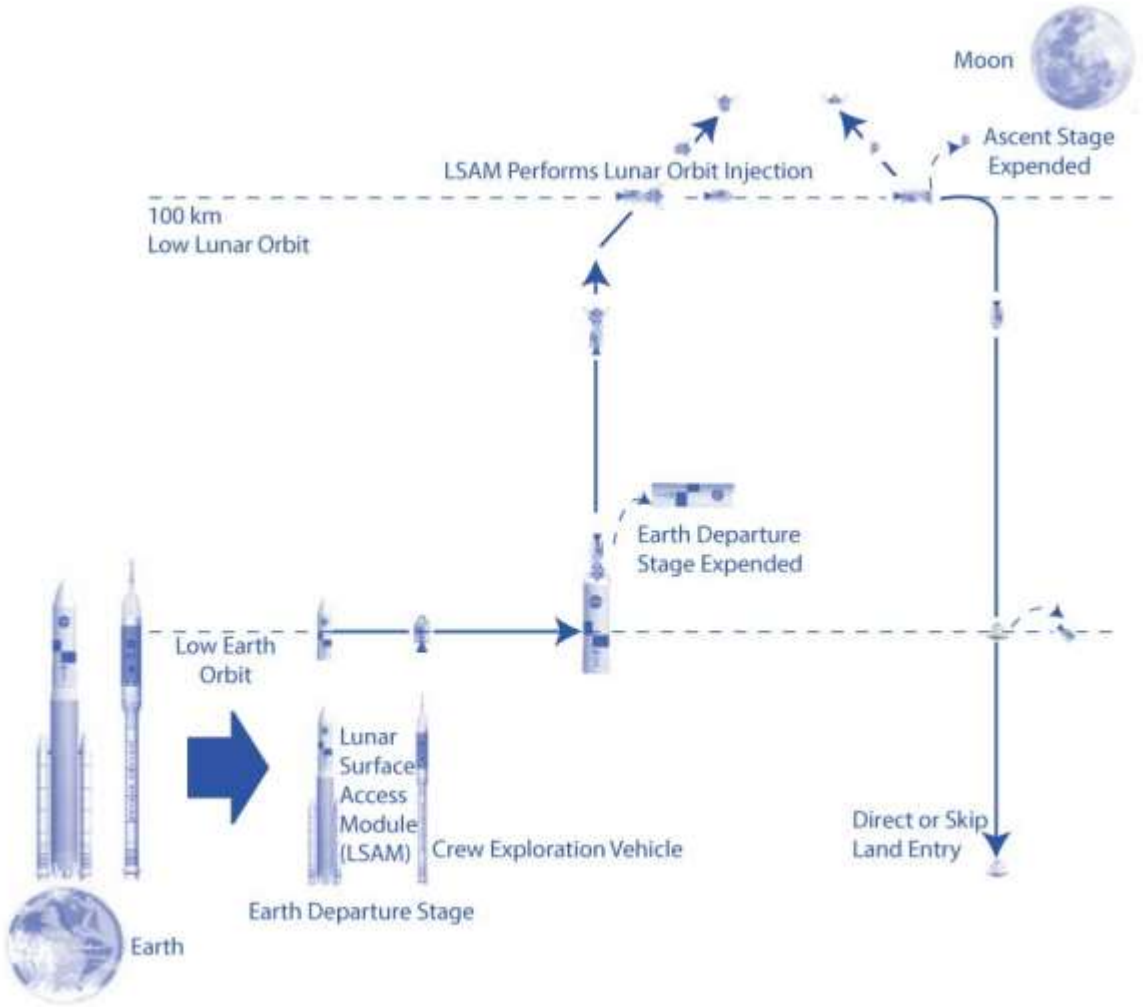


FIGURE 4.1-3 Example of a Lunar Sortie DRM Early in the Life Cycle

10. NASA PRD Pavyzdys

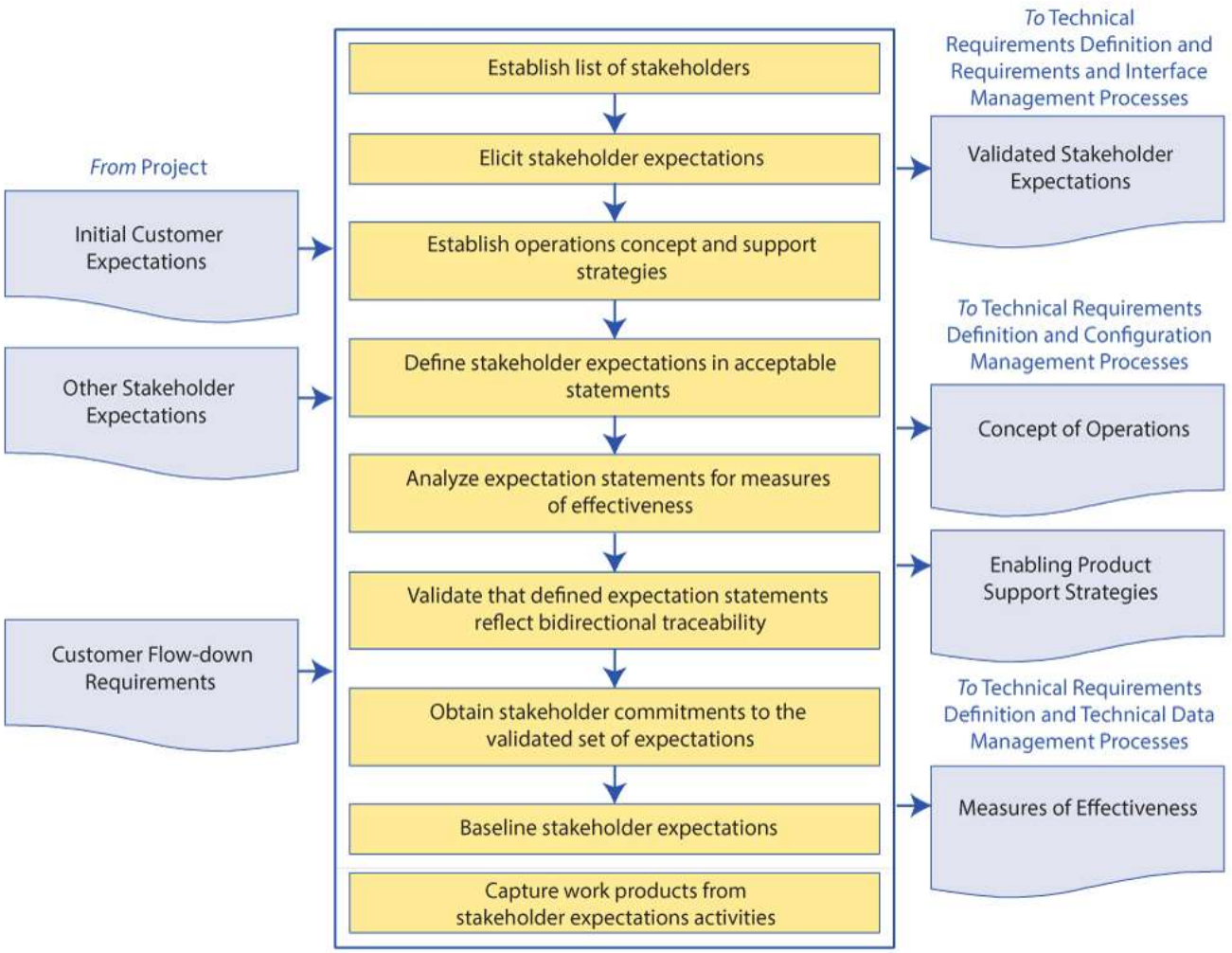


FIGURE 4.1-1 Stakeholder Expectations Definition Process

10. NASA PRD Pavyzdys

The Technical Requirements Definition Process transforms the stakeholder expectations into a definition of the problem and then into a complete set of validated technical requirements expressed as “shall” statements that can be used for defining a design solution for the Product Breakdown Structure (PBS) and related enabling products. The process of requirements definition is a recursive and iterative one that develops the stakeholders’ requirements, product requirements, and lower level product/component requirements. The requirements should enable the description of all inputs, outputs, and required relationships between inputs and outputs, including constraints, and system interactions with operators, maintainers, and other systems. The requirements documents organize and communicate requirements to the customer and other stakeholders and the technical community.

