



# Managing Requirements

Getting the Right Requirements Right

# Agenda

Why Requirements?

Writing Requirements

Requirements of Good Requirements

Where Do We Find Them?

Organizing Them



# Agenda

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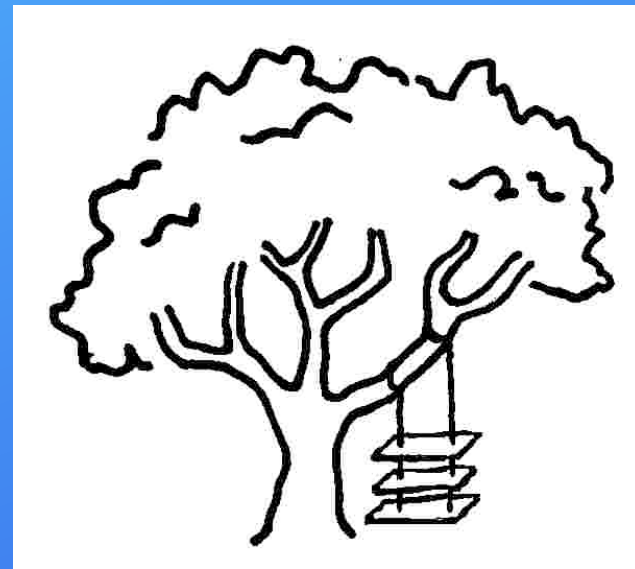


# Why Do We Need Requirements?

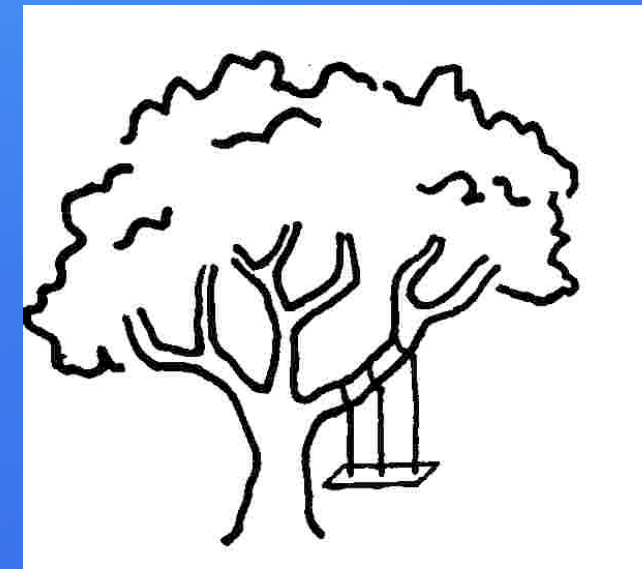
- Gathering and understanding requirements make projects more predictable
- Bad requirements historically account for most of the rework done later in the project
- Reducing the number of defects caused by poor requirements can yield a 7 to 1 return on investment



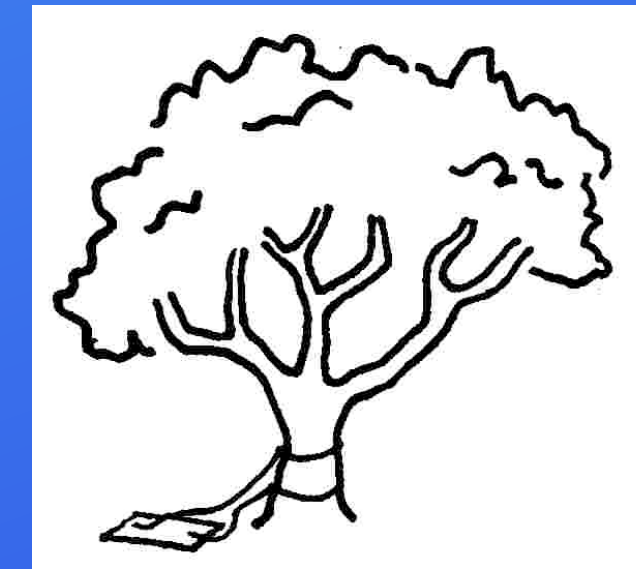
# Why Do We Need Requirements?



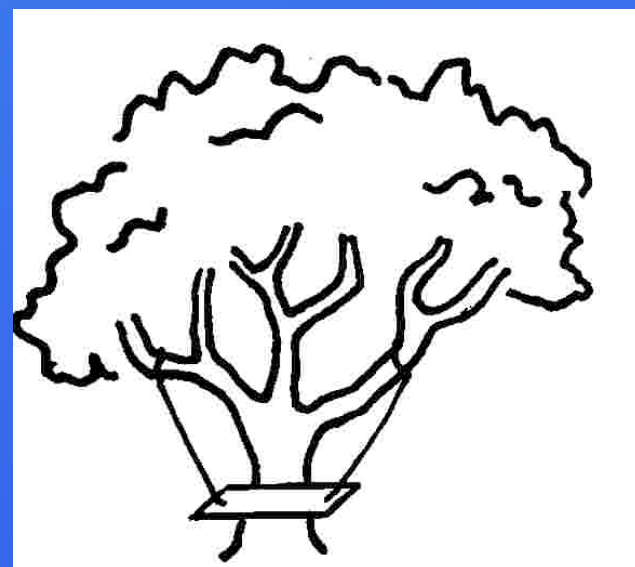
Marketing Specified



Management Approved



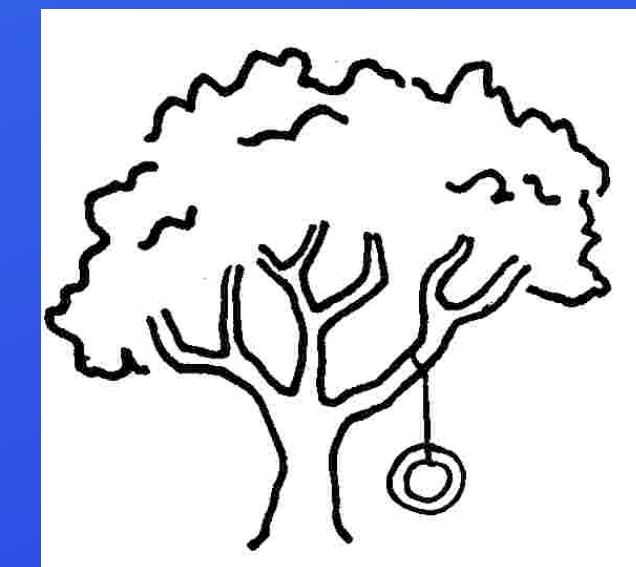
Engineering Designed



Manufacturing Built



Service Installed



Customer Wanted

# Why Are Requirements So Important?

Most Project Work is Best  
Driven By Requirements

- The product should provide only what is required of it, no more and no less
- Architecture and Design come directly from requirements
- All system-level tests relate directly to requirements



