Solution-Neutral Problem Statement and Task Clarification

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TASK CLARIFICATION

There are two important steps in the task clarification phase of the design process:

- Preparing a problem statement
- Elaborating a specification

PREPARING A PROBLEM STATEMENT

To avoid solving the wrong problem, it is wise to spend some time identifying the true needs and preparing a **solution-neutral problem statement** which avoids any indication of how the problem should be solved. A useful technique is to systematically raise the level of abstraction.

LAWN MOWER

Consider the problem statement:

> " *Design a 1kW lawn-mower to replace last year's 300 mm cylinder model. It must be powered by mains electricity, weigh not more than 10 kg, collect the grass cuttings and be quiet in operation.* "

This statement clearly indicates the direction of the solution.

A solution-neutral problem statement may be derived by successive abstraction:

- Replace *last year's model*
- Design a *lawn-mower*
- Create a *device* to *cut grass*
- Devise a means of keeping the *grass short*
- Plan a way of keeping the garden looking *pleasant*

increasing abstraction

ASTHMATIC INHALER

Consider another problem statement:

> " *Design an asthmatic inhaler for children based upon the 200 dose MDI inhaler.* "

This statement also indicates the direction of the solution.

A solution-neutral problem statement may be derived by successive abstraction:

- Modify an *MDI* *inhaler* for use by children
- Design an *easy-to-use* inhaler
- Create a *device* to rapidly *alleviate* asthma symptoms
- Devise a means of *preventing* asthma in children
- Reduce airborne *pollution*

increasing abstraction

DRAUGHT BEER IN A CAN

Consider yet another problem statement:

“ *Develop a ‘widget’ to enable draught bitter in a can to taste like the keg draught.* ”

This statement also indicates the direction of the solution.

A solution-neutral problem statement may be derived by successive abstraction:

- Develop a *widget* for use in a can of bitter
- Develop a means of creating a *good head* from a canned bitter
- Develop a *new beer*
- Develop a *refreshing drink* *alco pops*

increasing abstraction

FEMALE CONDOM

Consider another problem statement:

“ *Develop a polyurethane female condom.* ”

This statement also indicates the direction of the solution.

A solution-neutral problem statement may be derived by successive abstraction:

- Develop a *polyurethane* *female* condom
- Develop a *contraceptive* for use by *women*
- Create a means of *preventing* conception

increasing abstraction

ABSTRACTION

Abstraction has the following steps:

- *Eliminate requirements which have no direct bearing on the function and essential constraints*
- *Transform quantitative statements into qualitative ones*
- *Formulate the problem in solution-neutral terms at the appropriate level of generality*

Abstraction increases the search space.

ELABORATING A SPECIFICATION

It is now wise to limit the search space by preparing a detailed list of all the requirements and constraints.

The following are important when preparing a specification:

- *Adopting a clear structure (checklist)*
- *Quantifying whenever possible*
- *Identifying demands and wishes*
- *Indicating sources of statements*
- *Reviewing and updating regularly, and recording changes*

To help structure a specification, a checklist may be used such that from ‘Systematic Design - A Structured Approach’ by Pahl and Beitz.

Where possible use quantified statements. For example, ‘Height not to exceed 90 mm with MDI can loaded’ is much better than ‘Small enough to fit a child’s hand’.

ELABORATING A SPECIFICATION

To aid selection and evaluation of possible solution concepts it is useful to identify each requirements statement as being either:

- a demand (D) - *a requirement which must be fulfilled*
- a wish (W) - *a requirement which is desirable, but not essential*

It is useful to indicate the weighting (*Wt*) of wishes as high (H), medium (M) or low (L) importance. *may use a numeric scale*

The demands in the specification provide the criteria for a preliminary selection, and the wishes provide the criteria for evaluation.

The source of a requirement should be recorded and any subsequent changes logged.