Technical requirements definition activities apply to the definition of all technical requirements from the program, project, and system levels down to the lowest level product/component requirements document.

10. NASA PRD Pavyzdys

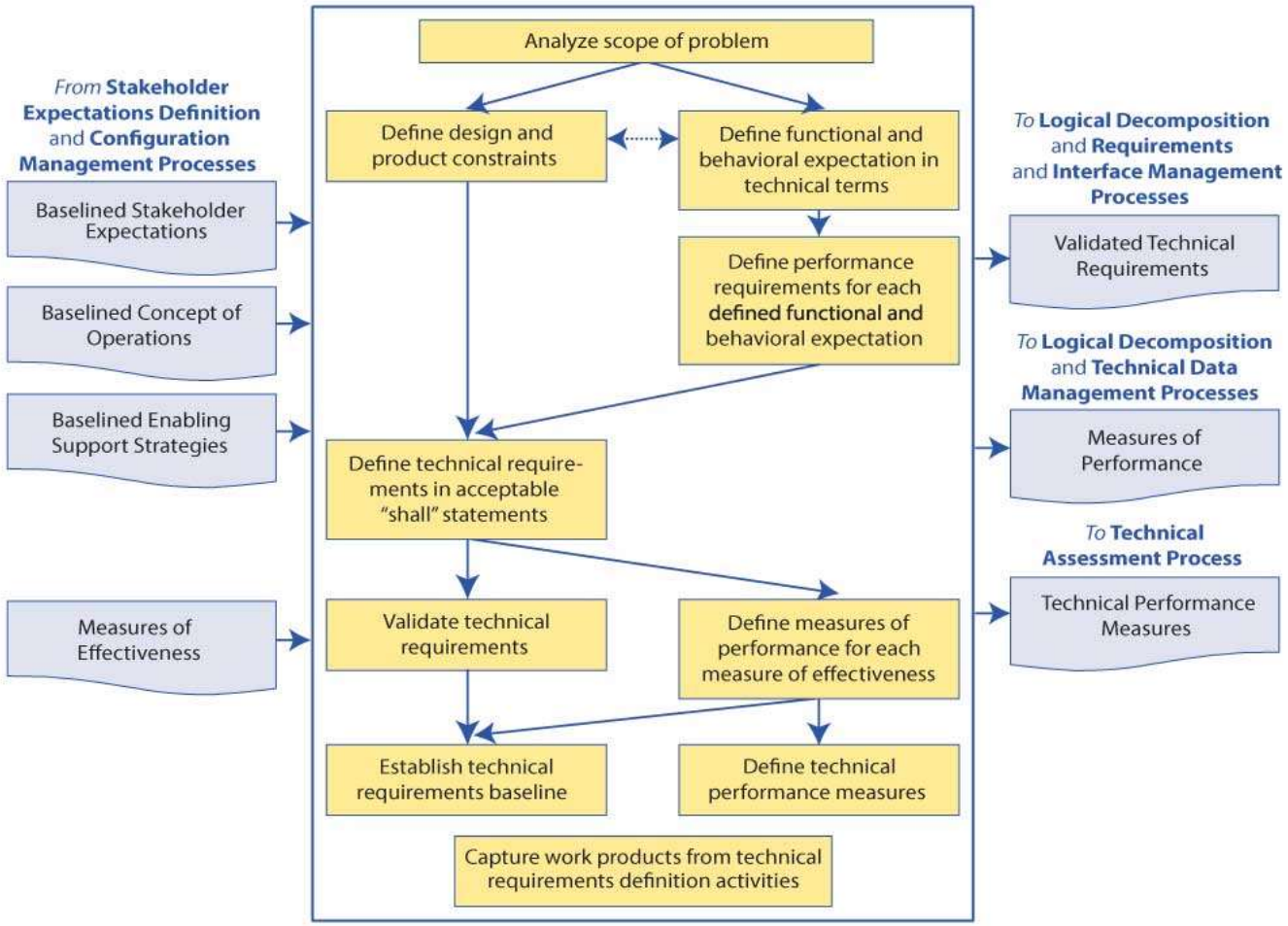


FIGURE 4.2-1 Technical Requirements Definition Process

10. NASA PRD Pavyzdys

A complete set of project requirements includes those that are decomposed and allocated down to design elements through the PBS and those that cut across product boundaries. Requirements allocated to the PBS can be functional requirements (what functions need to be performed), performance requirements (how well these functions should be performed), and interface requirements (product to product interaction requirements). Crosscutting requirements include environmental, safety, human factors, and those that originate from the “-ilities” and from Design and Construction (D&C) standards. Figure 4.2-2 is a general overview on the flow of requirements, what they are called, and who is responsible (owns) for approving waivers.