# Why Are Requirements So Important?

- Customer Acceptance Tests, Product Validation and System Verification are all based on meeting requirements
- This presentation deals with a more intensive, rigorous environment intended to develop large medical devices
  - Smaller projects or those for an unregulated industry will still benefit from many of these ideas

Good Management Practices, Good Engineering Practices



# Definitions

## Some Basics for Our Purposes

**Project** the management of people, material and procedures to produce a product

**Product** something our business or institution needs to produce

**System** the technical part of the product that we will design, build and test

## They Each Have Requirements



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# Types of Requirements

Let's consider two broad categories of Requirements for the Product and the System

- Functional • What the System will do
- Non-Functional • How well the System does it

Formal requirements are expressed with the word “shall”

# Examples

Functional • The automobile shall provide a mechanism to stop the motion of the vehicle

Non-Functional • The automobile shall be capable of coming to a complete stop in less than three seconds when moving at a speed of 100 km/h

# Examples

Functional • The System shall provide a self-destruct mechanism

Non-Functional • The self-destruct mechanism shall provide a delay of three seconds between the time of its activation and the time the system self-destructs

# Examples

Functional • The System shall start the process of producing electrons when the “Beam On” button is pressed

Non-Functional • The System shall provide a visual indication that the “Beam On” button has been pressed within 200 milliseconds of the button being pressed

# Common Pitfalls

- Anyone who has experience with or exposure to a certain technology tends to see requirements in terms of that technology
- It is common to place constraints on a solution for inconsistent reasons



# Common Pitfalls

Requirements need to specify what is required, not how it should be implemented

**X** The trend analysis system shall have a user interface running on Windows Vista using a standard Dell desktop computer

Backwards compatibility with existing systems should be treated as Design Constraints, not testable requirements





# Common Pitfalls

Requirements should be able to stand on their own,  
independent of the context in which they appear

 That software shall have an operating mode that  
complies with the following requirements

# Common Pitfalls

The System must be the subject of the requirement, not the user

-  The User shall be able to view beam diagnostics from a portable computer
-  The System shall provide beam diagnostics viewing software for use on a portable computer

# Examples

- ✗ The User Interface shall be easy to use
- ✓ The RFQ shall produce 3.5 MeV protons
- ✓ The beam pipe flange in the research area shall have a kapton window capable of supporting a pressure gradient of  $4 \times 10^{-3}$  Pa

# Examples



The User Interface shall be easy to use



The System shall be considered easy to use by at least 4 out of 5 trained dental assistants

# Examples

- ✘ The data access software shall support JSON as the data exchange format for web access
- ✘ The clinical couch shall be able to support extremely obese patients

# Words and Phrases to Avoid

among others

any

efficient

not limited to

rapid

simple

user-friendly

and so on

as well as

etc.

optimal

same as

state of the art

various

and / or

easy

improved

or

several

sufficient

# Words and Phrases to Avoid

acceptable  
and / or  
average  
improved  
optimum  
rapid  
safe  
simple  
timely

adequate  
any  
easy  
normal  
or  
reasonable  
same as  
state of the art  
typical

among others  
appropriate  
efficient  
not limited to  
possible  
reliable  
secure  
sufficient  
user-friendly

and so on  
as well as  
etc.  
optimal  
proper  
robust  
several  
suitable  
various



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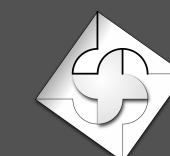
Where Do We Find Them?

Organizing Them



# What Makes a Good Requirement?

- **Understandable;** It must be communicated in a formal way
- **Measurable;** It must be testable to ensure it has been implemented
- **Feasible;** It must be possible for someone to implement



# What Makes a Good Requirement?

## Consistency

Requirements must not conflict with any other requirements at any level

Inconsistencies between them must be resolved before development can proceed

# What Makes a Good Requirement?

## Controlled

Requirements must be uniquely identified for the lifetime of the project

A history of changes made to each requirement should be maintained

Requirements are more usable and maintainable when related ones are kept together

# What Makes a Good Requirement?

There are several characteristics of good requirements

Traceable  
Unambiguous  
Verifiable  
Prioritized  
Correct  
Focused  
Necessary

# Requirements of Good Requirements

Correct  
Necessary  
Focused  
Verifiable  
Traceable  
Unambiguous  
Prioritized

Good Requirements Will  
Exhibit These Characteristics



# Requirements of Good Requirements

Correct  
Necessary  
Focused  
Verifiable  
Traceable  
Unambiguous  
Prioritized

The best way to ensure correctness is to have experts review the requirement

# Requirements of Good Requirements

Correct  
Necessary  
Focused  
Verifiable  
Traceable  
Unambiguous  
Prioritized

Is the requirement really required? Determine where the it came from and ensure it was from a source of authority. Reduce “gold-plating” by repeatedly asking *Why* until you find the source



# Requirements of Good Requirements

Correct  
Necessary  
**Focused**  
Verifiable  
Traceable  
Unambiguous  
Prioritized

A requirement should address  
a single, testable need

Break compound requirements  
into separate statements

# Requirements of Good Requirements

Correct  
Necessary  
Focused  
Verifiable  
Traceable  
Unambiguous  
Prioritized

Each requirement has to be testable

We need to know if the requirement has been met

# Requirements of Good Requirements

Correct  
Necessary  
Focused  
Verifiable  
**Traceable**  
Unambiguous  
Prioritized

Each requirement needs a reference to its source. Also, the tests which verify that a requirement has been met and the designs to implement the requirement need to reference that requirement

# Requirements of Good Requirements

Correct  
Necessary  
Focused  
Verifiable  
Traceable  
Unambiguous  
Prioritized

Someone reading the requirement must be able to draw only one conclusion from it.  
Different stakeholders must arrive at the same interpretation



# Requirements of Good Requirements

Correct  
Necessary  
Focused  
Verifiable  
Traceable  
Unambiguous  
Prioritized

Each requirement should have an indication of priority, ideally with only a few (3) levels

# What Makes a Good Requirement?

## Traceable

Requirements shall provide a way to reference a more general source, such as a higher-level (product) requirement or a Use Case

Links (references, dependencies) can be made to requirements from design elements, test cases and other artifacts coming later in the development process

# What Makes a Good Requirement?

## Prioritized

Critical, high-priority requirements are visible and can be met within given cost and schedule constraints

Lower priority requirements can be postponed if necessary.