THE REQUIREMENTS SPECIFICATION

There are three types of requirements:

- ***technical*** **requirements** - the functional and performance requirements of the product
- ***business*** **requirements** - cost, scheduling, and other managerial requirements
- ***regulatory*** **requirements** - governmental laws, industrial standards, or product regulations

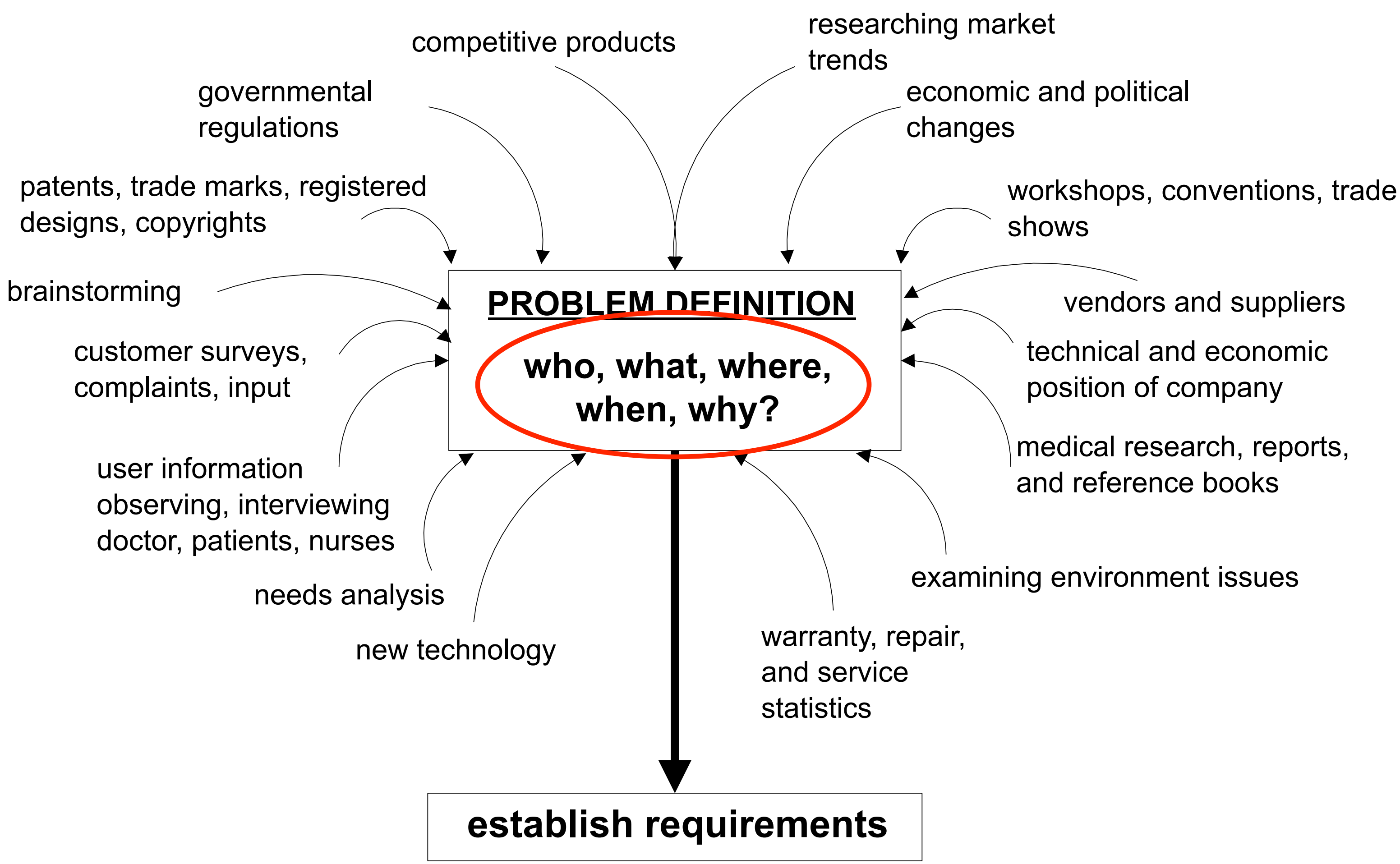
DESIRED CHARACTERSITICS OF REQUIREMENTS

Requirements should be:

- ***solution independent*** - requirements should not specify a solution to the problem; they should specify what needs to be done, but not how it will be done.
- ***complete*** - the requirements must include all areas of concern, including all phases of the product life cycle.
- ***clear*** - requirements should not leave anyone guessing what is required.
- ***concise*** - unnecessary requirements should be omitted; the wording of requirements should be concise – do not bury the requirement in unneeded text.
- ***testable*** - Quantitative (numerical) limits, tolerances, ranges, and intended values should be indicated when possible; testable requirements can be measured in order to determine if the design goal is met.

DEFINE THE PROBLEM

The information used to define the problem comes from many different sources.



DEFINE THE PROBLEM

After gathering this information, write down:

- **WHO?** Who will be using the product?
  Who will be affected by the product?
- **WHAT?** What must the product do?
  What needs must it serve?
- **WHERE?** Where will the product be used?
- **WHEN?** When will the product be used?
- **WHY?** Why will the product be used?

LAWN MOWER

After gathering this information, write down:

- **WHO?** *home owner*
- **WHAT?** *need to cut grass*
- **WHERE?** *Home*
- **WHEN?** *every two weeks during the summer months*
- **WHY?** *to keep the garden looking tidy*

DRAUGHT BEER IN A CAN

After gathering this information, write down:

- **WHO?** *beer drinker*
- **WHAT?** *‘keg’ beer in a can*
- **WHERE?** *at home*
- **WHEN?** *not too frequently*
- **WHY?** *enjoy ‘pub’ beer at home*

DETERMINE BUSINESS REQUIREMENTS

For most new product developments business objectives must also be met. Examples of typical business or commercial objectives include:

- *pay back development costs* within a specified time period
- *increase market share* within a defined segment
- *extend product life* through cost reduction or introduction of new features
- *enhance product range* by adding new variants

USE OF CHECKLISTS

Information may be structured in many ways, for example:

- ***Process*** - requirements of methods, modes and uses. Many of these items will also be captured in functional analysis. Scheduling, including timelines, dates, and milestones. References to regulations where appropriate.
- ***Performance*** - usability, availability, reliability, and other general performance requirements. Use of existing products with the developing product and the future improvements of the developing product. Characterisation of the environment for each stage of the life cycle. References to regulations where appropriate.
- ***Safety*** - features, standards, and issues concerning the product throughout its entire life cycle.
- ***Cost*** - target costs and sources of cost for each stage.
- ***Documentation*** - appropriate records, logs, and documents to be produced.

USE OF CHECKLISTS

operational view of all issues *lifecycle view of process issues*

		Process	Performance	Safety	Cost	Documentation
Product in Use	**Operation**	operation process	operation performance	operation safety	operation cost	operation documentation
	Maintenance	maintenance process	maintenance performance	maintenance safety	maintenance cost	maintenance documentation
	Disposal	disposal process	disposal performance	disposal safety	disposal cost	disposal documentation
Product Design/ Manufacture/ Supply	**Design**	design process	design performance	design safety	design cost	design documentation
	Manufacture	manufacture process	manufacture performance	manufacture safety	manufacture cost	manufacture documentation
	Distribution	distribution process	distribution performance	distribution safety	distribution cost	distribution documentation
	Installation	installation process	installation performance	installation safety	Installation cost	installation documentation

USE OF CHECKLISTS

Operation Process

Identify what functions occur in each Type and Mode of Use:

Types of Use

- ☐ intended use
- ☐ special use
- ☐ non-use
- ☐ misuse (abuse)