10. NASA PRD Pavyzdys

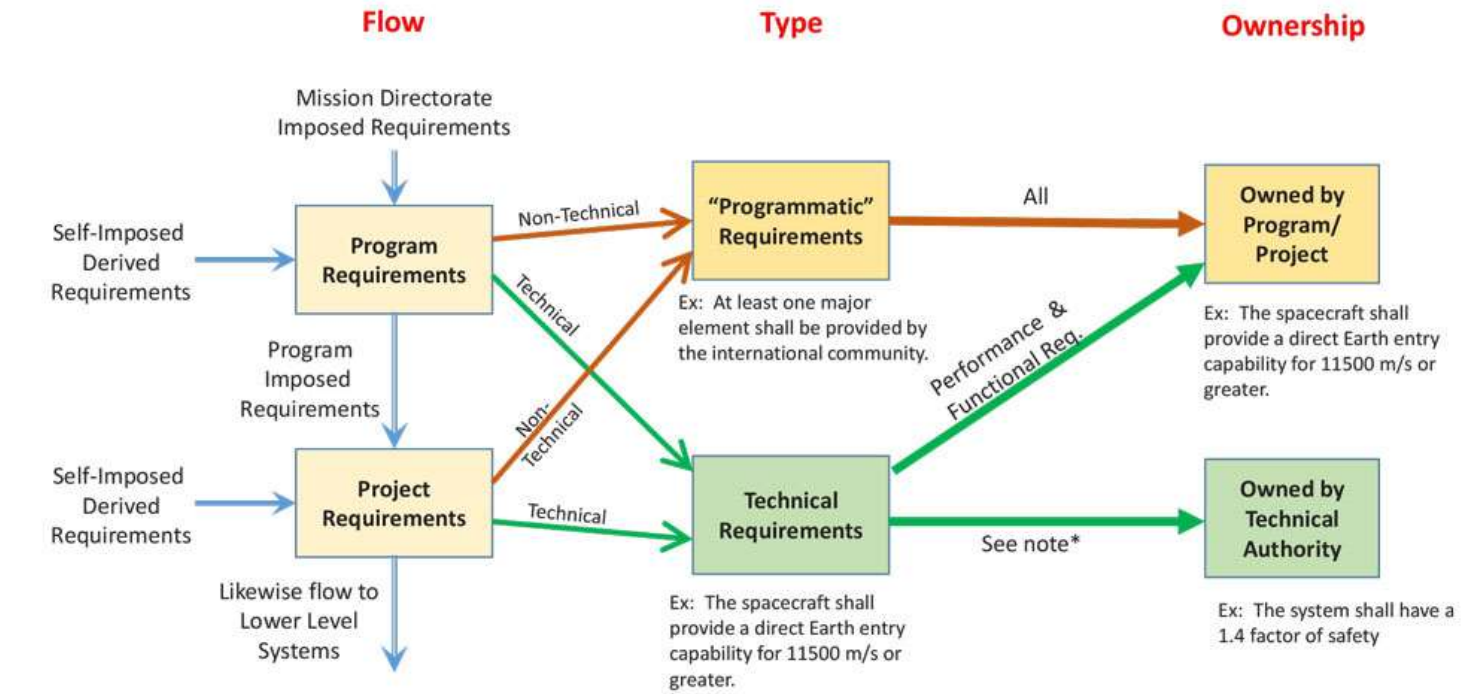


FIGURE 4.2-2 Flow, Type and Ownership of Requirements

10. NASA PRD Pavyzdys

Example of Functional and Performance Requirements
Initial Function Statement

The Thrust Vector Controller (TVC) shall provide vehicle control about the pitch and yaw axes.

This statement describes a high-level function that the TVC must perform. The technical team needs to transform this statement into a set of design-to functional and performance requirements.