# Requirements

need to include Attributes

Traceability, Priority and most qualities imply that one or more attributes are saved with each Requirement

We need to keep this information with each Requirement for all stakeholders to see

Some attributes are not really optional



# Requirements

need to include Attributes

- Requirement Text
- Unique ID
- Requirement Type
- Summary Phrase
- Rationale (justification)
- Originator
- Fit Criterion
- Priority
- Customer Satisfaction Index
- Customer Dissatisfaction Index
- History
- Conflicts

# Customer Satisfaction

The degree of happiness if this requirement has been successfully implemented in the product

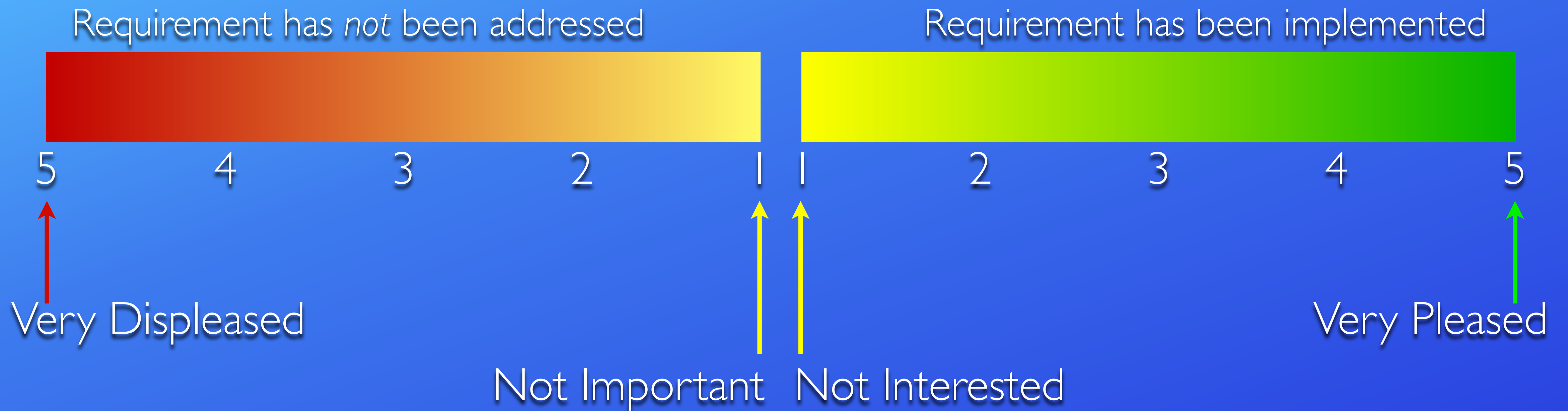


# Customer Dissatisfaction

Measure of unhappiness if this requirement is missing from the final product



# The Customer Perspective



# Non-Functional Requirements

Qualities of Good Requirements  
and the attributes associated with them  
are used for both Functional  
and Non-Functional Requirements



# Non-Functional Requirements

Non-Functional Requirements address the qualities that the System must possess, essentially describing how well the System will perform its Functional Requirements



# Non-Functional Requirements

Non-Functional Requirements are critical to  
the success of the product

Not just performance, but usability and the  
product's look and feel

# Non-Functional Requirements

Access

Appearance

Extensibility

Internationalization

Maintainability

Privacy

Reliability and Availability

Scalability

Style

Accessibility

Capacity

Fault Tolerance

Learning (Training)

Personalization

Productization

Robustness

Security

Supportability

Adaptability

Ease of Use

Integrity

Longevity

Precision or Accuracy

Release

Safety-Critical

Speed and Latency

Understandability



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# Requirements

Where do they come from?

**Project** requirements come from cost, schedule and “performance” goals

**Product** requirements come from marketing research and customer needs

**System** requirements are derived from product and project requirements



# Requirements

some examples

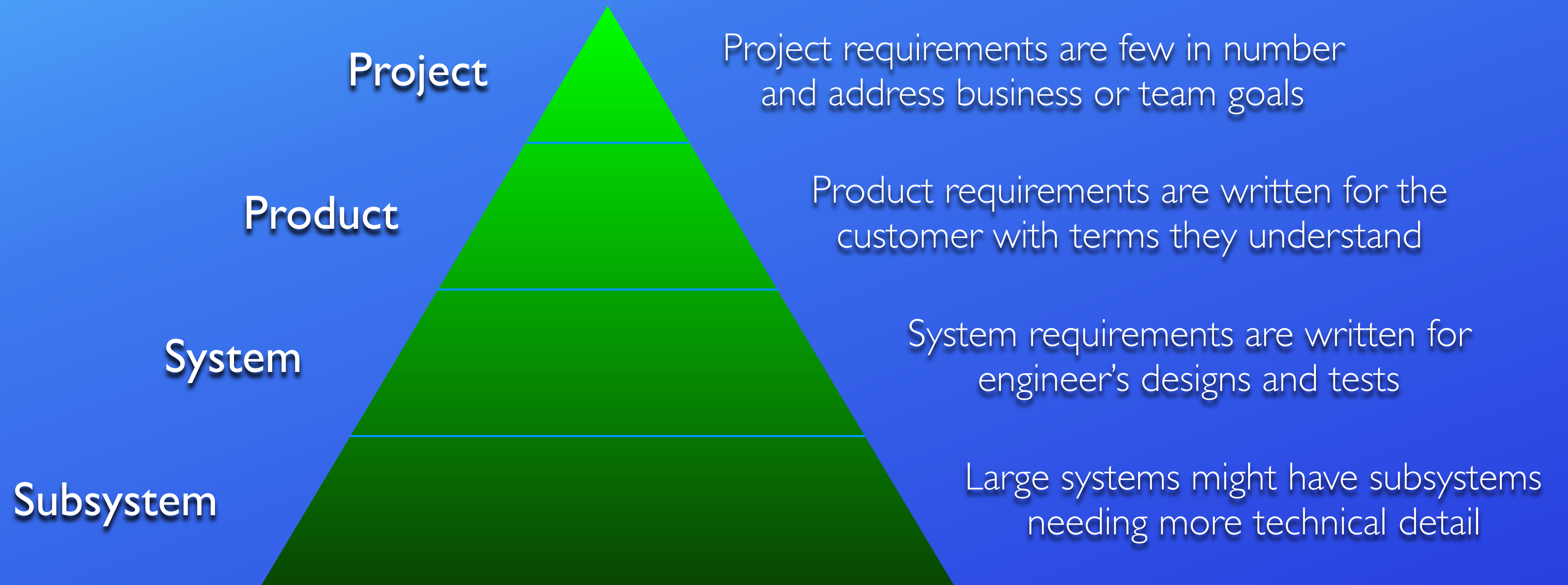
**Project** The Super Duper CT product will sell for \$300,000 and accommodate larger patients