Modes of Use

- ☐ automatic
- ☐ manual
- ☐ on/off
- ☐ standby
- ☐ start up/shut down
- ☐ normal operating
- ☐ saving
- ☐ failure
  - ☐ recovery from failure
  - ☐ signals/warnings/fault alarms
  - ☐ operation in event of power loss
- ☐ maintenance

Identify infrastructure requirements:

- ☐ energy (electricity, gas, hydraulic power, compressed air)
- ☐ water and sewerage
- ☐ cooling
- ☐ communications (data, telecomms)

Operational Performance

Physical characteristics:

- ☐ geometry
  - ☐ shape
  - ☐ size (height, breadth, length, volume, diameter)
  - ☐ space requirement
  - ☐ maximum dimensions
- ☐ weight
- ☐ operating temperature range
- ☐ operating pressure range
- ☐ forces (magnitude, direction, frequency, resonance effects)
- ☐ aesthetics
  - ☐ appearance
  - ☐ finish
  - ☐ colour
  - ☐ texture
- ☐ materials
  - ☐ prescribed materials
  - ☐ corrosion resistance
  - ☐ physical and chemical properties
  - ☐ coating requirements
  - ☐ chemical compatibility (cleaning agents)
  - ☐ bio-compatibility
  - ☐ sterilization needed

USE OF CHECKLISTS

Operational Performance (continued)

Performance parameters:

- ☐ speed of operation
- ☐ cycle time/run time
- ☐ capacity
- ☐ load handling
- ☐ accuracy
- ☐ repeatability
- ☐ response time
- ☐ quietness
- ☐ expected lifetime
  - ☐ working life- number of operations or hours of operation
  - ☐ shelf life
  - ☐ total life span
- ☐ *for manufacturing:* production rate
- ☐ *for manufacturing:* scrap rate

User Interface:

- ☐ man-machine relationship
- ☐ operator skill/training requirements
- ☐ clarity of interface
  - ☐ operator input
  - ☐ product output
  - ☐ visual displays in all lighting conditions
  - ☐ visual instructions
  - ☐ guidance/prompting for user
  - ☐ feedback to user
  - ☐ display language
- ☐ ergonomics
  - ☐ height
  - ☐ reach
  - ☐ lighting
  - ☐ posture of operator
  - ☐ operator fatigue
- ☐ access levels to controls
  - ☐ normal
  - ☐ maintenance
  - ☐ system development (programming)

Guidance:

ANSI/AAMI HE44-1193 Human Factors: Engineering Guidelines and Preferred Practices for the Design of Medical Devices

External Interfaces:

- ☐ signals (sensors, control equipment, displays)
- ☐ type (electronic, pneumatic, hydraulic)
- ☐ transmission standards (analogue, digital, serial, parallel)
- ☐ audible signals
  - ☐ volume
  - ☐ option to mute

Adaptability:

- ☐ compatibility with existing equipment/previous products
- ☐ design features for future expansion
- ☐ capacity for future expansion
- ☐ likelihood of future enhancements
- ☐ ease of modification

USE OF CHECKLISTS

Availability:

- acceptable downtime
- mean availability
- MTBF (operating time)

Reliability:

- level of reliability required
- MTTF (operations or hours of operation before failure)
- Mean elapsed time between failures
- possible failure mechanisms
  - inherent weakness
  - misuse
  - wear
  - corrosion
  - stress corrosion
  - ageing

Working environment:

- geographic locations
- ambient temper
- humidity range
- external pressure
- vibration and shock
- ventilation
- permitted noise level
- dust and dirt (IP rating)
- gases and vapours
- corrosion from fluids
- EMC

for machinery:

- clean room requirements
- environmental monitoring during use
- microbiologocal controls during use
- effluent measurement and disposal

Operational Safety

Check that product conforms with relevant safety regulations – see Appendix 3 for details:

- Medical Device Directives
- Machinery Directive for moving parts
- Electrical Device Safety Standards and Requirements
- Machinery Safety Regulations

Product safety:

- safety hazards in use
- safety factors
- preventive measures to safeguard against hazards
- warning labels
- fault alarms/warnings
- fault hierarchy

Environmental impact – lifetime considerations:

- energy consumption
- consumables used
- effluent disposal
- cleaning/sterilisation

USE OF CHECKLISTS

Operating Costs

- initial costs
  - product (target consumer price, selling discounts)
  - delivery/distribution
  - acceptance tests
  - operator and support personnel training
- running costs
  - operating and support personnel wages
  - energy
  - communications infrastructure
  - other services
  - depreciation
  - on-going operator and support personnel training

Operating documentation

- user manuals
- operating instructions
- safety instructions
- drawings
- specifications
- risk analysis for hazards in use

USE OF CHECKLISTS

Headings	Examples
Geometry	Size, height, breadth, length, space requirement, number, arrangement, connection, extension;
Kinematics	Type of motion, direction of motion, velocity, acceleration;
Forces	Direction of force, magnitude of force, frequency, weight, load, deformation, stiffness, elasticity, inertia forces, resonance;
Energy	Output, efficiency, loss, friction, ventilation, state, pressure, temperature, heating, cooling, supply, storage, capacity, conversion;
Material	Flow and transport of materials, physical and chemical properties of the initial and final product, auxiliary materials, prescribed materials;
Signals	Inputs and outputs, form, display, control equipment;
Safety	Direct protection systems. operational and environmental safety, legal requirements;
Ergonomics	Human-machine interface, type of operation, operating height, clearness of layout, sitting comfort, lighting, shape compatibility;

USE OF CHECKLISTS

Headings	Examples
Production	Factory limitations, maximum possible dimensions, preferred production methods, means of production, achievable quality and tolerances, wastage;
Quality control	Possibilities of testing and measuring, application of special regulations and standards;
Assembly	Limitations due to lifting gear, clearance, means of transport (height and weight), nature and conditions of dispatch;
Operation	Quietness, wear, special uses, marketing area, destination (for example sulphurous atmosphere, tropical conditions);
Maintenance	Servicing intervals (if any), inspection, exchange and repair, painting, cleaning;
Costs	Maximum permissible manufacturing costs, cost of tools, investment and depreciation;
Schedules	End date of development, product planning and control, delivery date.

ASTHMATIC INHALER

A LARGE DRUG COMPANY	DESIGN SPECIFICATION Asthmatic Inhaler	**Issued: 11/11/94** **Page: 1 of 1**

Changes	D/W	Wt	REQUIREMENTS	Source
			GEOMETRY	
	W	M	• Maximum length 90 mm	PJC
			FORCES	
_15/1/95_	_D_		• Activation force not to exceed _25 N_	_KMW_
	W	H	• Activation force to exceed 10 N	KMW
			MATERIAL	
	D		• All materials used to be FDA approved	PJC
			SAFETY	
	D		• No loose parts	KMW
	D		• Must always dose correctly ± 2%	PJC
			ERGONOMICS	
	W	H	• Easy to operate	PJC
	W	H	• Pleasant appearance	PJC
			PRODUCTION	
	D		• Production in Class K clean room	KMW

ASTHMATIC INHALER

A LARGE DRUG COMPANY	DESIGN SPECIFICATION Asthmatic Inhaler	**Issued: 11/11/94** **Page: 1 of 1**

Changes	D/W	Wt	REQUIREMENTS	Source
			QUALITY CONTROL	
28/2/95	D		• All devices to be tested prior to packaging	PJC
			ASSEMBLY	
	D		• Assembly and testing in *<u>Class K</u>* clean room	KMW
			OPERATION	
	D		• No particulate contamination	PJC
	W	M	• Refillable with additional drug	KMW
			MAINTENANCE	
	W	M	• No maintenance should be required	KMW
			COSTS	
	W	H	• Unit cost less than *<u>£10</u>*	KMW
			SCHEDULES	
	W	H	• Device launch 3rd quarter 1997	KMW
	W	M	• Deliver 10,000 units / month pre-launch	KMW
	W	L	• Deliver 50,000 units / month post-launch	KMW