Functional Requirements with Associated Performance Requirements

The TVC shall gimbal the engine a maximum of 9 degrees, ± 0.1 degree.
The TVC shall gimbal the engine at a maximum rate of 5 degrees/second ± 0.3 degrees/second.
The TVC shall provide a force of 40,000 pounds, ± 500 pounds.
The TVC shall have a frequency response of 20 Hz, ± 0.1 Hz.

10. NASA PRD Pavyzdys

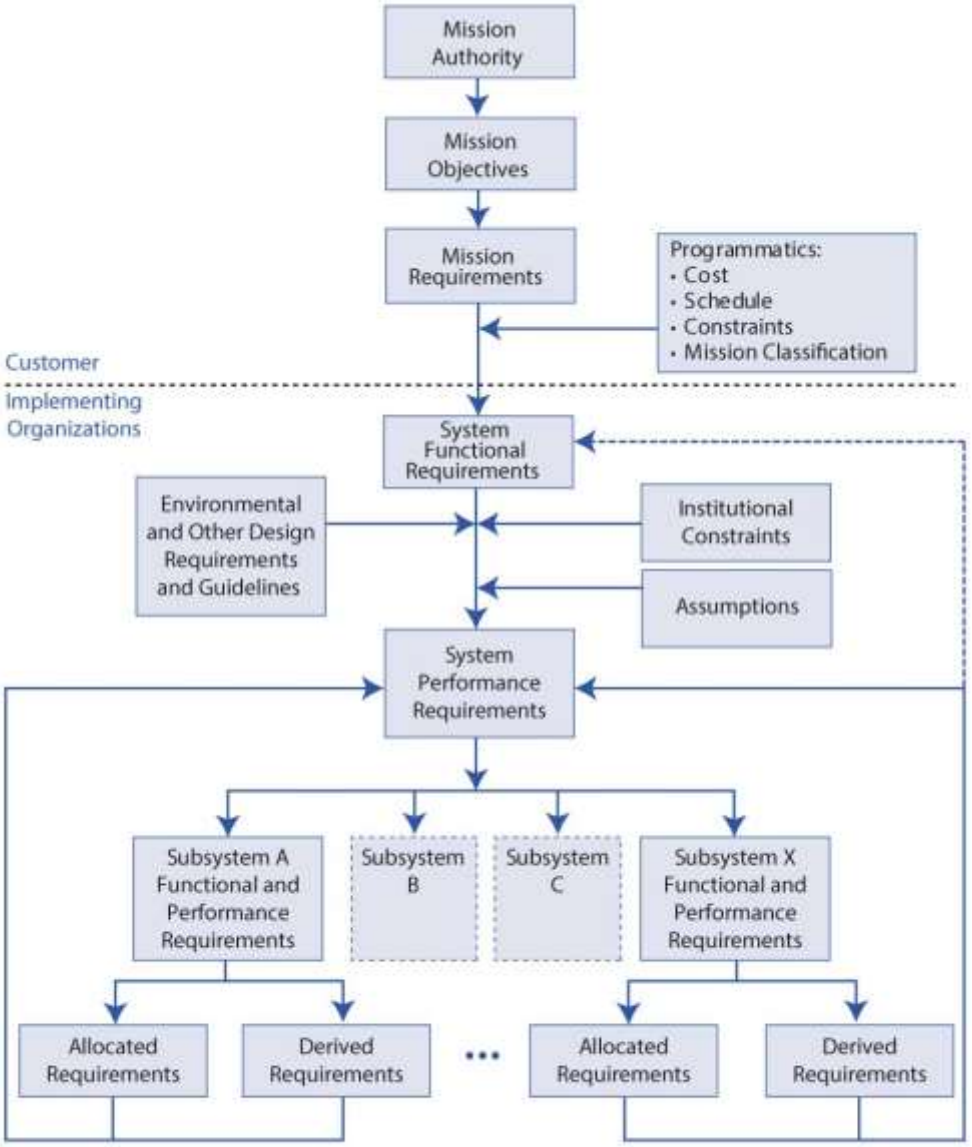


FIGURE 4.2-3 The Flowdown of Requirements

10. Kas yra reikalavimų atsekamumo matrica