**Product** The SDCT product can image patients weighing 380 lbs

**System** The System shall provide a patient imaging table capable of supporting patients in a supine position weighing 380 pounds or less

# Requirements

from general to specific needs



# Where Do Requirements Come From?



Typically from Marketing - “the Voice of the Customer”

- From previous personal experience
- From interactive workshops with experts
- From direct observation in a daily work setting
- From insight, interpolation, understanding, abstraction

# Where Do Requirements Come From?



- Use Case Analysis
- Brainstorming
- Customer Feedback and Specific Requests
- Corrective and Preventative Action Reports (CAPA)
- Competitive Reviews

# Where Do Requirements Come From?

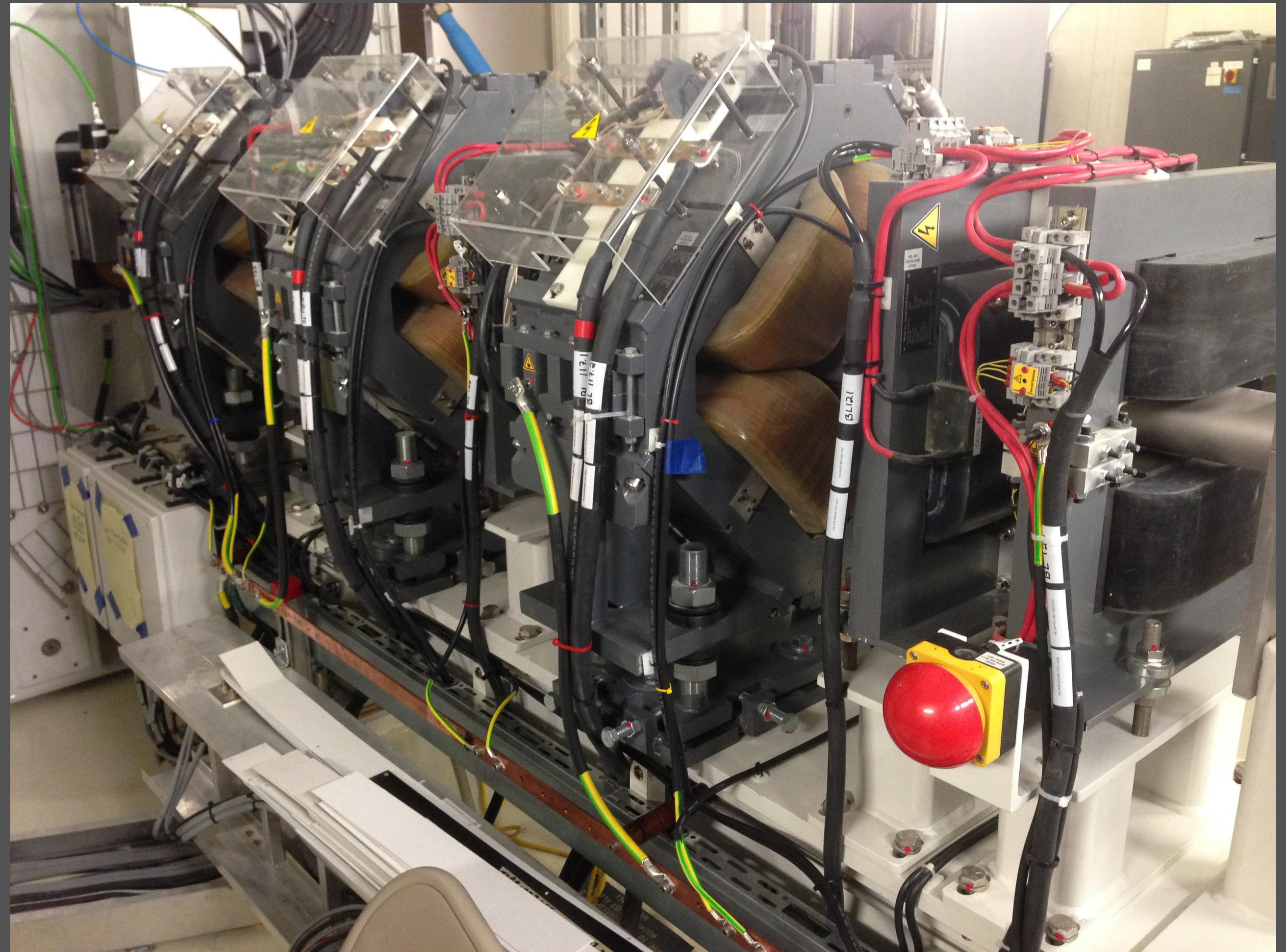
- High-level Requirements come from business strategy, market research and “the voice of the customer”