D • *Unit cost less than £12*

DRAUGHT BEER IN A CAN

A WELL KNOWN BREWERY			DESIGN SPECIFICATION Draught beer in a can	**Issued: 11/11/93** **Page: 1 of 1**
Changes	D/W	Wt	REQUIREMENTS	Source
			GEOMETRY	
	W	H	• Must use a *standard* can define	PJC
			FORCES	
	W	M	• Additional weight not to exceed 10 g	KMW
			MATERIAL	
15/3/94	D		• All materials used to be food approved	PJC
			SAFETY	
	D		• No loose parts what conditions	KMW
	W	H	• Safe to open under *all* conditions	PJC
			PRODUCTION	
	D		• Production in a Class K clean room	KMW
	D		• Fill on existing canning line	PJC
			QUALITY CONTROL	
	W	M	• 0.01% sample testing of product batches	PJC

DRAUGHT BEER IN A CAN

A WELL KNOWN BREWERY	DESIGN SPECIFICATION Draught beer in a can	**Issued: 11/11/93** **Page: 1 of 1**

Changes	D/W	Wt	REQUIREMENTS	Source
			ASSEMBLY	
14/5/94	D		• Assembly in ‘food’ clean conditions	KMW
			OPERATION ?	
	W	H	• Tastes *as good as* keg draught beer	PJC
			COSTS	
	W	H	• Additional unit cost less than 10 pence	KMW
			SCHEDULES	
	W	H	• Product launch 3rd quarter 1994	KMW
	W	M	• Deliver 1,000,000 cans / month pre-launch	KMW
	W	L	• Deliver 2,000,000 cans / month post-launch	KMW

FEMALE CONDOM

A SMALL NEW COMPANY			DESIGN SPECIFICATION Female Condom	**Issued: 11/11/92** **Page: 1 of 1**
Changes	D/W	Wt	REQUIREMENTS	Source
			GEOMETRY	
	D		• Minimum length 170 mm	PJC
	D		• Minimum width 80 mm	PJC
			MATERIAL	
	D		• All materials used to be FDA approved	PJC
			SAFETY	
	D		• No loose parts	KMW
			ERGONOMICS	
	W	H	• *Easy to use*	PJC
	W	H	• *Pleasant appearance*	PJC
			PRODUCTION	
	D		• Production in Class K clean room	KMW
			QUALITY CONTROL	
12/1/93	D		• All devices to be leak tested	PJC
	W	H	• Easy to validate	PJC

how measurable?

FEMALE CONDOM

A SMALL NEW COMPANY			DESIGN SPECIFICATION Female Condom	**Issued: 11/11/92** **Page: 1 of 1**
Changes	D/W	Wt	REQUIREMENTS	Source
			ASSEMBLY	
	D		• Assembly and testing in Class K clean room	KMW
			OPERATION	
	D		• No particulate contamination	PJC
	W	H	• <u>*Barrier performance*</u> equal to male condom *define*	KMW
			COSTS	
	W	H	• Unit cost less than £1	KMW
			SCHEDULES	
	W	H	• Device launch 3rd quarter 1994	KMW
	W	M	• Deliver 100,000 units / month pre-launch	KMW
	W	L	• Deliver 800,000 units / month post-launch	KMW

ELABORATING A SPECIFICATION

Specifications may be structured in many ways, for example:

- Introduction
- Regulations and standards
- Functional properties
- Physical properties
- Interface requirements
- Additional performance requirements (‘ilities’)
- Environmental conditions
- Maintenance
- Disposal