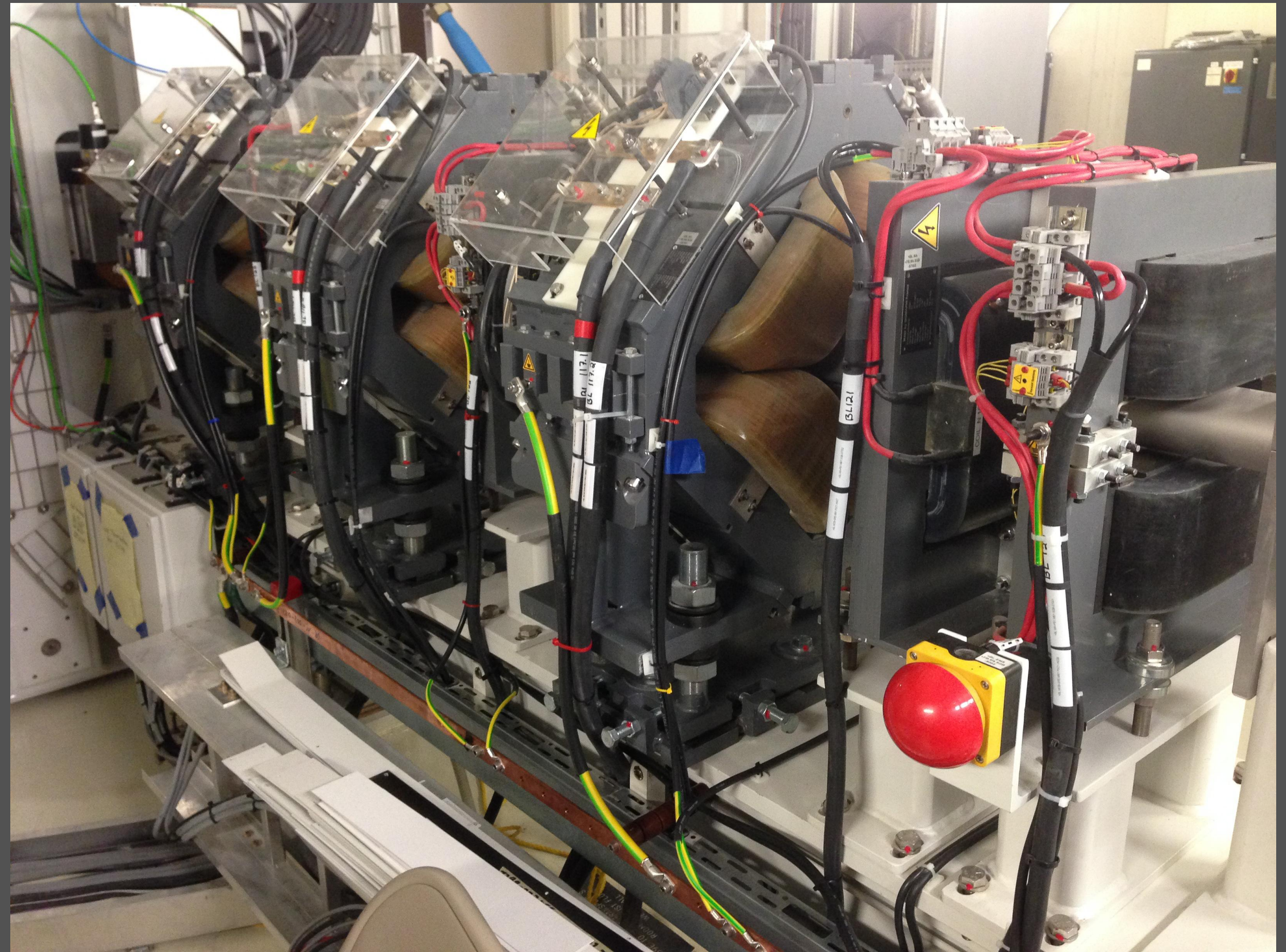
# Where Do Requirements Come From?

- High-level Requirements come from business strategy, market research and “the voice of the customer”
- Lower-level Requirements can be based on customer input only if they understand specific technologies or specifications that are important to *their* business



# Where Do Requirements Come From?

- Lower-level Requirements come from technical experts, based on the Product or Customer high-level requirements
- These experts will translate informal requirements into formal ones that are unambiguous and testable, and able to be realized by way of a buildable system



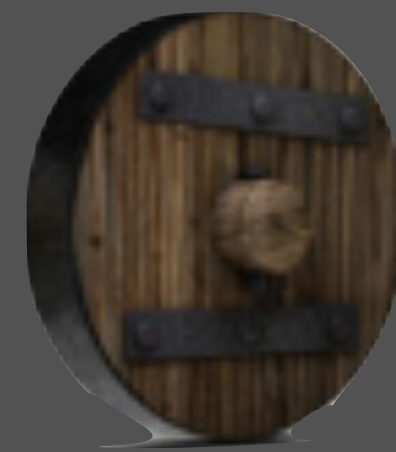
# Where Do Requirements Come From?

Management will suggest that once in place, requirements need never change

*“...we’ve already built this, why look for new requirements for something we already understand?”*

## Why re-invent the wheel?

To Improve! We want steel-belted radial tires



# How Do We Gather Requirements?

first steps, gather the most general ones

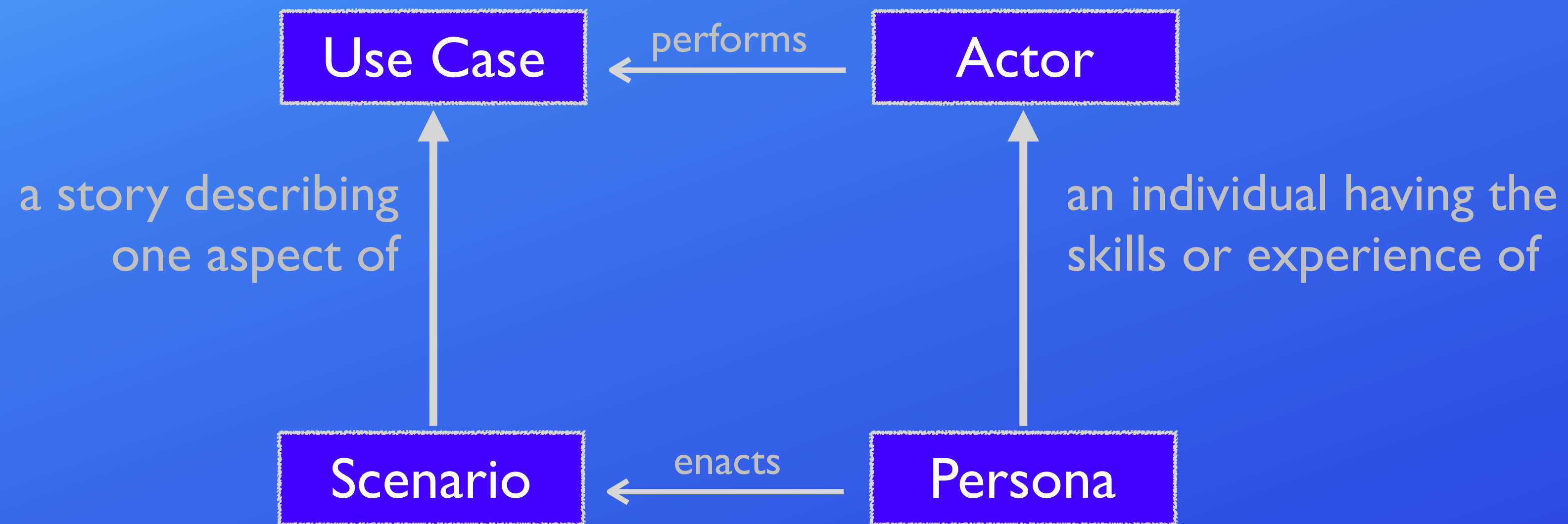
- |          |   |
|----------|---|
| Actor    | ✓ Identify the stakeholders of the product, the roles they play |
| Use Case | ✓ Discover the actions the system must perform for them         |
| Persona  | ✓ Think of specific individuals in each of those roles          |
| Scenario | ✓ Consider how the system operates as those individuals work    |

# How Do We Gather Requirements?

examples

|          |  |
|----------|--|
| Actor    | Radiotherapist   |
| Use Case | Position patient on treatment table  |
| Persona  | Jennifer, 32 year old female Oncologist, working in RT role this day   |
| Scenario | She brings an obese patient in a wheelchair to the couch, lowers it to its lowest point. She decides to request help from Jim, her associate to transfer the patient to the couch. |

# How Do We Gather Requirements?



# How Do We Gather Requirements?

|          |   |
|----------|---|
| Actor    | The <i>types</i> of users involved with the Use Case  |
| Use Case | Describes activities the product needs to perform   |
| Persona  | Specific but fictitious individuals involved with the scenario's story                                  |
| Scenario | Detailed account of how that individual makes use of the system, told as a story using natural language |

# How Do We Gather Requirements?

## Actor

Requirements exist to satisfy *all* stakeholders. Identify the roles played by people that will interact directly with the System, or be affected by it. That could include managers expecting reports from it, or patients expecting treatment from it.

## Use Case

A good set of Use Cases helps ensure that we're not missing any requirements. Without Use Cases, the missing requirements are hard to find because they have no source or basis in necessity



# How Do We Gather Requirements?

Requirements should be traceable back to the  
Use Cases and Scenarios that inspired them

Functional Requirements are often gleaned from Actors and Use Cases  
Non-Functional Requirements are often gleaned from Personas and Scenarios



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# How Do We Organize?

Functional Requirements are usually determined first, but requirements gathering is an iterative process

Architecture, Design or Development work can start when only a few functional requirements are understood

Beware - Requirements and the development work that they trigger can change, especially at the project's start!

# Organizing Requirements

- Requirements will ultimately be recorded and stored with their attributes in a repository
- Requirements should be organized in a way that helps engineers, testers, quality assurance experts and other stakeholders do their work

# Organizing Requirements

- Modern software tools will generate documents (artifacts) based on the repository content
- They will also provide version control for each requirement
- These tools can also provide stakeholders with custom views of the requirements



# Organizing Requirements



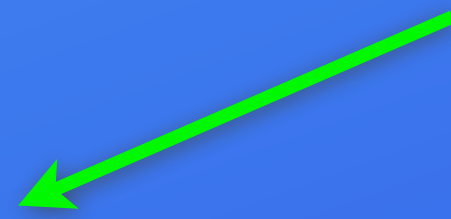
Entry



View for Document Control



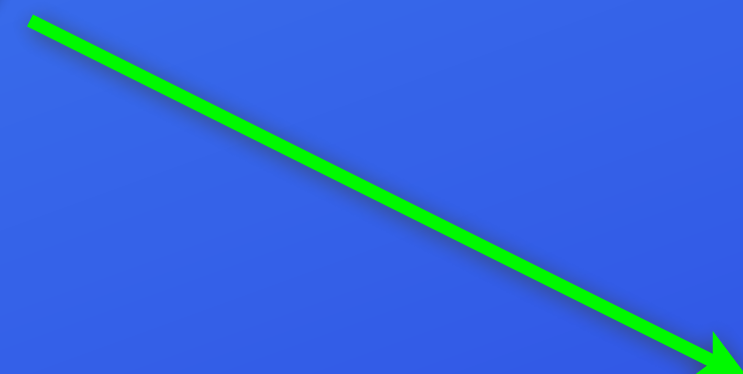
View for QA



View for Engineering



View for Service



# Organizing Requirements

Some projects need to maintain other requirements-related information which is not specific to any single requirement

- Project Drivers
- Project Constraints
- Project Issues
- Design Constraints

By keeping additional sections in the repository, more complete and useful documents can be generated



# Organizing Requirements

Functional  
Non-Functional  
Project Constraints  
Design Constraints  
Project Drivers  
Project Issues

These categories ensure the requirements are grouped logically so engineers can easily find them and documents are easily maintained

# Organizing Requirements

Functional  
Non-Functional  
Project Constraints  
Design Constraints  
Project Drivers  
Project Issues

They also make it easier to develop complete architectures and designs, development plans, good test plans and protocols. All but the first two are optional.

# Organizing Requirements

Functional

Non-Functional

Project Constraints

Design Constraints

Project Drivers

Project Issues

The fundamental, essential subject matter of the product. They describe what the product has to do or the processing actions it must take

# Organizing Requirements

Functional

Non-Functional

Project Constraints

Design Constraints

Project Drivers

Project Issues

The properties that the functions must have, such as performance, usability or security. These are often referred to as qualities of the product.

# Organizing Requirements

Functional

Non-Functional

Project Constraints

Design Constraints

Project Drivers

Project Issues

These remaining categories don't provide true requirements, but can be used to better communicate those things that affect the requirements

# Organizing Requirements

Functional

Non-Functional

Project Constraints

Design Constraints

Project Drivers

Project Issues

These are restrictions on the product such as the budget or time available to build it, market assumptions, naming conventions and more

# Organizing Requirements

Functional

Non-Functional

Project Constraints

Design Constraints

Project Drivers

Project Issues

These are technical constraints upon the design, often from legacy issues; use a 4-20 mA signal, using TTL level logic or being backwards compatible with an existing API

# Organizing Requirements

Functional

Non-Functional

Project Constraints

Design Constraints

Project Drivers

Project Issues

The business related forces driving the project forward. Trade shows, market changes, supplier schedules



# Organizing Requirements

Functional  
Non-Functional  
Project Constraints  
Design Constraints  
Project Drivers  
Project Issues

The business related forces holding the project back, or impacting its success. Project risks, postponed requirements, upgrade paths

# Organizing Requirements

At the System level or lower, Functional Requirements are kept separate from Non-functional ones

Non-functional requirements will probably change more often than Functional ones during the development process.