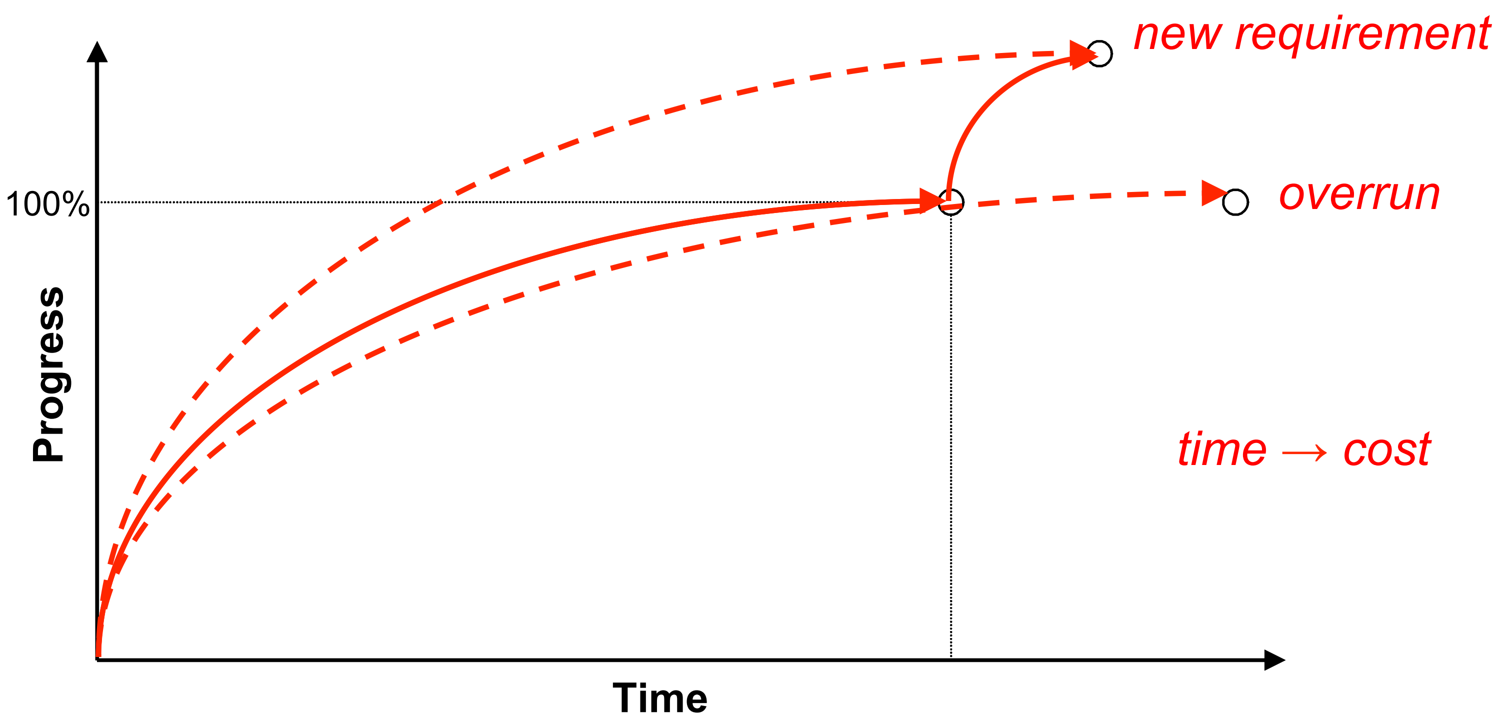
ELABORATING A SPECIFICATION

Specifications may be structured in many ways, for example:

- Schedule
- Validation
- Manufacturability
- Distribution and storage requirements
- Installation
- Training of personnel
- Safety
- Cost
- Documentation

ELABORATING A SPECIFICATION

A specification defines a ***target*** for a project team to aim for and the ***criteria*** by which they know that they have got there. A specification is also a '***live***' document - the target often moves and progress towards it is not always straightforward.



SUMMARY

It is important to appreciate that the process of task clarification does not take much effort but conversely may have a significant effect on the success of the project.