Keeping them separate can make documents easier to maintain and tests easier to repeat

# How Do We Organize?

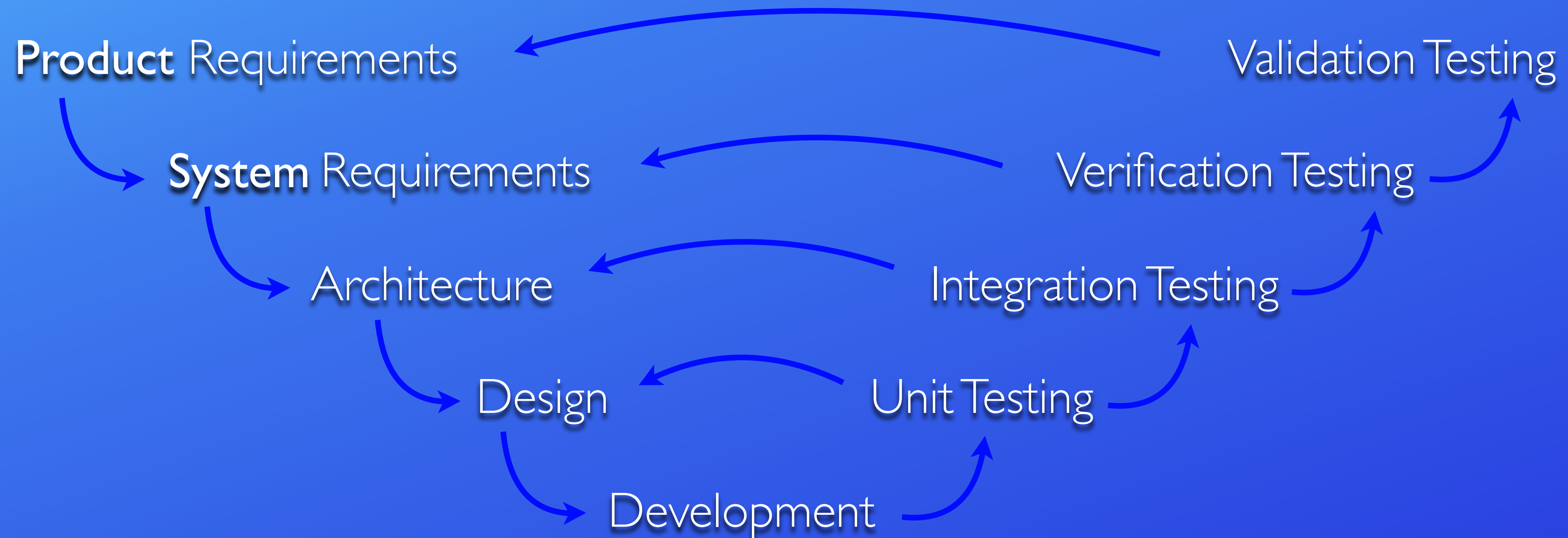
**Project** requirements are informal and often communicated through a concept document

**Product** or customer requirements are a bit more specific, communicated through a requirements document

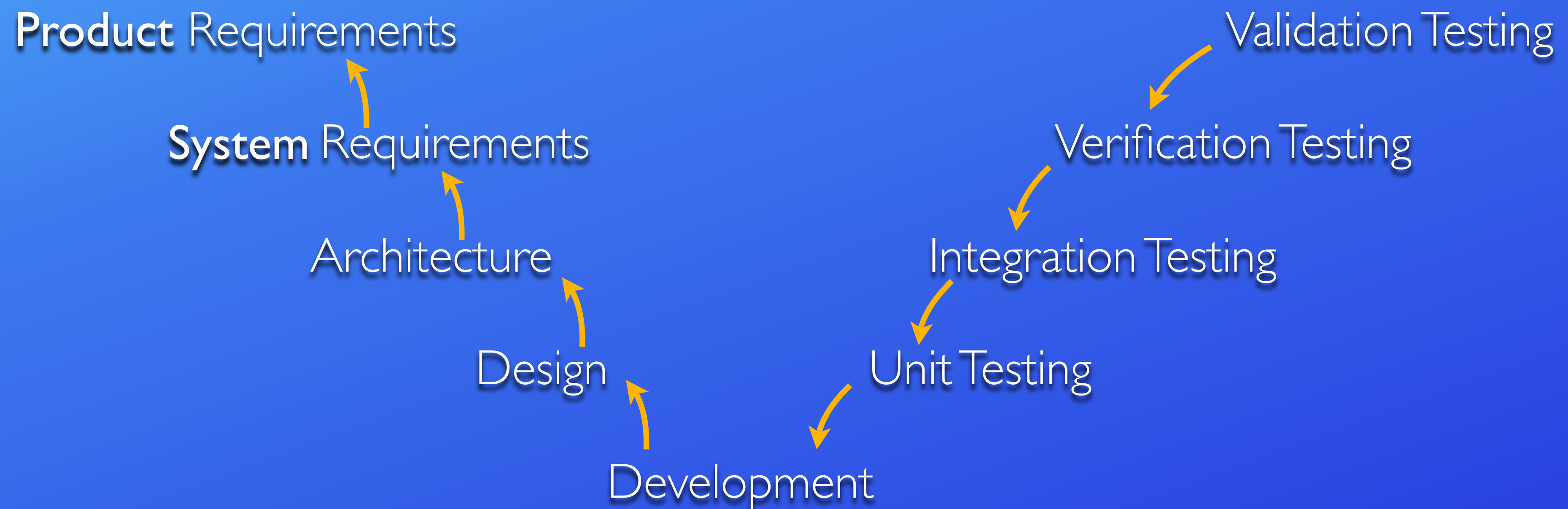
**System** requirements are quite formal and require thorough review, especially in regulated environments

# Project Model

Requirements play a crucial role in the “V” process

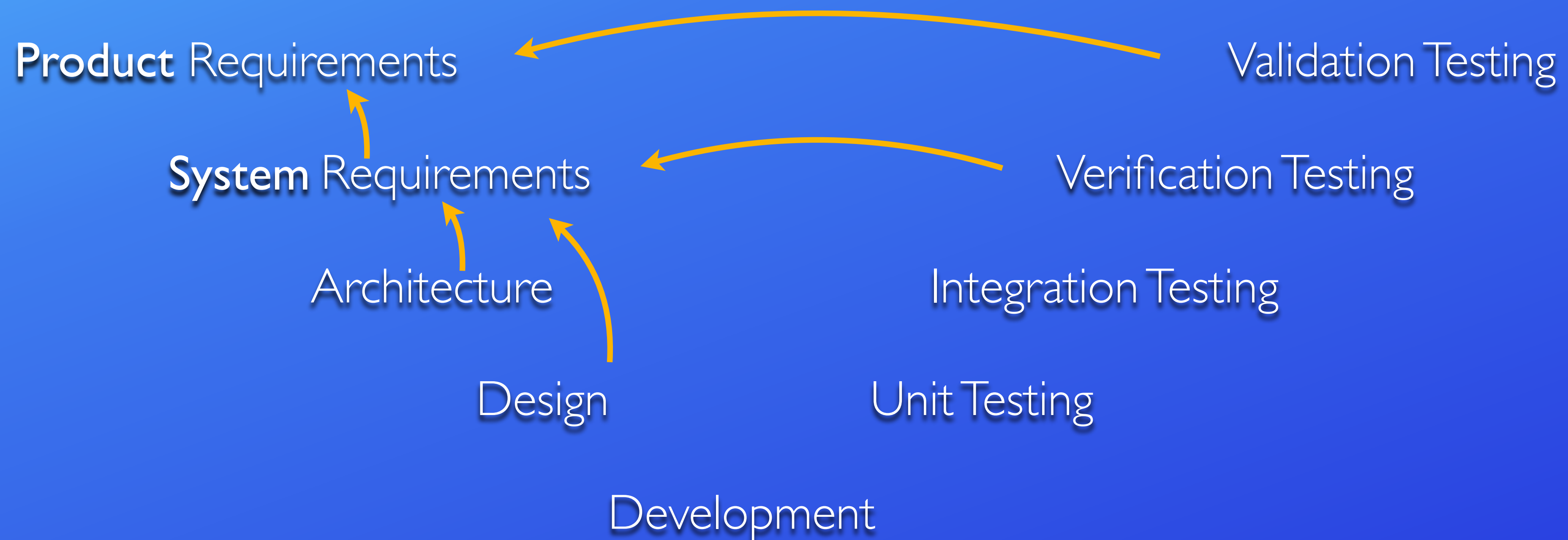


# Dependencies

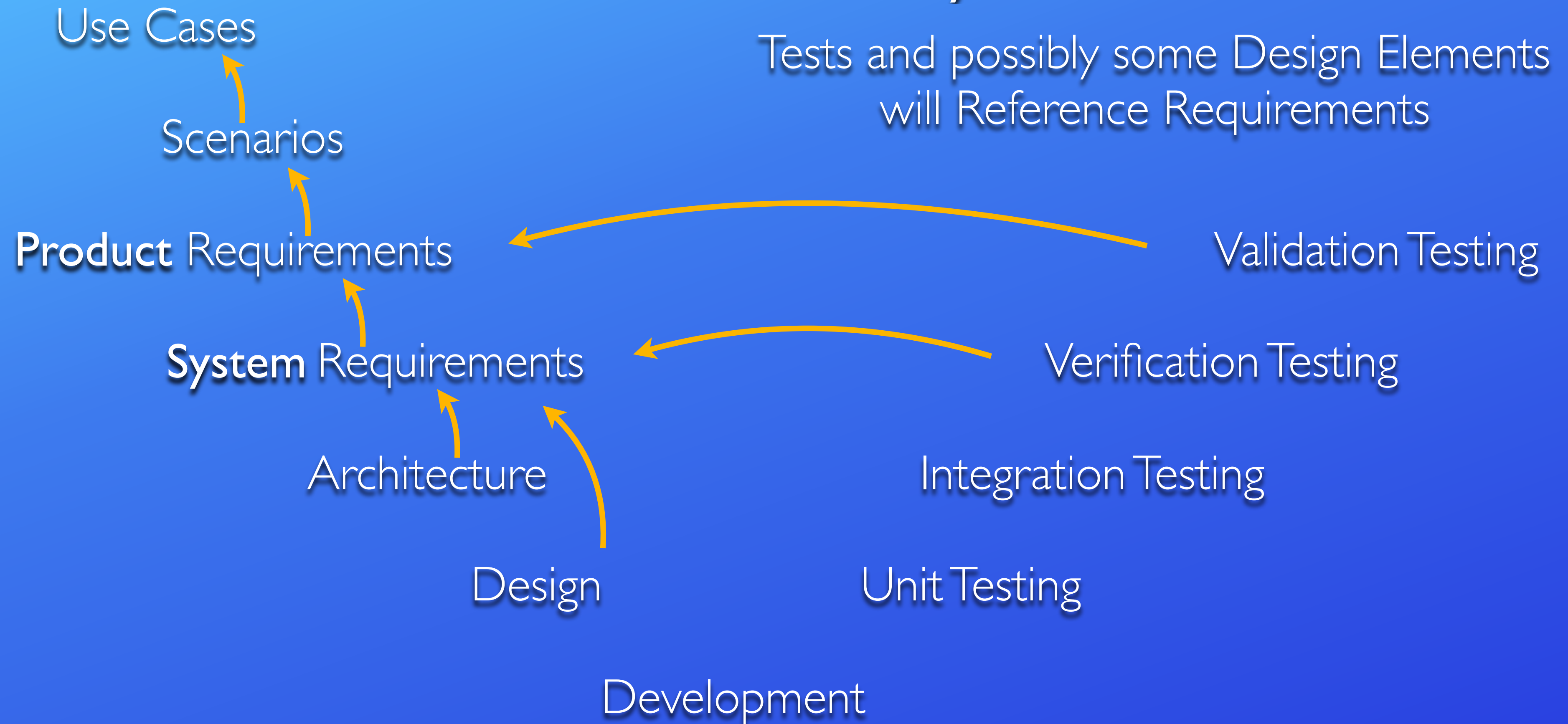


# Traceability

Tests and possibly some Design Elements will Reference Requirements



# Traceability



# V & V

- Verification tells us that we've built the system right
- Validation tells us the we've built the right system



# Organizing Requirements

A Product Requirements Document  
Describes the Intended Use of the Product

A System Requirements Specification describes what  
the System will do and how well it will do it

For larger systems, subordinate Requirements Documents describe  
enough detail to build a testable subsystem

# Organizing Requirements

A Product Requirements Document  
Describes what we will Validate

A System Requirements Specification indicates  
What to Test in the Verification Process

Subordinate Requirements Documents describe  
What must be Tested to Enable Verification

# Organizing Requirements

- At some point in time, requirements are reviewed and a “baseline” established
- Requirements will still change or be added
- After the baseline has been set, changes will affect the project’s schedule and cost
  - Each change must be reviewed and the impact considered



# Organizing Requirements

- A Complete end-to-end Requirements Specification is a daunting task, especially for complex or large systems
- Requirements Specification must be a team effort

None of us is as smart as all of us

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# Managing Requirements

Thank you for your attention